# IMMUNIZATION POLICIES AND PROCEDURES MANUAL

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**This Immunization Manual is dedicated to the Immunization Consultants, Public Health Nurses, Clerks, Vaccines for Children providers in recognition of their outstanding achievement in improving immunization coverage rates of Louisiana children.**

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# 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 childcare 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. Philosophy and General Clinic Policy

II. Policy Regarding Clinic Organization

III. General Policy Regarding Immunization

IV. Policies Regarding Specific Immunizations

We hope that it 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. Provider should be aware that this is the only form that is mandated by the Vaccine Injury Act of 1986. For further information read pages 30-31 of this manual. 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:<br>Site of Injection: | Expiration Date:<br>Site of Injection: | Expiration Date:<br>Site of Injection: | Expiration Date:<br>Site of Injection: |
| VIS Pub Date: | VIS Pub Date: | VIS Pub Date: | VIS Pub Date: |
| Immunization & Dose<br>DT Td DTaP DTaP-Hib<br>1 2 3 4 5 | Immunization & Dose<br>IPV<br>1 2 3 4 5 | Immunization & Dose<br>MMR<br>1 2 3 | Immunization & Dose<br>HIB<br>1 2 3 4 |

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

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

1. 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.

2. 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:

1. 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.

2. 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.

3. 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.

4. 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.

5. 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.

**POLICY ON MAXIMIZING TIME (cont.)**

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.

## PROTOCOL FOR IMMUNIZATION CLINIC ORGANIZATION

Objectives:

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

2. 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<br>Patient Education Materials<br>Child's Immunization Records | |

**PROTOCOL FOR IMMUNIZATION CLINIC ORGANIZATION (cont.)**

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.
5. Set up the immunization site with sufficient vaccine (properly stored), related supplies, and with provisions for safe waste disposal.
6. Assign appropriate personnel to clinic activities. See Chart below for suggested duties and responsibilities.

| Suggested Duties/Responsibilities | Clerk | Volunteer | PHN and/or LPN |
|---|---|---|---|
| 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.

**PROTOCOL FOR IMMUNIZATION CLINIC ORGANIZATION (cont.)**

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 on one Vaccine Order Form. 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:

1) A Vaccine Order Form must be used to order all vaccines.

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

3) The Vaccine Order Form should be completed by the nurse/clerk and must be signed by the nurse supervisor. The AC-23 requisition should be completed by the nurse/clerk and approved by the cost center manager.

4) The parish health unit or branch offices should mail or fax (504-838-5255) the Vaccine Order Form and the AC-23 (Immunization supplies only) directly to the Immunization Program in New Orleans. The parish health unit should retain a copy of the Vaccine Order Form or the AC-23 until the order is received.

5) The Immunization Program will approve the requisition after it is received 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.

**ORDERING OF IMMUNIZATION SUPPLIES (cont.)**

6) 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. 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.

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

# Parish Health Unit Vaccine Order Form

| Date submitted: | PIN (state assigned): |
|---|---|
| Facility Name: | |

| Vaccine/Biological | Unit Size | Doses Ordered | Additional Information | | | |
|---|---|---|---|---|---|---|
| | | | | | | |
| Dt | 1 single dose vial | | NAME AND DOB: | | | |
| DTaP | 10 single dose vials | | | | | |
| DTaP-Hep B-IPV (Pediarix) | 10 single dose vials | | | | | |
| DTaP-IPV (Kinrix) | 5 prefilled syringes | | | | | |
| DTaP-IPV-Hib (Pentacel) | 5 prefilled syringes | | | | | |
| Hep A (pediatric)¶ | 10 single dose vials | | | | | |
| Hep A (Adult)* | 10 single dose vials | | | | | |
| Hep A & B (Adult) Twinrix* | 10 single dose vials | | | | | |
| Hep B (Adult)* | 10 single dose vials | | | | | |
| Hep B (Infants & Adolescents) | 10 single dose vials | | | | | |
| HiB | 10 single dose vials | | | | | |
| HPV (Gardasil) | 10 single dose vials | | | | | |
| Influenza Preservative free (6-35mos) | 10 prefilled syringes | | | | | |
| Influenza (3yrs & older) | 10 dose vial | | | | | |
| Influenza Intranasal (FluMist) | 10 prefilled sprayers | | | | | |
| IPV | 10 dose vial | | | | | |
| Meningococcal | 5 single dose vials | | | | | |
| MMR | 10 single dose vials | | | | | |
| Pneumococcal (PCV-13) | 10 prefilled syringes | | | | | |
| Pneumococcal (PPV 23) | 5 dose vial | | | | | |
| Rotavirus | 10 squeezable tubes | | | | | |
| Td (adult) | 10 prefilled syringes | | | | | |
| Tdap | 10 single dose vials<br>10 prefilled syringes | | | | | |
| Varicella# | 10 single dose vials<br>20 dose minimum | | | | | |

12. Delivery instructions** _____

13. Signature _____

* These vaccines/biologicals are not routinely provided to healthcare facilities; provider orders for these products are subject to State Immunization Program approval.

** Days and Hours Your Facility is open.

¶ Hepatitis A vaccine is available to all children 12-23 months and children 2-18 years of age in epidemiologically recognized endemic areas; i.e. Ouachita Parish. Vaccine is available for any child in the state with chronic liver disease and children with clotting factor disorders.

\# Product shipped directly from Manufacturer—Allow 15-20 working days for routine delivery.

## 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 Metairie. 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. (See the attached log sheet). Calibration must be traceable to standards provided by the National Institute of Standards and Technology (NIST) – a US government agency within the Dept. 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.

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 Program at (504) 838-5300.

**VACCINE STORAGE REQUIREMENTS (cont.)**

Proper temperature monitoring is 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 35° 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 (PPV) | | √ | | √ |
| PNEUMO (PCV7) | | √ | | √ |
| MCV-4 | | √ | | √ |
| 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

Month/Year _____

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

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

| Date | Morning Temp | | Time | Initials | Afternoon Temp | | Time | Initials |
|---|---|---|---|---|---|---|---|---|
| | *Refrigerator* | *Freezer* | | | *Refrigerator* | *Freezer* | | |
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## POLICY ON POWER OUTAGES

Policy:

Recommendations regarding the use of vaccine after power outage or refrigerator/freezer failure are specific by vaccine. Please use the following guidelines:

**MEASLES MUMPS RUBELLA** - Should be considered inactive if it is no longer cool to the touch (above 60 degrees or so); again, save the inactive vaccine for later return to the Immunization Office. If the vaccine is still cool to the touch it can be used.

**DTaP, Td, DT, Tdap, HIB, HAV, HBV, IPV, INFLUENZA, PNEUMOCOCCAL (PPV 23 and PCV-7), HPV and MCV-4** - are stable at room temperature for at least 72 hours and probably longer. If the power has been off for less than 72 hours the vaccines can be used; if power has been off for more than 72 hours, contact your regional Immunization Consultant for further advice.

**ROTAVIRUS VACCINE** – currently there is insufficient data regarding the stability of rotavirus vaccine when the vaccine has been left out of refrigeration for an extended period of time and will require consultation with Merck at 1-800- NSC-MERCK (1-800- 672-63725) with regards to the usage of the vaccine.

**VARICELLA, MMR-VAR** - should be considered inactive if unfrozen. It may be possible to use this vaccine with a shorter expiration date if it is known how long it has been left unfrozen. Prior to sending the unfrozen vaccine back to the Immunization Office, contact Merck Vaccine Co. at 1-800-VARIVAX to determine whether the vaccine can be refrozen and given a shorter expiration date.

Of course, if you think you will be without power for a long period of time, it is important to move the vaccine to another site that has a working refrigerator/freezer. If space is a limitation, **Varicella, MMR-VAR, and MMR** are the highest priority vaccines to save.

### ***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 dry ice to temporarily store vaccine.

## BACKUP FACILITIES CONTACT INFORMATION

| Name of Facility | Primary & Backup Contact | Contact Phone Number Work/Home/Cell |
|---|---|---|
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## 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.

**Labeling is required for the following multi-dose vial vaccines:**

Polio (IPV)

Influenza

Pneumococcal – PPV23

Td

Immune Serum Globulin (ISG)

**No labeling is required for the following single-dose unit vaccines:**

DTaP, DT, Tdap, or any DTaP combination

HIB, HBV, HAV or any HIB or HBV combination

MCV-4

Pneumococcal – PCV7

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 2 to 8 degrees C (35.6-46.4 degrees F).

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 (2-8 °C/36-46 °F) for up to 72 continuous hours. Vaccine stored at 2-8 °C/35.6-46.4°F 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 <u>at any time</u> 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 1-800-827-4829 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 (IPV, Salk)**
**Influenza**
**MCV-4**
**Pneumococcal (PPV & PCV-7)**
**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**

Specific instructions for transport of other vaccines:

**Varicella, MMR-VAR**

a. 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.

b. Unreconstituted Varicella/MMR-VAR vaccine can be transported in an insulated container.

c. Dry ice must be used to maintain the vaccine in the frozen state.

d. If dry ice is not available, unreconstituted Varicella (single antigen vaccine only) can be transported using cold packs to maintain a refrigerator temperature of 2-8 °C/35.6-46.4 °F for up to 72 continuous hours. Vaccine stored at 2-8 °C/35.6-46.4°F that is not used within 72 hours of removal from freezer storage (-15 °C/35.6-46.4°F) should be discarded.

**TRANSPORTING OF VACCINE (cont.)**

e. MMR- VAR combination can NOT be transported using cold packs.

**Yellow Fever:**

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

General Handling:

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

b. 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.

c. 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.

d. 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. Note: No freeze thaw cycles are allowed with Varicella and MMR-VAR vaccine.

e. MMR and MMR-VAR vaccine must be protected from light at all times.

f. Syringes must not be pre-filled and left in a refrigerated location even for brief periods of time.

g. Labeling specifications previously outlined must be closely followed.

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

## 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, MCV-4, 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 L and A Road, Metairie, LA 70001.

Persons picking up vaccine at our office must have an ice chest with frozen ice packs and/or dry ice, when applicable, in which to transport the 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;

or:

**Destroyed:** If Vaccine being destroyed has expired **OR** if other than vaccine expiration; only after consultation from the Immunization Program in New Orleans.

**POLICY ON VACCINE TRANSFERS (cont.)**

**Vaccine Type**: DTaP, HIB, DT, Td, 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 transferring**: Name of parish health unit or branch that is transferring vaccine to another health unit or branch.

**Signature**: Name of person transferring the vaccine.

**Date of Transfer**: Date vaccine is released to another health unit.

***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

THE FOLLOWING VACCINE(S) WAS

☐ TRANSFERRED

TO

☐ DESTROYED

| Vaccine Type | Number of Doses | Lot # | Expiration Date |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

**REMARKS:**

**WHEN TRANSFER TAKES PLACE**
**PLEASE SEND REPORT TO:**

State of Louisiana
Department of Health and Hospitals
**Office of Public Health**
Immunization Program
1450 L & A Road
Metairie, LA 70001
Fax: (504) 838-5255

Parish Health Unit or Branch Transferring

Signature

Date of Transfer

**EPI-6 10/84**

## POLICY ON VACCINE USAGE AND INVENTORY

Policy:

The Vaccine Inventory and Usage form is to be submitted showing vaccine usage and inventory each month by each parish health unit/facility immunizing clients.

Rationale:

The data collected on this vaccine usage report is used in the budgetary process both to justify and to document the Immunization Program's funding requirements. In addition, the evaluation of the antigens and specific age groups given vaccines may or may not demonstrate that the program is reaching the appropriate age groups. If the Immunization Program is not reaching the necessary groups, then adjustments in program strategy can be made.

I. Vaccine Usage Section:

The Vaccine Usage Report is available through the LINKs network 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 ADMINSTERED under VACCINES FOR CHILDREN and enter the appropriate information for the vaccine report compilation.

***In the event that the LINKS system is not operational***, this form should be completed manually. Instructions for completing the EPI-5 are as follows:

DTaP: Tabulate the total number of DTaP doses given by age group along with the corresponding dose number.

Td(Adult): Tabulate the total number of Td doses given by age group and the corresponding dose number.

DT(Ped.): Tabulate the total number of DT(Ped.) given and the corresponding dose number.

Tdap: Tabulate the total number of Tdap doses given by age group and the corresponding dose number.

INJECTABLE POLIO (Salk): Tabulate the total number of IPV doses given by age group and the corresponding dose number.

| | |
|---|---|
| HIB: | Tabulate the total number of HIB doses given by age group and the corresponding dose number. Be sure to specify type of HIB if known. |
| PNEUMOCOCCAL (PPV): | Tabulate the total number of doses given by age group and show as given at the health unit (HU) or the nursing homes (NH). |
| PNEUMOCOCCAL (PCV-7): | Tabulate the total number of PCV7 doses given by age group and the corresponding dose number. |
| MCV-4: | Tabulate the total number of MCV4 doses given by age group and the corresponding dose number. |
| MMR-VAR: | Tabulate the total number of MMR-VAR doses given by age group and the corresponding dose number. |
| HBV: | Tabulate the total number of HBV doses given by age group and the corresponding dose number. |
| MMR: | Tabulate the total number of MMR doses given by age group and the corresponding dose number. |
| INFLUENZA: | Tabulate the total number of doses by type given by age group and show as given at the health unit (HU) or the nursing homes (NH). |
| VARICELLA: | Tabulate the total number of doses given by age group and the corresponding dose number. |
| HEPATITIS A: | Tabulate the total number of doses given by age group and the corresponding dose number. |
| ROTAVIRUS: | Tabulate the total number of doses given by age group and the corresponding dose number. |
| HPV: | Tabulate the total number of doses given by age group and the corresponding dose number. |
| OTHER: | This should be completed whenever a situation deems it necessary. In such cases the type of antigen should be identified. |
| TOTALS: | The sum of the total for each specific antigen is entered. |

II. 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 system and go to 'REPORTS'. Scroll down to 'REPORT MODULE' and click this selection. Then select LOT NUMBER SUMMARY under VACCINATIONS and enter the appropriate information for the vaccine report compilation. In the event the LINKS system is not operational, a manual EPI-5 inventory report will be necessary and instructions are as follows:

| | |
|---|---|
| Date of Inventory: | Enter the date when inventory was taken. |
| Vaccine inventory by antigen: | Inventory, by dose and specific antigen, must be done each month. Partial vials can be estimated. A chart labeled "other" has been designated for specific circumstances. |
| A word of Caution: | The person responsible for vaccine inventory should be careful in the accounting of vaccine doses given and the accounting of vaccine in stock. The Vaccine Usage report is a status report which reflects vaccine usage and inventory for each parish. It is from these reports that the Immunization Program in New Orleans projects usage and distributes vaccine for each health unit. |
| Deadline: | The Immunization Usage and Inventory Report is due in the Immunization Program office in New Orleans by the 5th of the month following the usage. In order to meet such deadline the Immunization Program asks the parishes to cut off tabulation of its report early enough in the month for the report to be mailed and received in Immunization Program office by the 5th. |

**Special note:** Vaccine is not to be distributed or loaned outside of OPH health units. If there is a need for exemption to this rule, consult with the Immunization Program VFC Manager.

# Louisiana Department of Health and Hospitals
## Office of Public Health
## Immunization Report
(Vaccine Usage In Doses)

Clinic Name _____ PIN #_____

Parish _____ Month/Year _____

| Vaccine | Age <1 | Age 1 | Age 2 | Age 3-4 | Age 5 | Age 6-9 | Age 10-14 | Age 15-19 | Age 20-24 | Age 25-44 | Age 45-64 | Age 65+ | TOTAL |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DTaP | | | | | | | | | | | | | |
| DT | | | | | | | | | | | | | |
| DTaP/HIB | | | | | | | | | | | | | |
| Td | | | | | | | | | | | | | |
| Vaccine | <1 | 1 | 2 | 3-4 | 5 | 6-9 | 10-14 | 15-19 | 20-24 | 25-44 | 45-64 | 65+ | TOTAL |
| HIB | | | | | | | | | | | | | |
| Vaccine | <1 | 1 | 2 | 3-4 | 5 | 6-9 | 10-14 | 15-19 | 20-24 | 25-44 | 45-64 | 65+ | TOTAL |
| HAV | | | | | | | | | | | | | |
| HBV | | | | | | | | | | | | | |
| HBV-HIB | | | | | | | | | | | | | |
| Vaccine | <1 | 1 | 2 | 3-4 | 5 | 6-9 | 10-14 | 15-19 | 20-24 | 25-44 | 45-64 | 65+ | TOTAL |
| PCV7 | | | | | | | | | | | | | |
| PPV | | | | | | | | | | | | | |
| FLU (HU) | | | | | | | | | | | | | |
| FLU (NH) | | | | | | | | | | | | | |
| Vaccine | <1 | 1 | 2 | 3-4 | 5 | 6-9 | 10-14 | 15-19 | 20-24 | 25-44 | 45-64 | 65+ | TOTAL |
| POLIO | | | | | | | | | | | | | |
| Vaccine | <1 | 1 | 2 | 3-4 | 5 | 6-9 | 10-14 | 15-19 | 20-24 | 25-44 | 45-64 | 65+ | TOTAL |
| MMR | | | | | | | | | | | | | |
| Vaccine | <1 | 1 | 2 | 3-4 | 5 | 6-9 | 10-14 | 15-19 | 20-24 | 25-44 | 45-64 | 65+ | TOTAL |
| VARICELLA | | | | | | | | | | | | | |
| Vaccine | <1 | 1 | 2 | 3-4 | 5 | 6-9 | 10-14 | 15-19 | 20-24 | 25-44 | 45-64 | 65+ | TOTAL |
| Other | | | | | | | | | | | | | |
| Other | | | | | | | | | | | | | |

**VACCINE FOR CHILDREN**
**VACCINE INVENTORY**

**Date of Inventory**_____ **PIN #**_____

| DT | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| DTaP | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| DTaP - Hep B - IPV | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| DTaP - Hib | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| HAV | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| HBV | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| HBV - Hib | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| Hib | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| Influenza | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| IPV | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| MCV-4 | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| MMR | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| MMR-Varicella | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| Pneumococcal (PCV-7) | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| Td | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| Tdap | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| Varicella | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

| Other | |
|---|---|
| Number Doses | Expiration Date |
| 1. | |
| 2. | |
| 3. | |
| Total | |

## INSTRUCTIONS

### VACCINE USAGE, IN DOSES, SECTION

THERIA, TETANUS, ACELLULAR PERTUSSIS (DTaP)
Tabulate the total number of DTaP doses given by age group.

PHTHERIA, TETANUS (DT)
Tabulate the total number of DT doses given by age group.

PHTHERIA, TETANUS, ACELLULAR PERTUSSIS AND HEMOPHILUS INFLUENZAE B (DTaP-HIB)
Tabulate the total number of DaTP-HIB doses given by age group.

ETANUS, DIPHTHERIA (Td)
Tabulate the total number of Td doses given by age group.

EMOPHILUS INFLUENZAE B (HIB)
Tabulate the total number of HIB doses given by age group.

EPATITIS A (HAV)
Tabulate the total number of HAV doses given by age group.

EPATITIS B (HBV)
Tabulate the total number of HBV doses given by age group.

EPATITIS B and HEMOPHILUS INFLUENZAE B (HBV-HIB)
Tabulate the total number of HBV-HIB doses given by age group.

leptavalent Pneumococcal Conjugate Vaccine (PCV7)
Tabulate the total number of PCV7 doses given by age group.

'neumococcal Polysaccharide Vaccine (PPV)
Tabulate the total number of PPV doses given by age group.

NFLUENZA (FLU)
Tabulate the total number of doses given by age group and provider source. Separate on the report vaccine given in nursing homes (N.H.) from those given in the Health Unit (H.U.).

'OLIO (IPV)
Tabulate the total number of IPV doses given by age group along with the corresponding dose number.

MEASLES, MUMPS, RUBELLA (MMR)
Tabulate the total number of MMR doses given by age group.

VARICELLA
Tabulate the total number of VARICELLA doses given by age group.

OTHER
SPACE RESERVED FOR ANY "NEW" VACCINES. Tabulate the total number of doses given by age group.

### VACCINE INVENTORY SECTION

DATE OF INVENTORY:
Enter the date when inventory was taken.

VACCINE INVENTORY BY ANTIGEN:
Inventory, by dose and specific antigen, must be done each month. Partial vials can be estimated. Extra charts labeled "other" has been designated for specific circumstances.

DEADLINE:
The Immunization Report (EPI-5) is due in our office by the 5th of the month following the usage.

This form is available from the Division of Administration, Forms Management Warehouse and can be obtained following standard form request procedure (DAFM-1).

Inquiries may be directed to the Immunization Program at (504) 838 - 5300

**Louisiana Department of Health and Hospitals**
**Office of Public Health**
**Vaccines for Children Immunization Report**

Physician or Clinic_____

PIN#_____ Month/Year _____

| VFC VACCINES | DOSES GIVEN |
|---|---|
| DT | |
| DTaP | |
| DTaP-HepB-IPV | |
| DTaP-Hib | |
| HAV | |
| HBV | |
| HBV-Hib | |
| HiB | |
| HPV (Gardasil) | |
| Influenza | |
| IPV | |
| MCV4 (Menactra) | |
| MMR | |
| MMR-Varicella | |
| Pneumo (PCV-7) | |
| Rotavirus | |
| Td | |
| Tdap | |
| Varicella | |

**VACCINES FOR CHILDREN ELIGIBILITY BY CATEGORY**

**Number of Individuals Immunized:*** _____

**Category of Individuals Immunized:**

Medicaid _____

Uninsured _____

Native Americans _____

Total* _____

***Total should equal the number of individuals immunized.**

Inquiries may be directed to the Immunization Program at (504) 838-5300
Fax to: (504) 838-5255
(Revised 9/06)

## 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 federal regulations, the Vaccine Administration Record/VFC Patient Eligibility Screening Record/Registry Authorization must be retained for a period of 10 years following the end of the calendar year in which the form is signed. 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, PCV7, 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, PCV7 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. 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). 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. 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. 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, page 45).

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: <u>option of two sites</u>

      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: <u>options according to age of patient</u>

      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, <u>DO NOT</u> 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.

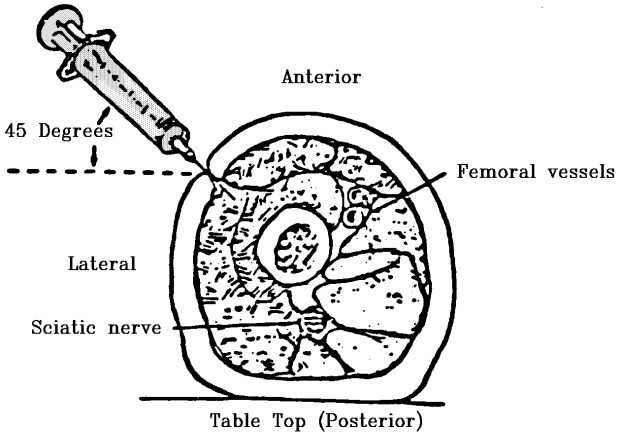
   **Note:** When giving subcutaneous and intramuscular injections, lightly compress the skin so as to increase the penetrable subcutaneous or muscle mass.

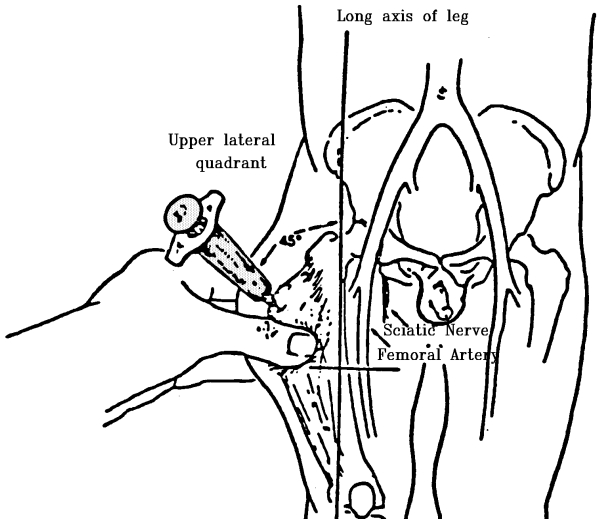
   a. When giving an intradermal injection, spread the skin taut with thumb and index finger, Intradermal injections: at 15 degrees or less

b. Subcutaneous injections: at 45-60 degrees.

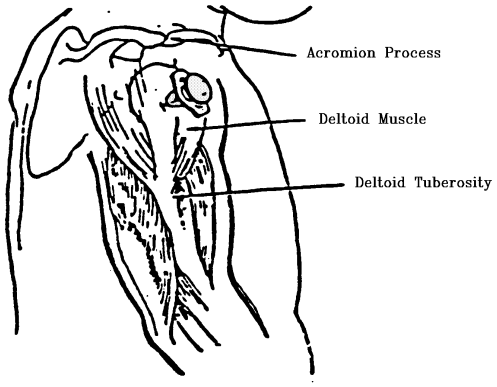
c. Intramuscular Injection:

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



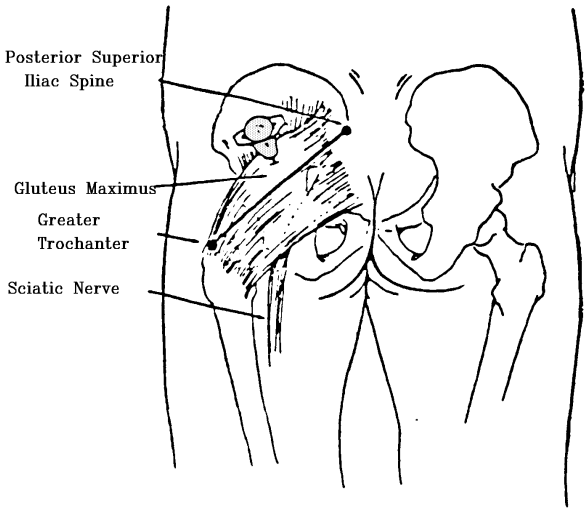




2) In the deltoid -- insert the needle at a point halfway from the acromion to the deltoid tuberosity. (See picture below.)



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 90° 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.

12. When the needle is in the desired anatomic location (intradermal, subcutaneous, or intramuscular), aspirate to make sure that the needle has not gone into a blood vessel. (If the blood is aspirated, withdraw the needle immediately, **DO NOT GIVE THE INJECTION. Discard the needle and syringe, and start over again.)**

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

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

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

16. Place syringe into a sharps container for disposal.

17. 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. The nurse will 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 Metairie. Immediately (within 24 hours) upon a patient's report or occurrence of adverse events following vaccination, the vaccine provider must submit a VAERS report to the Program Office for further investigation and followup to be conducted. Once the VAERS report is submitted to the Program Office, the case report shall be assigned with a Louisiana ID number prior to submission to the VAERS system. This information is reported as part of the Centers for Disease Control and Prevention surveillance system.

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

Rationale:

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

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

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, PCV7, 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 PCV7. 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 as a temperature greater than:

1) 37.8°C or 100°F orally
2) 38.3°C or 101°F rectally

## POLICY ON IMMUNIZATIONS OF HIV-INFECTED INDIVIDUALS

Policy:

The following vaccines will be given to children and adults with HIV infection that are served in the parish health units. Whether they are symptomatic or asymptomatic determines whether certain antigens should be administered to HIV-infected individuals. 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 | |
|---|---|---|
| | Known Asymptomatic | Symptomatic |
| DtaP | YES* | YES* |
| Td | YES* | YES* |
| Tdap | YES* | YES* |
| IPV | YES | YES |
| MMR | YES | NO |
| Hepatitis A | YES | YES |
| Hepatitis B | YES | YES |
| Hib | YES | YES |
| Varicella | NO | NO |
| MCV4 | YES | YES |
| MMR-VAR | NO | NO |
| Pneumococcal (PPV) | YES | YES |
| Pneumococcal (PCV-7) | YES | YES |
| Influenza | YES | YES |
| Rotavirus | NO | NO |
| HPV | YES | YES |

* Age appropriate vaccine and schedule used.
** Alternative choice of OPV should be IPV.
For additional information on the immunization of persons with altered immunocompetence see MMWR1993; 42(RR-4): 1-18 or www.cdc.gov/mmwr/preview/mmwrhtml/00023141.htm on the internet.

## 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:

   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. 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 "tickler file" as a reminder that a review is needed.

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.

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

**PROTOCOL ON VACCINE REACTIONS AND THEIR MANAGEMENT (cont.)**

The 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 Tray.

Standing Orders

See Policy Memorandum Number 119 (Revision 5), dated 6-1-2009, 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:

| 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 mg/Kg or 0.5 mg/lb body weight per dose.

If the exact weight is not known, estimate weight and use the following guidelines:

| 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.

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

**NAME**_____ **ID#**_____

**ADDRESS**_____**PHONE**_____

**AGE**_____ **WEIGHT**_____ **ALLERGIE(S)**_____

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

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

_____

_____

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

_____

_____

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

**INTERVENTIONS:** OXYGEN: [ ] BLS: [ ] IV: [ ]

**DISCHARGED TO:** Hospital _____ Home _____

**CONDITION:** Stable _____ Unstable_____

Clinic Personnel_____ _____
(Print Name) (Signature)

EMS Personnel _____ _____
(Print Name) (Signature)

TIME EMS assumes care _____

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| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | 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).

4. 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. If 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.

e. 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.

f. 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.

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

h. 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 PARISH HEALTH UNIT 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. 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.

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

3. 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.

4. 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.

5. 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. All vaccine recipients through 64 years of age should receive at least a one-time dose of tetanus-diphtheria-pertussis vaccine (Tdap) either as a booster dose or as one of the three dose Td series. It is recommended that a minimum of 5 years should elapse between booster doses of Td and Tdap.

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 employees 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. Any employee may elect to receive influenza vaccine, if they wish to avoid influenza disease. This vaccine is offered yearly during the late fall. Influenza immunization is given yearly because the specific strain of influenza changes slightly each year, requiring new vaccines to be developed annually.

II. LABORATORY WORKERS WHO HAVE POSSIBLE EXPOSURE TO RABIES

A. **Rabies**

1. 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.

2. 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 504-219-4563.

3. 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).

4. 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.

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

III. ALL OTHER PERSONNEL

1. Disease immunity determination is not required, nor is vaccination required for other employees. However, vaccination is available to any employee wishing to have it. All female employees of childbearing age, whether or not they have contact with patients, should have documentation of rubella immunity.

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 insure 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 (refer to Infection Control Guidelines for Ambulatory Care Settings, 1st ed., 2004, Chapter 3 Employee Immunizations, see website address http://www.dhh.louisiana.gov/offices/publications/pubs-249/OPHInfectionControlManual.pdf).

**DEPARTMENT OF HEALTH AND HOSPITALS**

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 SCHEDULES

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 Medical Consultant.

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.

The current schedule can be found at the end of this chapter.

LOUISIANA DEPARTMENT OF HEALTH AND HOSPITALS
OFFICE OF PUBLIC HEALTH

# IMMUNIZATION SCHEDULE

2010 through 2011

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) |

## ACCELERATED SCHEDULE FOR CHILDREN STARTING IMMUNIZATIONS LATE

### CHILDREN 4 MONTHS TO 7 YEARS OF AGE

| | |
|---|---|
| 1st Visit[‡] | DTaP, Hib*,IPV,MMR,HBV,HAV, Var, Flu, PCV[◊] |
| 2nd Visit (4 wks. after the 1st visit) | DTaP, Hib, HBV, IPV, PCV, Flu |
| 3rd Visit (4 wks. after the 2nd visit) | DTaP, Hib, PCV |
| 4th Visit (6 mos. after the 3rd visit) | DTaP, Hib, HBV, IPV, PCV,HAV |
| 4 Years Of Age[†] | DTaP, IPV, MMR (Var if needed) Or Prior To School Entry |
| 11-12 Years | Tdap, MCV4, HPV∝ (Var, MMR, HBV if needed) |

### CHILDREN 7-18 YEARS OF AGE

| | |
|---|---|
| 1st Visit | Td, IPV, HBV, MMR, Var |
| 2nd Visit (4 wks. after the 1st visit) | Td, IPV, HBV, MMR |
| 3rd Visit (6 mos. after the 2nd visit) | Td, IPV, HBV |
| 11-12 Years | Tdap, MCV4, HPV∝ (Var, MMR,HBV,IPV if needed) |

**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.

**THE SCHEDULE ABOVE AND THE FOLLOWING GUIDELINES ARE SUMMARIES, FOR MORE DETAILED INFORMATION ON EACH VACCINE REFER TO THE MANUFACTURERS' PRODUCT INSERT.**

**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 -** Hepatitis A is recommended for all children at age 1 year (i.e. 12-23 months). 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. Td vaccine should be used for those 7 – 10 years of age. Tdap is recommended at age 11-12 years for those who have completed the recommended DTaP series and have not received a Td booster 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. A 5 year interval from last Td dose is encouraged when Tdap is used as a booster dose. 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 (PPV) 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.

**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, 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 11-18 years

**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. Two doses of Varicella is required as part of the School immunization requirement and also for children 4 years and older that are enrolled in Day Care, Headstart, and Pre-K. 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.

§ • 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 are administered after the 4th birthday. Sixth graders (11 -12 years of age) are required: 1 Tdap, 2 VAR, 2MMR, 3 HBV, 1 MCV.

‡ • 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.

**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.

For additional information about vaccines, including precautions and contraindications for immunizations and vaccine shortages, please visit 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).

**LOUISIANA IMMUNIZATION REQUIREMENTS FOR STUDENTS 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.

Protocol:

Vaccination records for all children entering school or childcare facilities are to be reviewed by the responsible school official (e.g. the school nurse) or childcare 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:

A. 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. PCV7 is required for all children 2 years of age and younger for childcare and pre-school entry.

B. 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.*

C. 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.

**LOUISIANA IMMUNIZATION REQUIREMENTS FOR STUDENTS IN ACCORDANCE TO R.S. 17:170**
**STUDENT IMMUNIZATIONS – SCOPE OF REQUIREMENT (cont)**

D. 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.

E. 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.

F. Beginning school year 2009-2010, two doses of varicella vaccine will be 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.

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 (PCV7 – 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.

**G.** 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 Statement regarding HPV at (http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hpv.pdf) 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. PCV7 is required for all children entering childcare 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 childcare 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 childcare/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 childcare/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-carriage[1] |
| Hib disease (*Haemophilus influenzae*) | Well & proof of non-carriage[1] |
| 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 LA 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

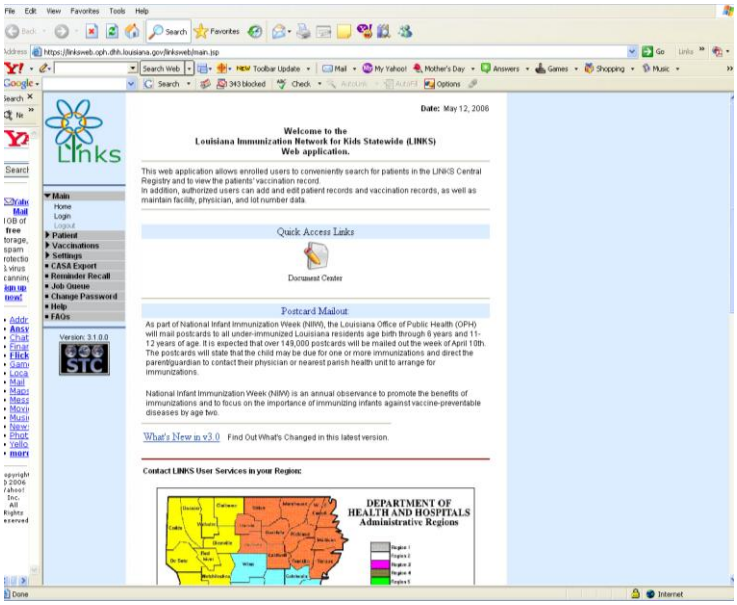
Policy:

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



## IMMUNIZATION REQUIREMENTS FOR STUDENTS ENTERING SCHOOLS OF HIGHER LEARNING 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 regulation "to report to the State Health Officer, through the Health Unit of the parish or municipality wherein such physician practices, any case or suspected case of reportable disease which he/she is attending, or has examined, or for which such physician has prescribed."

Guidelines:

1. Confidential Disease Case report cards (EPI-2430) are utilized for the purpose of reporting all those communicable diseases and reportable conditions that are not reported directly to the Sexually Transmitted Disease or Tuberculosis Control Sections. (Cases of STD's are reported on the STD-43 and cases of tuberculosis are reported on the CDC-72.5 forms).
2. Disease reports may be phoned in by the physician or mailed to parish health units in sealed envelopes marked "Confidential". Regional or parish health unit personnel shall obtain all the necessary additional information, retain a copy of the report and forward reports to the Infectious Disease Epidemiology Section. The Regional Immunization Consultant should also be contacted regarding any vaccine preventable disease reports originating at the parish health unit 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.
3. Physicians can utilize a 24-hour toll free telephone line to reach the Infectious Disease Epidemiology Section to report cases: 1-800-256-2748. An on-call epidemiologist is available 24 hours, 7 days a week including holidays. For those physicians that have access to a FAX machine and wish to report diseases in that manner, the FAX number of the Epidemiology Section is (504) 219-4522. All information obtained from physicians by these methods will be shared with the local parish health units and regional offices.
4. The Epidemiology Section sends computerized data to CDC on a weekly basis. Each month, the Epidemiology Section sends each parish health unit a statistical summary and a list of all case reports received from that parish. Each regional office receives a copy of the statistical summary as well.
5. Parish health units are also required to provide annually to the physicians in their area a packet of EPI-2430s with an updated list of reportable diseases. Parish health units are to identify those physicians/groups of physicians who are most likely to see patients with communicable diseases (family practice, internal medicine, obstetrics, pediatrics, infectious disease, and others) for this purpose. Supplies of the case report cards can be obtained by ordering them from the OPH warehouse. Additional packets of reporting cards can be forwarded to the physicians throughout the year as well.

Inquiries are to be directed to the Infectious Disease Epidemiology Section at (504) 219-4563

Mailing address: Louisiana Department of Health and Hospitals
Office of Public Health- Infectious Disease Epidemiology Section
3101 W. Napoleon Avenue (PO Box 60630)
Metairie, LA 70001

Further questions regarding surveillance can be answered by referencing the CDC published "Manual for the Surveillance of Vaccine Preventable Diseases".

## 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).

5) 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.

6) 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.

7) 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.

8) Measles (MMR) vaccine may be given to household contacts of persons with altered immunity or immune deficiency.

9) 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.

## PROTOCOL FOR MEASLES RE-VACCINATION

There are several reasons why re-vaccination against measles might be indicated:

1. the original vaccine was not potent

2. the original vaccine was given at an age when the vaccine's "take" is significantly reduced.

3. the original vaccine was given with another product (Immune Globulin - IG) which may interfere with the antigenicity of the vaccine.

Person already vaccinated with measles vaccine may require re-vaccination in order to ensure that they are protected against measles. Measles vaccines and recommendations for their use have changed since the first vaccines were licensed in this country in 1963. The risks of re-vaccination are:

1. no greater than the risk of the original measles vaccination; and

2. significantly less than the morbidity of natural measles infection

The following policy outlines the categories of persons for whom measles (MMR) re-vaccination is indicated.

The following persons must be re-vaccinated with live measles vaccine both for their individual protection against measles and in order to comply with the mandatory school immunization law:

1. Those who received live measles vaccine prior to their first birthday (12 months of age).

2. Those who received killed (inactivated) measles vaccine. If a person received killed measles vaccine and subsequently received a dose of live measles vaccine more that 3 months after the last dose of killed vaccine, re-vaccination is not necessary (as long as the dose of live vaccine was given at 12 months of age or older).

3. Those who received live measles vaccine within 3 months after the administration of immune globulin (IG). An example might involve a 1-year old child given IG for exposure to hepatitis A; if measles vaccination was then given less than 3 months later, the vaccine's effectiveness would be reduced and re-vaccination would be indicated.

4. Those who received live measles vaccine after their first birthday but who also received a simultaneous injection of gamma globulin.

5 Persons who were administered MMR less than 28 days after having received another live virus vaccine.

6. Persons vaccinated prior to l968 who have no documentation of the strain of vaccine that was used for their immunization. (i.e., the record states the child was given live measles vaccine but does not state Moraten, Schwartz or Edmonston B). Questions on the specific policy requirements as well as on the broader (optional) guideline should be addressed to the OPH Immunization Program at (504) 838-5300 or fax (504) 838-5206.

## CHRONOLOGY OF MEASLES VACCINE

1963: First measles vaccines licensed in the United States. Two vaccines were licensed: a live attenuated vaccine (Edmonston B strain) and an inactivated (killed) vaccine.

Inactivated (killed) vaccine was given as a series of 2-3 injections, without immune serum globulin.

Live vaccine was frequently given with immune serum globulin

1965: A new live virus measles vaccine was licensed (Schwartz strain of further attenuated, live vaccine).

Schwartz vaccine was given as a single dose without any immune serum globulin.

Edmonston B vaccine remained on the market.

Inactivated (killed) vaccine remained on the market.

1967: Final lots of further inactivated (killed) vaccine produced; product withdrawn from further use.

1968: A new strain of further attenuated, live measles vaccine was licensed (Moraten strain).

Moraten vaccine was given as single dose without any gamma globulin.

Schwartz vaccine remained on the market.

Edmonston B vaccine remained on the market but was infrequently used; it was virtually completely replaced by the further attenuated (Schwartz and Moraten) strains.

1968 to present:

Measles vaccine on the market was live, further attenuated type to be given as a single dose without any gamma globulin.

## POLICY ON POST-EXPOSURE TREATMENT FOR MEASLES CONTACTS

*These recommendations apply only to measles outbreak situations and should be implemented under the direction of the Immunization Program and/or Infectious Disease Epidemiology Program.*

Background

Children and adults who have been in close contact with a case of measles should be evaluated as quickly as possible in order to avoid secondary cases, with their associated morbidity and mortality. Approximately 10% of patients with active measles require hospitalization, and approximately 1 in 1000 die. Severe complications of measles include pneumonia (bacterial or viral) and encephalitis.

**Policy on post-exposure treatment for various high-risk groups**:

Household contacts

Household contacts under the age of one year or with immunodeficiencies should be given immunoglobulin within 6 days of exposure. Immunoglobulin should be given intramuscularly (preferably in the gluteus) at a dose of 0.25 ml/kg (maximum 15 ml - maximum per injection site 5 ml in children and 10 ml in adults). Measles vaccine should be given 5 months later or after the first birthday.

If immunoglobulin is not available, household contacts 6 months to 1 year should be given measles vaccine (single antigen or MMR) within 72 hours of exposure.

Children less than 6 months old should not be given measles vaccine, and have a high likelihood of protection from maternal antibodies.

Immunodeficient household contacts should not be given measles vaccine.

Immunodeficient contacts

Immunodeficient individuals exposed to measles should be given immunoglobulin within 6 days of exposure, in a dose of 0.25 ml/kg (maximum dose 15 ml, with 5 ml maximum per injection site) intramuscularly. Immunodeficient individuals should not be given measles vaccine.

Other non-household contacts

Children and adults over the age of 6 months with non-household exposure to measles should be evaluated for previous measles immunization.

If they have previously received 2 doses of measles vaccine after the first birthday or have a history of laboratory confirmed measles, no treatment is recommended.

If one previous dose of measles vaccine was given more than 1 month prior to the exposure, a second dose of measles vaccine (single antigen or MMR) should be administered immediately. All doses given

**POLICY ON POST-EXPOSURE TREATMENT FOR MEASLES CONTACTS (cont.)**

after the first birthday and at least one month apart are valid toward school entry requirements.

If no previous doses of measles vaccine were given, and the child is 6 months of age or older, 1 dose of measles vaccine should be given immediately (single antigen or MMR).

## 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 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 POLIOMYELITIS VACCINATION

Policy:

1. 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.

2. IPV may be given in OPH clinics to women who are pregnant.

3. 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).

4. IPV may be given to household contacts of persons with diseases that cause immune deficiency or receiving therapy that cause immune suppression.

5. 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.

## POLICY ON POLIO SCHEDULES AND RECOMMENDATIONS

Introduction

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.

I. Schedule:

**IPV schedule**

| Dose Number | Age of Child | Minimum Interval |
|---|---|---|
| 1 | 2 months | 6 weeks of age |
| 2 | 4 months | 1 month |
| 3 | 6 - 18 months | 1 month |
| First booster | 4-6 years | ------ |
| Subsequent boosters | Unknown | ------ |

II. 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.

**POLICY ON POLIO SCHEDULES AND RECOMMENDATIONS (cont.)**

III. 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.

IV. 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.

V. Adult Immunization

If adults were to be vaccinated in special circumstances, IPV should be used.

VI. 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 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**):

   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.

   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.

   Unimmunized children **12-14 months of age** should receive a primary series of one dose and a booster two months later.

   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.**

**ADMINISTRATION OF HAEMOPHILUS INFLUENZAE TYPE B (cont.)**

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-HbOC | Lederle/Praxis | HibTITER | Yes |
| HIB-PRP-OMP | Merck | PedvaxHIB | Yes |
| HIB-PRP-T | Pasteur Merieux | ActHib, OmniHib | Yes |
| DTaP/HIB | Sanofi-Pasteur | TriHIBit | No* |
| HIB-HBV | Merck | Comvax | Yes |
| 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 HbOC or 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 HEPATITIS A IMMUNIZATION

Policy:

Routine vaccination of children 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.

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:

1. All children should receive hepatitis A vaccine at age 1 year (i.e., 12--23 months). Vaccination should be completed according to the licensed schedules and integrated into the routine childhood vaccination schedule. Children who initiated HAV vaccine prior to 24 months of age can be completed at subsequent visits.

2. States, counties, and communities with existing hepatitis A vaccination programs for children aged 2--18 years are encouraged to maintain these programs. In these areas, new efforts focused on routine vaccination of children aged 1 year should enhance, not replace, ongoing programs directed at a broader population of children.

3. In areas without existing hepatitis A vaccination programs, catch-up vaccination of unvaccinated children aged 2--18 years can be considered. This may be especially warranted in the context of increasing incidence or ongoing outbreaks among children or adolescents.

4. 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.

5. Primary immunization with TWINRIX for high risk adults (18 years of age and older) consists of 3 does 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 and other individuals who do not 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 - 23 months | 720 EL.U | 0.5 | 2 | 1st dose @ 12 mos. Booster dose @ 18 – 24 mos |
| **VAQTA®*** | 12 – 23 months | 25 U | 0.5 | 2 | 1st dose @ 12 mos. Booster dose @ 18 – 24 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-, 21to 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, PCV7 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 (DCC) children and employees. (Consultation with the Infectious Disease Epidemiology Section should precede DCC 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 state laboratory.

A. Contraindications for ISG:
    1. Should not be given to persons with isolated immunoglobulin A(IgA) deficiency.
    2. Should not be given to patients who have severe thrombocytopenia or any other coagulation disorder that would contraindicate intramuscular injection.
    3. Should not be given to persons who are known to have an allergic response to thimerosal.
    4. 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.

B. Precautions: Do not administer intravenously.
C. Reactions: Very rarely causes adverse reactions. Discomfort may occur at the site of injection. The risk of hypersensitivity is very small.
D. 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.
E. Storage: Immune Globulin may be used up to the expiration date on the label if kept refrigerated at 2-8°C (35-46°F). It should not be frozen.
F. 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:

Hepatitis B vaccine shall be given in OPH clinics to all age groups from zero through eighteen years of age. The hepatitis B vaccine series should be started at birth (before hospital discharge), or at 1-2 months of age, when the usual infant universal Hepatitis B vaccinations are started. The 1st dose of HBV is recommended at birth, 2nd dose at 1-2 months of age with a minimum interval of 4 weeks and 3rd dose at 6-18 months of age with a minimum interval 8 weeks between the 2nd and 3rd dose, but at least 16 wks from the first dose.

1. Catch-up vaccination for older children in this group can happen at any time with a minimum interval of 1 month between dose 1 and dose 2, and a minimum interval of 2 months between dose 2 and dose 3 and be at least 16 weeks from the first dose.

2. Hepatitis B vaccine should be given intramuscularly in the anterolateral thigh. Infants with a known bleeding diathesis, such as hemophilia, may be given the vaccine subcutaneously. Do not administer the hepatitis B vaccine in the buttock.

3. Hepatitis B vaccine does not interfere with childhood immunizations, and may be given simultaneously with DTaP, DT, Td, Tdap, IPV, MMR, Varicella, Hib, HAV, PCV7, Rotavirus and Influenza. Two vaccinations may be given in the same thigh; however, different administration sites must be used.

4. Recombivax Hb can be used to complete a vaccination series which has been started with Engerix-B or visa-versa. Dosages must follow the correct dosing schedule which can be found in Appendix D-2.

5. Infants who are not immunized, or if there are doubts whether the infants have been immunized with hepatitis B vaccine at the time of birth, should be given the first dose of hepatitis B vaccine on the first visit to the parish health unit. The hepatitis B surface antigen negative dosage schedule should then be followed if maternal status documentation is unavailable.

    A. If the initial vaccination occurs before the age of one month, subsequent doses can be given according to the standard schedule (ages 2 months and 6 months).

    B. If the initial vaccination occurs after one month of age, the second and third doses should be given 1-2 months and four (4) months after the initial dose, respectively.

6. There will be no need for post-vaccination serologic testing of infants born to HBsAg-negative mothers.

7. In addition to the immunization of all infants born since July 1992, several special groups are eligible to receive hepatitis B. They are the following:

    A. Any child born since October 1, 1983 to a mother from an area recognized as an area of high hepatitis B endemicity. This includes Vietnam, Cambodia, Laos, Thailand, Peoples Republic of China, Taiwan, North and South Korea, Philippines, and the western Pacific islands, in Louisiana primarily targeting all Southeast Asians (Vietnamese, Cambodians, Laotians).

B. HBV vaccine is routinely recommended for all adolescents 18 years or less. See policy on Adolescent Immunization.

C. All persons who are household or sexual contacts to carriers of the hepatitis B virus, primarily for contacts of female carriers identified as part of the perinatal hepatitis B program. See policy on the Immunization of High-Risk Contacts of Hepatitis B Carriers.

D. Additional procedures are required for children born to HBsAg positive women. See policy on Antepartum Program for Hepatitis B Screening and Prevention of Hepatitis B in High-Risk Newborns.

For additional information on Hepatitis B immunizations see the following articles:

Protection against viral hepatitis: MMWR 1990; 39(RR-2): 1-26 or www.cdc.gov/mmwr/preview/mmwrhtml/00041917.htm on the internet.

A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States. MMWR 2005; 54(No. RR-16): 1-23 or www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm on the internet.

Update: Recommendations to prevent Hepatitis B virus transmission—United States: MMWR 1995; 44(30): 574-575 or www.cdc.gov/mmwr/preview/mmwrhtml/00038437.htm on the internet.

## ANTEPARTUM PROGRAM FOR HEPATITIS B SCREENING AND PREVENTION OF HEPATITIS B IN HIGH RISK NEWBORNS

Rationale:

Perinatal transmission of hepatitis B virus is associated with substantial morbidity and mortality. Up to 90% of newborn infants infected with Hepatitis B become chronically infected, with a high risk of eventual liver failure or liver cancer. These chronically infected infants will also be carriers of the disease and can infect close contacts throughout their lives.

Policy:

In order to interrupt this continuing cycle of disease, all pregnant women receiving prenatal care should be screened for Hepatitis B surface antigen (HBsAg), in order to preventively treat their newborn infants shortly after birth. Infants of HBsAg positive women will receive hepatitis B immune globulin and the initial dose of hepatitis B vaccine in the hospital immediately after birth and will receive the second and third doses of hepatitis B vaccine at the parish health units. Follow-up hepatitis B serologic testing of infants born to HBsAg positive mothers will be performed to determine vaccine response.

Guidelines:

I. Hepatitis B blood screening of pregnant women

A. The hepatitis B blood screening should be performed during the initial prenatal visit. One tube of blood will be drawn using a red-gray top (serum separation tube – SST) also referred to as tiger top tube for blood collection.

B. Hepatitis B serologic testing will be available through the State Laboratory. Results of the screening will be mailed to the health unit where it will be attached to the patient's prenatal medical record. HBsAg positive women's records will be flagged. This will ensure immediate identification of the carrier status on future prenatal visits and on admission for delivery. This will be accomplished by placing an adhesive indication label on the outside cover of the chart. A copy of the Imm-27 for HBsAg positive women should be sent to the Immunization Program.

C. No routine follow-up testing to monitor the hepatitis B serologic status of pregnant women will be provided. Exceptions will be made if the results of the first test were questionable. If retesting is indicated to confirm initial results, then follow-up testing will be provided.

D If a woman has not been screened for HBsAg prenatally, or if test results are not available at the time of admission for delivery, HBsAg testing should be done on admission. During medical emergencies, health units can provide HBsAg results over the telephone to hospitals and physicians caring for women at delivery.

E. Women found to be HBsAg positive will be counseled regarding their own health and the risks to their sexual and household contacts.

**ANTEPARTUM PROGRAM FOR HEPATITIS B (cont.)**

II. Tracking of infants born to HBsAg-positive women

A. The parish health unit staff will work with personnel in hospitals to assure that infants born to HBsAg positive women are identified, followed and appropriately vaccinated. The mothers' carrier status will be indicated on the copies of the prenatal records that are sent to the hospitals. Information about the mothers' carrier status and the immunization status of their infants will be indicated on the newborn referral forms that are sent from hospitals to parish health units. The date(s) that HBIG and the initial dose of Hepatitis B vaccine were given should be indicated on the newborn referral. Copies of the newborn referral forms will be sent to the Immunization Section.

B. The Immunization Program of the Office of Public Health will maintain a registry of HBsAg positive women and their infants identified in the program. Each Health Unit will maintain a tickler file on the children born to the HBsAg positive women to ensure timely vaccination.

C. The registry will be used to monitor the success of the vaccination program. Infants who have not received Hepatitis B Vaccine at the recommended ages will be identified, and the Regional Immunization Consultants will work with parish health unit staff to assure that these infants are brought to the health units for vaccination. The health unit will send an immunization update to the Immunization Program.

III. Hepatitis B Vaccine for Infants

A. All infants born to known HBsAg positive mother qualify for free hepatitis B immune globulin and hepatitis B vaccine and should receive the entire series outlined below.

B. Infants who were begun on the hepatitis B vaccine series elsewhere, but are brought to any OPH clinic prior to completion of the vaccine series, are eligible for free hepatitis B vaccine.

C. If a mother is identified to be HBsAg positive a month or more after birth, the infant should be given the first dose of Hep B vaccine (high risk newborn dose) if not yet vaccinated and be tested for Hepatits B core antibody and HBsAg. If the infant tests negative for both of these, the baby should continue to receive Hepatitis B vaccine and complete the hepatitis B vaccine series.

IV. Vaccine Dosage, Schedule and Administration

A. The following immunization schedule is recommended by the Advisory committee on Immunization Practices (ACIP) to the Centers for Disease Control and the American Academy of Pediatrics (AAP), and adopted by the Office of Public Health (OPH):

1. Administer Hepatitis B immunoglobulin (HBIG) intramuscularly in the anterolateral thigh muscle as soon as the newborn is stabilized, preferably in the delivery room, and within 12 hours of birth. In addition, administer hepatitis B vaccine intramuscularly in the alternate anterolateral thigh muscle. **Do not administer hepatitis B vaccine in the buttocks**.

2. Complete the remaining two doses of the Hepatitis B vaccine series in a timely manner, with the second dose given at 1-2 months of age, and the third at a minimum of 6 months of age.

B. The amount of each dose is shown in the "Recommended Doses of Currently licensed Hepatitis B Vaccines" at the end of the chapter.

C. HBIG does not interfere with routine childhood immunizations, except MMR, MMR-Var, varicella and Rotavirus vaccines. MMR, MMR-Var and varicella vaccines should not be given for 3 months after HBIG. Other childhood vaccines, specifically DTaP, IPV, HAV, HBV, PCV7 and Hib can be given simultaneously with HBIG. All childhood vaccines can be given simultaneously with Hepatitis B vaccine.

D. HIV infection and AIDS are not contraindications for Hepatitis B vaccine and HBIG. Infants born to HIV-infected women should receive appropriate hepatitis prevention based on the mother's HBsAg results.

V. Strategies if an interruption occurs in the administration of the hepatitis B series.

A. Never restart the series because there has been an interruption. Example: If two years elapse after dose #2 in the series, extra doses are not added to the series and the series is not restarted. The next dose given will be dose #3 and will complete the primary series.

B. If the second dose is off-schedule:

1. If 1-2 months late for the second dose, continue the vaccine series and administer the third dose on schedule (four (4) months after the first dose).

2. If the second dose is delayed by more than two months, administer the third dose now as long as it has been a minimum of 4 months from the first dose.

3. If there has been more than 6 months delay in the administration of the second dose, please telephone the Immunization Program to discuss the possibility of testing the baby for infection before restarting the series.

C. If the third dose is off schedule:

1. If the third dose is late by 1-6 months, complete the vaccine series by giving the third dose and obtain post-vaccination serologic testing when the baby is 15 months of age.

2. If the baby is 15 months of age or older at the time of completion of the vaccine series, the baby should receive post-vaccination serologic testing one month after the last dose.

VI. Babies who begin on the Hepatitis B vaccine series after the age of 12 months.

A. Babies who start the hepatitis B vaccine series more than 12 months after birth are not routinely offered post-vaccination serology testing by OPH. Exceptions may be made if the vaccine doses were administered significantly off schedule. Please telephone the Immunization Program regarding these situations.

VII. Follow-up Hepatitis B Serologic Testing of Infants.

A. For those infants who started the hepatitis B vaccine series at birth and who have been on schedule in receiving the hepatitis B vaccine, the follow-up serologic testing of the baby is performed at 15 months of age.

B. For infants 15 months of age or older at the time of completion of the vaccination series, post-vaccination testing should be performed one month after the last dose of the series.

C. To request post vaccine testing, use the Lab 95 lab slip and request HBsAg and anti-HBs. Also include on the lab slip the baby's age and reason for testing (Post Vaccine Testing). The minimum amount of blood needed to perform the test is 3 ml.

D. A successful immune response to immunization is demonstrated by negative serologic results for HBsAg and positive anti-HBs, showing that the child has antibodies to the virus, and no active virus present to produce surface antigen. A carrier is identified when the HBsAg is positive and the Anti-HBs is negative. This indicates that the child did not make antibodies to the viral antigen in the vaccine, was infected, and continues to have active virus present to produce surface antigen. Uninfected vaccine failure is indicated by a negative test for anti-HBs and HBsAg. This child has no antibodies to hepatitis B antigens, and no active virus to produce surface antigen, thus the child remains susceptible to Hepatitis B infection. Further information for the interpretation of hepatitis B lab results is available through the Immunization Program.

VIII. Non-responder re-vaccination

A. If the infant's post-vaccination serologic results are negative for HBsAg and antibodies to surface antigen (anti-HBs), a fourth dose of vaccine should be administered. Repeat the post-vaccine testing 1-2 months after the fourth dose is given. If the HBsAg and anti-HBs results are still negative, complete the revaccination with two additional doses following the same schedule as before (i.e. 5th dose 1-2 months after 4th, 6th dose 6 months after 4th).

B. Re-test infants after completion of the second series. If HBsAg and anti-HBs are still negative, document it. No further Hepatitis B vaccination will be given. Please report any infants who have negative results at the end of the first and second series to the Immunization Program.

IX. Breast-feeding in infants of HBsAg-positive mothers

A. Breast-feeding poses no risk of hepatitis B infection to infants of HBsAg-positive women as long as their infants have received prophylaxis (HBIG and the first dose of hepatitis B vaccine).

# POLICY ON THE IMMUNIZATION OF HIGH-RISK CONTACTS OF HEPATITIS B CARRIERS

Policy:

This policy describes the procedures for identification, referral, screening, vaccination, and monitoring of persons who are household or sexual contacts to carriers of the hepatitis B virus. The procedures are designed primarily for contacts of female carriers identified as part of the perinatal hepatitis B program. However, should this program expand in the future the same procedures may be followed if parish health units identify other hepatitis B carriers whose contacts require vaccination.

Guidelines:

I. Identification and Referral

After a person is identified as a HBsAg carrier, a nurse from the parish health unit will ask her/him at the time of the next clinic visit to name all household members and sexual contacts. Household members to be considered for vaccination are those who are currently living with the carrier, regardless of age; sex partners to be considered are regular partners during the previous year. The carrier will be given a referral card (available from the Immunization Section) for each household member and instructed to tell each household member to come to the health unit for screening and vaccination. Referral cards will also be given for sex partners who are not also household members if their names are supplied by the carrier.

The names of contacts will be listed in the Hepatitis B Contact Follow-up Form (Epi-32) and a copy of this form should be sent to the Immunization Program. Two additional copies of this form will remain in the parish health unit to record information on contacts as they are vaccinated.

II. Screening and Vaccination

A. Children Under Age 7

All named contacts under age 7 who come to the health unit should be vaccinated without prior screening for hepatitis B markers. The recommended vaccination schedule should be used.

B. Older Children and Adults

Contacts age 7 or above who come to the health unit will have blood drawn for Hepatitis B Core Antibody (anti-HBC) to test for susceptibility to hepatitis B. Three ml of blood should be drawn in a red-gray top (serum separation tube – SST) also referred to as tiger top tube for blood collection with an attached hepatitis laboratory slip. This blood sample should be sent to the state central laboratory for testing in the same way as the prenatal HBsAg test.

At the same initial visit, the first dose of HBV should be given, and follow-up appointments should be made for the second and third doses of vaccine (one and four months later respectively).

**HIGH-RISK CONTACTS OF HEPATITIS B CARRIERS (cont.)**

If the contact is found to have already been 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 contact is susceptible to hepatitis B (anti-HBC negative), the contact should keep the appointments at the health unit for the second and third doses.

III. Vaccine Administration

The vaccine should be given intramuscularly in the deltoid region for adults and older children and in the antero-lateral thigh for infants under 12 months of age. The second and third doses should be given one and six months after the initial dose. The amount of each dose is shown in the "Recommended Doses of Currently Licensed Hepatitis B Vaccines" form.

IV. Interruptions in the vaccine schedule

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 a minimum of 2 months. If the vaccine series is interrupted after the second dose, the third dose should be given as soon as practical.

V. Follow-up of contacts who do not come for vaccination

The amount of effort to be spent in locating a contact should include consideration of the contact's risk and on the likelihood that he/she will complete the three-dose series. Household contacts that are children (under age 15) and household contacts that are also sexual contacts (such as spouses) are at the highest risk, and if possible telephone calls should be made to encourage them to come to the health unit for vaccination if they do not do so on their own. Those household contacts who have come to the health unit for the initial dose of vaccine should be telephoned and reminded to come in for subsequent doses; if they do not come in after three attempted telephone calls their names should be referred to the regional Immunization Consultant, who should continue to encourage them to complete the vaccine series. Other household contacts that do not come to the health unit voluntarily for the first dose of vaccine will be called as time permits. Additional follow-up to remind them of the availability of vaccination will depend on the resources available at the parish health unit.

VI. Post-vaccination Testing

No post-vaccination serologic testing will be done for contacts of carriers. Contacts who wish to be tested for antibodies to hepatitis B should be referred to a private physician.

VII. Tracking

Information about the contacts will be maintained in both the central office (Immunization Program) and the parish health units. Initially, all names of contacts should be listed on the Hepatitis B Carrier Follow-up Form and a copy (printed or photocopied) of the form should be sent to the Immunization Program. As each contact comes to the health unit and receives vaccine, the vaccination dates should be recorded in LINKS and provide the contact with a vaccine record. When all contacts are completely vaccinated of one year after the form was begun, the form should be closed and the second copy of the form forwarded to the Immunization Program. The third copy of the form should remain in the parish health unit.

Louisiana Department of Health and Hospitals
Office of Public Health

**PERINATAL HEPATITIS B SURVEILLANCE FORM**

SECTION I: PRENATAL CARE

Part A: Identifying Information(Mother)

1. Last Name _____ 2. First Name _____

3. Address _____

4. City _____ 5. Zip _____ 6. Parish _____

7. Telephone _____

8. Age _____ 9. Date of Birth ____/____/____ (mo day yr)

10. Race(check): ☐White ☐Black ☐Asian/Pacific Islander ☐Other _____ 11. Ethnicity: ☐Hispanic ☐Non-Hispanic

Part B: Medical Information (Mother)

1. Prenatal care received? ☐Yes ☐No

2. Name of prenatal care provider/clinic name _____ 3. Clinic Phone #: _____

4. Expected delivery date ____/____/____ (mo day yr)

5. Date hepatitis blood drawn ____/____/____ (mo day yr)

HBsAg test result (during this pregnancy): ☐Pos ☐Neg Date: _____
anti-HBs: ☐Pos ☐Neg Date: _____
anti-HBc: ☐Pos ☐Neg Date: _____

6. Expected hospital of delivery _____

7. Expected clinic/provider to care for infant _____

SECTION II: HOSPITAL CARE

Part A: Mother

1. Pregnancy outcome ☐ live birth ☐ stillborn ☐ miscarriage ☐preg. terminated

2. Hospital of delivery _____

Part B: Infant

1. Last Name _____ 2. First Name _____

3. Date of Birth ____/____/____ (mo day yr) 4. Sex ☐ Male ☐

5. HBIG date ____/____/____ (mo day yr) 6. HBIG time ____:____ am/pm (hr mn) 7. 1st dose HBV date ____/____/____ (mo day yr)

Please fax or email form to:

Louisiana Department of Health and Hospitals
Office of Public Health-Immunization Program
Attn: Adrienne Mercadel Whitney, MPH
(504) 838-5300
(504) 838-5206 fax
Adrienne.Mercadel@la.gov

# INSTRUCTIONS FOR COMPLETING
# PERINATAL HEPATITIS B SURVEILLANCE AND FOLLOW-UP FORM

## SECTION I: PRENATAL CARE

Part A: Identifying Information – Mother

1 – 7. Enter the patient's name, street address, city, zip code, parish of residence and home telephone number.

8 – 9. Enter the patient's age and date of birth.

10 – 11. Check the race and ethnicity of the patient. If the patient is neither Black, White, nor Asian, enter the race of the patient in the space provided.

Part B: Medical Information

1. Indicate whether or not the patient received prenatal medical care from any health care provider.
2. If the patient received prenatal care, enter the name of the clinic or physician's office where prenatal care was given.
3. Enter the clinic or physician's office phone number.
4. Enter the date in which the patient is expected to deliver.
5. Enter the date in which blood was drawn from the patient for the purpose of HbsAg testing
6. Enter the name of the hospital in which the patient is expected to deliver.
7. Enter the name of the clinic/physician's office in which the infant will receive medical care (after delivery).

## SECTION II: HOSPITAL CARE

Part A: Mother

1. Check the outcome of the patient's pregnancy.
2. Enter the name of the hospital in which the delivery took place.

Part B: Infant

1 – 2. Enter the infant's given name.
3. Enter the infant's date of birth.
4. Enter the sex of the infant.
5 - 6. Enter the date and time that HBIG was administered to the infant.
7. Enter the date of the first dose of HBV given to the infant.

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LOUISIANA DEPARTMENT OF HEALTH AND HOSPITALS
OFFICE OF PUBLIC HEALTH

# HEPATITIS B CONTACT FOLLOW-UP FORM

Clinic/Health Unit _____ Interviewer _____ Date of interview____/____/____

**Carrier Information:**

Name _____ Address _____ Telephone _____
DHH Id# _____

Age _____ Sex _____ Race _____ Ethnicity _____ City _____ Parish _____ Zip Code _____

Contacts: (attach additional forms if necessary)

| Name | Age | Race | Sex | (1) Relation to Carrier | (2) Hepatitis Serology | Address (if different from carrier address) | Hepatitis B Vaccination Dates | (3) Final Disposition |
|---|---|---|---|---|---|---|---|---|
| 1. _____ | Y<br>M | | | | Anti-HBC____<br>HBsAg ____<br>Anti-HBS____ | Street _____ Telephone<br>City _____ Parish _____ Zip | Dose #1 ____/____/____<br>Dose #2 ____/____/____<br>Dose #3 ____/____/____ | ____ |
| 2. _____ | Y<br>M | | | | Anti-HBC____<br>HBsAg ____<br>Anti-HBS____ | Street _____ Telephone<br>City _____ Parish _____ Zip | Dose #1 ____/____/____<br>Dose #2 ____/____/____<br>Dose #3 ____/____/____ | ____ |
| 3. _____ | Y<br>M | | | | Anti-HBC____<br>HBsAg ____<br>Anti-HBS____ | Street _____ Telephone<br>City _____ Parish _____ Zip | Dose #1 ____/____/____<br>Dose #2 ____/____/____<br>Dose #3 ____/____/____ | ____ |
| 4. _____ | Y<br>M | | | | Anti-HBC____<br>HBsAg ____<br>Anti-HBS____ | Street _____ Telephone<br>City _____ Parish _____ Zip | Dose #1 ____/____/____<br>Dose #2 ____/____/____<br>Dose #3 ____/____/____ | ____ |

(1) For family members. List relationship to carrier (e.g. son, daughter, cousin), for others use HH-household member, SP-sex partner, IV-intravenous drug use companion
(2) List known results as Pos-positive, Neg-Negative. Leave blank if unknown or not done.
(3) Use these codes: 1-Received 3 doses, 2-Received 1-2 doses, 3-Preveiously vaccinated, 4-Previously infected, 5-Refused vaccination, 6-Unable to contact



Rev. 09/2010

# HEPATITIS B CONTACT FOLLOW-UP FORM
# INSTRUCTIONS

## General

The purpose of this form is to identify high-risk contacts of carriers of hepatitis B, and to maintain information on the results of their blood tests and their vaccination against hepatitis B. At the time of the carrier is told of his/her carrier status, all household members, sex partners, and intravenous drug using companions should be identified and listed on the form. A photocopy of the form should be submitted to the Immunization Section at this time. Attempts should be made to contact these persons listed and offer them vaccination against hepatitis B (three doses of vaccine given at 0, 1, and 6 months). When all contacts have completed the series, or 12 months after the initial interview, all contacts regardless of number of vaccinations received should be given final disposition and a second copy of the form should be submitted to the Immunization Section.

## Top Portion

List: Name of clinic or parish health unit
Name of interviewer
Date of interview to elicit contacts of carrier

## Carrier Information

List the hepatitis B carrier's name, street address, home telephone number, DHH identification number, age, sex, race, ethnicity (e.g. Hispanic), city, parish, and zip code of residence.

## Contact Information

List each person who is identified by the carrier as a household member, sexual partner, or intravenous drug use companion.

For each contact, list:

Name
Age (in years, or in months for children < 2; circle Y or M to indicate years to months)
Race (W-White, B-Black, A-Asian/Pacific Islander, O-Other)
Relationship to carrier – For family members, list relationship to carrier (e.g. son, daughter, sister, husband, cousin), for others code as HH-Household member, SP-Sex partner, or IV-Intravenous drug use companion (use as many codes as apply)
Hepatitis serology results (Pos-Positive, Neg-Negative, leave blank if unknown/not done)
Address, telephone number, city, parish, and zip code of residence – if different from carrier address)
Hepatitis B Vaccination dates (month, day, and year the three doses of vaccine given)
Final disposition – list final outcome regarding hepatitis B vaccine using the following codes:

1 – Received complete vaccine series (3 doses)
2 – Received partial vaccine series (1 or 2 doses)
3 – Previously vaccinated against hepatitis B
4 – Previously infected with hepatitis B (positive for anti-HBC, HBsAg, or anti-HBS)
5 – Refused vaccination
6 – Unable to contact

Return form to:

Louisiana Department of Health and Hospitals
Office of Public Health-Immunization Program
Attn: Adrienne Mercadel Whitney, MPH
1450 L & A Rd.
Metairie, LA 70001

Rev. 09/2010

## POLICY ON VARICELLA 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.

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 between administration of the 2 doses.

> **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.

**Simultaneous vaccine administration:**

Varicella vaccine and MMR/VAR combination vaccine do not interfere with other routine childhood 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 and MMRV combination vaccine are less stable than other vaccines that are routinely handled. Both 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. Dormitory style refrigerators, usually smaller, are **not acceptable** for the storage of either vaccine.

**Reconstituted Vaccine**

Do not store reconstituted vaccine. Both Varicella 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. Inquiries concerning varicella vaccine or MMRV vaccine may be directed to the Immunization Program at (504) 838-5300.

## POLICY ON DTaP, DT, Td AND Tdap VACCINATIONS

Policy:

1. 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. For children who have started the vaccination series with one, two, three, or four doses of whole-cell DTP, DTaP is also recommended for all remaining doses in the schedule. Exceptions are outlined below.

2. Three acellular pertussis vaccines (Tripedia® and Infanrix™ for the first four doses and ACEL-IMUNE® for all five doses) are licensed for the diphtheria, tetanus, and pertussis vaccination series. FDA has not approved Tripedia® or Infanrix™ as the fifth dose among persons who have only received Tripedia® or only Infanrix™ for the first four doses in the vaccination series. TriHIBit (ActHIB® reconstituted with Tripedia®) is licensed only for the fourth dose of the vaccination series, and is not licensed for the first three doses. TriHIBit™ can be used for the fourth dose following three doses of either DTaP or whole-cell DTP and a primary series of any Hib vaccine. See chart below.

| DTaP Product | Dose 1 | Dose 2 | Dose 3 | Dose 4 | Dose 5 |
|---|---|---|---|---|---|
| Tripedia® | √ | √ | √ | √ | * |
| ACEL-IMUNE® | √ | √ | √ | √ | √ |
| Infanrix™ | √ | √ | √ | √ | * |
| TRIHIBit™ | | | | √ | |

* Tripedia® and Infanrix™ can be used as a fifth dose for children who start the vaccination series with one, two, three, or four doses of whole-cell pertussis vaccines (DTP).

3. 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.

4. The dose of all four 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:
   a. less than recommended doses of 0.5 ml.
   b. 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.

5. 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.

6. 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. Two new tetanus diphtheria toxoids and acellular pertussis (Tdap) vaccines have been licensed by the FDA. One formulation is licensed for use in persons aged 10 – 64 years of age and the other is licensed for persons aged 11- 64 years. Tdap has so far been approved for one-time use per person as a booster. **NOTE:** The Advisory Committee on Immunization Practices (ACIP) recommends Tdap vaccine for adolescents age 11-12 years for those who have completed the recommended childhood DTP/DtaP vaccination series and have not yet received a Td booster dose.

7. No minimum interval is required between giving doses of Td and Tdap to an adolescent who is or might be in contact with an infant. This includes adolescents who are older siblings of infants, babysitters, or hospital employees or volunteers, etc. In circumstances like this, give Tdap without delay. For adolescents who will not be in contact with infants, CDC/ACIP recommends a routine wait of 5 years between Td and Tdap administration unless a school vaccination mandate requires giving 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.

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

   a. 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.

   b. 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.

   c. 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.

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

   e. 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.

f. 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.

9. 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.

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

## Inadvertant 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 thses 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.

a) 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 stuill 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.

b) If the **Tdap** is inadvertently administered as the foruth or fifth dose in the tetanus-diphtheri-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.

c) 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.

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 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 7-valent pneumococcal conjugate vaccine formulation (PCV7).

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).

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).

Unvaccinated children 7 months of age and older

**Infants 7 through 11 months of age**

- 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 give at age 12 through 15 months, at least 8 weeks after the second PCV13 dose (Table 1).

**Children 12 through 23 months of age**

- Two doses are recommended, with an interval of at least 8 weeks between doses (Table 1).

**Children 24 months of age and older**

- 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).

2. Children incompletely vaccinated with PCV7 or PCV13

**Children <24 months of age**

- o 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).

**Children >24 months of age**

- o 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).
- o 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).
- o The minimum interval between doses is 8 weeks.

3. Children completely vaccinated with PCV7

- o 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).
- o 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).
- o PCV13 should be given at least 8 weeks after the last dose of PCV7 or PPSV23.

4. Children 6 through 18 years of age with high risk conditions

- o 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.

5. Use of PPSV23 among children 2 through 18 years of age who are at increased risk for invasive pneumococcal disease

- o 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.
- o Doses of PCV13 should be completed before PPSV23 is given.
- o The minimum interval is at least 8 weeks after the last dose of PCV13.
- o However, children who have previously received PPSV23 should also receive the recommended PCV13 doses.
- o 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
- o 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 Regimen[1] |
|---|---|---|
| **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 dose[2] |
| | 2 or 3 doses before age 12 mo | 1 dose, ≥ 8 weeks after the most recent dose[2] |
| | 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 Regimen[1] |
|---|---|---|
| **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*<br>Chronic lung disease†<br>Diabetes mellitus<br>Cerebrospinal fluid leaks<br>Cochlear implant |
| **Children with functional or anatomic asplenia** | Sickle cell disease and other hemoglobinopathies<br>Congenital or acquired asplenia, or splenic dysfunction |
| **Children with immunocompromising conditions** | HIV infection<br>Chronic renal failure and nephrotic syndrome<br>Diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; or solid organ transplantation<br>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

Invasive disease from *Streptococcus pneumoniae* (pneumococcus) is a major cause of illness and death in the United States, with an estimated 43,500 cases and 5,000 deaths among persons of all ages in 2009. Pneumococcal pneumonia is the most common clinical presentation of pneumococcal disease among adults. Since the introduction of the routine infant 7-valent pneumococcal conjugate vaccine (PCV7), by 2007, the overall incidence rate of Invasive Pneumococcal Disease (IPD) among persons of all ages had decreased by 45% (from 24.4. to 13.5 per 100,000 population), compared with 1998--1999 before PCV7 was introduced. The decreases resulted from reductions of 87% to 92% in cases of infection with serotypes covered in PCV7. Despite the major direct and indirect PCV7 effects, IPD remains an important cause of illness and death; approximately 84% of IPD cases and nearly all deaths occurred in adults. Rates of pneumococcal infection in the United States vary among demographic groups, with higher rates among infants, young children, and older persons.

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.

Guidelines

**NOTE: Due to limited supplies of vaccine and authorized funding, the state can not serve all the population at high risk or others listed in the information sheets. Therefore, first priority will be given to persons ≥ 65 years of age and those ≥ 65 years classified as high risk individuals listed in this policy that attend the Office of Public Health clinics. All other groups should be encouraged to see their primary care physicians for PPSV.**

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 124)

All persons should be vaccinated with PPSV23 at age 65 years. Those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine 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.

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.

Vaccination Schedule and Dosage

Only one dose of Pneumococcal Polysaccharide Vaccine (0.5 ml.) which contains 25 ug of each antigen is all that is needed. Persons with uncertain or unknown vaccination status should be vaccinated. Routine revaccination of immunocompetent persons previously vaccinated with 23-valent polysaccharide vaccine is not recommended.

Individuals that received the 14-valent polysaccharide vaccine licensed in 1974, need to be revaccinated. Also a second dose is recommended for those people aged 65 and older who got their first dose (whether 14-valent polysaccharide vaccine, or 23-valent polysaccharide vaccine) when they were under 65 years of age, if five or more years have passed since the first dose.

Only one revaccination dose is recommended for high risk persons. If a second dose is warranted, the second dose should be administered five or more years after the first dose. Revaccination three years after the previous dose may be considered for children at highest risk for severe pneumococcal infection who would be aged 10 years or less at the time of revaccination.

Simultaneous Vaccine Administration

Pneumococcal Polysaccharide Vaccine (PPV) does not interfere with other routine childhood immunizations and may be given simultaneously with IPV, OPV, DtaP, DT, Tdap, Td, MMR, HBV, HAV, PCV7, 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 PPSV, see MMWR 2010; 59(34):1102- 1106 or http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm on the internet.

# POLICY ON INFLUENZA VACCINE

Policy:

Influenza vaccination shall be given in OPH clinics in keeping with the ACIP and CDC recommendations. The OPH Immunization Program recommends immunization of the elderly and those individuals who are at high risk of serious illness or death from influenza. While influenza immunization is recommended for the same high risk individuals as in previous years, and this program targets high risk only, CDC has classified high-risk groups on the basis of priority, based upon epidemiologic studies and observations of morbidity and mortality due to 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. While DHH-OPH vaccine supply is limited, vaccination efforts should focus on delivering vaccination to the following persons:

- all children aged 6 months-- 18 years;
- all persons aged ≥50 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 persons who live with or care for persons at higher risk for influenza-relate 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.

Healthy persons who are infected with influenza virus, including those with subclinical infection, can transmit influenza virus to persons at higher risk for complications from influenza. In addition to HCP, groups that can transmit influenza to high-risk persons include:

- employees of assisted living and other residences for persons in groups at high risk;
- persons who provide home care to persons in groups at high risk; and
- household contacts of persons in groups at high risk, including contacts such as children or mothers of newborns.

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 public funding preclude OPH from serving all population groups as listed.

Groups not served by OPH should be encouraged to see their own physicians or to organize immunization programs for influenza. Additionally, many health services organizations other than OPH institute their own immunization programs for personnel each year.

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. **NOTE:** The 2010--11 seasonal influenza vaccine will contain an influenza A (H1N1) California/7/2009-like strain, which was also the strain used for the 2009 pandemic H1N1 monovalent vaccines.

The effectiveness of influenza vaccine in preventing or attenuating illness varies, depending primarily on the age and immunocompetence of the vaccine recipient and the degree of similarity between the virus strains included in the vaccine and those that circulate during the influenza season. Influenza viruses for both the inactivated and live attenuated influenza vaccines are initially grown in embryonated hens eggs. Thus, both vaccines might contain limited amounts of residual egg protein. LAIV is contraindicated in individuals with a history of hypersensitivity, especially anaphylactic reactions to eggs, egg protein, gentamicin, gelatin, or arginine or with life-threatening reactions to previous influenza vaccinations. Do not administer LAIV vaccine to children < 24 months of age or older than 49 years of age.

Either trivalent inactivated vaccine (TIV) or live, attenuated influenza vaccine (LAIV) should be used when vaccinating persons aged 2 through 49 years who do not have medical conditions that put them at higher risk for flu complications. LAIV is an option for vaccination of healthy nonpregnant persons aged 2--49 years without contraindications, including HCP and other close contacts of high-risk persons (excepting severely immunocompromised hospitalized persons who require care in a protected environment). The precaution regarding use of LAIV in protected environments is based upon a theoretic concern that the live attenuated vaccine virus could be transmitted to severely immunocompromised persons. Vaccine recipients or their parents/guardians should be informed by the health care provider that LAIV is an attenuated live virus vaccine and has the potential for transmission to immunocompromised household contacts (e.g., patients with hematopoietic stem cell transplants). Household contacts of these immunocompromised persons should receive the TIV vaccine. In addition, vaccine providers and staff must screen for possible reactive airway disease when considering use of LAIV for children aged 2 through 4 years, and should avoid use of this vaccine in children with asthma or recent wheezing episode within the past 12 months. Instead, they should be given the TIV vaccine.

For children aged 2 years through 8 years who have not previously received influenza vaccine, the recommended dosage schedule for LAIV intranasal administration is one 0.2 ml (0.1 ml per nostril) followed by a second 0.2 ml dose (0.1ml per nostril) given at least one month later. The effectiveness or safety of LAIV is not known or is of potential concern for certain persons, and LAIV is not recommended for these persons. Do not administer LAIV to the following groups:

- persons with a history of hypersensitivity, including anaphylaxis, to any of the components of LAIV or to eggs;
- children aged <2 years, because of an increased risk for hospitalization and wheezing observed in clinical trials;
- children aged 2--4 years whose parents or caregivers report that a health-care provider has told them during the preceding 12 months that their child had wheezing or asthma or whose medical record indicates a wheezing episode has occurred during the preceding 12 months;
- persons with asthma;
- persons aged ≥50 years;
- adults and children who have chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic/neuromuscular, hematologic, or metabolic disorders (including diabetes mellitus);
- adults and children who have immunosuppression (including immunosuppression caused by medications or by HIV);

- children or adolescents aged 6 months--18 years receiving aspirin or other salicylates (because of the association of Reye syndrome with wild-type influenza virus infection); or
- pregnant women.

All health care personnel administering any influenza vaccine should review the package insert for vaccine dosage and vaccine administration information.

**Recommended dosing by patient age and formulation:**

As in previous recommendations, all children aged 6 months--8 years who receive a seasonal influenza vaccine for the first time should receive 2 doses. Children who received only 1 dose of a seasonal influenza vaccine in the first influenza season that they received vaccine should receive 2 doses, rather than 1, in the following influenza season. New dosing guidance was issued for 2010-2011 influenza vaccine for children 6 months through 8 years:

- A child with an unknown or uncertain history of seasonal influenza vaccine should get 2 doses.
- A child who did not get H1N1 vaccine during the 2009-10 influenza season should get 2 doses.
- A child who got H1N1 vaccine during the 2009-2010 season and who got seasonal influenza vaccine prior to the 2009-10 season flu season should get 1 dose.

For children aged 6 months--8 years ***not previously vaccinated***, or ***vaccinated for the first time during the 2009-2010 influenza season***, use the following table:

| Number of influenza vaccine doses received in 2009-2010 season for **H1N1** | Number of influenza vaccine doses received in 2009-2010 season for **Seasonal** | Number of doses recommended for the 2010-2011 season |
|---|---|---|
| 0 | 0, 1 or 2 | 2 |
| 1 | 0 | 2 |
| 1 | 1 | 2 |
| 1 | 2 | 1 |
| 2 | 2 | 1 |
| 2 | 0 | 2 |
| 2 | 1 | 2 |

***2010-2011 Influenza Vaccines for different age groups:***

| **Age Group** | **Dosage** | **Formulation** | **No. of Doses** | **Route*** |
|---|---|---|---|---|
| 6-35 months | 0.25ml | Fluzone® Preservative-free:Pediatric Dose<br><br>Afluria | 1 or 2† | Intramuscular |
| 3-8 years | 0.50ml | Fluzone® | 1 or 2† | Intramuscular |
| ≥9 years | 0.50ml | Fluzone® | 1 | Intramuscular |
| ≥ 3 years | 0.5 ml | FluArix | 1 | Intramuscular |
| ≥ 4 years | 0.5 ml | FluVirin | 1 or 2† | Intramuscular |
| ≥ 18 years | 0.5 ml | FluLaval | 1 | Intramuscular |
| 2 – 49 years | 0.2 ml sprayer, divided dose | FluMist | 1 or 2† | Intranasal |

*For older children, the recommended site of vaccination in the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh.

†Two doses administered at least 1 month apart are recommended for children <9 years who are receiving seasonal influenza vaccine for the first time based on receipt of the seasonal influenza vaccine and/or monovalent H1N1 vaccine of the previous 2009-2010 influenza year.

Note: Persons who were given a live virus vaccine (eg, MMR, MMRV, varicella, yellow fever) in the past 4 weeks should wait 28 days before receiving another live virus vaccine (eg, intranasal influenza vaccine).

For more information on influenza, see MMWR 2010; 59 (RR08); pages 1 -62 or http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5908a1.htm on the internet

# 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. 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. Caveat: 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:**

### I. 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

### II. 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) are the recommended tests. 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), the patient should keep the 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

### III. 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 does 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.

## POLICY ON THE IMMUNIZATION OF HIGH RISK ADULTS (cont)

**Recommended dosages of Twinrix®**

| Vaccine Recipients age (yrs) | Dose (EL.U and µg† | Volume (mL) | No. Doses | Schedule (mos) § |
|---|---|---|---|---|
| >18 | 720 (hepatitis A)<br>20 (hepatitis B) | 1.0 | 3 | 0, 1, 6 |
| Accelerated schedule<br>> 18 | 720 (hepatitis A)<br>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<br>Adult Hepatitis B vaccine | Adult Hepatitis A vaccine*<br>Adult Hepatitis B vaccine |
| Twinrix | Twinrix | Adult Hepatitis A vaccine<br>Adult Hepatitis B vaccine |
| Adult Hepatitis A vaccine<br>Adult Hepatitis B vaccine | Twinrix | Adult Hepatitis A vaccine*<br>Adult Hepatitis B vaccine |
| Adult Hepatitis A vaccine<br>Adult Hepatitis B vaccine | Adult Hepatitis A vaccine*<br>Adult Hepatitis B vaccine | Adult Hepatitis B vaccine** |

*Separated from prior Hepatitis A vaccine dose by ≥5 months
**May use Twinrix for this dose

### IV. 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.

### V. 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.

### VI. Post- vaccination Testing

No post – vaccination serologic testing will be done for adult patients.

### VII. 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 MENINGOCOCCAL (Group A, C, Y and W-135) VACCINATION

Policy:

Two quadrivalent conjugate meningoccal vaccines (MCV-4), Menactra™, manufactured by Sanofi Pasteur and approved for persons 2 through 55 years of age and (Menveo), MenACWY-CRM, manufactured by Novartis Vaccines and Diagnostics and approved for persons 11 through 55 years of age were 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, Menomune™ (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 the **routine use** of 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 (see www.cdc.gov/travel - this travel recommendation is for informational purposes and is not for availability via the parish health unit);
- College freshmen living in dormitories

MenACWY-CRM or MCV4 may be used in persons aged 11--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, 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 $\geq$ 3 years previously and remain at increased risk for meningococcal disease.

***High risk re-vaccination*** with MCV vaccine should continue every 5 years as long as persons remain at increased risk including persons 55 years of age and younger should receive MCV, while persons 56 years and older should receive MPSV4. **High risk persons** to be revaccinated include those with: persistent complement component deficiency, anatomic or functional asplenia, HIV infection, and frequent travelers to or persons living in areas with high rates of meningococcal disease. **Revaccination does not apply to children who previously received age appropriate MCV vaccine on or after 11 years of age and who will be a freshman living in a dormitory.** Revaccination of children 2 through 6 years of age should be 3 year intervals while children 7 years or older should be revaccinated every 5 years. According to the LA School Immunization Law, all 11 year old children must be vaccinated with meningococcal conjugate vaccine as part of the adolescent immunization schedule. 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.

ADMINISTRATION:

Quadrivalent meningococcal conjugate vaccines (MCV-4 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 Varicella, IPV, Td, MMR, HBV and Influenza.

# 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, hematopoetic 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, icluding 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 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. Two vaccines have been licensed by FDA recently – Gardasil (HPV4, Merck) and Cervarix (HPV2, GSK). HPV4 vaccine is effective against HPV types 16 and 18 which causes approximately 70% of cervical cancers and against types 6 and 11 which causes approximately 90% of genital warts. HPV2 vaccine offers protection against HPV types 16 and 18 only and not approved for males or for the prevention of genital warts. Neither HPV vaccines protect against the diseases caused by all HPV types and will not treat existing disease caused by HPV types contained in the vaccine.

Guidelines:

HPV4 vaccine is indicated for females and males 9 through 26 years of age for the prevention of the female cervical cancers, precancers and genital warts while HPV4 is approved for males for the prevention of genital warts. HPV2 is approved for females 10 through 25 years of age for the prevention of cervical cancers and precancers and not approved for use in males.

Both HPV4 and HPV2 vaccines are administered as a 3-dose series. Individuals who may have been infected with HPV can still benefit from receiving either 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. **Gardasil® is the only HPV vaccine 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.

The vaccine is recommended for routine administration at 11-12 years of age and 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. Catch-up vaccination is recommended for females and males 13-18 years of age who have not been vaccinated previously.

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) Neither HPV vaccine is 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. A vaccine pregnancy registry has been established; patients and health care providers are encouraged to report any exposure to quadrivalent HPV vaccine during pregnancy by calling 1-800-986-8999.

HPV vaccine is contraindicated for those who are hypersensitive or have a severe allergic reaction to a vaccine component or to yeast (HPV4) or latex (HPV2 prefilled syringe). 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, especially in adolescents and young adults, so 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.

Use With Other Vaccines

The vaccine is recommended for routine administration at 11-12 years of age and 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.

Vaccine Information Statement (VIS)

The Vaccine Information Statement (VIS) entitled "HPV Human Papillomavirus 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 is available at http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hpv-gardasil.pdf or http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hpv-cervarix.pdf

# POLICY ON ADMINISTRATION OF RABIES VACCINATION

Policy

**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.

• 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.

• 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 $\mu$g neomycin sulfate, <100 mg albumin, and 20 $\mu$g 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, HyperRab™ 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<br>Phone: 800-822-2463<br>Website: http://www.vaccineplace.com/products/ | 1 mL | Intramuscular | Pre-exposure or postexposure† |
| Purified chick embryo cell vaccine | RabAvert® | Novartis Vaccines and Diagnostics<br>Phone: 800-244-7668<br>Website: http://www.rabavert.com | 1 mL | Intramuscular | Pre-exposure or postexposure† |
| **Rabies immune globulin** | Imogam® Rabies-HT | sanofi pasteur<br>Phone: 800-822-2463<br>Website: http://www.vaccineplace.com/products/ | 20 IU/kg | Local§ | Postexposure only |
| | HyperRab™ S/D | Talecris Biotherapeutics<br>Bayer Biological Products<br>Phone: 800-243-4153<br>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).

**Where to find vaccine and immunoglobulin**

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 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.

**TriHIBit** (DTaP-Hib)

TriHIBit{Trademark} is the first vaccine to be licensed in the United States that combines DTaP with a Haemophilus b Conjugate Vaccine. TriHIBit™ (ActHIB® reconstituted with Tripedia®) is licensed **only for the fourth dose of the vaccination series** at age 15-18 months following administration of three doses of either DTaP or whole-cell DTP and a primary series of any Hib vaccine. TriHIBit has **not been licensed for use as the first three doses** of the vaccination series. Vaccine should be used immediately (within 30 minutes) after reconstitution. Local reactions were mild and resolved within 48 hours following vaccination. The most common local reaction was pain at the injection site.

**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.

The availability of the Pentacel vaccine will improve the Hib vaccine supply situation in the U.S. However, the availability of Pentacel is not sufficient to reinstate the last (booster) dose of the Hib vaccine series (i.e., the dose administered after the first birthday). Although Pentacel is licensed by FDA for the fourth dose in the DTap, IPV and Hib series, providers should not use it for the fourth dose until there is further improvement in the Hib vaccine supply. **Until the Hib supply improves Pentacel should be used ONLY for the first three doses of the DTap, IPV and Hib vaccination series.**

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 During the 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* | | |

**Table 2. Using Single Antigen 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 |
| | | | | | IPV |
| | | Pentacel* | Pentacel* | | |
| | 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"

## POLICY ON USAGE OF COMBINATION VACCINES (cont)

**Comvax** (Hep B–Hib)

On October 2, 1996, the Food and Drug Administration (FDA) licensed a combined Hib conjugate and hepatitis B (recombinant) vaccine (COMVAX TM) for infants. Since 1991, the antigenic components of COMVAX TM have been used routinely in separate vaccines and have contributed to the declining incidence of infant Hib disease and hepatitis B virus (HBV) infection in the United States.

COMVAX TM is indicated for vaccination against invasive Hib disease and HBV infection in infants born to HBsAg-negative women. Three doses of COMVAX TM should be administered at ages 2, 4, and 12-15 months. This vaccine must not be administered to infants younger than age 6 weeks because of potential suppression of the immune response to PRP-OMPC with subsequent doses of COMVAX TM. The use of COMVAX TM has not yet been studied in infants born to women who are HBsAg-positive or women of unknown HBsAg status.

| Vaccine | Minimum age at first dose | Minimum interval from dose 1 to 2 | Minimum interval from dose 2 to 3 (when applicable) | Minimum interval from dose 1 to 3 (when applicable) |
|---|---|---|---|---|
| Infants | | | | |
| Hepatitis B (3 dose schedule with pediatric single antigen formulation | Birth | 4 weeks | 8 weeks | 16 weeks ♦ |
| COMVAX®* | 6 weeks | 4 weeks | 8 weeks‡ | N/A‡ |

‡ If Comvax is® given for the first two doses of Hib vaccine, the third dose (booster should be given at 12 –15 months of age.

## PRE-SCHOOL AND SCHOOL IMMUNIZATION REQUIREMENTS

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.

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. Compliance will be based on the individual having received an appropriate number of immunizations for his/her age of the following types:

1. vaccines which contain tetanus and diphtheria toxoids, including DTP, DtaP, DT, Tdap or Td or combinations which include these components;
2. polio vaccine, including OPV, eIPV, IPV, or combinations which include these components;
3. vaccines which contain measles antigen, including MMR and combinations which include these components.

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. PCV7 is required for all children entering childcare and pre-school up to 24 months of age.

# 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 |

# Example of "Shots for Tots by One" Schedule Using Comvax

| Vaccine/Age | Birth | 2 mos | 4 mos | 6 mos | 12 mos | Total |
|---|---|---|---|---|---|---|
| Hep B | Hep B | Comvax | Comvax | | Comvax | |
| DTaP | | DTaP | DTaP | DTaP | DTaP | |
| Hib | | Comvax | Comvax | | Comvax | |
| IPV | | IPV | IPV | IPV | | |
| PCV | | PCV | PCV | PCV | PCV | |
| MMR | | | | | MMR | |
| Varicella | | | | | Varicella | |
| # of injections | 1 | 4 | 4 | 3 | 5 | 17 |

## 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:**

A. 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;

B. the availability of staff to pack and move the vaccine;

C. the use of appropriate packing materials and containers, cold packs, and dry ice (for Varicella and/or MMR/VAR vaccine) and

D. 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 dry ice 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. Dry ice vendor:
9. Emergency generator repair company:
10. National weather service:
11. Vaccine Manufacturers:

    a. Merck: www.merckvaccines.com or 1- 800-637-2579

    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. Wyeth: www.wyeth.com or 1-800-572-8221

e. Novartis: www.novartis.com or 1-800-244-7668

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 floodplain 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, **using dry ice only**, immediately before it is to be transported.

F. Pack and transport all vaccine 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.

1. **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.

**PROCEDURES FOR VACCINE PROTECTION AND HURRICANE/DISASTER PREPAREDNESS (cont)**

a. **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:

1) 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.

2) 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.

3) For vaccines requiring freezer storage, consider removing them from the freezer after one day (if the power outage continues) and packing them in dry ice. If the vaccines are not cold to the touch, upon removal from the freezer, the vaccine should not be used.

b. **When Power is Restored** – Record the temperature in the refrigrerator 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 with dry ice.
Location where dry ice may be purchased_____ Ph#_____

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 _____Ph# _____

**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 | 1-800-637-2579 | |
| GlaxoSmithKline www.gsk.com | 1-866-475-8222 | |
| Wyeth www.wyeth.com | 1-800-572-8221 | |
| Novartis www.novartis.com | 1-800-244-7668 | |
| MedImmune www.medimmune.com | 1-877-633-4411 | |

## FOUR DAY GRACE PERIOD – 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.

## 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?<br><br>**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?<br><br>**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.<br><br>**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?<br><br>**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?<br><br>**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?<br><br>**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

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).

√ The origin of the suspected discrepancy and/or misuse should be documented.

√ 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.

√ The Immunization Program Office will determine if the situation warrants further investigation.

√ 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

1. 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.
2. Continue regular meetings with Medicaid.
3. Ensure Medicaid is up to date on Louisiana Immunization Program - Vaccines For Children changes.
4. 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,
5. Update CDC/NIP on Louisiana Immunization Program – Vaccines For Children activity in this area.

## FOREIGN-BORN PERSONS AND IMMUNIZATIONS, AND FREQUENTLY ASKED QUESTIONS

**General Policy**: The CDC and The U.S. Department of Justice strongly encourage all health departments to immunize foreign-born persons when ever possible. 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.

There are, however, some unique challenges. 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?

This section should answer some of your basic immunization questions concerning foreign-born persons.

A quick overview of what is included in this section:

- Who are Louisiana's foreign-born persons?
- Frequently asked questions about immunizations and foreign-born persons.
- Varicella, measles, mumps, rubella, polio, and Mantoux tests.
- Vaccine information statements in languages other than English
- Table of foreign language vaccine terms to help you interpret vaccines given outside the United States

### A. Who are Louisiana's foreign-born persons?

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.

Immigrants: Persons lawfully admitted for permanent residence in the U.S.

Migrants: (Documented/un-documented) generally, foreign-born persons (and their families) who are seasonally employed in Louisiana.

Internationally Adopted Children: Children from foreign countries who are adopted by U.S. families.

Foreign Students: Persons from outside the U.S. who are studying in this country.

## B. 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 my parent's vaccination record card?

Answer: See the tables 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.

**C. 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 vaccine**s: 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). *Please check with your Tuberculosis policy protocol to determine if PPD testing is offer routinely to Foreign – Persons as part of the U.S. Department of Justice and CDC recommendations*)

**D. 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. To learn what languages are available, visit the CDC web site.

**E. Tables to help you interpret vaccines given outside the U.S.**

**Table 1 Disease, Vaccine and Related terms**

**Table 2 Trade names**

# Foreign Language Terms

## Table 1: Disease, Vaccine, and Related Terms

| **Albanian** | |
|---|---|
| Difteria | Diphtheria |
| Fruthi | Measles |
| Pertusisi | Pertussis |
| Tetanozi | Tetanus |
| **Arabic** | |
| Alhasiba | Rubella |
| As'al | Pertussis |
| Athab | Mumps |
| Difteria | Diphtheria |
| El Safra | Hepatitis |
| Has 'ba | Measles |
| Shel'el | Polio |
| **Bosnian** | |
| Beseže | BCG |
| Detepe | DTP |
| Difterija | Diphtheria |
| Dječja paraliza | Polio |
| Gripa | Influenza |
| Male boginje | Rubella |
| Ospice | Measles |
| Rubeola | Rubella |
| Upala pluća | Pneumonia |
| Veliki boginje | Smallpox |
| Veliki kašalj | Pertussis |
| Zauške | Mumps |
| Žutica | Hepatitis |

| **Croatian** | |
|---|---|
| Beseže | BCG |
| Detepe | DTP |
| Difterija | Diphtheria |
| Dječja paraliza | Polio |
| Gripa | Influenza |
| Hri pavac | Pertussis |
| Kašalj hripavac | Pertussis |
| Upala pluća | Pneumonia |
| Veliki boginje | Smallpox |
| Vodene kozice | Varicella |
| Zapaljenje | Hepatitis |
| Zaušnjaci | Mumps |
| Žutica | Hepatitis |
| **Czech** | |
| Davivy Kasel | Pertussis |
| Difterie | Diphtheria |
| Hepatitida | Hepatitis |
| Parotitida | Mumps |
| Pertuse | Pertussis |
| Poliomyelitis | Polio |
| Spalnicky | Measles |
| Subinuira | Influenza |
| Zardenky | Rubella |
| Zaškrt | Diphtheria |
| **Danish** | |
| Bornelammelse | Polio |
| Difteritis | Diphtheria |
| DKTP | DTP + IPV |
| Faaresyge | Mumps |
| Kighoste | Pertussis |
| Leverbetaendelse | Hepatitis |
| Meslinger | Measles |

| | |
|---|---|
| Rode Hunde | Rubella |
| Stivkrampe | Tetanus |
| **Dutch** | |
| BMR | MMR |
| Bof | Mumps |
| Difterie | Diphtheria |
| Gelekoorts | Yellow fever |
| Gordelroos | Varicella |
| Griep | Influenza |
| Kinderverlamming | Polio |
| Kinkhoest | Pertussis |
| Longontsteking | Pneumonia |
| Mazelen | Measles |
| Pokken | Smallpox |
| Rode hond | Rubella |
| Stijfkramp | Tetanus |
| Tering | Tuberculosis |
| **Ethopian (Oromiffaa)** | |
| Cufaa | Tetanus |
| Difteeriyaa | Diphtheria |
| Gifira | Measles |
| Gifira farangli | Rubella |
| Laamsheesaa | Polio |
| Qakkee | Pertussis |
| Shimbiraa | Hepatitis |
| **Finnish** | |
| Hinkuyska | Pertussis |
| Jaykkakouristus | Tetanus |
| Kurkkumata | Diphtheria |
| Lapsihalvaus | Polio |
| Sikotauti | Mumps |
| Tuhkarokko | Measles |
| Vihurirokko | Rubella |

| **French** | |
|---|---|
| Coqueluche | Pertussis |
| Diphtérie | Diphtheria |
| DTC, DT Coq | DTP |
| Fievre jaune | Yellow Fever |
| Grippe | Influenza |
| l'Haemophilus b | Hib |
| Oreillons | Mumps |
| Poliomyélite | Polio |
| ROR | MMR |
| Rougeole | Measles |
| Rubéole | Rubella |
| Tétanos | Tetanus |
| Tuberculose | Tuberculosis |
| Variole | Smallpox |
| **German** | |
| Diphtherie | Diphtheria |
| FSME | Tick-borne encephalitis |
| Grippe | Influenza |
| Keuchhusten | Pertussis |
| Kinderlähmung | Polio |
| Masern | Measles |
| Pocken | Smallpox |
| Rötein | Rubella |
| Starrkramph | Tetanus |
| Tuberkulose | Tuberculosis |
| Wundstarrkrampf | Tetanus |
| Zei Genpeter | Mumps |
| **Greek** | |
| Διφθερίτιδα, ΤέτανοςκαιΚοκκύτης | DTP |
| Ο Αιμόφιλος της γρίππης τύπου Β | Hib |

| | |
|---|---|
| ΜηνιγγοκοκκικήΑσθένεαομάδας C | Meningococcal (C) |
| Ιλαρά -Μαγουλάδες Ερυθρά | MMR |
| Πολιομυελίτιδα | Polio |
| Τέτανος και Διφθερίτιδα | Td |

| **Haitian Creole** | |
|---|---|
| Difteri | Diphtheria |
| Epatit | Hepatitis |
| Flou | Influenza |
| Koklich | Pertussis |
| Lawoujòl, Laroujòl | Measles |
| Malmouton | Mumps |
| Polyo | Polio |
| Ribeyòl | Rubella |
| Saranpyon | Varicella |
| Tetanòs | Tetanus |
| **Hmong** | |
| Hawb pob | Pertussis |
| Kabmob siab hom B | Hepatitis B |
| Kub cer | Diphtheria |
| Qhua Maj | Rubella |
| Qhua Pias | Measles |
| Qog | Mumps |
| Tuag tes tuag taw | Polio |
| Ua npuag | Tetanus |
| **Indonesian** | |
| Batuk rejan | Pertussis |
| Beguk | Mumps |
| Biring Peluh | Rubella |
| Campak | Measles |
| Difteri | Diphtheria |
| Penyakit lumpuh | Polio |
| Radang hati | Hepatitis |

| **Italian** | |
|---|---|
| Antipolio inattivato | IPV |
| Difterite | Diphtheria |
| Emofilo b | Hib |
| Epatite | Hepatitis |
| Morbillo | Measles |
| MPR (morbillo, parotite, rosolia) | MMR |
| Parotite | Mumps |
| Pertosse | Pertussis |
| Poliomielite | Polio |
| Polmonite | Pneumonia |
| Rosolia | Rubella |
| Tetano | Tetanus |
| Tosse Asinina | Pertussis |
| Tubercolosi | Tuberculosis |
| Vaioloso | Smallpox |
| **Japanese** | |
| Fushin | Rubella |
| Hashika | Measles |
| Hashofu | Tetanus |
| Hyakaseki | Pertussis |
| Jifuteria | Diphtheria |
| Otafukukuaze | Mumps |
| Sh niamahi | Polio |
| **Malay** | |
| Batok rejan | Pertussis |
| Penyaakit bengok | Mumps |
| Sakit champak | Measles |
| Sakit rengkong | Diphtheria |
| **Norwegian** | |
| Difteri | Diphtheria |
| Kikhoste | Pertussis |
| Kopper | Smallpox |

| | |
|---|---|
| Kusma | Mumps |
| Leverbetennelse | Hepatitis |
| Meslinger | Measles |
| Poliomyelitt | Polio |
| Røde hunder | Rubella |
| Stivkrampe | Tetanus |
| Vannkopper | Varicella |
| **Polish** | |
| Błonicy, Błonica, Błonnica | Diphtheria |
| Dyfteria | Diphtheria |
| Gruzlica | Tuberculosis |
| Grypa | Influenza |
| Koklusz | Pertussis |
| Krztuscowi, Krztusiec | Pertussis |
| Odra | Measles |
| Ospa | Smallpox |
| Paraliz dzieciecy | Polio |
| Pojar German | Rubella |
| Pojarul, Pojarului | Measles |
| Przypominajace | Booster |
| Rozyczka | Rubella |
| Swinka | Mumps |
| Tezec, Tężcowi | Tetanus |
| Zapalenie pluc | Pneumonia |
| Zapalenie watroby | Hepatitis |
| **Portugese** | |
| Cachumba (papeira) | Mumps |
| Coqueluche | Pertussis |
| Difteria | Diphtheria |
| Gripe | Influenza |
| Hepatite | Hepatitis |
| Paralisia infantil | Polio |

| | |
|---|---|
| Parotidite epidémica | Mumps |
| Poliomielite | Polio |
| Rúbéola | Rubella |
| Sarampo | Measles |
| Tetânica, Tétano | Tetanus |
| Triplice | DTP |
| VAHB | Hepatitis B Vaccine |
| VAP | Polio Vaccine |
| VAS | Measles Vaccine |
| VASPR | MMR |
| VAT | Tetanus Vaccine |
| **Romanian** | |
| AR | Measles |
| Difteria (Difteriei) | Diphtheria |
| Di Te | DT |
| Di-Te-Per | DTP |
| Febra Galbena | Yellow Fever |
| Gripa | Influenza |
| Hepatita | Hepatitis |
| Holera | Cholera |
| Oreion, Oreionului | Mumps |
| Pneumoniei | Pneumonia |
| Poliomielitic | Polio |
| Rubeolei, Rubeola | Rubella |
| Rujeola, Rujeolei | Measles |
| Tetanos,Tetanosul, Tetanosului | Tetanus |
| Tuse convulsiva, Tusei convulsive | Pertussis |
| Varicelă, Varicelei | Varicella |
| Variola, Variolei | Smallpox |
| **Russian** | |
| Бцж | BCG |

| | |
|---|---|
| АКДС | DTP |
| Дифтерит, Дифтерия | Diphtheria |
| Гемоифлюс инфлюзнцы типа Б | Hib |
| Гепатит | Hepatitis |
| Грипп | Influenza |
| Корь | Measles |
| Свинка, Паротит | Mumps |
| Коклюш | Pertussis |
| Воспале лёгких Пневмония | Pneumonia |
| Полиомиелит | Polio |
| Краснуха | Rubella |
| Оспа | Smallpox |
| Столбняк, Столбняка | Tetanus |
| Туберкулез | Tuberculosis |
| Ветрянка | Varicella |
| Манту | Mantoux (TB test) |
| Вакцина | Vaccine |
| Вакцинация | Series |
| Ревакцинация | Booster |
| **Samoan** | |
| Mami | Mumps |
| Misela | Measles |
| Rupela | Rubella |
| **Serbian** | |
| Beseže | BCG |
| Detepe | DTP |
| Difterija | Diphtheria |
| Dječja paraliza | Polio |
| Gripa | Influenza |
| Hri pavac | Pertussis |
| Male boginje | Rubella |
| Pljuskavice, Kozice | Varicella |

| | |
|---|---|
| Upala pluća | Pneumonia |
| Veliki boginje | Smallpox |
| Veliki kašalj | Pertussis |
| Zapaljenje | Hepatitis |
| Zaušnjaci | Mumps |
| Žutica | Hepatitis |
| **Slovak** | |
| Chripka | Influenza |
| Cierny kasel | Pertussis |
| Diftéria | Diphtheria |
| DiTePe | DTP |
| Hepatitida | Hepatitis |
| Krzamak | Measles |
| Osypky | Measles |
| Parotitis | Mumps |
| Polyomyelitida | Polio |
| Priusnica | Mumps |
| Ruzienka | Rubella |
| Zápaľ plüc | Pneumonia |
| **Spanish** | |
| Cólera | Cholera |
| Coqueluche | Pertussis |
| Difteria | Diphtheria |
| Doble Antigen | Td (Mexico) |
| Doble Viral | Measles-Rubella (Mexico) |
| Duple | DT (Cuba) |
| Gripe | Influenza |
| Hemófilo tipo b | Hib |
| Numonía | Pneumonia |
| Paperas, Parotiditis | Mumps |
| Poliomielitis | Polio |
| Pulmonía | Pneumonia |

| | |
|---|---|
| Rubéola | Rubella |
| Sarampión, Sarampión Comun | Measles |
| Sarampión Aleman | Rubella |
| SPR | MMR |
| Tetánica, Tétano | Tetanus |
| Pertussis | Tos Ferina |
| Varicela | Varicella |
| Viruela | Smallpox |
| **Somali** | |
| Bus-buska | Varicella |
| Cagaarshowga | Hepatitis |
| Cuno xanuun | Diphtheria |
| Dabayl | Polio |
| Duf | Polio |
| Furuq | Smallpox |
| Gowracato | Diphtheria |
| Gurra dhaabsis | Mumps |
| Hablobaas | Varicella |
| Haemophilus nooca b | Hib |
| Infilowense | Influenza |
| Jadeeco | Measles |
| Jadeeco been, Jadeeco jarmalka | Rubella |
| Joonis | Hepatitis |
| Kix | Pertussis |
| Qaamow-Qashiir | Mumps |
| Qaaxo-Tiibi | Tuberculosis |
| Qanja Barar | Mumps |
| Sambabaha | Pneumonia |
| Tallaakla Qaaxada | BCG |
| Taytano | Tetanus |
| Wareento | Pneumonia |
| Xiiqdheer | Pertussis |

| **Swedish** | |
|---|---|
| Difteri | Diphtheria |
| Duplex | DT |
| Gula Febern | Yellow fever |
| Kikhosta | Pertussis |
| Kolera | Cholera |
| Mässling, Masslingormerly | Measles |
| Pǎssjura | Mumps |
| Polio | Polio |
| Rőda Hund | Rubella |
| Smittkoppor | Smallpox |
| Stelkramp | Tetanus |
| Trippel | DTP |
| **Tagalog** | |
| Beke | Mumps |
| Dipterya | Diphtheria |
| Pertusis | Pertussis |
| Polyo | Polio |
| Tetano | Tetanus |
| Tigdas | Measles |
| **Turkish** | |
| Bođmaca | Pertussis |
| Çocuk Felci | Polio |
| DBT | DPT |
| Difteri | Diphtheria |
| Grýp | Influenza |
| KKK | MMR |
| Kabakulak | Rubella |
| Kýzamýk | Measles |
| Kýmamýkçýk | Mumps |
| Pnömokok | Pneumococcal |
| Su Çýçeđý | Varicella |

| | |
|---|---|
| Tetanos | Tetanus |
| Ýnfluenza | Influenza |
| **Ukranian** | |
| Кір | Measles |
| Поліо | Polio |
| Стово́няк | Tetanus |
| **Vietnamese** | |
| Bach Hâu | Diphtheria |
| Bai liet | Polio |
| Ban Đo | Rubella |
| Dai | Rabies |
| Ho Gà | Pertussis |
| Quai Bi | Mumps |
| Sài Uon Ván | Tetanus |
| So'i | Measles |
| Sot Tê Liêt | Polio |
| Thuong hàn | Typhoid |
| Uon ván | Tetanus |
| Viêm gan siêu vi B (VGSV B) | Hepatitis B |
| VNNB | Japapese encephalitis |

# Foreign Language Terms

Table 2: Trade Names

| Trade name | Antigen(s) | Manufacturer, Country |
|---|---|---|

| | | |
|---|---|---|
| A.D.T. | Diphtheria, tetanus (adsorbed) | Commonwealth, Australia |
| A.K.D.S. | Diphtheria, tetanus, pertussis | UK |
| ACVax | Meningococcal (polysaccharide A & C) | GSK, UK |
| ACWYVax | Meningococcal (polysaccharide A, C, W, Y135) | GSK, UK |
| Acelluvax | Pertussis (acellular) | Chiron, Italy |
| ACTAcel | Diphtheria, tetanus, pertussis, Hib | Sanofi Pasteur, Argentina |
| Adifteper | Diphtheria, tetanus, pertussis | Ism, Italy |
| Adinvira A+B | Influenza (whole virus) | Imuna |
| Adiugrip | Influenza | Sanofi Pasteur |
| Admun | Influenza (whole virus) | Duncan |
| Admune GP | Influenza (whole virus) | Duncan |
| Agrippal | Influenza | Socopharm |
| Aimmugen | Hepatitis A (inactivated) | Chemo-Sero-Therapeutic Resh Inst, Japan |
| Aldiana | Diphtheria (absorbed) | Sevac, Czech Republic |
| Alditeana | Diphtheria, tetanus (absorbed) | Sevac, Czech Republic |
| Alditerpera | Diphtheria, tetanus (adsorbed), pertussis | Sevac, Czech Republic |
| Almevax | Rubella | Evans |
| Alorbat | Influenza (whole virus) | Asta Pharma |
| Alteana Sevac | Tetanus | Institute of Sera and Vaccines |
| Amaril | Yellow fever | Sanofi Pasteur, France |
| AmBirix | Hepatitis A, Hepatitis B | GSK, Europe |
| AMC | Hib (polysaccharide) | Cuba |
| Anadifterall | Diphtheria (adsorbed) | Chiron, Italy |
| Anatetall | Tetanus (adsorbed) | Chiron, Italy |
| Anatoxal Di Te | Diphtheria, tetanus | Berna Biotech, Europe |
| Anatoxal Di Te Per | Diphtheria, tetanus, pertussis | Berna Biotech, Europe |
| Arilvax | Yellow fever | MEDI, UK |
| AVAC-1, AVA | Anthrax | (for U.S. military use) |
| **Trade name** | **Antigen(s)** | **Manufacturer, Country** |
| AVAXIM | Hepatitis A | Aventis Pasteur, France |
| B-Hepavac II | Hepatitis B | Merck, Singapore |
| Begrivac | Influenza (split virus) | Chiron, Germany |
| Betagen | Hepatitis B | Sanofi Pasteur |
| Biaflu Zonale | Influenza (whole virus) | Farmabiagini, Itali |
| Biken-HB | Hepatitis B | Biken, Japan |
| Bilive | Hepatitis A/Hepatitis B (Recombinant) | Sinovac, China |

| | | |
|---|---|---|
| Bimmugen | Hepatitis B (recombinant, adsorbed, yeast derived) | Chemo-Sero-Therapeutic Resh Inst, Japan |
| Biviraten Berna | Measles, mumps (live) | Berna Biotech, Switzerland |
| Buccopol Berna | Polio (oral) | Berna Biotech, Europe |
| BVAC | Botulinum antitoxin | (for U.S. military use) |
| B-Vaxin | Hepatitis B | Laboratorios Pablo Cassara, Argentina |
| C.D.T. | Diphtheria, tetanus (pediatric, adsorbed) | Commonwealth, Australia |
| CEF | Measles (Schwarz strain) | Chiron, Italy |
| Cacar | Smallpox | Indonesia |
| Campak Kerig | Measles | Pasteur Institute, Indonesia |
| Celluvax | Pertussis (acellular) | Chiron, Italy |
| Cinquerix | Diphtheria, tetanus, pertussis, Hib, Polio | GSK, Europe |
| Cocquelucheau | Pertussis (adsorbed) | Sanofi Pasteur, France |
| D-Immun | Diphtheria | Osterreichisches Institut, Austria |
| D.S.D.P.T. | Diphtheria, tetanus, pertussis (adsorbed) | Dong Shin Pharm, Korea |
| D.T. Bis Rudivax | Diphtheria, tetanus, rubella | Sanofi Pasteur, France |
| Di Anatoxal | Diphtheria | Berna Biotech, Europe |
| Di Te Per Pol Impfstoff | Diphtheria, tetanus, pertussis, polio | Berna Biotech, Switzerland |
| Di-Te-Pol SSI | Diphtheria, tetanus, polio | Statens Seruminstitut, Denmark |
| Dif-Tet-All | Diphtheria, tetanus | Chiron, Italy |
| Diftavax | Diphtheria, tetanus | Sanofi Pasteur |
| Ditanrix | Diphtheria, tetanus | GSK, Europe |
| DiTe Anatoxal | Diphtheria, tetanus (adsorbed) | Berna Biotech, Switzerland |
| Ditoxim | Diphtheria, tetanus (adsorbed) | Dong Shin Pharm, Korea |
| Double Anigen B.I. | Diphtheria, tetanus | Bengal Immunity Co, India |
| DT Adulte | Diphtheria, tetanus (adult) | Sanofi Pasteur, France |
| **Trade name** | **Antigen(s)** | **Manufacturer, Country** |
| DT Bis | Diphtheria, tetanus (booster) | Sanofi Pasteur, France |
| DT Coq | Diphtheria, tetanus, pertussis | Sanofi Pasteur, France |
| DT Polio | Diphtheria, tetanus, polio | Sanofi Pasteur, France |
| DT TAB | Diphtheria, tetanus, *Salmonella typhi, Paratyphi A & B* | Sanofi Pasteur, France |
| DT Vax | Diphtheria, tetanus (pediatric) | Sanofi Pasteur, France |
| DT Wellcovax | Diphtheria, tetanus (pediatric) | Chiron, UK |
| Dual Antigen SII | Diphtheria, tetanus (adsorbed) | Serum Institute of India (India) |
| Dultavax | Diphtheria, tetanus, polio | Aventis Pasteur, France |
| Dupla | Diphtheria, tetanus | Instituto Butantan, Brazil |

| | | |
|---|---|---|
| Duplex | Diphtheria, tetanus | Sweden |
| Ecolarix | Measles, rubella (Schwarz & RA 27/3) | GSK, Europe |
| Elvarix | Influenza (split virus) | VEB Sachsesches Serumwerk Dresden |
| Encepur | Tick-borne encephalitis | Chiron, Europe |
| Enivac-HB | Hepatitis B (Recombinant DNA) | Centro de Ingenieria Genetica Y Biotecnologia, Cuba |
| Enterovaccino | Typhoid (IM) | Isi |
| Eolarix | Measles, rubella (Schwarz & RA 27/3) | GSK, Europe |
| Epaxal Berna | Hepatitis A - virosomal vaccine | Berna Biotech, Switzerland |
| Ervax | Rubella (live) | GSK, Mexico |
| Ervevax RA 27/3 | Rubella (live) | GSK, Belgium |
| Esavalenti | Diphtheria, tetanus, pertussis, polio, Hib, hepatitis B | Italy |
| Euvax-B | Hepatitis B (recombinant DNA) | LG Chemical, South Korea |
| Fendrix | Hepatitis B (dialysis formulation) | GSK, Europe |
| Fluad Agrippal-S1 | Influenza | Chiron, Italy |
| Flubron | Influenza (whole virus) | Pfizer |
| Flugen | Influenza | UK |
| Fluvax | Influenza | CSL, Australia |
| Fluvirine | Influenza | CellTech Pharma SA |
| FOH-M | Polio (Inactivated) | Russia |
| FrocuoOke | Polio (Inactivated) | Russia |
| FSME-IMMUNE | Tick-borne encephalitis | Baxter, Austria |
| FSPD | Measles | Russia |
| **Trade name** | **Antigen(s)** | **Manufacturer, Country** |
| Funed-CEME | Diphtheria, tetanus, pertussis | Belo Horizonte, Brazil |
| Gen H-B-Vax | Hepatitis B | Merck-Behringwerke |
| GenHevac B Pasteur | Hepatitis B | Sanofi Pasteur |
| Gripax | Influenza (whole virus) | Hebrew University |
| Gripe | Influenza (whole virus) | Spain |
| Gripovax | Influenza (whole virus) | GSK |
| Gunevax | Rubella | Chiron, Italy |
| H-Adiftal | Diphtheria | Ism, Italy |
| H-Adiftetal | Diphtheria, tetanus (adult) | Ism, Italy |
| H-Atetal | Tetanus | Ism, Italy |
| HarPaBreHnr B CtauOHAP | Rubella | Russia |
| HAVPur | Hepatitis A | Chiron, Germany |

| | | |
|---|---|---|
| HB Vax Pro | Hepatitis B | SP |
| HBY | Hepatitis B (recombinant) | KGC, Japan |
| Heberbiovac HB | Hepatitis B | Heberbiotec, Cuba |
| Hepabest | Hepatitis A | Sanofi Pasteur, Mexico |
| Hepacare | Hepatitis B (recombinant) | Chiron, Europe |
| Hepaccine-B | Hepatitis B (plasma derived) | Chiel Jedang, South Korea |
| Hepagene | Hepatitis B | Chiron, Europe |
| Hepativax | Hepatitis B | LG Life Sciences, Korea |
| Hepavax-B | Hepatitis B (plasma derived) | Korea Green Cross, South Korea |
| Hepavax-Gene | Hepatitis B (recombinant DNA) | Korea Green Cross, South Korea |
| Hepcare | Hepatitis B | Chiron, Europe |
| Heprecomb | Hepatitis B (yeast derived) | Berna Biotech, Switzerland |
| Hevac B | Hepatitis B (plasma derived) | Sanofi Pasteur, France |
| Hexavac (Hexavax) | Diphtheria, tetanus, pertussis, polio, hepatitis B, Hib | Sanofi Pasteur, Europe |
| Hiberix | Hib conjugate | GSK |
| HIBest | *Haemophilus influenzae* type b | Sanoti Pasteur |
| Hinkuys karokoe | Pertussis (adsorbed) | Natl. Public Health Institute, Finland |
| HIS | Influenza | Serbian Institute, Yugoslavia |
| IBV | Polio (inactivated) | Statens Seruminstitut, Denmark |
| **Trade name** | **Antigen(s)** | **Manufacturer, Country** |
| Immravax | Measles, mumps, rubella | Sanofi Pasteur, Europe |
| Immugrip | Influenza | Pierre Fabre Médicament |
| Immunil | Pneumococcal (polysaccharide) | Sidus |
| Imovax Parotiditis | Mumps | Sanofi Pasteur, Europe |
| Imovax Polio | Polio | Sanofi Pasteur, Europe |
| Imovax Sarampion | Measles | Sanofi Pasteur, Europe |
| Imovax D.T. | Diphtheria, tetanus (adult) | Sanofi Pasteur, Europe |
| Imovax Gripe | Influenza | Sanofi Pasteur, Europe |
| Imovax R.O.R. | Measles, rubella, mumps (live) | Sanofi Pasteur, Europe |
| Imovax Rubeola | Measles | Sanofi Pasteur, Europe |
| Imovax Mumps | Mumps | Sanofi Pasteur, Europe |
| Imovax Oreillons | Mumps | Sanofi Pasteur, Europe |
| Imovax Rage | Rabies vaccine | Sanofi Pasteur, Europe |
| Imovax Tetano | Tetanus | Sanofi Pasteur, Europe |
| Infanrix Hexa | DTaP, polio, Hib, hepatitis B | GSK, France |
| Infanrix Penta | DTaP, hepatitis B, polio | GSK, Europe |

| | | |
|---|---|---|
| Infanrix Quinta | DTaP, polio, Hib | GSK, Europe |
| Infanrix Tetra | DTaP, polio | GSK, Europe |
| Inflexal | Influenza | Swiss Serum and Vaccine Institute |
| Influmix | Influenza (whole virus) | Schiapparelli |
| Influpozzi Zonale | Influenza (whole virus) | Ivp |
| Influsplit SSW | Influenza (split virus) | VEB Sachsecsches Serumwerk Dresden |
| Influvac | Influenza | Solvay-Pharma |
| Influvirus | Influenza | Ism, Italy |
| Invirin | Influenza (whole virus) | GSK |
| Ipad TP | Tetanus, polio | Sanofi Pasteur, France |
| IPV-Virelon | Polio (inactivated) | Chiron, Europe |
| Isiflu Zonale | Influenza (whole virus) | Isi, Italy |
| Istivac | Influenza | Sanofi Pasteur, Europe |
| Kaksoisrokote Dubbelvaccin | Diphtheria, tetanus (pediatric) | Natl. Public Health Institute, Finland |
| Kikhoste-Vaksine | Pertussis | Statens Institutt for Folkehelse, Norway |
| Koplivac | Measles (Edmonston strain) | Philips-Duphar, Australia |
| **Trade name** | **Antigen(s)** | **Manufacturer, Country** |
| Kotipa | Cholera, typhoid, paratyphoid | Perum Bio Farma, Indonesia |
| Krztuscowi | Pertussis | (Poland) |
| Ksztu | Pertussis | (Poland) |
| Lancy Vaxina | Smallpox | Swiss Serum and Vaccine Institute, Switzerland |
| Lavantuu tirokote | Typhoid | Central Pub Health La, Finland |
| Liomorbillo | Measles | |
| Liovaxs | Smallpox | Chiron, Italy |
| Lirugen | Measles | Sanofi Pasteur |
| LM - 3 RIT | Measles, mumps, rubella (live) | Dong Shin Pharm, Korea |
| LM - 2 RIT | Measles, mumps (live) | Dong Shin Pharm, Korea |
| Lteanas Imuna | Tetanus (adsorbed) | Imuna sp., Slovakia |
| Lyssavac N | Rabies | Berna Biotech, Europe |
| M-M-Rvax | Measles, mumps, rubella | Chiron, Europe |
| M-M-Vax | Measles, mumps | Merck, Europe |
| Masern-Impfstoff SSW | Measles (live) | Chiron, Germany |
| Massling | Measles | Sweden |
| MDPH-PA | Anthrax | |
| Measavac | Measles (Edmonston strain) | Pfizer, UK |
| Mencevax A | Meningococcal (polysaccharide) (Group A) | SmithKline/RIT, Belgium |

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| Mencevax ACWY | Meningococcal quadravalent | GSK |
| Mengivax A/C | Meningococcal (conjugate) (Groups A & C) | Sanofi Pasteur, Europe |
| Meningitec | Meningococcal (conjugate) (Group C) | Wyeth, UK, Australia |
| Meningtec | Meningococcal (conjugate) (Group C) | Wyeth, Canada |
| Meninvact | Meningococcus (conjugate) (Group C) | Sanofi Pasteur |
| Menjugate | Meningococcus (conjugate) (Group C) | Socopharm |
| Menpovax 4 | Meningococcal (polysaccharide) (Groups A, C, Y & W135) | Chiron, Europe |
| Menpovax A+C | Meningococcal (Groups A & C) | Chiron, Italy |
| Mesavac | Measles (Edmonston strain) | Pfizer, UK |
| Mevilin-L | Measles (Schwarz strain) | Chiron, UK |
| MFV | Influenza (whole virus) | Servier, UK |
| MFV-Ject | Influenza (whole virus) | Sanofi Pasteur, Europe |
| Miniflu | Influenza | Schiapparelli, Italy |
| **Trade name** | **Antigen(s)** | **Manufacturer, Country** |
| Mo-Ru Viraten | Measles, rubella | Berna Biotech, Canada |
| Moniarix | Pneumococcal (polysaccharide) | GSK, Europe |
| Monovax / Monovac | BCG | Sanofi Pasteur, France |
| Mopavac | Measles, mumps (live, attenuated) | Sevac, Czech Republic |
| Morbilvax | Measles (live, attenuated) | Chiron, Italy |
| Morubel | Measles, rubella (live, attenuated) | Chiron, Italy |
| Moruman Berna | Measles immunoglobulin | Berna, Switzerland |
| Morupar | Measles, mumps, rubella (live, attenuated) | Chiron, Italy |
| Movivac | Measles (live, attenuated) | Sevac, Czech Republic |
| Mumaten | Mumps (live) | Berna Biogech, Switzerland |
| Munevan | Influenza (whole virus) | Medeva |
| Mutagrip | Influenza | Sanofi Pasteur, Germany |
| Nasoflu | Influenza | GSK, Europe |
| Neis Vac-C | Meningococcal (conjugate) (Group C) | Baxter, Europe & Canada |
| Neotyf | Typhoid (oral) | Chiron, Italy |
| Nivgrip | Influenza (whole virus) | Nicolau Institute of Virology, Romania |
| NorHOMHerHTA | Polio (Inactivated) | Russia |
| Nothav | Hepatitis A | Chiron, Italy |
| Okavax | Varicella | Sanofi Pasteur, Japan & Europe |
| Oral Virelon | OPV | Chiron, Germany |
| Pariorix | Mumps (live) | GSK, Mexico & Europe |
| Pavivac | Mumps (live) | Sevac, Czech Republic |

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| Pediacel | DTaP, Hib, IPV | Europe |
| Penta | Diphtheria, tetanus, (acellular) pertussis, Hib, IPV | Sanofi Pasteur, Europe |
| PENT-HIBest | Diphtheria, tetanus, pertussis, polio, Hib | Sanofi Pasteur |
| Pentacel | Diphtheria, tetanus, pertussis, polio, Hib | Sanofi Pasteur, Canada |
| Pentacoq | Diphtheria, tetanus, pertussis, polio, Hib | Sanofi Pasteur |
| PentAct-HIB | Diphtheria, tetanus, pertussis, polio, Hib | Sanofi Pasteur, Europe |
| Pentavac | Diphtheria, tetanus, pertussis, polio, Hib | Sanofi Pasteur |
| Pentavalente | Diphtheria, tetanus, pertussis, hepatitis B, Hib | Mexico |
| **Trade name** | **Antigen(s)** | **Manufacturer, Country** |
| Pentavalenti | Diphtheria, tetanus, pertussis, polio, Hib OR<br>Diphtheria, tetanus, pertussis, polio, hepatitis B | Italy |
| Pentaxim | Diphtheria, tetanus, pertussis, polio, Hib | Aventis Pasteur, France |
| Pluserix | Measles, rubella | GSK, Mexico & Europe |
| Pneumopur | Pneumococcal (polysaccharide) | Chiron, Europe |
| POLIAcel | Diphtheria, tetanus, pertussis, polio, HIB | Sanofi Pasteur, Argentina |
| Poliomyelite | Polio (inactivated) | France |
| Polioral | Polio (oral) | Chiron, Germany |
| Polio Sabin | Polio (oral) | GSK, Europe |
| Poloral | Polio (oral) | Swiss Serum and Vaccine Institute |
| Prevenar | Pneumococcal (7-valent, conjugate) | Wyeth, France |
| Previgrip | Influenza | Chiron France |
| Primavax | Diphtheria, tetanus, hepatitis B | Sanofi Pasteur, Europe |
| Priorix | Measles, mumps, rubella (live) | GSK, Europe & Australia |
| Priorix-Tetra | Measles, mumps, rubella, varicella | GSK, Europe |
| Probivac-B | Hepatitis B | Probiomed, Mexico |
| Procomvax | Hib, hepatitis B | Merck, Sanofi Pasteur, Europe |
| Pulmovax | Pneumococcal (polysaccharide) | Merck |
| Quadracel | Diphtheria, tetanus, pertussis, polio | Sanofi Pasteur, Mexico |
| QUADRAcel/Hibest | Diphtheria, tetanus, pertussis, polio, Hib | Sanofi Pasteur, Argentina |
| Quadravax | DTP + polio | GSK |
| Quatro-Virelon | Diphtheria, tetanus, pertussis, polio | Chiron, Europe |
| Quinivax-IN | Diphtheria, tetanus, pertussis, Hib, polio | Valda Laboratori, Europe |
| Quintuple | Diphtheria, tetanus, pertussis, Hib, Polio | GSK, Mexico |
| R-HB Vaccine | Hepatitis B (recombinant) | Mitsubishi Chem Corp, Japan |
| R-Vac | Rubella (live) | Serum Institute, India |

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| Rabdomune | Rabies | Impdfstofwerke, Germany |
| Rabipur | Rabies | Chiron, Germany |
| Rabivac | Rabies | Chiron, Germany |
| Rasilvax | Rabies | Chiron, Italy |
| RDCV | Rabies | |
| **Trade name** | **Antigen(s)** | **Manufacturer, Country** |
| Repevax | DTaP, IPV | Sanofi Pasteur |
| Revaxis | Td, IPV | Sanofi Pasteur, Europe |
| Rimevax | Measles (live) | GSK, Mexico & Europe |
| Rimparix | Measles, mumps (live) | GSK, Europe |
| RIT - LM-2 | Measles, mumps (live) | Dong Shin Pharm, Korea |
| RIT - LM-3 | Measles, mumps, rubella (live) | Dong Shin Pharm, Korea |
| Rorvax | Measles, mumps, rubella (live) | Sanofi Pasteur, Europe & Brazil |
| Rosovax | Rubella | Ism, Italy |
| Rotarix | Rotavirus (serotype G1, P1A[P8]) Attenuated, clinical trial | GSK |
| Rouvax | Measles (live, attenuated) | Sanofi Pasteur, Europe |
| Rubavax | Rubella (live) | Sanofi Pasteur, UK |
| Rubeaten | Rubella (live) | Berna Biotech, Europe |
| Rubellovac | Rubella | Chiron, Germany |
| Rubilin | Rubella (live) | Chiron, UK |
| Rudi-Rouvax | Measles, rubella (live) | Sanofi Pasteur, France |
| Rudivax | Rubella (live, attenuated) | Sanofi Pasteur, Europe |
| Sahia | Polio (live, oral) | Multiple manufacturers |
| Sampar | Plague | Sanofi Pasteur, Indonesia |
| Sandovac | Influenza | Sandoz, Austria |
| Serap | Diphtheria, tetanus, pertussis | Perum Bio Farma, Indonesia |
| Shanvac-B | Hepatitis B | Shantha, India |
| SMBV | Rabies | Sanofi Pasteur, Europe |
| Sii Triple Antigen | Diphtheria, tetanus, pertussis | Serum Institute, India |
| Stamaril | Yellow fever (live, attenuated) | Sanofi Pasteur, Europe |
| Streptopur | Pneumococcal (polysaccharide) | Chiron, Europe |
| Subinvira | Influenza (split virus) | Imuna, Czech Republic |
| T. Polio | Tetanus toxoid, polio | SP (Canada) |
| T.A.B. | Typhoid, paratyphoid (A & B) | - Institute Pasteur, Tunisia - Egypt - Pharmaceutical Industries Corp, Burma |
| T-Immun | Tetanus (adsorbed) | Baxter, Germany |

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| T-Vaccinol | Tetanus | Roehm Pharma, Germany |
| **Trade name** | **Antigen(s)** | **Manufacturer, Country** |
| T-Wellcovax | Tetanus | Wellcopharm, Germany |
| Tanrix | Tetanus | GSK, Europe |
| Td-Pur | Tetanus, diphtheria | Chiron, Europe |
| Td-Virelon | Tetanus, diphtheria, polio | Chiron, Europe |
| Te Anatoxal | Tetanus | Berna Biotech, Switzerland |
| Telvaclptap | Tetanus | Yugoslavia |
| Tet-Aktiv | Tetanus | Tropon-Cutter, Germany |
| Tet-Tox | Tetanus | CSL Limited, Australia |
| Tetagrip | Tetanus, influenza | SP (France) |
| Tetamun SSW | Tetanus (fluid, nonadsorbed) | Veb Sachsisches Serumwerk, Germany |
| Tetamyn | Tetanus | Bioclon, Mexico |
| Tetanol | Tetanus (adsorbed) | Chiron, Sanofi Pasteur, Europe & Mexico |
| Tetanovac | Tetanus | Sanofi Pasteur, Mexico |
| Tetasorbat SSW | Tetanus (adsorbed) | Veb Sachsisches Serumwerk, Germany |
| Tetatox | Tetanus (adsorbed) | Berna Biotech, Italy |
| Tetavax | Tetanus (adsorbed) | Sanofi Pasteur, Europe |
| Tetracoq 05 | Diphtheria, tetanus, pertussis, polio | Sanofi Pasteur, France |
| TetrAct-HIB | Diphtheria, tetanus, pertussis, Hib | Sanofi Pasteur, Europe |
| Tetravac Acellulaire | Diphtheria, tetanus, pertussis, polio | Sanofi Pasteur, Europe |
| Tetravalenti | Diphtheria, tetanus, pertussis, hepatitis B | Italy |
| Tetraxim | Tetanus, diphtheria, pertussis, polio | Sanofi Pasteur, Europe |
| Theracys | BCG | Aventis Pasteur, Canada |
| Ticovac | Tick-borne encephalitis | Baxter SA |
| Tifovax | Typhoid (Vi polysaccharide) | Sanofi Pasteur, Mexico |
| Titifica | Typhoid and para typhoid | Italy |
| TOPV | Trivalent oral polio vaccine | Multiple manufacturers and countries |
| Trenin DPT Behring | Diphtheria, tetanus, pertussis | Chiron Behring GmbH, Germany |
| Tresivac | Measles, mumps, rubella | Serum Institute, India |
| Triacel | Diphtheria, tetanus, (acellular) pertussis | Sanofi Pasteur, Europe & Mexico |
| Triacelluvax | Diphtheria, tetanus, (acellular) pertussis | Chiron, Europe |
| Trimovax | Measles, mumps, rubella (live) | Sanofi Pasteur, Europe |
| Tripacel | Diphtheria, tetanus, (acellular) pertussis | Sanofi Pasteur, Europe |
| **Trade name** | **Antigen(s)** | **Manufacturer, Country** |

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| Triple antigen | Diphtheria, tetanus, pertussis | - Chowgule & Co., India - CSL Limited, Australia |
| Triple Sabin | Polio (live, oral) | Mexico |
| Triple | Diphtheria, tetanus, pertussis | Cuba, Mexico |
| Triple Viral | Measles, mumps, rubella | Mexico Immunology Institute, Croatia |
| Triplice (VT) | Diphtheria, tetanus, pertussis | Instituto Butantan, Brazil |
| Triplice Viral (VTV) | Measles, mumps, rubella | Instituto Butantan, Brazil |
| Triplovax | Measles, mumps, rubella | Sanofi Pasteur, Europe & Brazil |
| Tritanrix | DTwP | GSK |
| Tritanrix-HB | DTwP/hepatitis B | GSK, Mexico |
| Tritanrix-HB-Hib | DTwP/hepatitis B/Hib | GSK |
| Trivacuna Leti | Diphtheria, tetanus (adsorbed), pertussis | Laboratory Leti, Spain |
| Trivax | Diphtheria, tetanus (plain), pertussis | Chiron, UK |
| Trivax-AD | Diphtheria, tetanus (adsorbed), pertussis | Chiron, UK |
| Trivax-Hib | Diphtheria, tetanus, pertussis, Hib | GSK, Europe |
| Trivb | Diphtheria, tetanus, pertussis | Brazil |
| Triviraten | Measles, mumps, rubella (live, attenuated) | Berna Biotech, Switzerland |
| Trivivac | Measles, mumps, rubella (live, attenuated) | Sevac, Czech Republic |
| Trivivax | Measles, mumps, rubella | Sanofi Pasteur, Mexico |
| Tussitrupin Forte | Pertussis | Staatliches Institut, Germany |
| Tuvax | BCG | Japan BCG Laboratory, Japan |
| Tyne | BCG | Sweden |
| Typherix | Typhoid (Vi polysaccharide) | GSK, Europe & Australia |
| Typhopara-typhoidique | Typhoid and para typhoid | France |
| Typhoral-L | Typhoid (Ty21a oral) | Berna Biotech, Germany |
| Typh-Vax | Typhoid | CSL Limited, Australia |
| Va-Diftet | Diphtheria, tetanus | Finlay Vacunas y Sueros, Cuba |
| Va-Mengoc-BC | Meningococcal (Groups B & C) | Finlay Vacunas y Sueros, Cuba |
| Vac-DPT | Diphtheria, tetanus, pertussis | Bioclon, Mexico |
| Vaccin Difteric Adsorbit | Diphtheria toxoid (adsorbed) | Cantacuzino Institute, Romania |
| Vaccin Rabique Pasteur | Rabies | Pasteur Vaccins |
| **Trade name** | **Antigen(s)** | **Manufacturer, Country** |
| Vaccin Combinat Diftero-Tetanic | Diphtheria, tetanus (adsorbed) | Cantacuzino Institute, Romania |
| Vaccin tuberculeux attenue lyophilise | BCG | Sanofi Pasteur, France |

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| Vaccinum Morbillorum Vivum | Measles (live) | Moscow Research Institute, Russia |
| Vacina Dupla | Diphtheria, tetanus | Instituto Butantan, Brazil |
| Vacina Triplice | Diphtheria, tetanus, pertussis | Instituto Butantan, Brazil |
| Vacina Triplice Viral | Measles, mumps, rubella | Brazil |
| Vacunol | Tetanus | Temis-Lostato, Brazil |
| Vakcin Sampar | Plague | Perum Bio Farma, Indonesia |
| Vaksin Cacar | Smallpox | Indonesia |
| Vaksin Serap | Diphtheria, tetanus, pertussis | Perum Bio Farma, Indonesia |
| Vaksin Campak Kerig | Measles (live, attenuated) | Perum Bio Farma, Indonesia |
| Vaksin Kotipa | Cholera, typhoid and paratyphoid A, B & C | Perum Bio Farma (Indonesia) |
| Vamoavax | Measles, mumps (live) | Institute of Immunology, Croatia |
| Varicella-RIT | Varicella | GSK, Europe |
| Varicellon | Varicella zoster immunoglobulin | Behringwerke Aktiengesellischaft, Germany |
| Varie | Smallpox (lyophilized) | Institute of Sera and Vaccine, Czech Republic |
| Varilrix | Varicella (live, Oka strain) | GSK, Europe & Mexico |
| Tax-Tet | Tetanus | Finlay Vacunas & Sueros, Cuba |
| Vaxem-Hib | Hib (polysaccharide) | Chiron, Europe |
| Vaxicoq | Pertussis (adsorbed) | Sanofi Pasteur, France |
| Vaxigrip | Influenza | Sanofi Pasteur, Europe & Australia |
| Vaxihaler-Flu | Influenza (inhaler) | Riker, UK |
| Vaxipar | Mumps (live) | Chiron, Italy |
| VCDT | Diphtheria, tetanus (pediatric) | Cantacuzino Institute, Romania |
| VDA Vaccin Difteric Adsorbit | Diphtheria | Cantacuzino Institut, Romania |
| Verorab | Rabies (purified vero cell) | Sanofi Pasteur, France |
| Vibriomune | Cholera | Duncan Flockhart, UK |
| Viralinte | Hepatitis B | Ivax Pharmaceuticals, Mexico |
| Virelon C | Polio (Inactivated) | Chiron, Germany |
| **Trade name** | **Antigen(s)** | **Manufacturer, Country** |
| Virelon T 20 | Polio (live, oral, trivalent) | Chiron, Germany |
| Virivac | Measles, mumps, rubella (live) | Merck, Finland |
| Virovac Massling, Perotid, Rubella | Measles, mumps, rubella | Sweden |
| Vopix | OPV | PT Biofarma, Indonesia |
| VT (Vacina Triplice) | Diphtheria, tetanus, pertussis | Instituto Butantan, Brazil |
| VTV (Vacina Triplice Viral) | Measles, mumps, rubella | Brazil |

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| VVR | Measles (live, attenuated) | Cantucuzino Institute, Romania |
| Welltrivax trivalente | Diphtheria, tetanus, pertussis | Spain |
| Zaantide | Diphtheria anti-toxin | Imunoloski Zavod, Croatia |
| Zaantite | Tetanus anti-toxin | Imunoloski Zavod, Croatia |
| Zaditeadvax | Diphtheria, tetanus | Imunoloski Zavod, Croatia |
| Zaditevax | Diphtheria, tetanus | Imunoloski Zavod, Croatia |
| Zamevax A+C | Meningococcal (polysaccharide, Groups A & C) | Imunoloski Zavod, Croatia |
| Zamovax | Measles (live) | Imunoloski Zavod, Croatia |
| Zamruvax | Measles, rubella (live) | Imunoloski Zavod, Croatia |
| Zapavax | Mumps | Imunoloski Zavod, Croatia |
| Zaruvax | Rubella (live) | Imunoloski Zavod, Croatia |
| Zatetravax | Diphtheria, tetanus, pertussis, parapertussis | Imunoloski Zavod, Croatia |
| Zatevax | Tetanus | Imunoloski Zavod, Croatia |
| Zatribavax | Diphtheria, tetanus, pertussis | Imunoloski Zavod, Croatia |
| Zatrivax | Measles, rubella, mumps (live) | Imunoloski Zavod, Croatia |

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

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

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

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

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

It is also suggested that the latest OPH immunization schedules and the protocol for handling anaphylaxis be brought to the immunization site for reference as needed. The sheets may be laminated for durability!

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Together we can protect all Louisianans against vaccine preventable diseases.