

# Immunization Policies and Procedures Manual



Louisiana Department of Health  
Office of Public Health  
Immunization Program

Revised September 2017

**Center for Community and Preventive Health  
Bureau of Infectious Diseases  
Immunization Program**

**TABLE OF CONTENTS**

|  |           |
|--|-----------|
| <b>I. POLICY AND GENERAL CLINIC POLICY .....</b>   | <b>1</b>  |
| <b>PURPOSE .....</b>   | <b>1</b>  |
| <b>POLICY ON CLINIC SCHEDULING .....</b>   | <b>2</b>  |
| <b>POLICY ON PUBLICITY FOR IMMUNIZATION ACTIVITIES.....</b>  | <b>4</b>  |
| <b>POLICY ON EDUCATIONAL ACTIVITIES (HEALTH EDUCATION IN IMMUNIZATION CLINICS) .....</b>   | <b>5</b>  |
| <b>POLICY ON CHECKING IMMUNIZATION STATUS OF ALL CHILDREN RECEIVING SERVICES THROUGH THE HEALTH DEPARTMENT .....</b>                   | <b>6</b>  |
| <b>POLICY ON MAXIMIZING TIME SPENT WITH PARENTS DURING IMMUNIZATION CLINICS .....</b>  | <b>7</b>  |
| <b>POLICY ON ASSISTANCE TO FOREIGN TRAVELERS.....</b>  | <b>9</b>  |
| <b>II. POLICY REGARDING CLINIC ORGANIZATION .....</b>  | <b>10</b> |
| <b>PROTOCOL FOR IMMUNIZATION CLINIC ORGANIZATION .....</b>   | <b>10</b> |
| <b>ORDERING OF IMMUNIZATION SUPPLIES .....</b>   | <b>13</b> |
| <b>VACCINE STORAGE REQUIREMENTS .....</b>  | <b>15</b> |
| <b>POLICY ON POWER OUTAGES .....</b>   | <b>40</b> |
| <b>HANDLING OF VACCINE IN THE CLINIC AREA .....</b>  | <b>42</b> |
| <b>POLICY ON TRANSPORTING VACCINE.....</b>   | <b>44</b> |
| <b>POLICY ON EXPIRATION OF VACCINES AND BIOLOGICS .....</b>  | <b>47</b> |
| <b>POLICY ON VACCINE TRANSFERS .....</b>   | <b>48</b> |
| <b>VACCINE TRANSFER REPORT IMMUNIZATION PROGRAM (EPI-6; REV 09/2012) .....</b>   | <b>50</b> |
| <b>POLICY ON VACCINE USAGE AND INVENTORY .....</b>   | <b>51</b> |
| <b>POLICY ON MOBILE VACCINATION UNITS .....</b>  | <b>53</b> |
| <b>III. GENERAL POLICY REGARDING IMMUNIZATION .....</b>  | <b>56</b> |
| <b>VACCINE ADMINISTRATION RECORD; VACCINE FOR CHILDREN (VFC) PATIENT ELIGIBILITY SCREENING RECORD; AND REGISTRY AUTHORIZATION.....</b> | <b>56</b> |
| <b>POLICY ON ROUTE OF ADMINISTRATION.....</b>  | <b>58</b> |
| <b>TECHNIQUES FOR ADMINISTRATION OF INJECTIONS.....</b>  | <b>59</b> |
| <b>POLICY ON INFORMING PARENTS OF POTENTIAL VACCINE REACTIONS.....</b>   | <b>64</b> |
| <b>REPORTING OF ADVERSE VACCINE REACTIONS .....</b>  | <b>65</b> |
| <b>SIMULTANEOUS ADMINISTRATION OF VACCINES .....</b>   | <b>67</b> |
| <b>MIXING VACCINES .....</b>   | <b>68</b> |
| <b>CHILDREN WITH INTERCURRENT ILLNESS .....</b>  | <b>69</b> |
| <b>POLICY ON IMMUNIZATIONS OF HIV-INFECTED INDIVIDUALS.....</b>  | <b>70</b> |
| <b>POLICY ON IMMUNE GLOBULIN, BLOOD PRODUCTS AND ROUTINE VACCINATION .....</b>   | <b>72</b> |
| <b>POLICY REGARDING UNRULY AND RESISTING CHILDREN .....</b>  | <b>73</b> |

|   |            |
|---|------------|
| <b>RECOMMENDED HANDLING OF THE RESISTING CHILD WHEN A PROCEDURE MUST BE DONE.....</b>   | <b>74</b>  |
| <b>POLICY ON THE MANAGEMENT OF EMERGENCY REACTIONS.....</b>   | <b>75</b>  |
| <b>PROTOCOL ON VACCINE REACTIONS AND THEIR MANAGEMENT.....</b>  | <b>76</b>  |
| <b>CARDIAC ARREST PROTOCOL .....</b>  | <b>79</b>  |
| <b>ANAPHYLAXIS PROTOCOL.....</b>  | <b>80</b>  |
| <b>PROTOCOL FOR BRONCHOSPASM.....</b>   | <b>84</b>  |
| <b>PROTOCOL FOR RASH AND URTICARIA .....</b>  | <b>85</b>  |
| <b>PROTOCOL FOR DIZZINESS AND FAINTING .....</b>  | <b>86</b>  |
| <b>EMPLOYEE VACCINATION POLICY.....</b>   | <b>88</b>  |
| <b>REFUSAL OF VACCINATION AND RELEASE FROM RESPONSIBILITY.....</b>  | <b>91</b>  |
| <b>VACCINE SCHEDULE .....</b>   | <b>93</b>  |
| <b>SCHOOL ENTRY REQUIREMENTS IN ACCORDANCE TO R.S. 17:170 STUDENT IMMUNIZATIONS-SCOPE OF REQUIREMENT.....</b>                                   | <b>97</b>  |
| <b>POLICY ON ISSUANCE OF THE STATE OF LOUISIANA UNIVERSAL CERTIFICATE OF IMMUNIZATIONS FOR SCHOOL/ CHILD CARE - PRESCHOOL REGISTRATION.....</b> | <b>100</b> |
| <b>GUIDELINES FOR EXCLUSION FROM SCHOOL OR DAYCARE.....</b>   | <b>101</b> |
| <b>POLICY ON IMMUNIZATION RECORDS UTILIZING LINKS .....</b>   | <b>103</b> |
| <b>HIGHER LEARNING ENTRY REQUIREMENTS FOR STUDENTS IN LOUISIANA .....</b>   | <b>105</b> |
| <b>POLICY ON COMMUNICABLE DISEASE REPORTING .....</b>   | <b>106</b> |
| <b>V. POLICY REGARDING SPECIFIC IMMUNIZATIONS .....</b>   | <b>108</b> |
| <b>POLICY ON DTAP, DT, TD AND TDAP VACCINATIONS .....</b>   | <b>108</b> |
| <b>POLICY ON THE ADMINISTRATION OF HAEMOPHILUS INFLUENZAE TYPE B CONJUGATE VACCINES .....</b>   | <b>113</b> |
| <b>POLICY ON HEPATITIS A VACCINE.....</b>   | <b>117</b> |
| <b>ADMINISTRATION OF IMMUNE SERUM GLOBULIN (ISG) PROPHYLAXIS OR HEPATITIS A VACCINE FOR HEPATITIS A CONTACTS.....</b>                           | <b>121</b> |
| <b>POLICY ON UNIVERSAL HEPATITIS B VACCINATION.....</b>   | <b>123</b> |
| <b>PERINATAL HEPATITIS B PREVENTION PROGRAM – SCREENING AND PREVENTION OF HEPATITIS B TRANSMISSION IN HIGH-RISK INFANTS .....</b>               | <b>126</b> |
| <b>HEPATITIS B SURVEILLANCE AND FOLLOW-UP FORM .....</b>  | <b>134</b> |
| <b>POLICY ON HUMAN PAPILLOMAVIRUS (HPV) VACCINES.....</b>   | <b>136</b> |
| <b>POLICY ON INFLUENZA VACCINE .....</b>  | <b>139</b> |
| <b>POLICY ON MEASLES VACCINATION .....</b>  | <b>146</b> |
| <b>POLICY ON MENINGOCOCCAL (GROUP A, C, Y AND W-135) VACCINATION .....</b>  | <b>148</b> |
| <b>POLICY ON MENINGOCOCCAL DISEASE (MENB) SEROGROUP B VACCINATION .....</b>   | <b>150</b> |
| <b>POLICY ON MUMPS VACCINATION .....</b>  | <b>151</b> |
| <b>POLICY ON PNEUMOCOCCAL CONJUGATE VACCINE (PCV) .....</b>   | <b>152</b> |
| <b>POLICY ON PNEUMOCOCCAL POLYSACCHARIDE VACCINE (PPSV).....</b>  | <b>157</b> |
| <b>POLICY ON POLIOMYELITIS VACCINATION.....</b>   | <b>160</b> |
| <b>POLICY ON ADMINISTRATION OF RABIES VACCINATION.....</b>  | <b>162</b> |
| <b>POLICY ON LIVE, ORAL ROTAVIRUS VACCINATION .....</b>   | <b>168</b> |

|   |            |
|---|------------|
| <b>POLICY ON RUBELLA VACCINATIONS.....</b>  | <b>171</b> |
| <b>POLICY ON VARICELLA, ZOSTAVAX AND MMRV COMBINATION VACCINATION.....</b>                          | <b>172</b> |
| <b>POLICY ON THE IMMUNIZATION OF ADOLESCENTS.....</b>   | <b>176</b> |
| <b>POLICY ON THE IMMUNIZATION OF HIGH RISK ADULTS WITH HEPATITIS VACCINE.....</b>                   | <b>177</b> |
| <b>POLICY ON USAGE OF COMBINATION VACCINES.....</b>   | <b>181</b> |
| <b>VI. MISCELLANEOUS IMMUNIZATION INFORMATION.....</b>  | <b>185</b> |
| <b>PROCEDURES FOR VACCINE PROTECTION AND HURRICANE/DISASTER PREPAREDNESS .....</b>                  | <b>186</b> |
| <b>EMERGENCY RESPONSE PLAN &amp; WORKSHEET (PART 1).....</b>  | <b>191</b> |
| <b>IMMUNIZATION GUIDELINES FOR DISPLACED CHILDREN - POST-NATURAL DISASTER.....</b>                  | <b>194</b> |
| <b>VACCINES FOR CHILDREN (VFC) DISCREPANCY OR MISUSE POLICY .....</b>                               | <b>197</b> |
| <b>POSSIBLE ORIGINS OF SUSPECTED DISCREPANCIES AND/OR MISUSE:.....</b>                              | <b>197</b> |
| <b>FOREIGN-BORN PERSONS AND IMMUNIZATIONS WITH FREQUENTLY ASKED QUESTIONS.....</b>                  | <b>201</b> |
| <b>FREQUENTLY ASKED QUESTIONS ABOUT IMMUNIZATIONS AND FOREIGN-BORN PERSONS .....</b>                | <b>202</b> |
| <b>SPECIAL CONSIDERATION FOR EMERGENCY PROTOCOL TO BE FOLLOWED IN A NON-MEDICAL FACILITY: .....</b> | <b>206</b> |
| <b>VACCINATION OF HEMATOPOIETIC CELL TRANSPLANT RECIPIENTS.....</b>                                 | <b>208</b> |

## **I. POLICY AND GENERAL CLINIC POLICY**

### **PURPOSE**

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

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

- I. Policy and General Clinic Policy
- II. Policy Regarding Clinic Organization
- III. General Policy Regarding Immunization
- IV. OPH Program Vaccine Policies
- V. Policies Regarding Specific Immunizations
- VI. Miscellaneous Immunization Information

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

## **POLICY ON CLINIC SCHEDULING**

### **Policy:**

1. The scheduling of times and places for immunization clinics is a local and regional responsibility.
2. Clinics shall be held at times and places that effectively promote vaccination and make efficient use of staff time and facilities.
3. Scheduling shall be periodically reviewed to ensure that the schedule still fulfills program goals.
4. During power outage and/or Louisiana Immunization Network for Kids Statewide (LINKS) system failure individuals should bring their personal immunization record to the clinic. Individuals without their personal immunization record shall be given age appropriate vaccinations.
5. Individuals being served at the time of power or system failure would have their vaccinations recorded in the Vaccine Administration Record, Vaccine for Children (VFC) Patient Eligibility Screening, AND Registry Authorization (Imm-5, Revised). A copy of the record brought by the parent should be attached to the Imm-5 form. Providers should be aware that this is the only form that is mandated by the Vaccine Injury Act of 1986. To obtain a blank copy of the VFC VAR form in LINKS, sign-onto LINKS registry, go to 'REPORTS' and scroll down to 'STATE REPORTS' and then select 'VFC VAR BLANK' to print copies.
6. A copy of the patient's updated immunization record will be mailed no later than a week after system becomes operational.

### **Rationale:**

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

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

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

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

|   |        |         |               |      |
|---|--------|---------|---------------|------|
| Information About Person Receiving Vaccine:   |        |         |               |      |
| Last Name:  | First: | Middle: | DOB:          | Age: |
| Name (Parent or Guardian, if applicable):   |        |         | Phone Number: |      |
| Address:  |        | City:   | State:        | Zip: |
| I agree to allow information about all vaccinations given to me or to the person for whom I am authorized to consent to be released to other medical care providers, schools, child care, or head start centers to avoid the administration of unnecessary vaccinations and to determine immunization status. I understand that this will remain in effect until canceled by me in writing. |        |         |               |      |
| Signature of Parent/Guardian or adult vaccine recipient _____   |        |         |               |      |

|  |                                    |  |
|--|------------------------------------|--|
| <b>FOR CLINIC USE ONLY</b>   |                                    |  |
| 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 vaccine(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 |

|   |
|---|
| <b>DTaP DT Td DTaP-Hib</b>                              |
| Manufacturer and Lot#:                                  |
| Expiration Date:<br>Site of Injection:                  |
| VIS Pub Date:   |
| Immunization & Dose<br>DT Td DTaP DTaP-Hib<br>1 2 3 4 5 |

|   |
|---|
| <b>IPV</b>                              |
| Manufacturer and Lot#:                  |
| Expiration Date:<br>Site of Injection:  |
| VIS Pub Date:                           |
| Immunization & Dose<br>IPV<br>1 2 3 4 5 |

|  |
|--|
| <b>MMR</b>                             |
| Manufacturer and Lot#:                 |
| Expiration Date:<br>Site of Injection: |
| VIS Pub Date:                          |
| Immunization & Dose<br>MMR<br>1 2 3    |

|  |
|--|
| <b>HIB</b>                             |
| Manufacturer and Lot#:                 |
| Expiration Date:<br>Site of Injection: |
| VIS Pub Date:                          |
| Immunization & Dose<br>HIB<br>1 2 3 4  |

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

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

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

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

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

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

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

|  |
|--|
| <b>OTHER</b>                           |
| Manufacturer and Lot#:                 |
| Expiration Date:<br>Site of Injection: |
| VIS Pub Date:                          |
| Immunization & Dose<br><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: In the waiting room; coloring books, posters for walls, pamphlets for distribution, use of audio-visual presentations such as immunization video tapes and small conferences.
- With the nurse: this is the best time for person-to-person educational process (health education); the potential benefits are highest during this time.
- After Clinic: Printed information on immunizations and side effects given to parents; availability of personnel in the event if problems or questions arise.

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

### **Policy:**

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

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

- Each private care WIC patient's status of immunization shall be checked at each visit by use of the LINKS immunization registry or assessing the patient's immunization record. The immunization record shall be checked to see if it has been entered in the LINKS registry with documentation of the most current immunizations received. Encourage the parent or guardian to bring the immunization record at each clinic visit.
- If the patient has no immunization record, urge the parent or guardian to obtain one from the private physician or obtain a signed Release of Information form that allows for the exchange of immunization records between the private physician and the Health Department.
- For the child who is up to date, the parent or guardian should be so informed, and also told when the next immunizations are due.
- For the child who is behind in the immunization schedule, the parent or guardian should be so informed, and offered the option of having the immunizations at the parish health unit at that visit, or seeing the private physician as soon as possible to have the immunizations.
- If the child is not present at the visit to the parish health unit, the parent or guardian should be urged to have the child immunized as soon as possible at the parish health unit or at the private physician's office.

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

## **POLICY ON MAXIMIZING TIME SPENT WITH PARENTS DURING IMMUNIZATION CLINICS**

### **Policy:**

1. It is the policy of the Office of Public Health to maximize the time that parents/patients and the health professional spend together.
2. The health professional will continuously review practices and procedures so that adequate time may be spent with each parent/patient, according to specific circumstances involved.

### **Guidelines:**

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

### **The Setting:**

- A. Establish the setting in the most efficient manner possible, assuring that needed supplies and their layout are completed before patients enter the clinic area.
- B. Establish a setting conducive to interaction by eliminating to the highest degree possible, other activities, conversations, and non-essential personnel from the immediate clinic area.

### **Interaction-System:**

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

### **Health Education:**

- A. Develop a systematic approach to allow inclusion of time to provide health education during all parent/patient contacts.
- B. The following sequence of health education may be useful:
  1. Review importance of immunization and how immunizations work.
  2. Review details of specific vaccines including important information statements or vaccine information pamphlets and other materials presented in writing.
  3. Review importance and need for boosters, and remind parents/patients to return

for the next immunization appointment.

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

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

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

## **POLICY ON ASSISTANCE TO FOREIGN TRAVELERS**

### **Policy:**

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

1. Advice to travelers, or their physicians, on the need for certain immunizations, biologics, medications, or other precautions that may be necessary to maintain their health when traveling overseas (Refer to the yellow book – CDC Health Information for International Travel – current version to provide foreign travel information specific to visiting countries or check the CDC website).
2. Clinics conducted by the Office of Public Health shall not provide immunizations or biologics to international travelers except those designated as International Travel or yellow fever vaccination centers with the exception of bringing children “up-to-date” for their normal childhood immunizations and giving adults Td boosters as appropriate for their immunization status. Only those health unit clinics designated as approved yellow fever vaccination centers shall provide yellow fever vaccinations.

### **Guidelines:**

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

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

## II. POLICY REGARDING CLINIC ORGANIZATION

### PROTOCOL FOR IMMUNIZATION CLINIC ORGANIZATION

#### Objectives:

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

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

| <b>Equipment</b>  | <b>Educational Materials</b>  |
|---|---|
| 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<br>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 |   |

## Staff

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

## Procedure

1. Assess needs - pre-plan and estimate how many children will attend the immunization clinic.
2. Publicize the clinic schedule.
3. Coordinate with school nurses.
4. Order enough vaccine and supplies for a one month period.

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

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

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

---

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

The nurse in the clinic shall be responsible for:

1. Administering all of the appropriate immunizations;
2. Instructing parents about and assisting in positioning or restraining of children;
3. Maintaining aseptic technique during clinic;
4. Assuring that the vaccine cold chain (use of ice packs) is maintained;
5. Proper disposal of syringes, needles and other waste supplies after clinic;
6. Explaining any possible side effects and recommendations regarding immunizations received.

## **RECOMMENDATIONS**

1. If two nurses are giving immunizations, arrange separate or screened areas for each nurse to provide privacy for discussion and vaccine administration.
2. Have one nurse complete the entire sequence of events for a given patient, i.e., contraindications, precautions, questions/answers, immunizations, reactions, and next appointment.
3. Take advantage of waiting room time to provide educational activity.
4. When possible as parent/child leave immunization room/space, have the clerk or a volunteer send in the next person (this may help maximize efficiency of nursing time).
5. If there is an obvious communication problem due to a language barrier and someone is available in the office that can help, bring them into the setting early to avoid disruption and confusion on the part of the parent or child as to what is going to happen. Contact the Language Line for assistance with language interpretation (e.g., Latino/Hispanic population) at 1-800-367-9559.

## **ORDERING OF IMMUNIZATION SUPPLIES**

### **Policy:**

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

- A. maintaining adequate inventories of vaccines and related supplies
- B. ordering/receiving vaccines and related supplies and compare vaccine received with vaccine invoice
- C. proper storage of vaccines and related supplies immediately upon arrival
- D. checking expiration dates and taking appropriate action with outdated vaccines/supplies and any discrepancies with vaccine shipment order

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

### **Procedure:**

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

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

The procedure for ordering is as follows:

VOMS must be used to order all vaccines.

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

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

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

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

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

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

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

## VACCINE STORAGE REQUIREMENTS

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

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

### **Policy:**

1. Vaccines are to be stored in parish health units and regional laboratories according to the manufacturers' recommendation as given in the package insert.
2. Vaccines should be stored centrally in the refrigerator or freezer, not in the door or on the bottom of the storage unit or vegetable bins (crisper), and sufficiently away from walls to allow air to circulate. Post warning signs (i.e., Do Not Unplug) on the refrigerator and freezer to prevent inadvertent unplugging of the unit.
3. Vaccines that have been improperly stored will be removed from the clinic area to prevent accidental use, and returned to the Immunization Program in New Orleans. The regional Immunization Consultant must be notified of the return.
4. Calibrated certified thermometers must be used to monitor temperatures for each freezer and refrigerator compartments that are used to store vaccine or biologics. Temperatures must be logged twice a day on a daily basis and the log should be maintained for at least 3 years per unit. Please see the log sheet. Calibration must be traceable to standards provided by the National Institute of Standards and Technology (NIST) – a U. S. government agency within the Department of Commerce or a laboratory recognized by NIST. Calibration can be traceable to NIST using American Society for Testing and Materials (ASTM) methods for the calibration process.
5. Rotate stock and ensure that vaccines with the earliest expiration dates are to be used first and are in front of vaccines with longer expirations dates. Check and rotate your stock weekly with a monthly review of rotation and documentation. The designated staff person should rotate stock when new vaccine is added to inventory.
6. Effective January 2009, dormitory style refrigerators are not acceptable for permanent or long-term storage of vaccines. Refrigerators and freezers used for vaccine storage must comply with the following requirements: a) be able to maintain required vaccine storage temperatures year-round; b) be large enough to hold the year's largest inventory; c) at minimum, have a working certified and calibrated thermometer inside each storage compartment; and d) be dedicated to the storage of vaccines.

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

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

**Rationale:**

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

**Information:**

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

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

| VACCINE TYPE        | Freezer<br>-15° to -2° C<br>0° TO 30° F | Refrigerator<br>2° to 8° C<br>36° to 46° F | Protect from Light | Do Not Freeze |
|---------------------|---|--|--------------------|---------------|
| POLIO (IPV)*        |   | √  |                    | √             |
| DTaP, DT, Td, Tdap* |   | √  |                    | √             |
| MMR <sub>1</sub>    |   | √  | √                  | √             |
| HIB*                |   | √  |                    | √             |
| VARICELLA           | √                                       |  | √                  |               |
| MMR-VAR             | √                                       |  | √                  |               |
| HAV                 |   | √  |                    | √             |

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

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

\* Applies to combination vaccines with these antigens

---



# Temperature Log for Refrigerator – Celsius

DAYS 1-15

Month/Year \_\_\_\_\_ VFC PIN or other ID # \_\_\_\_\_ Page 1 of 3

Facility Name \_\_\_\_\_

### Monitor temperatures closely!

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

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

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

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

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

DISTRIBUTED BY THE

**IMMUNIZATION ACTION COALITION** 1573 Selby Avenue • St. Paul, MN 55104 • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

Adapted with appreciation from California Department of Public Health

Technical content reviewed by the Centers for Disease Control and Prevention  
www.immunize.org/catg.d/p3037c.pdf • Item #P3037F (8/13)



# Temperature Log for Refrigerator – Celsius

DAYS 16–31

Month/Year \_\_\_\_\_ VFC PIN or other ID # \_\_\_\_\_ Page 2 of 3

Facility Name \_\_\_\_\_

### Monitor temperatures closely!

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

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

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

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

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

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

Page 3 of 3

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

| Date & Time of Event<br><small>If multiple, related events occurred, see Description of Event below.</small>   | Storage Unit Temperature<br><small>at the time the problem was discovered</small> | Room Temperature<br><small>at the time the problem was discovered</small> | Person Completing Report |   |
|--|---|---|--------------------------|---|
| Date:  | Temp when discovered:   | Temp when discovered:   | Name:                    |   |
| Time:  | Minimum temp:   | Maximum temp:   | Comment (optional):      | Title: <span style="float: right;">Date:</span> |
| <b>Description of Event</b> <i>(If multiple, related events occurred, list each date, time, and length of time out of storage.)</i> <ul style="list-style-type: none"> <li>General description (i.e., what happened?)</li> <li>Estimated length of time between event and last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)</li> <li>Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)</li> <li>At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?</li> <li>Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?</li> <li>Include any other information you feel might be relevant to understanding the event.</li> </ul> |   |   |                          |   |
| <b>Action Taken</b> <i>(Document thoroughly. This information is critical to determining whether the vaccine might still be viable.)</i> <ul style="list-style-type: none"> <li>When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer(s).)</li> <li>Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)</li> <li><b>IMPORTANT:</b> What did you do to prevent a similar problem from occurring in the future?</li> </ul>   |   |   |                          |   |
| <b>Results</b> <ul style="list-style-type: none"> <li>What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)</li> </ul>  |   |   |                          |   |

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

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

| Date & Time of Event<br><small>If multiple, related events occurred, see Description of Event below.</small>   | Storage Unit Temperature<br><small>at the time the problem was discovered</small> | Room Temperature<br><small>at the time the problem was discovered</small> | Person Completing Report            |                        |
|--|---|---|-------------------------------------|------------------------|
| Date: (see below)  | Temp when discovered: 7°C   | Temp when discovered: 25°C  | Name: Nancy Nurse                   |                        |
| Time: (see below)  | Minimum temp: 3°C   | Maximum temp: 12°F  | Comment (optional): temp is approx. | Title: VFC Coordinator |
| Date: 6/24/13  |   |   |                                     |                        |
| <b>Description of Event</b> (If multiple, related events occurred, list each date, time, and length of time out of storage.)   |   |   |                                     |                        |
| <ul style="list-style-type: none"> <li>- General description (i.e., what happened?)</li> <li>- Estimated length of time between event &amp; last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -8° to 5°F [-20° to -15°C] for freezer)</li> <li>- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record)</li> <li>- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?</li> <li>- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?</li> <li>- Include any other information you feel might be relevant to understanding the event.</li> </ul> |   |   |                                     |                        |
| <p>At 8 am on Monday (6/24/13) morning when clinic opened, identified 3 temperature excursions over the weekend in refrigerator with readings as high as 12°, 10° &amp; 9°C in primary vaccine storage unit #1. Recordings taken every 15 min on calibrated digital data logger overnight. Data logger probe in glycol located in middle of refrigerator with vaccines.</p> <p>Total time out of range: approximately 3 hrs — maximum temp 12°F (see attached document of continuous temp readings)</p> <p>Inventory of vaccines: see attached</p> <p>Water bottles in refrigerator door. No vaccine stored in freezer. No problems with storage unit prior to Saturday night. Thunderstorms in area over weekend may have affected power.</p>   |   |   |                                     |                        |
| <b>Action Taken</b> (Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)  |   |   |                                     |                        |
| <ul style="list-style-type: none"> <li>- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].)</li> <li>- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)</li> <li>- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?</li> </ul>   |   |   |                                     |                        |
| <p>Vaccines currently stored appropriately at 7°C. Refrigerator and vaccines labeled "Do Not Use."</p> <p>My State Immunization Program contacted at 8:30 am. Spoke with Victor Vaccine. Provided Victor with details of event and list of vaccines. Vaccine to remain quarantined until we hear back from Victor.</p> <p>Called electric company and confirmed 2 short power outages during weekend.</p> <p>Checked refrigerator seals — called refrigerator maintenance company to replace seals.</p> <p>Checked plug on unit — placed tape over plug to prevent inadvertent dislodging. Plan to purchase plug guard.</p> <p>Plan to follow up with Immunization Program on data loggers with alarms that could be sent to coordinator and back-up phones.</p>   |   |   |                                     |                        |
| <b>Results</b>   |   |   |                                     |                        |
| <ul style="list-style-type: none"> <li>- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public purchase vaccine, follow your state/local health department instructions for vaccine disposition.)</li> </ul>   |   |   |                                     |                        |
| <p>Late on Monday, I talked with Victor regarding continued use of vaccine. Victor had checked with manufacturers which confirmed that vaccine is acceptable for use. He told me that vaccine could therefore be removed from quarantine. I discussed the entire situation with Susie Supervisor and Dr. Director (clinic medical director) who agreed that we could put vaccine back in use.</p>  |   |   |                                     |                        |

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

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

| Date & Time of Event<br><small>If multiple, related events occurred, see Description of Event below.</small>  | Storage Unit Temperature<br><small>at the time the problem was discovered</small> | Room Temperature<br><small>at the time the problem was discovered</small> | Person Completing Report            |                        |
|---|---|---|-------------------------------------|------------------------|
| Date: 7/16/2013   | Temp when discovered: -2°C  | Temp when discovered: 25°C  | Name: Nancy Nurse                   |                        |
| Time: 8:00 am   | Minimum temp: -2°C  | Maximum temp: 6°C   | Comment (optional): temp is approx. | Title: VFC Coordinator |
| Date: 7/15/13   |   |   |                                     |                        |
| <b>Description of Event</b> (If multiple, related events occurred, list each date, time, and length of time out of storage.)  |   |   |                                     |                        |
| <ul style="list-style-type: none"> <li>• General description (i.e., what happened?)</li> <li>• Estimated length of time between event &amp; last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)</li> <li>• Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record)</li> <li>• At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?</li> <li>• Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?</li> <li>• Include any other information you feel might be relevant to understanding the event.</li> </ul> <p>When checked main clinic fridge (in lab) at 8:00 am on Tuesday, 7/16/2013, digital readout on data logger read -2°C. Data logger located in center of fridge with probe in glycol. Review of computer readings (taken every 15 minutes) showed steady drop in temps from 6°C at 8:15 pm (7/15/2013) to -2°C reading discovered when arrived at clinic on Tuesday morning (7/16/2013). Readings hit 1°C at 11 pm (7/15) and 0°C at 2 am (7/16). Total time out of recommended storage temps = 9 hours, with 6 hours at freezing or below (see attached document of continuous temp readings). Inventory of vaccines attached.</p> <p>Water bottles in refrigerator door and crisper area. No vaccines stored in freezer. No recent adjustments to temp controls and no previous temp excursions noted with this refrigerator before 7/15.</p> |   |   |                                     |                        |
| <b>Action Taken</b> (Document thoroughly. This information is critical to determining whether the vaccine might still be viable.)   |   |   |                                     |                        |
| <ul style="list-style-type: none"> <li>• When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer(s).)</li> <li>• Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)</li> <li>• <b>IMPORTANT:</b> What did you do to prevent a similar problem from occurring in the future?</li> </ul> <p>Upon discovery, vaccines marked "Do Not Use" and stored in 2nd clinic fridge (in exam room #3 at 5°C). Also placed "Do Not Use" note on main fridge in lab. Notified Susie Supervisor about the issue. Contacted Victor Vaccine at My State Immunization Program at 8:30 am. Provided Victor with details of event and list of vaccines in fridge. Victor said to maintain vaccines in 2nd fridge and that he would check with manufacturers to determine next steps.</p> <p>Called Jim's Appliance Repair to examine fridge. Repairman found and replaced faulty thermostat in unit.</p> <p>Reset data logger on center shelf in fridge with probe in glycol.</p>   |   |   |                                     |                        |
| <b>Results</b>  |   |   |                                     |                        |
| <ul style="list-style-type: none"> <li>• What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)</li> </ul> <p>After fridge thermostat repaired, monitored temps in empty fridge for 1 week, per state requirements. Fridge maintained 3° to 4°C temps for entire week. Submitted repair documentation and data logger readings to Victor Vaccine for approval and ordered replacement vaccines. Victor had checked with manufacturers who confirmed that all vaccines in fridge EXCEPT MMR were no longer viable and should be returned per state policy guidelines. MMR may be used because pkg insert allows storage down to -50°C. Discussed entire situation with Susie Supervisor and clinic director, Dr. Director, who agreed on continued use of MMR. Will continue to monitor fridge closely to watch for pattern of temp fluctuations indicating potential problem with thermostat. If problems, contact Victor Vaccine for advice on purchasing new fridge meeting criteria for appropriate vaccine storage.</p>   |   |   |                                     |                        |

DISTRIBUTED BY THE

**IMMUNIZATION ACTION COALITION** 1573 Selby Avenue • St. Paul, MN 55104 • 651-647-9009 • [www.immunize.org](http://www.immunize.org) • [www.vaccineinformation.org](http://www.vaccineinformation.org)

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