Georgia Department of Public Health

IMMUNIZATION OFFICE MANUAL

VOL. 12-10 **October 2012**

DPH -

Georgia Department of Public Health
Brenda Fitzgerald, MD, Commissioner Nathan Deal, Governor
2 Peachtree St. NW, 15th Floor
Atlanta, Georgia 30303-3142
www.health.state.ga.us

Department of Public Health
Policy and Procedure Approval

This publication, in combination with the Advisory Committee on Immunization Practices Recommendations Manual, represents the official Policies and Procedures for the Administration of Vaccines and Provision of Immunization Services of the Georgia Department of Public Health. In addition, these manuals serve as an Annex to the Standard Operating Procedures (SOP) of the Department of Public Health (DPH) Emergency Operations Plan (EOP).

The purpose of this manual is two-fold. First, to serve either as the official Policies and Procedures for the Administration of Vaccines and Provision of Immunization Services by a health district, or to be utilized as a guide for writing a district's Immunization Policies and Procedures. District Health Directors who choose to utilize these two publications as their district Policies and Procedures should review and sign both manuals annually.

We encourage District Health Directors, Clinical Coordinators and Immunization Coordinators, as well as other providers, to review this manual and ensure that their district's policies are in conformance with those outlined in this document. Secondly, the purpose is to delineate the responsibilities and working relationships of state, district and county personnel in matters that concern the Immunization Office.

Any discrepancies or errors found in the manual should be brought to the attention of the Immunization Office at (404) 657-3158 or email immunization@dhr.state.ga.us. Thank you for your support of the Immunization Office in Georgia.

Signed by, Brenda Fitzgerald, MD
Department of Public Health

Date April 27, 2012

Georgia Department of Public Health
Brenda Fitzgerald, MD, Commissioner Nathan Deal, Governor
2 Peachtree St. NW, 15th Floor
Atlanta, Georgia 30303-3142
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Novmeber 07, 2012

MEMORANDUM

TO: District Health Directors
District Program Managers
District Administrators
District Immunization Coordinators

FROM: Steve Mitchell, Director
Georgia Immunization Section

SUBJECT: Georgia Immunization Office Manual Updates

In the interest of saving resources and space, the complete manuals as well as the manual updates are on the Immunization Office website - http://health.state.ga.us/programs/immunization/index.asp. Below is a listing of those documents included in the update as well as guidance for adding, deleting, or replacing same:

Transmittal Memo---use this to assist in adding and replacing documents, then place in Chapter 11, Transmittal Memos.

Manual Update Documentation page---Immunization Coordinators are to complete this, send a copy to the state immunization office attention nurse consultant by the deadline noted on the form, and place it in Chapter 11, Transmittal Memos.

Cover page **(REPLACE)**

Division of Public Health Policy and Procedure Approval **(REPLACE)**

Table of Contents:

- Complete set of Table of Contents Pages **(REPLACE)**

Chapter 1 Introduction

- Table of Contents Page **(REPLACE)**
- Introduction to Manual **(REPLACE)**
- Georgia Immunization Office: Central Office and Immunization Office Consultants **(REPLACE)**
- District Immunization Coordinators **(REPLACE)**
- Request for Immunization Forms --- Form 3184 **(REPLACE)**
- U.S. Vaccines **(Move To Chapter 2, After Eligibility Criteria for Vaccines Supplied)**

Chapter 2 Recommended Schedule and Guidelines

- Table of Contents Page **(REPLACE)**
- DPH GA Immunizations Program Vaccine Guidelines Approval Sheet (**ADD**) (**Do Not Remove Previous Sheets**)
- Immunization Guidelines for DPH Clinics
- Eligibility Criteria for Vaccines Supplied by the Georgia Immunization Program for Children, Adolescents, and Adults **(REPLACE)**
- U.S. Vaccines (**ADD**)
- Georgia Department of Public Health, Immunization Office Vaccine Guidelines **(REPLACE ALL)**
  - Combination Vaccines (**REPLACE**)
  - Vaccines to Prevent Diphtheria, Tetanus, and Pertussis (**REPLACE**)
  - Vaccines to Prevent H1N1 (**REMOVE**)
  - Vaccines to Prevent Haemophilus influenzae Type B (**REPLACE**)
  - Vaccines to Prevent Hepatitis A (includes use of Immune Globulin [IG]) (**REPLACE**)
  - Vaccines to Prevent Hepatitis B (**REPLACE**)
  - Vaccines to Prevent Herpes Zoster (Shingles) (**REPLACE**)
  - Vaccines to Prevent Human Papillomavirus Infection (**REPLACE**)
  - Vaccines to Prevent Influenza (**REPLACE**)
  - Vaccines to Prevent Measles, Mumps, and Rubella (**REPLACE**)
  - Vaccines to Prevent Meningococcal Disease (**REPLACE**)
  - Vaccines to Prevent Pneumococcal Disease (**REPLACE**)
  - Vaccines to Prevent Polio (**REPLACE**)
  - Vaccines to Prevent Rotavirus Gastroenteritis (**REPLACE**)
  - Vaccines to Prevent Varicella (**REPLACE**)
- Recommended Childhood and Adolescent Immunization Schedule 2010 and Catch-up Schedule for Children with Lapsed Immunization 2010 **(REPLACE)**
- Recommended and Minimum Ages and Intervals Between Vaccine Doses (Table1) **(REPLACE)**
- Recommended Adult Immunization Schedule 2010 **(REPLACE)**
- Screening Questionnaires for Child and Teen Immunization (English/Spanish) **(REPLACE BOTH)**
- Screening Questionnaires for Adult Immunization (English/Spanish) **(REPLACE BOTH)**

Chapter 3 Informed Request Policies

- Table of Contents Page **(REPLACE)**
- Informed Request Policy **(REPLACE)**
- Vaccine Information Statements - **(Remove All VIS's) (VIS's can be found at the following link www.immunize.org)**
- After The Shot (English) **(REPLACE)**
- Después de las vacunas (After The Shots -Spanish 4 pages now (**REPLACE)**
- Georgia Vaccine Administration Record **(REPLACE)**
- Refusal to Vaccinate Form (English) (**REPLACE**)
- Refusal to Vaccinate Form (Spanish) **(ADD)**

Chapter 4 Adverse Events Following Immunizations

- Policy for Reporting Vaccine Adverse Events Following Immunizations **(REPLACE)**
- Handling of Emergencies Following the Administration of Vaccines **(REPLACE)**
- Vaccine Adverse Event Reporting System- Form VAERS (FDA) **(REPLACE)**
- Frequently Asked Questions About VAERS **(Remove from manual)** (**Update go to Link http://vaers.hhs.gov/about/faqs**)
- VAERS Brochure **(REPLACE)**
- Frequently Asked Questions (**Go to Link http://hrsa.gov/vaccinecompensation/faq.html**)
- National Vaccine Injury Compensation Program Vaccine Injury Table **(REPLACE)**
- Vaccine Injury compensation Program (VICP) **(Remove from manual) (Update go to Link http://www.hrsa.gov/vaccinecompensation/index.html)**

Chapter 5 Requirements of School/Child Care Law

- Summary of Immunization Policies Relative to Georgia Law **(REPLACE)**
- Official Code of Georgia, Annotated **(REPLACE)**
  - Section 20-2-771
  - Section 49-4-182
  - Section 49-4-183
  - Section 31-12-3.1
- DPH Rules, Chapter 290-5-4
- Historical Statement Listing Dates of Immunization Requirements **(REPLACE)**
- School Certificate of Immunization Form 3231 (Rev. 4/12) **(REPLACE)**
- Policy Guide 3231INS: Standards for Issuing and Filing Certificates of Immunization **(REPLACE)**
- Policy Guide 3231REQ: Vaccine Requirements for Attending Child Care Facilities and Schools in Georgia Relative to the Certificate of Immunization **(REPLACE)**
- Summary Of Georgia Immunization Requirements For Child Care and School Attendance **(REPLACE)**
- Immunization Requirements and Recommendations for University System of Georgia Students **(REPLACE)**
- University System Of Georgia Required Certificate Of Immunization **(ADD)**

Chapter 6 Surveillance and Reporting - Remove all of chapter 6 and replace with the documents below.

- Procedure for the Investigation and Reporting of Vaccine Preventable Diseases **(REPLACE)**
- Contact Persons for VPD Surveillance at the District Health Office **(REPLACE)**
- Vaccine Preventable Disease Fact Sheets
  - Diphtheria Fact Sheet **(REPLACE)**
  - Hepatitis A Fact Sheet and Q & A **(REPLACE)**
  - Hepatitis B Fact Sheet and Q & A **(REPLACE)**
  - Haemophilus influenzae Invasive Disease Fact Sheet and Q & A **(REPLACE)**
  - Measles Fact Sheet and Q & A **(REPLACE)**
  - Mumps Fact Sheet **(REPLACE)**
  - Pertussis Fact Sheet and Q & A **(REPLACE)**
  - Polio Fact Sheet and Q & A **(REPLACE)**
  - Rubella Fact Sheet and Q & A **(REPLACE)**
  - Streptococcus pneumoniae Fact Sheet and Q & A **(REPLACE)**
  - Tetanus Fact Sheet **(REPLACE)**
  - Neisseria Meningitidis Fact Sheet **(ADD)**
  - Varicella Fact Sheet **(ADD)**

Chapter 6 Surveillance and Reporting (Cont.)

- Resources for Influenza Prevention and Control **(REPLACE)**
- Influenza Outbreak Control in a Long Term Care Facility **(REPLACE)**
- Georgia Notifiable Disease Report, Form 3095 (Rev. 8/04) **(REPLACE)**
- Diphtheria Worksheet **(REPLACE)**
- Measles Surveillance Worksheet **(REPLACE)**
- Mumps Surveillance Worksheet **(REPLACE)**
- Pertussis Surveillance Worksheet **(REPLACE)**
- Rubella Surveillance Worksheet **(REPLACE)**
- Tetanus Surveillance Worksheet **(REPLACE)**
- Bacteriology Submission Form **(ADD)**
- GPHL Microbial Immunology Submission Form **(REPLACE)**
- GPHL Molecular Biology Submission Form **(REPLACE)**
- Varicella Reporting and Case Investigation Form **(ADD)**
- Virology Culture Submission Form (Rev. 1/10) **(REPLACE)**

Chapter 7 Hepatitis - Remove all of chapter 7 and replace with the documents below.

- Perinatal Hepatitis B Prevention Program Guidelines **(REPLACE)**
- **Appendix Table (All Appendix REPLACE)**
  - A---Perinatal Hepatitis B Prevention Case Management Flow Chart
  - B---Obstetrician & Medical Provider Notification Materials
    - B-1---Sample Letter for Medical Providers Caring for HBsAg-Positive Pregnant Patients
    - B-2---Perinatal Hepatitis B Chart Alert From
    - B-3---Perinatal Hepatitis B Delivery Report Form
  - C-- Patient Notification Materials
    - C-1---Sample Letter for Pregnant HBsAg-Positive Women
    - C-2---Sample Letter for Foster Parents of Infants Born to HBsAg (+) Women
    - C-3---Hepatitis B & Moms-to-Be Pamphlet (2006)
  - D---Patient Interview Guide
    - D-1---Example Hepatitis B Interviewing/Counseling Format
    - D-2---Sample Perinatal Hepatitis B Interview Questions
  - E---Pediatrician Notification Materials
    - E-1---Sample Letter for Pediatricians Caring for Infant Born to HBsAg-Positive Mother
    - E-2---Quick Reference for Care of Infants Born to Hepatitis B Infected Mothers
  - F---HIPAA Information for Perinatal Hepatitis B Prevention Program
  - G---Birth Hospital Resources
    - G-1---Guidelines for Standing Orders in Labor & Delivery and Nursery Units to Prevent Hepatitis B Virus Transmission to Newborns (5/09)
    - G-2---Give the Birth Dose…Hepatitis B at Birth Saves Lives! (9/09)
  - H---Medical Provider Resources
    - H-1---Hepatitis B Facts: Testing and Vaccination (6/10)
    - H-2---Patient Notification Letter Regarding Hepatitis B Test Results (4/02)
    - H-3---What the Physician Can Do to Help the Child with Chronic Hepatitis B Virus Infection (7/08)
    - H-4---Interpretation of Hepatitis B Serologic Test Results (2005)
  - I---Patient Educational Materials
    - I-1---Questions Frequently Asked About Hepatitis B (8/07)
    - I-2---If You Have Chronic Hepatitis B Virus (HBV) Infection… (6/10)

Chapter 7 Hepatitis (Cont.)

- J---Vaccine Information
  - J-1---Recommended Immunizations for Children from Birth Through 6 Years Old (4/11)
  - J-2---Hepatitis B Vaccine Information Sheet (2/12)
- K---Georgia Public Health Laboratory
  - K-1---Lab Service Manual Excerpt
  - K-2---GPHL submission Form 3432 (11/11)

- State Hepatitis Program **(REPLACE)**
- Hepatitis B Vaccination in STD, HIV and Family Planning Clinics, Guidelines for Public Health **(REPLACE)**

Chapter 9---Vaccine Distribution and Storage - Remove all of chapter 9 and replace with the documents below.

- Distribution of Vaccines **(REPLACE)**
- Temperature Log Sheet **(REPLACE)**
- Provider Agreement For Public Health Providers **(REPLACE)**
- Accountability Policy **(ADD)**
- Vaccine Loss Policy For Public Health Providers **(REPLACE)**
- Fraud and Abuse Policy **(REPLACE)**
- Handling Of Vaccine During Inclement Weather Conditions **(REPLACE)**
- Temperature Conversion Chart **(REPLACE)**
- Vaccine Storage & Handling Guide (December 2011) **(REPLACE)**
- Vaccine Storage and Handling Interim Guidance **(ADD)**
- Chart of Refrigerated /Frozen Pack Needs **(REPLACE)**
- Transporting Refrigerated Vaccine **(ADD)** (This replaces Maintaining the Cold Chain during Transport)
- McKesson Vaccine Return Instructions **(REPLACE)** (This replaces the Guidelines for Returning Vaccine Products to the Manufacturer for Disposal)
- McKesson Form for Return of Outdated, Unused, or Overstocked Drugs **(REPLACE)**
- Title X Unaccompanied Minor without Insurance Information VFC Vaccine Log (**REPLACE**)
- Centralized Distribution Information and Instruction for VFC Providers **(REPLACE)**
- Routine and Emergency Vaccine Handling Plans **(ADD)**
- Vaccine Incident Report **(ADD)**

Chapter 12---Travel Information - - Remove all of chapter 12 and replace with the documents below.

- Foreign Travel Information **(REPLACE)**
- Travel and Yellow Fever Vaccination Clinics in Georgia **(REPLACE)**
- Vaccines and Biologics Used in U.S. and Foreign Markets (**REMOVE**)
- Translation of Foreign Vaccine-Related Terms into English **(REPLACE)**

Chapter 13--- Quality Assurance

- Appendices
  - Attachment A - Immunization Reference Video Information and Resources, Training Sessions (**REPLACE**)
  - Attachment B - Post Test **(REPLACE)**
  - Attachment C - Post Test Answers **(REPLACE)**
  - Attachment D – Injections: IM/SC (Intramuscular),(Subcutaneous) Injections **(REPLACE)**
  - Attachment E - Vaccine Administration Techniques Post Test **(REPLACE)**
  - Attachment F - Vaccine Administration Techniques Post Test Answer Key **(REPLACE)**
  - Attachment G - Clinical Skills Checklist **(REPLACE)**
  - Attachment H - QA/QI Review Assessment Tool **(REPLACE)**
  - Attachment I - Influenza Vaccine Administration Routes (**ADD)**

As always, this transmittal as well as an updated version of the complete Immunization Office Manual will be posted on the Immunization Program website at www.health.state.ga.us/programs/immunization and can be accessed from the main web page or from the link to Publications. If you have any questions about this update, please contact the Georgia Immunization Office at 404-657-3158.

Attachment
cc: Brenda Fitzgerald, MD
Steve Mitchell, MPH

Georgia Department of Public Health

2 Peachtree St. NW, 15th Floor
Atlanta, Georgia 30303-3142
Brenda Fitzgerald, MD, Commissioner Nathan Deal, Governor www.health.state.ga.us

DISTRICT _____

MANUAL UPDATE: IMMUNIZATION PROGRAM MANUAL

TRANSMITTAL DATE: January 25, 2013

Manual update(s) have been completed at the following sites on the indicated dates:

(Site)	(Date)	(Person responsible for update)

Please submit one (1) form for your District. Or, if individual counties/clinics complete a form, please collect all and combine on (1) form before submitting to State office. Fax document to Immunization Education Section Nurse Consultant Penny Conner, Thank you.

DUE: March 25, 2013

FAX 404-657-1463

_____
District Immunization Coordinator

_____
Date

TABLE OF CONTENT

1. INTRODUCTION

Introduction to the Manual **(REPLACE)**
Georgia Immunization Office Central Staff **(REPLACE)**
Immunization Office Consultants **(REPLACE)**
District Immunization Coordinators **(REPLACE)**
Request for Immunization Forms---Form 3184 **(REPLACE)**
U.S. Vaccines **(Move To Chapter 2 After Eligibility Criteria for Vaccines Supplied)**

2. RECOMMENDED SCHEDULE & GUIDELINES*

DPH GA Immunizations Office Vaccine Guidelines Approval Sheet (**ADD**) (**Do Not Remove Previous Sheets**)
Immunization Guidelines for DPH Clinics **(REPLACE)**
Eligibility Criteria for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults **(REPLACE)**
U.S. Vaccines **(ADD)**
Georgia Department of Public Health, Immunization Office Vaccine Guidelines
- Combination Vaccines (**REPLACE**)
- Vaccines to Prevent Diphtheria, Tetanus, and Pertussis (**REPLACE**)
- Vaccines to Prevent H1N1 (**REMOVE**)
- Vaccines to Prevent Haemophilus influenzae Type B (**REPLACE**)
- Vaccines to Prevent Hepatitis A (includes use of Immune Globulin [IG]) (**REPLACE**)
- Vaccines to Prevent Hepatitis B (**REPLACE**)
- Vaccines to Prevent Herpes Zoster (Shingles) (**REPLACE**)
- Vaccines to Prevent Human Papillomavirus Infection (**REPLACE**)
- Vaccines to Prevent Influenza (**REPLACE**)
- Vaccines to Prevent Measles, Mumps, and Rubella (**REPLACE**)
- Vaccines to Prevent Meningococcal Disease (**REPLACE**)
- Vaccines to Prevent Pneumococcal Disease (**REPLACE**)
- Vaccines to Prevent Polio (**REPLACE**)
- Vaccines to Prevent Rotavirus Gastroenteritis (**REPLACE**)
- Vaccines to Prevent Varicella (**REPLACE**)

Recommended Childhood/Adolescent Immunization Schedule 2012 and Catch Up for Children with Lapsed Immunization Schedule **(REPLACE)**
Recommended and Minimum Ages and Intervals Between Vaccine Doses (Table1) **(REPLACE)**
Suggested Intervals between Administration of Antibody-containing Products and Measles-containing and Varicella Vaccines (Table 4) **(REPLACE)**
Recommended Adult Immunization Schedule United States, 2012 **(REPLACE)**
Summary of ACIP General Recommendations **(REPLACE)**
Screening Questionnaires for Child and Teen Immunization (English/Spanish)**(REPLACE BOTH)**
Screening Questionnaires for Adult Immunization (English/Spanish) **(REPLACE BOTH)**
Standards For Child & Adolescent Immunization Practices **(REPLACE)**
Standards For Adult Immunization Practices

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3. INFORMED REQUEST POLICY

Informed Request Policy **(REPLACE)**

Vaccine Information Statements (**REMOVE**) (VISs) are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. Federal Law requires that VISs be handed out whenever (before each dose) certain vaccinations are given. Please access links below for all current VISs. They can be downloaded as a .pdf file and printed. http://www.cdc.gov/vaccines/pubs/vis/default.htm**.** VIS's in English and different languages can be found at http://www.immunize.org/vis/

After The Shots (simplified version)	English	3199	(10/11)**(REPLACE)**
Después de las vacunas (After The Shots simplified version)	Spanish	3196	(09/11)**(REPLACE)**
Georgia Vaccine Administration Record	English	25-IMM-002E	(02/12)**(REPLACE)**
Refusal to Vaccinate Form	English	25-IMM-012E	(02/12)**(REPLACE**)
Refusal to Vaccinate Form	Spanish	25-IMM-012S	(09/12)**(ADD**)

4. ADVERSE EVENTS FOLLOWING IMMUNIZATIONS

Policy for Reporting Vaccine Adverse Events Following Immunizations **(REPLACE)**
Handling of Emergencies Following the Administration of Vaccines
Vaccine Adverse Event Reporting System- Form VAERS (FDA) **(REPLACE)**
Frequently Asked Questions About VAERS (**Go to Link http://vaers.hhs.gov/about/faqs**)
VAERS Brochure **(REPLACE)**
Frequently Asked Questions (**Go to Link http://hrsa.gov/vaccinecompensation/faq.html**)
National Vaccine Injury Compensation Program Vaccine Injury Table **(REPLACE)**
Vaccine Injury compensation Program (VICP) **(Go to Link http://www.hrsa.gov/vaccinecompensation/index.html)**

5. REQUIREMENTS OF SCHOOL/CHILD CARE LAW

Summary of Immunization Policies Relative to Georgia Law **(REPLACE)**
Official Code of Georgia, Annotated **(REPLACE)**
- Section 20-2-771
- Section 49-4-182
- Section 49-4-183
- Section 31-12-3.1

DPH Rules, Chapter 290-5-4
Historical Statement Listing Dates of Immunization Requirements **(REPLACE)**
School Certificate of Immunization Form 3231 (Rev. 4/12) **(REPLACE)**
Policy Guide 3231INS: Standards for Issuing and Filing Certificates of Immunization **(REPLACE)**
Policy Guide 3231REQ: Vaccine Requirements for Attending Child Care Facilities and Schools in Georgia Relative to the Certificate of Immunization **(REPLACE)**
Summary Of Georgia Immunization Requirements For Child Care and School Attendance **(REPLACE)**
Immunization Requirements and Recommendations for University System of Georgia Students **(REPLACE)**
University System Of Georgia Required Certificate Of Immunization **(ADD)**

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6. SURVEILLANCE AND REPORTING

Procedure for the Investigation and Reporting of Vaccine Preventable Diseases **(REPLACE)**
Contact Persons for VPD Surveillance at the District Health Office **(REPLACE)**
Vaccine Preventable Disease Fact Sheets
- Diphtheria Fact Sheet **(REPLACE)**
- Hepatitis A Fact Sheet and Q & A **(REPLACE)**
- Hepatitis B Fact Sheet and Q & A **(REPLACE)**
- Haemophilus influenzae Invasive Disease Fact Sheet and Q & A **(REPLACE)**
- Measles Fact Sheet and Q & A **(REPLACE)**
- Mumps Fact Sheet **(REPLACE)**
- Pertussis Fact Sheet and Q & A **(REPLACE)**
- Polio Fact Sheet and Q & A **(REPLACE)**
- Rubella Fact Sheet and Q & A **(REPLACE)**
- Streptococcus pneumoniae Fact Sheet and Q & A **(REPLACE)**
- Tetanus Fact Sheet **(REPLACE)**
- Neisseria Meningitidis Fact Sheet **(ADD)**
- Varicella Fact Sheet **(ADD)**

Resources for Influenza Prevention and Control **(REPLACE)**
Influenza Outbreak Control in a Long Term Care Facility **(REPLACE)**
Georgia Notifiable Disease Report, Form 3095 (Rev. 8/04) **(REPLACE)**
Diphtheria Worksheet **(REPLACE)**
Measles Surveillance Worksheet **(REPLACE)**
Mumps Surveillance Worksheet **(REPLACE)**
Pertussis Surveillance Worksheet **(REPLACE)**
Rubella Surveillance Worksheet **(REPLACE)**
Tetanus Surveillance Worksheet **(REPLACE)**
Bacteriology Submission Form **(ADD)**
GPHL Microbial Immunology Submission Form **(REPLACE)**
GPHL Molecular Biology Submission Form **(REPLACE)**
Varicella Reporting and Case Investigation Form **(ADD)**
Virology Culture Submission Form (Rev. 1/10) **(REPLACE)**

TABLE OF CONTENT

7. HEPATITIS

Perinatal Hepatitis B Prevention Program Guidelines **(REPLACE)**

Appendix Table (All Appendix REPLACE)

A---Perinatal Hepatitis B Prevention Case Management Flow Chart

B---Obstetrician & Medical Provider Notification Materials

B-1---Sample Letter for Medical Providers Caring for HBsAg-Positive Pregnant Patients

B-2---Perinatal Hepatitis B Chart Alert From

B-3---Perinatal Hepatitis B Delivery Report Form

C-- Patient Notification Materials

C-1---Sample Letter for Pregnant HBsAg-Positive Women

C-2---Sample Letter for Foster Parents of Infants Born to HBsAg (+) Women

C-3---Hepatitis B & Moms-to-Be Pamphlet (2006)

D---Patient Interview Guide

D-1---Example Hepatitis B Interviewing/Counseling Format

D-2---Sample Perinatal Hepatitis B Interview Questions

E---Pediatrician Notification Materials

E-1---Sample Letter for Pediatricians Caring for Infant Born to HBsAg-Positive Mother

E-2---Quick Reference for Care of Infants Born to Hepatitis B Infected Mothers

F---HIPAA Information for Perinatal Hepatitis B Prevention Program

G---Birth Hospital Resources

G-1---Guidelines for Standing Orders in Labor & Delivery and Nursery Units to Prevent Hepatitis B Virus Transmission to Newborns (5/09)

G-2---Give the Birth Dose…Hepatitis B at Birth Saves Lives! (9/09)

H---Medical Provider Resources

H-1---Hepatitis B Facts: Testing and Vaccination (6/10)

H-2---Patient Notification Letter Regarding Hepatitis B Test Results (4/02)

H-3---What the Physician Can Do to Help the Child with Chronic Hepatitis B Virus Infection (7/08)

H-4---Interpretation of Hepatitis B Serologic Test Results (2005)

I---Patient Educational Materials

I-1---Questions Frequently Asked About Hepatitis B (8/07)

I-2---If You Have Chronic Hepatitis B Virus (HBV) Infection… (6/10)

J---Vaccine Information

J-1---Recommended Immunizations for Children from Birth Through 6 Years Old (4/11)

J-2---Hepatitis B Vaccine Information Sheet (2/12)

K---Georgia Public Health Laboratory

K-1---Lab Service Manual Excerpt

K-2---GPHL submission Form 3432 (11/11)

State Hepatitis Program **(REPLACE)**

Hepatitis B Vaccination in STD, HIV and Family Planning Clinics, Guidelines for Public Health **(REPLACE)**

8. RECALL OF PATIENTS

Recall of Immunization Patients Policy Statement

Immunization Documentation, “Moved or Gone Elsewhere” (MOGE) Categories

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9. VACCINE DISTRIBUTION AND STORAGE
Distribution of Vaccines **(REPLACE)**
Temperature Log Sheet **(REPLACE)**
PH Provider Agreement **(REPLACE)**
Accountability Policy **(ADD)**
Vaccine Loss Policy For Public Health Providers **(REPLACE)**
Fraud and Abuse Policy **(REPLACE)**
Handling Of Vaccine During Inclement Weather Conditions **(REPLACE)**
Temperature Conversion Chart **(REPLACE)**
Vaccine Storage & Handling Guide (December 2011) **(REPLACE)**
Vaccine Storage and Handling Interim Guidance **(ADD)**
Chart of Refrigerated /Frozen Pack Needs **(REPLACE)**
Transporting Refrigerated Vaccine **(ADD)** (This replaces Maintaining the Cold Chain during Transport)
McKesson Vaccine Return Instructions **(REPLACE)** (This replaces the Guidelines for Returning Vaccine Products to the Manufacturer for Disposal)
McKesson Form for Return of Outdated, Unused, or Overstocked Drugs **(REPLACE)**
Title X Unaccompanied Minor without Insurance Information VFC Vaccine Log **(REPLACE)**
Centralized Distribution Information and Instruction for VFC Providers **(REPLACE)**
Routine and Emergency Vaccine Handling Plans **(ADD)**
Vaccine Incident Report **(ADD)**

10. DISTRICT/COUNTY INSERTS
Empty section for the District/County to use for items considered necessary to complement or supplement the material provided by the State Program

11. TRANSMITTAL MEMOS
Section for filing memos which accompany revised pages, forms or documents

12. TRAVEL INFORMATION*
Foreign Travel Information
Travel and Yellow Fever Vaccination Clinics in Georgia **(REPLACE)**
Vaccines and Biologics Used in U.S. and Foreign Markets (**REMOVE**)
Translation of Foreign Vaccine-Related Terms into English **(REPLACE)**

*For travel information specific to travel vaccines or destinations, consult the ACIP Recommendations manual and/or the Center for Disease Control and Prevention's current edition of Health Information for International Travel.

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13. QUALITY ASSURANCE
Quality Assurance/Quality Improvement for Immunization Practice for Public Health Nurses and Immunization Support Staff

Appendices
Attachment A - Immunization Reference Video Information and Resources, Training Sessions **(REPLACE)**
Attachment B - Post Test **(REPLACE)**
Attachment C - Post Test Answers **(REPLACE)**
Attachment D – Injections: IM/SC (Intramuscular),(Subcutaneous) Injections **(REPLACE)**
Attachment E - Vaccine Administration Techniques Post Test **(REPLACE)**
Attachment F - Vaccine Administration Techniques Post Test Answer Key **(REPLACE)**
Attachment G - Clinical Skills Checklist **(REPLACE)**
Attachment H - QA/QI Review Assessment Tool **(REPLACE)**
Attachment I - Influenza Vaccine Administration Routes **(ADD)**

14. STANDARD OPERATING GUIDELINES FOR MASS VACCINATION CLINICS
Standard Operating Guidelines for Conducting Mass Vaccination Clinics
Appendix A: Sample Vaccination/Administration Site Flowchart
Appendices B1, B2, B3, B4: Sample Vaccination Site Command Charts
Appendices C1, C2, C3: Sample Clinic, District and State Vaccination Reports

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Georgia Immunization Office Central Staff **(REPLACE)**
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District Immunization Coordinators **(REPLACE)**
Request for Immunization Forms---Form 3184 **(REPLACE)**
U.S. Vaccines **(Move To Chapter 2 After Eligibility Criteria for Vaccines Supplied)**

INTRODUCTION TO THE MANUAL

The Georgia Immunization Manual is intended to provide District and County personnel with up-to-date information and guidance. The Georgia Immunization Manual is based primarily on the Recommendations of the Advisory Committee on Immunization Practices (ACIP). The ACIP Recommendations are provided as a separate manual. These two manuals should be utilized together as the basis for formulating policies and procedures for administering vaccines and providing immunization services. The **Department of Public Health** also recognizes the Red Book (Report of the Committee on Infectious Diseases) of the American Academy of Pediatrics.

Another important reference is the package insert supplied by the manufacturer of the vaccine.

This manual and the ACIP Recommendations Manual represent official state policies and standards, and the recommended policies and procedures for administering vaccines, providing immunization services, and documenting and evaluating quality assurance. In addition these manuals serve as an annex to the Standard Operations Procedures (SOP) of the Department of Public Health (DPH), Emergency Operations Plan EOP). Districts may utilize these two manuals as the district's written Policies and Procedures for Administering Vaccines by Registered and Licensed Practical Nurses or use this manual as a guide to write their own. In addition, districts may utilize the Quality Assurance (QA) document included in this manual as a tool to document and evaluate the credentialing, policies, training, administration of vaccine and provision of immunization services. If a district chooses to utilize their own QA instrument, it should include all elements in the QA document in this manual. Constructive criticism, questions and notification of apparent error will be welcome, but deviation from state policy should not be undertaken lightly. Statements made in this manual take precedence over contradictory policy statements or memos that predate the manual pages.

Occasionally, due to ongoing research and evaluation, ACIP recommendations may differ from the manufacturer's package insert or the information in the Red Book, which is published every three years. When this occurs, the State Immunization Program utilizes the most current ACIP Recommendations.

Frequently, the ACIP publishes provisional guidelines prior to receiving final approval from the Director of the CDC and the Secretary of the Department of Health and Human Services (HHS). To facilitate the administration of newly licensed vaccines, the Georgia Immunization Program will utilize these provisional recommendations when necessary in developing guidelines.

From time to time, children present at DPH clinics with requests or orders from private physicians to administer vaccines under unusual circumstances. When the request clearly falls outside the ACIP Recommendations, such as using reduced dosage schedules, it simply should not be honored. When a child has a history or condition which calls for careful judgment as to whether it might be a contraindication and the physician assures that vaccine may be given safely, the District Health Director must make a decision whether to immunize or refer the child back to the physician.

Each subject in the manual is dated. When changes are made, appropriately indexed pages will be made available on the program website to replace outdated material. Transmittal letters should be logged and filed in the Memo section in the manual.

When recommendation changes occur between the annual manual updates, health districts will be notified by memos from the State Immunization Program. The Immunization Program Manual will be updated at least annually to include the recommended changes. Health districts are responsible for developing and implementing a plan to ensure that all memos and manual revisions are distributed, discussed, and implemented within a month of receipt with all appropriate clinics and staff and that the Immunization Program Manuals and ACIP manuals are kept current.

When questions arise that are not covered adequately anywhere in the manual, the Immunization Program personnel are eager to field them and provide or obtain clarification. A staff person is available for on-call questions Monday through Friday, from 8:00 A.M. until 5:00 P.M. The Immunization Program telephone numbers may be found in Section 1 of this manual.

Immunization
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Sheila Lovett, Deputy Director
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Vaccines for Children

Sherrionda [Sherri] Grady
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Dorlisa Tillman
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(VFC Coordinator)

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Team Room 13-240

(404) 463-0814

Vacant Positions

Adm. Ops. Coordinator
Data Processor
GRITS Manager
Operations Analyst II
PHSO Program Consultant I
Program Assistant
Program Evaluator
PS: Database Administrator
Program Associate (GRITS)
Program Associate (VFC)
IPC's Districts 1-1, 3-3, 3-4, 3-5, & 6

GroupWise e-mail via internet: immunization@dhr.state.ga.us
Program Website: http://health.state.ga.us/programs/immunization/index.asp

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Gainesville – District 2
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Cobb, Douglas District 3-1
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Vacant
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&
Angie Webster (Acting)
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Dekalb – District 3-5
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&
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Savannah & Brunswick
District 9-1
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Athens – District 10
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GroupWise e-mail via internet: immunization@dhr.state.ga.us
Program Website: http://health.state.ga.us/programs/immunization/index.asp

Immunization District Coordinators & Contacts List

Revised 02/04/13

District: 1-1
Coordinator: Janet Eberhart
District Immunization Coordinator
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*Additional Contact: Mitzi Smith
Director Nursing PH & Clinical Services
Northwest GA. Public Health
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(706) 802-5219(w), (706) 802-5681(f)
Email: mosmith@dhr.state.ga.us

Counties: Bartow, Catoosa, Chattooga, Dade, Floyd, Gordon, Haralson, Paulding, Polk, Walker
IPC: Rick Naus (Acting)

District: 1-2
Coordinator: Marie Smith
District Immunization Coordinator
North Georgia Health District
100 West Walnut Ave, Ste. 92
Dalton, GA 30720-8427
(706) 272-2125(w), 338 (706) 272-2221(f)
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*Additional Contact: Debbie Robbins
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Dalton, GA 30720-8427
(706) 272-2342(w), 339 (706) 272-2221(f)
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Counties: Cherokee, Fannin, Gilmer, Murray, Pickens, Whitfield
IPC: Rick Naus

District: 2
Coordinator: Connee Martin
Immunization Coordinator/Communicable Disease Coordinator
District 2 Public Health
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Gainesville, GA 30507-7000
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Counties: Banks, Dawson, Forsyth, Franklin, Habersham, Hall, Hart, Lumpkin, Rabun, Stephens, Towns, Union, White
IPC: Jan Slaughter

District: 3-1
Coordinator: Karen Thomas
District Immunization Coordinator
Marietta Public Health Center
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Marietta, GA 30008-4009
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IPC: Noreen Dahill

Immunization District Coordinators & Contacts List

Revised 02/04/13

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*Additional Contact: Juliet Cooper
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99 Jesse Hill Jr. Dr.
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Counties: Fulton
IPC: Janet Kelly - Private & Public
Valerie Pritchett - Private only

District: 3-4
Coordinator: Gloria Melvin
District Immunization Coordinator
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455 Grayson Hwy, Ste. 500
Lawrenceville, GA 30046-6387
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Counties: Gwinnett, Newton, Rockdale
IPC: Jan Slaughter - Acting
Angie Webster - Acting

District: 3-3
Coordinator: Chishaunna Calhoun
Immunization & Health Check Coordinator
Clayton County Board of Health
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Counties: Clayton
IPC: Janet Kelly - Private & Public - Acting
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Immunization District Coordinators & Contacts List

Revised 02/04/13

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Counties: Butts, Carroll, Coweta, Fayette, Heard, Henry, Lamar, Meriwether, Pike, Spalding, Troup, Upson
IPC: Tina Dempsey

District: 5-1
Coordinator: Kelly Knight
District Immunization Coordinator
South Central Health District
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Counties: Bleckley, Dodge, Johnson, Laurens, Montgomery, Pulaski, Telfair, Tretutlen, Wheeler, Wilcox
IPC: DeAnna Brown

District: 5-2
Coordinator: Judy McChargue
Immunization Coordinator
North Central Health District
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Counties: Baldwin, Bibb, Crawford, Hancock, Houston, Jasper, Jones, Monroe, Peach, Putnam, Twiggs, Washingon, Wilkson
IPC: Kelly Duke

District: 6
Coordinator: Susan Edmunds
Child Health & District Immunization Coordinator
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IPC: Kelly Duke - Acting

Immunization District Coordinators & Contacts List

Revised 02/04/13

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Counties: Chattahoochee, Clay, Crisp, Dooly, Harris, Macon, Marion, Muscogee, Quitman, Randolph, Schley, Stewart, Sumter, Talbot, Taylor, Webster
IPC: Libby Massiah

District: 8-2
Coordinator: Rebecca McAlpin
District Immunization Coordinator
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Counties: Baker, Calhoun, Colquitt, Decatur, Dougherty, Early, Grady, Lee, Miller, Mitchell, Seminole, Terrell, Thomas, Worth
IPC: Kelly Seegmueller

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Counties: Ben Hill, Berrien, Brooks, Cook, Echols, Irwin, Lanier, Lowndes, Tift, Turner
IPC: Jenny Howell

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District Immunization Coordiantor
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IPC: Georgia Dittmar

Immunization District Coordinators & Contacts List

Revised 02/04/13

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IPC: Lorie Banks

District: 10
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Counties: Barrow, Clarke, Elbert, Greene, Jackson, Madison, Morgan, Oconee, Oglethorpe, Walton
IPC: Angie Webster

Department of Public Health
REQUEST FOR IMMUNIZATION FORMS

(DATE OF REQUEST)

SEND TO: ***Georgia Immunization Program***
2 Peachtree Street, NW, 13-276
Atlanta, GA 30303
(404) 657-3158 Or Fax To: (404) 657-1463

NOTE:
All forms are to be ordered individually, not by package.
(***example: 50, 100 etc.***)

Please Stamp Or Type Below Your Information:

Person Ordering
Name

Office Name

Address
City, State, ZipCode
County Name

Telephone#

County Name

QTY	FORM NO.	DESCRIPTION	QTY	FORM NO.	DESCRIPTION
Vaccine Information Statements(or print from (http://www.immunize.org/vis/)			**Vaccine Information Statements (Cont.)**		
	3039	Hepatitis B (English)		25-IMM-011-E	Tetanus, Diphtheria (Td) or Tetanus, Diphtheria, Pertussis (Tdap) (Replaces Td and Tdap)
	3170	Hepatitis B (Spanish)		25-IMM-011-S	Tetanus, Diphtheria (Td) or Tetanus, Diphtheria, Pertussis (Tdap) (Replaces Td and Tdap)
	3177	DTP/DTaP (English)		25-IMM-013-E	HPV Cervarix (English)
	3162	DTP/DTaP (Spanish)		25-IMM-013-S	HPV Cervarix (Spanish)
	3157	Varicella (English)	**Certificates For School/Child Care Attendance**		
	3174	Varicella (Spanish)		3231	Certificate of Immunization
	3198	MMR (English)		3231REQ	Outlines Vaccine Requirements For Form 3231
	3160	MMR (Spanish)		3231 INS	Instructions On How To Complete Form 3231
	3180	Hib (English)	**Parent & Client Education**		
	3172	Hib (Spanish)		3193	Give 'Em Your Best Shot (GA. Requirement For School/Child Care) (Infant & Child) (English)
	3173	Polio IPV (English)		3194	Hay que Vacunarlos (GA. Requirement For School/Child Care) (Infant & Child) (Spanish)
	3163	Polio IPV (Spanish)		3227	Be There For Your Child During Shots (English & Spanish)
	3178	Pneumococcal Conjugate PCV13 (English)		3266	Proteja la salud de su hijo (a) -icon vacunas! (Guard Your Childs Health With Shots) (Spanish)
	3179	Pneumococcal Conjugate PCV13 (Spanish)		3116	Hop to It! (Infant, Child and Adolescent)
	25-IMM-001-E	Meningococcal (Conjugate & Polysaccharide) (English)		3110	Word to the Wise: Immunize (Adult) (English)
	25-IMM-001-S	Meningococcal (Conjugate & Polysaccharide) (Spanish)		3110	Word to the Wise: Immunize (Adult) (Spanish)
	25-IMM-004-E	Hepatitis A (English)		3199	After the Shots (Infant & Child) (English)
	25-IMM-004-S	Hepatitis A (Spanish)		3199S	After the Shots (Infant & Child) (Spanish)
	25-IMM-006-E	Rotavirus (English)		25-IMM-005-E	GRITS (Keeping Georgians Healthy) (English)
	25-IMM-006-S	Rotavirus (Spanish)		25-IMM-005-S	GRITS (Manteniendo A Los Residentes De Georgia Saludables) (Spanish)
	25-IMM-007-E	HPV Gardasil (English)	**Records, Reports & Request Forms**		
	25-IMM-007-S	HPV Gardasil (Spanish)		3184	Request for Immunization Forms
	25-IMM-008-E	Inactivated Influenza TIV (English)		3185	Temperature Log
	25-IMM-008-S	Desactivada Contra LA Influenza TIV (Spanish)		3034	Vaccine Adverse Event Reporting System
	25-IMM-009-E	Live, Intranasal Influenza LAIV (English)		3187	Personal Immunization Record (English & Spanish)
	25-IMM-009-S	Intranasal Viva Contra La Influenza LAIV (Spanish)		25-IMM-002-E	Georgia Vaccine Administration Record (for charts)
	25-IMM-010-E	Your Baby's First Vaccines Multiple VIS (English)		25-IMM-012-E	Refusal to Vaccinate Form
	25-IMM-010-S	Your Baby's First Vaccines Multiple VIS (Spanish)		25-IMM-012-S	Negativa A LA VaccunaciÓ (Refusal to Vaccinate Form)

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DPH GA Immunizations Office Vaccine Guidelines Approval Sheet (**ADD**) (**Do Not Remove Previous Sheets**)
Immunization Guidelines for DPH Clinics **(REPLACE)**
Eligibility Criteria for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults **(REPLACE)**
U.S. Vaccines **(ADD)**
Georgia Department of Public Health, Immunization Office Vaccine Guidelines
- Combination Vaccines (**REPLACE**)
- Vaccines to Prevent Diphtheria, Tetanus, and Pertussis (**REPLACE**)
- Vaccines to Prevent H1N1 (**REMOVE**)
- Vaccines to Prevent Haemophilus influenzae Type B (**REPLACE**)
- Vaccines to Prevent Hepatitis A (includes use of Immune Globulin [IG]) (**REPLACE**)
- Vaccines to Prevent Hepatitis B (**REPLACE**)
- Vaccines to Prevent Herpes Zoster (Shingles) (**REPLACE**)
- Vaccines to Prevent Human Papillomavirus Infection (**REPLACE**)
- Vaccines to Prevent Influenza (**REPLACE**)
- Vaccines to Prevent Measles, Mumps, and Rubella (**REPLACE**)
- Vaccines to Prevent Meningococcal Disease (**REPLACE**)
- Vaccines to Prevent Pneumococcal Disease (**REPLACE**)
- Vaccines to Prevent Polio (**REPLACE**)
- Vaccines to Prevent Rotavirus Gastroenteritis (**REPLACE**)
- Vaccines to Prevent Varicella (**REPLACE**)

Recommended Childhood/Adolescent Immunization Schedule 2012 and Catch Up for Children with Lapsed Immunization Schedule **(REPLACE)**
Recommended and Minimum Ages and Intervals Between Vaccine Doses (Table1) **(REPLACE)**
Suggested Intervals between Administration of Antibody-containing Products and Measles-containing and Varicella Vaccines (Table 4) **(REPLACE)**
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Summary of ACIP General Recommendations **(REPLACE)**
Screening Questionnaires for Child and Teen Immunization (English/Spanish)**(REPLACE BOTH)**
Screening Questionnaires for Adult Immunization (English/Spanish) **(REPLACE BOTH)**
Standards For Child & Adolescent Immunization Practices **(REPLACE)**
Standards For Adult Immunization Practices

Georgia Department of Public Health
Immunization Office Vaccine Guidelines

These vaccine guidelines represent a summary of the pertinent information on each vaccine found in the most current ACIP Recommendations statements, Epidemiology and Prevention of Vaccine-Preventable Diseases, 12th edition 2nd printing (The Pink Book), the 2012 Red Book: Report of the Committee on Infectious Diseases, and in the most recent Vaccines for Children Program resolutions.

These guidelines have been developed for use by RNs and LPNs and are intended to be used as a quick but accurate source of guidance for practitioners giving immunizations or providing information about vaccines. For more specific details about any portion of these guidelines, the above-named references should be consulted.

These vaccine guidelines will be updated at least on a yearly basis, and more often as circumstances dictate. In addition to staff members of the Georgia Immunization Office, the following physicians have reviewed and approved the information provided therein:

David Harvey, MD
David Harvey, M.D.
District Health Director,
North Central District, 5-2

2/15/2012
Date Signed

Immunization Guidelines For DPH Clinics

A. Guidelines for Administration

The Georgia Immunization Office recommends that all DPH clinics follow the current Recommended Childhood Immunization Schedule that is developed and published annually by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP). A copy of the most current schedule, including the footnotes, is inserted in this section of the manual. Additional charts and tables are included to provide assistance in further defining and clarifying the recommended schedule. Also included is a recommended infant/child screening questionnaire to assist providers in identifying possible contraindications and precautions for administering vaccines.

The Recommended Adult Immunization Schedule and a Screening Questionnaire for Adults are also included in this section.

The charts and tables are meant to serve as guidelines and provide quick references for individuals assessing immunization records and administering vaccines. Detailed information regarding vaccines and vaccine administration policies should be obtained from the most current ACIP Recommendations. These recommendations may be accessed from CDC's web site (see Immunization Resources in Section 13, Attachment A of this manual).

It is imperative that all those who administer vaccines follow the guidelines put forth in the General Recommendations on Immunization ACIP statement[1], the Epidemiology and Prevention of Vaccine-Preventable Diseases (the "Pink Book"),[2] as well as those found in this manual in Chapter 13, Quality Assurance. The following principles are merely a summary of these recommendations and are not meant to be all-inclusive:

1. Ascertain the client's need for the recommended immunizations to avoid drawing up vaccine that will not be used.
2. Select correct needle size for vaccine, route, and size of client.
3. Double-check the vial label and expiration date before AND after drawing up vaccine.
4. If preparing multiple vaccinations, label each syringe or use labeled tray in order to correctly identify vaccines before administration.
5. Use aseptic technique throughout vaccine preparation, administration, and disposal of syringes and other materials.
6. Avoid prefilling syringes because of the risk for administration errors. Other problems that could be associated with this practice are vaccine wastage and possible bacterial growth in vaccines that do not contain a preservative. In addition, syringes other than those that are prefilled by the manufacturer are designed for immediate administration, not for vaccine storage.
7. If it is necessary to reconstitute more than one vaccine dose, as for a large influenza clinic, only prefill a FEW syringes at a time, which you can administer while someone else is prefilling a few syringes they will administer. Any syringes left at the end of the clinic day **should be discarded**.
8. Under NO CIRCUMSTANCES should MMR, MMRV, Zoster or varicella vaccine ever be reconstituted and drawn prior to the immediate need for the vaccines. These live virus vaccines are unstable and begin to deteriorate as soon as they are reconstituted with diluent.

9. All providers who administer vaccinations should be aware of the potential for syncope (fainting) after vaccination and take appropriate measures to prevent it. Thus, clinicians should (1) make sure that people who are being vaccinated are always seated; (2) be aware of symptoms that precede fainting (weakness, dizziness, pallor, etc.); and (3) take appropriate measures to prevent injuries if such symptoms occur.[3] Vaccine providers should strongly consider observing vaccinated people for 15 minutes after vaccination.[4] This is particularly important when vaccinating adolescents and young adults.

B. Guidelines for Eligibility for VFC and State-Supplied Vaccines

Eligibility criteria are outlined in each of the Immunization Program Vaccine Guidelines in this section. In addition, the table following this document outlines the eligibility criteria for vaccines provided by the Vaccines for Children Office (VFC) and by the Georgia Immunization Office. All clinics are responsible for screening and documenting a person's eligibility for receiving state supplied vaccines. For the purposes of these documents, a child is defined as a person from 0 through 18 years of age. An adult is anyone 19 years of age or older. The following mandates should be utilized when conducting eligibility screening for either group:

I. Eligibility Criteria for Children

A. All children 0 through18 years of age should be screened to determine VFC eligibility using the following terms and definitions:

1. Medicaid---is eligible for Medicaid services.
2. American Indian/Alaska Native---self-reported by the patient.
3. Uninsured children---have no health insurance.
4. Underinsured children---have insurance but vaccines are not a covered benefit.[5]
   - Example: An insurance company may not cover certain vaccines, such as the pneumococcal conjugate vaccine. The child will qualify for VFC for that particular vaccine only.
   - Example: An insurance company may cover immunizations up to a certain age. Up to that age, the child is fully insured. After that age, the child is considered underinsured (has insurance but vaccines are not a covered benefit).
   - Example: An insurance company may only provide $100.00 per year to cover the costs of immunizations. The child is fully insured up to $100.00. Once this amount is exhausted, the child is then eligible to receive VFC vaccine.
5. PeachCare for Kids---has a current PeachCare for Kids card at the time of service.[5]

B. Any child who has insurance coverage for immunizations is not eligible to receive state-supplied vaccines. This is the case even when the insured has a high deductible --- the child is considered fully insured. These children should be:

1. referred to their private provider; or
2. administered vaccine purchased by the district.

II. Eligibility Criteria for Vaccines Supplied by VFC for minors presenting for services without proof of insurance. Please use the following guidance:

A. Unaccompanied minors through the age of 18 who are being seen in a public health STD or Family Planning clinic, and who present without proof of insurance, may be immunized using VFC vaccine.

1. Hep A, Hep B, and HPV are the only vaccines that may be administered to someone under the age of 18 **based on their own consent.**

2. Be aware that you may come across an 18 year old patient who is still covered by their parent's insurance, but is unable to access it. Because the patient is 18 she or he may legally consent for additional vaccines, all of which should be included on the Title X form.

B. To document eligibility screening, records should reflect 'Uninsured' for this population.

C. Complete Title X log sheet for any minor receiving vaccine in this category.

III. Eligibility Criteria for Vaccines Supplied by the Georgia Immunization Program for Children, Adolescents, and Adults (Refer to table on following pages.)

C. Guidelines for Documentation

All public health clinics should be utilizing the Georgia Registry of Immunization Transactions and Services (GRITS) for reviewing and documenting the immunization status of all clients. Public health clinics should have the technological capability and staff trained to ensure that, regardless of the individual software system used, immunizations administered will be entered into the GRITS system within 2 business days.

[1] General Recommendations on Immunization, *MMWR*, January 28, 2011, Vol. 60, RR-2.
[2] Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Hamborsky J, McIntyre L., Wolfe S, eds. 11th ed. Washington DC: Public Health Foundation, May 2009, Appendix D.
[3] "Medical Management of Vaccine Reactions in Children and Teens" at www.immunize.org/catg.d/p3082a.pdf and "Medical Management of Vaccine Reactions in Adult Patients" at www.immunize.org/catg.d/p3082.pdf]
[4] General Recommendations on Immunization, *MMWR*, January 28, 2011, Vol. 60, RR-2, pg. 9.
[5] Vaccines provided for these groups come from state or federal funding sources other than VFC.

Eligibility Criteria for Vaccines Supplied by the GA Immunization Office for Children, Adolescents, and Adults seen in GA Public Health Clinics

The Georgia Immunization Office (GIO) manages vaccines funded by:

- Federal Vaccines for Children (VFC) program
- Federal Section 317 immunization grant

The following tables indicate which vaccines:

- are available for VFC eligible children
- are available for other clients seen in Georgia public health clinics.

The intent of these tables:

- **IS NOT to determine which children, adolescents and/or adults should be immunized, but**
- **IS to define which groups can be immunized with federally funded VFC or federally funded Section 317 purchased vaccines.**

For specific vaccine guidelines refer to Section 2, Recommended Schedules and Guidelines, of the Georgia Immunization Office Manual (GIO). The vaccine must be provided at no cost to the patient. Vaccine administration fees for self-pay clients are capped at $21.93 per injection for both VFC and Section 317 funded vaccine. No client should be refused vaccination with VFC or Section 317 vaccine due to inability to pay the administration fee. **If a client meets at least one eligibility criterion for each component of a combination vaccine** (e.g., Pediarix, Comvax, MMRV, Twinrix), they are eligible to receive that combination vaccine if the state supplies it.

Eligibility	Diphtheria, Tetanus, Pertussis vaccines	Hib vaccine	Influenza vaccine	Meningococcal vaccines
Supplied for VFC eligible children: VFC eligibility criteria[1] • Age 0 through 18 years and • No insurance or • Underinsured or • Eligible for Medicaid or PeachCare or • American Indian or Alaska native	Yes: VFC eligible children: **DTaP**--Children less than 7 years of age **Tdap** – One dose for children 7 to 10 years with an incomplete DTaP primary series **Tdap-**One dose for unvaccinated adolescent males and non-pregnant females **Tdap**- For pregnant adolescents for each pregnancy irrespective of past history of Tdap receipt **Td---** Children 7 years through 18 years of age **Pediatric DT---(VFC does not supply)**	Yes: VFC eligible children: • 6 weeks through 4 years of age	Yes: VFC eligible children: • 6 months through 18 years of age	Yes: VFC eligible children: **MCV4** • Children with reduced immune response [8] 9 months through 18 years should receive 2 dose primary series (8 weeks apart) • Adolescents aged 11 through 18 years should receive one dose • Booster dose for children with reduced immune response [7]every 5 years through 18 • One booster dose for eligible adolescents through 18 years
Federal funded Section 317 immunizations for other groups seen in GA public health clinics[1]	Yes, for uninsured and underinsured adults 19 years or older **Tdap-** One dose for unvaccinated males and non-pregnant females **Tdap**- For pregnant women for each pregnancy irrespective of past history of Tdap receipt **Td** - for boosters or to complete primary series • Refugees[1] ≥ 19 years of age	Yes • For unvaccinated individuals who are uninsured, or underinsured and older than 59 months of age with a high-risk condition[3]	No	Yes, for uninsured or underinsured college students 19 through 21 years • One MCV4 primary dose if unvaccinated • One MCV4 booster dose if previous dose given at age younger than 16 years Yes, booster dose every 5 yrs for uninsured or underinsured adults 19 yrs and older who continue to be at highest risk for meningococcal infection[7]
Groups in Georgia NOT covered by VFC nor Federal Section 317 immunization funds[2]	• Insured clients with immunization coverage • International travelers • Health care workers • Inmates	• Insured clients with immunization coverage		• Insured clients with immunization coverage • International travelers • Refugees ≥ 19 years of age

Eligibility Criteria for Vaccines Supplied by the GA Immunization Office for Children, Adolescents, and Adults seen in GA Public Health Clinics

Eligibility	Hepatitis B vaccine[4]	Hepatitis A vaccine[4]	Measles, Mumps, and Rubella vaccine	Inactivated Polio vaccine
Supplied for VFC eligible children:[1] VFC eligibility criteria • Age 0 through 18 years and • No insurance or • Underinsured or • Eligible for Medicaid or PeachCare for Kids or • American Indian or Alaska native	Yes: VFC eligible children birth through 18 years of age	Yes: VFC eligible children 12 months through 18 years of age	Yes: VFC eligible children 12 months through 18 years of age	Yes: VFC eligible children 6 weeks through 18 years of age
Federal funded Section 317 immunizations for other groups seen in GA public health clinics[1]	Yes,(pediatric formulations for persons <20 yrs and adult formulations for persons ≥ 20 yrs) for uninsured, or underinsured individuals meeting one of the high risk criteria: • Men having sex with men • Illegal drug users • Persons seeking STD/HIV clinic services, including HIV testing and counseling and HIV care services • Individuals with multiple partners (more than 1 partner in 6 months) • Persons recently diagnosed with an STD • Homeless adults • Persons seeking Family Planning clinic services • Sexual partners of persons with acute or chronic hepatitis B virus infection and household contacts of persons with acute and chronic HBV infection (includes contacts to perinatal hepatitis B case investigations) • Hemodialysis/transplant patients • Diabetics (Type I or Type II) • Persons who began the series using VFC or state-supplied vaccine and still need to complete the series • Refugees[1] ≥ 19 years of age	Yes, for uninsured, or underinsured individuals meeting one of the high risk criteria: • Men having sex with men • Illegal drug users • Female partners of MSM • Persons who engage in sexual practices that could facilitate fecal-oral transmission of hepatitis A • Person with chronic liver disease, including hepatitis C • HIV-infected persons seeking HIV care services • American Indians and Alaska natives • Persons who began the series using VFC or state-supplied vaccine and still need to complete the series • Persons 19 through 40 years of age (and persons over aged 40 years, if IG cannot be obtained) designated by district or state epidemiology personnel as eligible contacts to a documented case of hepatitis A disease [5] • Refugees[1] ≥ 19 years of age	Yes, for uninsured, or underinsured individuals meeting one of the following criteria: • Persons born during or after 1957 and who specifically request it • College students of any age • HIV-infected persons seeking HIV care services [3] • Persons seeking Family Planning clinic services • Women who could become pregnant regardless of age • Persons 19 years of age and older with negative serology results for measles, mumps, or rubella immunity • Refugees[1] ≥ 19 years of age (Refugee Health Program funds the cost of vaccine)	No
Groups in Georgia NOT covered by VFC nor Federal Section 317 immunization funds[2]	• Insured clients with immunization coverage • International travelers • Public safety workers • Health care workers	• Insured clients with immunization coverage • International travelers • Public safety workers • Health care workers • Food handlers	• Insured clients with immunization coverage • International travelers • Health care workers	

Eligibility Criteria for Vaccines Supplied by the GA Immunization Office for Children, Adolescents, and Adults seen in GA Public Health Clinics

Eligibility	Pneumococcal vaccines	Varicella vaccine	Rotavirus Vaccine	IG
Supplied for VFC eligible children:[1] VFC eligibility criteria: • Age 0 through 18 years and • No insurance or • Underinsured or • Eligible for Medicaid or PeachCare or • American Indian or Alaska native	Yes: VFC eligible children • PCV13 for children 6 weeks through 59 months of age • One PCV13 dose for children 6 yrs through 18 yrs with high risk conditions[6] • One or Two doses of PPSV23 for high-risk children 2 years through 18 years[6]	Yes: VFC eligible children • 12 months through 18 years of age are eligible for 2 doses of vaccine	Yes: VFC eligible children • 6 weeks through 32 weeks of age	No
Federal funded Section 317 immunizations for other groups seen in GA public health clinics[1]	Yes, PPSV23 for uninsured, or underinsured individuals • 19 years of age and older with high-risk criteria. (See "Pneumococcal Vaccine Guidelines" in the GIO Manual) • Refugees[1] ≥ 19 years of age ((Refugee Health Program funds the cost of vaccine) State will only supply 2 doses of PPSV23 during a person's lifetime.	Yes, for uninsured, or underinsured individuals • Who began the series using VFC or state supplied vaccine • Refugees[1] ≥ 19 years of age (Refugee Health Program funds the cost of vaccine)	No	Yes for: • Hepatitis A contacts who fall within specific guidelines. See "Vaccines to Prevent Hepatitis A" guidelines in the GIP Manual To obtain IG, contact the Hepatitis Program Director at (404) 657-3171.
Groups in Georgia NOT covered by VFC nor Federal Section 317 immunization funds[2]	• Insured clients with immunization coverage • Individuals wanting more than 2 documented doses of PPSV23 • Prevnar13 for adults	• Insured clients with immunization coverage • International travelers • Healthcare workers		• International travelers • Pre-exposure vaccination for persons with occupational exposure

Eligibility Criteria for Vaccines Supplied by the GA Immunization Office for Children, Adolescents, and Adults seen in GA Public Health Clinics

Eligibility	HBIG	HPV	Zoster vaccine	
Supplied for VFC eligible children:[1] VFC eligibility criteria: • Age 0 through 18 years and • No insurance or • Underinsured or • Eligible for Medicaid or PeachCare or • American Indian or Alaska native	No	Yes: Routine vaccination for VFC eligible males and females • Either HPV4 or HPV2 for females 9 through 18 years of age • HPV4 for males 9 through 18 years of age	No	
Federal funded Section 317 immunizations for other groups seen in GA public health clinics[1]	Yes for: • Infants of HBsAg positive mothers, if HBIG was not received at birth in the hospital, and if it can be administered within 7 days of birth • Unvaccinated infants whose primary caregiver has **acute** hepatitis B • Persons not previously immunized with hepatitis B vaccine who have had recent sexual exposure (in the past 14 days) to a person who is **acutely** infected with the hepatitis B virus • Household contacts of any age in direct contact with the blood of an **acutely** infected person within 7 days of exposure To obtain HBIG, contact the Hepatitis Program Director at (404) 657-3171.	Yes for uninsured, or underinsured • Females and Males 19 through 26 years who began the series using VFC or state-supplied vaccine and still need to complete the series • Unvaccinated Females and Males 19 through 26 years	No	
Groups in Georgia NOT covered by VFC nor Federal Section 317 immunization funds[2]	• International travelers • Persons exposed to needle sticks • Persons with occupational exposure	• Insured clients with immunization coverage • Refugees ≥ 19 years of age		

[1] Children aged 0 through 18 years of age who are in "refugee" status **and** meet VFC eligibility criteria are considered VFC eligible. Vaccine for adult refugee populations may be administered out of 317/State supplied stock using above guidelines. Medicaid should be billed for the administration fee only for vaccines given to refugees in the 19-20 year old age group. Reimbursement for vaccine administration for refugees aged ≥ 21 years of age will continue to be billed to and paid by the Refugee Health Program. *(Note: US citizenship is not required to receive any federal or state-supplied vaccine.)*
[2] Persons in these groups are not eligible to receive VFC or Federal 317 funded vaccine as described above.
[3] For guidance re: specific conditions, refer to "General Recommendations on Immunization," MMWR, January 28, 2011, Vol. 60, RR-2.
[4] A person under 19 years of age who may have insurance but because of the circumstances for seeking services does not have access to that insurance coverage is uninsured for the purposes of the VFC program.
[5] Such persons would be eligible for both doses of the hepatitis A vaccine series.
[6] For further guidance see MMWR 2010:59(No. RR-11), available at www.cdc.gov/mmwr/pdf/rr/rr5911.pdf
[7] For guidance re: specific conditions refer to "Updated Recommendation for Use of Meningococcal Conjugate Vaccines- ACIP 2010," MMWR, January 28, 2011 Vol. 60, No.3, pg 72-76

U.S. Vaccines

Vaccine	Trade Name	Abbreviation	Manufacturer	Type	Route	Comments
Adenovirus	Adenovirus		Barr Labs Inc.	Live Viral	Oral	Adenovirus Type 4 & Type 7. Two tablets taken together. Approved for military populations 17 through 50 years of age.
Anthrax	BioThrax	AVA	Emergent BioSolutions	Inactivated Bacterial	IM	
DTaP	Daptacel	DTaP	sanofi	Inactivated Bacterial	IM	Tetanus & diphtheria toxoids and acellular pertussis vaccine.
	Infanrix	DTaP	GlaxoSmithKline	Inactivated Bacterial	IM	Tetanus & diphtheria toxoids and acellular pertussis vaccine.
	Tripedia	DTaP	sanofi	Inactivated Bacterial	IM	Tetanus & diphtheria toxoids and acellular pertussis vaccine.
DT	Generic	DT	sanofi	Inactivated Bacterial Toxoids	IM	Pediatric formulation (through age 6).
DTaP–IPV	Kinrix	DTaP-IPV	GlaxoSmithKline	Inactivated Bacterial & Viral	IM	Licensed for 5th (DTaP) and 4th (IPV) booster at 4-6 years.
DTaP-HepB-IPV	Pediarix	DTaP-HepB-IPV	GlaxoSmithKline	Inactivated Bacterial & Viral	IM	Licensed for doses at 2, 4, & 6 months (through 6 years of age). Not licensed for boosters.
DTaP-IPV/Hib	Pentacel	DTaP-IPV/Hib	sanofi	Inactivated Bacterial & Viral	IM	Licensed for 4 doses at 2, 4, 6, and 15-18 months.
Haemophilus influenzae type b (Hib)	PedvaxHIB	Hib	Merck	Inactivated Bacterial	IM	**PRP-OMP**. Polysaccharide conjugate (mening. protein carrier). 2-dose primary series.
	ActHIB	Hib	sanofi	Inactivated Bacterial	IM	**PRP-T**. Polysaccharide conjugate (tetanus toxoid carrier). 3-dose primary series.
	Hiberix	Hib	GlaxoSmithKline	Inactivated Bacterial	IM	Polysaccharide conjugate (tetanus toxoid carrier). Booster only.
Haemophilus influenzae type b – hepatitis B	Comvax	Hib-HepB	Merck	Inactivated Bacterial & Viral	IM	Should not be used for hepB birth dose.
Hepatitis A	Havrix	HepA	GlaxoSmithKline	Inactivated Viral	IM	Pediatric (≤18) and adult formulations. Pediatric = 720 EL.U., 0.5mL Adult = 1,440 EL.U., 1.0mL Minimum age = 1 year

Vaccine	Trade Name	Abbreviation	Manufacturer	Type	Route	Comments
Hepatitis A	Vaqta	HepA	Merck	Inactivated Viral	IM	Pediatric (≤18) and adult formulations. Pediatric = 25 U. 0.5mL Adult = 50 U. 1.0mL Minimum age = 1 year
Hepatitis B	Engerix-B	HepB	GlaxoSmithKline	Inactivated Viral	IM	Pediatric (≤19) and adult formulations. Pediatric formulation not licensed for adults.
	Recombivax HB	HepB	Merck	Inactivated Viral	IM	Pediatric (≤19), adult, and dialysis formulations. Two pediatric doses may be substituted for an adult dose.
Hepatitis A - Hepatitis B	Twinrix	HepA-HepB	GlaxoSmithKline	Inactivated Viral	IM	Pediatric dose of HepA + adult dose of HepB. Minimum age = 18 years. 3-dose routine series (4-dose alternate schedule for rapid protection).
Herpes Zoster (Shingles)	Zostavax	ZOS	Merck	Live Attenuated Viral	SC	Licensed for age 50 and older.
Human Papillomavirus (HPV)	Gardasil	HPV4	Merck	Inactivated Viral	IM	Quadrivalent (types 6, 11, 16, 18). Licensed for males and females 9 through 26 years.
	Cervarix	HPV2	GlaxoSmithKline	Inactivated Viral	IM	Bivalent (types 16, 18). Licensed for females 10 through 26 years.
Influenza (Trivalent, types A & B)	Fluarix	TIV	GlaxoSmithKline	Inactivated Viral	IM	Minimum age = 3 years.
	Fluvirin	TIV	Chiron	Inactivated Viral	IM	Purified surface antigen. Minimum age = 4 years.
	Fluzone	TIV	sanofi	Inactivated Viral	IM	Subvirion. Minimum age (multidose vial) = 6 mo. Age range (0.25mL prefilled syringe) = 6 through 35 mo. Minimum age (0.5mL prefilled syringe) = 3 years.
	Fluzone High- Dose	TIV	sanofi	Inactivated Viral	IM	Licensed for age 65 and older.
	Fluzone Intradermal	TIV	sanofi	Inactivated Viral	Intradermal	Age range 18 through 64 years. 0.1 mL dose.
	FluLaval	TIV	GlaxoSmithKline	Inactivated Viral	IM	Minimum age = 18 years.
	Afluria	TIV	CSL	Inactivated Viral	IM	Minimum age = 6 months.
	Agriflu	TIV	Novartis	Inactivated Viral	IM	Minimum age 18 years.
	FluMist	LAIV	Medimmune	Live Attenuated Viral	Intranasal	Age range = 2 through 49 years.

Vaccine	Trade Name	Abbreviation	Manufacturer	Type	Route	Comments
Japanese encephalitis	Ixiaro	JE	Novartis	Inactivated Viral	IM	Licensed for age 17 and older. 2-dose series.
Measles, Mumps, Rubella	M-M-R II	MMR	Merck	Live Attenuated Viral	SC	Minimum age = 12 months
Measles, Mumps, Rubella, Varicella	ProQuad	MMRV	Merck	Live Attenuated Viral	SC	Age range = 1 through 12 years.
Meningococcal	Menomune	MPSV4	sanofi	Inactivated Bacterial	SC	Polysaccharide (serogroups A, C, Y, W135). Minimum age = 2 years.
	Menactra	MCV4	sanofi	Inactivated Bacterial	IM	Polysaccharide conjugate (diphtheria toxoid carrier, serogroups A, C, Y, W135). Age range = 9 months through 55 years.
	Menveo	MCV4	Novartis	Inactivated Bacterial	IM	Polysaccharide conjugate (diphtheria toxoid carrier, serogroups A, C, Y, W135). Age range = 2 through 55 years.
Pneumococcal	Pneumovax 23	PPSV23	Merck	Inactivated Bacterial	SC or IM	Polysaccharide (contains 23 strains). Minimum age = 2 years.
	Prevnar 13	PCV13	Wyeth	Inactivated Bacterial	IM	Polysaccharide conjugate (diphtheria protein carrier, contains 13 strains). Age ranges = 6 months through 5 years ***and*** 50 years & older.
Polio	Ipol	IPV	sanofi	Inactivated Viral	SC or IM	Trivalent, Types 1, 2, 3
Rabies	Imovax Rabies		sanofi	Inactivated Viral	IM	
	RabAvert		Chiron	Inactivated Viral	IM	
Rotavirus	Rota Teq	RV5	Merck	Live Viral	Oral	Pentavalent. First dose between 6 weeks and 14 weeks 6 days; complete 3-dose series by 8 months 0 days.
	Rotarix	RV1	GlaxoSmithKline	Live Viral	Oral	Monovalent. First dose between 6 weeks and 14 weeks 6 days; complete 2-dose series by 8 months 0 days.
Tetanus – (reduced) Diphtheria	Decavac	Td	sanofi	Inactivated Bacterial Toxoids	IM	Adult formulation (age 7 and older).
	Tenivac	Td	sanofi	Inactivated Bacterial Toxoids	IM	Adult formulation (age 7 and older).
	(Generic)	Td	Massachusetts Biological Labs	Inactivated Bacterial Toxoids	IM	Adult formulation (age 7 and older).

Vaccine	Trade Name	Abbreviation	Manufacturer	Type	Route	Comments
Tetanus – (reduced) Diphtheria (reduced) Pertussis	Boostrix	Tdap	GlaxoSmithKline	Inactivated Bacterial	IM	Tetanus and diphtheria toxoids & pertussis vaccine. Minimum age = 10 years.
Tetanus – (reduced) Diphtheria (reduced) Pertussis	Adacel	Tdap	sanofi	Inactivated Bacterial	IM	Tetanus and diphtheria toxoids & acellular pertussis vaccine. Age range 11 through 64 years.
Tetanus toxoid	(Generic)	TT	sanofi	Inactivated Bacterial Toxoid	IM	May be used for adults or children.
Typhoid	Typhim Vi		sanofi	Inactivated Bacterial	IM	Polysaccharide
	Vivotif Berna		Berna	Live Attenuated Bacterial	Oral	Ty21a strain.
Varicella	Varivax	VAR	Merck	Live Attenuated Viral	SC	Minimum age = 12 months.
Vaccinia (Smallpox)	ACAM2000		Acambis	Live Attenuated Viral	Percutaneous	
Yellow Fever	YF-Vax	YF	sanofi	Live Attenuated Viral	SC	Minimum age = 9 months.

February, 2012

The abbreviations on this table (Column 3) were standardized jointly by staff of the Centers for Disease Control and Prevention, ACIP Work Groups, the editor of the *Morbidity and Mortality Weekly Report* (*MMWR*), the editor of *Epidemiology and Prevention of Vaccine-Preventable Diseases* (the *Pink Book*), ACIP members, and liaison organizations to the ACIP.

These abbreviations are intended to provide a uniform approach to vaccine references used in ACIP Recommendations and Policy Notes published in the *MMWR*, the *Pink Book*, and the American Academy of Pediatrics *Red Book*, and in the U.S. immunization schedules for children, adolescents, and adults.

A dash (-) in an abbreviation for a combination vaccine indicates products that are supplied in their final form by the manufacturer and do not require mixing or reconstitution. A slash (/) indicates products that must be mixed or reconstituted by the user.

Georgia Department of Public Health
Immunization Office Vaccine Guidelines

COMBINATION VACCINES

The purpose of these guidelines is to provide public health clinics with a summary of the current Recommendations of the Advisory Committee on Immunization Practices (ACIP) for each of the vaccines supplied by the Georgia Immunization **Office**. These guidelines were developed from the pertinent Vaccine Resolutions from the Vaccines for Children Program and the references below and will be updated as needed. These guidelines should serve as a quick reference for clinics administering currently available combination vaccines which include: **(A)** TriHIBit® (ActHIB reconstituted with Tripedia® DTaP; **(B)** Comvax® (PRP-OMPC as PedvaxHIB® and Hepatitis B vaccine as Recombivax®; **(C)** TwinRix® (Hepatitis A Inactivated [Havrix®] & Hepatitis B (Recombinant) Vaccine [Engerix B®]); **(D)** Pediarix® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B Recombinant] and Inactivated Poliovirus Vaccine Combined); and ***(E)*** *Kinrix™ (Diphtheria, Tetanus, acellular pertussis [DTap] and inactivated poliovirus vaccine [IPV]);* ***(F)*** *Pentacel®* (DTap-IPV and ActHIB®); **(G)** ProQuad® (Measles, Mumps, Rubella and Varicella vaccines combined). The guidelines are not all inclusive and when more information is needed, the following publications should be referenced:

- "Notice to readers: Licensure of a Combined Live Attenuated Measles, Mumps, Rubella and Varicella Vaccine", *MMWR*, December 2, 2005, Vol. 4, No. RR-46
- "Notice to Readers: FDA Licensure of Diphtheria and Tetanus Toxoids and Acellular Pertussis
- Absorbed, Hepatitis B (Recombinant), and Poliovirus Vaccine Combined, (PEDIARIX™) for Use in Infants," *MMWR*, March 14, 2003, **Vol. 52, No. RR-10**
- **"Notice to Readers: Licensure of a Haemophilus influenzae Type b (Hib) Vaccine (Hiberix) and Updated Recommendations for Use of Hib Vaccine", *MMWR,* September 18, 2009, Vol. 58, No. RR-36**
- **"Notice to Readers: Updated Recommendations for Use of Haemophilus influenzae Type b (Hib) Vaccine: Reinstatement of the Booster Dose at Ages 12-15 Months", *MMWR*, June 26, 2009, Vol. 58, No. RR-24**
- The VFC Resolution "Vaccines to Prevent Diphtheria, Tetanus and Pertussis," Resolution No. **6/11-2**
- "License of a Diphtheria and Tetanus Toxoids and acellular Pertussis Absorbed Inactivated Poliovirus vaccine and Guidance for use as a Booster Dose," *MMWR,* October 3, 2008, Vol. 57, No. RR-39
- The 2012 Red Book: Report of the Committee on Infectious Diseases published by the American Academy of Pediatrics
- Epidemiology and Prevention of Vaccine Preventable Diseases, *12th* edition, 2nd printing.
- "*ACIP Provisional Recommendations for Use of Measles, Mumps, Rubella and Varicella*
- *(MMRV)," October 20, 2009, linked at*
  http://www.cdc.gov/vaccines/recs/provisional/default.htm
- **"General Recommendations on Immunization: Recommendations of the ACIP", *MMWR,* January 28, 2011, Vol. 60, No. RR-2**
- **"Use of Combination Measles, Mumps, Rubella, and Varicella Vaccine Recommendations of the ACIP", *MMWR,* May 7, 2010, Vol. 59, No. RR-3**

General Guidelines for the Use of Combination Vaccines[1]

- To minimize the number of injections children receive, parenteral combination vaccines should be used, if licensed and indicated for the patient's age, instead of their equivalent component vaccines.
- Recommended intervals and ages for single antigen vaccines, when used in combination series, should be observed.
- Hepatitis A, hepatitis B, and *Haemophilus influenzae* type b vaccines, in either monovalent or combination formulations from the same or different manufacturers, are interchangeable for sequential doses in the vaccination series.
- Using the same acellular pertussis vaccine product from the same manufacturer is preferable for at least the first three doses. However, if the brand is not known, ACIP recommends to vaccinate the child using the DTaP vaccine that is available.
- When patients have already received the recommended vaccinations for some of the components in a combination vaccine, administering the extra antigen(s) in the combination is often permissible if doing so will reduce the number of injections required and if the other components are not contraindicated.
- To avoid recording errors and ambiguities in the names of vaccine combinations, extra care should be taken to record exactly what was given.

[1] General Recommendations on Immunization, *MMWR*, **January 28, 2011, Vol. 60, No. RR-2**

B. COMVAX®

Vaccine Description

COMVAX® is a combination of *Haemophilus b* Conjugate (PRP-OMPC or PedvaxHIB®) and hepatitis B vaccine (Recombinant pediatric formula or Recombivax HB™). This vaccine is recommended when the needed vaccinations include both hepatitis B and Hib.

Brand Name & Manufacturer

VACCINE	MANUFACTURER
COMVAX®	Merck

Eligible Groups for State Supplied Vaccine

For Adults, Children, and Adolescents, see "Eligibility for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults" located in the front of this section.

Indications for Use

Administer if:

- Both PedvaxHIB® and Recombivax HB® are needed, **and**
- The child is ≥6 weeks of age and 59 months of age or younger

Comvax® is not approved for hepatitis B doses given at birth or at 1 month of age. Consequently, for those infants born to mothers whose HBsAg status is positive or unknown and who should therefore receive the first 2 doses of hepatitis B vaccine at birth and age 1 month, this vaccine would be inappropriate. It may be used for the 3rd dose of hepatitis B if given at the recommended 6 months of age, but not before 24 weeks of age.

Recommended COMVAX® Vaccine Schedule

For infants and children of HBsAg negative mothers. The COMVAX® series schedule depends upon the age at which the first dose was given.

AGE Dose 1	NO. OF COMVAX® DOSES REQUIRED	ADDITIONAL DOSES OF HEPATITIS B REQUIRED
2-11 months	3 doses (2nd dose 2 months after 1st 3rd dose 8-11 months after 2nd)	None
12-14 months	2 doses (2nd dose 2 months after 1st)	1 dose (at appropriate intervals)
15-60 months	1 dose intervals)	2 doses (at appropriate

Minimum Age and Dose Intervals

DOSE	AGE	INTERVAL BETWEEN DOSES
1	6 weeks	-------
2	-----	4 weeks after 1st dose
3	12 months	8 weeks after 2nd dose and child must be 12 months of age or older

Recommended Dosage and Route

0.5 mL administered intramuscularly

Note: Do not give in gluteal area. Use only deltoid or vastus lateralis (antero-lateral aspect of thigh)

Contraindications and Precautions

A. Contraindications and Precautions

1. Anaphylactic reaction to a prior dose or any component of the vaccine.
2. Hypersensitivity to any component of the vaccine including yeast or dry natural rubber latex.
3. Moderate or severe acute illness **with or without fever.**
4. This vaccine is not approved for hepatitis B vaccine doses given at birth or at one month of age, and can only be given to infants 6 weeks of age or older. As long as this guideline is followed, it can be used for infants of mothers whose HBsAg status is positive or unknown, when administering the remaining dose(s) of the hepatitis B vaccine series.

Simultaneous Vaccine Administration

May be administered simultaneously with any of the following routinely recommended vaccines: DTaP, RV, Hepatitis A, MMR, IPV, Varicella, PCV**13** or PPSV**23**, and Influenza

C. TWINRIX®

Vaccine Description

- **TwinRix®** is a bivalent inactive vaccine containing the antigenic components used in producing Havrix® (Hepatitis A Vaccine, Inactivated) and Engerix-B® [Hepatitis B Vaccine (Recombinant)].
- A 1 mL dose contains 720 ELISA Units (ELU) of inactivated hepatitis A virus (pediatric dose of Havrix®) and 20 mcg. of recombinant HBsAg protein (adult dose of Engerix-B®).
- The advantage of using this vaccine over single antigen vaccines is that it reduces the number of shots. The time to complete the series is the same.
- **TwinRix Junior®** is licensed in other countries but not in the United States and consists of 360 ELU hepatitis A antigen and 10 mcg. of hepatitis B antigen usually given in a 3 dose series at 0,1, and 6 months for children <18 years of age.

Brand Name & Manufacturer

VACCINE	MANUFACTURER
TwinRix® (Hepatitis A/Hepatitis B)	GlaxoSmithKline
TwinRix Junior® (Pediatric Hepatitis A/Hepatitis B)	GlaxoSmithKline

Eligible Groups for State Supplied Vaccine

TwinRix® is provided by the Georgia Immunization Program for use by certain populations age 18 years and older. Refer to "Eligibility Criteria for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults" for those persons eligible for hepatitis A and hepatitis B vaccines.

Recommended Schedule

The recommended schedules for TwinRix® and TwinRix Junior® are the same as for single antigen hepatitis B vaccine.

Dose 1	Dose 2	Dose 3
--------	1 month	6 months

Single antigen Hepatitis A and Hepatitis B vaccine may be used to complete a series begun with Twinrix® and vice versa. Follow one of the schedules below using recommended dose intervals:[1]

Dose 1	Dose 2	Dose 3[2]
Twinrix®	Adult hepatitis A vaccine **and** Adult hepatitis B vaccine	Twinrix® **OR** Adult hepatitis A vaccine **and** Adult hepatitis B vaccine
Twinrix®	Twinrix®	Adult hepatitis A vaccine **and** Adult hepatitis B vaccine
Adult Hepatitis A **and** Adult Hepatitis B	Twinrix®	Twinrix® **OR** Adult hepatitis A vaccine **and** Adult hepatitis B vaccine

[1] Pink Book, January, 2011, pg. **109**
[2] The minimum time interval between doses 2 and 3 should be 5 months or longer.

Minimum Age & Dose Intervals

TwinRix® may only be administered to persons ≥18 years of age.

DOSE	MINIMUM AGE	MINIMUM INTERVAL BETWEEN DOSES
Dose 1	18 years of age and older	--------
Dose 2	----------	4 wks. after 1st dose
Dose 3	----------	5 months after 2nd dose

Accelerated Schedule for Administration of Twinrix® [1,2]

Dose 1	Dose 2	Dose 3	Dose 4
Now	7 days after Dose 1	21-**31** days after Dose 1	12 months after Dose 1

[1] This schedule may be preferable 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.
[2] Refer to "Eligibility Criteria for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults" for those persons eligible for hepatitis A and hepatitis B vaccines.

Recommended Dosage and Route

1 mL administered intramuscularly

NOTE: Do not give in gluteal area. Use only deltoid or vastus lateralis (antero-lateral aspect of thigh.)

Contraindications and Precautions

A. Contraindications

1. Known hypersensitivity to any component of the vaccine or to a previous dose of TwinRix® or its component vaccines including yeast neomycin and latex.
2. Persons < 18 years of age.

B. Precautions

1. Moderate or severe acute illness with or without fever.
2. If administered to immunosuppressed persons, the expected immune response may not be obtained.

Simultaneous Vaccine Administration

May be administered simultaneously with any of the following routinely recommended vaccines: Tdap, Td, MMR, IPV, Varicella, PPSV**23,** MCV**4,** MPSV**4**, HPV, Zoster and Influenza

D. PEDIARIX®

Vaccine Description

- Pediarix® is a combined diphtheria and tetanus toxoids and acellular pertussis adsorbed (DTaP), hepatitis B (HepB) (recombinant), and inactivated poliovirus vaccine (IPV).
- It contains Infanrix®, Engerix-B®, and the same strains and quantity of inactivated poliovirus Types 1, 2, and 3 as IPV from a different manufacturer (IPOL®, Sanofi Pasteur).

Brand Names & Manufacturer

Vaccine	Manufacturer
Pediarix®	GlaxoSmithKline

Eligible Groups for State Supplied Vaccine

For Adults, Children, and Adolescents, see "Eligibility for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults" located in the front of this section.

Recommended Vaccine Schedule[1]

- Pediarix® is recommended for the primary series of DTaP, hepatitis B, and IPV vaccination (Doses 1-3).
- It should not be given before 6 weeks of age or after the child turns 7 years old.
- This vaccine is not approved for booster doses. To complete the DTaP and IPV series, use those individual vaccines.
- Pediarix® is not approved for hepatitis B vaccine doses given at birth or at 1 month of age. Consequently, for those infants born to mothers whose HBsAg status is positive or unknown and who should therefore receive the first 2 doses of hepatitis B vaccine at birth and age 1 month, this vaccine would be inappropriate. It may be used for the 3rd dose of hepatitis B if given at the recommended 6 months of age.

Dose 1	Dose 2[2]	Dose 3	Booster
2 months of age	4 months of age	6 months of age	Not approved for booster doses

[1] This reflects the **routinely** recommended schedule. However, the vaccine may be administered as a **primary** series (Doses 1, 2, and 3) at any time between 6 weeks and 7 years of age.

Conditional Pediarix Vaccine Schedule for Infants

This conditional Pediarix schedule only validates the Pediarix dose given as the 3rd dose in the series at age 4 months. This allows the series to be completed in 4 doses starting with a routine single antigen hepatitis B vaccine birth dose and the 2nd and 4th dose being any Hepatitis B antigen containing vaccine. This Pediarix hepatitis B series is considered acceptable as long as the last dose of hepatitis B vaccine is given at or after age 6 months. The Hepatitis B series algorithm highlights are listed below.

Dose 1*	Dose 2	Dose 3	Dose 4
Birth dose	**2 months of age**	**4 months of age**	**6 months of age**

Highlights:

Doses given at 0*, 2M, 4M, 6M

Dose 3 given at age 4M must be Pediarix and the trade name must be entered to be valid

Dose 4 given on or after age 6M will be valid if there is at least a 28 day interval from Dose 3; 56 day interval from Dose 2; and 112 day interval from Dose 1.

***This special series is conditional on the use of Pediarix after that routine birth dose**

Minimum Age and Dose Intervals[1]

Dose	Minimum Age	Time Interval to Dose 2	Time Interval to Dose 3[2]
1	6 weeks	4 weeks[3]	8-12 weeks[3]

[1] If the Pediarix® series is not completed until after age 4, the IPV series would be considered to be complete. However, an additional dose of DTaP would still be needed.

[2]Though Pediarix® cannot be used for a 4th or 5th booster dose, the intervals to the 4th or booster doses of any of the component vaccines (DTaP, hepatitis B, and IPV) should reflect the minimum interval for each of those vaccines. (Refer to individual Vaccine Guidelines for DTaP, hepatitis B, and IPV found in this section.)

Recommended Dosage and Route

0.5 mL administered intramuscularly

Note: Do not give in gluteal area. Use only deltoid or vastus lateralis (antero-lateral aspect of thigh)

Contraindications and Precautions

A. Contraindications

- Anaphylactic reaction to a previous dose of vaccine or to a dose of any of the component vaccines, or to a vaccine component including yeast, neomycin, and polymyxin B. (See "Contraindications and Precautions" section for each component vaccine under that Vaccine Guideline found in this section.)
- Administration at age less than 6 weeks and after 7 years of age
- Encephalopathy within 7 days of administration of a previous dose of DTP or DTaP
- Progressive neurologic disorder. Defer DTaP until neurologic status is clarified and stabilized.
- Do not give for birth dose or at age 1 month for any infant. Infants born to mothers who are HBsAg positive or whose status is unknown should receive single antigen hepatitis B vaccine for the birth dose and for Dose 1 when it is given at 1 month of age.

B. Precautions:

- Fever of ≥105°F (≥ 40.5° C.) 48 hours after vaccination with a previous dose of DTP or DTaP, or a combination vaccine that contains DTP or DTaP
- Collapse or shock like state in same circumstances as #1
- Seizure occurring 3 days after receiving a previous dose of DTP or DTaP or combination vaccine that contains DTP or DTaP
- Persistent, inconsolable crying lasting 3 hours and occurring 48 hours after vaccine containing DTP or DTaP
- Moderate or severe acute illness with or without fever
- **Guillain-Barre' syndrome (GBS) within 6 weeks after a previous dose of tetanus toxoid-containing vaccine**
- **Latex Allergy**

Simultaneous Vaccine Administration

May be administered simultaneously with any of the following routinely recommended vaccines:

RV, Hepatitis A, MMR, Hib, Varicella, Influenza, and PCV**13**

NOTE: When administered simultaneously with Hib and PCV**13** vaccines, use separate injection sites.

E. KINRIX™

Vaccine Description
• Kinrix ™ is a combined diphtheria and tetanus toxoids and acellular pertussis adsorbed (DTaP) and inactivated poliovirus vaccine (IPV). • It contains Infanrix® and the same strains and quantity of inactivated poliovirus types 1, 2, and 3 as IPV from a different manufacturer (IPOL®, Sanofi Pasteur). • Kinrix™ is the first combination vaccine to offer protection against diphtheria, tetanus, pertussis and polio diseases in one shot.

Brand Names & Manufacturer	
Vaccine	**Manufacturer**
Kinrix™	GlaxoSmithKline

Eligible Groups for State Supplied Vaccine
For Adults, children, and adolescents, see “Eligibility for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults” located in the front of this section.

Indications and Usage
Kinrix ™ is approved for: • 5th dose in the DTap series, and • 4th dose in the IPV series • children 4 through 6 years of age • previous DTaP vaccine doses were Infanrix® and/or Pediarix® for the first three doses and Infanrix® for the fourth dose. Use of Kinrix™ for any dose except the 5th dose of DTaP and 4th dose of IPV should be considered a vaccine administration error.

Recommended Dosage and Route
0.5 mL administered intramuscularly

Minimum Age and Dose Intervals

Minimum age for first dose	Minimum interval between doses 3 to 4 (IPV)
4 years of age[1]	6 months[2]
	Minimum interval between doses 4 to 5 (DTaP)
4 years of age	6 months[3]

[1]Kinrix™ is not approved for use in persons < 4 years of age or ≥ 7 years of age. If Kinrix™ is inadvertently administered as an earlier dose in the series, the dose may be counted as valid and does not need to be repeated if the minimum age and minimum interval since the prior dose are met.
[2]The fourth dose is not necessary if the third dose was given on or after the fourth birthday.
[3]The fifth dose is not necessary if the fourth dose was given on or after the fourth birthday.

Contraindications and Precautions

A. Contraindications

- Anaphylactic reaction to a previous dose of vaccine or to a dose of any of the component vaccines, or to a vaccine component including neomycin, and polymyxin B. (See "Contraindications and Precautions" section for each component vaccine under that Vaccine Guideline found in this section.)
- Administration at age less than 4 years or greater than 7 years
- If Guillain-Barre´ syndrome occurs within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give Kinrix™ should be based on potential benefits and risks.
- Encephalopathy within 7 days of administration of a previous dose of DTP or DTaP
- Progressive neurologic disorder. Defer DTaP until neurologic status is clarified and stabilized.

C. Precautions:

- Fever of ≥ 105° F, 48 hours after vaccination with a previous dose of DTP or DTaP, or a combination vaccine that contains DTP or DTaP
- Collapse or shock like state in same circumstances as #1
- Seizure occurring 3 days after receiving a previous dose of DTP or DTaP or combination vaccine that contains DTP or DTaP
- Persistent, inconsolable crying lasting 3 hours and occurring 48 hours after vaccine containing DTP or DTaP
- Moderate or severe acute illness with or without fever
- Latex sensitivity (needleless prefilled syringes contain dry natural latex rubber)

Simultaneous Vaccine Administration

May be administered simultaneously with any of the following routinely recommended vaccines:
MMR, Hib, Varicella, Hepatitis B, Influenza, **PCV13, PPSV23, and Hepatitis A**

F. PENTACEL®

Vaccine Description

Pentacel® consists of Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus (DTaP-IPV) component and an ActHIB® vaccine component. ActHIB® vaccine (Haemophilus b Conjugate Vaccine [Tetanus Toxoid Conjugate]), consists of Haemophilus influenzae type b capsular polysaccharide (polyribosyl-ribitol-phosphate [PRP]) covalently bound to tetanus toxoid (PRP-T). The DTaP-IPV component is supplied as a sterile liquid used to reconstitute the lyophilized ActHIB® vaccine component to form Pentacel vaccine.

Brand Names & Manufacturer

Vaccine	Manufacturer
Pentacel®	sanofi pasteur

Eligible Groups for State Supplied Vaccine

For Adults, Children, and Adolescents, see “Eligibility for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults” located in the front of this section

Recommended Vaccine Schedule[1] [2]

The recommended schedule for Pentacel® is similar to those for DTaP and ActHib®.

Dose 1	Dose 2	Dose 3	Dose 4
2 months	4 months	6 months	15-18 months

[1] Pentacel® is approved for the primary series and first booster dose (Doses 1-4) of DTaP, Hib, and IPV vaccination. Four doses of Pentacel® vaccine constitute a primary immunization course against pertussis. Three doses of Pentacel® vaccine constitute a primary immunization course against diphtheria, tetanus, *H influenzae* type b invasive disease, and poliomyelitis; the fourth dose constitutes a booster vaccination against diphtheria, tetanus, *H influenzae* type b invasive disease, and poliomyelitis.
[2] Licensed combination vaccines can be used whenever any components of the combination are indicated and its other components are not contraindicated and if licensed by the Food and Drug Administration (FDA) for that dose in the series.

Recommended Doses & Intervals[1]

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 (do not administer at age 5 or older)

[1] The schedule, minimum intervals, and minimum ages are determined by the individual components.

Recommended Dosage and Route

0.5 mL administered intramuscularly

Contraindications and Precautions

A. Contraindications

- Anaphylactic reaction to a previous dose of vaccine or to a dose of any of the component vaccines, or to a vaccine component including neomycin, and polymyxin B. (See "Contraindications and Precautions" section for each component vaccine under that Vaccine Guideline found in this section.)
- Administration at < 6 months of age or >5 years of age or older
- Encephalopathy within 7 days of administration of a previous dose of DTP or DTaP
- Progressive neurologic disorder. Defer DTaP until neurologic status is clarified and stabilized.

B. Precautions:

- Fever of ≥105°F (≥ 40.5° C.) 48 hours after vaccination with a previous dose of DTP or DTaP, or a combination vaccine that contains DTP or DTaP
- Collapse or shock like state in same circumstances as #1
- Seizure occurring 3 days after receiving a previous dose of DTP or DTaP or combination vaccine that contains DTP or DTaP

- Persistent, inconsolable crying lasting 3 hours and occurring 48 hours after vaccine containing DTP or DTaP
- Moderate or severe acute illness with or without fever
- Latex Allergy
- Guillain-Barré Syndrome (GBS0 within 6 weeks after a previous dose of tetanus toxoid containing vaccine.
- Hypersensivity to yeast and latex

Simultaneous Vaccine Administration
May be administered simultaneously with any of the following routinely recommended vaccines: MMR, Varicella, Hepatitis B, Hepatitis A, RV, Influenza, PPSV**23,** and PCV**13**

G. ProQuad®

Vaccine Description

- ProQuad® (MMRV) is a live virus vaccine containing measles, mumps, rubella, and varicella viruses. In September, 2005 it was licensed by the FDA for use in children ages 12 months through 12 years.
- It is a lyophilized preparation of the components of M-M-R II® (measles, mumps and rubella combination vaccine); and Varicella (Oka/Merck) Virus Vaccine Live.
- This vaccine contains no preservative and comes packaged as single dose vials with separate vials of sterile water diluent.
- Special storage and handling guidelines include:
  - MMRV must be transported and stored at temperatures of 5^0 F. or colder.
  - It cannot be stored at refrigerator temperatures and must be used within 30 minutes of being reconstituted and cannot be refrozen.
- Guidance is provided in the December 2, 2005 *MMWR* article, "Notice to Readers: Licensure of Combined Live Attenuated Measles, Mumps, Rubella, Varicella Vaccine," and in the VFC Resolution "Vaccines to Prevent Measles, Mumps, Rubella, and Varicella," Resolution No. 6/06-3.
- **"Use of Combination Measles, Mumps, Rubella, and Varicella Vaccine Recommendations of the ACIP", *MMWR,* May 7, 2010, Vol. 59, No. RR-3**

Brand Name & Manufacturer

Vaccine	Manufacturer
ProQuad®	Merck

Eligible Groups for State Supplied Vaccine

For Adults, Children, and Adolescents, see "Eligibility for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults" located in the front of this section.

Recommended Vaccine Schedule[1]

Dose 1	Dose 2
12-15 months	4-6 years
12-47 months [2]	15-12 years [3]
48 months and older [3]	

[1] MMRV should only be used when both of the component vaccines (MMR and varicella) are indicated and the child is 12 months through 12 years of age. Routinely recommended ages for measles, mumps, rubella and varicella vaccination are 12 through 15 months of age for dose 1 and 4 through 6 years of age for dose 2.

[2] Dose 1 at Ages 12 through 47 Months *

For the first dose of measles, mumps, rubella, and varicella vaccines at ages 12 through 47 months, either MMR and varicella vaccines or MMRV vaccine can be used. Providers who are considering administering MMRV vaccine should discuss the benefits and risks of both vaccination options with the parents or caregivers. Compared with use of MMR and varicella vaccines at the same visit, use of MMRV vaccine results in one fewer injection but is associated with a higher risk for fever and febrile seizures 5 through 12 days after the first dose among children aged 12 through 23 months* (about one extra febrile seizure for every 2,300–2,600 MMRV vaccine doses). Use of MMR and varicella vaccines avoids this increased risk for fever and febrile seizures following MMRV vaccine. Providers who face barriers to clearly communicating these benefits and risks for any reason (e.g., language barriers) should administer MMR and varicella vaccines.

[3] Dose 1 at Ages 48 Months and Older and Dose 2 at any Age

For the first dose of measles, mumps, rubella, and varicella vaccines at ages 48 months and older and for dose 2 at any age (15 months through 12 years), use of MMRV vaccine generally is preferred over separate injections of its equivalent component vaccines (i.e., MMR and varicella vaccines). Considerations should include provider assessment†, patient preference, and the potential for adverse events.

* The 47 month cut-off was chosen on the basis of the epidemiology of febrile seizures: first febrile seizures are uncommon after ages 4 years, approximately 94% of febrile seizures occur in children aged less than 4 years.

Minimum Age and Dose Intervals

Dose	Minimum Age	Time Interval to Dose 2
1	12 months	3 months

Spacing and timing of MMRV from individual component vaccines (MMR and varicella):

- At least 1 month should elapse between a dose of a measles-containing vaccine and a dose of MMRV.
- At least 3 months should elapse between a dose of varicella vaccine and a dose of MMRV. However, if a 2nd dose was administered after at least 28 days following the 1st dose, the 2nd dose does not need to be repeated.

Recommended Dosage and Route

0.5 mL administered subcutaneously

Contraindications

A. Contraindications

- Anaphylactic reaction to a prior dose of any of the vaccines (measles, mumps, rubella, or varicella) or to the vaccine components to include gelatin and neomycin
- Moderate or severe illness, with or without fever
- Altered immune status due to such things as malignancy, immunodeficiency, or immunosuppressive therapy
- Receipt of blood products---consult Appendix A of the listed reference for a table denoting the spacing of live virus vaccines and blood products.
- Steroid therapy---doses of systemic prednisone or equivalent at a dose of >2 mg/kg of body weight per day or 20 mg/day
- Persons receiving ongoing salicylate therapy
- In persons who develop a rash post-vaccination, there is a minimal risk of transmission of vaccine virus to close contacts. Thus, vaccinees in which vaccine-related rash develops, particularly healthcare workers and household contacts of immunocompromised persons, should avoid contact with susceptible persons who are at high risk of serious complications.
- Pregnancy
- Untreated, active TB
- **MMRV should not be administered to HIV infected persons who are severely immunocompromised.** Consult Appendix A of the "Pink Book," 12th edition, for directions on administration of single antigen live virus vaccines to immunocompromised persons.

B. Precaution

- A personal or family (i.e., sibling, parent) history of seizures is a precaution for MMRV vaccination. Studies suggest that children who have a personal or family history of febrile seizures or family history of epilepsy are at increased risk for febrile seizures compared with children who do not have such histories. Children with a personal or family history of seizures generally should be vaccinated with MMR and varicella vaccines because the risks of using MMRV vaccine in this group of children generally outweigh the benefit of MMRV vaccine.
- Recent (≤ 11 months) receipt of antibody-containing blood product (specific interval depends on product)
- Moderate or severe acute illness with or without fever
- History of thrombocytopenia or thrombocytopenic purpura
- Need for tuberculin skin testing (if TST (Tuberculosis skin test) and MMR are both need but not fiven on same day, delay TST for 4-6 weeks after MMR
- Varicella component-Receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24 hours before vacation, if possible; delay resumption of these antivirals for 14 days after vaccination
- Use caution when administering to those with anaphylaxis or immediate hypersensitivity to eggs or contact hypersensitivity to neomycin

Simultaneous Vaccine Administration

May be administered simultaneously with any of the following routinely recommended vaccines:

Hepatitis A, Hepatitis B, DTaP, Tdap, Td, IPV, Hib, Influenza, MCV**4**, MPSV**4**, HPV, PCV**13**, and PPSV**23**

Georgia Department of Public Health
Immunization Office Vaccine Guidelines

VACCINES TO PREVENT DIPHTHERIA, TETANUS, AND PERTUSSIS

The purpose of these guidelines is to provide public health clinics with a summary of the current Recommendations of the Advisory Committee on Immunization Practices (ACIP) for these vaccines or vaccine components supplied by the Georgia Immunization Office: diphtheria toxoid; tetanus toxoid; or acellular pertussis vaccine; (A) DTaP; (B) DT; (C) Tdap; and (D) Td. These guidelines were developed from the pertinent Vaccine Resolution from the Vaccines for Children Program and the references below and will be updated as needed. The guidelines are not all inclusive and when more information is needed, the following publications should be referenced:

- "Preventing Tetanus, Diphtheria, and Pertussis Among Adults**:** Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine " *MMWR*, December 15, 2006, Vol. 55, RR-17
- "Preventing Tetanus, Diphtheria, and Pertussis Among Adolescents: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccines," *MMWR,* March 24, 2006, Vol. 55, No. RR-3
- "Use of Diphtheria Toxoid-Tetanus Toxoid-Acellular Pertussis Vaccine as a Five-Dose Series," *MMWR*, November 17, 2000, Vol. 49, No. RR-13
- "Pertussis Vaccination: Use of Acellular Pertussis Vaccines Among Infants and Young Children," *MMWR*, March 28, 1997, Vol. 46, No. RR-7
- "Diphtheria, Tetanus, and Pertussis: Recommendations for Vaccine Use and Other Preventive Measures," *MMWR*, August 8, 1991, Vol. 40, No. RR-10
- ACIP Diphtheria, Tetanus, and Pertussis Resolution for the Vaccines for Children Program (VFC), (Resolution No. 6/11-2)
- 2012 Red Book: Report of the Committee on Infectious Diseases published by the American Academy of Pediatrics
- Epidemiology and Prevention of Vaccine Preventable Diseases, 12th edition, 2nd printing.
- "License of a Diphtheria and Tetanus Toxoids and acellular Pertussis Absorbed and Inactivated Poliovirus vaccine and Guidance for Use as a Booster Dose," MMWR Weekly, October 3, 2008, Vol. 57(39); 1078-1079.
- Updated Recommendations for Use of Tetanus Toxoid, reduced Diphtheria toxoid and acellular Pertussis (Tdap) Vaccine from the ACIP, 2010, January 14, 2011, Vol.60, RR 60-1
- FDA Approval of Expanded Age Indication For a Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, April 17, 2009, Vol. 58. RR-14
- ***"General Recommendations on Immunization,"* MMWR*, January 28, 2011 Vol. 60, RR-2***
- **"Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap) in Pregnant Women and Persons Who Have or Anticipate Having Close Contact with an Infant Aged <12 Months," *MMWR*, October 21, 2011, Vol. 60, No. RR-41**
- **ACIP Provisional Recommendations for Health Care Personnel on use of Tetanus Toxoid,Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap) and use of Postexposure Antimicrobial Prophylaxis, April 4, 2011**
  This document available at: http://www.cdc.gov/vaccines/recs/provisional/default.htm
- **ACIP provisional updated recommendations on use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) for pregnant women.**
  December 6, 2012, linked at http://www.cdc.gov/vaccines/recs/provisional/downloads/Tdap-pregnant-Oct-2012.pdf

Vaccine Description

A. DTaP

- Diphtheria and Tetanus and Acellular Pertussis Vaccine is an inactivated vaccine containing diphtheria and tetanus toxoids and purified inactivated components of *Bordetella pertussis* cells.
- DTaP is the recommended substitute for whole-cell DTP but should not be used if DTP has been contraindicated.
- Combination diphtheria and tetanus toxoid and whole-cell pertussis (DTP) vaccine is no longer available.

B. TT

- Tetanus toxoid is an inactivated bacterial toxoid that may be prescribed for active immunization of persons over age 7 years. It is NOT to be used for the treatment of tetanus infection.

F. Other information

- Single antigen diphtheria toxoid is not available. Diphtheria toxoid is available combined with tetanus as pediatric DT or adult Td, and with tetanus toxoid and acellular pertussis vaccine as DTaP or Tdap.
- **Use of single antigen tetanus toxoid is not recommended**.
- DTaP and DT vaccines contain similar amounts of tetanus toxoid as adult Td vaccine, but 3-4 times as much diphtheria toxoid as adult Td vaccine.

Brand Name & Manufacturer

VACCINES	MANUFACTURERS
Current brands of diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed (DTaP):	
Infanrix ®	GlaxoSmithKline
Tripedia®	sanofi pasteur
(See "Combination Guidelines" for further information on Pediarix®)	
Daptacel®	sanofi pasteur
(This vaccine is licensed for the first 4 doses only)	

Brand Name & Manufacturer (cont'd)

Current brand of diphtheria and tetanus toxoids, pediatric (DT):

Diphtheria/Tetanus, Pediatric	sanofi pasteur

Current brands of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine, adsorbed (Tdap):

Boostrix®	GlaxoSmithKline
Adacel™	sanofi pasteur

Current brand of tetanus and diphtheria toxoids, adult (Td):

Tetanus/Diphtheria, Adult	Massachusetts Biological Labs
Tenivac	**sanofi pasteur**

Current brand of tetanus toxoid (TT):

Tetanus Toxoid, Adsorbed USP	sanofi pasteur

DTaP Combination Vaccines (*See "Combination Vaccines" for more information.)*

TriHIBit® (**ActHIB reconstituted with Tripedia DTaP**) sanofi pasteur
(This vaccine is licensed for 4th dose of DTaP only and is currently not available through the Vaccines for Children Program.)

Pediarix® **(DTap-IPV/Hib)** GlaxoSmithKline
(*This vaccine is licensed for primary series only [Doses 1-3].)*

Pentacel™ **(DTap-Hepb/IPV)** sanofi pasteur
(This vaccine is licensed for primary series, and 1st booster dose [Doses 1-4].)

Kinrix™ **(DTap-IPV)** GlaxoSmithKline
(This vaccine is licensed for booster dose at age 4-6.)

Eligible Groups for State Supplied Vaccine

For Adults, Children, and Adolescents, see "Eligibility for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults" located in the front of this section.

Recommended Diphtheria, Tetanus and Pertussis Vaccine Schedule

A. DTaP [1, 2, 3]

Diphtheria, tetanus, and pertussis vaccine is recommended as part of the routine childhood immunization schedule at 2, 4, 6, and 15-18 months of age, and 4-6 years of age. Regardless of age and timing of doses, no more than a total of 6 DTaP vaccines should be given before 7 years of age.

Dose	Age	Interval[4]
Primary 1	2 months	----------
Primary 2	4 months	8 weeks after 1st dose
Primary 3	6 months	8 weeks after 2nd dose
First Booster	15-18 months[5,6,11]	6-12 months after 3rd dose[7,8]
Second Booster	4-6 years[9, 10]	
Tdap or Td Booster	11-12 years	

B. DT

- If the child begins the series at <1 year of age, follow the schedule outlined above.
- If the child is ≥12 months of age at the time the 1st dose of DT is administered, a 2nd dose should be administered 4-8 wks. later, followed by a 3rd dose given 6-12 months after the 2nd dose. This completes primary vaccination with DT. A booster dose should be given at 4-6 years of age.

C. Tdap use in adolescents and adults- based on ACIP guidelines for use of Tdap in adolescents and the guidelines for use of Tdap in adults.

A (**one-time dose**) is recommended for persons ≥11 years of age through adulthood, providing they have previously completed the recommended DTP/DTaP/Td series and have not already received a dose of Td:

- Give in place of Td at the 11-12 year old healthcare visit.
- For those older adolescents or adults who have not already received a dose of Td.
- Can be given one time for tetanus prophylaxis in wound management, if a dose of Tdap has not previously been given.
- Can be used as any one of the 3 doses when administering a primary Td series to a person in the licensed age groups.
- **Adults aged 65 years and older (e.g., grandparents, child-care providers, and health- care practitioners) who have or who anticipate having close contact with an infant less than 12 months of age and who previously have not received Tdap should receive a single dose of Tdap to protect against pertussis and reduce the likelihood of transmission. For other adults aged 65 years and older, a single dose of Tdap vaccine may be given instead of Td vaccine, in persons who have not previously received Tdap. Tdap can be administered regardless of interval since the last tetanus- or diphtheria-toxoid containing vaccine.**
- **Healthcare personnel (HCP), regardless of age, should receive a single dose of Tdap as soon as feasible if they have not previously received Tdap and regardless of the time since the last Td dose.**

D. Tdap use in pregnancy
Pregnancy is not considered a contraindication of the use of Tdap.

- Pregnant women should receive a dose of Tdap during each pregnancy irrespective of their prior history of receiving Tdap.

  Optimal timing for Tdap administration is between 27 and 36 weeks gestation. For women not previously vaccinated with Tdap, if Tdap is not administered during pregnancy, Tdap should be administered immediately postpartum.

E. Td (refer to Tdap guidelines above for situations when that vaccine would be recommended instead of a dose of Td.)

- If administering as a primary series at ≥7 years of age, give at 0, 1, and 6 months.
- A Td booster is recommended at any age for persons regardless of interval since the previous dose of any tetanus-containing vaccine.
- Subsequent boosters are recommended at 10 year intervals.
- For wound management, give booster if >5 years have elapsed since last dose.

F. Use of DTaP, DT, Td, Tdap, and Tetanus Immune Globulin (TIG)[12] for Wound Management

- *Refer to wound management guidelines in ACIP Manual: "Diphtheria, Tetanus, and Pertussis: Recommendations for Vaccine Use and Other Preventive Measures, " MMWR, August 8, 1991, pg. 16; "Preventing Tetanus, Diphtheria, and Pertussis Among Adolescents: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccines," MMWR, March 24, 2004, pg. 25.*

[1] Use diphtheria and tetanus toxoids, adsorbed (DT), if encephalopathy has occurred after administration of a previous dose of pertussis-containing vaccine.
[2] ACIP recommends using the same brand of DTaP vaccine for all doses of the series. However, if the brand used for previous doses is not known or not available, use any brand of DTaP to complete the series.
[3] Pertussis vaccine given as DTaP is not recommended for children ≥7 years of age.
[4] Prolonging the interval does not require restarting the series.
[5] If using Daptacel™, this dose is recommended to be given at 17-20 months of age. (*MMWR*, July 5, 2002, Vol. 51, No. 26, pp.574.)
[6] Pediarix™ is licensed only for the primary series of 3 doses, not for the booster doses (#4and #5)
[7] The 4th dose of DTaP may be given as early as 12 months of age, provided 6 months have elapsed since the 3rd dose and if the child is unlikely to return at 15-18 months of age. TriHIBit ™ can be administered as the 4th dose following a primary series with either DTaP or whole-cell DTP and following a primary series with any *Haemophilus influenzae* type b conjugate vaccine.
[8] DTaP #4 does not need to be repeated if administered ≥4 months after DTaP #3.
[9] A 5th dose is not necessary if the 4th dose was given on or after the 4th birthday.
[10] Kinrix™ is licensed for the booster dose at age 4-6.
[11] Pentacel™ is licensed for the primary series and 1st booster dose (Doses 1-4.)
[12] The state does not supply TIG. There are 2 brands of TIG; hyperlet and baylet. Providers can order TIG from their wholesaler or FFS Enterprise (-1-800-843-7477) or from the manufacturer, Talecris (1-800-243-4153).

Minimum Age and Dose Intervals[8]

Vaccine	Minimum age	Minimum interval between doses			
		Dose 1-2	Dose 2-3	Dose 3-4	Dose 4-5
DTaP	6 weeks	4 weeks	4 weeks	6 months	6 months[1]
DTaP-HepB-IPV[2]	6 weeks	4 weeks	4 weeks		
DTaP-Hib-IPV[3]	6 weeks	4 weeks	4 weeks	6 months	
DT	6 weeks	4 weeks	4 weeks	6 months	6 months[1]
DTaP-Hib[4]	15-18 months			6 months	
DTaP-IPV[5]	4 years				6 months[1]
Tdap/Td	11 years				
Tdap/Td (catch-up schedule)[7]	7 years	4 weeks	6 months	5 years[7]	

Note: DT containing vaccines are not indicated for children >6 years of age.

[1] The fifth dose is not necessary if the fourth dose was given after the fourth birthday.

[2] The recommended DTaP-HepB-IPV vaccine may be used when any component of the combination is indicated, and if the other components are not contraindicated. The combined DTaP-HepB-IPV vaccine is approved for the primary series only (Doses 1-3). For adequate immune response, the last dose of hepatitis B vaccine should be given at ≥ 24 weeks of age and therefore this combination vaccine should not be administered as a complete primary series on an accelerated schedule at 4 week intervals for prevention of pertussis.

[3] The combined DTaP-Hib-IPV vaccine may be used when any component of the combination is indicated, and if the other components are not contraindicated. The combined DTaP-Hib-IPV vaccine is approved for the primary series and first booster dose (Doses 1-4). The combined DTaP-Hib-IPV vaccine is not indicated for children ≥ 5 years.

[4] The combined DTaP/Haemophilus influenzae type b (Hib) vaccine is indicated for the fourth dose at age 15-18 months.

[5] The combined DTaP-IPV vaccine may be used when any component of the combination is indicated, and if the other components are not contraindicated. The combined DTaP-IPV vaccine is approved for the booster dose at age 4-6 years.

[6] Tdap is indicated for a single booster dose at age 11 or 12 years if the childhood DTP/DTaP vaccination series has been completed. Tdap is preferred over Td as adolescents are susceptible to pertussis due to waning immunity, though Td may be indicated rather than Tdap in special situations (more information is available at: http://www.cdc.gov/mmwr/preview/mmwrhtm/rr5503a1.htm?s_cid=rr5503al_e). Adolescents who did not receive Tdap at age 11 or 12 should receive a single dose of Tdap in place of a single Td booster dose. Tdap can be administered regardless of interval since the last tetanus of diphtheria containing vaccine.

[7] Tdap should be given to children 7 through 18 years of age who have received tetanus and diphtheria containing vaccines (DT or Td) instead of DTP/DTaP for some or all doses of the childhood series; have received fewer than 5 doses of DTP/DTaP or 4 doses if the fourth dose was administered at age 4 years or older; or have never been vaccinated against tetanus, diphtheria, or pertussis (no doses of pediatric DTP/DTaP/DT or Td). The preferred schedule is a single Tdap dose, followed by a dose of Td four weeks after the first dose and a second dose of Td 6-12 months later. If not administered as the first dose, Tdap can be substituted for any of the other Td doses in the series. More information about the catch-up is available in Appendix D at: http://www.cdc.gov/mmwr/preview/mmwrhtm/rr5503a1.htm?s_cid=rr5503al_e Of note this appendix which was designed to provide catch up guidance for adolescents aged 11 through 18 years, now applies to children aged 7 through 18 years. Tdap is preferred over Td as adolescents are susceptible to pertussis due to waning immunity, though Td may be indicated rather than Tdap in special situations.

[8] the ACIP Diphtheria, Tetanus, and Pertussis Resolution for the Vaccines for Children Program (VFC), (Resolution No. 6/11-2)

Recommended Dosage and Route

A. DTaP: 0.5 mL administered intramuscularly

B. DT: 0.5 mL administered intramuscularly

C. Tdap: 0.5 mL administered intramuscularly

D. Td: 0.5 mL administered intramuscularly

Contraindications and Precautions for DTaP, DT, Tdap, and Td[1 2]

I. DTaP

- **CONTRAINDICATIONS**
- An immediate anaphylactic reaction following a previous dose. Defer further use of this vaccine because of the uncertainty as to which component of the vaccine might be responsible. However, because of the importance of tetanus vaccination, persons who experience anaphylactic reactions may be referred to an allergist for evaluation and, if specific allergy can be demonstrated, desensitized to tetanus toxoid.
- Encephalopathy following a previous dose not attributable to another identifiable cause. An acute, severe central nervous system disorder occurring within 7 days after vaccination and generally consisting of major alterations in consciousness, unresponsiveness, or generalized or focal seizures that persist more than a few hours, without recovery within 24 hours, is a contraindication to further administration of any DTaP-containing vaccine.

B. PRECAUTIONS

If any of the following events occurs within the specified period after administration of DTaP vaccine, providers and parents should evaluate the risks and benefits of administering subsequent doses of a pertussis-containing vaccine:

- Temperature of ≥105°F. (≥40.5°C.) within 48 hours, not attributable to another identifiable cause.
- Collapse or shock-like state (hypotonic hyporesponsive episode) within 48 hours.
- Persistent crying lasting ≥ 3 hours, occurring within 48 hours.
- Convulsions with or without fever, occurring within 3 days.
- Acute, moderate or severe illnesses with or without fever.
- Latex Allergy
- Progressive neurological disorder including infantile spasms, uncontrolled epilepsy (postpone until stabilized).

II. DT

A. CONTRAINDICATIONS

- An immediate anaphylactic reaction. Defer further use of this vaccine because of the uncertainty as to which component of the vaccine might be responsible. However, because of the importance of tetanus vaccination, persons who experience anaphylactic reactions may be referred to an allergist for evaluation and, if specific allergy can be demonstrated, desensitized to tetanus toxoid.

B. PRECAUTIONS

- Arthus-type hypersensitivity reactions. These are exaggerated local reactions that present as extensive, painful swelling, often from the shoulder to the elbow. Persons who experience arthus-type hypersensitivity reactions or a temperature of ≥103°F (39.4°C.) following a prior dose of tetanus toxoid usually have high serum tetanus antitoxin levels and should not be given DT or even emergency doses of Td more frequently than every 10 years, even if they have a wound that is neither clean nor minor.
- Acute, moderate or severe illnesses with or without fever.
- Latex Allergy.

III. Tdap

A. CONTRAINDICATIONS

- An immediate anaphylactic reaction to any vaccine containing any of the 3 Tdap components: tetanus, diphtheria, or pertussis.
- Encephalopathy not attributed to another identifiable cause, within 7 days of administration of a pertussis-containing vaccine (this is a contraindication for the pertussis components; Td can be used).

B. PRECAUTIONS

- Arthus-type hypersensitivity reactions following a prior dose of a tetanus toxoid
- Progressive neurological disorder, uncontrolled epilepsy, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized. If decision is made to withhold pertussis vaccination, then Td may be used instead of Tdap.
- Latex allergy. The tip cap and rubber plunger of the BOOSTRIX® needleless prefilled syringe presentation contain dry natural latex rubber. The vial stoppers of both BOOSTRIX® and Adacel™ are latex-free.
- Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus toxoid-containing vaccines.
- Acute, moderate or severe illnesses with or without fever.

IV. Td

A. CONTRAINDICATIONS

- An immediate anaphylactic reaction. Defer further use of this vaccine because of the uncertainty as to which component of the vaccine might be responsible. However, because of the importance of tetanus vaccination, persons who experience anaphylactic reactions may be referred to an allergist for evaluation and, if specific allergy can be demonstrated, desensitized to tetanus toxoid.
- Moderate or severe illnesses with or without fever.

B. PRECAUTIONS

- Arthus-type hypersensitivity reactions. Persons who experience Arthus-type hypersensitivity reactions following a prior dose of tetanus toxoid usually have high serum tetanus antitoxin levels and should not be given even emergency doses of Td more frequently than every 10 years, even if they have a wound that is neither clean nor minor.
- Guillain-Barre´ syndrome (GBS) within 6 weeks after a previous dose of tetanus toxoid containing vaccines.
- Acute, moderate or severe illness with or without fever.
- Latex Allergy.

[1] For other contraindications and precautions, refer to Table 6, Contraindications and Precautions to Commonly Used Vaccines, in the ACIP statement, "General Recommendations on Immunization," *MMWR*, January 28, 2011 Vol. 60, RR-2

[2] the ACIP Diphtheria, Tetanus, and Pertussis Resolution for the Vaccines for Children Program (VFC), (Resolution No. 6/11-2)

Simultaneous Vaccine Administration

DTaP, DT, Tdap, and Td may be administered simultaneously with any of the following routinely recommended vaccines:

- MMR, Hib, Hepatitis A, Hepatitis B, RV, IPV, Varicella, PCV13 or PPSV23, HPV, Zoster and Influenza
- Tdap or Td may also be administered simultaneously with MCV4, or at any time before or after.
- If administering DTaP and either PCV13 or PPSV23, it is recommended to administer the vaccines in separate limbs.

Appendix E

Guide to catch-up vaccination with Td for children aged 7--10 years*

Vaccination history before catch-up: number of pediatric DTP/DTaP/DT or Td doses administered before age 7 years		No. of Td/ doses needed to catch-up*†	Minimum interval between doses of tetanus and diphtheria toxoid–containing vaccines*†			
No. doses at age <1 year	No. doses at age 1–6 years		Last pediatric DTP/DTaP/DT dose to Td dose 1 at age ≥7 years	Td dose 1 to Td dose 2	Td dose 2 to Td dose 3	Td dose 3 to Td dose 4
Unknown	Unknown	3	NA§	4 weeks	6 months	—¶
0	0	3	NA	4 weeks	6 months	—¶
0	1	2	4 weeks	6 months	—¶	NA
0	2	1	6 months	—¶	NA	NA
0	3	0	—¶**	NA	NA	NA
1	0	3	NA: administer now	4 weeks	6 months	—¶
1	1	2	4 weeks	6 months	—¶	NA
1	2	1	6 months	—¶	NA	NA
1	3	0	—¶**	NA	NA	NA
2	0	2	NA: administer now	6 months	—¶	NA
2	1	1	6 months	—¶	NA	NA
2	2	0	—¶**	NA	NA	NA
3	0	1	NA: administer now	—¶	NA	NA
3	1	0	—¶**	NA	NA	NA

* Td is recommended for children aged 7–10 years; a single dose of BOOSTRIX® Tdap vaccine is licensed for persons aged 10 years and can be used instead of Td for one of the doses in children aged 10 years. If BOOSTRIX® is administered to a child aged 10 years, the dose counts as the adolescent Tdap dose. Pediatric DTaP/DTP/DT vaccines are not indicated for persons aged ≥7 years. See Appendix F for a complete list of vaccine abbreviations.

† Number of doses and the minimum intervals between the last dose administered and the next dose of tetanus and diphtheria toxoid–containing vaccine needed to provide protection against tetanus and diphtheria.

§ Not applicable.

¶ These children should receive Tdap to provide protection against tetanus, diphtheria and pertussis according to the routine vaccination recommendations for adolescents who completed the pediatric DTP/DTaP series, when they become adolescents aged 11–18 years; an interval of at least 5 years between Td and Tdap is encouraged, but shorter intervals can be used (see text, Routine Tdap Vaccination [1-A]).

** Some experts suggest administering a dose of Td now to children aged 7–10 years with this vaccination history if no dose of a tetanus and diphtheria toxoid–containing vaccine was administered at age ≥4 years.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

References to non-CDC sites on the Internet are provided as a service to *MMWR* readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of pages found at these sites. URL addresses listed in *MMWR* were current as of the date of publication.

This appendix taken from the ACIP statement "Preventing Tetanus, Diphtheria, and Pertussis Among Adolescents: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccines," MMWR, March 24, 2006, Vol. 55, No. RR-3.

3-J. Inadvertent Administration of Tdap or Pediatric DTaP

To help prevent inadvertent administration of Tdap when pediatric DTaP is indicated or pediatric DTaP when Tdap is indicated, vaccine providers should review product labels before administering these vaccines; the packaging might appear similar. Tdap is not indicated for children aged <10 years. Tdap contains lower amounts of diphtheria toxoid and lower amounts of some pertussis antigens compared with pediatric DTaP. Studies of the immune responses to Tdap among infants have not been conducted. Pediatric DTaP is not indicated for persons aged >7 years; the increased diphtheria toxoid content is associated with higher rates of adverse reactions in older persons (*24–28*).

Guidance on the best approach to vaccination following inadvertent administration of Tdap or pediatric DTaP is based primarily on expert opinion. The family should be informed of any inadvertent vaccine administration. Adverse events associated with inadvertent vaccine administration can be reported to VAERS (see Reporting of Adverse Events after Vaccination). If Tdap is inadvertently administered instead of pediatric DTaP to a child aged <7 years as any one 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 the inadvertent administration is discovered while the child is in the office, the pediatric DTaP can be administered during the same visit. If the child has left the office, some experts suggest administering the replacement dose of pediatric DTaP within approximately 72 hours, or administering it 4 weeks later to optimize the child's immune response to the antigens in pediatric DTaP. This practice helps ensure that the child stays on the primary series schedule and has adequate protection against diphtheria and pertussis. However, the replacement dose of pediatric DTaP can be administered as soon as feasible at any interval after the inadvertent Tdap dose. The remaining doses of the pediatric DTaP series 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. For example, if an 8-week week old infant inadvertently received a dose of Tdap instead of the first dose of pediatric DTaP and does not receive a replacement dose of pediatric DTaP within about 72 hours, a replacement dose of pediatric DTaP can be administered 4 weeks after the inadvertent Tdap dose (age 12 weeks). The routine schedule of pediatric DTaP can then be resumed 4 weeks after the pediatric DTaP replacement dose (age 16 weeks) with the other recommended vaccines (*1*,*23*).

If Tdap is inadvertently administered as the fourth or the fifth dose in the tetanus-diphtheria-pertussis vaccination series to a child aged <7 years, the Tdap dose should be counted as valid and does not need to be repeated; the child who received Tdap as a fourth dose should complete the pediatric DTaP schedule (*23*). The routine adolescent Tdap vaccination recommendations would apply when this child becomes an adolescent. For example, a child who inadvertently receives Tdap at age 5 years instead of the fifth dose of pediatric DTaP should receive a second dose of Tdap at age 11–12 years.

If Tdap or pediatric DTaP is inadvertently administered to a child aged 7-9 years instead of Td as part of 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 to Tdap (see Routine Tdap Vaccination [section 1-A] and Pertussis Outbreaks and Other Settings with Increased Risk for Pertussis or its Complications [section 3-C]). In either case, the child should receive a dose of vaccine containing tetanus and diphtheria toxoids no longer than 10 years after the inadvertent Tdap or pediatric DTaP dose or according to the guidance for catch-up vaccination (Appendix E).

If pediatric DTaP is inadvertently administered to an adolescent aged 11–18 years, the dose should be counted as the adolescent Tdap booster. The adolescent should receive the next dose of a vaccine containing tetanus and diphtheria toxoids 10 years after the inadvertent pediatric DTaP dose or according to the guidance for catch-up vaccination (Appendix D).*

* This page excerpted from "Preventing Tetanus, Diphtheria, and Pertussis Among Adolescents: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccines," *MMWR*, March 24, 2006, Vol. 55, No. RR-3, pg. 27.

Georgia Department of Public Health
Immunization Office Vaccine Guidelines

VACCINES TO PREVENT *HAEMOPHILUS INFLUENZAE* TYPE B

The purpose of these guidelines is to provide public health clinics with a summary of the current Recommendations of the Advisory Committee on Immunization Practices (ACIP) for each of the vaccines supplied by the Georgia Immunization Office. These guidelines should serve as a quick reference for clinics administering *Haemophilus influenzae* type b vaccine. The guidelines are not all inclusive and when more information is needed, the complete ACIP Recommendations statement should be referenced:

- "Haemophilus b Conjugate Vaccines for Prevention of *Haemophilus influenzae* type b Disease Among Infants and Children Two Months of Age and Older," *MMWR*, January 11, 1991, Vol. 40, No. RR-1.
- ACIP *Haemophilus influenzae* type b Resolution for the Vaccines for Children Program (VFC), (Resolution No. 6/08-5)
- 2012 Red Book: Report of the Committee on Infectious Diseases published by the American Academy of Pediatrics
- Epidemiology & Prevention of Vaccine Preventable Diseases, 12th edition, 2nd printing.
- "Licensure of a Haemophilus influenzae Type b (Hib) Vaccine (Hiberix) and Updated Recommendations for Use of Hib Vaccine," *MMWR,* September 18, 2009,Vol. 58, RR-36

Vaccine Description

- *Haemophilus influenzae* type b polysaccharide-protein conjugate vaccines are produced by chemically bonding a polysaccharide (a poor antigen) to a protein "carrier," which is a more effective antigen.
- **There are three types of Hib conjugate vaccines:**
  1. **PRP-T (ActHIB®and OmniHIB®)**
  2. **PRP-OMP (PedvaxHIB®)**
  3. **PRP-T (Hiberix)**
- PRP-T and PRP-OMP containing vaccines are highly immunogenic and are licensed for use in infants. These vaccines are interchangeable for use in the primary series and booster doses. However, the number of doses recommended depends upon the type of vaccine administered and the age at the time of the first dose. See "Recommended Schedule" Section.

Brand Name & Manufacturer

HIB VACCINES	MANUFACTURERS
PRP-T (ActHIB®)	Sanofi Pasteur
PRP-OMP (PedvaxHIB®)	Merck
PRP-T (Hiberix) (Booster only)	**Novartis**
Hib Combination Vaccines:	
DTaP/Hib (for booster only)	
TriHIBit ® [1]	Sanofi Pasteur
Hib/Hepatitis B	
Comvax® (PedvaxHIB® and RecombivaxB®)	Merck
DTap/IPV/Hib	
Pentacel (ActHIB® and liquid DTap-IPV solution)	Sanofi Pasteur

[1]Not available from GA VFC Program

Eligible Groups for State Supplied Vaccine

For Adults, Children, and Adolescents, see “Eligibility for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults” located in the front of this section.

ACIP-Recommended Haemophilus influenzae type b (Hib) Routine Vaccination Schedule

Vaccine	2 Months	4 Months	6 Months	12-15 Months
PRP-T* (ActHIB)	Dose 1	Dose 2	Dose 3	Booster
PRP-OMP (PedvaxHIB)	Dose 1	Dose 2		Booster

*** Hiberix brand PRP-T vaccine is approved only for the last dose of the Hib series among children 12 months of age.**

Recommended *Haemophilus influenzae* type b (Hib) Vaccine Schedule

Vaccine	Age at 1st dose (months) [1]	Primary series	Booster
PRP-T + (ActHIB)	2-6 [1]	3 doses, 2 months apart	12-15 months*
	7-11	2 doses, 2 months apart	12-15 months*
	12-14	1 dose	2 months later
	15-59 [2]	1dose	--
PRP-OMP (PedvaxHIB)	2-6	2 doses, 2 months apart	12-15 months*
	7-11	2 doses, 2 months apart	12-15 months*
	12-14	1 dose	2 months later
	15-59[2]	1 dose	

Comvax® Hib-Hep B (See Section on "Combination Vaccines")
Pentacel™ DTap-IPV/Hib (See Section on "Combination Vaccines")
[1] Limited data suggest that Hib conjugate vaccines given before 6 weeks of age may induce immunologic tolerance to subsequent doses of Hib vaccine.
[2]Generally not recommended for persons older than 59 months of age
* At least 8 weeks after a previous dose

+ **Hiberix brand PRP-T vaccine is approved only for the last dose of the Hib series among children 12 months of age and older.**

Minimum Age and Dose Intervals

Vaccine	Age Dose 1	Interval Dose 1 to 2	Interval Dose 2 to 3	Interval Booster Dose	Age Booster Dose
ActHIB®	6 weeks	4 weeks	4 weeks	8 weeks	12 months
PedvaxHIB®	6 weeks	4 weeks	**not needed**	8 weeks	12 months

Comvax® (See Section on "Combination Vaccines")
Pentacel™ (See Section on "Combination Vaccines")

Recommended Dosage and Route

0.5mL administered intramuscularly
Note: Do not give in gluteal area. Use only deltoid or vastus lateralis (antero-lateral aspect of thigh)

Contraindications and Precautions

A. Contraindications and Precautions

1. Anaphylactic reaction to a prior dose or to any component of the vaccine
2. Acute, moderate, or severe illness with or without fever. Immunize as soon as illness subsides.
3. Do not administer to infants < 6 weeks of age because of the potential for development of immunologic tolerance.

Simultaneous Vaccine Administration

May be administered simultaneously with any of the following routinely recommended vaccines:

DTaP, RV, MMR, Varicella, Hepatitis A, Hepatitis B, IPV, PCV13 or PPSV23, Zoster and Influenza

Georgia Department of Public Health
Immunization Office Vaccine Guidelines

VACCINES TO PREVENT HEPATITIS A

The purpose of these guidelines is to provide public health clinics with a summary of the current Recommendations of the Advisory Committee on Immunization Practices (ACIP) for each of the vaccines supplied by the Georgia Immunization Office. These guidelines were developed from the pertinent Vaccine Resolution from the Vaccines for Children Program and the references below and will be updated as needed. The guidelines are not all inclusive and when more information is needed, the following publications should be referenced:

- "Update: Prevention of Hepatitis A After Exposure to Hepatitis A Virus and in International Travelers," *MMWR*, October 19, 2007, Vol. 56, No. 41
- "Prevention of Hepatitis A Through Active or Passive Immunization." *MMWR*, May 19, 2006, Vol. 55, No. RR-7
- "Notice to Readers: FDA Approval of Havrix® (Hepatitis A Vaccine, Inactivated) for Persons Aged 1--18 Years," *MMWR*, December 9, 2005, Vol. 54, No. 49
- "Notice To Readers: FDA Approval of VAQTA® (Hepatitis A Vaccine, Inactivated) for Children Aged >1 Year," *MMWR*, October 14, 2005, Vol. 54, No. 40
- "Protection Against Viral Hepatitis," *MMWR*, February 9,1990, Vol.39, No.RR-2;
- CDC STD Prevention website at *http://www.cdc.gov/STD/treatment/7-2002TG.htm#VaccinePreventableSTDs*
- Hepatitis A Vaccine Resolution for the Vaccines for Children Programs (VFC), (Resolution No.06-07-1)
- 2012 Red Book, Report of the Committee on Infectious Diseases by the American Academy of Pediatrics
- Epidemiology and Prevention of Vaccine-Preventable Diseases, 12th edition, 2nd printing.
- "Updated Recommendation from the Advisory Committee on Immunization (ACIP) for use of Hepatitis A Vaccine in Close Contacts of Newly Arriving International Adoptees," *MMWR*, September 18, 2009, Vol. 58. No. 36

Vaccine Description

- Hepatitis A vaccine is an inactivated vaccine grown in cell culture.
- There are 2 monovalent hepatitis A vaccine products licensed for use in the U.S. Both are available in 2 formulations: adult and pediatric.
- Both products are currently licensed for persons aged 12 months and older.
- An additional vaccine product available in the U.S. combines hepatitis A and hepatitis B vaccine (Twinrix®) in an adult formulation for administration to persons ages 18 and older.

Brand Names & Manufacturer

VACCINES	MANUFACTURER
Havrix®	GlaxoSmithKline Biologicals
Pediatric Formulation 720 EL.U./0.5 mL	
Adult Formulation 1440 EL.U./1 mL	
Vaqta®	Merck & Co., Inc.
Pediatric/Adolescent Formulation 25U/0.5 mL	
Adult Formulation 50U/1 mL	
Twinrix® (combination hepatitis A and hepatitis B) (see "Combination Vaccines Guidelines" in this section for more information)	GlaxoSmithKline Biologicals

Eligible Groups for State Supplied Vaccine

For Adults, Children, and Adolescents, see "Eligibility for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults" located in the front of this section.

Groups Recommended to Receive Hepatitis A Vaccine

Routine childhood/adolescent recommendations for vaccination:

- Children at 1 year of age. Children who are not vaccinated by age 2 years can be vaccinated at subsequent visits.
- States, counties, and communities with existing hepatitis A vaccination programs for children aged 2-18 years are encouraged to maintain these programs.

Recommendations for persons who are at increased risk of infection:

- Persons traveling to developing countries which have high or intermediate endemicity of hepatitis A
- Men who have sex with men (MSM)
- Users of injecting and non-injecting illegal drugs
- Persons who have clotting factor disorders
- Persons working with HAV infected primates or with HAV in a research laboratory setting
- Persons with chronic liver disease
- Close personal contacts of children adopted from countries with high rates of hepatitis A Virus (HAV)[1]

Groups Recommended to Receive Hepatitis A Vaccine (cont'd)

Although hepatitis A may occur in other groups or settings, serologic surveys have **not** found that they are at increased risk for hepatitis A because of their occupation or setting, and are therefore **not** routinely recommended to receive vaccine. These would include:

- Food service establishments or food handlers
- Child care centers, employees or attendees
- Health-care institutions including specific hospital units
- Institutions for persons who have developmental disabilities
- Schools
- Sewage plants or sanitation workers

[1] "Updated Recommendations from the Advisory Committee on Immunization (ACIP) for use of Hepatitis A Vaccine in Close Contacts of Newly Arriving International Adoptees," *MMWR,* September 18, 2009, Vol. 58. No. 36

Recommended Hepatitis A Vaccine Schedule

Vaccine	Age Group	Number of Doses	Volume	Schedule
Havrix®				
Pediatric	12 months through18 yrs.	2	0.5 mL	0, 6-12 mos.
Adult	≥19 years	2	1 mL	0, 6-12 mos.
Vaqta® Pediatric	12 months through 18 yrs.	2	0.5 mL	0, 6-18 mos.
Adult	≥19 years	2	1 mL	0, 6-18 mos.

For Twinrix® schedule, see "Combination Vaccine Guidelines" in this section.

Recommended Minimum Age & Time Intervals & Interchangeability of Vaccine Brands

Vaccine[1]	Minimum age for first dose	Minimum interval from dose 1 to dose 2[2]
Havrix®	12 months	6 months
Vaqta®	12 months	6 months
Twinrix®	See "Combination Vaccine Guidelines" in this section	

[1] The 2 brands of vaccine can be considered interchangeable.
[2]The minimum interval between the first and booster doses of hepatitis A vaccine is six calendar months. If the interval between the first and booster doses of hepatitis A vaccine is longer than the recommended interval of 6-18 months, it is not necessary to repeat the first dose. For both vaccines, the booster dose given should be based on the person's age at the time of the booster dose, not the age when the first dose was given. For example, if a child received the first dose of the pediatric formulation of VAQTA at 18 years of age, and returns for the booster dose at age 19 years, the booster dose should be the adult formulation, not the pediatric formulation.

Recommended Vaccine Dosage and Route

0.5 mL (pediatric formulations) administered intramuscularly
1 mL (adult formulations) administered intramuscularly

Contraindications and Precautions to Vaccine[1]

Contraindications:

1. Allergy to any vaccine component. (For a complete listing of components, see package insert.)
2. Acute, moderate or severe illnesses with or without fever

Precautions:

1. Pregnancy. The safety of hepatitis A vaccination given during pregnancy has not been determined; however, because hepatitis A vaccine is produced from inactivated HAV, the theoretical risk to the developing fetus is expected to be low. The risk associated with vaccination should be weighed against the risk for hepatitis A in women who may be at high risk for exposure to HAV.

[1]For Twinrix® Contraindications and Precautions see "Combination Vaccine Guidelines" in this section.

Simultaneous Vaccine Administration

Hepatitis A vaccine may be administered simultaneously with any of the following routinely recommended vaccines:

DTaP, Tdap, Td, Hib, hepatitis B, IPV, Influenza, PCV13, PPSV23, MMR, Varicella, Zoster, HPV, MCV4, and MPSV4.

Recommendations for Hepatitis A Immunoprophylaxis

(see January 2, 2008 Memorandum, "New Policy for Hepatitis A Postexposure Prophylaxis" located at the end of these guidelines)

A. Immune Globulin (IG)

- Hepatitis A Immunoprophylaxis with Immune Globulin (IG) is routinely recommended in 2 situations:
  1. Pre-exposure prophylaxis for international travel; and
  2. Post-exposure prophylaxis for persons <12 months of age or >40 years of age who are contacts to acute cases of hepatitis A
- The provision of IG is available from the Epidemiology Branch for hepatitis A postexposure prophylaxis. The State Office of Pharmacy no longer stocks an IG supply. To obtain IG for this purpose, contact:
  1. The appropriate designated district epidemiology personnel; and
  2. Hepatitis epidemiology staff in the state office at (404) 657-3158 or (404) 657-2588. (When calling to request IG, please have on hand the necessary information regarding name of hepatitis A case and number of contacts, with some descriptive information [i.e., ages].)
- Supplies of IG given for pre-exposure prophylaxis, i.e. international travel, should be purchased by districts.
- The guidelines below are only a minimum reference and any decision to use IG should be prefaced by further research using available resources, including medical providers. **For more specific information, please see Chapter 6, "Surveillance and Reporting" in this manual, the ACIP Hepatitis A statement and the 2012 Red Book references cited in the opening paragraph of "Vaccines to Prevent Hepatitis A."**

Pre-exposure Prophylaxis

- For persons traveling to certain parts of the world where hepatitis A has high or intermediate endemicity, immunoprophylaxis is indicated. For persons ≥1 years of age, vaccine is preferable over IG. However, for children under 1 year of age, and for those whose travel plans are imminent and therefore do not allow enough time for vaccine to provide adequate protection, IG may be the better choice. (Not supplied by the State)

Post-exposure Prophylaxis for persons <12 months of age or >40 years of age

- Household and sexual contacts of persons with acute hepatitis A. Administration of IG should take place within 2 weeks of most recent exposure, and is not indicated if that period of time has already elapsed.
- IG should be administered as age appropriate to all previously unvaccinated staff and attendees of child care centers or homes if 1) one or more cases of hepatitis A are recognized in children or employees, or 2) cases are recognized in two or more households of center attendees.
- If a food handler is diagnosed with hepatitis A, IG should be administered to other food handlers at the same establishment. In the event of a common-source outbreak, IG should NOT be administered to exposed patrons after cases have begun to occur because the 2-week period during which IG is effective will have been exceeded.

Recommendations for Hepatitis A Immunoprophylaxis (cont'd)

- For children aged <12 months, immunocompromised persons, persons who have had chronic liver disease diagnosed, and persons for whom vaccine is contraindicated, IG should be used.

NOTE: IG would **not** routinely be recommended for:

- School settings, unless transmission within the school is documented.
- Hospital personnel caring for patients with hepatitis A disease, unless an outbreak among patients or between patients and staff is documented

B. Hepatitis A Vaccine[1,2]

- For healthy persons ages 12 months through 40 years, single-antigen hepatitis A vaccine at the age-appropriate dose is preferred to IG for post-exposure prophylaxis to hepatitis A infection because of vaccine advantages that include long-term protection and ease of administration.
- For person over 40 years of age, IG is preferred; vaccine can be used if IG cannot be obtained.

[1] "Update: Prevention of Hepatitis A After Exposure to Hepatitis A Virus and in International Travelers," *MMWR*, October 19. 2007, Vol. 56, No. 41
[2] See pages 1-5 of the Hepatitis A guidelines for the recommended schedule, minimum intervals, and contraindications and precautions for hepatitis A vaccine.

Recommended IG[1] Dosage and Route

Time Since Exposure[2]	Age of Patient	Recommended Prophylaxis
≤2 weeks	<12 months of age or >40 years of age[3]	IG, 0.02 mL/kg[4]
> 2 weeks	All ages	**No prophylaxis**

[1] This product does **NOT** contain thimerosal.
[2] Because hepatitis A cannot be reliably diagnosed on clinical presentation alone, serologic confirmation of HAV infection in index patients by IgM anti-HAV testing is recommended before postexposure treatment of contacts.
[3] Hepatitis A vaccine is recommended for post-exposure prophylaxis for persons ages ≥12 months of age through 40 years of age.
[4] Immune Globulin should be administered deep into a large muscle mass (deltoid, gluteus, or in children under 24 months of age, the anterolateral thigh muscle.) Ordinarily, no more than 5 mL should be administered in 1 site in an adult or large child; lesser amounts (maximum 3 mL) should be given to small children and infants in one site.

Contraindications and Precautions to IG

Contraindications:

1. Persons with IgA deficiency. Anaphylaxis has been reported after repeated administration of IG to these persons.
2. **Pregnancy or lactation is NOT a contraindication to IG use.**

Precautions:

1. IG can interfere with the response to live injected vaccines, such as MMR, varicella, and LAIV. Administration of live vaccines should be delayed for at least 3 months after administration of IG (See Table 4 of ACIP "General Recommendations on Immunization" for more specific guidelines.)
2. Unless the benefits of IG prophylaxis exceed the benefits of vaccination, IG should not be administered for 2 weeks after measles-, mumps-, and rubella-containing vaccines, and for 3 weeks after vaccination with varicella vaccine. If IG is given during this period, the person should be revaccinated with the live vaccine, but not sooner than 3 months after administration of IG.

Simultaneous Administration of IG with Vaccines

Immune Globulin does not interfere in general with inactivated vaccines or to yellow fever vaccine. It may be administered simultaneously with any of the following routinely recommended vaccines:

DTaP, Tdap, Td, Hib, hepatitis A, hepatitis B, IPV, Inactivated Influenza, PCV13, PPSV23, HPV, MCV4.

Seroconversion rates are not impaired by simultaneous administration of IG with the first dose of Hepatitis A vaccine, but lower serum antibody concentrations may be achieved. This decreased immunogenicity is not likely to be clinically important.

See "Contraindications and Precautions" section regarding administration of IG with or near live virus vaccines such as MMR, varicella., and LAIV

Georgia Department of Public Health
Immunization Office Vaccine Guidelines

VACCINES TO PREVENT HEPATITIS B

The purpose of these guidelines is to provide public health clinics with a summary of the current Recommendations of the Advisory Committee on Immunization Practices (ACIP) for each of the vaccines supplied by the Georgia Immunization Office. These guidelines should serve as a quick reference for clinics administering hepatitis B vaccine. The guidelines are not all inclusive and when more information is needed, the complete ACIP Recommendations statements should be referenced:

- "A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States---Part II: Immunization of Adults," *MMWR,* December 8, 2006, Vol. 55, RR-16
- "A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States - Part 1: Immunization of Infants, Children, and Adolescents," MMWR, December 23, 2005, Vol. 54, No. RR-16
- *ACIP* Hepatitis B Vaccine Resolution for the Vaccines for Children Program (VFC), (Resolution No.10/03-2)
- 2012 Red Book: Report of the Committee on Infectious Diseases published by the American Academy of Pediatrics
- Epidemiology and Prevention of Vaccine Preventable Diseases, 12th edition, 2nd printing.
- **"Use of Hepatitis B Vaccination for Adults with Diabetes Mellitus: Recommendations of the Advisory Committee on Immunization Practices (ACIP)", December 23, 2011, Vol. 60,RR-50**

Vaccine Description

- Two types of hepatitis B vaccine (Hep B) have been licensed in the U.S.
  1. The first was plasma-derived and is no longer produced in the U.S.
  2. The currently available vaccines are produced by recombinant DNA technology using yeast cells. Since they contain no potentially infectious viral DNA or complete viral particles, they are incapable of causing hepatitis B infection.
- Hepatitis B vaccine is manufactured by two different companies. Although the antigen content differs, the vaccines are interchangeable.

Brand Name & Manufacturer

VACCINES		MANUFACTURERS
Engerix B®	Pediatric/Adolescent Formulation (10µg/0.5mL) Adult Formulation (20 µg/1 mL) (Administered to dialysis/compromised persons 20 years of age and older as 2 doses [2 mL total] on the same visit)	Glaxo SmithKline
Recombivax HB®	Pediatric/Adolescent Formulation (5µg/0.5mL)[1] Adult Formulation (10µg/1 mL) Formulation for dialysis/compromised [2, 3] (40 µg/2 mL)	Merck
Hepatitis B Immune Globulin (HBIG)[4]		Bayer Corp. Biological Products
Hepatitis B Combination Vaccines		
a. COMVAX® Hib (PedvaxHIB®) and HepB (Recombivax HB®)		Merck
b. TwinRix® [5] Hepatitis B (Engerix B®) and Hepatitis A (Havrix®)		Glaxo SmithKline
c. Pediarix® (Infanrix®, EngerixB®, and inactivated poliovirus vaccine)[6]		Glaxo SmithKline

(See "Combination Guidelines" for more information on these 3 vaccines.)

[1] Recombivax HB® Pediatric/Adolescent formulation is also licensed for administration to persons 20 years of age and older. However, the dose should be increased to1 mL (10µg).
[2] Not supplied by the GA VFC or Georgia Immunization Program.
[3] In this case, use the Engerix B® product as directed in the package insert for these at risk populations.
[4] State-supplied HBIG is available by calling the Hepatitis Program Director at the GA Immunization Office at 404-657-3171. See "Eligibility Criteria for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults" for further information.
[5] Licensed only for persons 18 years and older.
[6] Licensed only for the primary series of DTaP and polio and cannot be administered before the child is 6 weeks of age or to anyone 7 years of age or older.

Recommended Doses of Currently Licensed Formulations of Hepatitis B Vaccine, by Age Group and Vaccine Type

	Single-Antigen Vaccine				Combination Vaccine					
	Recombivax HB		Engerix-B		Comvax		Pediarix		Twinrix	
Age Group	Dose (µg)[1]	Volume (mL)	Dose (µg)[1]	Volume (mL)	Dose (µg)[1]	Volume (mL)	Dose (µg)[1]	Volume (mL)	Dose (µg)[1]	Volume (mL)
Infants (<1 yr)	5	0.5	10	0.5	5	0.5	10	0.5	N/A[6]	N/A
Children (1-10 yrs)	5	0.5	10	0.5	5	0.5	10	0.5	N/A	N/A
Adolescents										
11-15 yrs	10[2]	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
11-19 yrs	5	0.5	10	0.5	N/A	N/A	N/A	N/A	N/A	N/A
Adults (≥ 20 yrs)	10	1	20	1	N/A	N/A	N/A	N/A	20	1
Hemodialysis patients and other immunocompromised persons										
< 20 yrs[3]	5	0.5	10	0.5	N/A	N/A	N/A	N/A	N/A	N/A
≥ 20 yrs	40[4]	1	40[5]	2	N/A	N/A	N/A	N/A	N/A	N/A

[1] Recombinant hepatitis B surface antigen protein dose.

[2] Adult formulation administered on a 2-dose schedule.

[3] Higher doses might be more immunogenic, but no specific recommendations have been made.

[4] Dialysis formulation administered on a 3-dose schedule at age 0,1, and 6 months.

[5] Two 1 mL doses administered at one site, on a 4-dose schedule at age 0, 1, 2, and 6 months.

[6] Not applicable.

Epidemiology and Prevention of Vaccine-Preventable Diseases, 12th edition, May 2011, pg. 125

Eligible[1,2] Groups for State Supplied Vaccine

For Adults, Children, and Adolescents, see “Eligibility for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults” located in the front of this section.

Recommended Hepatitis B Vaccine Schedule

Recommended Infant and Child Schedules

The hepatitis B vaccine series is routinely recommended for all infants. The first dose should be given at birth, but the recommended schedule for an infant depends upon the mother's hepatitis B surface antigen (HBsAg) status and infant's birth weight. See Minimal Age and Time Interval Section for requirements for minimum spacing of doses. Persons ≤19 years of age should receive the pediatric/adolescent vaccine formulation.

A. Infant born to mother known to be HBsAg-negative

Dose	(Option 1) Age of Infant	(Option 2) Age of Infant
Hep B-1	Birth[1]	1-2 months[1]
Hep B-2	1-2 months	4 months
Hep B-3	6-18 months[2]	6-18 months[2]

B. Infant born to mother known to be HBsAg-positive

Dose	Age of Infant
Hep B-1	Birth (within 12 hours)[1]
HBIG	Birth (within 12 hours)[3]
Hep B-2	1-2 months
Hep B-3	6 months[2, 4]

C. Infant born to mother whose HBsAg status is unknown

Dose	Age of Infant
Hep B-1	Birth (within 12 hours)[1]
HBIG	Mother should be tested and if HBsAg-positive, HBIG should be given to the infant no later than 7 days after birth[3]
Hep B-2	1-2 months
Hep B-3	6 months[2]

D. Infants born weighing less than 2 kg. (4.4 lbs.)

If mother's status is HBsAg negative by laboratory testing

Dose	Age of Infant
Hep B-1	Chronological age of 1 month or at hospital discharge

Complete the vaccine series using recommended intervals

If mother's status is unknown or HBsAg positive by laboratory testing

Dose	Age of Infant
Hep B-1	Birth (within 12 hours)[1]
HBIG	Birth (within 12 hours)[3]

Continue vaccine series beginning at age 1-2 months according to recommended schedule based on mother's HBsAg status. Do not count birth dose as part of vaccine series.[4]

Recommended Adult Schedule

A. Hepatitis B vaccination should be administered to unvaccinated adults with diabetes mellitus who are aged 19 through 59 years. Hepatitis B vaccination usually consists of 3 doses of vaccine administered intramuscularly at 0, 1, and 6 months; other schedules are available. Hepatitis B vaccination may be administered at the discretion of the treating clinician to unvaccinated adults with diabetes mellitus who are aged equal to or greater than 60 years

B. Administer hepatitis B vaccination to persons beginning hemodialysis

C. Adults at Risk for HBV Infection

- **Sexual exposure**
  - **sex partners of HBsAg-positive persons**
  - **sexually active persons not in a long-term, mutually monogamous relationship (persons with more than one sex partner during the previous six month)**
  - **persons seeking evaluation or treatment for a sexually transmitted disease**
  - **men who have sex with men**
- **Percutaneous or mucosal exposure to blood**
  - **Current or recent IDU (intravenous drug users)**
  - **Household contacts of HBsAg-positive persons**
  - **Residents and staff of facilities for developmentally disabled persons**
  - **Healthcare and public safety workers with risk for exposure to blood or blood-contaminated body fluids**
  - **Persons with end-stage renal disease**
- **Other groups**
  - **International travelers to regions with high or intermediate levels (HBsAg prevalence of 2% or higher) of endemic HBV infection**
  - **Persons with HIV infection**

[1] COMVAX®, the combination HIB/Hepatitis B vaccine is licensed for use at 2, 4, and 12-15 months of age. Pediarix® is a combination of DTaP, hepatitis B, and IPV and is licensed only for the primary series of 3 doses of DTaP and polio. Neither of these combination vaccines should be used for doses given before the child is 6 weeks of age. See the "Combination Vaccines" section in this section of the manual for more information on both of these vaccines.

[2] This dose is recommended at 6 calendar months of age, but should not be administered before 24 weeks of age.

[3] Hepatitis B Immune Globulin: 0.5ml administered IM at a site different from that used for the vaccine.

[4] When the mother is HBsAg positive, the infant should receive the final dose of hepatitis B vaccine at 6 months of age and have a follow up serology for anti-HBs and HBsAg **3-12** months after the final dose in the vaccine series.

Recommended Schedules for Infants ≥ 4 Months of Age, Children, Adolescents and Adults

Previously unvaccinated infants older than 4 months of age, children, adolescents and adults should begin the vaccination series at the earliest opportunity. There are 2 optional schedules for vaccinating these age groups; however, minimum time intervals between doses apply.

Option 1: The pediatric/adolescent formulation should be used for persons ≤19 years of age, and those ≥ 20 years of age should receive the adult formulation.

Dose	Usual Time Interval	Minimum Time Interval Between Doses
Hep B-1	-----	-----
Hep B-2	1-2 months	4 weeks
Hep B-3	4-6 months	8 weeks from dose #2 **and** 16 weeks from dose #1

Option 2: Alternative 2 Dose Schedule for Adolescents (age 11 through 15 years only) and using Adult Formulation (Recombivax™ only). This vaccine is not available from the GA VFC Program.

Dose	Usual Time Interval	MinimumTime Interval Between Doses
Hep B-1	------	
Hep B-2	4-6 months	16 weeks

In view of the fact that there are 2 combination vaccines containing hepatitis B vaccine, Comvax® and Pediarix,® the following table may be helpful in determining how to administer these combination vaccines in a schedule where the first dose of hepatitis B vaccine is given at birth.

Recommended schedule for hepatitis B vaccination for infants born to hepatitis B surface antigen (HBsAg) negative mothers:

Vaccination Schedule Options

Dose	Single antigen[1]	Single antigen[1] and PEDIARIX®	Single antigen[1] and COMVAX®
1	Birth	Birth (single antigen)[2]	Birth (single antigen)[2]
2	1-2 months	2 months	2 months
3	6 months	4 months[3]	4 months
4	NA	6 months	12-15 months

[1] Single antigen vaccine: ENGERIX-B® or RECOMBIVAX HB®
[2] Only a single antigen hepatitis B vaccine can be given at birth

Recommended Hepatitis B Post-Exposure Prophylaxis

All contacts should be pre-tested and vaccinated at the same visit.

1. Infants of HBsAg Positive Mom	HBIG: 0.5mL IM plus Hepatitis B Vaccine within 12 hours of birth but administered in different sites. Give subsequent doses of Hepatitis B vaccine according to the recommended vaccine schedule.
2. Preterm infants weighing < 2000 gms. (4.4 lbs.)	If the mother's HBsAg status cannot be determined ≤ 12 hrs. of birth, infants should receive both single antigen hepatitis B vaccine and HBIG (0.5 mL). The infants should receive 3 additional doses of hepatitis B vaccine according to the routine schedule------the birth dose should not be counted.
3. Unvaccinated Infants (0-12 months) whose primary caregiver is acutely infected	HBIG: 0.5mL IM plus Hepatitis B Vaccine: age-specific dose at the time of HBIG but administered in different sites. Give subsequent doses according to the vaccine schedule.
4. Unvaccinated Household contacts (>12 mos. of age) with identifiable blood exposure to acutely infected person within 7 days of exposure.	HBIG: single dose (0.06mL/kg IM) plus Hepatitis B Vaccine: age-specific dose at the time of HBIG but administered in different sites. Give subsequent doses according to the vaccine schedule.
5. Unvaccinated sexual contact to acutely infected person within 14 days of last sexual exposure	HBIG: single dose (0.06mL/kg IM) plus Hepatitis B Vaccine: age-specific dose at the time of HBIG but administered in different sites Give subsequent doses according to the vaccine schedule.
6. Percutaneous or permucosal exposure	See "Recommended Hepatitis B Post-Exposure Prophylaxis" Tables, for exposure in occupational and nonoccupational settings

Recommendations for postexposure prophylaxis after percutaneous or mucosal exposure to HBV in an OCCUPATIONAL setting				
Vaccination and antibody response status of exposed persons[1]	**Treatment when source is:**			
	HBsAg positive	**HBsAg negative**	**Source unknown or not tested**	
			High Risk	**Low Risk**
Unvaccinated	HBIG[2] (1 dose) and begin Hep B vaccine series	Begin Hep B vaccine series	Begin the Hep B vaccine series	Begin the Hep B vaccine series
Previously Vaccinated Known responder[3]	No treatment	No treatment	No treatment	No treatment
Previously Vaccinated Known Nonresponder[3]	HBIG (1 dose) and begin a revaccination[4] series or HBIG (2 doses)[5]	No treatment	HBIG (1 dose) and begin a revaccination[4] series	Begin a revaccination[4] series
Previously Vaccinated Antibody response unknown	Test for anti-HBs[6] If adequate[3]: no treatment If inadequate: HBIG x 1 dose and vaccine booster	No treatment	Test for anti-HBs[6] If adequate[3]: no treatment If inadequate: give vaccine booster and check anti-HBs in 1-2 months	

[1]Persons known to have had HBV infection in the past or who are chronically infected do not require HBIG or vaccine.
[2] Hepatitis B immune globulin (0.06 mL/kg) administered IM
[3] Adequate response is anti-HBs of at least 10 mIU/mL after vaccination.
[4] Revaccination means an additional 3-dose series of hepatitis B vaccine administered after the primary series.
[5] The option of giving one dose of HBIG and revaccinating the series is preferred for nonresponders who have not completed a second 3-dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.
[6] Testing for antibody to HBsAg should be done as soon as possible after exposure.

Reference: *MMWR* 2001; 50(RR-11) pg 22

Postexposure Prophylaxis[1] of Persons with Nonoccupational[2] Exposure

Exposure	Treatment	
	Unvaccinated person[3]	Previously vaccinated person[4]
HBsAg-positive source		
Percutaneous (e.g. bite or needlestick) or mucosal exposure to HBsAg-positive blood or body fluids	Administer hep B vaccine series and HBIG	Administer hep B vaccine booster dose
Sex or needle-sharing contact of an HBsAg-positive person	Administer hep B vaccine series and HBIG	Administer hep B vaccine booster dose
Victim of sexual assault/abuse by a perpetrator who is HBsAg-positive	Administer hep B vaccine series and HBIG	Administer hep B vaccine booster dose
Source with unknown HBsAg status		
Victim of sexual assault/abuse by a perpetrator with unknown HBsAg status	Administer hep B vaccine series	No treatment
Percutaneous or mucosal exposure to potentially infectious blood or body fluids from a source with unknown HBsAg status	Administer hep B vaccine series	No treatment
Sex or needle-sharing contact of person with unknown HBsAg status	Administer hep B vaccine series	No treatment

[1] When indicated, immunoprophylaxis should be initiated as soon as possible, preferably within 24 hours. The interval during which postexposure prophylaxis is effective is unlikely to exceed 7 days for percutaneous exposures or 14 days for sexual exposures. The hep B vaccine series should be completed.
[2] These guidelines apply to nonoccupational exposures. See previous table for management of occupational exposures.
[3] A person who is in the process of being vaccinated but who has not completed the vaccine series should complete the series and receive treatment as indicated.
[4] A person who has written documentation of a complete hep B vaccine series and who did not receive postvaccination testing.

Reference: "A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States," *MMWR*, December 8, 2006, Vol. 55, No. RR-16

Minimum Age & Dose Intervals

Vaccine	Age Dose 1	Interval Dose 1 to 2	Interval Dose 2 to 3	Interval Dose 1 to 3
Hep B (3-dose schedule with pediatric or adolescent formulation)	Birth	4 weeks	8 weeks	16 weeks[1]
Hep B (2-dose schedule adult formulation for children 11-15 years of age)[2,3]	11 years	16 weeks	-----	-----

[1]The 3rd dose is recommended to be given to infants at 6 calendar months of age. It should not be administered before 24 weeks of age.
[2]Adult vaccine for this specific use is not available through VFC.
[3]This schedule can be used only with Recombivax™ brand vaccine and if started ≥11 years of age, must be completed before 16 years of age. If not completed within these minimal age and time intervals, the series should be completed following the 3 dose schedule.

NOTE: Post-vaccine serologic testing is not routinely recommended. However, testing is recommended 1-2 months after the 3rd vaccine dose for the following:

1. Hemodialysis patients
2. Persons with HIV infection
3. Those at occupational risk of exposure from sharps injuries
4. Immunocompromised patients at risk of exposure to HBV. Infants born to HBsAg positive mothers should be tested **3-12** months after the final dose of Hep B vaccine is administered.
5. Sex partners of HBsAg positive persons

Recommended Dosage and Route

Hepatitis B Vaccines[1]

Pediatric/adolescent formulations: 0.5mL administered intramuscularly
Adult formulations: 1 mL administered intramuscularly

NOTE: Hepatitis B vaccine should be administered in the deltoid or antero-lateral aspect (vastus lateralis) of the thigh. It should not be administered in the buttocks.

Hepatitis B Immune Globulin (HBIG)

Infant (birth-12 months): 0.5 mL intramuscularly in vastus lateralis
Children and adults: 0.06 mL/kg intramuscularly

[1] Refer to chart on pg. 3 of these guidelines for more dosing information.

Contraindications and Precautions

I. Hepatitis B Vaccine

A. Contraindications and Precautions

1. Anaphylactic reaction to a previous dose of hepatitis B vaccine, whether given as a single antigen or in a combination product.
2. Known allergy to yeast or yeast products.
3. COMVAX® , Pediarix™, or other combination vaccines containing hepatitis B vaccine, should not be given to infants younger than 6 weeks of age. Pediarix® should not be given to anyone 7 years of age or older. Comvax must not be administered to infants younger than 6 weeks of age because of potential suppression of the immune response to the Hib component.
4. Moderate or severe illnesses with or without fever.
5. Administration of TwinRix® vaccine to persons younger than 18 years of age. See the "Combination Vaccine Guidelines" in this section of the manual.

Note:

1. Pregnancy is not a contraindication to receiving HepB vaccine.
2. Since hepatitis B vaccine does not contain live virus, it may be used in persons with immunodeficiencies, although their response may be suboptimal.

II. Hepatitis B Immune Globulin

A. Contraindications

1. Anaphylactic reaction to a previous dose of any immune globulin preparation.
2. Serum immunoglobulin A deficiency.

Note: HBIG is not contraindicated for a pregnant woman and should be administered if clearly indicated.

Simultaneous Vaccine Administration

Hepatitis B Vaccine

May be administered simultaneously with any of the following routinely recommended vaccines: DTaP, Tdap, Td, DT, RV, MMR, Hib, Varicella, IPV, Hepatitis A, MCV4, PCV13 or PPSV23, HPV, Zoster and Influenza

Hepatitis B Immune Globulin (HBIG)1

May be administered simultaneously with any of the following routinely recommended vaccines: DTaP, Tdap, Td, DT, hepatitis B, Hib, IPV, Hepatitis A, MCV4, PCV13 or PPSV23, HPV, RV, Zoster, MMR, Varicella and Influenza

[1] For guidelines on spacing of HBIG and MMR or varicella vaccines, see "General Recommendations on Immunization," *MMWR*, **January 28, 2011, Vol. 60, No. 2**.

Georgia Department of Public Health
Immunization Office Vaccine Guidelines

VACCINES TO PREVENT HERPES ZOSTER (SHINGLES) DISEASE

The purpose of these guidelines is to provide public health clinics with a summary of the current Recommendations of the Advisory Committee on Immunization Practices (ACIP) for this vaccine, though it is not supplied by the Georgia Immunization Office. These guidelines were developed from the vaccine package insert and the references below and will be updated as needed. The guidelines are not all inclusive and when more information is needed, the following publications should be referenced:

- "ACIP Recommendations for the Use of the Prevention of Herpes Zoster," MMWR, June 6, 2008, Vol. 57, No. RR-5.
- Vaccine package insert; available at *http://www.fda.gov/cber/label/zosmer052506LB.pdf*
- "**Update on Herpes Zoster Vaccine: Licensure for Persons Aged 50-59 Years," MMWR, November 11, 2011, Vol. 60, No. RR-44**

Vaccine Description
Licensed zoster vaccine is a lyophilized preparation of a live, attenuated strain of VZV, the same strain used in the varicella vaccines. However, its minimum potency is at least 14-times the potency of single-antigen varicella vaccine. To maintain potency, lyophilized zoster vaccine must be stored frozen at an average temperature of ≤ 5˚ F (≤-15˚C) until it is reconstituted for injection.

Brand Names & Manufacturer	
Zostavax®	Merck

Eligible Groups for State Supplied Vaccine
This vaccine is not supplied by the Georgia Immunization Office. These guidelines are for informational purposes only.

ACIP Recommendations for Administration of ZosterVax®[1]
Zoster vaccine is recommended for all persons aged ≥60 years who have no contraindications, including persons who report a previous episode of zoster or who have chronic medical conditions. Zoster vaccination is not indicated to treat acute zoster, to prevent persons with acute zoster from developing postherpetic neuralgia (PHN), or to treat ongoing PHN. **Vaccination of Persons who have received Varicella Vaccine** Zoster vaccination is not recommended for persons of any age who have received varicella vaccine. However, health-care providers do not need to inquire about varicella vaccination history before administrating zoster vaccine because virtually all persons currently or soon to be in the recommended age group have not received varicella vaccine. In the United States, varicella vaccination began in 1995. Since that time, few adults aged ≥ 40 years would have been susceptible to varicella and thus eligible to receive varicella vaccine. The number of persons eligible for zoster vaccine who have received varicella vaccine is extremely small and will remain so for at least a decade.

Recommended Herpes Zoster Vaccine Schedule		
Vaccine	**Dose**	**Minimum Age**
Zostavax®	1	**50** years

Recommended Dosage and Route
0.65 mL administered subcutaneously in the deltoid region

[1]"ACIP Recommendations for the Use of the Prevention of Herpes Zoster," MMWR, June 6, 2008, Vol. 57, No. RR-5.

Contraindications and Precautions

Contraindications:

1. History of anaphylactic reaction to gelatin, neomycin, or any other vaccine component
2. History or primary or acquired immunodeficiency states including leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system; AIDS or other clinical manifestations of infection with HIV
3. Individuals on immunosuppressive therapy, including high-dose corticosteroids
4. Individuals with active untreated tuberculosis
5. Women who are or may become pregnant
6. Persons undergoing hematopoietic stem cell transplantation (HSCT)

Precautions:

1. Moderate to severe illness

Special Groups and Circumstances

1. Persons with a reported history of zoster can be vaccinated
2. Persons anticipating immunosuppression- The risk for zoster and its severe morbidity and mortality is much greater among persons who are immunosuppressed. Such patients without a history of zoster vaccination should receive 1 dose of zoster vaccine at the first possible clinical encounter while their immunity is intact. Zoster vaccine should be administered at least 14 days before initiation of immunosuppressive therapy, although some experts advise waiting 1 month after zoster vaccination to begin immunosuppressive therapy if delay is possible
3. Persons receiving antiviral medication- These agents might interfere with replication of the live, VZV-based zoster vaccine
4. Persons receiving blood products-Zoster vaccine can be administered to persons at any time before, concurrent with, or after receiving blood or other anti-body-containing blood products.

Simultaneous Vaccine Administration

May be administered simultaneously with any of the following routinely recommended vaccines:
Tdap, Td, MMR, Hepatitis A, Hepatitis B, Polio, Influenza, PPSV23

If simultaneous administration is not possible, zoster vaccine can be administered at any time before or after an inactivated vaccine, but at least 4 weeks before or after another live, attenuated vaccine

Georgia Department of Public Health
Immunization Office Vaccine Guidelines

VACCINES TO PREVENT HUMAN PAPILLOMAVIRUS INFECTION

The purpose of these guidelines is to provide public health clinics with a summary of the current Recommendations of the Advisory Committee on Immunization Practices (ACIP) for this vaccine. These guidelines were developed from the references below and will be updated as needed. The guidelines are not all inclusive and when more information is needed, the following publications should be referenced:

- "Quadrivalent Human Papillomavirus Vaccine," *MMWR*, March 23, 2007, Vol. 56, No. RR-2
- ACIP Human Papillomavirus Resolution for the Vaccines for Children Program (VFC), (Resolution No. 10/09-1)
- HPV vaccine package insert for HPV4 & HPV2
- Epidemiology and Prevention of Vaccine-Preventable Diseases, 12th edition, 2nd printing.
- **FDA Licensure of Bivalent Human Papillomavirus Vaccine (HPV2, Cervarix) for use in Females Updated HPV Vaccination Recommendations from the Advisory Committee on Immunization Practices (ACIP), *MMWR*, May 28, 2010, Vol. 59, No. RR-20**
- **FDA Licensure of Quadravalent Human Papillomavirus Vaccine (HPV4, Gardasil) for Use in Males and Guidance from the Advisory Committee on Immunization Practices (ACIP), *MMWR*, May 28, 2010, Vol. 59, No. RR-20**

Vaccine Description

Gardasil® is a non-infectious recombinant, quadrivalent vaccine prepared from virus-like particles of HPV Types 6, 11, 16, and 18. HPV types 16 and 18 cause approximately 70% of cervical cancer. Types 6 and 11 cause approximately 90% of genital wart cases.
This product does not contain a preservative or antibiotics. After thorough agitation, it is a white, cloudy liquid.

Cervarix® is a Human papillomavirus bivalent (types 16 and 18) vaccine, recombinant] for the prevention of cervical pre-cancers and cervical cancer associated with oncogenic human papillomavirus (HPV) types 16 and 18 for use in girls and young women (aged 10-25).

It is important to emphasize these points:

- Females should continue to have routine cervical cancer screening as recommended by their healthcare provider.

- Females do not need to get an HPV test, Pap test **or pregnancy test** before receiving vaccine. If the person is already infected, the tests cannot tell which type of HPV she has. There are many types of HPV and vaccination would provide protection against infection with those types not already acquired.

Brand Names & Manufacturer

Gardasil®	(HPV4)	Merck & Co., Inc.
Cervarix®	(HPV2)	GlaxoSmithKline

Eligible Groups for State Supplied Vaccine

For Adults, Children, and Adolescents, see "Eligibility for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults" located in the front of this section.

Recommended HPV Vaccine Schedule [1, 2]

Vaccine	Dose 1	Dose 2	Dose 3
Gardasil® [3,4,5,6]	11-12 years of age	1- 2 months after Dose	6 months after Dose 1
Cervarix® [4,6]	11-12 years of age	1-2 months after Dose	6 months after Dose 1

[1] Catch-up vaccination is recommended for **males** and females 13-26 years of age who have not been previously vaccinated or who have not completed the full series.
Note: Interrupted vaccine schedules
If the HPV vaccine schedule is interrupted, the vaccine series does not need to be restarted.
[2] HPV vaccines are most effective for both males and females when given before exposure to HPV through sexual contact.
[3] The ACIP recommendation is for this vaccine series to be administered to **males** and females aged 11-12 years at their pre-adolescent visit to their healthcare provider. HPV4 may be administered in a 3-dose series to males aged 9 through 18 years to reduce their likelihood of acquiring genital warts.
[4] HPV4 or HPV2 is recommended for the prevention of cervical precancers and cancers in females.
[5] HPV4 is recommended for prevention of cervical cancers and precancers and genital warts.
[6] Whenever possible, the same HPV vaccine product should be use for all doses in the series

Recommended Age & Dose Intervals

Vaccine	Recommended age for first dose	Minimum interval Dose 1 to Dose 2	Minimum Interval [1] Dose 2 to Dose 3
Gardasil®	11-12 years (minimum age is 9 years) [2]	4 weeks	12 weeks
Cervarix ®	11-12 years (minimum age is 9 years)	4 weeks	12 weeks

[1] The minimum interval between the first and third dose is 24 weeks.
[2] This vaccine is licensed for use in females and males 9-26 years of age.

Recommended Dosage and Route

0.5mL administered intramuscularly
In the deltoid region of the upper arm or in the higher anterolateral area of the thigh

Contraindications and Precautions

Contraindications:

1. Previous anaphylactic or allergic reaction to yeast, to any other vaccine component, or to a previous dose of HPV vaccine.
2. Cervarix does not contain yeast as a vaccine component

Precautions:

1. Persons with moderate or severe acute illness
2. Persons with impaired immune responsiveness either from disease or medication can receive the vaccine, but may have reduced antibody response to active immunization.
3. Not recommended for use in pregnant women. However, pregnancy testing is not needed before vaccination. Any exposure to vaccine during pregnancy should be reported to the appropriate vaccine pregnancy registry:
    - 1-800-986-8999 (Merck and Co. Inc. for quadrivalent HPV vaccine)
    - 1-888-452-9622 (GlaxoSmithKline for bivalent HPV vaccine)
4. Bivalent HPV (Cervarix) vaccine in prefilled syringes is contraindicated for persons with anaphylactic latex allergy.

Special Situations:

1. Lactating women can receive HPV vaccine.
2. Syncope can occur after vaccination, most commonly among adolescents and young adults. To avoid serious injury related to syncopal episode, observation for 15 minutes after administration is recommended.

Simultaneous Vaccine Administration

May be administered simultaneously with any of the following routinely recommended vaccines:

Tdap, Td, MMR, Varicella, Hepatitis A, Hepatitis B, IPV, MCV4, MPSV4, Influenza, and PPSV23

NOTE: Can be administered to lactating women.

Georgia Department of Public Health
Immunization Office Guidelines

VACCINES TO PREVENT INFLUENZA

The purpose of these guidelines is to provide public health clinics with a summary of the current Recommendations of the Advisory Committee on Immunization Practices (ACIP) for each of the vaccines supplied by the Georgia Immunization Program. These guidelines were developed from the pertinent Vaccine Resolution from the Vaccines for Children Program and the references below and will be updated as needed. The guidelines are not all inclusive and when more information is needed, the following publications should be referenced:

- ACIP Vaccine Resolution for the Vaccines for Children Programs (VFC), (Resolution No. 2/08-1)
- 2012 Red Book: Report of the Committee on Infectious Diseases published by the American Academy of Pediatrics
- Epidemiology and Prevention of Vaccine Preventable Diseases, 12th edition, 2nd printing.
- "Prevention & Control of Influenza," *MMWR*, August 8, 2008, Vol. 57, No. RR-07
- "Prevention & Control of Seasonal Influenza with Vaccines," *MMWR,* July 31, 2009, Vol.58, No. RR-08
- the provisional guidelines for the Use of Influenza Vaccines at: *http://www.cdc.gov/vaccines/recs/provisional/downloads/flu-vac-mar-2010-508.pdf*
- "Prevention & Control of Influenza with Vaccines." *MMWR,* August 6, 2010, Vol. 59. No. RR-08
- Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), *MMWR,* August 18, 2011, Vol. 60

Vaccine Description

Trivalent influenza vaccine (TIV) contains hemaglutinins of 3 strains of virus (typically two (2) type A and one (1) type B), representing the influenza viruses likely to circulate in the U.S. in the upcoming winter. This injectable vaccine is inactivated, but because the viruses were initially grown on embryonated hens' eggs, the vaccine might contain limited amounts of residual egg protein. Manufacturers may use different compounds to inactivate the viruses and add antibiotics to prevent bacterial contamination during production. Therefore, package inserts should be consulted for additional information regarding potential allergenic components.

Live attenuated influenza vaccine (LAIV) is a live, trivalent nasally- administered vaccine. It contains the same strains of influenza virus as the inactivated vaccine. It is manufactured in a manner similar to the TIV so the same precautions should be taken with regard to potential allergenic components.

Brand Name & Manufacturer

Fluzone®	Sanofi Pasteur
Fluzone Intradermal[1]	
Fluzone High-Dose®[1]	
Fluvirin®	Novartis
FluMist®	MedImmune
Fluarix® [1]	GlaxoSmithKline
Flulaval® [1]	GlaxoSmithKline
Afluria [1]	CSL
Agriflu[1]	Novartis

[1] Fluarix, ® Flulaval™, Afluria, Agriflu and Fluzone High-Dose and Fluzone intradermal are **currently not supplied by the Georgia Vaccines for Children Program.** Providers administering these vaccines should consult the current year's ACIP recommendations and /or the individual vaccine package inserts and develop their own protocols/guidelines. The recommendations of the Advisory Committee on Immunization Practices (ACIP) may differ in some respects from the information found in the package insert for these particular vaccines.

NOTE: Only split-virus vaccines are available in the United States due to the increased potential for febrile reactions with whole-virus preparations.

Eligible Groups for State Supplied Vaccine

The information included in this section is intended for use in administering Fluzone® and Fluvirin® available from VFC. All single dose units are preservative-free; the multidose vials contain preservative. Administer the specific vaccine formulations as indicated below:

- Fluzone® (Sanofi Pasteur) 0.25mL prefilled syringes (no preservative)---for Children ages **6 months through 35 months**
- Fluzone® (Sanofi Pasteur) 0.5 ml prefilled syringes (no preservative)---for children **Greater than or equal to 36 months of age**
- Fluzone® (Sanofi Pasteur) 10-dose vial (with preservative)---use product in appropriate dosage for children **greater than or equal to 6 months of age**
- Fluvirin® (Novartis)---10 dose vial (with preservative) for children **greater than or equal to 4 years of age**
- FluMist® (MedImmune)---0.2 mL intranasal spray applicator for healthy children Greater than or equal to **2 years of age**

For additional guidelines for Adults, Children, and Adolescents, see "Eligibility for Vaccines Supplied by the Georgia Immunization Program for Children, Adolescents, and Adults" located in the front of this section.

Routine annual influenza vaccination is recommended for all persons aged greater than or equal to 6 months. To permit time for production of protective antibody levels vaccination should optimally occur before onset of influenza activity in the community, and providers should offer vaccination as soon as vaccine is available. Vaccination also should continue to be offered throughout the influenza season.

Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), *MMWR,* August 18, 2011, Vol. 60

To avoid missed opportunities for vaccination of persons at high risk for serious complications, such persons should be offered vaccine beginning in September during routine health-care visits or during hospitalizations, if vaccine is available.
(Centers for Disease Control and Prevention. Prevention and Control of Influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR,* July 31, 2009/Vol. 58 No. RR-08)

For guidance on conducting mass influenza clinics, and for prioritizing groups in the event of an influenza vaccine shortfall, go to
http://www.cdc.gov/flu/professionals/vaccination/pdf/vax_clinic.htm

Recommended Influenza Vaccine Schedule[1, 2, 3, 4]

[4] Pregnant and Postpartum Women ACIP Routine influenza vaccination is recommended for all persons aged greater than or equal to 6 months.
[1] To avoid missed opportunities for vaccination of persons at high risk for serious complications, such persons should be offered vaccine beginning in September during routine health-care visits or during hospitalizations, if vaccine is available.
(Centers for Disease Control and Prevention. Prevention and Control of Influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR, August 2, 2010/Vol. 59 No. RR-08)
[2] For more information on seasonal flu to http://www.flu.gov/.
[3] If influenza antiviral medications are administered within 2 weeks after receipt of LAIV, the vaccine dose should be repeated 48 or more hours after the last dose of antiviral medication. Persons receiving antivirals within the period 2 days before to 14 days after vaccination with LAIV should be revaccinated at a later date with any approved vaccine formulation.
Vaccination of pregnant women protects women and newborns. The American College of Obstetricians and Gynecologists and the American Academy of Family Physicians also have previously recommended routine vaccination of all pregnant women. Women who are postpartum are also at risk for influenza complications and should be vaccinated. **No preference is indicated for use of TIV that does not contain thimerosal as a preservative for any group recommended for vaccination, including pregnant and postpartum women**. LAIV is not licensed for use in pregnant women, but postpartum women can receive LAIV or TIV. Pregnant and postpartum women do not need to avoid contact with persons recently vaccinated with LAIV.
http://www.cdc.gov/flu/professionals/acip/specificpopulations.htm

∗ *Vaccines to Prevent Influenza,* Georgia Immunization Program Manual/Department of Public Health, Recommended Schedule and Guidelines---8/2011.

Recommended Doses & Intervals [6 7]					
Vaccine	**Age Group**	**Dosage & Route**	**Number of Doses**	**Minimum Interval from dose 1 to 2**	**Pregnancy Category**
Trivalent Inactivated Vaccine (TIV)					
Fluzone®	6-35 months 3 through 8 years	0.25 mL IM 0.5 mL IM	1 or 2[1] 1 or 2[1]	28 days 28 days	
	Greater than or equal to 9 years	0.5 mL IM	1	-------	**C**
Fluzone® High Dose	Greater than or equal to 65 years	0.5 mL IM	1	-------	
Fluzone Intradermal	18 through 64 years	Intradermal 0.1 mL	1	------	**B**
Fluvirin® [2]	4 through 8 years	0.5 mL IM	1 or 2[1]	28 days	**C**
	Greater than or equal to 9 years	0.5 mL IM	1	---------	
Fluarix®	36 months and older	0.5 mL IM	1 or 2[1]	28 days	**B**
Flulaval®	18 years of age and older	0.5 mL IM	1	---------	**B**
Afluria®[3]	9 years of age and older	0.5 mL IM	1	---------	**C**
Live Attenuated Influenza Vaccine (LAIV)					
FluMist® [4]	Greater than or equal to 24 months through 8 years	0.2 mL [5] Intranasally	1 or 2[1]	28 days	Do not use in pregnancy
FluMist® [4]	Greater than or equal to 9 years through 49 years of age	0.2 mL [5] intranasally	1	--------	

For administration instructions.
[1] Children aged 6 months through 8 years who did not receive seasonal influenza vaccine during the 2010–11 influenza season should receive 2 doses at least 4 weeks apart for the 2011–12 season. Those children aged 6 months through 8 years who received greater than or equal to 1 dose of the 2010–11 seasonal vaccine require 1 dose for the 2011–12 season.
[2] Not licensed to be used in children less than 4 years of age.
[3] The Advisory Committee on Immunization Practices recommends Afluria not be used in children aged 6 months through 8 years because of increased reports of febrile reactions in this age group.
[4] Licensed for use only in **healthy, nonpregnant** persons 2 through 49 years of age. Children, 2-4 years, whose parents or caregivers report their child has had an asthma or wheezing episode noted in the medical record within the past 12 months should not receive Flumist.
[5] Administer as 0.1 mL in each nostril.
[6] All children ages 6 months to less than 8 years receiving the influenza vaccine for the first time and requiring 2 doses do not have to use the same type of vaccine for both doses. The first and second doses do not have to match; live or inactivated vaccine can be used for either dose. The doses should be separated by at least one month.
[7] The ACIP does not have a preference for any influenza vaccine presentation or formula.

***See package insert on Fluzone Intradermal Influenza Vaccine at**
http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM195479.pdf
For administration instructions.

If a person reports a severe (anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain natural rubber should not be administrated unless the benefit of vaccination outweighs the risk for a potential allergic reaction. The following 2011-2012 flu presentations have latex in the syringe tip cap: Fluzone, Fluzone High-Dose, Fluvirin and Fluarix.

Pregnancy Risk Categories	
A	Controlled studies in pregnant women fail to demonstrate a risk to the fetus in the first trimester with no evidence of risk in later trimesters. The possibility of fetal harm appears remote.
B	Either animal-reproduction studies have not demonstrated a fetal risk but there are not controlled studies in pregnant women, or animal-reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester and there is no evidence in later trimesters.
C	Either studies in animals have revealed adverse effects on the fetus and there are no controlled studies in women, or studies in women and animals are not available. Drugs should be given only if the potential benefits justify the potential risk to the fetus.
D	There is positive evidence of human fetal risk, but the benefits from use in pregnant may be acceptable despite the risk (e.g., if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective).
X	Studies in animals or humans beings have demonstrated fetal abnormalities or there is evidence of fetal risk based on human experience, or both, and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. The drug is contraindicated in women who are or may become pregnant.

Contraindications/ Precautions (TIV or LAIV)

Contraindications Trivalent Inactivated Influenza Vaccine (TIV)

- **Prior life-threatening reaction to previous influenza vaccination;** hypersensitivity to any component of the formulation (e.g. thimerosal, or any antibiotic used as a preservative).
- Moderate or severe illnesses with or without fever. Persons with moderate or severe illness should be immunized as soon as they have recovered from the acute phase of the illness. Minor illnesses (e.g., upper respiratory tract infection, allergic rhinitis) with or without fever should not contraindicate the use of influenza vaccine.
- Pregnant women should avoid TIV influenza vaccine containing thimerosal.

Contraindications specific to **Live Attenuated Influenza Vaccine (LAIV**)

- Persons with a history of hypersensitivity, including anaphylaxis, to any of the components of LAIV or to eggs (e.g. eggs, thimerosal, or any antibiotic used as a preservative).
- Moderate or severe illnesses with or without fever. Persons with moderate or severe illness should be immunized as soon as they have recovered from the acute phase of the illness. Minor illnesses (e.g., upper respiratory tract infection, allergic rhinitis) with or without fever should not contraindicate the use of influenza vaccine.
- Persons aged less than 2 years or those aged greater than or equal to 50 years.
- Persons with any of the underlying medical conditions that serve as an indication for routine influenza vaccination, including **asthma**, reactive airways disease, or other chronic disorders of the pulmonary or cardiovascular systems; other underlying medical conditions, including such metabolic diseases as diabetes, renal dysfunction, and hemoglobinopathies; or known or suspected immunodeficiency diseases or immunosuppressed states.

- 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.
- Children or adolescents receiving aspirin or other salicylates (because of the association of Reye syndrome with wild-type influenza virus infection).
- Persons with a history of Guillain-Barré Syndrome (GBS) within six weeks after receiving influenza vaccination.
- Pregnant women.
- Healthcare Providers, household/ close contacts of severely immunosuppressed persons requiring a protective environment.

Precautions specific to TIV

- **Anaphylactic reaction to eggs. See Figure 2 for persons who report allergy to eggs. If vaccination is administered, use TIV rather than LAIV.**

Precautions (TIV or LAIV)

- History of GBS following influenza vaccination is a precaution for administering Trivalent Influenza Vaccine. Avoiding vaccinating persons who are known to have experienced GBS within 6 weeks after a previous influenza vaccination is prudent. Although data are limited, the established benefits of influenza vaccination might outweigh the risks for many persons who have a history of GBS and who are also at high risk for severe complications from influenza.
- The tip cap and rubber plunger of Fluarix, Fluzone, Fluzone High-Dose, and Fluvirin. pre-filled syringes contain dry natural latex rubber and may cause allergic reactions in latex sensitive individuals.
- Immunization should be delayed in a patient with an active neurologic disorder, but **should be considered when the disease process has been stabilized.**
- Centers for Disease Control and Prevention. Prevention and Control of Influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP). **MMWR July 31, 2009/*Vol. 58, RR-08***

Recommended Dosage and Route
0.25 mL or 0.5 mL administered intramuscularly for TIV. For adults and older children, the recommended site of vaccinations is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh. * 0.1mL administered intradermally for TIV** 0.2 mL administered intranasally for LAIV*** *Please refer to the Georgia Immunization Program Manual Chapter 13 (Quality Assurance-Attachment D) on vaccine administration recommendations for appropriate site and needle size. **See package insert on Fluzone Intradermal Influenza Vaccine at http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM195479.pdf For administration instructions. *** **NOTE:** Before using the nasal spray, gently blow your nose to clear the nostrils. If the vaccine recipient sneezes after administration, the dose should not be repeated. However, if nasal congestion is present that might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration should be considered until resolution of the illness, or TIV should be administered instead.

FIGURE 1. Influenza vaccine dosing algorithm for children aged 6 months through 8 years — Advisory Committee on Immunization Practices (ACIP), 2011–12 influenza season

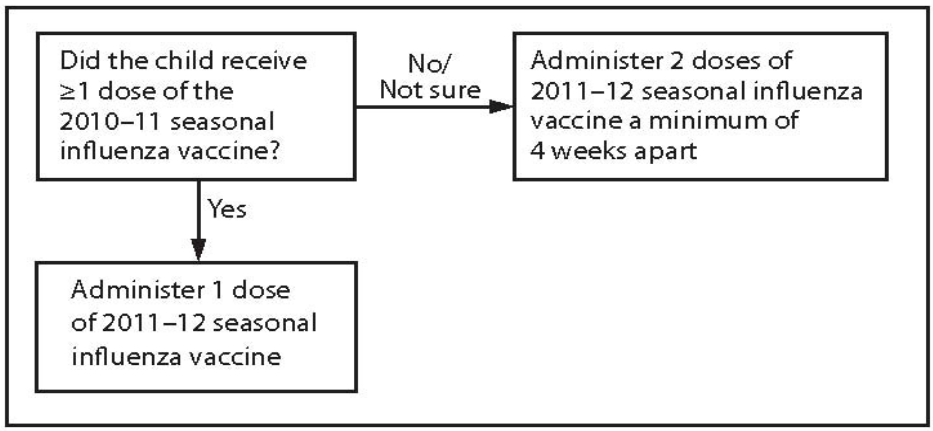
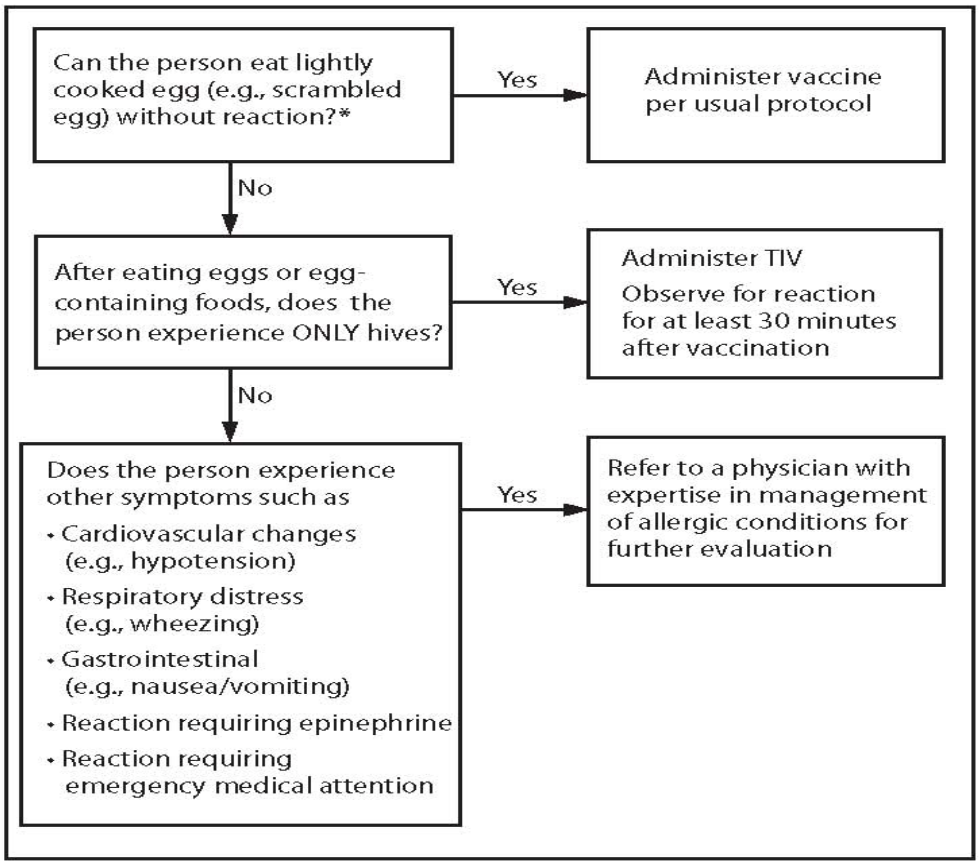


FIGURE 2. Recommendations regarding influenza vaccination for persons who report allergy to eggs — Advisory Committee on Immunization Practices (ACIP), 2011–12 influenza season



* Persons with egg allergy might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy.

Client Education / Counseling

1. Provide the current Vaccine Information Sheet to the patient, guardian, or caretaker prior to immunization and answer any questions related to the vaccine prior to giving the immunization.

Simultaneous Vaccine Administration

May be administered simultaneously with any of the following routinely recommended vaccines: DTaP, Tdap, Td, RV, MMR, Varicella, Hib, Hepatitis A, Hepatitis B, IPV, PPSV23, PCV13, HPV, Zoster, MCV4, and MPSV4

NOTE: See current ACIP statement regarding FluMist® and simultaneous administration with other vaccines. See package insert for the safety and immunogenicity of this practice.

2. Emphasize that inactivated influenza vaccine contains noninfectious killed viruses and cannot cause influenza.

3. Coincidental respiratory disease unrelated to influenza vaccination can occur after vaccination.

4. If two doses are required to achieve immunity, arrange for information about need for second dose and stress importance of second dose of vaccine.

5. Stress the importance of hand hygiene.

6. Support staying at home if ill.

FOLLOW UP

Patients who do not have regularly scheduled visits during the fall should be reminded by mail, telephone or other means of the need for vaccination. Use the call back system on the immunization registry.

CONSULTATION/REFERRAL

1. Refer to physician for complications of influenza, and/or history of Guillain-Barré Syndrome.

2. Refer to physician with expertise in management of allergic conditions for further evaluation for persons who report allergy to eggs or severe allergic reaction to previous influenza vaccinations.

REFERENCES

1. CDC, *Key Facts About Seasonal Influenza (Flu)*, (July 14, 2011) <http://www.cdc.gov/flu/keyfacts.htm> (July 14, 2011)).
2. Georgia Department of Community Health/Division of Public Health, *Georgia Immunization Program Manual, Immunization Program Guidelines - Vaccines to Prevent Influenza, Recommended Schedule and Guidelines*, June 2009 (8/27/09).
3. *Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, *MMWR*, CDC, July 31, 2009, volume 58, No. RR-08,
4. *Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, *MMWR*, August 6, 2010, Vol. 59. No.RR-8. < http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5908a1.htm>
5. *Licensure of a High-Dose Inactivated Influenza Vaccine for Persons Aged ≥65 Years (Fluzone High-Dose) and Guidance for Use, Weekly MMWR, April 30, 2010/ 59 (16): 485-486.*
6. **Intradermal Influenza (Flu) Vaccination <http://www.cdc.gov/flu/protect/vaccine/qa_intradermal-vaccine.htm>**

8. *Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR*, August 18, 2011, Vol. 60

Georgia Department of Community Health
Immunization Office Vaccine Guidelines

VACCINES TO PREVENT MEASLES, MUMPS, AND RUBELLA

The purpose of these guidelines is to provide public health clinics with a summary of the current Recommendations of the Advisory Committee on Immunization Practices (ACIP) for this vaccine which is supplied by the Georgia Immunization Office. These guidelines were developed from the pertinent Vaccine Resolution from the Vaccines for Children Program and the references below and will be updated as needed. The guidelines are not all inclusive and when more information is needed, the following publications should be referenced:

- "Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP) for the Control and Elimination of Mumps," *MMWR*, Vol. 55/June 1, 2006.
- "Measles, Mumps, and Rubella---Vaccine Use and Strategies for Elimination of Measles, Rubella, and Congenital Rubella Syndrome and Control of Mumps," *MMWR*, May 22, 1998, Vol. 47, No. RR-8
- the ACIP Measles, Mumps, Rubella, and Varicella Vaccine Resolution for the Vaccines for Children Program (VFC), (Resolution No. 6/06-3)
- 2012 Red Book: Report of the Committee on Infectious Diseases published by the American Academy of Pediatrics
- *Epidemiology and Prevention of Vaccine Preventable Diseases, 12th edition, 2nd printing.*
- "ACIP Provisional Recommendations for Measles-Mumps-Rubella (MMR) 'Evidence of Immunity' Requirements for Healthcare Personnel", August 28, 2009, linked at *http://www.cdc.gov/vaccines/recs/provisional/downloads/mmr-evidence-immunity-Aug2009-508.pdf*

Vaccine Description

Measles, mumps, and rubella vaccines are live virus vaccines and are available in monovalent form (Attenuvax®, Mumpsvax®, and Meruvax®, respectively) and in combinations as measles-mumps-rubella or MMR (M-M-R II®), and measles-mumps-rubella-varicella or MMRV (ProQuad®).

- The ACIP recommends that the combined vaccine MMR be used when any of the individual components is indicated, unless one component is contraindicated.
- **Single antigen** measles, mumps or rubella vaccines should be used only if:
    1. there is a specific contraindication to one component of the MMR vaccine; or
    2. the child is known to be immune or adequately vaccinated for one or more of the diseases; or
    3. measles vaccine is indicated for a child <1 year of age in an outbreak situation. (Routine vaccination should be completed with MMR, i.e. two doses given at appropriate intervals, on or after the first birthday.)

Brand Name & Manufacturer

VACCINES	MANUFACTURERS
Measles (Attenuvax®)[1]	Merck
Mumps (Mumpsvax®)[1]	Merck
Rubella (Meruvax®)[1]	Merck
MMR (M-M-R II®)	Merck
Measles-rubella (M-R-Vax®)[2]	Merck
Rubella-mumps (Biavax®)[2]	Merck
Measles-mumps-rubella-varicella (ProQuad®)	Merck
(See section on "Combination Vaccines")	Merck

[1] Not available from the GA Immunization Office. Manufacturer provides these only in packages containing 10 single doses.

[2] No longer available from the manufacturer

Eligible Groups for State Supplied Vaccine

For Adults, Children, and Adolescents, see "Eligibility for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults" located in the front of this section.

Recommended MMR Vaccine Schedule[1]

VACCINES	Dose 1[2]	Dose 2
MMR	12-15 months[2, 3]	4-6 years[2]

[1] Acceptable presumptive evidence of immunity to mumps is now the documentation of:

- 1 dose of mumps vaccine for preschool-aged children and adults not at high risk; and
- 2 doses of mumps vaccine for school-aged children grades K-12, and for adults at high risk (i.e., persons who work in healthcare facilities, international travelers, and students at post-high school educational institutions.)

[2] May be given as MMR or MMRV, if both MMR and varicella are indicated. See "Combination Vaccines" in this section for more information. Children whose vaccination history indicates they have received single antigen measles and/or mumps vaccine, should receive MMR to complete the 2nd dose requirement for each.

[3] Previously unvaccinated children beyond the recommended 12-15 months of age should receive the 1st dose of MMR as soon as possible. The 2nd dose can be provided at any age from 13 months on, as long as there has been an interval of at least 28 days between doses.

Minimum Age & Dose Intervals[1]

VACCINES	Minimum age	Minimum interval from dose 1 to 2
Dose 1	12 months[2]	-------
Dose 2	13 months	28 days

[1] MMR vaccine may offer some protection to persons exposed to measles if it is administered within 72 hours of exposure.

[2] Infants as young as 6 months of age may be given measles vaccine in an outbreak situation, or if it is recommended before travel to a foreign country where the child might be at risk for contracting measles. However, doses of MMR administered before 1 year of age should not be counted. Any child receiving vaccine before 1 year of age should be re-vaccinated at 12-15 months of age, with an additional dose at the time of school entry. Doses of any measles-containing vaccine should be separated by at least 28 days.

Recommended Dosage and Route

0.5 mL administered subcutaneously

'Evidence of Immunity' Requirements for Healthcare Personnel

Adequate presumptive evidence of immunity to measles, rubella, and mumps for persons who work in health care facilities:

Measles:

Documented administration of two doses of live measles virus vaccine1 *or*
Laboratory evidence of immunity or laboratory confirmation of disease *or*
Born before 1957[123]

Rubella

Documented administration of one dose of live rubella virus vaccine1 *or*
Laboratory evidence of immunity or laboratory confirmation of disease *or*
Born before 1957 (except women of childbearing age who could become pregnant)[123]

Mumps

Documented administration of two doses of live mumps virus vaccine1 *or*
Laboratory evidence of immunity or laboratory confirmation of disease *or*
Born before 1957[123]

[1] May vary depending on current state or local requirements.
[2] For unvaccinated personnel born before 1957 who lack laboratory evidence of measles, mumps and/or rubella immunity or laboratory confirmation of disease, healthcare facilities should consider vaccinating personnel with two doses of MMR vaccine at the appropriate interval (for measles and mumps) and one dose of MMR vaccine (for rubella), respectively.
[3] For unvaccinated personnel born before 1957 who lack laboratory evidence of measles, mumps and/or rubella immunity or laboratory confirmation of disease, healthcare facilities should recommend two doses of MMR vaccine during an outbreak of measles or mumps and one dose during an outbreak of rubella.
http://www.cdc.gov/mmwr/preview/mmwrhtml/00050577.htm

Contraindications and Precautions

A. Contraindications

1. Previous anaphylactic reactions to any vaccine component (i.e. gelatin or gelatin-containing products, or topically or systemically administered neomycin), or following a previous dose of MMR vaccine
2. Moderate or severe illness with or without fever
3. Pregnancy - Because of the theoretical risk to the fetus, women of childbearing age should receive MMR or its component vaccines only if they state they are not pregnant and are counseled not to become pregnant for 4 weeks after vaccination. However, MMR or measles, mumps, or rubella vaccination inadvertently given during pregnancy should not ordinarily be a reason to consider interruption of pregnancy.
   Known altered immunocompetence - Replication of vaccine viruses can be enhanced in persons with immune deficiency diseases and in persons with immunosuppression. Severe immunosuppression may be caused by many disease conditions (e.g., congenital immunodeficiency, HIV infection, hematologic or generalized malignancy) and by therapy with immunosuppressive agents, including large doses of corticosteroids. The degree to which affected persons are immunocompromised can depend on the disease, its severity, and the treatment stage. Ultimately, the patient's physician must assume responsibility for determining whether the patient is severely immuno-compromised based on clinical and laboratory assessment.

B. Precautions

1. Thrombocytopenia---Persons who have an episode of thrombocytopenic purpura within 6 weeks of vaccination with MMR should weigh the risk versus the benefit of receiving a 2nd dose. Serologic testing of immunity should be considered in lieu of MMR vaccination.
2. Recent receipt of blood, plasma, or immune globulin (in past 3-11 months) --- Blood and other antibody containing blood products, including immune globulin (IG) preparations, can diminish the immune response to MMR or its individual component vaccines. MMR or its component vaccines should be given at least 2 weeks before administration of an immune globulin or blood or blood-containing product or deferred until 3 or more months after administration of such preparations. (See Table 4 in this chapter for more specific guidelines regarding the time to wait before administering vaccine.)
3. Tuberculin skin tests --- MMR vaccine may interfere with the response to a tuberculin test. If such testing is otherwise indicated, it can be done either on the same day as MMR vaccine is administered or 4-6 weeks later.
4. Corticosteroid therapy --- Such therapy usually does not contraindicate the administration of live virus vaccines such as MMR when therapy is: a) short term (i.e. <14 days) low-to-moderate dose; b) low-to-moderate dose administered daily or on alternate days; c) long term alternate day treatment with short-acting preparations; d) physiologic maintenance doses (replacement therapy); or e) administered topically (skin or eyes), by aerosol, or by intra-articular, bursal, or tendon injection. Doses that are considered to be immunosuppressive are those equivalent to or greater than a prednisone dose of 2 mg/kg of body weight per day or a total of 20 mg per day. (For further information on this precaution, see the ACIP Recommendations Statement listed in the introductory paragraph.)

Simultaneous Vaccine Administration
May be administered simultaneously with any of the following routinely recommended vaccines: DTaP, Tdap, Td, Hib, Hepatitis A, Hepatitis B, Polio, Varicella, PCV13 or PPSV23, MCV4, HPV, and Influenza

Georgia Department of Public Health
Immunization Office Vaccine Guidelines

VACCINES TO PREVENT MENINGOCOCCAL DISEASE

The purpose of these guidelines is to provide public health clinics with a summary of the current Recommendations of the Advisory Committee on Immunization Practices (ACIP) for each of the vaccines supplied by the Georgia Immunization **Office**. These guidelines should serve as a quick reference for clinics administering **A) meningococcal conjugate (MCV4) and B) meningococcal polysaccharide (MPSV4) vaccines**. These guidelines were developed from the pertinent Vaccine Resolution from the Vaccines for Children Program and the references below and will be updated as needed. The guidelines are not all inclusive and when more information is needed, the following publications should be referenced:

- Notice to Readers: Recommendation from the Advisory Committee on Immunization Practices (ACIP) for Use of Quadrivalent Meningococcal Conjugate Vaccine (MCV4) in Children Aged 2-10 Years at Increased Risk for Invasive Meningococcal Disease, *MMWR*, December 7, 2007, Vol. 56, No. RR-48
- Notice to Readers: Revised Recommendations of the Advisory Committee on Immunization Practices to Vaccinate All Persons Aged 11-18 Years with Meningococcal Conjugate Vaccine, *MMWR*, August 10, 2007, Vol. 56, No. RR-31
- "Prevention and Control of Meningococcal Disease," *MMWR*, May 27, 2005, Vol. 54, No. RR-7
- "Control and Prevention of Meningococcal Disease and Control and Prevention of Serogroup C Meningococcal Disease: Evaluation and Management of Suspected Outbreaks," *MMWR*, February 14, 1997, Vol. 46, No. RR-5
- ACIP Vaccines to Prevent Meningococcal Disease, Vaccine Resolution for the Vaccines for Children Programs (VFC), (Resolution No. **10-10-1**)
- 2012 Red Book: Report of the Committee on Infectious Diseases published by the American Academy of Pediatrics
- Epidemiology and Prevention of Vaccine Preventable Diseases, 12th edition, 2nd printing.
- **CDC. Updated Recommendation from the Advisory Committee on Immunization Practices (ACIP) for revaccination of persons at prolonged increased risk for meningococcal disease. *MMWR,* September 25, 2009, Vol. 58, No. RR-37**
- **CDC. Updated Recommendations for Use of Meningococcal Conjugate Vaccines (ACIP), 2010, *MMWR,* January 28, 2011, Vol. 60, No. RR-3**

A. Meningococcal Conjugate Vaccine (MCV4)

Vaccine Description

- Meningococcal (Groups A, C, Y, and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (MCV4) contains *Neisseria meningitidis* serogroup A, C, Y, and W-135 capsular polysaccharide antigens individually conjugated to diphtheria toxoid protein. MCV4 vaccine is available only in single dose vials. No preservative or adjuvant is added during manufacture.
- Menactra® was licensed in January, 2005 for use in persons **11**-55 years of age, and relicensed to include persons 2-10 years of age in October, 2007. Protective antibody levels are usually achieved within 7-10 days of vaccination.
- MENVEO was licensed in **2011** for use in persons **2**-55 years of age.

Brand Names and Manufacturer

VACCINE	MANUFACTURER
Menactra®	sanofi pasteur
MENVEO	Novartis

Eligible Groups for State Supplied MCV4

For Adults, Children, and Adolescents, see "Eligibility for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults" located in the front of this section.

ACIP Recommendations for Administration of MCV4

In addition to the priority categories listed above, ACIP recommends routine vaccination for certain other persons who are at increased risk for meningococcal disease. Due to limited funds, the state does not supply vaccine for these additional categories. These guidelines are meant to provide information for those districts and clinics that administer this vaccine from privately purchased stock. The following populations are at increased risk for meningococcal disease and are recommended to be vaccinated:

- College freshman who live in dormitories
- Military recruits
- Persons who will be traveling to or reside in areas in which meningococcal disease is hyperendemic or epidemic
- Research, industrial, and clinical laboratory personnel who are routinely exposed to *N. meningitidis* in solutions that may be aerosolized
- Patients with anatomic or functional asplenia and patients with terminal complement deficiency

Other populations that may consider vaccination with MCV4:

- HIV–infected persons, although the efficacy of MCV4 among HIV-infected patients is unknown
- Persons 2-55 years of age who do not have high risk factors, but wish to decrease their risk for meningococcal disease

Syncope

- Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. If syncope develops, patients should be observed until the symptoms resolve.

Use of Meningococcal Conjugate Vaccine (MCV4) vs. Meningococcal Polysaccharide Vaccine (MPSV4):

MCV4 is the preferred vaccine for people 2-55 years of age in these risk groups, but MPSV4 can be used if MCV4 is not available. MPSV4 should be used for adults over 55 who are at risk. (See Section B, MPSV4, of this document.)

MCV4 is not indicated for:

- The prevention of meningitis caused by other microorganisms or for the prevention of invasive meningococcal disease caused by *N. meningitidis* serogroup B
- The treatment of meningococcal infections
- Immunization against diphtheria

Recommended Doses and Intervals

TABLE 2. Summary of meningococcal conjugate vaccine recommendations, by risk group---Advisory Committee on Immunization Practices (ACIP), 2010

Risk group	Primary series	Booster dose
Persons aged 11 through 18 years	1 dose, preferably at age 11 or 12 years	At age 16 if primary dose at age 11 or 12 years
		At age 16 through 18 years if primary dose at age 13 through 15 years
		No booster needed if primary dose on or after age 16 years
HIV-infected persons in this age group	2 doses, 2 months apart	At age 16 years if primary dose at age 11 or 12 years
		At age 16 through 18 years if primary dose at age 13 through 15 years
		No booster needed if primary dose on or after age 16 years
Persons aged 2 through 55 years with persistent complement component deficiency* or functional or anatomical asplenia	2 doses, 2 months apart	Every 5 years
		At the earliest opportunity if a 1-dose primary series administered, then every 5 years
Persons aged 2 through 55 years with prolonged increased risk for exposure†	1 dose	Persons aged 2 through 6 years: after 3 years
		Persons aged 7 years or older: After 5 years§

Abbreviation: HIV= human immunodeficiency virus.

*Such as C_5--C_9, properidian, or factor D.

†Microbiologists routinely working with *Neisseria meningitidis* travelers to or residents of countries where meningococcal disease is hyperendemic or epidemic.

§If the person remains at increased risk.

MCV4	Recommended age for first dose	Booster Doses
Dose 1	11 years[1]	See Previous Page

[1] This vaccine is licensed for persons ≥2-55 years of age if indicated.

Recommended Dosage and Route

0.5 mL administered **intramuscularly**[1], preferably in the deltoid

[1] For guidance on the follow-up of vaccine doses inadvertently administered subcutaneously, rather than intramuscularly, please reference "Inadvertent Misadministration of Meningococcal Conjugate Vaccine---- United State, June---August, 2005," *MMWR*, September 22, 2006, Vol. 55 No. 37.

Contraindications

The following conditions are contraindications to the administration of MCV4:

1. **Allergy to vaccine components**
   Anaphylactic reaction to either MCV4 or MPSV4 or a constituent of either of these vaccines, including diphtheria toxoid (for MCV4) or dry natural rubber latex.
2. **Acute, moderate or severe illnesses with or without fever**
   Persons with moderate or severe illness should be immunized as soon as they have recovered from the acute phase of the illness. Minor illnesses (e.g. upper respiratory tract infection, allergic rhinitis) with or without fever should not contraindicate the use of meningococcal conjugate vaccine.
3. **Previous history of Guillain-Barré syndrome (GBS)[1,2]**

NOTE: MCV4 is a new vaccine and has not been studied as much as MPSV4 with regard to pregnant women. Women of childbearing age who become aware that they were pregnant at the time of MCV4 vaccination should contact their healthcare provider or the vaccine manufacturer.

[1] "Guillain-Barré Syndrome Among Recipients of Menactra® Meningococcal Conjugate Vaccine --- United States, June--July 2005," *MMWR,* October 14, 2005, Vol. 54, No. 40
[2] "Update: Guillain-Barré Syndrome Among Recipients of Menactra® Meningococcal Conjugate Vaccine-- United States, October 2005---February 2006," *MMWR*, April 7, 2006, Vol. 55, No. 13
[3] "Update: Guillain-Barré Syndrome Among Recipients of Menactra® Meningococcal Conjugate Vaccine -- United States, June 2005--September 2006," *MMWR*, October 20, 2006, Vol. 55. No. 41

Simultaneous Vaccine Administration

MCV4 may be administered simultaneously with any of the following routinely recommended vaccines:

DTaP, Tdap, Td, MMR, Varicella, Hepatitis A, Hepatitis B, IPV, Influenza, HPV, Hib, PCV13 and PPSV**23**

B. Meningococcal Polysaccharide Vaccine (MPSV4)

Vaccine Description

Meningococcal Polysaccharide Vaccine, Groups A, C, Y, and W-135 Combined (MPSV4) is a freeze-dried preparation of the group-specific polysaccharide antigens from *Neisseria meningitidis*, Group A, Group C, Group Y, and Group W-135. It is available in single dose (0.5mL) and 10 dose (5 mL) vials. The vials of diluent used to reconstitute single doses of vaccine are preservative-free. However, the 6 mL vial of diluent intended for reconstitution of the10 mL vial of freeze-dried vaccine contains thimerosal that has been added as a preservative. **Not indicated for treatment of meningococcal infections.** This vaccine was licensed for use in the United States in 1981.

Protective antibody levels may be achieved within 7-10 days after vaccination.

Brand Names and Manufacturer

VACCINE	MANUFACTURER
Menomune®	sanofi pasteur

Eligible Groups for State Supplied Vaccine (MPSV4)

The Georgia Immunization Program and the Georgia Vaccines for Children Program do not currently supply meningococcal polysaccharide vaccine (Menomune®) for any populations. These guidelines are meant to provide information for those districts and clinics that administer this vaccine using privately purchased stock.

ACIP Recommendations for Administration of MPSV4

ACIP recommends that MPSV4 should be used for adults age 56 and older who are at risk for meningococcal disease. The following high risk populations in that age group are recommended to be vaccinated with MPSV4:

- Persons who are traveling to countries in which *N. meningitidis* is hyperendemic or epidemic, particularly if contact with the local population will be prolonged
- Persons with terminal complement deficiencies and those with anatomic or functional asplenia
- Persons who are infected with HIV
- Research, industrial, and clinical laboratory personnel who routinely are exposed to *N. meningitidis* in solutions that may be aerosolized
- Persons who might have been exposed to meningococcal disease during an outbreak

Revaccination:

- Persons who previously were vaccinated with MPSV4 at age ≥7 years and are at prolonged increased risk should be revaccinated 5 years after their previous meningococcal vaccine with MCV4. Persons who previously were vaccinated at ages 2--6 years and are at prolonged increased risk should be revaccinated 3 years after their previous meningococcal vaccine with MCV4. Persons at prolonged increased risk for meningococcal disease include 1) persons with increased susceptibility such as persistent complement component deficiencies (e.g., C3, properdin, Factor D, and late complement component deficiencies), 2) persons with anatomic or functional asplenia, and 3) persons who have prolonged exposure (e.g., microbiologists routinely working with Neisseria meningitidis, or travelers to or residents of countries where meningococcal disease is hyperendemic or epidemic. Persons who remain in one of these increased risk groups indefinitely should continue to be revaccinated at 5-year intervals with MCV4.
- College freshmen living in dormitories who were vaccinated with MPSV4 ≥5 years previously are recommended to be vaccinated with MCV4.[1]

[1] **"Updated Recommendation from the Advisory Committee on Immunization Practices (ACIP) for Revaccination of Persons at Prolonged Increased Risk for Meningococcal Disease", MMWR, September 25, 2009/ 58(37)**

Recommended Doses and Intervals[1]

TABLE 2. Summary of meningococcal conjugate vaccine recommendations, by risk group---Advisory Committee on Immunization Practices (ACIP), 2010

Risk group	Primary Series	Booster dose
Persons aged 2 through 55 years with persistent component deficiency* or functional or anatomical asplenia	2 doses, 2 months apart	Every 5 years
		At the earliest opportunity if a 1-dose primary series administered, then every 5 years
Persons aged 2 through 55 years with prolonged increased risk for exposure†	1 dose	Persons aged 2 through 6 years: after 3 years
		Persons aged 7 years or older: after 5 years§

[1] Multidose vials of MPSV4 must be used within 35 days of reconstitution. Any doses remaining after that date should not be administered. **Vaccine from single dose vials should be used immediately after reconstitution.**
[2] MCV4 is the recommended vaccine for children 2 years of age and older
[3] In general, use of MPSV4 should be restricted to persons 2 years of age and older; however, children as young as 3 months of age may be vaccinated to elicit short-term protection against serogroup A meningococcal disease (two doses administered 3 months apart should be considered for children 3-18 months of age).

Abbreviation: HIV= human immunodeficiency virus.

*Such as C_5– – C_9, properidin, or factor D.

†Microbiologists routinely working with *Neisseria meningitidis* travelers to or residents of countries where meningococcal disease is hyperendemic or epidemic.

§If the person remains at increased risk.

Recommended Dosage and Route

0.5 mL administered **subcutaneously deltoid region**

Contraindications and Precautions

The following conditions are contraindications to the administration of MPSV4:

1. **Allergy to vaccine components**
   Anaphylactic reaction to either MPSV4 or MCV4 or a constituent of either of these vaccines, including diphtheria toxoid (for MCV4) or dry natural rubber latex.
2. **Acute, moderate, or severe illnesses with or without fever**
   Persons with moderate or severe illness should be immunized as soon as they have recovered from the acute phase of the illness. Minor illnesses (e.g. upper respiratory tract infection, allergic rhinitis) with or without fever should not contraindicate the use of meningococcal polysaccharide vaccine.
3. **Latex**
   The stoppers to the vials of lyophilized vaccine and diluents contain dry natural latex rubber that may cause allergic reactions in latex sensitive persons.
4. **Altered Immunocompetence**
   Persons who are immunosuppressed, including persons receiving immunosuppressive therapy, may have a diminished immune response to **MPSV4**

Based on data from studies involving use of meningococcal vaccines and other polysaccharide vaccines administered during pregnancy, altering meningococcal vaccination recommendations for MPSV4 during pregnancy is unnecessary.

Simultaneous Vaccine Administration

MPSV4 may be administered simultaneously with any of the following routinely recommended vaccines:
DTaP, Tdap, Td, MMR, Varicella, Hib, Hepatitis A, Hepatitis B, IPV, Influenza, PCV13, PPSV23, ZOS and HPV

Georgia Department of Public Health
Immunization Office Vaccine Guidelines

VACCINES TO PREVENT PNEUMOCOCCAL DISEASE

The purpose of these guidelines is to provide public health clinics with a summary of the current Recommendations of the Advisory Committee on Immunization Practices (ACIP) for each of the vaccines supplied by the Georgia Immunization Office. These guidelines should serve as a quick reference for clinics administering **A) pneumococcal conjugate (PCV**) and **B) pneumococcal polysaccharide (PPSV) vaccines**. The guidelines are not all inclusive and when more information is needed, the complete ACIP Recommendations statements should be referenced:

- "Preventing Pneumococcal Disease Among Infants and Young Children", *MMWR*, October 6, 2000, Vol.49, No. RR-9
- "Prevention of Pneumococcal Disease", *MMWR*, April 4, 1997, Vol. 46, No.RR-8.
- **ACIP Pneumococcal Vaccine Resolution for the Vaccines for Children Program (VFC), (Resolution No. 6/10-1)**
- Epidemiology and Prevention of Vaccine Preventable Diseases, 12th edition, 2nd .
- 2012 Red Book: Report of the Committee on Infectious Diseases published by the American Academy of Pediatrics
- **Licensure of a 13-Valent Pneumococcal Conjugate Vaccine (PCV13) and Recommendations for use Among Children---Advisory Committee on Immunization Practices (ACIP), 2010 can be found at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm**

A. Pneumococcal Conjugate Vaccine (PCV)

Vaccine Description

Pneumococcal Conjugate Vaccine (PCV13) is a 13-valent formulation composed of capsular polysaccharides derived from the seven pneumococcal serotypes contained in the current 7-valent Prevnar (4, 6B, 9V, 14, 18C, 19F, and 23F), and from six additional serotypes (1, 3, 5, 6A, 7F, and 19A). It is manufactured in the same way as Prevnar, by individual conjugation of each capsular polysaccharide to diphtheria protein. The vaccine is for active immunization of infants and children aged 6 weeks through 5 years against *Streptococcus pneumonia*–caused invasive pneumococcal diseases, such as pneumonia and meningitis, and against otitis media.

Brand Name & Manufacturer

VACCINE	MANUFACTURER
Prevnar13®	Pfizer

Eligible Groups for State Supplied Vaccine

Pneumococcal Conjugate Vaccine (PCV13) is supplied for:
For Adults, Children, and Adolescents, see "Eligibility for Vaccines Supplied by the Georgia Immunization Program for Children, Adolescents, and Adults" located in the front of this section.

This vaccine is supplied for all VFC eligible children ages 6 weeks through 59 months.

ACIP Recommendations for the use of PCV13

Children for Whom PCV13 is Recommended :

1) routine vaccination of all children aged 2--59 months with PCV13,
2) vaccination with PCV13 of children aged 60--71 months with underlying medical conditions that increase their risk for pneumococcal disease or complications, and
3) PCV13 vaccination of children who previously received 1 or more doses of PCV7

Recommended PCV13 Vaccine Schedule[3]

Among infants and children who have not received previous doses of 7-valent vaccine (PCV7) or PVC13, by age at first dose

The routinely recommended schedule is a primary series at 2, 4, and 6 months of age with a booster at 12-15 months of age. However, the recommended schedule for pneumococcal conjugate vaccine varies with the age of the child and the presence of underlying conditions.

Recommended Schedule for Previously Unvaccinated Infants and Children

Age at first dose	Primary PCV 13 Series[1]	PCV13 Booster[2] dose
2-6 months	3 doses, 2 months apart	1 dose at 12-15 months
7-11 months	2 doses, 2 months apart	1 dose at 12-15 months
12-23 months	2 doses, 2 months apart	None
24-59 months (healthy children)	1 dose	None
24-59 months (children with certain chronic diseases or immunocompromising conditions) See High-Risk vaccination table below.	2 doses	None

[1]Minimum interval between doses is 8 weeks except for children vaccinated at age <12 months for whom minimum interval between doses is 4 weeks. Minimum age for administration of first dose is 6 weeks.
[2]The booster dose should be administered at least 2 months (8 weeks) after the primary series is completed.
[3]Licensure of a 13-Valent Pneumococcal Conjugate Vaccine (PCV13) and Recommendations for use Among Children---Advisory Committee on Immunization Practices (ACIP), 2010 can be found at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm

Vaccination among children by risk group—Advisory Committee on Immunization Practices (ACIP) 2010	
Risk group	**Condition**
Immunocompetent children	Chronic heart disease[1]
	Chronic lung disease[2]
	Diabetes mellitus
	Cerebrospinal fluid leaks
	Cochlear Implants
Children with functional or anatomic asplenia	Sickle cell disease and other hemoglobinopathies Congenital or acquired asplenia, or splenic dysfunction
Children with immunocompromising conditions	HIV infection
	Chronic renal failure and nephritic syndrome
	Diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; or solid organ transplantation
	Congenital immunodeficiency[3]

[1] Particularly cyanotic congenital heart disease and cardiac failure
[2] 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).

Minimum Age and Dose Intervals For PCV_{13} Vaccine

Minimum age and dose intervals:

- Vaccination should not begin earlier than 6 weeks of age.
- The minimum age for the booster dose is 12 months of age.
- The minimum time interval between the last dose of the primary series and the booster dose is 8 weeks.
- If a child has received the polysaccharide vaccine (PPSV23), and is recommended to receive the conjugate vaccine (PCV13) vaccine, the minimum time interval between the polysaccharide and conjugate vaccine is 8 weeks.

Recommended Dosage and Route

0.5 mL administered intramuscularly

Contraindications and Precautions

A. Contraindications and Precautions

1. **Vaccination with PCV13 is contraindicated among persons known to have severe allergic reactions (e.g., anaphylaxis) to any component of PCV13 or PCV7, or any diphtheria toxoid-containing vaccine.**
2. **Moderate or severe illnesses with or without fever. Pneumococcal conjugate vaccine can be administered to persons with minor illness, such as diarrhea; mild upper respiratory tract infection, with or without low grade fever; or other illnesses with low grade fever. Persons with an illness associated with a moderate or severe fever should be vaccinated as soon as they have recovered from the acute phase of the illness.**
3. **Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including PCV13, to infants born prematurely should be based on consideration of the individual infant's medical status and potential benefits and possible risks of vaccination.**

Simultaneous Vaccine Administration

PCV may be administered simultaneously with any of the following routinely recommended vaccines:
DTaP, DT, RV, MMR, Hib, Hepatitis A, Hepatitis B, Polio, Varicella and Influenza

Concurrent administration of PCV and PPSV is not recommended because safety and efficacy of concurrent vaccination has not been established. See "Minimum Age and Dose Interval" section.

Vaccine Description

Pneumococcal Polysaccharide Vaccine (PPSV23) is a purified capsular polysaccharide vaccine that protects against **23 serotypes of pneumococcal bacteria** that cause 88% of bacteremic pneumococcal disease. It is not effective in children under 2 years of age.

B. Pneumococcal Polysaccharide Vaccine ($PPSV_{23}$)

Brand Name & Manufacturer

PNEUMOCOCCAL POLYSACCHARIDE VACCINE ($PPSV_{23}$)	MANUFACTURER
Pneumovax 23®	Merck

Eligible Groups for State Supplied Vaccine

Pneumococcal Polysaccharide Vaccine ($PPSV_{23}$):

For Adults, Children, and Adolescents, see “Eligibility for Vaccines Supplied by the Georgia Immunization Program for Children, Adolescents, and Adults” located in the front of this section.

Recommended $PPSV_{23}$ Vaccine Schedule

One dose of Pneumococcal Polysaccharide Vaccine (PPSV23) is recommended for all persons ≥ 65 years of age.

One to two doses of Pneumococcal Polysaccharide Vaccine (PPSV23) are recommended for all persons aged 2-64 years who have one of the following high-risk conditions. (The number of doses is dependent upon the person's age and high-risk condition. Refer to the ACIP statement on Prevention of Pneumococcal Disease for specific guidelines.) If earlier vaccination status is unknown, these persons should be administered PPSV23 vaccine. (See the "Recommended Doses and Intervals" section for dosage recommendations for children receiving both pneumococcal conjugate (PCV) and pneumococcal polysaccharide (PPSV23) vaccines.)

High-risk Conditions:

1. **A chronic illness**
   a. Chronic cardiovascular disease (e.g., congestive heart failure or cardiomyopathies)
   b. Chronic pulmonary disease (e.g., COPD, emphysema, or asthma) [4]
   c. Diabetes mellitus
   d. Alcoholism
   e. Chronic liver disease (cirrhosis)
   f. Cerebrospinal fluid (CSF) leaks

2. **Functional or anatomic asplenia**
   a. Sickle cell disease
   b. Splenectomy[1]

3. **Living in special environments or social settings**
   a. Alaska Natives or American Indians **where risk of invasive pneumococcal disease is increased** [4]
   b. Residents of nursing homes or long-term care facilities

4. **Immunocompromised [2] persons with**
   a. HIV infection
   b. Leukemia
   c. Lymphoma, Hodgkins disease, multiple myeloma, generalized malignancy
   d. Chronic renal failure, nephrotic syndrome
   e. Organ or bone marrow transplants
   f. Immunosuppressive chemotherapy and long term corticosteroids
5. **Cochlear implant recipients** [3]
6. **Adults who smoke cigarettes**[4]

[1]When an elective splenectomy is planned, PPV should be administered at least 2 weeks before surgery (Prevention of Pneumococcal Disease, *MMWR*, April 4, 1997, Vol. 46, RR-8, p.11).
[2]See "Contraindications and Precautions" section.
[3] "Pneumococcal Vaccination of Cochlear Implant Recipients," *MMWR*, October 18, 2002/51(41); 931.
[4] "ACIP Provisional Recommendation for use of Pneumococcal vaccines" October 22, 2008, linked @ http://www.cdc.gov/vaccines/recs/provisional/downloads/pneumo-oct-2008-508.pdf

Recommended Doses and Intervals for $PPSV_{23}$ Vaccine[1]		
Population	**Schedule for follow-up with $PPSV_{23}$ for children ≥2 years of age**	**Revaccinate with $PPSV_{23}$**
Persons >65 years	Not Applicable	**Give 2nd dose of vaccine if:** 1. Person was < 65 years of age at the time of first dose **And** 2. It has been > 5 years since first dose
Persons ages 2-64 years with: • Sickle cell disease or anatomic or functional asplenia • Immunocompromised[2] • HIV-Infected	1 dose $PPSV_{23}$ given at age ≥ 2 years and at least 8 weeks after last dose of PCV[3]	**Give 2nd dose of vaccine 5 years after the first dose**
Persons ages 2-64 years with: • Cardiovascular disease[2] • Chronic pulmonary disease[2] • Diabetes mellitus • Alcoholism • Chronic liver disease • Cerebrospinal Fluid (CSF) leaks • Cochlear implant recipients • Adults who smoke cigarettes[4] • Adults with asthma[4]	1 dose $PPSV_{23}$ given at ≥2 years and at least 8 weeks after last dose of PCV[3]	Not recommended
Persons ages 2-64 years who live in special environments or social settings: • Alaska Natives or American Indians aged 50 through 64 years who are living in areas with increased risk of invasive pneumococcal disease • Residents of nursing homes or long-term facilities	Health care providers of Alaska Natives and American Indians may recommend PPSV for children aged 24-59 months who are living in areas in which risk of invasive pneumococcal disease is increased	Not recommended
Healthy Children	None	No

[1]See 1997 ACIP Recommendations, Vol. 46, RR-8, p. 12 and 2000 ACIP Recommendations, Vol. 49, RR-9, p. 25, for more detailed information.
[2]See detailed listing in "Recommended PPSV Vaccine Schedule" section.
[3]Regardless of when administered, a second dose of PPSV should not be given earlier than 3 years following the previous PPSV dose. Revaccination is recommended only once. (1997 ACIP, Vol. 46, RR-8, p.15; 2006 Red Book, pp. 534-535). If a child has received the polysaccharide vaccine (PPSV), and is recommended to receive the conjugate vaccine (PCV), the minimal time interval between the polysaccharide and conjugate vaccine, is 8 weeks.
[4] "ACIP Provisional Recommendation for use of Pneumococcal vaccines" October 22, 2008, linked @ http://www.cdc.gov/vaccines/recs/provisional/downloads/pneumo-oct-2008-508.pdf

Recommended Dosage and Route

0.5 mL administered intramuscularly or subcutaneously

Contraindications and Precautions

A. CONTRAINDICATIONS

1. Allergy to vaccine components. Anaphylactic reaction to the vaccine or a constituent of the vaccine.
2. Moderate or severe illnesses with or without fever. Pneumococcal polysaccharide vaccine (PPSV) can be administered to persons with a minor illness, such as: diarrhea; mild upper respiratory tract infection, with or without low grade fever; or other illnesses with low grade fever. Persons with an illness associated with a moderate or severe fever should be vaccinated as soon as they have recovered from the acute phase of the illness.
3. Anaphylactic reaction or localized arthus-type reaction (extensive painful swelling from shoulder to elbow) to the initial dose. (1997 ACIP, Vol. 46, RR-8, p.15).

B. PRECAUTIONS

1. Pregnancy. It is prudent on theoretical grounds to avoid vaccinating pregnant women.
2. When cancer or immunosuppressive therapy is being considered (e.g., for patients with Hodgkin's Disease or those who undergo organ or bone marrow transplantation) the interval between vaccination and initiation of immunosuppressive therapy should be at least 2 weeks. Vaccination during chemotherapy or radiation should be avoided (1997 ACIP, Vol. 46, RR-8, p.13).

Simultaneous Vaccine Administration

PPSV may be administered simultaneously with any of the following routinely recommended vaccines:
DTaP, DT, Td, Tdap, MMR, Hib, Hepatitis A, Hepatitis B, Polio, MCV4, Varicella, HPV, Zoster and Influenza

Concurrent administration of PCV and PPSV is not recommended because safety and efficacy of concurrent vaccination has not been established. See "PCV Minimum Age and Dose Interval" section.

Georgia Department of Public Health
Immunization Office Vaccine Guidelines

VACCINES TO PREVENT POLIO

The purpose of these guidelines is to provide public health clinics with a summary of the current Recommendations of the Advisory Committee on Immunization Practices (ACIP) for each of the vaccines supplied by the Georgia Immunization **Office.** These guidelines should serve as a quick reference for clinics administering polio vaccine. The guidelines are not all inclusive. When more information is needed, the complete ACIP Recommendation statement should be referenced.

- "Poliomyelitis Prevention in the United States," *MMWR*, May 19, 2000, Vol. 49, No. RR-5.
- ACIP Polio Vaccine Resolution for the Vaccines for Children Program (VFC), (Resolution No**. 6/09-1**)
- Epidemiology and Prevention of Vaccine Preventable Diseases, **12th** edition, 2nd printing.
- 2012 Red Book: Report of the Committee on Infectious Diseases published by the American Academy of Pediatrics
- "Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP) Regarding Routine Poliovirus Vaccination, "MMWR, Vol. 58/August 7, 2009.

Vaccine Description

- Trivalent oral polio vaccine was the vaccine of choice in the U.S. from the time it was licensed in 1963. Since wild virus-induced paralytic polio was essentially eliminated in the western hemisphere by 1979, vaccine-induced paralytic polio (VAPP) became the greater risk. Therefore, in order to further the goal of eliminating any paralytic polio in the U.S., the ACIP recommended that inactivated polio vaccine be used exclusively, beginning in 2000. Oral polio vaccine is no longer available in the U.S.
- Inactivated polio vaccine (IPV) was introduced in the U.S. in 1955 but was largely replaced by OPV in the 1960's. Enhanced-potency IPV (e-IPV) was licensed in 1987 and is now the preferred polio vaccine.

Brand Name & Manufacturer

VACCINES	MANUFACTURERS
IPOL™ (e-IPV)	sanofi pasteur
Poliovax™ (IPV) (licensed but not distributed in the U.S.)	sanofi pasteur
Orimune™ (OPV) (not available for use in U.S.)	Wyeth-Lederle
Pediarix™ (combination of Infanrix™, EngerixB™, and inactivated polio vaccine)	GlaxoSmithKline
Kinrix™ (combination DTaP-IPV)	GlaxoSmithKline
Pentacel™ (combination DTaP-IPV/Hib)	sanofi pasteur

(See Section on "Combination Vaccines" for more information on Kinrix™, Pediarix™, And Pentacel™)

Eligible Groups for State Supplied Vaccine

For Adults, Children, and Adolescents, see "Eligibility for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults" located in the front of this section.

Recommended Polio Vaccine Schedule[1]

Infants

Vaccine	Dose 1	Dose 2	Dose 3	Dose 4[1, 2, 3, 4, 5,6]
IPV	age 2 mos.	age 4 mos.	age 6-18 mos.	age 4-6 yrs.

Children and Persons < 18 years of age [7]

Vaccine	Dose 1	Dose 2	Dose 3	Dose 4[2, 3, 4, 5, 6]
IPV	------	4 – 8 wks. after Dose 1	6-12 mos. after Dose 2	3.5 years after Dose 3

[1] Prior to 2001 individuals may have received a combination of OPV and IPV. **Any combination of 4 doses of IPV and OPV by 4-6 years of age constitutes a complete series.**

[2] The 4-dose IPV series is administered at ages 2 months, 4 months, 6-18 months, and 4-6 years.

[3] **The final dose in the IPV series should be administered at age ≥ 4 years regardless of the number of previous doses. The minimum interval between the final dose and previous dose is 6 months.**

[4] Pediarix® is licensed only for the primary series of 3 doses of IPV and should not be used for the booster dose. Not indicated for children > 6 years of age.

[5] Pentacel™ is approved for the primary series and first booster dose (doses 1-4). It is not indicated for children ≥ 5 years.

[6] Kinrix™ is approved for the booster dose at age 4-6. Not to be administered to children aged < 4 years or ≥ 7 years.
[7] Polio vaccination is not routinely recommended for healthy persons ≥18 years of age even if living in the U.S. and even if they have never received or completed a primary polio series. **Some immunocompromised persons may need to be vaccinated. For more information, see "General Recommendations on Immunization," *MMWR*, January 11, 2011 Vol. 60, No. RR-2.**

Minimum Age & Dose Intervals for IPV[1]

DOSE	MINIMUM AGE	MINIMUM DOSE INTERVAL
1	6 weeks	--------
2	10 weeks	4 weeks after 1st dose
3	14 weeks	4 weeks after 2nd dose
4	≥4 years	6 months after 3rd dose.

[1]Use of the minimum age and minimum intervals for vaccine administration in the first 6 months of life are recommended only if the vaccine recipient is at risk for imminent exposure to circulating poliovirus (e.g., during outbreak or because of travel to a polio-endemic region). ACIP is making this precaution because shorter intervals and earlier start dates lead to lower seroconversion rates.

Recommended Dosage and Route

0.5 mL administered subcutaneously or intramuscularly

Contraindications and Precautions

A. Contraindications

1. Allergy to any vaccine component. Persons who have had anaphylactic reactions to topically or systemically administered streptomycin, neomycin, or Polymyxin B should not receive IPV. Persons with only skin contact sensitivity may be vaccinated.

B. Precautions

Pregnancy. In general, polio vaccine should not be administered to pregnant women unless immediate protection against poliomyelitis is needed. If determined necessary, IPV is recommended.

1. **Moderate or severe illness with or without fever**

Simultaneous Vaccine Administration
May be administered simultaneously with any of the following routinely recommended vaccines: DTaP, RV, Td, Tdap, MMR, Hib, Hepatitis A, Hepatitis B, Varicella, MCV4, PCV13 or PPSV23, HPV, and Influenza

Georgia Department of Public Health
Immunization Office Vaccine Guidelines

VACCINES TO PREVENT ROTAVIRUS GASTROENTERITIS

The purpose of these guidelines is to provide public health clinics with a summary of the current Recommendations of the Advisory Committee on Immunization Practices (ACIP) for each of the vaccines supplied by the Georgia Immunization **Office**. These guidelines were developed from the pertinent Vaccine Resolution from the Vaccines for Children Program and the references below and will be updated as needed. The guidelines are not all inclusive and when more information is needed, the following publications should be referenced:

- ”Prevention of Rotavirus Gastroenteritis among Infants and Children,” *MMWR*, August 11, 2006, Vol. 55
- ACIP Rotavirus Gastroenteritis Vaccine Resolution for the Vaccines for Children Programs (VFC), (Resolution No. 6/08-1)
- “Prevention of Rotavirus Gastroenteritis among Infants and Children,” *MMWR*, Feb 6, 2009, Vol. 58, RR-02
- **“Addition of Severe Combined Immunodeficiency as a Contraindication for Administration of Rotavirus, *MMWR,* June 11, 2010, Vol. 59, RR-22**

A. Rotateq® (RV5) Vaccine Description

Pentavalent rotavirus vaccine is an oral vaccine that contains 5 live, reassortant rotaviruses isolated from human and bovine hosts. There are no preservatives or thimerosal present. The vaccine is a pale yellow clear liquid that may have a pink tint. It is supplied in a squeezable plastic, latex-free dosing tube with a twist-off cap, allowing for direct oral administration.

Brand Names & Manufacturer

RotaTeq®	Merck & Co.

Eligible Groups for State Supplied Vaccine

For Adults, Children, and Adolescents, see “Eligibility for Vaccines Supplied by the Georgia Immunization Program for Children, Adolescents, and Adults” located in the front of this section.

Recommended RV5 Rotavirus Vaccine Schedule

Dose	Age
Primary 1	2 months
Primary 2	4 months
Primary 3	6 months

Recommended Doses & Intervals [2]	
Rotateq®	
Number of doses in series	3
Recommended ages for doses	2 , 4 and 6 months
Minimum age for first dose	6 weeks
Maximum age for first dose	14 weeks 6 days[1]
Interval between doses	4 weeks or more
Maximum age for last dose	8 months 0 days

[1] Vaccination should not be initiated for infants >15 weeks of age. However, for infants in whom the first dose is inadvertently administered off label at age 15 weeks and 0 days or later, the rest of the vaccine series should be completed as per the schedule.

[2] ACIP recommends that the rotavirus vaccine series be completed with the same product whenever possible. However, vaccination should not be deferred because the product used for a previous dose(s) is not available or unknown. Continue or complete the series with product available.

NOTE: Infants who have had rotavirus gastroenteritis before receiving the full course of rotavirus vaccinations should still initiate or complete the 3-dose schedule because the initial infection frequently provides only partial immunity.

Special Situations:

1. Premature infants (< 37 weeks gestation)----immunize if they are:
    a. At least 6 weeks of age
    b. Clinically stable
    c. Being or have been discharged from the nursery
2. Infants living in households with immunocompromised persons can be vaccinated. The benefit to the household members of vaccinating young children outweighs the small risk for transmitting vaccine virus to immunocompromised persons. To minimize even this risk, all household members should employ good hygiene practices, especially after changing the infant's diapers.
3. Regurgitation of the vaccine dose---if for any reason an incomplete dose is administered (e.g., infant spits or regurgitates the vaccine), a replacement dose is not recommended. The infant should continue to receive any remaining doses in the recommended series at appropriate intervals.
4. Infants living in households with pregnant women can be vaccinated.
5. Hospitalization after recent rotavirus vaccination---no precautions other than routine standard precautions need be taken.

Rotavirus may be administered at any time before, concurrent with, or after administration of any blood product, including antibody-containing products.

Contraindications and Precautions

Contraindications:

1. Serious allergic reaction to vaccine components or after receiving a previous dose of rotavirus vaccine
2. **Infants with Severe Immunodeficiency Disease (SCID)**

Precautions:

1. Acute gastroenteritis--- rotavirus vaccine should not be administered to infants with acute, moderate to severe gastroenteritis until the condition improves.
2. Moderate to severe illness---vaccinate infants as soon as they have recovered from the acute phase of the illness.
3. Preexisting chronic gastrointestinal disease---providers should consider the potential risks and benefits of administering this vaccine to infants with this preexisting condition. Infants with preexisting chronic gastrointestinal conditions (i.e. congenital malabsorption syndromes, Hirschsprung's disease, short-gut syndrome, or persistent vomiting of unknown cause) and not undergoing immunosuppressive therapy should benefit from rotavirus vaccination and the benefits outweigh the theoretical risks.
4. Intussusception---the current rotavirus vaccine has shown no evidence of an association with intussusception. However, additional post-licensure surveillance data are required to confirm that the vaccine is not associated with intussusception. Until post-licensure data on safety of rotavirus vaccine are available, the risks and benefits of vaccination should be considered when vaccinating infants with a previous episode of intussusception. Until further safety data is available, vaccination of these infants with rotavirus vaccine should be delayed.
5. Altered immunocompetence---providers should consider the potential risks and benefits of administering rotavirus vaccine in this situation. Shedding of the vaccine virus may be possible, particularly after administration of the first dose. Caution is advised when considering whether to administer rotavirus vaccine to individuals with immunodeficient close contacts. No safety or efficacy data are available for the administration of this vaccine to infants who are potentially immunocompromised including:
    a. Infants with blood dyscrasias, leukemia, lymphomas of any type or other malignant neoplasms
    b. Infants on immunosuppressive therapy (including high-dose systemic corticosteroids)
    c. Infants with primary and acquired immunodeficiency states
    d. Infants who are HIV-exposed or infected. However, two considerations support vaccination of HIV-exposed or infected infants: first, the HIV diagnosis might not be established in infants born to HIV-infected mothers before the age of the first rotavirus vaccine and second, vaccine strains of rotavirus are considerably attenuated.

Simultaneous Vaccine Administration

May be administered simultaneously with any of the following routinely recommended vaccines:

DTaP, Hib, Hepatitis B, IPV, inactivated influenza and PCV13

B. Rotarix (RV1) Vaccine Description

Rotarix® (RV1) is a live, oral, attenuated rotavirus vaccine derived from the human 89-12 strain which belongs to G1P[8] type. The liquid diluent contains calcium carbonate, sterile water, and xanthan. The diluent includes an antacid component (calcium carbonate) to protect the vaccine during passage through the stomach and prevent its inactivation due to the acidic environment of the stomach. ROTARIX contains no preservatives. The tip cap and the rubber plunger of the oral applicator contain dry natural latex rubber. The vial stopper and transfer adapter are latex-free.

Brand Names & Manufacturer

Rotarix®	GlaxoSmithKline

Eligible Groups for State Supplied Vaccine

For Adults, Children, and Adolescents, see “Eligibility for Vaccines Supplied by the Georgia Immunization Office for Children, Adolescents, and Adults” located in the front of this section.

Recommended RV1 Rotavirus Vaccine Schedule

Dose	Age
Primary 1	2 months
Primary 2	4 months

Recommended Doses & Intervals [3]	
Rotateq®	
Number of doses in series	2
Recommended ages for doses	2 and 4 months
Minimum age for first dose	6 weeks
Maximum age for first dose	14 weeks 6 days[1]
Interval between doses	4 weeks or more[2]
Maximum age for last dose	8 months 0 days

[1] Vaccination should not be initiated for infants aged 15 weeks 0 days or older because of insufficient data on safety of dose 1 of rotavirus vaccine in older infants. For infants to whom dose 1 is administered inadvertently at age 15 weeks and 0 days or older, the rest of the rotavirus vaccination series should be completed according to the schedule and by 8 months and 0 days.
[2] The minimum interval between doses of rotavirus vaccine is 4 weeks; no maximum interval is set.
[3] ACIP recommends that the rotavirus vaccine series be completed with the same product whenever possible. However, vaccination should not be deferred because the product used for a previous dose(s) is not available or unknown. Continue or complete the series with product available. If any dose in the series is RV5 or the vaccine product is unknown for any dose in the series, a total of 3 doses of rotavirus should be administered.

NOTE: Infants who have had rotavirus gastroenteritis before receiving the full course of rotavirus vaccinations should still initiate or complete the 2-dose schedule because the initial infection frequently provides only partial immunity.

Special Situations:

1. Premature infants (< 37 weeks gestation)----immunize if they are:
    a. At least 6 weeks of age
    b. Clinically stable
    c. Are being or have been discharged from the nursery
2. Infants living in households with immunocompromised persons can be vaccinated. The benefit to the household members of vaccinating young children outweighs the small risk for transmitting vaccine virus to immunocompromised persons. To minimize even this risk, all household members should employ good hygiene practices, especially after changing the infant's diapers.
3. Regurgitation of the vaccine dose---if for any reason an incomplete dose is administered (e.g., infant spits or regurgitates the vaccine), a replacement dose is not recommended. The infant should continue to receive any remaining doses in the recommended series at appropriate intervals.
4. Infants living in households with pregnant women can be vaccinated.
5. Hospitalization after recent rotavirus vaccination---no precautions other than routine standard precautions need be taken.

Rotavirus may be administered at any time before, concurrent with, or after administration of any blood product, including antibody-containing products.

Simultaneous Vaccine Administration

May be administered simultaneously with any of the following routinely recommended vaccines:

DTaP, Hib, Hepatitis B, IPV, inactivated Influenza, and PCV13

Georgia Department of Public Health
Immunization Program Vaccine Guidelines

VACCINES TO PREVENT VARICELLA

The purpose of these guidelines is to provide public health clinics with a summary of the current Recommendations of the Advisory Committee on Immunization Practices (ACIP) for each of the vaccines supplied by the Georgia Immunization Office. These guidelines were developed from the pertinent Vaccine Resolution from the Vaccines for Children Program and the references below and will be updated as needed. The guidelines are not all inclusive and when more information is needed, the following publications should be referenced:

- "Prevention of Varicella," *MMWR*, June 22, 2007, Vol. 56, No. RR-4
- ACIP Measles, Mumps, Rubella, and Varicella Vaccine Resolution for the Vaccines for Children Program (VFC), (Resolution No.6/06-3)
- 2012 Red Book: Report of the Committee on Infectious Diseases published by the American Academy of Pediatrics
- Epidemiology and Prevention of Vaccine Preventable Diseases, 12th edition, 2nd printing.
- Update: Recommendations from the Advisory Committee on Immunization Practices (ACIP) Regarding Administration of Combination MMRV vaccine, *MMWR,* March 14, 2008, Vol. 57, No. RR-10
- Notice to Readers: Licensure of a Combined Live Attenuated Measles, Mumps, Rubella, and Varicella Vaccine, December 2, 2005, Vol. 54, No. RR-47

Vaccine Description

Varicella zoster vaccine is a live attenuated viral vaccine, derived from the Oka strain of varicella zoster virus.

Brand Name & Manufacturer

VACCINE	MANUFACTURER
Varicella (Varivax ®)	Merck
Measles-mumps-rubella-varicella (ProQuad®) (See "Combination Vaccines" in this section)	Merck

Eligible Groups for State Supplied Vaccine

For Adults, Children, and Adolescents, see "Eligibility for Vaccines Supplied by the Georgia Immunization Program for Children, Adolescents, and Adults" located in the front of this section.

The varicella immune globulin (VZIG) product currently used in the U.S. is VariZIG. ™ It is available under an Investigational New Drug Application Expanded Access protocol. This product can be obtained 24 hours a day from the sole authorized U.S. distributor (FFF Enterprises, Temecula, California) at 1-800-843-7477 or online at hppt://www.fffenterprises.com

Recommended Varicella Vaccine Schedule

Two doses of varicella vaccine are recommended for all susceptible[1] persons beginning at 12-15 months of age. If a child is 15 months or older and has not had the disease, the child should be immunized at the earliest opportunity.

Vaccine	Dose[2]	Age (for routine vaccination)[3]
Varicella	1	12-15 months
	2	4-6 years

In addition, varicella vaccination is recommended in the following situations:

- A 2nd dose catch-up for all children, adolescents, and adults who previously had received one dose.
- Vaccination should be considered for HIV-infected children with age-specific CD4+ T-lymphocyte percentage ≥15% and may be considered for adolescents and adults in with CD4+ T-lymphocyte count ≥200 cells/µL. **DO NOT** use MMRV vaccine for these persons.
- For postpartum women whose prenatal assessment indicated susceptibility to varicella disease, the 1st dose of vaccine should be administered before discharge from the healthcare facility and the 2nd dose scheduled at an appropriate interval.
- During a varicella outbreak, a 2nd dose of vaccine should be given to those who had previously only received 1 dose, provided the appropriate minimum interval has elapsed since the first dose.[3]

Recommended Varicella Vaccine Schedule (cont'd)

- Other adults who should receive special consideration for varicella vaccine if determined not to be immune:
  - Healthcare providers
  - Household contacts of immunocompromised persons
  - Persons in environments where transmission of VZV is likely, such as teachers, childcare employees, persons in institutional settings, college students, staff and inmates of correctional institutions, and military personnel.
  - Nonpregnant women of childbearing age
  - Adolescents and adults living in households with children
  - International travelers

[1] See Guidelines for Documentation of Immunity below.
[2] Doses of varicella may be given as MMRV if the child is 12 months through 12 years of age, and a dose of MMR is also indicated. See "Combination Vaccine" guidelines in this section for more information.
[3] Minimum interval from dose 1 to 2:
3 months if 1st dose is given at <13 years of age
4 weeks if 1st dose is given at ≥13 years of age

NOTE:
Varicella vaccine is effective in preventing illness or modifying varicella severity if it is administered within 3 days and possibly up to 5 days after exposure.

Guidelines for Public Health Clinics
Documentation of Varicella Immunity

These guidelines are to be used by nurses in public health clinics to document varicella immunity. This documentation will be for issuing a "Certificate of Immunization" for childcare and school attendance.

1. Documentation of age-appropriate vaccination:
   - Ages 12 months through preschool----1 dose
   - Kindergarten through adulthood---2 doses
2. Laboratory evidence of immunity or confirmation of disease
3. Born in the US before 1980. For healthcare providers & pregnant women birth before 1980 should not be considered evidence of immunity.
4. Healthcare provider diagnosis of disease or documentation of history of disease
   - Typical case history
     - Recollection of an itchy, blister-like rash that lasted about a week with
     - History of known exposure to shingles or a typical case of chickenpox (fever and maculopapular rash with successive crops of vesicular lesions in different stages)
     - Documentation should be made by **licensed** medical personnel (e.g., physician, public health nurse, physician's assistant, or nurse practitioner); however, the Immunization Certificate must be signed by a physician, **advanced practice registered nurse or physician assistant** licensed in Georgia or by a Public Health Official.

Guidelines for Public Health Clinics Documentation of Varicella Immunity (cont'd)

- Mild or atypical case history
  - Assessment should be made by **licensed** medical personnel (e.g., physician, public health nurse, **physician's assistant, or nurse practitioner**) and one of the following should be sought:
    - An epidemiologic link to a typical varicella case, or a laboratory confirmed case
    - Evidence of laboratory confirmation (if the testing was performed at the time of acute disease)
- **If none of the above can be ascertained, vaccination with appropriate doses of varicella vaccine should be considered.**

5. History of herpes zoster (shingles) based on healthcare provider diagnosis

Recommended Doses & Intervals

Vaccine	Minimum age	Minimum interval from dose 1 to 2[1]
Dose 1	12 months	3 months
Dose 2	13 months	-----

[1] If 2 doses of varicella vaccine are given during the time the child is 12 months through 12 years of age, the minimum interval between doses is **3 months.** Once the child turns 13 years of age, the minimum interval between the 2 doses is **1 month**. However, regardless of the child's age, if the 2nd dose was administered after at least 28 days following the 1st dose, the 2nd dose does not need to be repeated.

Recommended Dosage and Route

0.5 mL administered subcutaneously

Contraindications and Precautions

A. Contraindications and Precautions

1. Allergy to vaccine components
   Anaphylactic reaction to the vaccine or a constituent of the vaccine (e.g., gelatin or neomycin)
2. Moderate or severe illnesses with or without fever
   Varicella vaccine can be administered to persons with minor illness, such as diarrhea; mild upper respiratory tract infection, with or without low grade fever; or other illnesses with low grade fever. Persons with an illness associated with a moderate or severe fever should be vaccinated as soon as they have recovered from the acute phase of the illness. Although no data exist as to whether varicella or live varicella virus vaccine exacerbates tuberculosis, vaccination is not recommended for persons who have untreated, active tuberculosis. Tuberculin skin testing is not a prerequisite for varicella vaccination.
3. Altered immune status
   Altered immune status due to: a malignant condition (blood dyscrasia, leukemia,[1] lymphoma, or other neoplasms affecting the bone marrow or lymphatic system); primary or acquired immune deficiency, including acquired immunodeficiency syndrome (AIDS) or other clinical manifestations of HIV infection, cellular immunodeficiencies, hypogammaglobulinemia, and dysgammaglobulinemia; family history of congenital or hereditary immunodeficiency, unless immune competence of possible vaccine recipient is demonstrated; and individuals receiving immunosuppressive therapy. See ACIP statement cited in the opening paragraph of "Vaccines to Prevent Varicella."
4. Receipt of blood products
   Varicella virus vaccine should not be given for at least 5 months after receipt of blood (except washed red blood cells) or plasma transfusions, Immune Globulin (IG), or Varicella Zoster Immune Globulin (VZIG). In addition, IG and VZIG should not be administered for 3 weeks after vaccination unless the benefits of receiving the IG or VZIG exceed the benefits of vaccination.
5. Steroid therapy
   Receiving doses of systemic prednisone or its equivalent at a dose of ≥2 mg/kg of body weight per day or 20 mg/day.
6. Exposure of immunocompromised persons to vaccinees
   In persons who develop a rash post-vaccination, there is a minimal risk of transmission of vaccine virus to close contacts. Thus, vaccinees in whom vaccine-related rash develops, particularly health care workers and household contacts of immunocompromised persons, should avoid contact with susceptible persons who are at high risk of serious complications.
7. Salicylates
   Due to the association between wild varicella zoster infection, salicylates, and Reye syndrome, if feasible, vaccine recipients should avoid using salicylates for 6 weeks after receiving varicella virus vaccine. Vaccination with subsequent close monitoring should be considered for children who have conditions requiring therapeutic aspirin because the risk for serious complications associated with aspirin is likely to be greater in children in whom natural varicella disease develops than in children who receive the vaccine containing attenuated varicella zoster virus.

8. Pregnancy
   Theoretically, it is best not to administer varicella vaccine to pregnant women. Woman who are not pregnant but are of childbearing age who receive the vaccine should be advised not to become pregnant for at least 1 month after each injection. Merck and the CDC have established a hotline to monitor the maternal/fetal outcomes of women who are vaccinated with varicella 3 months before or at any time during the pregnancy. The phone number is (800) 986-8999.
9. Nursing mothers
   Whether attenuated varicella (VZV) vaccine is excreted in human milk and, if so, whether the infant could be infected, are not known. Most live vaccines have not been demonstrated to be secreted in human milk. Therefore, varicella vaccine may be considered for a nursing mother.

[1] Except under research protocol

Note: A prior history of chicken pox is not a contraindication to varicella vaccination.

Simultaneous Vaccine Administration

Varicella vaccine may be administered simultaneously with any of the following routinely recommended vaccines:
DTaP, Tdap, Td, MMR, Hib, Hepatitis A, Hepatitis B, Polio, PCV13 and PPSV23, Influenza, HPV, and MCV4

Tuberculin Skin Testing: While no data are available regarding the effect of varicella vaccination on tuberculin reactivity, it is prudent to apply the same precautions as with MMR when using the varicella vaccine. See guidelines for simultaneous tuberculin skin testing (TST) and the administration of live virus vaccines in the ACIP statement, "General Recommendations on Immunization," *MMWR*, January 28, 2011, Vol. 60, RR-2, page 24.

FIGURE 1: Recommended immunization schedule for persons aged 0 through 6 years—United States, 2012 (for those who fall behind or start late, see the catch-up schedule [Figure 3])

Vaccine ▼ / Age ▶	Birth	1 month	2 months	4 months	6 months	9 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B[1]	Hep B	HepB			HepB							
Rotavirus[2]			RV	RV	RV[2]							
Diphtheria, tetanus, pertussis[3]			DTaP	DTaP	DTaP		see footnote[3]	DTaP				DTaP
Haemophilus influenzae type b[4]			Hib	Hib	Hib[4]		Hib					
Pneumococcal[5]			PCV	PCV	PCV		PCV				PPSV	
Inactivated poliovirus[6]			IPV	IPV	IPV							IPV
Influenza[7]					Influenza (Yearly)							
Measles, mumps, rubella[8]							MMR		see footnote[8]			MMR
Varicella[9]							Varicella		see footnote[9]			Varicella
Hepatitis A[10]							Dose 1[10]				HepA Series	
Meningococcal[11]						MCV4 — see footnote[11]						

Range of recommended ages for all children

Range of recommended ages for certain high-risk groups

Range of recommended ages for all children and certain high-risk groups

This schedule includes recommendations in effect as of December 23, 2011. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at http://www.cdc.gov/vaccines/pubs/acip-list.htm. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (http://www.vaers.hhs.gov) or by telephone (800-822-7967).

1. **Hepatitis B (HepB) vaccine.** (Minimum age: birth)
   At birth:
   - Administer monovalent HepB vaccine to all newborns before hospital discharge.
   - For infants born to hepatitis B surface antigen (HBsAg)–positive mothers, administer HepB vaccine and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth. These infants should be tested for HBsAg and antibody to HBsAg (anti-HBs) 1 to 2 months after receiving the last dose of the series.
   - If mother's HBsAg status is unknown, within 12 hours of birth administer HepB vaccine for infants weighing ≥2,000 grams, and HepB vaccine plus HBIG for infants weighing <2,000 grams. Determine mother's HBsAg status as soon as possible and, if she is HBsAg-positive, administer HBIG for infants weighing ≥2,000 grams (no later than age 1 week).

   Doses after the birth dose:
   - The second dose should be administered at age 1 to 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks.
   - Administration of a total of 4 doses of HepB vaccine is permissible when a combination vaccine containing HepB is administered after the birth dose.
   - Infants who did not receive a birth dose should receive 3 doses of a HepB-containing vaccine starting as soon as feasible (Figure 3).
   - The minimum interval between dose 1 and dose 2 is 4 weeks, and between dose 2 and 3 is 8 weeks. The final (third or fourth) dose in the HepB vaccine series should be administered no earlier than age 24 weeks and at least 16 weeks after the first dose.
2. **Rotavirus (RV) vaccines.** (Minimum age: 6 weeks for both RV-1 [Rotarix] and RV-5 [Rota Teq])
   - The maximum age for the first dose in the series is 14 weeks, 6 days; and 8 months, 0 days for the final dose in the series. Vaccination should not be initiated for infants aged 15 weeks, 0 days or older.
   - If RV-1 (Rotarix) is administered at ages 2 and 4 months, a dose at 6 months is not indicated.
3. **Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine.** (Minimum age: 6 weeks)
   - The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose.
4. ***Haemophilus influenzae* type b (Hib) conjugate vaccine.** (Minimum age: 6 weeks)
   - If PRP-OMP (PedvaxHIB or Comvax [HepB-Hib]) is administered at ages 2 and 4 months, a dose at age 6 months is not indicated.
   - Hiberix should only be used for the booster (final) dose in children aged 12 months through 4 years.
5. **Pneumococcal vaccines.** (Minimum age: 6 weeks for pneumococcal conjugate vaccine [PCV]; 2 years for pneumococcal polysaccharide vaccine [PPSV])
   - Administer 1 dose of PCV to all healthy children aged 24 through 59 months who are not completely vaccinated for their age.
   - For children who have received an age-appropriate series of 7-valent PCV (PCV7), a single supplemental dose of 13-valent PCV (PCV13) is recommended for:
     — All children aged 14 through 59 months
     — Children aged 60 through 71 months with underlying medical conditions.
   - Administer PPSV at least 8 weeks after last dose of PCV to children aged 2 years or older with certain underlying medical conditions, including a cochlear implant. See *MMWR* 2010:59(No. RR-11), available at http://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf.
6. **Inactivated poliovirus vaccine (IPV).** (Minimum age: 6 weeks)
   - If 4 or more doses are administered before age 4 years, an additional dose should be administered at age 4 through 6 years.
   - The final dose in the series should be administered on or after the fourth birthday and at least 6 months after the previous dose.
7. **Influenza vaccines.** (Minimum age: 6 months for trivalent inactivated influenza vaccine [TIV]; 2 years for live, attenuated influenza vaccine [LAIV])
   - For most healthy children aged 2 years and older, either LAIV or TIV may be used. However, LAIV should not be administered to some children, including 1) children with asthma, 2) children 2 through 4 years who had wheezing in the past 12 months, or 3) children who have any other underlying medical conditions that predispose them to influenza complications. For all other contraindications to use of LAIV, see *MMWR* 2010;59(No. RR-8), available at http://www.cdc.gov/mmwr/pdf/rr/rr5908.pdf.
   - For children aged 6 months through 8 years:
     — For the 2011–12 season, administer 2 doses (separated by at least 4 weeks) to those who did not receive at least 1 dose of the 2010–11 vaccine. Those who received at least 1 dose of the 2010–11 vaccine require 1 dose for the 2011–12 season.
     — For the 2012–13 season, follow dosing guidelines in the 2012 ACIP influenza vaccine recommendations.
8. **Measles, mumps, and rubella (MMR) vaccine.** (Minimum age: 12 months)
   - The second dose may be administered before age 4 years, provided at least 4 weeks have elapsed since the first dose.
   - Administer MMR vaccine to infants aged 6 through 11 months who are traveling internationally. These children should be revaccinated with 2 doses of MMR vaccine, the first at ages 12 through 15 months and at least 4 weeks after the previous dose, and the second at ages 4 through 6 years.
9. **Varicella (VAR) vaccine.** (Minimum age: 12 months)
   - The second dose may be administered before age 4 years, provided at least 3 months have elapsed since the first dose.
   - For children aged 12 months through 12 years, the recommended minimum interval between doses is 3 months. However, if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.
10. **Hepatitis A (HepA) vaccine.** (Minimum age: 12 months)
    - Administer the second (final) dose 6 to18 months after the first.
    - Unvaccinated children 24 months and older at high risk should be vaccinated. See *MMWR* 2006;55(No. RR-7), available at http://www.cdc.gov/mmwr/pdf/rr/rr5507.pdf.
    - A 2-dose HepA vaccine series is recommended for anyone aged 24 months and older, previously unvaccinated, for whom immunity against hepatitis A virus infection is desired.
11. **Meningococcal conjugate vaccines, quadrivalent (MCV4).** (Minimum age: 9 months for Menactra [MCV4-D], 2 years for Menveo [MCV4-CRM])
    - For children aged 9 through 23 months 1) with persistent complement component deficiency; 2) who are residents of or travelers to countries with hyperendemic or epidemic disease; or 3) who are present during outbreaks caused by a vaccine serogroup, administer 2 primary doses of MCV4-D, ideally at ages 9 months and 12 months or at least 8 weeks apart.
    - For children aged 24 months and older with 1) persistent complement component deficiency who have not been previously vaccinated; or 2) anatomic/functional asplenia, administer 2 primary doses of either MCV4 at least 8 weeks apart.
    - For children with anatomic/functional asplenia, if MCV4-D (Menactra) is used, administer at a minimum age of 2 years and at least 4 weeks after completion of all PCV oses.
    - See *MMWR* 2011;60:72–6, available at http://www.cdc.gov/mmwr/pdf/wk/mm6003. pdf, and Vaccines for Children Program resolution No. 6/11-1, available at http://www. cdc.gov/vaccines/programs/vfc/downloads/resolutions/06-11mening-mcv.pdf, and *MMWR* 2011;60:1391–2, available at http://www.cdc.gov/mmwr/pdf/wk/mm6040. pdf, for further guidance, including revaccination guidelines.

This schedule is approved by the Advisory Committee on Immunization Practices (http://www.cdc.gov/vaccines/recs/acip), the American Academy of Pediatrics (http://www.aap.org), and the American Academy of Family Physicians (http://www.aafp.org).
Department of Health and Human Services • Centers for Disease Control and Prevention

FIGURE 2: Recommended immunization schedule for persons aged 7 through 18 years—United States, 2012 (for those who fall behind or start late, see the schedule below and the catch-up schedule [Figure 3])

Vaccine ▼ Age ▶	7–10 years	11–12 years	13–18 years
Tetanus, diphtheria, pertussis[1]	1 dose (if indicated)	1 dose	1 dose (if indicated)
Human papillomavirus[2]	*see footnote*[2]	3 doses	Complete 3-dose series
Meningococcal[3]	See footnote[3]	Dose 1	Booster at 16 years old
Influenza[4]	Influenza (yearly)		
Pneumococcal[5]	See footnote [5]		
Hepatitis A[6]	Complete 2-dose series		
Hepatitis B[7]	Complete 3-dose series		
Inactivated poliovirus[8]	Complete 3-dose series		
Measles, mumps, rubella[9]	Complete 2-dose series		
Varicella[10]	Complete 2-dose series		

Range of recommended ages for all children

Range of recommended ages for catch-up immunization

Range of recommended ages for certain high-risk groups

This schedule includes recommendations in effect as of December 23, 2011. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at http://www.cdc.gov/vaccines/pubs/acip-list.htm. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (http://www.vaers.hhs.gov) or by telephone (800-822-7967).

1. **Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine.** (Minimum age: 10 years for Boostrix and 11 years for Adacel)
   - Persons aged 11 through 18 years who have not received Tdap vaccine should receive a dose followed by tetanus and diphtheria toxoids (Td) booster doses every 10 years thereafter.
   - Tdap vaccine should be substituted for a single dose of Td in the catch-up series for children aged 7 through 10 years. Refer to the catch-up schedule if additional doses of tetanus and diphtheria toxoid–containing vaccine are needed.
   - Tdap vaccine can be administered regardless of the interval since the last tetanus and diphtheria toxoid–containing vaccine.
2. **Human papillomavirus (HPV) vaccines (HPV4 [Gardasil] and HPV2 [Cervarix]).** (Minimum age: 9 years)
   - Either HPV4 or HPV2 is recommended in a 3-dose series for females aged 11 or 12 years. HPV4 is recommended in a 3-dose series for males aged 11 or 12 years.
   - The vaccine series can be started beginning at age 9 years.
   - Administer the second dose 1 to 2 months after the first dose and the third dose 6 months after the first dose (at least 24 weeks after the first dose).
   - See *MMWR* 2010;59:626–32, available at http://www.cdc.gov/mmwr/pdf/wk/mm5920.pdf.
3. **Meningococcal conjugate vaccines, quadrivalent (MCV4).**
   - Administer MCV4 at age 11 through 12 years with a booster dose at age 16 years.
   - Administer MCV4 at age 13 through 18 years if patient is not previously vaccinated.
   - If the first dose is administered at age 13 through 15 years, a booster dose should be administered at age 16 through 18 years with a minimum interval of at least 8 weeks after the preceding dose.
   - If the first dose is administered at age 16 years or older, a booster dose is not needed.
   - Administer 2 primary doses at least 8 weeks apart to previously unvaccinated persons with persistent complement component deficiency or anatomic/functional asplenia, and 1 dose every 5 years thereafter.
   - Adolescents aged 11 through 18 years with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series of MCV4, at least 8 weeks apart.
   - See *MMWR* 2011;60:72–76, available at http://www.cdc.gov/mmwr/pdf/wk/mm6003.pdf, and Vaccines for Children Program resolution No. 6/11-1, available at http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/06-11mening-mcv.pdf, for further guidelines.
4. **Influenza vaccines (trivalent inactivated influenza vaccine [TIV] and live, attenuated influenza vaccine [LAIV]).**
   - For most healthy, nonpregnant persons, either LAIV or TIV may be used, except LAIV should not be used for some persons, including those with asthma or any other underlying medical conditions that predispose them to influenza complications. For all other contraindications to use of LAIV, see *MMWR* 2010;59(No.RR-8), available at http://www.cdc.gov/mmwr/pdf/rr/rr5908.pdf.
   - Administer 1 dose to persons aged 9 years and older.
   - For children aged 6 months through 8 years:
     - For the 2011–12 season, administer 2 doses (separated by at least 4 weeks) to those who did not receive at least 1 dose of the 2010–11 vaccine. Those who received at least 1 dose of the 2010–11 vaccine require 1 dose for the 2011–12 season.
     - For the 2012–13 season, follow dosing guidelines in the 2012 ACIP influenza vaccine recommendations.
5. **Pneumococcal vaccines (pneumococcal conjugate vaccine [PCV] and pneumococcal polysaccharide vaccine [PPSV]).**
   - A single dose of PCV may be administered to children aged 6 through 18 years who have anatomic/functional asplenia, HIV infection or other immunocompromising condition, cochlear implant, or cerebral spinal fluid leak. See *MMWR* 2010:59(No. RR-11), available at http://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf.
   - Administer PPSV at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions, including a cochlear implant. A single revaccination should be administered after 5 years to children with anatomic/functional asplenia or an immunocompromising condition.
6. **Hepatitis A (HepA) vaccine.**
   - HepA vaccine is recommended for children older than 23 months who live in areas where vaccination programs target older children, who are at increased risk for infection, or for whom immunity against hepatitis A virus infection is desired. See *MMWR* 2006;55(No. RR-7), available at http://www.cdc.gov/mmwr/pdf/rr/rr5507.pdf.
   - Administer 2 doses at least 6 months apart to unvaccinated persons.
7. **Hepatitis B (HepB) vaccine.**
   - Administer the 3-dose series to those not previously vaccinated.
   - For those with incomplete vaccination, follow the catch-up recommendations (Figure 3).
   - A 2-dose series (doses separated by at least 4 months) of adult formulation Recombivax HB is licensed for use in children aged 11 through 15 years.
8. **Inactivated poliovirus vaccine (IPV).**
   - The final dose in the series should be administered at least 6 months after the previous dose.
   - If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.
   - IPV is not routinely recommended for U.S. residents aged18 years or older.
9. **Measles, mumps, and rubella (MMR) vaccine.**
   - The minimum interval between the 2 doses of MMR vaccine is 4 weeks.
10. **Varicella (VAR) vaccine.**
    - For persons without evidence of immunity (see *MMWR* 2007;56[No. RR-4], available at http://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf), administer 2 doses if not previously vaccinated or the second dose if only 1 dose has been administered.
    - For persons aged 7 through 12 years, the recommended minimum interval between doses is 3 months. However, if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.
    - For persons aged 13 years and older, the minimum interval between doses is 4 weeks.

FIGURE 3. Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind —United States • 2012

The figure below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. **Always use this table in conjunction with the accompanying childhood and adolescent immunization schedules (Figures 1 and 2) and their respective footnotes.**

Persons aged 4 months through 6 years					
Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to dose 2	Dose 2 to dose 3	Dose 3 to dose 4	Dose 4 to dose 5
Hepatitis B	Birth	4 weeks	8 weeks and at least 16 weeks after first dose; minimum age for the final dose is 24 weeks		
Rotavirus[1]	6 weeks	4 weeks	4 weeks[1]		
Diphtheria, tetanus, pertussis[2]	6 weeks	4 weeks	4 weeks	6 months	6 months[2]
Haemophilus influenzae type b[3]	6 weeks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose) if first dose administered at age 12–14 months No further doses needed if first dose administered at age 15 months or older	4 weeks[3] if current age is younger than 12 months 8 weeks (as final dose)[3] if current age is 12 months or older and first dose administered at younger than age 12 months and second dose administered at younger than 15 months No further doses needed if previous dose administered at age 15 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 months through 59 months who received 3 doses before age 12 months	
Pneumococcal[4]	6 weeks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose for healthy children) if first dose administered at age 12 months or older or current age 24 through 59 months No further doses needed for healthy children if first dose administered at age 24 months or older	4 weeks if current age is younger than 12 months 8 weeks (as final dose for healthy children) if current age is 12 months or older No further doses needed for healthy children if previous dose administered at age 24 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 months through 59 months who received 3 doses before age 12 months or for children at high risk who received 3 doses at any age	
Inactivated poliovirus[5]	6 weeks	4 weeks	4 weeks	6 months[5] minimum age 4 years for final dose	
Meningococcal[6]	9 months	8 weeks[6]			
Measles, mumps, rubella[7]	12 months	4 weeks			
Varicella[8]	12 months	3 months			
Hepatitis A	12 months	6 months			
Persons aged 7 through 18 years					
Tetanus, diphtheria/ tetanus, diphtheria, pertussis[9]	7 years[9]	4 weeks	4 weeks if first dose administered at younger than age 12 months 6 months if first dose administered at 12 months or older	6 months if first dose administered at younger than age 12 months	
Human papillomavirus[10]	9 years	Routine dosing intervals are recommended[10]			
Hepatitis A	12 months	6 months			
Hepatitis B	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Inactivated poliovirus[5]	6 weeks	4 weeks	4 weeks[5]	6 months[5]	
Meningococcal[6]	9 months	8 weeks[6]			
Measles, mumps, rubella[7]	12 months	4 weeks			
Varicella[8]	12 months	3 months if person is younger than age 13 years 4 weeks if person is aged 13 years or older			

1. **Rotavirus (RV) vaccines (RV-1 [Rotarix] and RV-5 [Rota Teq]).**
   - The maximum age for the first dose in the series is 14 weeks, 6 days; and 8 months, 0 days for the final dose in the series. Vaccination should not be initiated for infants aged 15 weeks, 0 days or older.
   - If RV-1 was administered for the first and second doses, a third dose is not indicated.
2. **Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine.**
   - The fifth dose is not necessary if the fourth dose was administered at age 4 years or older.
3. ***Haemophilus influenzae* type b (Hib) conjugate vaccine.**
   - Hib vaccine should be considered for unvaccinated persons aged 5 years or older who have sickle cell disease, leukemia, human immunodeficiency virus (HIV) infection, or anatomic/functional asplenia.
   - If the first 2 doses were PRP-OMP (PedvaxHIB or Comvax) and were administered at age 11 months or younger, the third (and final) dose should be administered at age 12 through 15 months and at least 8 weeks after the second dose.
   - If the first dose was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a final dose at age 12 through 15 months.
4. **Pneumococcal vaccines.** (Minimum age: 6 weeks for pneumococcal conjugate vaccine [PCV]; 2 years for pneumococcal polysaccharide vaccine [PPSV])
   - For children aged 24 through 71 months with underlying medical conditions, administer 1 dose of PCV if 3 doses of PCV were received previously, or administer 2 doses of PCV at least 8 weeks apart if fewer than 3 doses of PCV were received previously.
   - A single dose of PCV may be administered to certain children aged 6 through 18 years with underlying medical conditions. See age-specific schedules for details.
   - Administer PPSV to children aged 2 years or older with certain underlying medical conditions. See *MMWR* 2010:59(No. RR-11), available at http://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf.
5. **Inactivated poliovirus vaccine (IPV).**
   - A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.
   - In the first 6 months of life, minimum age and minimum intervals are only recommended if the person is at risk for imminent exposure to circulating poliovirus (i.e., travel to a polio-endemic region or during an outbreak).
   - IPV is not routinely recommended for U.S. residents aged 18 years or older.
6. **Meningococcal conjugate vaccines, quadrivalent (MCV4).** (Minimum age: 9 months for Menactra [MCV4-D]; 2 years for Menveo [MCV4-CRM])
   - See Figure 1 ("Recommended immunization schedule for persons aged 0 through 6 years") and Figure 2 ("Recommended immunization schedule for persons aged 7 through 18 years") for further guidance.
7. **Measles, mumps, and rubella (MMR) vaccine.**
   - Administer the second dose routinely at age 4 through 6 years.
8. **Varicella (VAR) vaccine.**
   - Administer the second dose routinely at age 4 through 6 years. If the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.
9. **Tetanus and diphtheria toxoids (Td) and tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccines.**
   - For children aged 7 through 10 years who are not fully immunized with the childhood DTaP vaccine series, Tdap vaccine should be substituted for a single dose of Td vaccine in the catch-up series; if additional doses are needed, use Td vaccine. For these children, an adolescent Tdap vaccine dose should not be given.
   - An inadvertent dose of DTaP vaccine administered to children aged 7 through 10 years can count as part of the catch-up series. This dose can count as the adolescent Tdap dose, or the child can later receive a Tdap booster dose at age 11–12 years.
10. **Human papillomavirus (HPV) vaccines (HPV4 [Gardasil] and HPV2 [Cervarix]).**
    - Administer the vaccine series to females (either HPV2 or HPV4) and males (HPV4) at age 13 through 18 years if patient is not previously vaccinated.
    - Use recommended routine dosing intervals for vaccine series catch-up; see Figure 2 ("Recommended immunization schedule for persons aged 7 through 18 years").

Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (http://www.vaers.hhs.gov) or by telephone (800-822-7967). Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (http://www.cdc.gov/vaccines) or by telephone (800-CDC-INFO [800-232-4636]).

Recommended and Minimum Ages and Intervals Between Doses				
Vaccine and dose number	**Recommended age for this dose**	**Minimum age for this dose**	**Recommended interval to next dose**	**Minimum interval to next dose**
Hepatitis B (HepB)-1[3]	Birth	Birth	1-4 months	4 weeks
HepB-2	1-2 months	4 weeks	2-17 months	8 weeks
HepB-3[4]	6-18 months	24 weeks	—	—
Diphtheria-tetanus-acellular pertussis (DTaP)-1[3]	2 months	6 weeks	2 months	4 weeks
DTaP-2	4 months	10 weeks	2 months	4 weeks
DTaP-3	6 months	14 weeks	6-12 months	6 months[5,6]
DTaP-4	15-18 months	12 months	3 years	6 months[5]
DTaP-5	4-6 years	4 years	—	—
Haemophilus influenzae type b (Hib)-1[3,7]	2 months	6 weeks	2 months	4 weeks
Hib-2	4 months	10 weeks	2 months	4 weeks
Hib-3[8]	6 months	14 weeks	6-9 months	8 weeks
Hib-4	12-15 months	12 months	—	—
Inactivated poliovirus (IPV)-1[3]	2 months	6 weeks	2 months	4 weeks
IPV-2	4 months	10 weeks	2-14 months	4 weeks
IPV-3	6-18 months	14 weeks	3-5 years	6 months
IPV-4[9]	4-6 years	4 years	—	—
Pneumococcal conjugate (PCV)-1[7]	2 months	6 weeks	8 weeks	4 weeks
PCV-2	4 months	10 weeks	8 weeks	4 weeks
PCV-3	6 months	14 weeks	6 months	8 weeks
PCV-4	12-15 months	12 months	—	—
Measles-mumps-rubella (MMR)-1[10]	12-15 months	12 months	3-5 years	4 weeks
MMR-2[10]	4-6 years	13 months	—	—
Varicella (Var)-1[10]	12-15 months	12 months	3-5 years	12 weeks[11]
Var-2[10]	4-6 years	15 months	—	—
Hepatitis A (HepA)-1	12-23 months	12 months	6-18 months[5]	6 months[5]
HepA-2	≥18 months	18 months	—	—
Influenza, inactivated (TIV)[12]	≥6 months	6 months[13]	1 month	4 weeks
Influenza, live attenuated (LAIV)[12]	2-49 years	2 years	1 month	4 weeks
Meningococcal conjugate (MCV4)-1[14]	11-12 years	2 years	4-5 years	8 weeks
MCV4-2	16 years	11 years (+ 8 weeks)	—	—
Meningococcal polysaccharide (MPSV4)-1[14]	—	2 years[15]	5 years	5 years
MPSV4-2	—	7 years	—	—
Tetanus-diphtheria (Td)	11-12 years	7 years	10 years	5 years
Tetanus-diphtheria-acellular pertussis (Tdap)[16]	≥11 years	7 years	—	—
Pneumococcal polysaccharide (PPSV)-1	—	2 years	5 years	5 years
PPSV-2[17]	—	7 years	—	—
Human papillomavirus (HPV)-1[18]	11-12 years	9 years	2 months	4 weeks
HPV-2	11-12 years (+ 2 months)	9 years (+ 4 weeks)	4 months	12 weeks[19]
HPV-3[19]	11-12 years (+ 6 months)	9 years (+24 weeks)	—	—
Rotavirus (RV)-1[21]	2 months	6 weeks	2 months	4 weeks
RV-2	4 months	10 weeks	2 months	4 weeks
RV-3[21]	6 months	14 weeks	—	—
Herpes zoster[22]	≥60 years	60 years	—	—

1 Combination vaccines are available. Use of licensed combination vaccines is generally preferred to separate injections of their equivalent component vaccines. When administering combination vaccines, the minimum age for administration is the oldest age for any of the individual components; the minimum interval between doses is equal to the greatest interval of any of the individual components.

2 Information on travel vaccines including typhoid, Japanese encephalitis, and yellow fever, is available at www.cdc.gov/travel. Information on other vaccines that are licensed in the US but not distributed, including anthrax and smallpox, is available at www.bt.cdc.gov.

3 Combination vaccines containing a hepatitis B component (Comvax, Pediarix, and Twinrix) are available. These vaccines should not be administered to infants younger than 6 weeks because of the other components (i.e., Hib, DTaP, HepA, and IPV).

4 HepB-3 should be administered at least 8 weeks after HepB-2 and at least 16 weeks after HepB-1, and should not be administered before age 24 weeks.

5 Calendar months.

5 The minimum recommended interval between DTaP-3 and DTaP-4 is 6 months. However, DTaP-4 need not be repeated if administered at least 4 months after DTaP-3.

7 Children receiving the first dose of Hib or PCV vaccine at age 7 months or older require fewer doses to complete the series.

8 If PRP-OMP (Pedvax-Hib) was administered at ages 2 and 4 months, a dose at age 6 months is not required.

9 A fourth dose is not needed if the third dose was administered on or after the 4th birthday and at least 6 months after the previous dose.

10 Combination measles-mumps-rubella-varicella (MMRV) vaccine can be used for children aged 12 months through 12 years. (See CDC. General recommendations on Immunization: recommendations of the ACIP. *MMWR* 2011;60[No. RR-2],7.)

11 For persons beginning the series on or after the 13th birthday, the minimum interval from varicella-1 to varicella-2 is 4 weeks.

12 One dose of influenza vaccine per season is recommended for most people. Children younger than 9 years of age who are receiving influenza vaccine for the first time should receive 2 doses this season. See current influenza recommendations for other factors affecting the decision to administer one vs. two doses to children younger than 9 years.

13 The minimum age for inactivated influenza vaccine varies by vaccine manufacturer and formulation. See package inserts for vaccine-specific minimum ages.

14 Revaccination with meningococcal vaccine is recommended for previously vaccinated persons who remain at high risk for meningococcal disease. (See CDC. Updated recommendations from the ACIP for vaccination of persons at prolonged increased risk for meningococcal disease. *MMWR* 2009;58:[1042-3])

15 Menactra may be given as young as 9 months for high-risk children.

16 Only one dose of Tdap is recommended. Subsequent doses should be given as Td. For one brand of Tdap (Adacel), the minimum age is 11 years. For management of a tetanus-prone wound in a person who has received a primary series of a tetanus-toxoid containing vaccine, there is no minimum interval between a previous dose of any tetanus-containing vaccine and Tdap.

17 A second dose of PPSV 5 years after the first dose is recommended for persons ≤65 years of age at highest risk for serious pneumococcal infection, and for those who are likely to have a rapid decline in pneumococcal antibody concentration. (See CDC. Prevention of pneumococcal disease: recommendations of the ACIP. *MMWR* 1997;46[No. RR-8].)

18 Bivalent HPV vaccine (Cervarix) is approved for females 10 through 25 years of age. Quadravalent HPV vaccine (Gardasil) is approved for males and females 9 through 26 years of age.

19 The minimum age for HPV-3 is based on the baseline minimum age for the first dose (108 months) and the minimum interval of 24 weeks between the first and third doses. Dose 3 need not be repeated if it is given at least 16 weeks after the first dose (and if the intervals between doses 1 and 2 and doses 2 and 3 are maintained at 4 weeks and 12 weeks, respectively).

20 The first dose of rotavirus must be administered between 6 weeks 0 days and 14 weeks 6 days. The vaccine series should not be started after age 15 weeks 0 days. Rotavirus should not be administered to children older than 8 months 0 days, regardless of the number of doses received before that age.

21 If two doses of Rotarix are administered as age appropriate, a third dose is not necessary.

22 Herpes zoster vaccine is recommended as a single dose for persons 60 years of age and older.

Recommended intervals between administration of **immune globulin preparations** and **measles-** or **varicella-containing vaccine**

Product / Indication	Dose, including mg immunoglobulin G (IgG)/kg body weight	Recommended interval before measles or varicella-containing[1] vaccine administration
Botulinum Immune Globulin Intravenous (Human)	1.5 mL/kg (75 mg IgG/kg) IV	5 months
Tetanus IG (TIG)	250 units (10 mg IgG/kg) IM	3 months
Hepatitis A IG		
- Contact prophylaxis	0.02 mL/kg (3.3 mg IgG/kg) IM	3 months
- International travel	0.06 mL/kg (10 mg IgG/kg) IM	3 months
Hepatitis B IG (HBIG)	0.06 mL/kg (10 mg IgG/kg) IM	3 months
Rabies IG (RIG)	20 IU/kg (22 mg IgG/kg) IM	4 months
Varicella IG	125 units/10 kg (60-200 mg IgG/kg) IM, maximum 625 units	5 months
Measles prophylaxis IG		
- Standard (i.e., nonimmunocompromised) contact	0.25 mL/kg (40 mg IgG/kg) IM	5 months
- Immunocompromised contact	0.5 mL/kg (80 mg IgG/kg) IM	6 months
Blood transfusion		
- Red blood cells (RBCs), washed	10 mL/kg (negligible IgG/kg) IV	None
- RBCs, adenine-saline added	10 mL/kg (10 mg IgG/kg) IV	3 months
- Packed RBCs (hematocrit 65%)[2]	10 mL/kg (60 mg IgG/kg) IV	6 months
- Whole blood (hematocrit 35%-50%)[2]	10 mL/kg (80-100 mg IgG/kg) IV	6 months
- Plasma/platelet products	10 mL/kg (160 mg IgG/kg) IV	7 months
Cytomegalovirus IGIV	150 mg/kg maximum	6 months
IGIV		
- Replacement therapy for immune deficiencies[3]	300-400 mg/kg IV	8 months
- Immune thrombocytopenic purpura treatment	400 mg/kg IV	8 months
- Immune thrombocytopenic purpura treatment	1,000 mg/kg IV	10 months
- Kawasaki disease	2 g/kg IV	11 months
- Postexposure varicella prophylaxis[4]	400 mg/kg IV	8 months
Monoclonal antibody to respiratory syncytial virus F protein (Synagis™)[5]	15 mg/kg (IM)	None

This table is not intended for determining the correct indications and dosages for using antibody-containing products. Unvaccinated persons might not be fully protected against measles during the entire recommended interval, and additional doses of IG or measles vaccine might be indicated after measles exposure. Concentrations of measles antibody in an IG preparation can vary by manufacturer's lot. Rates of antibody clearance after receipt of an IG preparation also might vary. Recommended intervals are extrapolated from an estimated half-life of 30 days for passively acquired antibody and an observed interference with the immune response to measles vaccine for 5 months after a dose of 80 mg IgG/kg.

1 Does not include zoster vaccine. Zoster vaccine may be given with antibody-containing blood products.

2 Assumes a serum IgG concentration of 16 mg/mL.

3 Measles and varicella vaccinations are recommended for children with asymptomatic or mildly symptomatic human immunodeficiency virus (HIV) infection, but are contraindicated for persons with severe immunosuppression from HIV or any other immunosuppressive disorder.

4 The investigational product VariZIG, similar to licensed VZIG, is a purified human IG preparation made from plasma containing high levels of anti-varicella antibodies (IgG). The interval between VariZIG and varicella vaccine (Var or MMRV) is 5 months.

5 Contains antibody only to respiratory syncytial virus

Adapted from Table 5, ACIP General Recommendations on Immunization

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Recommended Adult Immunization Schedule—United States - 2012

Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

Figure 1. Recommended adult immunization schedule, by vaccine and age group[1]

VACCINE ▼ AGE GROUP ▶	19-21 years	22-26 years	27-49 years	50-59 years	60-64 years	≥ 65 years
Influenza [2]	1 dose annually					
Tetanus, diphtheria, pertussis (Td/Tdap) [3,*]	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs					Td/Tdap[3]
Varicella [4,*]	2 Doses					
Human papillomavirus (HPV) Female [5,*]	3 doses					
Human papillomavirus (HPV) Male [5,*]	3 doses					
Zoster [6]					1 dose	
Measles, mumps, rubella (MMR) [7,*]	1 or 2 doses			1 dose		
Pneumococcal (polysaccharide) [8,9]	1 or 2 doses					1 dose
Meningococcal [10,*]	1 or more doses					
Hepatitis A [11,*]	2 doses					
Hepatitis B [12,*]	3 doses					

*Covered by the Vaccine Injury Compensation Program

- **For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection**
- **Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)**
- **Tdap recommended for ≥65 if contact with <12 month old child. Either Td or Tdap can be used if no infant contact**
- **No recommendation**

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 8:00 a.m. - 8:00 p.m. Eastern Time, Monday - Friday, excluding holidays.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

Figure 2. Vaccines that might be indicated for adults based on medical and other indications[1]

VACCINE ▼ INDICATION ▶	Pregnancy	Immunocompromising conditions (excluding human immunodeficiency virus [HIV])[4,6,7,14]	HIV infection[4,7,13,14] CD4+ T lymphocyte count <200 cells/μL	HIV infection[4,7,13,14] CD4+ T lymphocyte count >200 cells/μL	Men who have sex with men (MSM)	Heart disease, chronic lung disease, chronic alcoholism	Asplenia[13] (including elective splenectomy and persistent complement component deficiencies)	Chronic liver disease	Diabetes, kidney failure, end-stage renal disease, receipt of hemodialysis	Health-care personnel
Influenza [2]	1 dose TIV annually	1 dose TIV annually	1 dose TIV annually	1 dose TIV annually	1 dose TIV or LAIV annually	1 dose TIV annually	1 dose TIV annually	1 dose TIV annually	1 dose TIV annually	1 dose TIV or LAIV annually
Tetanus, diphtheria, pertussis (Td/Tdap) [3,*]	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs
Varicella [4,*]	Contraindicated	Contraindicated	Contraindicated	2 doses	2 doses	2 doses	2 doses	2 doses	2 doses	2 doses
Human papillomavirus (HPV) Female [5,*]		3 doses through age 26 yrs	3 doses through age 26 yrs	3 doses through age 26 yrs		3 doses through age 26 yrs	3 doses through age 26 yrs	3 doses through age 26 yrs	3 doses through age 26 yrs	
Human papillomavirus (HPV) Male [5,*]		3 doses through age 26 yrs	3 doses through age 26 yrs	3 doses through age 26 yrs	3 doses through age 26 yrs	3 doses through age 21 yrs	3 doses through age 21 yrs	3 doses through age 21 yrs	3 doses through age 21 yrs	
Zoster [6]	Contraindicated	Contraindicated	Contraindicated		1 dose	1 dose	1 dose	1 dose	1 dose	1 dose
Measles, mumps, rubella (MMR) [7,*]	Contraindicated	Contraindicated	Contraindicated	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses
Pneumococcal (polysaccharide) [8,9]	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses	1 or 2 doses
Meningococcal [10,*]	1 or more doses	1 or more doses	1 or more doses	1 or more doses	1 or more doses	1 or more doses	1 or more doses	1 or more doses	1 or more doses	1 or more doses
Hepatitis A [11,*]	2 doses	2 doses	2 doses	2 doses	2 doses	2 doses	2 doses	2 doses	2 doses	2 doses
Hepatitis B [12,*]	3 doses	3 doses	3 doses	3 doses	3 doses	3 doses	3 doses	3 doses	3 doses	3 doses

*Covered by the Vaccine Injury Compensation Program

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), American College of Obstetricians and Gynecologists (ACOG) and American College of Nurse-Midwives (ACNM).

For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

Contraindicated

No recommendation

These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly indicated for adults ages 19 years and older, as of January 1, 2012. For all vaccines being recommended on the Adult Immunization Schedule: a vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/pubs/acip-list.htm). Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

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

Footnotes — Recommended Adult Immunization Schedule—United States - 2012

1. **Additional information**
   - Advisory Committee on Immunization Practices (ACIP) vaccine recommendations and additional information are available at: http://www.cdc.gov/vaccines/pubs/acip-list.htm.
   - Information on travel vaccine requirements and recommendations (e.g., for hepatitis A and B, meningococcal, and other vaccines) available at http://wwwnc.cdc.gov/travel/page/vaccinations.htm.
2. **Influenza vaccination**
   - Annual vaccination against influenza is recommended for all persons 6 months of age and older.
   - Persons 6 months of age and older, including pregnant women, can receive the trivalent inactivated vaccine (TIV).
   - Healthy, nonpregnant adults younger than age 50 years without high-risk medical conditions can receive either intranasally administered live, attenuated influenza vaccine (LAIV) (FluMist), or TIV. Health-care personnel who care for severely immunocompromised persons (i.e., those who require care in a protected environment) should receive TIV rather than LAIV. Other persons should receive TIV.
   - The intramuscular or intradermal administered TIV are options for adults aged 18–64 years.
   - Adults aged 65 years and older can receive the standard dose TIV or the high-dose TIV (Fluzone High-Dose).
3. **Tetanus, diphtheria, and acellular pertussis (Td/Tdap) vaccination**
   - Administer a one-time dose of Tdap to adults younger than age 65 years who have not received Tdap previously or for whom vaccine status is unknown to replace one of the 10-year Td boosters.
   - Tdap is specifically recommended for the following persons:
     - pregnant women more than 20 weeks' gestation,
     - adults, regardless of age, who are close contacts of infants younger than age 12 months (e.g., parents, grandparents, or child care providers), and
     - health-care personnel.
   - Tdap can be administered regardless of interval since the most recent tetanus or diphtheria-containing vaccine.
   - Pregnant women not vaccinated during pregnancy should receive Tdap immediately postpartum.
   - Adults 65 years and older may receive Tdap.
   - Adults with unknown or incomplete history of completing a 3-dose primary vaccination series with Td-containing vaccines should begin or complete a primary vaccination series. Tdap should be substituted for a single dose of Td in the vaccination series with Tdap preferred as the first dose.
   - For unvaccinated adults, administer the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second.
   - If incompletely vaccinated (i.e., less than 3 doses), administer remaining doses.

   Refer to the ACIP statement for recommendations for administering Td/Tdap as prophylaxis in wound management (See footnote 1).
4. **Varicella vaccination**
   - All adults without evidence of immunity to varicella (as defined below) should receive 2 doses of single-antigen varicella vaccine or a second dose if they have received only 1 dose.
   - Special consideration for vaccination should be given to those who
     - have close contact with persons at high risk for severe disease (e.g., health-care personnel and family contacts of persons with immunocompromising conditions) or
     - are at high risk for exposure or transmission (e.g., teachers; child care employees; residents and staff members of institutional settings, including correctional institutions; college students; military personnel; adolescents and adults living in households with children; nonpregnant women of childbearing age; and international travelers).
   - Pregnant women should be assessed for evidence of varicella immunity. Women who do not have evidence of immunity should receive the first dose of varicella vaccine upon completion or termination of pregnancy and before discharge from the health-care facility. The second dose should be administered 4–8 weeks after the first dose.
   - Evidence of immunity to varicella in adults includes any of the following:
     - documentation of 2 doses of varicella vaccine at least 4 weeks apart;
     - U.S.-born before 1980 (although for health-care personnel and pregnant women, birth before 1980 should not be considered evidence of immunity);
     - history of varicella based on diagnosis or verification of varicella by a health-care provider (for a patient reporting a history of or having an atypical case, a mild case, or both, health-care providers should seek either an epidemiologic link to a typical varicella case or to a
5. **Measles, mumps, rubella (MMR) vaccination (cont'd)**

   Rubella component:
   - For women of childbearing age, regardless of birth year, rubella immunity should be determined. If there is no evidence of immunity, women who are not pregnant should be vaccinated. Pregnant women who do not have evidence of immunity should receive MMR vaccine upon completion or termination of pregnancy and before discharge from the health-care facility.

   Health-care personnel born before 1957:
   - For unvaccinated health-care personnel born before 1957 who lack laboratory evidence of measles, mumps, and/or rubella immunity or laboratory confirmation of disease, health-care facilities should consider routinely vaccinating personnel with 2 doses of MMR vaccine at the appropriate interval for measles and mumps or 1 dose of MMR vaccine for rubella.
6. **Pneumococcal polysaccharide (PPSV) vaccination**
   - Vaccinate all persons with the following indications:
     - age 65 years and older without a history of PPSV vaccination;
     - adults younger than 65 years with chronic lung disease (including chronic obstructive pulmonary disease, emphysema, and asthma); chronic cardiovascular diseases; diabetes mellitus; chronic liver disease (including cirrhosis); alcoholism; cochlear implants; cerebrospinal fluid leaks; immunocompromising conditions; and functional or anatomic asplenia (e.g., sickle cell disease and other hemoglobinopathies, congenital or acquired asplenia, splenic dysfunction, or splenectomy [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]);
     - residents of nursing homes or long-term care facilities; and
     - adults who smoke cigarettes.
   - Persons with asymptomatic or symptomatic HIV infection should be vaccinated as soon as possible after their diagnosis.
   - When cancer chemotherapy or other immunosuppressive therapy is being considered, the interval between vaccination and initiation of immunosuppressive therapy should be at least 2 weeks. Vaccination during chemotherapy or radiation therapy should be avoided.
   - Routine use of PPSV is not recommended for American Indians/Alaska Natives or other persons younger than 65 years of age unless they have underlying medical conditions that are PPSV indications. However, public health authorities may consider recommending PPSV for American Indians/Alaska Natives who are living in areas where the risk for invasive pneumococcal disease is increased.
7. **Revaccination with PPSV**
   - One-time revaccination 5 years after the first dose is recommended for persons 19 through 64 years of age with chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy); and for persons with immunocompromising conditions.
   - Persons who received PPSV 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.
   - No further doses are needed for persons vaccinated with PPSV at or after age 65 years.
8. **Meningococcal vaccination**
   - Administer 2 doses of meningococcal conjugate vaccine quadrivalent (MCV4) at least 2 months apart to adults with functional asplenia or persistent complement component deficiencies.
   - HIV-infected persons who are vaccinated should also receive 2 doses.
   - Administer a single dose of meningococcal vaccine to microbiologists routinely exposed to isolates of *Neisseria meningitidis*, military recruits, and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic.
   - First-year college students up through age 21 years who are living in residence halls should be vaccinated if they have not received a dose on or after their 16th birthday.
   - MCV4 is preferred for adults with any of the preceding indications who are 55 years old and younger; meningococcal polysaccharide vaccine (MPSV4) is preferred for adults 56 years and older.
   - Revaccination with MCV4 every 5 years is recommended for adults previously vaccinated with MCV4 or MPSV4 who remain at increased risk for infection (e.g., adults with anatomic or functional asplenia or persistent complement component deficiencies).
9. **Hepatitis A vaccination**
   - Vaccinate any person seeking protection from hepatitis A virus (HAV) infection and persons with any of the following indications:
     - men who have sex with men and persons who use injection drugs;

laboratory-confirmed case or evidence of laboratory confirmation, if it was performed at the time of acute disease);
  - history of herpes zoster based on diagnosis or verification of herpes zoster by a health-care provider; or
  - laboratory evidence of immunity or laboratory confirmation of disease.

5. **Human papillomavirus (HPV) vaccination**
   - Two vaccines are licensed for use in females, bivalent HPV vaccine (HPV2) and quadrivalent HPV vaccine (HPV4), and one HPV vaccine for use in males (HPV4).
   - For females, either HPV4 or HPV2 is recommended in a 3-dose series for routine vaccination at 11 or 12 years of age, and for those 13 through 26 years of age, if not previously vaccinated.
   - For males, HPV4 is recommended in a 3-dose series for routine vaccination at 11 or 12 years of age, and for those 13 through 21 years of age, if not previously vaccinated. Males 22 through 26 years of age may be vaccinated.
   - HPV vaccines are not live vaccines and can be administered to persons who are immunocompromised as a result of infection (including HIV infection), disease, or medications. Vaccine is recommended for immunocompromised persons through age 26 years who did not get any or all doses when they were younger. The immune response and vaccine efficacy might be less than that in immunocompetent persons.
   - Men who have sex with men (MSM) might especially benefit from vaccination to prevent condyloma and anal cancer. HPV4 is recommended for MSM through age 26 years who did not get any or all doses when they were younger.
   - Ideally, vaccine should be administered before potential exposure to HPV through sexual activity; however, persons who are sexually active should still be vaccinated consistent with age-based recommendations. HPV vaccine can be administered to persons with a history of genital warts, abnormal Papanicolaou test, or positive HPV DNA test.
   - A complete series for either HPV4 or HPV2 consists of 3 doses. The second dose should be administered 1–2 months after the first dose; the third dose should be administered 6 months after the first dose (at least 24 weeks after the first dose).
   - Although HPV vaccination is not specifically recommended for health-care personnel (HCP) based on their occupation, HCP should receive the HPV vaccine if they are in the recommended age group.

6. **Zoster vaccination**
   - A single dose of zoster vaccine is recommended for adults 60 years of age and older regardless of whether they report a prior episode of herpes zoster. Although the vaccine is licensed by the Food and Drug Administration (FDA) for use among and can be administered to persons 50 years and older, ACIP recommends that vaccination begins at 60 years of age.
   - Persons with chronic medical conditions may be vaccinated unless their condition constitutes a contraindication, such as pregnancy or severe immunodeficiency.
   - Although zoster vaccination is not specifically recommended for health-care personnel (HCP), HCP should receive the vaccine if they are in the recommended age group.

7. **Measles, mumps, rubella (MMR) vaccination**
   - Adults born before 1957 generally are considered immune to measles and mumps. All adults born in 1957 or later should have documentation of 1 or more doses of MMR vaccine unless they have a medical contraindication to the vaccine, laboratory evidence of immunity to each of the three diseases, or documentation of provider-diagnosed measles or mumps disease. For rubella, documentation of provider-diagnosed disease is not considered acceptable evidence of immunity.

   Measles component:
   - A routine second dose of MMR vaccine, administered a minimum of 28 days after the first dose, is recommended for adults who
     - are students in postsecondary educational institutions;
     - work in a health-care facility; or
     - plan to travel internationally.
   - Persons who received inactivated (killed) measles vaccine or measles vaccine of unknown type from 1963 to 1967 should be revaccinated with 2 doses of MMR vaccine.

   Mumps component:
   - A routine second dose of MMR vaccine, administered a minimum of 28 days after the first dose, is recommended for adults who
     - are students in postsecondary educational institutions;
     - work in a health-care facility; or
     - plan to travel internationally.
   - Persons vaccinated before 1979 with either killed mumps vaccine or mumps vaccine of unknown type who are at high risk for mumps infection (e.g., persons who are working in a health-care facility) should be considered for revaccination with 2 doses of MMR vaccine.

8. **Hepatitis A vaccination**
   - Vaccinate persons with any of the following indications and any person seeking protection from hepatitis A virus (HAV) infection:
     - persons working with HAV-infected primates or with HAV in a research laboratory setting;
     - persons with chronic liver disease and persons who receive clotting factor concentrates;
     - persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A; and
     - unvaccinated persons who anticipate close personal contact (e.g., household or regular babysitting) with an international adoptee during the first 60 days after arrival in the United States from a country with high or intermediate endemicity. (See footnote 1 for more information on travel recommendations). The first dose of the 2-dose hepatitis A vaccine series should be administered as soon as adoption is planned, ideally 2 or more weeks before the arrival of the adoptee.
   - Single-antigen vaccine formulations should be administered in a 2-dose schedule at either 0 and 6–12 months (Havrix), or 0 and 6–18 months (Vaqta). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, administer 3 doses at 0, 1, and 6 months; alternatively, a 4-dose schedule may be used, administered on days 0, 7, and 21–30 followed by a booster dose at month 12.

12. **Hepatitis B vaccination**
   - Vaccinate persons with any of the following indications and any person seeking protection from hepatitis B virus (HBV) infection:
     - sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months); persons seeking evaluation or treatment for a sexually transmitted disease (STD); current or recent injection-drug users; and men who have sex with men;
     - health-care personnel and public-safety workers who are exposed to blood or other potentially infectious body fluids;
     - persons with diabetes younger than 60 years as soon as feasible after diagnosis; persons with diabetes who are 60 years or older at the discretion of the treating clinician based on increased need for assisted blood glucose monitoring in long-term care facilities, likelihood of acquiring hepatitis B infection, its complications or chronic sequelae, and likelihood of immune response to vaccination;
     - persons with end-stage renal disease, including patients receiving hemodialysis; persons with HIV infection; and persons with chronic liver disease;
     - household contacts and sex partners of persons with chronic HBV infection; clients and staff members of institutions for persons with developmental disabilities; and international travelers to countries with high or intermediate prevalence of chronic HBV infection; and
     - all adults in the following settings: STD treatment facilities; HIV testing and treatment facilities; facilities providing drug-abuse treatment and prevention services; health-care settings targeting services to injection-drug users or men who have sex with men; correctional facilities; end-stage renal disease programs and facilities for chronic hemodialysis patients; and institutions and nonresidential daycare facilities for persons with developmental disabilities.
   - Administer missing doses to complete a 3-dose series of hepatitis B vaccine to those persons not vaccinated or not completely vaccinated. The second dose should be administered 1 month after the first dose; the third dose should be given at least 2 months after the second dose (and at least 4 months after the first dose). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, give 3 doses at 0, 1, and 6 months; alternatively, a 4-dose Twinrix schedule, administered on days 0, 7, and 21–30 followed by a booster dose at month 12 may be used.
   - Adult patients receiving hemodialysis or with other immunocompromising conditions should receive 1 dose of 40 μg/mL (Recombivax HB) administered on a 3-dose schedule or 2 doses of 20 μg/mL (Engerix-B) administered simultaneously on a 4-dose schedule at 0, 1, 2, and 6 months.

13. **Selected conditions for which *Haemophilus influenzae* type b (Hib) vaccine may be used**
   - 1 dose of Hib vaccine should be considered for persons who have sickle cell disease, leukemia, or HIV infection, or who have anatomic or functional asplenia if they have not previously received Hib vaccine.

14. **Immunocompromising conditions**
   - Inactivated vaccines generally are acceptable (e.g., pneumococcal, meningococcal, and influenza [inactivated influenza vaccine]), and live vaccines generally are avoided in persons with immune deficiencies or immunocompromising conditions. Information on specific conditions is available at http://www.cdc.gov/vaccines/pubs/acip-list.htm.

GENERAL RECOMMENDTIONS APPLYING TO SPACING AND ADMINISTRATION OF ROUTINELY RECOMMENDED CHILDHOOD VACCINES

1) Simultaneous administration. This recommendation states that there are no contraindications to the simultaneous administration of any of the routinely recommended vaccines included on the current ACIP schedule. The only exception to this rule is that PCV and **PPSV** should be separated by 8 weeks.

2) No minimum time intervals between the administration of 2 different inactivated vaccines. For example, you could give a DTaP one day and a HIB the next, or 2 weeks later. Again, the one exception is for doses of PCV and **PPSV**.

3) If 2 different live virus vaccines are not administered on the same day, they must be separated by at least 4 weeks. This would apply specifically to doses of MMR and varicella, if not administered on the same day.

4) If 2 different live injectable vaccines are given <28 days apart, the one given second should be repeated ≥ 28 days after the second or invalid dose.

5) This recommendation states that vaccine doses should not be given at intervals less than the minimum intervals or earlier than the minimum age. Table 1 of the General Recommendations gives all the minimum intervals and ages for each dose of the recommended childhood vaccines.

6) The 4 day grace period
•In 2002 the ACIP instituted what is referred to as the grace period, for use in evaluating immunization records. Basically, it states that doses given ≤4 days before the minimum age or interval may be counted as valid doses.
•The exception to this is in regard to the spacing of doses of MMR and varicella.
•This rule should be used primarily for evaluating records, NOT for scheduling visits.
•In Georgia, this rule does not conflict with the requirements for school and day care. This is not true in some states.

7) If vaccines are administered later than the recommended schedule:
•Do not start over
•Do not repeat doses
•Continue with the rest of the series according to recommended intervals and ages.

8) The importance of administering vaccines by the recommended routes and sites. It does, however, state that in evaluating records, all doses given by nonstandard routes and sites may be accepted except:
•Rabies and hepatitis B given in the gluteus
•Hepatitis B not given IM
•Continue to discard and repeat vaccines given in "divided doses"
•Do not mix vaccines unless they are licensed to be mixed.

9) Combination vaccines may be used whenever any components of the combination are indicated AND its other components are not contraindicated. The manufacturers' package insert should be consulted for further information.

10 Contraindications and precautions are circumstances that dictate when vaccines should not be administered.
•A contraindication is a condition in the recipient that <u>increases</u> the risk for a serious adverse reaction.
•A precaution is a condition in the recipient that <u>might increase</u> the risk for a serious adverse reaction. In some circumstances it may be necessary to weigh benefits vs. risks, as in an outbreak.
•**Because the majority of contraindications and precautions are temporary, vaccines often can be given later if one or more exist**.

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

Screening Checklist for Contraindications to Vaccines for Children and Teens

For parents/guardians: The following questions will help us determine which vaccines your child may be given today. If you answer "yes" to any question, it does not necessarily mean your child should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

		Yes	No	Don't Know
1.	Is the child sick today?	☐	☐	☐
2.	Does the child have allergies to medications, food, a vaccine component, or latex?	☐	☐	☐
3.	Has the child had a serious reaction to a vaccine in the past?	☐	☐	☐
4.	Has the child had a health problem with lung, heart, kidney or metabolic disease (e.g., diabetes), asthma, or a blood disorder? Is he/she on long-term aspirin therapy?	☐	☐	☐
5.	If the child to be vaccinated is between the ages of 2 and 4 years, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months?	☐	☐	☐
6.	If your child is a baby, have you ever been told he or she has had intussusception?	☐	☐	☐
7.	Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problems?	☐	☐	☐
8.	Does the child have cancer, leukemia, HIV/AIDS, or any other immune system problem?	☐	☐	☐
9.	In the past 3 months, has the child taken medications that weaken their immune system, such as cortisone, prednisone, other steroids, or anticancer drugs, or had radiation treatments?	☐	☐	☐
10.	In the past year, has the child received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?	☐	☐	☐
11.	Is the child/teen pregnant or is there a chance she could become pregnant during the next month?	☐	☐	☐
12.	Has the child received vaccinations in the past 4 weeks?	☐	☐	☐

Form completed by: _____ Date: _____

Form reviewed by: _____ Date: _____

Did you bring your child's immunization record card with you? **yes** ☐ **no** ☐

It is important to have a personal record of your child's vaccinations. If you don't have one, ask the child's healthcare provider to give you one with all your child's vaccinations on it. Keep it in a safe place and bring it with you every time you seek medical care for your child. Your child will need this document to enter day care or school, for employment, or for international travel.

Technical content reviewed by the Centers for Disease Control and Prevention

www.immunize.org/catg.d/p4060.pdf • Item #P4060 (10/12)

Information for Health Professionals about the Screening Checklist for Contraindications (Children & Teens)

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

1. Is the child sick today? *[all vaccines]*
There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events (1, 2). However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (such as otitis media, upper respiratory infections, and diarrhea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics.

2. Does the child have allergies to medications, food, a vaccine component, or latex? *[all vaccines]*
If a person reports they have an allergy to egg, ask if they can eat lightly cooked eggs (e.g., scrambled eggs). If they can, trivalent influenza vaccine (TIV) may be administered. If after eating eggs or egg-containing foods, they have a reaction consisting of only hives, TIV may be given and the person should be observed for at least 30 minutes. If a person experiences a serious systemic or anaphylactic reaction (e.g., hives and either swelling of the lips or tongue, acute respiratory distress, or collapse) after eating eggs, do not administer TIV or live attenuated influenza vaccine (LAIV). It is possible that they may be eligible to be given TIV, but only after they have seen a physician with expertise in the management of allergic conditions. If a person has anaphylaxis after eating gelatin, do not administer LAIV, measles-mumps-rubella (MMR), MMR+varicella (MMRV), or varicella vaccine. A local reaction is not a contraindication. For a table of vaccines supplied in vials or syringes that contain latex, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/latex-table.pdf. For an extensive table of vaccine components, see reference 3.

3. Has the child had a serious reaction to a vaccine in the past?
[all vaccines] History of anaphylactic reaction (see question 2) to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses (1). History of encephalopathy within 7 days following DTP/DTaP is a contraindication for further doses of pertussis-containing vaccine. Precautions to DTaP (not Tdap) include the following: (a) seizure within 3 days of a dose, (b) pale or limp episode or collapse within 48 hours of a dose, (c) continuous crying for 3 or more hours within 48 hours of a dose, and (d) fever of 105°F (40°C) within 48 hours of a previous dose. There are other adverse events that might have occurred following vaccination that constitute contraindications or precautions to future doses. Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak).

4. Has the child had a health problem with lung, heart, kidney, or metabolic disease (e.g., diabetes), asthma, or a blood disorder? Is he/she on long-term aspirin therapy? *[LAIV]*
Children with any of the health conditions listed above should not be given the intranasal, live attenuated influenza vaccine (LAIV). These children should be vaccinated with the injectable influenza vaccine.

5. If the child to be vaccinated is between the ages of 2 and 4 years, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months? *[LAIV]*
Children who have had a wheezing episode within the past 12 months should not be given the live attenuated influenza vaccine. Instead, these children should be given the inactivated influenza vaccine.

6. If your child is a baby, have you ever been told that he or she has had intussusception? *[Rotavirus]*
Infants who have a history of intussusception (i.e., the telescoping of one portion of the intestine into another) should not be given rotavirus vaccine.

7. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problem? *[DTaP, Td, Tdap, TIV, LAIV, MMRV]* DTaP and Tdap are contraindicated in children who have a history of encephalopathy within 7 days following DTP/DTaP. An unstable progressive neurologic problem is a precaution to the use of DTaP and Tdap, and a progressive neurologic disorder in a teen is a precaution to the use of Td. For children with stable neurologic disorders (including seizures) unrelated to vaccination, or for children with a family history of seizures, vaccinate as usual (*exception:* children with a personal or family [i.e., parent or sibling] history of seizures generally should not be vaccinated with MMRV; they should receive separate MMR and VAR vaccines). A history of Guillain-Barré syndrome (GBS) is a consideration with the following:
1) Td/Tdap: if GBS has occurred within 6 weeks of a tetanus-containing vaccine and decision is made to continue vaccination, give age-appropriate Tdap instead of Td if no history of prior Tdap; 2) Influenza vaccine (TIV or LAIV): if GBS has occurred within 6 weeks of a prior influenza vaccination, vaccinate with TIV if at high risk for severe influenza complications.

8. Does the child have cancer, leukemia, HIV/AIDS, or any other immune system problem? *[LAIV, MMR, MMRV, RV, VAR]*
Live virus vaccines (e.g., MMR, MMRV, varicella, rotavirus, and the intranasal live, attenuated influenza vaccine [LAIV]) are usually contraindicated in immunocompromised children. However, there are exceptions. For example, MMR is recommended for asymptomatic HIV-infected children who do not have evidence of severe immunosuppression. Likewise, varicella vaccine should be considered for HIV-infected children with age-specific CD4+ T-lymphocyte percentage at 15% or greater and may be considered for children age 8 years and older with CD4+ T-lymphocyte counts of greater than or equal to 200 cells/μL. Immunosuppressed children should not receive LAIV. Infants who have been diagnosed with severe combined immunodeficiency (SCID) should not be given a live virus vaccine, including rotavirus (RV) vaccine. For details, consult the ACIP recommendations (4, 5, 6).

9. In the past 3 months, has the child taken medications that weaken their immune system, such as cortisone, prednisone, other steroids, or anticancer drugs, or had radiation treatments? *[LAIV, MMR, MMRV, VAR]*
Live virus vaccines (e.g., MMR, MMRV, varicella, LAIV) should be postponed until after chemotherapy or long-term high-dose steroid therapy has ended. For details and length of time to postpone, consult the ACIP statement (1). To find specific vaccination schedules for stem cell transplant (bone marrow transplant) patients, see reference 7. LAIV can be given only to healthy non-pregnant individuals age 2–49 years.

10. In the past year, has the child received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug? *[LAIV, MMR, MMRV, VAR]*
Certain live virus vaccines (e.g., LAIV, MMR, MMRV, varicella) may need to be deferred, depending on several variables. Consult the most current ACIP recommendations or the current *Red Book* for the most current information on intervals between antiviral drugs, immune globulin or blood product administration and live virus vaccines (1, 2).

11. Is the child/teen pregnant or is there a chance she could become pregnant during the next month? *[LAIV, MMR, MMRV, VAR]*
Live virus vaccines (e.g., MMR, MMRV, varicella, LAIV) are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus (1, 6). Sexually active young women who receive a live virus vaccine should be instructed to practice careful contraception for one month following receipt of the vaccine (5, 8). On theoretical grounds, inactivated poliovirus vaccine should not be given during pregnancy; however, it may be given if risk of disease is imminent (e.g., travel to endemic areas) and immediate protection is needed. Use of Td or Tdap is not contraindicated in pregnancy. At the provider's discretion, either vaccine may be administered during the 2nd or 3rd trimester (9).

12. Has the child received vaccinations in the past 4 weeks?
[LAIV, MMR, MMRV, VAR, yellow fever]
If the child was given either live, attenuated influenza vaccine (LAIV) or an injectable live virus vaccine (e.g., MMR, MMRV, varicella, yellow fever) in the past 4 weeks, they should wait 28 days before receiving another vaccination of this type. Inactivated vaccines may be given at the same time or at any spacing interval.

References:
1. CDC. General recommendations on immunization, at www.cdc.gov/vaccines/pubs/acip-list.htm.
2. AAP. *Red Book: Report of the Committee on Infectious Diseases* at www.aapredbook.org.
3. Table of Vaccine Components: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
4. CDC. Measles, mumps, and rubella—vaccine use and strategies for elimination of measles, rubella, and congenital rubella syndrome and control of mumps. *MMWR* 1998; 47 (RR-8).
5. CDC. Prevention of varicella: Recommendations of the Advisory Committee on Immunization Practices. *MMWR* 2007; 56 (RR-4).
6. CDC. Prevention and Control of Influenza—Recommendations of ACIP at www.cdc.gov/flu/professionals/vaccination/.
7. CDC. Excerpt from Guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients, *MMWR* 2000; 49 (RR-10), www.cdc.gov/vaccines/pubs/down-loads/b_hsct-recs.pdf.
8. CDC. Notice to readers: Revised ACIP recommendation for avoiding pregnancy after receiving a rubella-containing vaccine. *MMWR* 2001; 50 (49).
9. CDC. Prevention of pertussis, tetanus, and diphtheria among pregnant and postpartum women and their infants: Recommendations of the ACIP. *MMWR* 2008; 57 (RR-4).

Nombre del paciente: _____ Fecha de nacimiento: ____/____/____
(mes) (día) (año)

Cuestionario de contraindicaciones para vacunación de niños y adolescentes

A los padres/tutores: Las siguientes preguntas nos ayudarán a determinar cuáles vacunas le podremos dar hoy a su hijo. Si contesta "sí" a alguna pregunta, eso no siempre quiere decir que no deben vacunar a su hijo. Simplemente quiere decir que hay que hacerle más preguntas. Si alguna pregunta no está clara, pida a su profesional de la salud que se la explique.

		Sí	No	No sabe
1.	¿Está enfermo hoy el niño?	☐	☐	☐
2.	¿Es alérgico el niño a algún medicamento, alimento, a algún componente de las vacunas o al látex?	☐	☐	☐
3.	¿Tuvo alguna vez el niño alguna reacción seria a una vacuna en el pasado?	☐	☐	☐
4.	¿Ha tenido el niño algún problema de salud como enfermedad de los pulmones, del corazón, de los riñones o metabólica (como diabetes), asma o un trastorno de la sangre? ¿Está en terapia de aspirina a largo plazo?	☐	☐	☐
5.	Si el niño que va a ser vacunado tiene entre 2 y 4 años de edad, ¿le dijo algún profesional de la salud en los últimos 12 meses que el niño tuvo sibilancias o asma?	☐	☐	☐
6.	Si el niño es bebé, ¿le dijeron alguna vez que tuvo intususcepción?	☐	☐	☐
7.	¿El niño, uno de sus hermanos o padres, ha tenido convulsiones; ha tenido el niño problemas del cerebro o algún otro problema del sistema nervioso?	☐	☐	☐
8.	¿Tiene el niño cáncer, leucemia, VIH/SIDA o algún otro problema del sistema inmunológico?	☐	☐	☐
9.	En los últimos 3 meses, ¿ha tomado el niño medicamento que debiliten su sistema inmunológico, tales como cortisona, prednisona, otros esteroides o medicamentos contra el cáncer, o le han hecho tratamientos de radiación?	☐	☐	☐
10.	Durante el año pasado, ¿le hicieron al niño una transfusión de sangre o de productos de la sangre, o le dieron inmunoglobulina o gamaglobulina o algún medicamento antiviral?	☐	☐	☐
11.	¿Está la niña/adolescente embarazada o hay alguna posibilidad de que quede embarazada durante el próximo mes?	☐	☐	☐
12.	¿Le aplicaron alguna vacuna al niño en las últimas 4 semanas?	☐	☐	☐

Formulario llenado por: _____ Fecha: _____

Formulario revisado por: _____ Fecha: _____

¿Trajo el comprobante de vacunación de su hijo? **sí** ☐ **no** ☐

Es importante que tenga un comprobante de vacunación personal de las vacunas de su hijo. Si no lo tiene, pídale al profesional de la salud de su hijo que le dé uno con todas las vacunas de a su hijo. Guárdelo en un lugar seguro y llévelo todas las veces que su hijo reciba atención médica. Su hijo necesitará este documento importante por el resto de su vida para ingresar a la guardería o a la escuela, para empleos o para viajar al extranjero.

Translation by Transcend, Davis, CA

www.immunize.org/catg.d/p4060-01.pdf • Item #P4060-01 Spanish (10/12)

Information for Health Professionals about the Screening Checklist for Contraindications (Children & Teens)

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

1. Is the child sick today? *[all vaccines]*
There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events (1, 2). However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (such as otitis media, upper respiratory infections, and diarrhea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics.

2. Does the child have allergies to medications, food, a vaccine component, or latex? *[all vaccines]*
If a person reports they have an allergy to egg, ask if they can eat lightly cooked eggs (e.g., scrambled eggs). If they can, trivalent influenza vaccine (TIV) may be administered. If after eating eggs or egg-containing foods, they have a reaction consisting of only hives, TIV may be given and the person should be observed for at least 30 minutes. If a person experiences a serious systemic or anaphylactic reaction (e.g., hives and either swelling of the lips or tongue, acute respiratory distress, or collapse) after eating eggs, do not administer TIV or live attenuated influenza vaccine (LAIV). It is possible that they may be eligible to be given TIV, but only after they have seen a physician with expertise in the management of allergic conditions. If a person has anaphylaxis after eating gelatin, do not administer LAIV, measles-mumps-rubella (MMR), MMR+varicella (MMRV), or varicella vaccine. A local reaction is not a contraindication. For a table of vaccines supplied in vials or syringes that contain latex, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/latex-table.pdf. For an extensive table of vaccine components, see reference 3.

3. Has the child had a serious reaction to a vaccine in the past?
[all vaccines] History of anaphylactic reaction (see question 2) to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses (1). History of encephalopathy within 7 days following DTP/DTaP is a contraindication for further doses of pertussis-containing vaccine. Precautions to DTaP (not Tdap) include the following: (a) seizure within 3 days of a dose, (b) pale or limp episode or collapse within 48 hours of a dose, (c) continuous crying for 3 or more hours within 48 hours of a dose, and (d) fever of 105°F (40°C) within 48 hours of a previous dose. There are other adverse events that might have occurred following vaccination that constitute contraindications or precautions to future doses. Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak).

4. Has the child had a health problem with lung, heart, kidney, or metabolic disease (e.g., diabetes), asthma, or a blood disorder? Is he/she on long-term aspirin therapy? *[LAIV]*
Children with any of the health conditions listed above should not be given the intranasal, live attenuated influenza vaccine (LAIV). These children should be vaccinated with the injectable influenza vaccine.

5. If the child to be vaccinated is between the ages of 2 and 4 years, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months? *[LAIV]*
Children who have had a wheezing episode within the past 12 months should not be given the live attenuated influenza vaccine. Instead, these children should be given the inactivated influenza vaccine.

6. If your child is a baby, have you ever been told that he or she has had intussusception? *[Rotavirus]*
Infants who have a history of intussusception (i.e., the telescoping of one portion of the intestine into another) should not be given rotavirus vaccine.

7. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problem? *[DTaP, Td, Tdap, TIV, LAIV, MMRV]* DTaP and Tdap are contraindicated in children who have a history of encephalopathy within 7 days following DTP/DTaP. An unstable progressive neurologic problem is a precaution to the use of DTaP and Tdap, and a progressive neurologic disorder in a teen is a precaution to the use of Td. For children with stable neurologic disorders (including seizures) unrelated to vaccination, or for children with a family history of seizures, vaccinate as usual (*exception:* children with a personal or family [i.e., parent or sibling] history of seizures generally should not be vaccinated with MMRV; they should receive separate MMR and VAR vaccines). A history of Guillain-Barré syndrome (GBS) is a consideration with the following:
1) Td/Tdap: if GBS has occurred within 6 weeks of a tetanus-containing vaccine and decision is made to continue vaccination, give age-appropriate Tdap instead of Td if no history of prior Tdap; 2) Influenza vaccine (TIV or LAIV): if GBS has occurred within 6 weeks of a prior influenza vaccination, vaccinate with TIV if at high risk for severe influenza complications.

8. Does the child have cancer, leukemia, HIV/AIDS, or any other immune system problem? *[LAIV, MMR, MMRV, RV, VAR]*
Live virus vaccines (e.g., MMR, MMRV, varicella, rotavirus, and the intranasal live, attenuated influenza vaccine [LAIV]) are usually contraindicated in immunocompromised children. However, there are exceptions. For example, MMR is recommended for asymptomatic HIV-infected children who do not have evidence of severe immunosuppression. Likewise, varicella vaccine should be considered for HIV-infected children with age-specific CD4+ T-lymphocyte percentage at 15% or greater and may be considered for children age 8 years and older with CD4+ T-lymphocyte counts of greater than or equal to 200 cells/μL. Immunosuppressed children should not receive LAIV. Infants who have been diagnosed with severe combined immunodeficiency (SCID) should not be given a live virus vaccine, including rotavirus (RV) vaccine. For details, consult the ACIP recommendations (4, 5, 6).

9. In the past 3 months, has the child taken medications that weaken their immune system, such as cortisone, prednisone, other steroids, or anticancer drugs, or had radiation treatments? *[LAIV, MMR, MMRV, VAR]*
Live virus vaccines (e.g., MMR, MMRV, varicella, LAIV) should be postponed until after chemotherapy or long-term high-dose steroid therapy has ended. For details and length of time to postpone, consult the ACIP statement (1). To find specific vaccination schedules for stem cell transplant (bone marrow transplant) patients, see reference 7. LAIV can be given only to healthy non-pregnant individuals age 2–49 years.

10. In the past year, has the child received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug? *[LAIV, MMR, MMRV, VAR]*
Certain live virus vaccines (e.g., LAIV, MMR, MMRV, varicella) may need to be deferred, depending on several variables. Consult the most current ACIP recommendations or the current *Red Book* for the most current information on intervals between antiviral drugs, immune globulin or blood product administration and live virus vaccines (1, 2).

11. Is the child/teen pregnant or is there a chance she could become pregnant during the next month? *[LAIV, MMR, MMRV, VAR]*
Live virus vaccines (e.g., MMR, MMRV, varicella, LAIV) are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus (1, 6). Sexually active young women who receive a live virus vaccine should be instructed to practice careful contraception for one month following receipt of the vaccine (5, 8). On theoretical grounds, inactivated poliovirus vaccine should not be given during pregnancy; however, it may be given if risk of disease is imminent (e.g., travel to endemic areas) and immediate protection is needed. Use of Td or Tdap is not contraindicated in pregnancy. At the provider's discretion, either vaccine may be administered during the 2nd or 3rd trimester (9).

12. Has the child received vaccinations in the past 4 weeks?
[LAIV, MMR, MMRV, VAR, yellow fever]
If the child was given either live, attenuated influenza vaccine (LAIV) or an injectable live virus vaccine (e.g., MMR, MMRV, varicella, yellow fever) in the past 4 weeks, they should wait 28 days before receiving another vaccination of this type. Inactivated vaccines may be given at the same time or at any spacing interval.

References:
1. CDC. General recommendations on immunization, at www.cdc.gov/vaccines/pubs/acip-list.htm.
2. AAP. *Red Book: Report of the Committee on Infectious Diseases* at www.aapredbook.org.
3. Table of Vaccine Components: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
4. CDC. Measles, mumps, and rubella—vaccine use and strategies for elimination of measles, rubella, and congenital rubella syndrome and control of mumps. *MMWR* 1998; 47 (RR-8).
5. CDC. Prevention of varicella: Recommendations of the Advisory Committee on Immunization Practices. *MMWR* 2007; 56 (RR-4).
6. CDC. Prevention and Control of Influenza—Recommendations of ACIP at www.cdc.gov/flu/professionals/vaccination/.
7. CDC. Excerpt from Guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients, *MMWR* 2000; 49 (RR-10), www.cdc.gov/vaccines/pubs/down-loads/b_hsct-recs.pdf.
8. CDC. Notice to readers: Revised ACIP recommendation for avoiding pregnancy after receiving a rubella-containing vaccine. *MMWR* 2001; 50 (49).
9. CDC. Prevention of pertussis, tetanus, and diphtheria among pregnant and postpartum women and their infants: Recommendations of the ACIP. *MMWR* 2008; 57 (RR-4).

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

Screening Checklist for Contraindications to Vaccines for Adults

For patients: The following questions will help us determine which vaccines you may be given today. If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	Yes	No	Don't Know
1. Are you sick today?	☐	☐	☐
2. Do you have allergies to medications, food, a vaccine component, or latex?	☐	☐	☐
3. Have you ever had a serious reaction after receiving a vaccination?	☐	☐	☐
4. Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia, or other blood disorder?	☐	☐	☐
5. Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem?	☐	☐	☐
6. In the past 3 months, have you taken medications that weaken your immune system, such as cortisone, prednisone, other steroids, or anticancer drugs, or have you had radiation treatments?	☐	☐	☐
7. Have you had a seizure or a brain or other nervous system problem?	☐	☐	☐
8. During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?	☐	☐	☐
9. For women: Are you pregnant or is there a chance you could become pregnant during the next month?	☐	☐	☐
10. Have you received any vaccinations in the past 4 weeks?	☐	☐	☐

Form completed by: _____ Date: _____

Form reviewed by: _____ Date: _____

Did you bring your immunization record card with you? **yes** ☐ **no** ☐

It is important for you to have a personal record of your vaccinations. If you don't have a personal record, ask your healthcare provider to give you one. Keep this record in a safe place and bring it with you every time you seek medical care. Make sure your healthcare provider records all your vaccinations on it.

Technical content reviewed by the Centers for Disease Control and Prevention

www.immunize.org/catg.d/p4065.pdf • Item#P4065 (10/12)

Information for Health Professionals about the Screening Checklist for Contraindications To Vaccines for Adults

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

1. Are you sick today? *[all vaccines]*
There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events (1). However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (such as upper respiratory infections or diarrhea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics.

2. Do you have allergies to medications, food, a vaccine component, or latex? *[all vaccines]*
If a person reports they have an allergy to egg, ask if they can eat lightly cooked eggs (e.g., scrambled eggs). If they can, trivalent influenza vaccine (TIV) may be administered. If after eating eggs or egg-containing foods, they have a reaction consisting of only hives, TIV may be given and the person should be observed for at least 30 minutes. If a person experiences a serious systemic or anaphylactic reaction (e.g., hives and either swelling of the lips or tongue, acute respiratory distress, or collapse) after eating eggs, do not administer TIV or live attenuated influenza vaccine (LAIV). It is possible that they may be eligible to be given TIV, but only after they have seen a physician with expertise in the management of allergic conditions. If a person has anaphylaxis after eating gelatin, do not administer MMR or varicella vaccine. Local reactions are not contraindications. For a table of vaccines supplied in vials or syringes that contain latex, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/latex-table.pdf. For an extensive list of vaccine components, see reference 2.

3. Have you ever had a serious reaction after receiving a vaccination? *[all vaccines]*
History of anaphylactic reaction (see question 2) to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses (1). Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak).

4. Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia, or other blood disorder? *[LAIV]*
People with any of these health conditions should not be given the intranasal live attenuated influenza vaccine (LAIV). Instead, they should be vaccinated with the injectable influenza vaccine.

5. Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem? *[LAIV, MMR, VAR, ZOS]*
Live virus vaccines (e.g., LAIV, measles-mumps-rubella [MMR], varicella [VAR], zoster [ZOS]) are usually contraindicated in immunocompromised people. However, there are exceptions. For example, MMR vaccine is recommended and varicella vaccine should be considered for adults with CD4+ T-lymphocyte counts of greater than or equal to 200 cells/μL. Immunosuppressed people should not receive LAIV. For details, consult the ACIP recommendations (3, 4, 5).

6. In the past 3 months, have you taken medications that weaken your immune system, such as cortisone, prednisone, other steroids, or anticancer drugs, or have you had radiation treatments? *[LAIV, MMR, VAR, ZOS]*
Live virus vaccines (e.g., LAIV, MMR, VAR, ZOS) should be postponed until after chemotherapy or long-term high-dose steroid therapy has ended. For details and length of time to postpone, consult the ACIP statement (1, 5). To find specific vaccination schedules for stem cell transplant (bone marrow transplant) patients, see reference 6. LAIV can be given only to healthy non-pregnant people younger than age 50 years.

7. Have you had a seizure or a brain or other nervous system problem? *[influenza, Td/Tdap]*
Tdap is contraindicated in people who have a history of encephalopathy within 7 days following DTP/DTaP given before age 7 years. An unstable progressive neurologic problem is a precaution to the use of Tdap. For people with stable neurologic disorders (including seizures) unrelated to vaccination, or for people with a family history of seizure, vaccinate as usual. A history of Guillain-Barré syndrome (GBS) is a consideration with the following: 1) Td/Tdap: if GBS has occurred within 6 weeks of a tetanus-containing vaccine and decision is made to continue vaccination, give Tdap instead of Td if no history of prior Tdap; 2) Influenza vaccine (TIV/LAIV): if GBS has occurred within 6 weeks of a prior influenza vaccine, vaccinate with TIV if at high risk for severe influenza complications.

8. During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug? *[LAIV, MMR, VAR]*
Certain live virus vaccines (e.g., LAIV, MMR, VAR) may need to be deferred, depending on several variables. Consult the most current ACIP recommendations for current information on intervals between antiviral drugs, immune globulin or blood product administration and live virus vaccines. (1)

9. For women: Are you pregnant or is there a chance you could become pregnant during the next month? *[MMR, LAIV, VAR, ZOS]*
Live virus vaccines (e.g., MMR, VAR, ZOS, LAIV) are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus. Sexually active women in their childbearing years who receive live virus vaccines should be instructed to practice careful contraception for one month following receipt of the vaccine. On theoretical grounds, inactivated poliovirus vaccine should not be given during pregnancy; however, it may be given if risk of disease is imminent and immediate protection is needed (e.g., travel to endemic areas). Use of Td or Tdap is not contraindicated in pregnancy. At the provider's discretion, either vaccine may be administered during the 2nd or 3rd trimester. (1, 3, 4, 5, 7, 8)

10. Have you received any vaccinations in the past 4 weeks?
[LAIV, MMR, VAR, yellow fever] If the person to be vaccinated was given either LAIV or an injectable live virus vaccine (e.g., MMR, VAR, ZOS, yellow fever) in the past 4 weeks, they should wait 28 days before receiving another vaccination of this type. Inactivated vaccines may be given at any spacing interval if they are not administered simultaneously.

References:

1. CDC. General recommendations on immunization, at www.cdc.gov/vaccines/pubs/acip-list.htm.
2. Table of Vaccine Components: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
3. CDC. Measles, mumps, and rubella—vaccine use and strategies for elimination of measles, rubella, and congenital rubella syndrome and control of mumps. *MMWR* 1998; 47 (RR-8).
4. CDC. Prevention of varicella: Recommendations of the Advisory Committee on Immunization Practices. *MMWR* 2007; 56 (RR-4).
5. CDC. Prevention and control of influenza—recommendations of ACIP, at www.cdc.gov/flu/professionals/vaccination.
6. CDC. Excerpt from Guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients, *MMWR* 2000; 49 (RR-10), www.cdc.gov/vaccines/pubs/downloads/b_hsct-recs.pdf.
7. CDC. Notice to readers: Revised ACIP recommendation for avoiding pregnancy after receiving a rubella-containing vaccine. *MMWR* 2001; 50 (49).
8. CDC. Prevention of pertussis, tetanus, and diphtheria among pregnant and postpartum women and their infants: Recommendations of the ACIP. *MMWR* 2008; 57 (RR-4).

Nombre del paciente: _____ Fecha de nacimiento: ____/____/____
(mes) (día) (año)

Cuestionario de contraindicaciones para vacunación de adultos

A los pacientes: Las siguientes preguntas nos ayudarán a determinar cuáles vacunas le podemos dar hoy. Si contesta "sí" a alguna pregunta, eso no siempre quiere decir que no lo deben vacunar. Simplemente quiere decir que hay que hacerle más preguntas. Si alguna pregunta no está clara, pida a su profesional de la salud que se la explique.

		Sí	No	No sabe
1.	¿Está enfermo hoy?	☐	☐	☐
2.	¿Es alérgico a algún medicamento, alimento, a algún componente de las vacunas o al látex?	☐	☐	☐
3.	¿Tuvo alguna vez una reacción seria después de vacunarse?	☐	☐	☐
4.	¿Tiene algún problema de salud a largo plazo, como enfermedad del corazón, enfermedad de los pulmones, asma, enfermedad de los riñones, enfermedad metabólica (como la diabetes), anemia o algún otro trastorno de la sangre?	☐	☐	☐
5.	¿Tiene cáncer, leucemia, VIH/SIDA o algún otro problema del sistema inmunológico?	☐	☐	☐
6.	En los últimos 3 meses, ¿ha tomado medicamentos que debiliten su sistema inmunológico, tales como cortisona, prednisona, otros esteroides o medicamentos contra el cáncer, o le han hecho tratamientos de radiación?	☐	☐	☐
7.	¿Tuvo alguna vez convulsiones o problemas del cerebro o algún otro problema del sistema nervioso?	☐	☐	☐
8.	Durante el año pasado, ¿le hicieron una transfusión de sangre o de productos de la sangre, o le dieron inmunoglobulina o gamaglobulina o un medicamento antiviral?	☐	☐	☐
9.	Para las mujeres: ¿Está embarazada o hay alguna posibilidad de que quede embarazada en el próximo mes?	☐	☐	☐
10.	¿Le aplicaron alguna vacuna en las últimas 4 semanas?	☐	☐	☐

Formulario llenado por: _____ Fecha: _____

Formulario revisado por: _____ Fecha: _____

¿Trajo su comprobante de vacunación? **sí** ☐ **no** ☐

Es importante que tenga un comprobante de vacunación personal. Si no lo tiene, pídale a su profesional de la salud que le dé uno. Guárdelo en un lugar seguro y llévelo todas las veces que reciba atención médica. Asegúrese de que su profesional de la salud escriba allí todas las vacunas que reciba.

Translation by Transcend, Davis, CA

www.immunize.org/catg.d/p4065-01.pdf • Item#P4065-01 Spanish (10/12)

Information for Health Professionals about the Screening Checklist for Contraindications To Vaccines for Adults

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

1. Are you sick today? *[all vaccines]*
There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events (1). However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (such as upper respiratory infections or diarrhea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics.

2. Do you have allergies to medications, food, a vaccine component, or latex? *[all vaccines]*
If a person reports they have an allergy to egg, ask if they can eat lightly cooked eggs (e.g., scrambled eggs). If they can, trivalent influenza vaccine (TIV) may be administered. If after eating eggs or egg-containing foods, they have a reaction consisting of only hives, TIV may be given and the person should be observed for at least 30 minutes. If a person experiences a serious systemic or anaphylactic reaction (e.g., hives and either swelling of the lips or tongue, acute respiratory distress, or collapse) after eating eggs, do not administer TIV or live attenuated influenza vaccine (LAIV). It is possible that they may be eligible to be given TIV, but only after they have seen a physician with expertise in the management of allergic conditions. If a person has anaphylaxis after eating gelatin, do not administer MMR or varicella vaccine. Local reactions are not contraindications. For a table of vaccines supplied in vials or syringes that contain latex, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/latex-table.pdf. For an extensive list of vaccine components, see reference 2.

3. Have you ever had a serious reaction after receiving a vaccination? *[all vaccines]*
History of anaphylactic reaction (see question 2) to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses (1). Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak).

4. Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia, or other blood disorder? *[LAIV]*
People with any of these health conditions should not be given the intranasal live attenuated influenza vaccine (LAIV). Instead, they should be vaccinated with the injectable influenza vaccine.

5. Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem? *[LAIV, MMR, VAR, ZOS]*
Live virus vaccines (e.g., LAIV, measles-mumps-rubella [MMR], varicella [VAR], zoster [ZOS]) are usually contraindicated in immunocompromised people. However, there are exceptions. For example, MMR vaccine is recommended and varicella vaccine should be considered for adults with CD4+ T-lymphocyte counts of greater than or equal to 200 cells/μL. Immunosuppressed people should not receive LAIV. For details, consult the ACIP recommendations (3, 4, 5).

6. In the past 3 months, have you taken medications that weaken your immune system, such as cortisone, prednisone, other steroids, or anticancer drugs, or have you had radiation treatments? *[LAIV, MMR, VAR, ZOS]*
Live virus vaccines (e.g., LAIV, MMR, VAR, ZOS) should be postponed until after chemotherapy or long-term high-dose steroid therapy has ended. For details and length of time to postpone, consult the ACIP statement (1, 5). To find specific vaccination schedules for stem cell transplant (bone marrow transplant) patients, see reference 6. LAIV can be given only to healthy non-pregnant people younger than age 50 years.

7. Have you had a seizure or a brain or other nervous system problem? *[influenza, Td/Tdap]*
Tdap is contraindicated in people who have a history of encephalopathy within 7 days following DTP/DTaP given before age 7 years. An unstable progressive neurologic problem is a precaution to the use of Tdap. For people with stable neurologic disorders (including seizures) unrelated to vaccination, or for people with a family history of seizure, vaccinate as usual. A history of Guillain-Barré syndrome (GBS) is a consideration with the following: 1) Td/Tdap: if GBS has occurred within 6 weeks of a tetanus-containing vaccine and decision is made to continue vaccination, give Tdap instead of Td if no history of prior Tdap; 2) Influenza vaccine (TIV/LAIV): if GBS has occurred within 6 weeks of a prior influenza vaccine, vaccinate with TIV if at high risk for severe influenza complications.

8. During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug? *[LAIV, MMR, VAR]*
Certain live virus vaccines (e.g., LAIV, MMR, VAR) may need to be deferred, depending on several variables. Consult the most current ACIP recommendations for current information on intervals between antiviral drugs, immune globulin or blood product administration and live virus vaccines. (1)

9. For women: Are you pregnant or is there a chance you could become pregnant during the next month? *[MMR, LAIV, VAR, ZOS]*
Live virus vaccines (e.g., MMR, VAR, ZOS, LAIV) are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus. Sexually active women in their childbearing years who receive live virus vaccines should be instructed to practice careful contraception for one month following receipt of the vaccine. On theoretical grounds, inactivated poliovirus vaccine should not be given during pregnancy; however, it may be given if risk of disease is imminent and immediate protection is needed (e.g., travel to endemic areas). Use of Td or Tdap is not contraindicated in pregnancy. At the provider's discretion, either vaccine may be administered during the 2nd or 3rd trimester. (1, 3, 4, 5, 7, 8)

10. Have you received any vaccinations in the past 4 weeks?
[LAIV, MMR, VAR, yellow fever] If the person to be vaccinated was given either LAIV or an injectable live virus vaccine (e.g., MMR, VAR, ZOS, yellow fever) in the past 4 weeks, they should wait 28 days before receiving another vaccination of this type. Inactivated vaccines may be given at any spacing interval if they are not administered simultaneously.

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Standards for Child and Adolescent Immunization Practices

National Vaccine Advisory Committee

Pediatrics 2003;112;958

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SPECIAL ARTICLE

Standards for Child and Adolescent Immunization Practices

National Vaccine Advisory Committee

ABBREVIATIONS. NVAC, National Vaccine Advisory Committee; ACIP, Advisory Committee on Immunization Practices; AAP, American Academy of Pediatrics; AAFP, American Academy of Family Physicians; VFC, Vaccines for Children Program; CDC, Centers for Disease Control and Prevention; VIS, Vaccine Information Statement; VAERS, Vaccine Adverse Events Reporting System; VICP, Vaccine Injury Compensation Program.

In 1992, the National Vaccine Advisory Committee (NVAC), in collaboration with the Ad Hoc Working Group for the Development of Standards for Pediatric Immunization Practices, a working group representing public and private agencies with input from state and local health departments, physician and nursing organizations, and public and private providers, developed a set of standards as to what constitutes the most essential and desirable immunization policies and practices. These standards were endorsed by a variety of medical and public health organizations and represented an important element in our national strategy to protect America's children against vaccine-preventable diseases.

Since that time, vaccine delivery in the United States has changed in several important ways. First, vaccination coverage rates among preschool children have increased substantially and are now monitored by the National Immunization Survey.[1,2] Second, vaccination of children has shifted markedly from the public to the private sector,[3–5] with an emphasis on vaccination in the context of primary care and the medical home.[6] The Vaccines for Children Program has provided critical support to this shift by covering the cost of vaccines for the most economically disadvantaged children and adolescents. Third, the development and introduction of performance measures, such as the National Committee for Quality Assurance's Health Plan Employer Data and Information Set,[7] have focused national attention on the quality of preventive care, including vaccination. Finally, high-quality research in health services has helped to refine strategies for raising and sustaining vaccination coverage levels among children, adolescents, and adults.[8]

Health care professionals who vaccinate children and adolescents continue to face important challenges. These challenges include a diminishing level of experience—among patients, parents, and physicians—with the diseases that vaccines prevent, the ready availability of vaccine-related information that may be inaccurate or misleading, the increasing complexity of the vaccination schedule, and the failure of many health plans to pay for the costs associated with vaccination. In addition, recommendations from the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American Medical Association in 1996 underscored the need to focus on adolescent vaccination.[9]

In this context, NVAC, along with partners representing the federal agencies, state and local health departments, and professional organizations, revised and updated the standards during 2001–2002 to reflect these changes and challenges in vaccine delivery. The revision was approved by NVAC on February 8, 2002 (Table 1), and distributed widely among a variety of medical and public health organizations for review and endorsement. Table 2 lists those organizations that have formally endorsed the Standards for Child and Adolescent Immunization Practices.

The standards are directed toward "health care professionals," an inclusive term for the many people in clinical settings who share in the responsibility for vaccination of children and adolescents: physicians, nurses, midlevel practitioners (eg, nurse practitioners, physician assistants), medical assistants, and clerical staff. In addition to this primary audience, the standards are intended to be useful to public health professionals, policy makers, health plan administrators, employers who purchase health care coverage, and others whose efforts shape and support the delivery of vaccination services.

Of note, the use of the term "standards" should not be confused with a minimum standard of care. Rather, these standards represent the most desirable immunization practices, which health care professionals should strive to achieve. Given current resource limitations, some health care professionals may find it difficult to implement all of the standards, because of circumstances over which they have little control. The expectation is that, by summarizing best immunization practices in a clear and concise format, the standards will assist these providers in securing the resources necessary to implement this set of recommendations.

From the National Vaccine Advisory Committee, Providence, Rhode Island.
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TABLE 1. Standards for Child and Adolescent Immunization Practices

Availability of vaccines
1. Vaccination services are readily available.
2. Vaccinations are coordinated with other health care services and provided in a medical home[6] when possible.
3. Barriers to vaccination are identified and minimized.
4. Patient costs are minimized.

Assessment of vaccination status
5. Health care professionals review the vaccination and health status of patients at every encounter to determine which vaccines are indicated.
6. Health care professionals assess for and follow only medically accepted contraindications.

Effective communication about vaccine benefits and risks
7. Parents/guardians and patients are educated about the benefits and risks of vaccination in a culturally appropriate manner and in easy-to-understand language.

Proper storage and administration of vaccines and documentation of vaccinations
8. Health care professionals follow appropriate procedures for vaccine storage and handling.
9. Up-to-date, written vaccination protocols are accessible at all locations where vaccines are administered.
10. People who administer vaccines and staff who manage or support vaccine administration are knowledgeable and receive ongoing education.
11. Health care professionals simultaneously administer as many indicated vaccine doses as possible.
12. Vaccination records for patients are accurate, complete, and easily accessible.
13. Health care professionals report adverse events after vaccination promptly and accurately to the Vaccine Adverse Events Reporting System (VAERS) and are aware of a separate program, the Vaccine Injury Compensation Program (VICP).
14. All personnel who have contact with patients are appropriately vaccinated.

Implementation of strategies to improve vaccination coverage
15. Systems are used to remind parents/guardians, patients, and health care professionals when vaccinations are due and to recall those who are overdue.
16. Office- or clinic-based patient record reviews and vaccination coverage assessments are performed annually.
17. Health care professionals practice community-based approaches.

By adopting these standards, health care professionals can enhance their own policies and practices, making achievement of vaccination objectives for children and adolescents as outlined in *Healthy People 2010*, a nationwide health promotion and disease prevention agenda from the US Department of Health and Human Services,[10] both feasible and likely. Achieving these objectives will improve the health and welfare of all children and adolescents as well as the communities in which they live.

THE STANDARDS

Availability of Vaccines

1. Vaccination Services Are Readily Available

All health care professionals who provide primary care to children and adolescents should always include routinely recommended vaccines as a part of the care that they deliver in the medical home.[6] For some children and adolescents, the main contact with the health care system is not in a primary care provider's office; therefore, opportunities for vaccination may be missed. Thus, specialists and health care professionals in settings such as schools and school health clinics, sports physical clinics, family planning clinics, sexually transmitted disease clinics, and substance abuse treatment centers should assess each patient's vaccination status and either offer indicated vaccines or refer for vaccination if necessary. Information on vaccines administered outside the primary care setting should be communicated to the primary care provider.

2. Vaccinations Are Coordinated With Other Health Care Services and Provided in a Medical Home When Possible

Ideally, vaccines should be given as part of comprehensive health care. In primary care settings, vaccination services should be coordinated with routine well-care visits and other visits.[6] Patients who are vaccinated in other settings should be encouraged to receive subsequent vaccines in their primary care setting. Patients without a primary care provider should be assisted with identifying one.

3. Barriers to Vaccination Are Identified and Minimized

Barriers to receiving vaccines include delays in scheduling appointments, requiring a well-care visit, long waiting periods in the office, and lack of culturally and age-appropriate educational materials. A physical examination, although an important part of well care, should not be required before administering vaccines: simply observing the patient and questioning about the patient's health status, immunization history, and vaccine contraindications are sufficient. In addition, vaccination-only visits should be available. Health care professionals should seek advice from parents/guardians and patients to identify ways to make vaccination services easier to use.

4. Patient Costs Are Minimized

Out-of-pocket costs—including vaccine, administration, and office visit fees—should be as low as possible for all patients, and no child or adolescent should be denied vaccination because of inability to pay. Resources should be identified to keep patient vaccination costs as low as possible. Free vaccine is

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TABLE 2. Organizations That Provide Endorsement for the Revised Standards for Child and Adolescent Immunization Practices

Advisory Committee on Immunization Practices
Albert B. Sabin Vaccine Institute
Ambulatory Pediatric Association
American Academy of Family Physicians
American Academy of Pediatrics
American Academy of Physician Assistants
American College of Emergency Physicians
American College of Osteopathic Pediatricians
American College of Preventive Medicine
American Medical Association
American Nurses Association
American Osteopathic Association
American Public Health Association
Association of Immunization Program Managers
Association of Maternal and Child Health Programs
Association of State and Territorial Health Officials
Center for Pediatric Research
Centers for Medicare and Medicaid Services
Council of State and Territorial Epidemiologists
Every Child by Two
Health Resources and Services Administration
Immunization Action Coalition
Infectious Diseases Society of America
National Alliance for Hispanic Health
National Asian Women's Health Organization
National Assembly on School-Based Health Care
National Association for City and County Health Officials
National Association for Pediatric Nurse Practitioners
National Association of School Nurses
National Coalition for Adult Immunization
National Foundation for Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Medical Association
National Network of Immunization Nurses and Associates
National Partnership for Immunization
National Perinatal Association
Partnership for Prevention
Pediatric Infectious Disease Society
Project Immunize Virginia
Rotary International
Society for Adolescent Medicine
Society for Teachers of Family Medicine
Vaccine Education Center at the Children's Hospital of Philadelphia

available through some public programs, although health care professionals who offer these vaccines may charge a reasonable administration fee. Sources of publicly funded vaccines include the Vaccines for Children Program (VFC), Public Health Service Section 317 grants to states, and state or local programs. Children and adolescents should be screened for their eligibility to receive vaccines through these programs. Vaccinations provided through VFC or Section 317 grants may not be denied because of an inability to pay the administration fee, and health care professionals should ensure that parents/guardians and patients are aware of this requirement (applies to all vaccines purchased using Centers for Disease Control and Prevention [CDC] contracts, regardless of the setting—private or public—in which the vaccines are administered).

To minimize costs for patients, health plans and insurance plans should include the provision and administration of all routinely recommended vaccines as a covered benefit for all children and adolescents. Furthermore, to minimize costs for health care professionals, purchasers and health plans should reimburse health care professionals adequately for delivering vaccines, including the time required for vaccine administration and for communication about vaccine benefits and risks. The CDC maintains a web page about VFC at http://www.cdc.gov/nip/vfc.

Assessment of Vaccination Status

5. Health Care Professionals Review the Vaccination and Health Status of Patients at Every Encounter to Determine Which Vaccines Are Indicated

Health care professionals should review the vaccination status of all patients at all health care visits to minimize the number of missed opportunities to vaccinate. This review should determine whether the patient has received any vaccinations elsewhere or is at high risk for disease or undervaccination. This information should be documented in the patient's chart and preventive health summary. Health care professionals who do not offer vaccinations should refer patients to a primary care provider for needed vaccinations.

6. Health Care Professionals Assess for and Follow Only Medically Accepted Contraindications

Withholding vaccinations because of medical concerns that are not contraindications results in missed opportunities for prevention. Health care professionals should ask about any condition or circumstance that might indicate that a vaccination should be withheld or delayed and about previous adverse events temporally associated with any vaccination. Health care professionals should support their decisions about what constitutes a contraindication or deferral for each vaccine by consulting the Guide to Contraindications to Vaccinations published by the CDC (available at: http://www.cdc.gov/nip/recs/contraindications.pdf); the harmonized recommendations of the ACIP, the AAP, and the AAFP (available at: http://www.cdc.gov/nip/recs/child-schedule.htm#Printable); the AAP's *Red Book* and other relevant recommendations; Vaccine Information Statements; and manufacturers' package inserts. Contraindications and deferrals should be documented in the medical record.

Effective Communication About Vaccine Benefits and Risks

7. Parents/Guardians and Patients Are Educated About the Benefits and Risks of Vaccination in a Culturally Appropriate Manner and in Easy-to-Understand Language

Health care professionals should allow sufficient time with parents/guardians and adolescent patients to discuss the benefits of vaccines, the diseases that they prevent, any known risks from vaccines, the immunization schedule and the need to receive vaccines at the recommended ages, and the importance of bringing the patient's hand-held vaccination record to each health care visit. Health care professionals should encourage parents/guardians and adolescent patients to take responsibility for ensuring that the patient is fully vaccinated.

For all commonly used childhood vaccines, all

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health care professionals are required by federal law to give a Vaccine Information Statement (VIS) to vaccine recipients or their parents/guardians at each visit. A VIS is a vaccine-specific, 2-page information sheet, produced by the CDC, that describes the benefits and risks of a vaccine. If necessary, health care professionals should supplement the VIS with oral explanations or other written materials that are culturally and linguistically appropriate. Health care professionals should review written materials with patients and their parents/guardians and address questions and concerns.

Health care professionals should encourage parents/guardians and adolescent patients to inform the health care professional of adverse events after the vaccine to be administered and explain how to obtain medical care, if necessary. (See Standard 13 for a description of the Vaccine Adverse Events Reporting System [VAERS]).

General vaccination information for health care professionals, parents, and members of the public may be obtained by calling the CDC National Immunization Information Hotline at 1-800-232-2522 (English) or 1-800-232-0233 (Spanish). Information about vaccine risk communication for health care professionals can be found at http://www.cdc.gov/nip/vacsafe/research/peds.htm and in the latest edition of the *Red Book*. VISs are available in English and numerous other languages from state health departments and at http://www.cdc.gov/nip/publications/VIS/default.htm and http://www.immunize.org. Recommendations for national standards for culturally and linguistically appropriate services in health care may be found at http://www.omhrc.gov/omh/programs/2pgprograms/finalreport.pdf.

Proper Storage and Administration of Vaccines and Documentation of Vaccinations

8. Health Care Professionals Follow Appropriate Procedures for Vaccine Storage and Handling

Vaccines should be handled and stored as recommended in the manufacturers' package inserts; the expiration date for each vaccine should be noted. Temperatures at which vaccines are stored and transported should be monitored and recorded twice daily. Summary information about vaccine storage and handling procedures are also available from state and local health departments and the CDC. Health care professionals should monitor vaccine inventory and undertake efforts to reduce wastage and loss. CDC-recommended storage and handling procedures are available from the CDC by calling 404-639-8222.

9. Up-to-Date, Written Vaccination Protocols Are Accessible at All Locations Where Vaccines Are Administered

To promote the safe and effective use of vaccines, health care professionals should maintain written protocols that detail the following: vaccine storage and handling; the recommended vaccination schedule, vaccine contraindications, and administration techniques; treatment and reporting of adverse events; vaccine benefit and risk communication; and vaccination record maintenance and accessibility. These protocols should be consistent with established guidelines, reviewed frequently, and revised as needed to ensure that they remain up-to-date.

10. People Who Administer Vaccines and Staff Who Manage or Support Vaccine Administration Are Knowledgeable and Receive Ongoing Education

Health care professionals or others who administer vaccinations should be knowledgeable and receive continuing education in vaccine storage and handling; the recommended vaccine schedule, contraindications, and administration techniques; treatment and reporting of adverse events; vaccine benefit and risk communication; and vaccination record maintenance and accessibility. With appropriate training and in accordance with state law/regulation/policy, people other than physicians and nurses may administer vaccines. In addition, other staff should receive training and continuing education related to their specific roles and responsibilities that affect vaccination services.

The CDC sponsors distance-based training opportunities (eg, satellite broadcasts, web-based training, videotapes, self-administered print materials) for health care professionals. Information about training is available at http://www.cdc.gov/nip/ed.

11. Health Care Professionals Simultaneously Administer as Many Indicated Vaccine Doses as Possible

Administering vaccines simultaneously (at the same visit), in accordance with recommendations from the ACIP, the AAP, and the AAFP, is safe, effective and indicated. Although the immunization schedule provides age flexibility for administering certain vaccine doses, simultaneous administration decreases the number of visits needed and the potential for missed doses and enables earlier protection. When indicated vaccines are not simultaneously administered, arrangements should be made for the patient's earliest return to receive the needed vaccination(s). Additional information on the safety of simultaneous vaccination may be found at http://www.cdc.gov/nip/vacsafe/research/simultaneous.htm.

12. Vaccination Records for Patients Are Accurate, Complete, and Easily Accessible

Vaccination records for patients should be recorded on a standard form in an easily accessible location in the medical record to facilitate rapid review of vaccination status. Accurate record keeping helps to ensure that only needed vaccinations are given. As required by federal law (42 US Code 300aa-25), health care professionals should ensure that records contain the following information for each vaccination: the date of administration, the vaccine manufacturer and lot number, the signature and title of the person administering the vaccine, and the address where the vaccine was given. Vaccine refusal should also be documented.

The medical record maintained by the primary care provider should document all vaccines received, including those received at a specialist's office or in another health care setting. When a health care pro-

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fessional who does not routinely care for a patient vaccinates that patient, the patient's primary care provider should be informed.

All vaccinations administered should be reported to state or local immunization registries, where available, to ensure that each patient's vaccination history remains accurate and complete. Registries also may be useful for verifying the vaccination status of new patients, determining which vaccines are needed at a visit, printing official records, and providing reminders and recalls to parents, guardians, and patients.

Health care professionals should ensure that each patient has a hand-held vaccination record that documents each vaccine received, including the date and the name of the health care professional who administered the vaccine. Health care professionals should encourage parents/guardians and adolescent patients to bring the patient's hand-held record to each health care visit so that it can be updated.

The CDC maintains an Immunization Registry Clearinghouse. Information about this clearinghouse is available at http://www.cdc.gov/nip/registry/.

13. Health Care Professionals Report Adverse Events After Vaccination Promptly and Accurately to the Vaccine Adverse Events Reporting System (VAERS) and Are Aware of a Separate Program, the National Vaccine Injury Compensation Program (VICP)

Health care professionals should promptly report all clinically significant adverse events after vaccination to the VAERS even if the health care professional is not certain that the vaccine caused the event. Health care professionals should document in detail the adverse event in the patient's medical record as soon as possible. Providers should be aware that parents/guardians and patients may report to VAERS and that if they choose to do so, they are encouraged to seek the help of their health care provider.

The National Vaccine Injury Compensation Program (VICP) is a no-fault system that compensates people of any age for injuries or conditions that may have been caused by a vaccine recommended by the CDC for routine use in children. Health care professionals should be aware of the VICP to address questions raised by parents/guardians and patients.

Because VAERS and VICP are separate programs, a report of an event to VAERS does not result in the submission of a compensation claim to VICP. A brief description and contact information for both programs is provided on each VIS for those vaccines covered by the National Childhood Vaccine Injury Act.

Information about VAERS, as well as guidance about how to obtain and complete a VAERS form, can be found at http://www.vaers.org or by calling 1-800-822-7967. Information about the VICP is available at http://www.hrsa.gov/osp/vicp or by calling 1-800-338-2382.

14. All Personnel Who Have Contact With Patients Are Appropriately Vaccinated

Health care professionals and other personnel who have contact with patients should be appropriately vaccinated. Offices and clinics should have policies to review and maintain the vaccination status of staff and trainees. ACIP recommendations for vaccinating health care workers are available at ftp://ftp.cdc.gov/pub/publications/mmwr/rr/rr4618.pdf.

Implementation of Strategies to Improve Vaccination Coverage

15. Systems Are Used to Remind Parents/Guardians, Patients, and Health Care Professionals When Vaccinations Are Due and to Recall Those Who Are Overdue

Evidence demonstrates that reminder/recall systems improve vaccination coverage.[11] Patient reminder/recall interventions inform individuals that they are due (reminder) or overdue (recall) for specific vaccinations. Patient reminders/recalls can be mailed or communicated by telephone; an autodialer system can be used to expedite telephone reminders. Patients who might be at high risk for not complying with medical recommendations, for example, those who have missed previous appointments, should receive more intensive follow-up. Similarly, provider reminder/recall systems alert health care professionals when vaccines are due or overdue. Notices should be placed in patient charts or communicated to health care professionals by computer or other means. Immunization registries can facilitate automatic generation of reminder/recall notices.

16. Office- or Clinic-Based Patient Record Reviews and Vaccination Coverage Assessments Are Performed Annually

Evidence shows that assessments are most effective in improving vaccination coverage in a practice when they combine chart reviews to determine coverage with the provision of results to health care professionals and staff.[11] Effective interventions also may incorporate incentives or compare performance with a goal or a standard. Coverage should be assessed regularly so that reasons for low coverage in the practice or in a subgroup of patients are identified and addressed. For assistance in conducting vaccination coverage assessments, health care professionals should contact their state or local immunization program.

17. Health Care Professionals Practice Community-Based Approaches

All health care professionals share in the responsibility to achieve the highest possible degree of community protection against vaccine-preventable diseases. Immunization protects the entire community as well as the individual. No community is optimally protected against vaccine-preventable diseases without high vaccination coverage. Therefore, health care professionals should consider the needs of the community (especially underserved populations) as well as those of their patients. Community-based approaches may involve working with partners in the community, including public health departments, managed care organizations, other service providers such as the US Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), advocacy groups, schools,

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and service organizations to determine community needs and develop vaccination services that address these needs.

NATIONAL VACCINE ADVISORY COMMITTEE (NVAC)

The NVAC was chartered in 1988 to advise and make recommendations to the director of the National Vaccine Program and the assistant secretary for health, Department of Health and Human Services, on matters related to the prevention of infectious diseases through immunization and the prevention of adverse reactions to vaccines. The NVAC is composed of 15 members from public and private organizations representing vaccine manufacturers, physicians, parents, and state and local health agencies. In addition, representatives from governmental agencies involved in health care or allied services serve as ex-officio members of the NVAC.

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ERRATA

Numerical errors occurred in the article by Holt et al, titled "Response to Intravenous Immunoglobulin Predicts Splenectomy Response in Children With Immune Thrombocytopenic Purpura," that was published in the January 2003 issue of *Pediatrics* (2003;111:87–90). On page 88, right column (fourth paragraph of the "Response to IVIG" section), the second sentence currently reads: "Response to IVIG was a sensitive predictor of response to splenectomy in *91%* of patients, with a specificity of *66%*, a positive predictive value of *87%*, and a negative predictive value of *75%*." It should read: "Response to IVIG was a sensitive predictor of response to splenectomy in *88%* of patients, with a specificity of *75%*, a positive predictive value of *91%*, and a negative predictive value of *67%*."

Two errors occurred in the article by the National Vaccine Advisory Committee, titled "Standards for Child and Adolescent Immunization Practices," that was published in the October 2003 issue of *Pediatrics* (2003;112:958–963). On page 958, left column (first footnote), the National Vaccine Advisory Committee is based in Washington, DC. On page 963, left column (second paragraph of the "National Vaccine Advisory Committee (NVAC)" section), the correct affiliation for Peter R. Paradiso, PhD, is Wyeth Vaccines.

Decimal errors occurred in the article by Verstraeten et al, titled "Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases," that was published in the November 2003 issue of *Pediatrics* (2003;112:1039–1048). On page 1039, right column (first paragraph), the fifth sentence currently reads: ". . . may have exceeded the 1995 EPA guidelines for exposure to organic Hg (*1* μg/kg/d vs *3* μg/kg/d). . . ." It should read: ". . . may have exceeded the 1995 EPA guidelines for exposure to organic Hg (*0.1* μg/kg/d vs *0.3* μg/kg/d). . . ."

Also in this article, as indicated, Thomas Verstraeten, MD, was an employee of the Centers for Disease Control and Prevention when he worked on the study. He is currently employed by GlaxoSmithKline.

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Standards for Child and Adolescent Immunization Practices

National Vaccine Advisory Committee

Pediatrics 2003;112;958

Updated Information & Services	including high resolution figures, can be found at: http://pediatrics.aappublications.org/content/112/4/958.full.html
References	This article cites 9 articles, 2 of which can be accessed free at: http://pediatrics.aappublications.org/content/112/4/958.full.html#ref-list-1
Citations	This article has been cited by 18 HighWire-hosted articles: http://pediatrics.aappublications.org/content/112/4/958.full.html#related-urls
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TABLE OF CONTENT

3. INFORMED REQUEST POLICY

Informed Request Policy **(REPLACE)**

Vaccine Information Statements (**REMOVE**) (VISs) are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. Federal Law requires that VISs be handed out whenever (before each dose) certain vaccinations are given. Please access links below for all current VISs. They can be downloaded as a .pdf file and printed. http://www.cdc.gov/vaccines/pubs/vis/default.htm. VIS's in English and different languages can be found at http://www.immunize.org/vis/

After The Shots (simplified version)	English	3199	(10/11)	**(REPLACE)**
Después de las vacunas (After The Shots simplified version)	Spanish	3196	(09/11)	**(REPLACE)**
Georgia Vaccine Administration Record	English	25-IMM-002E	(02/12)	**(REPLACE)**
Refusal to Vaccinate Form	English	25-IMM-012E	(02/12)	**(REPLACE**)
Refusal to Vaccinate Form	Spanish	25-IMM-012S	(09/12)	**(ADD**)

INFORMED REQUEST POLICY

As providers of immunizations, it is important to furnish the vaccinee (or the parents/legal guardians of minors) with objective information on vaccine safety and the disease that the vaccine protects against, thereby making them active participants in decisions affecting their health or the health of their children. Vaccine Information Statements (VISs) are standardized to provide objective information about vaccine benefits and adverse events.

What are VISs?
VISs are developed by the staff of the Centers for Disease Control and Prevention (CDC) and undergo intense scrutiny by panels of experts for accuracy. Each VIS provides information to properly inform the adult vaccinee or, in the case of a minor, the child's parent or legal representative about the risks and benefits of each vaccine. VISs are not meant to replace interactions with health care providers who should attempt to answer questions and address concerns that the vaccinee or the parent/guardian may have.

VIS use is mandatory!
Before a health care provider (public or private) vaccinates a child or adult with a dose of any recommended childhood vaccine (DTaP, Td, Tdap, MMR, Varicella, Polio, Hib, hepatitis B, RV, human papillomavirus (HPV), pneumococcal conjugate, meningococcal (conjugate and polysaccharide), hepatitis A, and influenza), the provider is required by the National Childhood Vaccine Injury Act of 1986 to provide the most current copy of the VIS to either the adult vaccinee or the child's parent/legal guardian. If there is not a single VIS for a combination vaccine (e.g., Hib/hepatitis B), use the VISs for all the component vaccines.

A VIS is also available for the pneumococcal polysaccharide vaccine. Its use is not required by the National Childhood Injury Act, but is strongly encouraged-------and it must be used when giving vaccines purchased through a CDC contract (i.e. VFC vaccines).

State or local health departments or individual providers may place identifiers (such as form numbers) on the VISs but any other changes must be approved by CDC's National Immunization Program.

What to do with the VISs:

Some of the legal requirements concerning the use of VISs are as follows:

1) Before a routine vaccine is administered to anyone (including adults), you must give the patient or the parent/guardian a copy of the most current VIS available for that vaccine. Make sure you give your patient time to read the VIS prior to the administration of the vaccine and review the VIS with them.
2) Record on your patient's chart which VIS was given and the date that it was given.
3) **Record on the patient's chart the publication date of the VIS** (a date which appears on the lower right hand corner of the VIS).

How to get VISs:
VISs are available upon request from the Immunization Action Coalition (IAC) and the Georgia Immunization Office. (See order form 3184, included in Section 1 of this manual). English and translated statements may also be downloaded from the following websites:

Centers for Disease Control (CDC)	www.cdc.gov/nip/publications/vis
Immunization Action Coalition (IAC)	www.immunize.org/vis

INFORMED REQUEST POLICY

Physician offices will be provided with a single copy for duplication. Please go to the Immunization Action Coalition website at www.immunize.org/vis for most recent VIS in English and other languages.

Required Documentation:
Georgia law requires that vaccines administered to individuals of all ages must be documented in the Georgia Registry of Immunization Transactions and Services (GRITS). This legal requirement is referenced in the "Requirements of Law" section of the Immunization Office Manual under the Official Code of Georgia. Written documentation is required in the vaccine recipient's medical record (or in a permanent office file or log) of each immunization and the receipt by vaccine recipients (or their parents or legal representatives) of the appropriate VIS. The documentation shall consist of the following:

- vaccine administration date
- vaccine manufacturer and lot number
- name, title, and address of the person administering the vaccine (i.e., address where the medical record will be maintained)
- which VIS is given
- date printed on the appropriate VIS
- date the VIS was given to the vaccine recipient (or the parent/legal guardian)
- date vaccine was given, appropriate notation of the preparation given and date of administration should be provided on either an existing or newly issued Personal Immunization Record

It is recommended that Form 3199/3196, "After the Shots", or an equivalent description of common side effects be given to the patient or parent/guardian, along with a telephone number that may be called in the case of adverse events. A copy of form 3199/3196 is included in this section of the manual.

It is also recommended that each vaccine be recorded on a client's personal immunization record. Personal Immunization Records (Form 3187 [English and Spanish]) may be ordered from the GA Immunization Office utilizing form 3184, the Request for Immunization Forms (see section 1). In addition, GRITS may be utilized to document an immunization record and can print out the clients' immunization history.

VISs are not consent forms. In Georgia, the legal definition of a person authorized to make a request for immunization is very broad. Pertinent excerpts from the Official Code of Georgia, Annotated, Title 31, Chapter 9, 12/2001 cited as the Georgia Medical Consent Law are reproduced below:

INFORMED REQUEST POLICY

Official Code of Georgia, Annotated 2002

31-9-2

(a) In addition to such other persons as may be authorized and empowered, any one of the following persons is authorized and empowered to consent, either orally or otherwise, to any surgical or medical treatment or procedures not prohibited by law which may be suggested, recommended, prescribed, or directed by a duly licensed physician:

(1) Any adult, for himself, whether by living will or otherwise
(1.1) Any person authorized to give such consent for the adult under a health care agency complying with Chapter 36 of Title 31, the "Durable Power of Attorney for Health Care Act"
(2) In the absence or unavailability of a living spouse, any parent, whether an adult or a minor, for his minor child;
(3) Any married person, whether an adult or a minor, for himself and for his spouse;
(4) Any person temporarily standing in loco parentis, whether formally serving or not, for the minor under his care; and any guardian, for his ward;
(5) Any female, regardless of age or marital status, for herself when given in connection with pregnancy, or the prevention thereof, or childbirth;
(6) Upon the inability of any adult to consent for himself and in the absence of any person to consent under paragraphs (2) through (5) of this subsection, the following persons in the following order of priority:
(A) Any adult child for his parents;
(B) Any parent for his adult child;
(C) Any adult for his brother or sister; or
(D) Any grandparent for his grandchild.

(b) Any person authorized and empowered to consent under subsection (a) of this Code section shall, after being informed of the provisions of this Code section, act in good faith to consent to surgical or medical treatment or procedures which the patient would have wanted had the patient understood the circumstances under which such treatment or procedures are provided.
(c) For purposes of this Code section, "inability of any adult to consent for himself" shall mean a determination in the medical record by a licensed physician after the physician has personally examined the adult that the adult "lacks sufficient understanding or capacity to make significant responsible decisions" regarding his medical treatment or the ability to communicate by any means such decisions.

Cross References –

Authority of court in juvenile proceeding to order that a child undergo medical examination or treatment, § 15-11-12.

Right of minor to obtain medical services for treatment of venereal disease on his consent alone. § 31-17-7 (a).

INFORMED REQUEST POLICY

Official Code of Georgia, Annotated 2002

31-9-6.

(a) This chapter shall be liberally construed, and all relationships set forth in this chapter shall include the adoptive, foster, and step relations as well as blood relations and the relationship by common-law marriage as well as ceremonial marriage.

(b) A consent by one person authorized and empowered to consent to surgical or medical treatment shall be sufficient.

(c) Any person acting in good faith shall be justified in relying on the representations of any person purporting to give consent, including, but not limited to, his identity, his age, his marital status, his emancipation, and his relationship to any other person for whom the consent is purportedly given.

(d) A consent to surgical or medical treatment which discloses in general terms the treatment or course of treatment in connection with which it is given and which is duly evidenced in writing and signed by the patient or other person or persons authorized to consent pursuant to the terms of this chapter shall be conclusively presumed to be a valid consent in the absence of fraudulent misrepresentations of material facts in obtaining the same.

Vaccine Information Statements (VISs) are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. Federal Law requires that VISs be handed out whenever (before each dose) certain vaccinations are given.

Please access links below for all current VISs. They can be downloaded as a .pdf file and printed.

- **http://www.cdc.gov/vaccines/pubs/vis/default.htm**
- VISs in English and different languages can be found at

  http://www.immunize.org/vis/

After the Shots…

Your child may need extra love and care after getting vaccinated. Some vaccinations that protect children from serious diseases also can cause discomfort for a while. Here are answers to questions many parents have after their children have been vaccinated. If this sheet doesn't answer your questions, call your healthcare provider.

Vaccinations may hurt a little… but disease can hurt a lot!

Call your healthcare provider right away if you answer "yes" to any of the following questions:

- ☐ Does your child have a temperature that your healthcare provider has told you to be concerned about?
- ☐ Is your child pale or limp?
- ☐ Has your child been crying for more than 3 hours and just won't quit?
- ☐ Is your child's body shaking, twitching, or jerking?
- ☐ Is your child very noticeably less active or responsive?

▶ *Please see page 2 for information on the proper amount of medicine to give your child to reduce pain or fever.*

What to do if your child has discomfort

I think my child has a fever. What should I do?

Check your child's temperature to find out if there is a fever. An easy way to do this is by taking a temperature in the armpit using an electronic thermometer (or by using the method of temperature-taking your healthcare provider recommends). If your child has a temperature that your healthcare provider has told you to be concerned about or if you have questions, call your healthcare provider.

Here are some things you can do to help reduce fever:

- Give your child plenty to drink.
- Dress your child lightly. Do not cover or wrap your child tightly.
- Give your child a fever- or pain-reducing medicine such as acetaminophen (e.g., Tylenol) or ibuprofen (e.g., Advil, Motrin). The dose you give your child should be based on your child's weight and your heathcare provider's instructions. See the dose chart on page 2. *Do not give aspirin*. Recheck your child's temperature after 1 hour. Call your healthcare provider if you have questions.

My child has been fussy since getting vaccinated. What should I do?

After vaccination, children may be fussy because of pain or fever. To reduce discomfort, you may want to give your child a medicine such as acetaminophen or ibuprofen. See the dose chart on page 2. *Do not give aspirin*. If your child is fussy for more than 24 hours, call your healthcare provider.

My child's leg or arm is swollen, hot, and red. What should I do?

- Apply a clean, cool, wet washcloth over the sore area for comfort.
- For pain, give a medicine such as acetaminophen or ibuprofen. See the dose chart on page 2. *Do not give aspirin*.
- If the redness or tenderness increases after 24 hours, call your healthcare provider.

My child seems really sick. Should I call my healthcare provider?

If you are worried **at all** about how your child looks or feels, call your healthcare provider!

HEALTHCARE PROVIDER: PLEASE FILL IN THE INFORMATION BELOW.

If your child's temperature is _____ °F or _____ °C or higher, or if you have questions, call your healthcare provider.

Healthcare provider phone number: _____

Technical content reviewed by the Centers for Disease Control and Prevention

IMMUNIZATION ACTION COALITION 1573 Selby Avenue ▪ St. Paul, Minnesota 55104 ▪ www.vaccineinformation.org ▪ www.immunize.org

www.immunize.org/catg.d/p4015.pdf ▪ Item #P4015 (12/12)

Medicines and Dosages to Reduce Pain and Fever

Choose the proper medicine, and measure the dose accurately.

1. Ask your healthcare provider or pharmacist which medicine is best for your child.
2. Give the dose based on your child's weight. If you don't know your child's weight, give the dose based on your child's age. Do not give more medicine than is recommended.
3. If you have questions about dosage amounts or any other concerns, call your healthcare provider.
4. Always use a proper measuring device. For example:
   - When giving acetaminophen liquid (e.g., Tylenol), use the device enclosed in the package. If you misplace the device, consult your healthcare provider or pharmacist for advice. Kitchen spoons are not accurate measures.
   - When giving ibuprofen liquid (e.g., Advil, Motrin), use the device enclosed in the package. Never use a kitchen spoon!

Take these two steps to avoid causing a serious medication overdose in your child.

1. Don't give your child a larger amount of acetaminophen (e.g., Tylenol) or ibuprofen (e.g., Motrin, Advil) than is shown in the table below. Too much of any of these medicines can cause an overdose.
2. When you give your child acetaminophen or ibuprofen, don't also give them over-the-counter (OTC) cough or cold medicines. This can also cause a medication overdose because cough and cold medicines often contain acetaminophen or ibuprofen. In fact, to be safe, don't give OTC cough and cold medicines to your child unless you talk to your child's healthcare provider first.

Acetaminophen (Tylenol or another brand): How much to give?

Give every 4 to 6 hours, as needed, no more than 5 times in 24 hours (unless directed to do otherwise by your healthcare provider).

CHILD'S WEIGHT	CHILD'S AGE	OLD FORMULATIONS INFANTS' DROPS 80 mg in each 0.8 mL or in each 1.0 mL	INFANTS' NEW FORMULATION OR CHILDREN'S LIQUID 160 mg in each 5 mL (1 tsp) Kitchen spoons are not accurate measures.	CHILDREN'S CHEWABLES 80 mg in each tab	JUNIOR STRENGTH 160 mg in each tab
6–11 lbs (2.7–5 kg)	0–3 mos	Advised dose* _____ PRODUCT DISCONTINUED BY MANUFACTURERS	Advised dose* _____		
12–17 lbs (5.5–7.7 kg)	4–11 mos	Advised dose* _____	½ teaspoon or 2.5 mL		
18–23 lbs (8.2–10.5 kg)	12–23 mos	Advised dose* _____	¾ teaspoon or 3.75 mL		
24–35 lbs (10.9–15.9 kg)	2–3 yrs	1.6 mL (0.8 mL+0.8 mL)	1 teaspoon or 5 mL	2 tablets	
36–47 lbs (16.4–21.4 kg)	4–5 yrs		1½ teaspoon or 7.5 mL	3 tablets	
48–59 lbs (21.8–26.8 kg)	6–8 yrs		2 teaspoons or 10 mL	4 tablets	2 tablets
60–71 lbs (27.3–32.3 kg)	9–10 yrs		2½ teaspoons or 12.5 mL	5 tablets	2½ tablets
72–95 lbs (32.7–43.2 kg)	11 yrs		3 teaspoons or 15 mL	6 tablets	3 tablets

Ibuprofen (Advil, Motrin, or another brand): How much to give?

Give every 6 to 8 hours, as needed, no more than 4 times in 24 hours (unless directed to do otherwise by your healthcare provider).

CHILD'S WEIGHT	CHILD'S AGE	INFANTS' DROPS 50 mg in each 1.25 mL	CHILDREN'S LIQUID 100 mg in each 5 mL (1 tsp) Kitchen spoons are not accurate measures.	OLD FORMULATION CHILDREN'S CHEWABLES 50 mg in each tab	CHILDREN'S CHEWABLES OR JUNIOR TABLETS 100 mg in each tab
less than 11 lbs (5 kg)	0–5 mos				
12–17 lbs (5.5–7.7 kg)	6–11 mos	1.25 mL	Advised dose* _____	PRODUCT DISCONTINUED BY MANUFACTURERS	
18–23 lbs (8.2–10.5 kg)	12–23 mos	1.875 mL	Advised dose* _____		
24–35 lbs (10.9–15.9 kg)	2–3 yrs		1 teaspoon or 5 mL	2 tablets	1 tablet
36–47 lbs (16.4–21.4 kg)	4–5 yrs		1½ teaspoon or 7.5 mL	3 tablets	1½ tablets
48–59 lbs (21.8–26.8 kg)	6–8 yrs		2 teaspoons or 10 mL	4 tablets	2 tablets
60–71 lbs (27.3–32.3 kg)	9–10 yrs		2½ teaspoons or 12.5 mL	5 tablets	2½ tablets
72–95 lbs (32.7–43.2 kg)	11 yrs		3 teaspoons or 15 mL	6 tablets	3 tablets

* **HEALTHCARE PROVIDER:** PLEASE FILL IN THE ADVISED DOSE.

Know Concentration before Giving Acetaminophen to Infants and Children

The Food and Drug Administration (FDA) is urging consumers to carefully read the labels of liquid acetaminophen marketed for infants to avoid giving the wrong dose to their children.

A less concentrated form of the popular medication is arriving on store shelves, and giving the wrong dose of acetaminophen can cause the medication to be ineffective if too little is given or cause serious side effects and, possibly, death if too much is given.

In an attempt to reduce the confusion over different strengths that have been blamed for past overdoses, some manufacturers are voluntarily offering only the less concentrated version for all children.

Until now, liquid acetaminophen marketed for infants has only been available in a stronger concentration that doesn't require giving the infants as much liquid with each dose.

But right now both concentrations of liquid acetaminophen are in circulation. Before giving the medication, parents and caregivers need to know whether they have the less concentrated version or the older, more concentrated medication. FDA is concerned that infants could be given too much or too little of the medicine if the different concentrations of acetaminophen are confused.

"Be very careful when you're giving your infant acetaminophen" says Carol Holquist, director of FDA's Division of Medical Error Prevention and Analysis.

Here's what the agency wants parents and caregivers to do:

More concentrated, still available

Drug Facts

Active Ingredient (in each 0.8 mL)	Purpose
Acetaminophen 80 mg	Pain reliever/fever reducer

Drug Facts

Active Ingredient (in each 1.0 mL)	Purpose
Acetaminophen 80 mg	Pain reliever/Fever reducer

Less concentrated, newly available

Drug Facts

Active Ingredient (in each 5 mL)	Purpose
Acetaminophen 160 mg	Pain reliever/Fever reducer

- Read the Drug Facts label on the package very carefully to identify the concentration of the liquid acetaminophen, the correct dosage, and the directions for use.
- Do not depend on a banner proclaiming that the product is "new." Some medicines with the old concentration also have this headline on their packaging.
- Use only the dosing device provided with the purchased product in order to correctly measure the right amount of liquid acetaminophen.
- Consult your pediatrician before giving this medication and make sure you're both talking about the same concentration.

Overdosing Has Been a Risk

An April 2011 report from FDA's Center for Drug Evaluation and Research (CDER) found that confusion caused by the different concentrations of liquid acetaminophen for infants and children was leading to overdoses that made infants seriously ill, with some dying from liver failure.

So to avoid dosing errors, some manufacturers voluntarily changed the liquid acetaminophen marketed for infants from 80 mg per 0.8mL or 80 mg per 1 mL to be the same concentration as the liquid acetaminophen marketed for children—160 mg per 5mL. This less concentrated liquid acetaminophen marketed for infants now has new dosing directions and

Courtesy of the FDA. Title and header edited by the Immunization Action Coalition (12/12)

"Be very careful when you're giving your infant or child acetaminophen."

may have a new dosing device in the box, such as an oral syringe.

But this is a voluntary change and some of the older, stronger concentrations of acetaminophen marketed for infants are still available and may remain available.

"There is still some on store shelves; there is still some in homes; and there is still some in distribution," says Holquist.

Why does this pose a danger?

If a pediatrician prescribes a 5 mL dose of the less concentrated liquid acetaminophen, but the parents administer a 5 mL dose of the more concentrated liquid acetaminophen, the child can receive a potentially fatal overdose during the course of therapy, Holquist explains.

Conversely, if a physician prescribes a dose based on the more concentrated liquid acetaminophen and the less concentrated medication is used, the child might not receive enough medication to fight a fever, she says.

FDA has issued a Drug Safety Communication (*www.fda.gov/Drugs/DrugSafety/ucm284741.htm*) with more information for consumers about how to avoid confusion and potential dosing errors with the different concentrations of liquid acetaminophen.

What Should You Do?

Adding to the confusion is the fact that that the box and the bottle may look much the same for both old and new versions of the medication, Holquist says.

Read the Drug Facts label to tell the difference between the two liquid acetaminophen products:

- Look for the "Active ingredient" section of the Drug Facts label usually printed on the back of an over-the-counter medication package.
- If the package says "160 mg per 5 mL" or "160 mg (in each 5 mL)", then this is the less concentrated liquid acetaminophen. This medication should come with an oral syringe to help you measure the dose.
- If the package says "80 mg per 0.8 mL" or "80 mg per 1 mL," then this is the more concentrated liquid acetaminophen. This product may come with a dropper.

If the dosing instructions provided by your healthcare provider differ from what is on the label, check with a healthcare professional before administering the medication. Do not rely on dosing information provided from other sources such as the Internet, old dosing charts, or family members.

It is important to understand that there is no dosing amount specified for children younger than 2 years of age. If you have an infant or child younger than 2 years old, always check with your healthcare provider for dosing instructions.

Acetaminophen is marketed for infants under brand names such as Little Fevers Infant Fever/Pain Reliever, Pedia Care Fever Reducer Pain Reliever and Triaminic Infants' Syrup Fever Reducer Pain Reliever. There are also store brands on the shelves.

Find this and other Consumer Updates at *www.fda.gov/ForConsumers/ConsumerUpdates*

Sign up for free e-mail subscriptions at *www.fda.gov/consumer/consumerenews.html*

Courtesy of the FDA. Title and header edited by the Immunization Action Coalition (12/12)

Después de las vacunas...

Es posible que su hijo necesite mucho amor y atención después de que lo vacunen. Algunas vacunas que protegen a los niños contra enfermedades serias también pueden causar molestias por algún tiempo. Aquí tiene respuestas a preguntas que tienen muchos padres después de que vacunan a sus hijos. Si esta hoja no contesta sus preguntas, llame a su profesional de la salud.

¡Las vacunas pueden doler un poquito... pero la enfermedad puede doler mucho!

Llame inmediatamente a su profesional de la salud si contesta "sí" a alguna de las siguientes preguntas:

- ☐ ¿Tiene su hijo una temperatura a la que debe prestar atención, según lo que le dijo su profesional de la salud?
- ☐ ¿Está su hijo pálido o sin fuerzas?
- ☐ ¿Ha estado su hijo llorando por más de 3 horas y no deja de llorar?
- ☐ ¿Está el cuerpo de su hijo tembloroso, agitado o dando sacudidas?
- ☐ ¿Está su hijo notablemente menos activo o alerta?

Qué hacer si su hijo siente molestias

Creo que mi hijo tiene fiebre. ¿Qué debo hacer?

Tómele la temperatura a su hijo para ver si tiene fiebre. Una manera fácil de hacerlo es tomarle la temperatura en la axila usando un termómetro electrónico (o usando el método de tomar la temperatura que le recomiende su profesional de la salud). Si su hijo tiene una temperatura que su profesional le dijo que le tiene que preocupar o si tiene preguntas, llame a su profesional de la salud.

Aquí tiene algunas cosas que puede hacer para ayudar a reducir la fiebre:

- Déle a su hijo mucho líquido para tomar.
- Vístalo con ropa ligera. No lo tape ni lo envuelva de manera ceñida.
- Dele a su hijo un medicamento que reduzca la fiebre o el dolor, como acetaminofeno (Tylenol, por ejemplo) o ibuprofeno (como Advil o Motrin). La dosis que le dé a su hijo debe estar basada en el peso del niño y en las instrucciones de su profesional de la salud. *No dé aspirina*. Vuelva a tomarle la temperatura a su hijo después de 1 hora. Su tiene preguntas llame a su profesional de la salud.

Mi hijo ha estado molesto desde que lo vacunaron. ¿Qué debo hacer?

Es posible que los niños estén molestos después de que los vacunen porque tienen dolor o fiebre. Para reducir las molestias puede darle a su hijo un medicamento como acetaminofeno o ibuprofeno. *No dé aspirina*. Si su hijo está molesto por más de 24 horas, llame a su profesional de la salud.

Mi hijo tiene la pierna o el brazo hinchado, caliente y rojo. ¿Qué debo hacer?

- Aplique una toallita limpia mojada con agua fresca en la parte dolorida, para aliviar la molestia.
- Para el dolor dé un medicamento como acetaminofeno o ibuprofeno, según las instrucciones de su profesional de la salud (vea el casillero abajo). *No dé aspirina*.
- Si el enrojecimiento o el dolor aumentan después de 24 horas, llame a su profesional de la salud.

Mi hijo parece estar realmente enfermo. ¿Debo llamar a mi profesional de la salud?

Si está preocupado, **aunque un poco,** por la manera en que luce o se siente su hijo, ¡llame a su profesional de la salud!

HEALTHCARE PROVIDER: PLEASE FILL IN THE INFORMATION BELOW.
(Profesional de la salud: Llene la información a continuación.)

If your child's temperature is _____°F or _____°C or higher, or if you have questions, call your healthcare provider.

Healthcare provider phone number: _____

Medication (if needed): _____
Name of medication/type of formulation

Give _____ every _____ hours as needed
dose or amount

Translation by Transcend, Davis, CA

IMMUNIZATION ACTION COALITION 1573 Selby Avenue ▪ St. Paul, Minnesota 55104 ▪ www.vaccineinformation.org ▪ www.immunize.org

www.immunize.org/catg.d/p4014.pdf ▪ Item #P4014-01 Spanish (9/11)

Form #3196

Georgia Department of Public Health

GEORGIA VACCINE ADMINISTRATION RECORD

Rev. 06-2012

Clinic Name/Address:

Patient Name: _____ **Record #:** _____

Date of Birth: _____ **Patient Age:** _____

* Site: **RA – Right Arm** **LA – Left Arm** **PO- Orally** **ID- Intradermal** **IN- Intranasal** **IM- Intramuscular** **SQ- Subcutaneous**
RT - Right Thigh **LT – Left Thigh**

Vaccine (Circle) **Place √ in box "C" if combination vaccine given (e.g. Comvax®)	VACCINE ADMINISTERED						VFC Status ***	VACCINE			VACCINE INFORMATION STATEMENTS (VIS)		Vaccine Administrator Signature
	Date mm/dd/yy	Patient Age	Dosage	Route	Site*	C**		Manufacturer	Lot Number	Expiration Date	Date VIS Published	Date VIS Provided	
DTaP or DT – 1				IM									
DTaP or DT – 2				IM									
DTaP or DT – 3				IM									
DTaP or DT – 4				IM									
DTaP or DT – 5				IM									
Tdap-1				IM									
Rotavirus-1				PO									
Rotavirus-2				PO									
Rotavirus-3				PO									
Td – 1				IM									
Td – 2				IM									
Hib – 1				IM									
Hib – 2				IM									
Hib – 3				IM									
Hib – 4				IM									
Hep B – 1				IM									
Hep B – 2				IM									
Hep B – 3				IM									
Polio – 1				SQ/IM									
Polio – 2				SQ/IM									
Polio – 3				SQ/IM									
Polio – 4				SQ/IM									
MMR – 1				SQ									
MMR – 2				SQ									
Varicella – 1				SQ									
Varicella – 2				SQ									
MCV4				IM									
MPSV4				SQ									
Hep A - 1				IM									
Hep A - 2				IM									
PCV13 – 1				IM									
PCV13 – 2				IM									
PCV13 – 3				IM									
PCV13 – 4				IM									
Influenza –1 TIV/LAIV				IM/IN/ID									
Influenza –2 TIV/LAIV				IM/IN/ID									
Zoster - 1				SQ									
PPSV23 – 1				SQ/IM									
PPSV23 – 2				SQ/IM									
HPV – 1				IM									
HPV – 2				IM									
HPV - 3				IM									

DPH05/024H **Had chickenpox disease: Year** _____ **Age at time of disease:** _____ Form 25-IMM-002E

Georgia Department of Public Health

ADVERSE REACTION (AR)

Date	Immunization	Reaction

You must file a Vaccine Adverse Event by calling 1-877-721-0366 or logging on to www.vaers.org

Georgia Department of Public Health

GEORGIA VACCINE ADMINISTRATION RECORD
Addendum

Vaccine (Circle) **Place √ in box "C" if combination vaccine given (e.g. Comvax®)	VACCINE ADMINISTERED						VFC Status ***	VACCINE			VACCINE INFORMATION STATEMENTS (VIS)		Vaccine Administrator Signature
	Date mm/dd/yy	Patient Age	Dosage	Route	Site*	C**		Manufacturer	Lot Number	Expiration Date	Date VIS Published	Date VIS Provided	

Georgia Department of Public Health

REFUSAL TO VACCINATE

Client Name _____ Client DOB _____

Parent/Guardian Name _____

Healthcare Provider's Name _____ Healthcare Provider's Address & Phone _____

My healthcare provider has advised that I / my child *(circle one)* should receive the following vaccines:

Recommended	Vaccinations	Declined
☐	Diphtheria, Tetanus, acellular Pertussis (**DTaP** or **Tdap**) Vaccine	☐
☐	Diphtheria Tetanus (**DT**) or Tetanus diphtheria (**Td**) Vaccine	☐
☐	*Haemophilus influenzae* type b (**Hib**) Vaccine	☐
☐	Hepatitis A Vaccine (**HAV**)	☐
☐	Hepatitis B Vaccine (**HBV**)	☐
☐	Human Papillomavirus Vaccine (**HPV**)	☐
☐	Inactivated Polio Virus Vaccine (**IPV**)	☐
☐	Influenza (**flu**) Vaccine	☐
☐	Measles-Mumps-Rubella (**MMR**) Vaccine	☐
☐	Meningococcal Vaccine (**MCV** or **MPV**)	☐
☐	Pneumococcal Vaccine (**PCV** or **PPSV**)	☐
☐	Rotavirus Vaccine	☐
☐	Varicella (Chickenpox) Vaccine	☐
☐	Zoster Vaccine	☐
☐	Other	☐

I have read the Vaccine Information Statement(s) from the Centers for Disease Control and Prevention, which explain the vaccine(s) and the disease(s) they prevent. I have had the opportunity to discuss these with my healthcare provider, who has answered all of my questions regarding the recommended vaccine(s). I understand the following:

- The **purpose** of and the **need** for the recommended vaccine(s)
- The **risks and benefits** of the recommended vaccine(s)
- If (I) my child (do) does not receive the vaccine(s), **the consequences** may include:
  - Contracting the illness the vaccine should prevent (The outcomes of these illnesses may include but are not limited to one or more of the following: hospitalization, pneumonia, brain damage, meningitis, seizures, deafness, and death.)
  - transmitting the disease to others (If an outbreak of vaccine-preventable disease occurs at my child's school or child care and my child is not protected, he/she may not be permitted to return until risk of catching the disease has passed.)
- My healthcare provider, the Georgia Immunization Office, the American Academy of Pediatrics, the American Academy of Family Physicians, and the Centers for Disease Control and Prevention all strongly recommend that these vaccines be given according to the published Advisory Committee on Immunization Practices (ACIP) schedule. Nevertheless, I have decided at this time to decline the vaccine(s) recommended for me / my child, as indicated above, by checking the appropriate box under the column titled "declined."

I understand that failure to follow the recommendations about vaccination may endanger the health or life of me or my child and others with whom I or my child might come into contact.

I understand that I may discuss this issue with my (my child's) healthcare provider and that I may change my mind and accept vaccination for myself (my child) anytime in the future.

I understand that my refusal to have my child vaccinated does not exempt my child from Georgia school or child care facility immunization requirements and that he/she will be unable to attend school or child care without the required vaccinations.

Client/Parent/Guardian Signature _____ Date _____

Witness _____ Date _____

NEGATIVA A LA VACUNACIÓN

Nombre del cliente _____ Fecha de nacimiento del cliente _____

Nombre del(de la) padre/madre/ tutor legal _____

Nombre del proveedor de atención médica _____ Dirección y teléfono del proveedor de atención médica _____

Mi proveedor de atención médica recomendó que yo/mi hijo(a) *(marque con un círculo)* recibiera las siguientes vacunas:

Recomendada	Vacunación	Rechazada
☐	Vacuna contra la difteria, el tétanos y la tos ferina acelular (**DTaP** o **Tdap**)	☐
☐	Vacuna contra la difteria- tétanos (**DT**) o el tétanos-difteria (**Td**)	☐
☐	Vacuna contra la *Haemophilus influenzae* tipo b (**Hib**)	☐
☐	Vacuna contra la hepatitis A (**HAV**)	☐
☐	Vacuna contra la hepatitis B (**HBV**)	☐
☐	Vacuna contra el virus del papiloma humano (**HPV**)	☐
☐	Vacuna de poliovirus inactivado (**IPV**)	☐
☐	Vacuna contra la influenza (**gripe**)	☐
☐	Vacuna contra el sarampión, las paperas y la rubeola (**MMR**)	☐
☐	Vacuna contra el meningococo (**MCV** o **MPV**)	☐
☐	Vacuna contra el neumococo (**PCV** o **PPSV**)	☐
☐	Vacuna contra el rotavirus	☐
☐	Vacuna contra la varicela	☐
☐	Vacuna contra el herpes zóster (culebrilla)	☐
☐	Otras	☐

He leído la(s) Declaración(es) de Información Sobre la(s) Vacuna(s), creada(s) por los Centros Para el Control y la Prevención de Enfermedades, que explica(n) la(s) vacuna(s) y la(s) enfermedad(es) que ésta(s) previene(n). He tenido la oportunidad de hablar sobre este tema con mi proveedor de atención médica, quien ha respondido a todas mis preguntas acerca de la(s) vacuna(s) recomendada(s). Entiendo lo siguiente:

- El **propósito** y la **necesidad** de la(s) vacuna(s) recomendada(s)
- Los **riesgos y beneficios** de la(s) vacuna(s) recomendada(s)
- Si yo/mi hijo(a) recibo(e)/no recibo(e) la(s) vacuna(s), **las consecuencias** podrían incluir:
  - Contraer la enfermedad que la vacuna debería prevenir (Estas enfermedades podrían tener uno o más de los siguientes resultados: hospitalización, neumonía, daño cerebral, meningitis, convulsiones, sordera y muerte).
  - Transmitir la enfermedad a otros (Si se produce en la escuela o guardería de mi hijo(a) un brote de una enfermedad prevenible con vacunas y mi hijo(a) no está protegido(a), se le podría impedir que regrese hasta que el riesgo de contraer la enfermedad haya pasado).
- Mi proveedor de atención médica, la Oficina de Inmunización del Estado de Georgia, la Academia Americana de Pediatría, la Academia Americana de Médicos de Familia y los Centros Para el Control y la Prevención de Enfermedades recomiendan que estas vacunas se administren de acuerdo al calendario de vacunaciones publicado por el Comité Asesor Sobre Prácticas de Inmunización (ACIP, por sus siglas en inglés); sin embargo, he decidido rechazar en este momento la(s) vacuna(s) recomendada(s) para mí/mi hijo(a), tal como lo indiqué anteriormente al marcar la casilla correspondiente bajo la columna titulada "rechazada".

Entiendo que al no seguir las recomendaciones de vacunación, podría poner en peligro mi salud o vida y la de mi hijo(a), así como también la de otros con quienes yo o mi hijo(a) podríamos entrar en contacto.

Entiendo que puedo hablar sobre este tema con mi proveedor de atención médica (él de mi hijo/a) y que puedo cambiar de opinión y aceptar la vacunación para mí (mi hijo/a) en cualquier momento en el futuro.

Entiendo que mi negativa a vacunar a mi hijo(a) no lo(a) exime de los requisitos de vacunación para la escuela o guardería en Georgia y que él/ella no podrá asistir a la escuela o guardería si no cumple con estos requisitos de vacunación.

Firma del(de la) cliente/ padre/madre/tutor legal _____ Fecha _____

Testigo _____ Fecha _____

TABLE OF CONTENT

4. ADVERSE EVENTS FOLLOWING IMMUNIZATIONS

Policy for Reporting Vaccine Adverse Events Following Immunizations **(REPLACE)**
Handling of Emergencies Following the Administration of Vaccines
Vaccine Adverse Event Reporting System- Form VAERS (FDA) **(REPLACE)**
Frequently Asked Questions About VAERS (**REMOVE**) (**Go to Link http://vaers.hhs.gov/about/faqs**)
VAERS Brochure **(REPLACE)**
Frequently Asked Questions (**REMOVE**) (**Go to Link http://hrsa.gov/vaccinecompensation/faq.html**)
National Vaccine Injury Compensation Program Vaccine Injury Table **(REPLACE)**
Vaccine Injury compensation Program (VICP) (**REMOVE**) **(Go to Link http://www.hrsa.gov/vaccinecompensation/index.html)**

POLICY FOR REPORTING VACCINE ADVERSE EVENTS FOLLOWING IMMUNIZATION

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program. The National Vaccine Injury Compensation Program is a separate program designed to compensate individuals or families of individuals, who have been injured by childhood vaccines. Reporting an event to VAERS does NOT file a claim for compensation.

PUBLIC HEALTH CLINICS

When the recipient of an immunizing agent is known to have experienced a problem that was serious enough to involve a visit to a physician, hospital or health care facility within 30 days after the immunization, that event is to be reported to the Immunization Program as soon as possible on Form 3034 (Rev.11-90). A reproduction of Form 3034 is included in this section.

The original Form 3034 should be mailed immediately to the Georgia Immunization Program. Copies may be sent to the District Health Unit as established by the district health authority. It is no longer necessary to send VAERS Reports to the Immunization Program Field Staff.

Georgia Immunization Program
2 Peachtree Street, NW, Room 13-276
Atlanta, GA 30303

Phone 404-657-3158
FAX 404-657-1463

VAERS Reports alleging a death temporally associated with immunization should be FAXED **immediately** to the Immunization Program. An autopsy report should be sent to the Immunization Program as soon as it is available.

After evaluation of the VAERS Report(s) by the Immunization Program staff, it may be necessary to communicate with the person who completed the form to request additional information.

PRIVATE CLINICS and COMMUNITY HEALTH CENTERS

Private physicians should report adverse events on Form VAERS - 1 directly to:

VAERS
P. O. Box 1100
Rockville, MD 20849-1100

Phone 1-800-822-7967 ext. 214
FAX 301-217-9660

Private physicians may also submit vaccine adverse event data securely via the internet at
www.vaers.org
http://vaers.hhs.gov

★ATTENTION ALL PUBLIC CLINICS★
***Do not* send reports directly to the Centers for Disease Control and Prevention (CDC).**

HANDLING OF EMERGENCIES FOLLOWING THE ADMINISTRATION OF VACCINES

For the handling of emergencies following the administration of vaccines, the GA Immunization Office recommends the following:

1. Each district should follow the "Medical Emergency Procedures" included in the current State Nurse Protocol Manual or develop and utilize emergency protocols and procedures consistent with those outlined in the State Nurse Protocol.

2. Each district should utilize the Quality Assurance Standards for the "Management of Drug Reactions" that are outlined in Section IV of the "Quality Assurance/Quality Improvement for Immunization Practice for Public Health Nurses and Immunization Support Staff" document that is included in Chapter 13 of this manual.

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

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

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 children 5 and under

22. Birth weight _____ lb. _____ oz.

23. No. of brothers and sisters

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.

"Fold in thirds, tape & mail — DO NOT STAPLE FORM"

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL

FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD

POSTAGE WILL BE PAID BY ADDRESSEE

VAERS
P.O. Box 1100
Rockville MD 20849-1100

DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed.)

GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
- Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
- Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
- These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
- Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.

Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.

Item 10 and 11: Give dates and times as specifically as you can remember. If you do not know the exact time, please indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.

Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.

Item 13: List ONLY those vaccines given on the day listed in Item 10.

Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.

Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.

Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.

Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).

Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.

Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.

Item 26: This space is for manufacturers' use only.

Frequently Asked Questions About VAERS **(Remove from manual)**

(**Update go to Link http://vaers.hhs.gov/about/faqs**

What Types of Events Should I Report?

You should report any adverse event that happens after getting a vaccine, even if you are not sure that the vaccine caused the adverse event. It is especially important to report any adverse event that resulted in hospitalization, disability, or death. If you are not sure that a certain type of adverse event should be reported to VAERS, talk with your healthcare provider.

Healthcare providers are required by law to report certain adverse events. To get a list of these, please call 1-800-822-7967 or go to **www.vaers.hhs.gov/reportable.htm.**

How Do I Report?

It's very easy to report to VAERS.

- Report to VAERS online at **https://secure.vaers.org.**
- Fax a completed VAERS form to: 1-877-721-0366.
- Mail the completed report form to:
  VAERS,
  P.O. Box 1100
  Rockville, MD 20849-1100.

Report forms are available for printing at **www.vaers.hhs.gov** or by calling the VAERS Information Line at 1-800-822-7967. Operators are on duty from 9:00 a.m. to 5:00 p.m., Eastern Time, Monday through Friday. After you submit a report, VAERS staff may contact you for additional information.

FDA and CDC use VAERS data to monitor vaccine safety. VAERS data are also available to the public, after all identifying information, such as names and addresses, are removed to protect the privacy of the patient.

National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a separate federal program that provides compensation to individuals whose injuries may have been caused by certain vaccines. Please be aware that reporting an event to VAERS does not constitute filing a claim with the VICP. Information on the VICP can be obtained by calling 1-800-338-2382 or visiting their website at **http://www.hrsa.gov/vaccinecompensation/.**

For More Information

- **Food and Drug Administration**
  For safety and effectiveness information on FDA-licensed vaccines you can call 1-800-835-4709 or 301-827-2000 and visit **www.fda.gov/cber/vaers/vaers.htm.**
- **Centers for Disease Control and Prevention**
  For general information on vaccines and immunization schedules you can call 1-800- CDC-INFO (1-800-232-4636) or visit **www.cdc.gov/vaccines.**

VAERS
www.vaers.hhs.gov

P.O. Box 1100
Rockville, MD 20849-1100
Tel: 1-800-822-7967
Fax: 1-877-721-0366
info@vaers.org

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

CS205446-A

Do Your Part for Vaccine Safety — Report to VAERS

Vaccine Adverse Event Reporting System
A National Program for Monitoring Vaccine Safety

What is VAERS?

The Vaccine Adverse Event Reporting System (VAERS) is a national program that monitors the safety of vaccines after they are licensed. VAERS is managed by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA).

Vaccines prevent serious illnesses and even death in persons who receive them. Before a vaccine is licensed, FDA takes steps to make sure the vaccine is safe. FDA requires that a vaccine goes through extensive safety testing. After a vaccine is licensed, VAERS is one of the mechanisms used to monitor for any problems, or "adverse events," that happen after vaccination.

Not all events reported to VAERS are caused by the vaccine. Even though careful studies are done before a vaccine is licensed, rare adverse effects may not be found until a vaccine is given to millions of people with different backgrounds and medical histories. By continued monitoring, VAERS helps to make sure that the benefits of vaccines are far greater than the risks.

Anyone who receives a vaccine should be informed about both the benefits and risks of vaccination. Any questions or concerns should be discussed with a healthcare provider.

Limitation and Usefulness of VAERS

VAERS is unable to determine that a vaccine caused or did not cause an adverse event. Sometimes people who are vaccinated get sick from another cause unrelated to the vaccine.

Even though VAERS cannot determine that a vaccine caused an adverse event, it can give FDA and CDC important information that might signal a problem. If it looks as though a vaccine might be causing an adverse event, FDA and CDC will investigate further.

Does VAERS Provide Medical Advice?

No, VAERS does not provide medical advice. For medical advice, please contact your healthcare provider or state health department.

Who Can Report to VAERS?

- Parents
- Patients
- Healthcare Providers
- Others

FDA and CDC encourage anybody who experiences any problems after vaccination to report to VAERS. Healthcare providers are required by law to report certain problems.

Why Should I Report to VAERS?

- Reporting gives valuable information that helps CDC and FDA make sure that vaccines are safe.
- Reporting strengthens VAERS so it can be used to assess public health response to vaccines.
- Reporting allows for evaluating public health prevention and control measures.

Remember, no vaccine (or any medicine) is completely free of risk and adverse events are possible. If you have an adverse event after a vaccine, please report to VAERS. Each report is important!

Frequently Asked Questions **(Remove from manual)**

(**Update go to Link http://hrsa.gov/vaccinecompensation/faqs**

National Childhood Vaccine Injury Act
Vaccine Injury Table[a]

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, TT)	A. Anaphylaxis or anaphylactic shock B. Brachial neuritis C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	4 hours 2-28 days Not applicable
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib).	A. Anaphylaxis or anaphylactic shock B. Encephalopathy (or encephalitis) C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	4 hours 72 hours Not applicable
III. Measles, mumps and rubella vaccine or any of its components (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock B. Encephalopathy (or encephalitis) C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	4 hours 5-15 days (not less than 5 days and not more than 15 days) Not applicable
IV. Vaccines containing rubella virus (e.g., MMR, MR, R)	A. Chronic arthritis B Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	7-42 days Not applicable
V. Vaccines containing measles virus (e.g., MMR, MR, M)	A Thrombocytopenic purpura B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient C Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	7-30 days 6 months Not applicable
VI. Vaccines containing polio live virus (OPV)	A. Paralytic polio --- in a non-immunodeficient recipient --- in an immunodeficient recipient --- in a vaccine assoc. community case B. Vaccine-strain polio viral infection --- in a non-immunodeficient recipient --- in an immunodeficient recipient --- in a vaccine assoc. community case	 30 days 6 months Not applicable 30 days 6 months

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable Not applicable
VII. Vaccines containing polio inactivated (e.g., IPV)	A Anaphylaxis or anaphylactic shock B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	4 hours Not applicable
VIII. Hepatitis B. vaccines	A. Anaphylaxis or anaphylactic shock B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	4 hours Not applicable
IX. Hemophilus influenzae type b polysaccharide conjugate vaccines	No Condition Specified	Not applicable
X. Varicella vaccine	No Condition Specified	Not applicable
XI. Rotavirus vaccine	No Condition Specified	Not applicable
XII. Pneumococcal conjugate vaccines	No Condition Specified	Not applicable
XIII. Hepatitis A vaccines	No Condition Specified	Not applicable
XIV. Trivalent influenza vaccines	No Condition Specified	Not applicable
XV. Meningococcal vaccines	No Condition Specified	Not applicable
XVI. Human papillomavirus (HPV) vaccines	No Condition Specified	Not applicable
XII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by Secretary, HHS of a notice of coverage[b,c,d]	No Condition Specified	Not applicable

[a]**Effective date: July 22, 2011** See Revisions to the Vaccine Injury Table, www.hrsa.gov/vaccinecompensation/tablerevisions06222011.pdf

Qualifications and Aids to Interpretation

(1) Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs ofrespiratory distress, there may not be significant pathologic findings.

(2) Encephalopathy. For purposes of the Vaccine Injury Table, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) For children less than 18 months of age who present without an associated seizure event, an acute encephalopathy is indicated by a “significantly decreased level of consciousness” (see “D” below) lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) For adults and children 18 months of age or older, an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following:

(1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;

(2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and

(3) A seizure associated with loss of consciousness.

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (2)(I)(A) and (2)(I)(B) of this section for applicable timeframes):

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) Chronic encephalopathy occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-

related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record.

(3) Seizure and convulsion. For purposes of paragraphs (b)(2) of this section, the terms, "seizure" and "convulsion" include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(4) Sequela. The term "sequela" means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(5) Chronic Arthritis. For purposes of the Vaccine Injury Table, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination;

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination:

(C) Medical documentation of an antibody response to the rubella virus.

For purposes of the Vaccine Injury Table, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome, or blood disorders.

Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of the Vaccine Injury Table.

(6) Brachial neuritis is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities. Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple mononeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

(7) Thrombocytopenic purpura is defined by a serum platelet count less than 50,000/mm3. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. This does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura (ITP) that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, rhinovirus, human immunodeficiency virus (HIV), adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(8) Vaccine-strain measles viral infection is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests.

(9)Vaccine-strain polio viral infection is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation

of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

Vaccine Injury Compensation Program (VICP) **(Remove from manual)**

(**Update go to Link http://hrsa.gov/vaccinecompensation/index.html)**

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SUMMARY OF IMMUNIZATION POLICIES RELATIVE TO GEORGIA LAW

Copies of the pertinent immunization sections of the Georgia law and Rules of the **Department of Public Health** are included in this section along with copies of the Immunization Certificate and accompanying Policy Guides. Copies are also posted on the Immunization Program web site under the **school resources** section. The following is a summary of policies that relate to the law and rules. For more detailed information, please refer to the copies of the law and rules.

I. Georgia Law and DPH Rules

A. Georgia Law (Official Code of Georgia, Annotated, Section 20-2-771, Section 49-4-182 and Section 49-4-183) defines the target population for which immunity to specified diseases is required and sets standards for the use of immunization certificates.

B. The law also charges the **Department of Public Health (DPH)** with responsibility for specifying which immunizations are required and the standards for the same. These are defined in the immunization section (Chapter 290-5-4) of the Rules of the **Department of Public Health.**

C. The **DPH** Rules define terms such as “Immunization,” “Physician,” and “Health Authority,” list the diseases for which immunity is required, and state the standards for issuing certificates of immunization based on the current ACIP Recommended Childhood Immunization Schedule.

D. **Georgia Law (Official code of Georgia, Annotated, Article 2 of Chapter 34 of Title 43 in Code Section 43-34-23) was amended relating to medical practice, to authorize advanced practice registered nurses and physician assistants to sign off on certain documents relating to health care, to include the Georgia Certificate of Immunization (Form 3231).**

E. Standards for the Georgia **Department of Public Health (DPH)** Certificates of Immunization are also defined on the GA **DPH** Certificate of Immunization (Form 3231) and the accompanying Policy Guide 3231REQ and Policy Guide 3231INS.

F. Georgia law requires immunization of a preschool age child as a condition of receipt of Temporary Assistance for Needy Families (TANF) benefits. The implementation of the law is the responsibility of the Department of Family and Children Services. Proof of compliance will be provided on the GA **DPH** Certificate of Immunization (Form 3231).

G. Any school/facility official who does not enforce the requirements or any parent/guardian who does not comply with the requirements is subject to penalties as outlined in Subsection (h) of the Official Code of Georgia, Annotated, Section 20-2-771.

H. When persons in charge of child care facilities fail to improve unacceptable levels of compliance with the law, despite repeated requests by public health officials, Bright from the Start, Georgia Department of Early Care and Learning (DECAL) should be notified.

SUMMARY OF IMMUNIZATION POLICIES RELATIVE TO GEORGIA LAW

I. **Any infant/child who is under the age of four and is attending child care must be age appropriately immunized with the required vaccines during the time of attendance**. This means that the certificate for every child under four years of age must be marked with an expiration date that indicates the date the next immunization is due. Once a child is four years of age or older and has met the entry requirements for school, [kindergarten (5 year)], a copy of the Immunization Certificate which has been marked as "Complete for School" and includes the vaccine administration dates, or dates of immunity through disease history or serology, may be utilized as documentation for both school and child care facilities.

J. **Children attending school (5 year old kindergarten-12th grade) must be age appropriately immunized with all the required vaccines at the time of first entry into a school in Georgia.** "New entrant" is defined as any child entering a Georgia school or facility for the first time, or entering after having been absent for 12 months or 1 school year. This means that if a child is not "up-to-date" at the time of entry, he/she may attend school provided the certificate is marked with a current expiration date indicating that the child is in the process of receiving the required vaccines and doses. Once the entry requirements have been met, the certificate must be replaced with a certificate marked "Complete for School Entry."

K. Children who are entering a school or child care facility, may be granted a 30 day waiver period by the facility to accommodate the obtaining of immunization records. If necessary, this waiver may be extended from the date of first admittance or first attendance for up to 90 calendar days for children transferring into the school system from out-of-state or entering kindergarten or the school system from out-of-state, providing the parent/guardian can show documentation from their provider or public health clinic that the child is in the process of receiving the required immunizations. A school or child care facility should maintain a file of those children who have been granted a 30 day waiver and should keep the file current. Children who have not submitted an Immunization Certificate by the end of the 30 day grace period should be excluded from further attendance until the appropriate Immunization Certificate is submitted.

II. Immunization Certificates

A. Physicians, **Advanced Practice Registered Nurses, Physician Assistants** licensed in Georgia and qualified employees of a local health department or the State Immunization Program are responsible for certifying that a child has met all the immunization requirements for attendance to school/day care as stipulated by the **DPH** rules. This certification is documented by the physician's, **Advanced Practice Registered Nurse, Physician Assistant** or health official's signature.

B. Schools and child care facilities are responsible for filing and maintaining current certificates.

C. A Certificate of Immunization must be on file for each child attending any child care facility or school in Georgia, whether public or private. The certificates must be on site and available for inspection by health officials.

D. If a child attends more than one school/facility, a photocopy of the form must be submitted to the second school/facility.

SUMMARY OF IMMUNIZATION POLICIES RELATIVE TO GEORGIA LAW

E. When a provider utilizes computerized versions of the Immunization Certificate (Form 3231), it is the responsibility of that provider to have these versions approved by the Georgia Immunization Program. The certificates must include all of the information that is illustrated on the hard copy of these forms. In addition, when the Georgia Immunization Program makes updates to these certificates, it is the responsibility of the provider to update their computerized versions to reflect these changes and have them approved by the state office.

F. Certificates should be marked with either a “Date of Expiration” or as “Complete for School Attendance,” not both.

G. A certificate marked as “Complete for School Attendance” does not expire.

H. A certificate marked with a “Date of Expiration” expires on the date indicated. A current certificate must be submitted within 30 days after the expiration date or the child must be excluded from attendance until a current certificate is submitted.

III. Immunization Reports

By law, an annual report is required for each facility. This report indicates the percentage of adequately immunized children attending that facility.

A. For child care facilities, district or local health personnel must conduct inventories (audits) at least once per year. Licensed child care facilities should maintain at least a 90% compliance level. Health Districts are responsible for working with facilities to obtain and maintain this compliance level. The State Immunization Program will provide district health personnel with a listing of all child care facilities known to Bright from the Start, Georgia Department of Early Care and Learning (DECAL). Completed Child Care Facilities Status Review forms should be submitted to the State Immunization Program according to the time frame assigned to each district. State Immunization Program Consultants will annually validate the results of the audits.

B. For schools, inventories (audits) of immunization records of all kindergarten and sixth grade students must be conducted at least once per year by health departments. Schools should maintain at least a 90% compliance level. Health Districts are responsible for working with schools to obtain and maintain this compliance level. Health Districts may establish their own methodologies for collection of information, utilizing school or other designated personnel, but they are ultimately responsible for the accuracy and completeness of the reports. If a health district collaborates with schools or other agencies to conduct the inventory, they are responsible for the training of the individuals who perform and complete the forms. The information must be summarized on the Immunization Inventory for Georgia Schools form and must be submitted to the State Immunization Program. Inventories must be completed so that reports will be received at the State Program office by November 30 of each year. State Immunization Program Consultants will annually validate the results of the audits.

SUMMARY OF IMMUNIZATION POLICIES RELATIVE TO GEORGIA LAW

IV. Exemptions

Exemptions: Georgia Law (Section 20-2-771) provides for two (2) types of exemptions from immunization requirements.

A. Medical: A medical exemption for a vaccine should be completed on the GA **DPH** Certificate of Immunization (Form 3231) only when there is a physical disability or condition that contraindicates immunization for that particular vaccine. There must be an annual review of the medical exemption and certificates must be reissued with or without indication of the medical exemption. O.C.G.A. § 20-2-771 (d).

B. Religious: For a child to be exempt from immunizations on religious grounds, the parent or guardian must furnish the school/facility with a notarized statement stating that immunization conflicts with his or her religious beliefs. There is not a standard form for religious exemption. The notarized statement must be kept on file in lieu of an immunization certificate. O.C.G.A. § 20-2-771 (e).

The notarized statement must meet the following criteria:

(1) State that their religious beliefs conflict with immunization requirements.
(2) The statement must be signed and dated by the parent/guardian.
(3) The statement must be notarized, dated, and signed by a Notary Public.
(4) The statement should be submitted to the school or childcare facility in lieu of an immunization certificate.
(5) The statement does not expire.

Reference: The Official Code of Georgia, Annotated, Section 20-2-771(e):

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O.C.G.A. § 20-2-771 (Copy w/ Cite) Pages: **3**

O.C.G.A. § 20-2-771

GEORGIA CODE
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*** Current Through the 2011 Extraordinary Session ***
*** Annotations Current Through January 20, 2012 ***

TITLE 20. EDUCATION
CHAPTER 2. ELEMENTARY AND SECONDARY EDUCATION
ARTICLE 16. STUDENTS
PART 3. HEALTH

O.C.G.A. § 20-2-771 (2011)

§ 20-2-771. Immunization of students

(a) As used in this Code section, the term:

(1) "Certificate of immunization" means certification by a physician licensed under the laws of this state or by an appropriate official of a local board of health, on a form provided by the Department of Public Health, that a named person has been immunized in accordance with the applicable rules and regulations of the Department of Public Health.

(2) "Facility" means any public or private day-care center or nursery intended for the care, supervision, or instruction of children.

(3) "Responsible official" means a county school superintendent, a school principal, or a chief operating officer of a school or facility.

(4) "School" means any public or private educational program or institution instructing children at any level or levels, kindergarten through twelfth grade, or children of ages five through 19 if grade divisions are not used.

(b) No child shall be admitted to or attend any school or facility in this state unless the child shall first have submitted a certificate of immunization to the responsible official of the school or facility. The responsible official of any school or facility may grant a 30 calendar day waiver of the certification requirement for a justified reason. The waiver may be extended from the date of first admittance or of first attendance, whichever is earlier, for up to 90 calendar days provided documentation is on file at the school or facility from the local health department or a physician specifying that an immunization sequence has been started and that this immunization time schedule can be completed within the 90 day waiver period, provided confirmation is received during the waiver period from the health department or physician that immunizations are being received as scheduled, and provided the student under waiver is a transfer student, who is defined as a student who moves from an out-of-state school system to a Georgia school system, or a student entering kindergarten or first grade from out of state. The waiver may not be extended beyond 90 calendar days; and upon expiration of the waiver, the child shall not be admitted to or be permitted to attend the school or facility unless the child submits a certificate of immunization.

(c) The Department of Public Health shall promulgate rules and regulations specifying those diseases against which immunization is required and the standards for such immunizations. The school or facility shall maintain on file the certificates of immunization for all children attending the school or facility. All facilities shall file a report annually with the Department of Public Health. The report shall be filed on forms prepared by the Department of Public Health and shall state the number of children attending the school or facility, the number of children who did not submit certificates of immunization within the waiver period, and the number of children who are exempted from the certification requirement for medical or religious reasons.

(d) If, after examination by the local board of health or any physician licensed under the laws of this state or of any other state having comparable laws governing the licensure of physicians, any child to whom this Code section applies is found to have any physical disability which may make vaccination undesirable, a certificate to that effect issued by the local board of health or such physician licensed under the laws of this or such other state may be accepted in lieu of a certificate of immunization and shall exempt the child from the requirement of obtaining a certificate of immunization until the disability is relieved.

(e) This Code section shall not apply to a child whose parent or legal guardian objects to immunization of the child on the grounds that the immunization conflicts with the religious beliefs of the parent or guardian; however, the immunization may be required in cases when such disease is in epidemic stages. For a child to be exempt from immunization on religious grounds, the parent or guardian must first furnish the responsible official of the school or facility an affidavit in which the parent or guardian swears or affirms that the immunization required conflicts with the religious beliefs of the parent or guardian.

(f) During an epidemic or a threatened epidemic of any disease preventable by an immunization required by the Department of Public Health, children who have not been immunized may be excluded from the school or facility until (1) they are immunized against the disease, unless they present valid evidence of prior disease, or (2) the epidemic or threat no longer constitutes a significant public health danger.

(g) The requirement of a certificate of immunization shall become effective for all children entering or attending facilities on or after April 7, 1981. The certification requirement shall apply to all children entering or attending schools:

(1) On September 1, 1981, for all such children entering or attending kindergarten or the first, ninth, tenth, eleventh, or twelfth grades, or of the equivalent ages if grade divisions are not used;

(2) On September 1, 1982, for all such children entering or attending all grades, or of all ages if grade divisions are not used.

(h) Any responsible official permitting any child to remain in a school or facility in violation of this Code section, and any parent or guardian who intentionally does not comply with this Code section, shall be guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not more than $100.00 or by imprisonment for not more than 12 months. The Department of Public Health may adopt rules and regulations for the enforcement of this Code section. The Department of Public Health and the local board of health, or either of them, may institute a civil action in the superior court of the county in which the defendant resides for injunctive relief to prevent a threatened or continuing violation of any provision of this Code section.

HISTORY: Ga. L. 1880-81, p. 98, § 1; Ga. L. 1919, p. 288, § 87; Code 1933, § 32-911; Ga. L. 1946, p. 206, § 2; Ga. L. 1957, p. 455, § 1; Ga. L. 1964, p. 499, § 6; Ga. L. 1968, p. 1436, § 1; Ga. L. 1972, p. 1069, § 3; Ga. L. 1973, p. 910, §§ 1, 2; Ga. L. 1978, p. 941, § 1; Ga. L. 1979, p. 1284, § 1; Ga. L. 1981, p. 756, § 1; Ga. L. 1987, p. 319, § 1; Ga. L. 2009, p. 453, §

1-4/HB 228; Ga. L. 2011, p. 705, § 6-3/HB 214.

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O.C.G.A. § 49-4-182 (Copy w/ Cite) Pages: **2**

O.C.G.A. § 49-4-182

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*** Current Through the 2011 Extraordinary Session ***
*** Annotations Current Through January 20, 2012 ***

TITLE 49. SOCIAL SERVICES
CHAPTER 4. PUBLIC ASSISTANCE
ARTICLE 9. TEMPORARY ASSISTANCE FOR NEEDY FAMILIES

O.C.G.A. § 49-4-182 (2011)

§ 49-4-182. Temporary Assistance for Needy Families Program created

(a) There is created the Georgia Temporary Assistance for Needy Families Program, which shall be known as the "Georgia TANF Program." The purpose of such program is to provide necessary assistance to needy families with children on a temporary basis and to provide parents, legal guardians, or other caretaker relatives of children with the necessary support services to enable such parents, legal guardians, or caretaker relatives to become self-sufficient and leave the program as soon as possible. After an initial assessment and once the state determines an applicant is ready for work, applicants for assistance shall be required to engage in a work activity in accordance with Part A of Title IV of the federal Social Security Act, as amended, and the state plan as soon as possible after making application for assistance, but in any event no later than 24 months after first receiving cash assistance.

(b) Assistance shall be provided in accordance with the state plan and any future amendments thereto. Cash assistance to a recipient who is not a minor child and who is a head of a household or married to the head of a household shall be limited to a lifetime maximum of 48 months, whether or not consecutive, beginning January 1, 1997.

(c) Nothing in this article, the state plan, or any rules or regulations adopted pursuant to this article shall be interpreted to entitle any individual or any family to assistance under the Georgia TANF Program.

HISTORY: Code 1981, § 49-4-182, enacted by Ga. L. 1997, p. 1021, § 6.

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O.C.G.A. § 49-4-183

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TITLE 49. SOCIAL SERVICES
CHAPTER 4. PUBLIC ASSISTANCE
ARTICLE 9. TEMPORARY ASSISTANCE FOR NEEDY FAMILIES

O.C.G.A. § 49-4-183 (2011)

§ 49-4-183. Administration of article by department; promulgation of rules and regulations by board; duties of department

(a) This article shall be administered by the Department of Human Services. The Board of Human Services shall issue such rules and regulations as may be necessary to administer this article properly and to comply with the requirements of Part A of Title IV of the federal Social Security Act, as amended, the state plan, and any future amendments to such Act or plan. The initial rules and regulations for the Georgia TANF Program shall be promulgated by the board pursuant to Chapter 13 of Title 50, the "Georgia Administrative Procedure Act," and specifically Code Section 50-13-4 no later than July 1, 1997.

(b) The board shall ensure that such rules and regulations provide for:

(1) Methods of administration necessary for the proper and efficient operation of the state plan for implementation of this article;

(2) Reasonable standards for determining eligibility and the extent of assistance available for recipients;

(3) Consideration of the income and resources of an applicant for assistance in determining eligibility;

(4) Personal responsibility obligations and work activity requirements consistent with Part A of Title IV of the federal Social Security Act, as amended, and the state plan, provided that programs included in the personal responsibility obligations established by the board shall include counseling on abstinence until marriage;

(5) Criteria which make an applicant ineligible to receive benefits under the Georgia TANF Program, including but not limited to those specified in Code Section 49-4-184;

(6) Specific conduct which would authorize the reduction or termination of assistance to a recipient, including but not limited to that specified in Code Section 49-4-185;

(7) Standards whereby certain obligations, requirements, and criteria will be waived for specific applicants or recipients based on hardship;

(8) An administrative hearing process with hearings to be conducted by the Office of State Administrative Hearings in accordance with Chapter 13 of Title 50, the "Georgia Administrative Procedure Act," and subsection (b) of Code Section 49-4-13;

(9) Safeguards which restrict the use and disclosure of information concerning applicants for and recipients of assistance under this article and in accordance with Code Section 49-4-14 and Part A of Title IV of the federal Social Security Act, as amended;

(10) Immunizations for specified diseases for preschool age children as a condition of assistance being provided for such children, and the schedule of and standards for administering such immunizations, including the presentation of a certificate of immunization, unless:

(A) There is appropriate evidence from the local health department or a physician that an immunization sequence has been started and can be completed within a period of up to 180 days, in which case a waiver of the immunization requirement for up to 180 days shall be granted;

(B) After examination by the local board of health or a physician, any preschool age child is found to have a physical disability which may make vaccination undesirable, in which case a certificate to that effect issued by the local board of health or the physician may be accepted in lieu of a certificate of immunization and shall exempt the child from obtaining a certificate of immunization until the disability is relieved;

(C) The parent or legal guardian furnishes an affidavit swearing or affirming that the immunization conflicts with the religious beliefs of the parent or legal guardian; or

(D) The implementation of such an immunization requirement violates any federal law or regulations or would result in the loss of any federal funds to this state; and

(11) The establishment and maintenance of individual development accounts. The funds in such accounts may be used for postsecondary educational expenses, the purchase of a first home, or business capitalization. The funds in such accounts shall not be considered in determining eligibility for cash assistance pursuant to 42 U.S.C. Section 604(h).

(c) The department shall:

(1) Supervise the administration of assistance pursuant to the Georgia TANF Program by the division of family and children services;

(2) Prescribe necessary forms and procedures to carry out the Georgia TANF Program, subject to the rules and regulations prescribed by the board pursuant to this article;

(3) Publish in print or electronically an annual report and such interim reports as may be necessary. The annual report and such interim reports shall be provided to the Governor and members of the General Assembly. The department shall not be required to distribute copies of the annual report or the interim reports to the members of the General Assembly but shall notify the members of the availability of the reports in the manner which it deems to be most effective and efficient. The annual report and interim reports shall contain the following:

(A) The total TANF caseload count;

(B) Quarterly and annual TANF reports, in full, prepared for submission to the federal government;

(C) The percentage of the TANF caseload and the number of individuals given a hardship

exemption from the lifetime limit on cash assistance and a categorization of the reasons for such exemptions;

(D) The number of individuals who received transportation assistance and the cost of such assistance;

(E) The number of individuals who received diversionary assistance in order to prevent their requiring TANF assistance and the categories and cost of such diversionary assistance, and job acceptance and retention statistics;

(F) The number of individuals denied assistance due to a serious violent felony conviction;

(G) The number of mothers under 19 years of age who received assistance and their percentage of the total TANF caseload;

(H) The number of children receiving subsidized child care and the total and average per recipient cost of child care provided to TANF recipients;

(I) Data on teen pregnancy prevention;

(J) The number of families sanctioned;

(K) The number of legal immigrants receiving TANF benefits by category of immigration status;

(L) The number of families no longer eligible because of time limits;

(M) Follow-up information on job retention and earnings; and

(N) An evaluation of the effect of Code Section 49-4-186 on the number of births to TANF recipient families.

The information required under this paragraph shall be provided on a county-by-county basis where feasible; and

(4) Develop a plan, on or before January 1, 1998, to provide incentives for employers to hire those TANF recipients who have difficulty in finding employment.

HISTORY: Code 1981, § 49-4-183, enacted by Ga. L. 1997, p. 1021, § 6; Ga. L. 1998, p. 128, § 49; Ga. L. 2005, p. 1036, § 39/SB 49; Ga. L. 2009, p. 453, §§ 2-2, 2-3/HB 228; Ga. L. 2010, p. 838, § 10/SB 388.

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O.C.G.A. § 31-12-3.1 (Copy w/ Cite) Pages: **3**

O.C.G.A. § 31-12-3.1

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TITLE 31. HEALTH
CHAPTER 12. CONTROL OF HAZARDOUS CONDITIONS, PREVENTABLE DISEASES, AND METABOLIC DISORDERS

O.C.G.A. § 31-12-3.1 (2011)

§ 31-12-3.1. Vaccination registry; reporting requirements, maintenance, and use

(a) The department, for purposes of establishing and maintaining a single repository of accurate, complete, and current vaccination records to be used in aiding, coordinating, and promoting effective and cost-efficient disease prevention and control efforts, shall establish and maintain a vaccination registry.

(b) Any person who administers a vaccine or vaccines licensed for use by the United States Food and Drug Administration to a person shall for each such vaccination provide to the department such data as are deemed by the department to be necessary and appropriate for purposes of the vaccination registry established pursuant to subsection (a) of this Code section, including, without limitation:

(1) The name of the person;

(2) The person's date and place of birth, including the name of the hospital where delivered, if applicable;

(3) The names and addresses of the person's parents or guardians if the person is 18 years of age or younger;

(4) The date of the vaccination and the specific type or types of vaccine or vaccines administered to the person on that date; and

(5) Complications or side effects resulting from a vaccination, if any.

Vaccination data reporting requirements, including without limitation the types of data required to be reported and the time and manner of reporting such data, shall begin after the registry has established linkages to vaccine providers and shall be established by the department in consultation with the United States Centers for Disease Control and Prevention, the Georgia chapter of the American Academy of Pediatrics, and the Georgia Academy of Family Physicians.

(c) The department shall utilize the registry to provide notices, whether by mail, telephone, personal contact, or other means, to persons and to parents or guardians regarding their children or wards who are due or overdue for a particular type of vaccination according to recommended vaccination schedules. The department shall consult with medical services providers to determine the most effective and efficient manner of using the registry to provide such notices.

(d) Vaccination records for any person included within the vaccination registry shall be maintained as part of the registry until the person's death.

(e) Individually identifiable vaccination information regarding a person may be provided to the department by, or released by the department to, a local health department, hospital, physician, or other provider of medical services to the person or to a school or child care facility in which the person is enrolled if the person is 18 years of age or younger without the consent of the person or the person's parents or guardians. All persons shall be enrolled unless a specific exemption is requested by the person or the person's parent or guardian if the person is 18 years of age or younger. A parent or guardian may obtain and upon request to the department shall be provided with all individually identifiable vaccination registry information regarding his or her child or ward. Except as provided otherwise by this Code section, individually identifiable vaccination registry information shall be treated as confidential and shall not be released to a third party without consent of the person or the person's parent or guardian if the person is 18 years of age or younger.

(f) Nothing in this Code section shall:

(1) Prohibit the department from providing or publishing registry information in aggregate form for scientific, educational, or public health purposes, provided that such information is published without releasing or identifying individual names contained in the registry;

(2) Prohibit the department or any medical services provider from notifying a person or the person's parent or guardian if the person is 18 years of age or younger of the person's vaccination status or of a vaccination that is due or overdue according to recommended vaccination schedules; or

(3) Diminish a parent's or guardian's responsibility for having a child vaccinated properly.

(g) Any person, including but not limited to practitioners of the healing arts, submitting or obtaining in good faith vaccination reports or data to or from the department in compliance with the provisions of this Code section and any rules or regulations promulgated pursuant to this Code section shall not be liable for any civil damages therefor.

(h) The department is authorized to accept any grants, gifts, awards, and funds from government, public, and private sources to supplement any appropriation made for the purpose of funding the provisions of this Code section.

(i) The department is authorized and directed to promulgate such rules and regulations as are necessary and appropriate to implement the provisions of this Code section.

HISTORY: Code 1981, § 31-12-3.1, enacted by Ga. L. 1996, p. 646, § 1; Ga. L. 2004, p. 439, § 1.

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DPH Rules
Chapter 290-5-4

290-5-4-.01 Definitions.

Unless a different meaning is required by the context, the following terms as used in these rules shall have the meaning hereinafter respectively ascribed to same:

(a) "Immunization" means the presumptive presence in the body of an immunized person of sufficient protective antibodies or of cellular immunity, as a result of previous infection or introduction of specific antigenic agents, or a presumptive state of being so conditioned by previous experience with a particular disease so as to provide an immediate and protective response upon exposure to specific infectious agents of that disease;

(b) "Local Board of Health" means any county, city or District Board of Health supported entirely or in part by the Department through the allocation of public funds or other support;

(c) "Physician" means a practitioner of the healing arts licensed in accord with O.C.G.A. or the equivalent laws of the practitioner's jurisdiction if outside Georgia;

(d) "Physical Disability" means any physical condition or physiological idiosyncrasy which might in the opinion of a physician cause a specific immunization to endanger the life or health of the recipient;

(e) "Health Authority" means the Department of Human Resources or a local Board of Health in Georgia or the corresponding agencies in other states or nations;

(f) "Epidemic" means an outbreak, or rise in incidence rate, or spread of incidence of a contagious or infectious disease so as to constitute a clear and present risk of infection to the public at large or to congregated groups thereof;

(g) "Facility" means any public or private day center or nursery intended for the care, supervision, or instruction of children;

(h) "School" means any public or private educational program or institution instructing children at any level or levels, kindergarten through twelfth grade, or children of ages five through nineteen if grade divisions are not used;

(i) "Affidavit" means a written statement made under oath before an authorized magistrate or officer which certifies that the required immunization conflicts with religious beliefs of the parent or guardian.

(j) "New Entrant" means any child entering any school or facility in Georgia for the first time or entering after having been absent from a Georgia school or facility for more than twelve (12) months or one (1) school year.

Authority O.C.G.A. Secs. 20-2-771, 31-12-3, 49-5-12. **History.** Original Rule entitled "Definitions" adopted. F. Jan. 28, 1977; eff. Feb. 17, 1977. **Repealed:** New Rule of same title adopted. F. Nov. 29, 1979; eff. Dec. 19, 1979. **Repealed:** New Rule of same title adopted. F. Apr. 22, 1982; eff. May 12, 1982. **Amended:** F. July 19, 1989; eff. Aug. 8, 1989. **Amended:** F. Jan. 20, 2000; eff. Feb. 9, 2000. **Repealed**: New Rule of same title adopted. F. Feb. 22, 2007; eff. Mar. 14, 2007.

290-5-4-.02 Immunization Required.

(1) Except as otherwise provided by law or herein specified, immunization as specified by section 290-5-4-.03 of this chapter against the following named diseases, shall be required for entrance into any school or facility operating in the state:

(a) Diphtheria;

(b) Pertussis;

(c) Tetanus;

(d) Poliomyelitis;

(e) Measles;

(f) Rubella;

(g) Mumps;

(h) *Haemophilus influenzae* type B (Not required on or after 5th birthday);

(i) Hepatitis B;

(j) Varicella;

(k) Pneumococcal (Not required on or after 5th birthday);

(l) Hepatitis A.

(2) For any child attending any school or facility in the state of Georgia for the first time, a parent or guardian must submit a valid certificate of immunization. School or facility officials, for justified reasons, may allow a child to attend for up to 30 calendar days after first admittance without a valid certificate of immunization. Certificates of Immunization are to be issued in accord with the current Official Immunization Schedules. A certificate may be issued for a child who has not received all required immunizations with the conditions that the child is in the process of completing required immunizations and that immunizations are being scheduled with the shortest intervals recommended in the current Official Immunization Schedules. The certificate must be retained and monitored for currency by the school or facility while the child continues in attendance and must be made available for inspection during normal business hours by authorized health authority officials. When a child transfers to another school or facility, the certificate of immunization must be transferred. When a child ceases to attend without transfer, the certificate should be returned to the parent or guardian.

(3) A certificate for a child who is in the process of receiving all required vaccines must have a date of expiration that relates to the date the next required immunization is due or the date on which a medical exemption must be reviewed. A new certificate must then be obtained and submitted to the school or facility within 30 days after the expiration date. Children whose parents fail to renew said certificates within the time allotted shall not be permitted to continue in attendance.

(4) Effective July 1, 2007 for entrance into kindergarten and for new entrants into a Georgia School, students must have a total of two (2) doses of measles vaccine, two (2) doses of mumps vaccine, one (1) dose of rubella vaccine and a total of two (2) doses of varicella (chickenpox) vaccine.

(5) Effective July 1, 2007 for entrance into grade six (6), students must have a total of two (2) doses of measles vaccine, two (2) doses of mumps vaccine, one (1) dose of rubella vaccine and two (2) doses of varicella (chickenpox) vaccine.

(6) Effective July 1, 2007 children attending any childcare facility (including pre-kindergarten programs) must show evidence of protection against pneumococcal disease.

(7) Effective July 1, 2007 children born on or after January 1, 2006 who are attending childcare facilities (including pre-kindergarten programs) and schools must have proof of protection against hepatitis A disease (vaccination or serology).

(8) Requirements for hepatitis A, hepatitis B, measles, mumps, rubella and varicella vaccines may be waived with serologic proof of immunity. Requirements for varicella vaccine may be waived also with a healthcare provider diagnosis of varicella disease or healthcare provider verification of history of varicella disease.

Authority O.C.G.A. Secs. 20-2-771, 31-2-4, 31-12-3, 49-5-12. **History.** Original Rule entitled "Provisions; Certificate of Immunization" adopted. F. Jan. 28, 1977; eff. Feb. 17, 1977. **Repealed:** New Rule entitled "Immunization Required" adopted. F. Nov. 29, 1979; eff. Dec. 19, 1979. **Repealed:** New Rule of same title adopted. F. Apr. 22, 1982; eff. May 12, 1982. **Amended:** F. July 19, 1989; eff. Aug. 8, 1989. **Amended:** F. Aug. 19, 1993; eff. Sept. 8, 1993. **Amended:** F. Nov. 21, 1996; eff. Dec. 11, 1996. **Amended:** F. Jan. 20, 2000; eff. Feb. 9, 2000. **Repealed:** New Rule of same title adopted. F. Feb. 22, 2007; eff. Mar. 14, 2007.

290-5-4-.03 Official Immunization Schedules. Amended.

(1) An immunization regimen equivalent to the current immunization schedule developed by the Advisory Committee on Immunization Practices (ACIP), adopted by the Department of Human Resources, and promulgated in the official state immunization program manual shall be deemed the minimum regimen of immunization which satisfies the requirements of and creates the condition of immunization. Immunization certified by local Boards of Health shall be accomplished in accord with the departmental immunization schedule.

(2) Any other immunization schedule which includes the immunizations itemized in Rule 290-5-4-.02, Immunizations Required, and equals or exceeds the minimum requirements of the Departmental Immunization Schedule shall be deemed to satisfy the requirement for issuance of a Certificate of Immunization.

(3) Copies of the Departmental Immunization Schedule may be obtained from the Department or local Board of Health.

Authority Ga. L. 1964, pp. 499, 564, 644; Ga. L. 1968, pp. 1436-1438; Ga. L. 1973, pp. 910, 911; Ga. L. 1977, pp. 787-789; Ga. L. 1979, p. 1284; Ga. L. 1981, pp. 756, 757; O.C.G.A. Secs. 20-2-771, 31-12-3, 49-5-12. **History.** Original Rule entitled "Immunizations Required" was filed on Jan. 28, 1977; eff. Feb. 17, 1977. **Amended:** F. Apr. 25, 1978; eff. May 15, 1978. **Amended:** Rule repealed and a new Rule entitled "Official Immunization Schedules" adopted. F. Nov. 29, 1979; eff. Dec. 19, 1979. **Amended:** Rule repealed and a new Rule of the same title adopted. F. Apr. 22, 1982; eff. May 12, 1982. **Amended:** F. Jul. 19, 1989; eff. Aug. 8, 1989. **Amended:** F. Jan. 20, 2000; eff. Feb. 9, 2000.

290-5-4-.05 Certificate of Immunization Issued for Child with Physical Disability. Amended.

A physical disability having been found to exist, and in the opinion of a physician there being no clear prospect of when said disability or disabilities can be removed, said physician may at his discretion issue a Certificate of Immunization indicating medical exemption. A Certificate of Immunization indicating medical exemption shall be subject to review as provided by the certifying or another physician who may reissue it from year to year until and unless there is cause to believe that immunization or a specific immunization may finally be accomplished without danger to the child's health.

Authority Ga. L. 1964, pp. 499, 564, 644; Ga. L. 1968, pp. 1436-1438; Ga. L. 1973, pp. 910, 911; Ga. L. 1977, pp. 787-789; Ga. L. 1979, p. 1284; Ga. L. 1981, pp. 756, 757; O.C.G.A. Secs. 20-2-771, 31-12-3, 49-5-12. **History.** Original Rule entitled "Official Immunization Schedules" was filed on Jan. 28, 1977; eff. Feb. 17, 1977. **Amended:** Rule repealed and a new Rule entitled "Certificate of Immunization Issued for Child with Physical Disability" adopted. F. Nov. 29, 1979; eff. Dec. 19, 1979. **Amended:** Rule repealed and a new Rule of the same title adopted. F. Apr. 22, 1982; eff. May 12, 1982. **Amended:** F. Jan. 20, 2000; eff. Feb. 9, 2000. .

290-5-4-.06 Certificate of Immunization for a Child Immunized Outside of Georgia. Amended.

Upon presentation of written proof (by vaccine type with the date of each dose) attested to by a physician licensed by the State of Georgia, or another state, or attested to by an authorized representative of the Health Authority of another country, state or nation, that all required immunizations have been accomplished for a child for whom entrance into a school or facility in Georgia is sought, or that a physical disability exists in such child, regardless of the grade of school or facility to be entered, said local Board of Health or physician shall place the presented proof on file and may issue a Certificate of Immunization as provided by Rule 290-5-4-.04, or a Certificate of Immunization indicating medical exemption as provided by Rule 290-5-4-.05.

Authority Ga. L. 1964, pp. 499, 564, 644; Ga. L. 1968, pp. 1436-1438; Ga. L. 1973, pp. 910, 911; Ga. L. 1977, pp. 787-789; Ga. L. 1979, p. 1284; Ga. L. 1981, pp. 756, 757; O.C.G.A. Secs. 20-2-771, 31-2-4, 31-12-3, 49-5-12. **History.** Original Rule entitled "Certificate of Immunization Issued for Child with Physical Disability" was filed on Jan. 28, 1977; eff. Feb. 17, 1977. **Amended:** Rule repealed and a new Rule entitled "Certificate of Immunization for a Child Immunized Outside of Georgia" adopted. F. Nov. 29, 1979; eff. Dec. 19, 1979. **Amended:** Rule repealed and a new Rule of the same title adopted. F. Apr. 22, 1982; eff. May 12, 1982. **Amended:** F. Jul. 19, 1989; eff. Aug. 8, 1989. **Amended:** F. Aug. 19, 1993; eff. Sept. 8, 1993. **Amended:** F. Nov. 21, 1996; eff. Dec. 11, 1996. **Amended:** F. Jan. 20, 2000; eff. Feb. 9, 2000.

290-5-4-.07 Epidemics. Amended.

When in the opinion of the Department of Human Resources or local Board of Health an epidemic or the threat of an epidemic exists, said Department or Board shall immediately, by the most expedient means notify the governing authorities of all schools and facilities within the affected area. When the threat of epidemic exists, the health authority may require immunization for those who object on the grounds of religious beliefs, or may alternatively prohibit attendance at schools or facilities within the area by unimmunized children.

Authority Ga. L. 1964, pp. 499, 564, 644; Ga. L. 1968, pp. 1436-1438; Ga. L. 1973, pp. 910, 911; Ga. L. 1977, pp. 787-789; Ga. L. 1979, p. 1284; Ga. L. 1981, pp. 756, 757; O.C.G.A. Secs. 20-2-771, 31-12-3, 49-5-12. **History.** Original Rule entitled "Certificate of Immunization Issued for Child Exempt from Immunization Because of a Conflict with Religious Tenets and Practices" was filed on Jan. 28, 1977; eff. Feb. 17, 1977. **Amended:** Rule repealed and a new Rule entitled "Epidemics" adopted. Filed November 29, 1979; effective December 19, 1979. **Amended:** Rule repealed and a new Rule of the same title adopted. F. Apr. 22, 1982; eff. May 12, 1982. **Amended:** F. Jan. 20, 2000; eff. Feb. 9, 2000.

290-5-4-.08 Repealed.

Authority Ga. L. 1964, pp. 499, 564, 644; Ga. L. 1968, pp. 1436-1438; Ga. L. 1973, pp. 910, 911; Ga. L. 1977, pp. 787-789; and Ga. L. 1979, p. 1284. **History.** Original Rule entitled "Certificate of Immunization Issued for a Child Immunized Outside of Georgia" was filed on January 28, 1977; effective February 17, 1977. **Amended:** Rule repealed. Filed November 29, 1979; effective December 19, 1979.

290-5-4-.09 Repealed.

Authority Ga. L. 1964, pp. 499, 564, 644; Ga. L. 1968, pp. 1436-1438; Ga. L. 1973, pp. 910, 911; Ga. L. 1977, pp. 787-789; and Ga. L. 1979, p. 1284. **History.** Original Rule entitled "Enforcement" was filed on January 28, 1977; effective February 17, 1977. **Amended:** Rule repealed. Filed November 29, 1979; effective December 19, 1979.

HISTORICAL STATEMENT LISTING DATES FOR SCHOOL AND CHILDCARE IMMUNIZATION REQUIREMENTS AND OTHER VACCINE ISSUES

HISTORICAL STATEMENT LISTING

2/1977 Regulation requiring Immunization of Children as a Prerequisite to Admission to School becomes effective

1994 Second MMR required for entrance into 6th grade (Form 3189 introduced)
"Effective with the 1994-95 school year, for entrance into the sixth grade of schools in this state or at its equivalent age, the child must have at least one (1) additional dose of MMR vaccine, for a total of two (2) MMR vaccines administered on or after the child's first birthday and at least thirty (30) days apart."
[See DHR Rules 290-5-4-.02 (4) (b).]

4/1996 Legislation providing for the establishment of a statewide childhood immunization registry

1997-98 Hepatitis B vaccination requirement for all children born after 1-1-92 who are entering kindergarten (5 year old) or day care "Effective date: 1997-98 school year for kindergarten entrants and September 1, 1997 for children entering child centers."
"Affected children: all children born after January 1, 1992 entering kindergarten or child care facility."
[See DHR Rules 290-5-4-.02 (4) (a) (3).]
[See Memorandum of January 17, 1997]

1997 Change to an IPV/OPV sequential schedule recommended "begin to implement the new schedule on February 1, 1997, or as soon as possible."
[See Memorandum of January 29, 1997]

2000 All IPV schedule routinely recommended. (No OPV available in the US as of 11/2000.). "IPV is now the only polio vaccine recommended for routine use. A child should now receive IPV for all four scheduled doses."
[See Memorandum of January 14, 2000]

2000-01

- Requirement for 2nd measles/MMR for children entering a Georgia school for the first time

  "Two doses of a measles-containing vaccine, one dose of mumps vaccine, and one dose of rubella vaccine is now required at the time of entry to school."
  [See DHR Rules 290-5-4-.02 (4).]
- Varicella immunity required for entrance to school or attendance in Daycare .

  "A child entering any child care facility or school in Georgia for the first time (at any age up to 19 years) must be age-appropriately immunized with all of the required vaccines (DTP, DTaP, DT, or Td; Hepatitis B; Hib; OPV or IPV; Measles, Mumps and Rubella or MMR; and Varicella)."
  [See DHR Rules 290-5-4-.02 (1).]

HISTORICAL STATEMENT LISTING

2000-01 cont'd

- Began use of Immunization Certificate (Form 3231) for admission to school and day care "Children attending child care or Pre-K programs on or after August 1, 2000 whose immunization certificate expires will need to have their immunization status evaluated, the recommended immunizations administered, and a new certificate (Form 3231) issued within thirty days after the certificate (Form 3227) expires."

  "A new Certificate of Immunization (Form 3231) will serve as a means of documenting the immunization status for children who will be admitted to any facility or school in Georgia for the first time on or after August 1, 2000. The new Certificate of Immunization (Form 3231) will replace the current certificates for school (Form 3032) and day care (Form 3227) and may be used any time on or after February 1, 2000."

  [See Memorandum of January 20, 2000], the Ga. Code, and current DHR Rules and Regulations posted on the GA Immunization Program website at http://health.state.ga.us/programs/immunization.asp

2001-02 Requirement for 6th graders to show proof of immunity to varicella

"The requirement for children to show proof of immunity against prior to school entry and for attendance to day care was extended to include all students entering sixth grade (6th) or the age equivalent grade beginning 2001."

[See Memorandum of October 4, 2000]

5/2001 Began Td prioritization

"Two populations should be given priority for the administration of Td. The first are those who need treatment for acute wounds. The second priority is children between the ages of 7-18 who are traveling to a country where the risk for diphtheria is high."

[See Memorandum of May 1, 2001]

1/2002 Began PCV prioritization"Interim Recommendations for Pneumococcal Conjugate Vaccine Prevnar®)"

[See Memorandum of January 4, 2002]

2/2002 Changes to ACIP General Recommendations. Most significant for audit purposes were the institution of the 4-day grace period and the publication of a minimum age and interval chart. A copy of the 2002 Recommended Schedule accompanied this mail out.

[See Memorandum of February 20, 2002 and the GeneralRecommendations on Immunization, *MMWR*, February 8, 2002]

HISTORICAL STATEMENT LISTING

3/2002 Interim recommendations for prioritization of DTaP, varicella, MMR, and continued prioritization of Td and PCV. Recommendations were also made for the completion of immunization certificates (Forms 3231 and 3189) for school and day care attendance reflecting the deferred status of certain vaccines. Providers were strongly encouraged to institute or implement recall systems in order to immunize children as soon as vaccine supplies became available.
[See Memorandum of March 8, 2002]

6/2002 MMR and Td deferrals withdrawn. Recommendations were made for providers to start recalling children as soon as possible and to resume issuing regular certificates when deferred vaccines were administered.
[See Memorandum of June 6, 2002]

7/2002 DTaP and varicella deferrals withdrawn
Revision of 3231REQ and 3231INS. (NOTE: Form 3231 did not change.)
Development of Standardized Statement for Form 3231 **for public health providers** to use in dealing with students whose original certificate (Form 3032) is lost
[See Memorandums of July 8, 2002; July 30, 2002; July 18, 2002; and July 18, 2002]

4/2003 Pediarix™ (DTaP-Hep B-IPV) made available through the Georgia Immunization Program.
[See memorandum of April 21, 2003]

5/2003 PCV deferral withdrawn.
[See memorandum of May 16, 2003]

10/2003 Revision of 3231, 3231 INS, 3231 REQ
[See memorandum of October 1, 2003]

2/2004 & 3/2004 Suspension of 4th dose of PCV, followed 3 weeks later by suspension of doses 3 and 4.
[E-mails on February 12, 2004 and March 2, 2004]

7/1/2004 Legislation passed expanding statewide childhood registry to birth to death lifetime registry

7/2004 Influenza vaccine ROUTINELY recommended for 6-23 month old children
[Recommended Childhood & Adolescent Immunization Schedule, July-December 2004]

9/2004 PCV deferrals withdrawn
[E-mails on September 22, 2004]

7/2006 Rotavirus, MMRV, and Hepatitis A Vaccine Guidelines sent by emorandum
[E-mailed on July 24, 2006]

HISTORICAL STATEMENT LISTING

8/2006 Began shipments of rotavirus vaccine and MMRV vaccine to VFC providers

8/2006 Letter dated August 8, 2006 sent to all VFC Providers with information on MMRV and also documenting the categories of VFC-eligible children who could receive 2nd doses of varicella vaccine for the present time

5/07 Memo signed by Dr. Stuart Brown, Director of the Division of Public Health, authorizing public health clinics to administer hepatitis A, hepatitis B, and HPV vaccines without parental consent to teens being seen in STD and Family Planning clinics.
[Memorandum dated May 4 2007]

5/07 Human Papillomavirus Vaccine (HPV) was shipped to public health clinics

7/2007 New vaccine requirements for school and childcare attendance, effective 7-1-07 Children entering childcare, pre-K, and Head Start facilities will be required to show age appropriate vaccination against pneumococcal disease; and show proof of immunity to or vaccination against hepatitis A, if born on or after 1-1-06. Children entering a Georgia school for the first time, or those classified as "new entrants," and those students entering the 6th grade, will have to show evidence of 2 doses of mumps vaccine (or immunity) and 2 doses of varicella vaccine (or immunity).

12/2007 National limited supply of Hib vaccine. ACIP defers booster dose

4/2008 Hib shortage and 3231 in GRITS, if all other age-appropriate vaccines other than Hib are up-to- date, the 3231 will reflect an expiration date of 30 days prior to the child's 5th birthday. Once the child turns 5, a completed 3231 can be printed from GRITS as Hib is no longer recommended

5/2008 School and Daycare user given access and the ability to print up-to-date Form 3231 in GRITS

6/2008 Pentacel (DTap/IPV/Hib) made available through Georgia Immunization Program

2/2009 Statement from the Department of Health and Human Services regarding the decisions of the U.S. Court of Federal Claims in the Omnibus Autism Proceedings find no association between vaccines and autism

2/2009 ACIP HepA Overdue Changes and BOOSTRIX Max Age Chang
The HepA dose 1 is now overdue at 2 years of age. HepA dose 2 is now Overdue 7 months after dose 1, but no earlier than 2 years of age

2/2009 VFC sends communication letter addressing vaccine choice and switch from Rotateq to Rotarix vaccine

HISTORICAL STATEMENT LISTING

2/2009 Boostrix (manufactured by GlaxoSmithKline) is now licensed for adolescents and adults ages 10 through 64.

2/2009 Hib alert letter sent to Georgia Pediatricians by Dr. Elizabeth Ford regarding Hib Vaccine

2/2009 Hepatitis B vaccine supply limited

5/2009 Georgia Medical Practice Act adds language to allow medical assistants to give Injections

6/2009 Georgia Health Departments are approved for 3rd party billing

7/2009 CDC reinstated the Hib booster dose for children from 12-15 months. [Updated Recommendations for Use of *Haemophilus influenzae* Type b (Hib) Vaccine: Reinstatement of the Booster Dose at Ages 12--15 Months, June 26, 2009]

8/2009 GRITS algorithm for Pediarix vaccine changed. The spacing of Pediarix vaccine doses for the hepatitis B antigen did not meet the minimum intervals between doses

2009 Flu Vaccine law (HB 217) *O.C.G.A. § 43-34-26.1* enacted

08/2009 This report updates Advisory Committee on Immunization Practices (ACIP) recommendations for routine poliovirus vaccination. These updates aim to 1) emphasize the importance of the booster dose at age ≥4 years, 2) extend the minimum interval from dose 3 to dose 4 from 4 weeks to 6 months, 3) add a precaution for the use of minimum intervals in the first 6 months of life, and 4) clarify the poliovirus vaccination schedule when specific combination vaccines are used. MMWR August 7, 2009 / 58(30); 829-830

10/2009 ARRA (American Recovery and Reinvestment Act of 2009) grants funds used for purchase and / or administration fees for HPV, Hep A & B and Tdap (for post partum WIC mothers) for adult vaccines.

10/2009 Interim recommendations for prioritization of novel H1N1 vaccine established by CDC

10/2009 Novel H1N1 vaccine shipped to private and public approved H1N1 vaccine Providers

10/2009 FDA approved new indication for Gardasil to prevent genital warts in men and boys

10/2009 FDA approved new vaccine (Cervarix, GlaxoSmithKline) for the prevention of cervical cancer.

HISTORICAL STATEMENT LISTING

10/2009 Merck issued announcement that the company will not resume production of monovalent measles, mumps, and rubella vaccines.

12/2009 FDA approved high-dose inactivated influenza vaccine (Fluzone High-Dose) for people ages 65 years and older.

02/2010 FDA approved pneumococcal 13-valent conjugate vaccine (Prevnar 13), which offers broader protection against Streptococcus pneumoniae. ACIP recommends use of PCV13 for 1) all children aged 2--59 months and 2) children aged 60--71 months with underlying medical conditions that increase their risk for pneumococcal disease or complications

02/2010 ACIP recommended universal Influenza vaccination for those 6 months of age and older.

10/2010 ACIP approved the following additional recommendations: 1) use of Tdap regardless of interval since the last tetanus- or diphtheria-toxoid containing vaccine, 2) use of Tdap in certain adults aged 65 years and older, and 3) use of Tdap in under-vaccinated children aged 7 through 10 years.

1/2011 ACIP approved updated recommendations for the use of meningococcal conjugate vaccines in adolescents and persons at high risk for meningococcal disease. Two new recommendations approved: 1) routine vaccination of adolescents, preferably at age 11 or 12 years, with a booster dose at age 16 years and 2) a 2-dose primary series administered 2 months apart for persons aged 2 through 54 years with persistent complement component deficiency

04/2011 April 2011, the Food and Drug Administration approved the use of a quadrivalent meningococcal conjugate vaccine (MenACWY-D) (Menactra, Sanofi Pasteur) as a 2-dose primary series among children aged 9 through 23 months (1). Vaccination with meningococcal polysaccharide vaccine (MPSV4) is not recommended for children aged <2 years because of low immunogenicity and short duration of protection in this age group (2).

06/2011 Advisory Committee on Immunization Practices (ACIP) has recommended tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) booster vaccines to unvaccinated postpartum mothers and other family members of newborn infants to protect infants from pertussis, a strategy referred to as cocooning (1).

06/2011 In June 2011, the Advisory Committee on Immunization Practices (ACIP) declined to recommend the vaccine for adults aged 50 through 59 years and reaffirmed its current recommendation that herpes zoster vaccine be routinely recommended for adults aged 60 years and older.

HISTORICAL STATEMENT LISTING

07/2011 Georgia HB 303 granted advanced practice registered nurses and physician assistants the authority to sign off on certain documents relating to health care under delegation of authority by a physician.

08/2011 ACIP provided updated guidance for the use of influenza vaccines in the United States for the 2011--12 influenza season. Information is presented in this report regarding vaccine strains for the 2011--12 influenza season, the vaccination schedule for children aged 6 months through 8 years, and considerations regarding vaccination of persons with egg allergy. Availability of a new Food and Drug Administration (FDA)--approved intradermally administered influenza vaccine formulation for adults aged 18 through 64 years is reported.

08/2011 Licensure of a Meningococcal Conjugate Vaccine for Children Aged 2 Through 10 Years and Updated Booster Dose Guidance

10/2011 ACIP recommended the use of Quadrivalent Meningococcal Conjugate Vaccine (MenACWY-D) Among Children Aged 9 Through 23 Months at Increased Risk for Invasive Meningococcal Disease

10/2011 ACIP Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria To Toxoid and Acellular Pertussis Vaccine (Tdap) in Pregnant Women and Persons who Have or Anticipate Having Close contact with an Infant Aged <12 months. In October 2010, ACIP recommended expanded use of Tdap. This report provides the updated recommendations, summarizes the safety and effectiveness data considered by ACIP, and provides guidance for implementing the recommendations. ACIP recommends a single Tdap dose for persons aged 11 through18 years who have completed the recommended childhood diphtheria and tetanus toxoids and pertussis/diphtheria and tetanus toxoids and acellular pertussis (DTP/DTaP) vaccination series and for adults aged 19 through 64 years (4,5).

10/2011 Advisory Committee on Immunization Practices (ACIP) recommended routine use of quadrivalent human papillomavirus (HPV) vaccine (HPV4; Gardasil, Merck & Co. Inc.) in males aged 11 or 12 years. ACIP also recommended vaccination with HPV4 for males aged 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series; males aged 22 through 26 years may be vaccinated. These recommendations replace the October 2009 ACIP guidance that HPV4 may be given to males aged 9 through 26 years (1).

10/2011 ACIP recommended that all previously unvaccinated adults aged 19 through 59 years with diabetes mellitus (type 1 and type 2) be vaccinated against hepatitis B as soon as possible after a diagnosis of diabetes is made (recommendation category A).

HISTORICAL STATEMENT LISTING

10/2011 FDA communicated on the use of Jet Injectors with Inactivated Influenza Vaccine. The Food and Drug Administration (FDA) is recommending that health care professionals use a sterile needle and syringe to administer inactivated influenza vaccines. The FDA is clarifying its October 21, 2011, communication to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector. FDA's recommendation to administer inactivated influenza vaccines using a sterile needle and syringe is based on studies submitted to FDA in support of the vaccine approvals.

02/2012 **On February 22, 2012, the ACIP voted to recommend tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) for adults aged 65 years and older. Providers should not miss an opportunity to vaccinate persons aged 65 years and older with Tdap, and may administer the vaccine that they have available. When feasible, for adults aged 65 years and older, Boostrix should be used; however, either vaccine product administered to a person aged 65 years and older provides protection and is considered valid.**

04/2012 **Temporary shortage of Pentacel® and DAPTACEL® due to manufacturer delays.**

04/2012 **Directive for 3231 GRITS Certificate.**

CERTIFICATE OF IMMUNIZATION

Child's Name (Last name first)

Birthdate

(Optional) Parent/Guardian Name (Last name first)

Date of Expiration

(Next required immunization or review of medical exemption due.)

OR

Complete For School Attendance (Fill in X)

Child must be ≥ 4 years and have met all requirements for school attendance. The vaccine history section must be filled in.

Unless specifically exempted by law, Georgia law (O.C.G.A. 20-2-771) requires a certificate on file for each child in attendance in any school or child care facility in Georgia with penalties for failure to comply. Detailed instructions for this form and immunization requirements by age are spelled out in policy guides 3231INS and 3231REQ distributed by the Georgia Immunization Office.

VACCINE	DATE MM DD YY	DATE MM DD YY	DATE MM DD YY	DATE MM DD YY	DATE MM DD YY	DATE MM DD YY	Total Doses	Diagnosed	Serology +	History	Med. Exemption
Required Vaccines for School or Child Care Attendance											
DTP, DTaP, DT											
Td or Tdap											
Hepatitis B											
OPV											
IPV											
HIB (Under Age 5)											
PCV (Under Age 5)											
Measles											
Mumps											
Rubella											
Hepatitis A (Born on/after 1/1/06)											
Varicella											
Recommended Vaccines (For Information Only)											
MCV/MPSV											
Rotavirus											
HPV											
Influenza											
Td or Tdap (Booster Dose)											

SAMPLE COPY ONLY

Notes:
A licensed Georgia physician, **Advanced Practice Registered Nurse, Physician Assistant** qualified employee of a local Board of Health or the State Immunization Office is responsible for the content and certification of this certificate with legible name, address, signature and date of issue . All dates must include month, day and year. In cases of natural immunity or Medical Exemption, the 4 digit year of infection, test or exemption must be filled in the appropriate box(es). ***The certificate is NOT valid without name and birthdate of the child, date of expiration OR "X" in Complete for School Attendance box.*** A school or facility official is responsible for keeping a current valid certificate on file for each child in attendance. A certificate must be replaced within 30 days after expiration. ***When a child leaves or transfers to another facility, the Certificate of Immunization should be given to a parent/guardian or sent to the new facility.***

Printed, Typed or Stamped Name, Address and Telephone # of Licensed Physician or Health Department

Certified by (Signature)

Date of Issue

Policy Guide 3231INS
Standards for Issuing and Filing Certificates of Immunization
[Form 3231 (Rev. August-2012)]
For Georgia Facilities and Schools

Who is required to have the Certificate of Immunization (Form 3231)?

Children attending any childcare facility, pre-kindergarten, Head Start program, nursery, or school are required to have this form on file. This includes public and private operations and all enterprises, educational programs and institutions involved in the care, supervision or instruction of children. Certificates are required for all children through grade 12.

Who may issue certificates?

Only a **licensed Georgia physician**, **Advanced Practice Registered Nurse, Physician Assistant** or qualified employee of a local Board of Health or the State Immunization **Office** may issue this certificate. The physician, **APRN, PA** or health department is responsible for interpretation of and compliance with the requirements set forth in Chapter 290-5-4 of the *Rules of the* ***Department of Public Health***.

How to file and maintain the certificates:

1. **A valid certificate for all children** must have the following information legibly completed:
   - Child's Name
   - Birth date
   - Name, address, and phone number of a Physician or Health Department
   - Certified by Signature
   - Date of Issue
   - Dates (month, date and year) in the vaccine history (dates vaccines administered) section and/or 4 digit year in the "Disease Dx", "Serology +", "Disease Hx" or "Medical Exemption" boxes.
2. **A valid certificate for children under 4 years of age** must have:
   - All of the information in item #1 and a "Date of Expiration" noted in the appropriate space.
3. **A valid certificate for a child age 4 years or older** must have:
   - All of the information in item #1 and either an X in the "Complete For School Attendance" box or a marked "Date of Expiration"
4. Valid certificates marked "Complete for School Attendance" do not expire.
5. **The certificate becomes invalid on the expiration date indicated. If a current certificate has not been submitted within 30 days after the expiration date, the child must be excluded from attendance until a current certificate is obtained.**
6. A school/facility official is responsible for keeping track of certificates with expiration dates and for notifying a parent/guardian of an upcoming expiration date and requesting that an up-to-date certificate be submitted**.**
7. A valid certificate of immunization must be kept on file by the school/facility and be available for inspection by health officials. The school/facility is **not** responsible for the accuracy of immunization information filled in by the certifying authority.
8. If a child attends more than one school/facility, a photocopy of this form must be on file at the second school/facility.
9. If a child leaves **or** transfers to another school/facility, this certificate should be given to a parent/guardian **or** sent to the new school/facility.
10. Any school/facility official who does not enforce the requirements and any parent/guardian who intentionally does not comply with the requirements shall be guilty of a misdemeanor. See *Official Code of Georgia Annotated, § 20-2-771(h)*.

Instructions for completing certificates:

1. **ALL** dates **must** include month, day and year.
2. The "Child's Name" and **"**Birthdate" **must** be filled in.
3. The "Date of Expiration" is the date the child's next immunization is due **or** the date a review of the medical exemption is due.
   - This date **must** be filled in when a child is in the process of receiving the required number of vaccine doses appropriate for age as set forth in *Policy Guide 3231REQ, Vaccine Requirements for Attending Facilities and Schools in Georgia*.
   - The date filled in **may** be the date a review of a medical exemption for a vaccine is due. The "Date of Expiration" **must** be filled in if "Complete for School Attendance" is not marked.
4. Put an X in the **"**Complete For School Attendance" box **if** a child who is **four years of age or older** has completed all the immunization requirements for first time attendance in a **school** in Georgia as set forth in

Policy Guide 3231REQ, Vaccine Requirements for Attending Facilities and Schools in Georgia. Note that requirements for kindergarten (age 5 years) **include** doses indicated by the ACIP for 4-6 years. The "Complete for School Attendance" box **must** be filled in if the "Date of Expiration" is not.

5. The Georgia Department of Public Health establishes the requirements for immunization for school/facility attendance in accord with the *Recommended Childhood Immunization Schedule, United States*, developed and approved annually by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP). See *Policy Guide 3231REQ Vaccine Requirements for Attending Facilities and Schools in Georgia* for requirements for doses for age, minimum ages, and minimum intervals between doses for children who are behind schedule.
6. Hib and PCV vaccine are not required on or after the 5th birthday. The number of doses for both vaccines is dependent on age at first dose and/or the brand(s) of vaccine administered. If the "Complete for School Attendance" box is marked for a child who **is** 4 years of age, dates for Hib and PCV vaccine must be filled in.
7. The Hepatitis A, Hepatitis B, Measles, Mumps, Rubella and Varicella vaccine requirements may be waived with serologic proof of immunity. Filling in a 4-digit year is required for each requirement waived.
8. For varicella vaccine, the dates for each dose given must be entered **or** the 4 digit year in **one** of the columns indicating "Diagnosed" disease, "Serology +" (serologic evidence of immunity), "History" of disease or "Medical Exemption" must be filled in. The Varicella vaccine requirement may be waived with: (a) a physician's diagnosis of disease; or (b) a health care provider's interpretation that a parent/guardian description of chickenpox disease history is indicative of past infection. Filling in a 4-digit year for the year of infection is required.
9. In the interest of having a more complete record, providers are requested to fill in dates of Recommended Vaccines the child has received, but are not required to do so.
10. The certificate is **not** valid without a printed, typed or stamped name, address, and phone number of the certifying authority in the certification section in the lower right corner. There **must** be a written or stamped licensed physician's signature, **APRN, PA** or a signature of a qualified employee of a local Board of Health or State Immunization **Office** on the "Certified by" signature line. **A stamp of a physician, APRN, or PA's signature with official title is permissible when cosigned by an office staff.**
11. The "Date of Issue" is the date a child's immunization status was reviewed and the certificate was issued. It **must** be filled in.
12. During times when vaccine shortages may necessitate deferral of doses of specific vaccines, the GA Immunization Program will follow the recommendations made by the ACIP and will send providers the interim plans for issuing certificates based on these temporary recommendations.

Exemptions:

The Official Code of Georgia provides for only two types of exemptions from immunization requirements:

1. **Medical:** Medical exemption for a vaccine should be filled in only when there is a physical disability or condition that contraindicates immunization for that particular vaccine. There must be an annual review of medical exemptions, and certificates must be reissued with or without indication of exemption. *O.C.G.A. §20-2-771(d)*
2. **Religious:** For a child to be exempt from immunizations on religious grounds, the parent or guardian must furnish the school/facility with a notarized affidavit stating that immunization conflicts with his or her religious beliefs. There is **no** standard form for Religious Exemption. The school/facility must keep the affidavit on file and available for inspection by health officials in lieu of an Immunization Certificate.
   Affidavits denoting religious exemption do not expire. *O.C.G.A. §20-2-771(e)*

Certificate ordering and computer generated facsimiles:

1. Certificates of Immunization (Form 3231) may be ordered in bulk from:
   Georgia Immunization **Office**
   2 Peachtree Street N.W, Suite 13-276
   Atlanta, GA 30303-3186
   The order form can be printed from: http://health.state.ga.us/programs/immunization/
2. Computerized versions of the Certificate of Immunization (Form 3231) must contain all the information included in the current form provided by the Georgia Department of Public Health and must be approved by the Georgia Immunization **Office** prior to use. References: Official Code of Georgia Annotated, § 20-2-771 and Rules of the **Department of Public Health**, Chapter 290-5-4.

Policy Guide 3231REQ

Vaccine Requirements for Attending Facilities and Schools in Georgia

Relative to the Certificate of Immunization (Form 3231)

Required Doses for Attendance in Facilities and Schools For Children Who Started Immunizations Before Age 7 Years*

Required Vaccines with footnote numbers in [ ]	2 Months of Age	4 Months of Age	6 Months of Age	12 Months of Age	15 Months of Age	18 Months of Age	24 Months of Age	4-6 Yrs.* (School Entry)	**Total Doses Required** For Checking Complete For School Attendance Box on Immunization Certificate**
[1] DTP, DTaP, DT	1	2	3	4				5	**4 or 5 (See Footnote [1])**
[2]Hepatitis B	1	2	3						**3 (See Footnote [2])**
[3]Hib PRP-T or	1	2	3	4					**N/A for school (See Footnote [3])**
[3]Hib PRP-OMP	1	2		3					**N/A for school (See Footnote [3])**
[4]Polio	1	2	3					4	**3 or 4 (See Footnote [4])**
[5]MMR				1				2	**2 (See Footnote [5])**
[6] Varicella				1				2	**2 (See Footnote [6])**
[7] PCV	1	2	3	4					**N/A for school (See Footnote [7])**
[8] Hepatitis A				1			2		**(See Footnote [8])**

*These requirements were established in accordance with the current Recommended Childhood and Catch-Up Immunization Schedules, United States. (See references on reverse side.) Georgia requirements for Kindergarten (5 years) include doses indicated for 4-6 years.

**Children who are behind schedule may attend while in the process of completing the requirements with minimum intervals as indicated below.

Minimum Ages For Initial Immunization And Minimum Intervals Between Doses

Vaccine	Minimum Age For For First Dose	Minimum interval from dose 1 to 2	Minimum interval from dose 2 to 3	Minimum interval from dose 3 to 4	Minimum interval from dose 4 to 5
[1] DTP/DTaP (DT)	6 weeks	1 month	1 month	6 months	See Footnote [1]
[2] Hepatitis B	birth	1 month	See Footnote [2]	N/A	N/A
[3]Hib(Primary Series)					
PRP-T (ActHIB)	6 weeks	1 month	1 month	See Footnote [3]	N/A
PRP-OMP (Pedvax)	6 weeks	1 month	See Footnote [3]	N/A	N/A
[4] Polio	6 weeks	1 month	1 month	See Footnote [4]	N/A
[5] MMR	12 months	1 month	N/A	N/A	N/A
[6] Varicella	12 months	3 months	N/A	N/A	N/A
[7] PCV	6 weeks	1 month	1 month	See Footnote [7]	N/A
[8] Hepatitis A	12 months	6 months			

With respect to these intervals, 1 month is a minimum of 4 weeks or 28 days.

Don't restart any series, no matter how long since the previous dose. Doses given ≤ 4 days before the minimum age or the minimum interval may be counted as valid. Two different live vaccines must be given on the same day or spaced at least 28 days apart.

[1] One dose of DTP/DTaP/DT must be on or after the 4th birthday. If the 4th dose was on or after the 4th birthday, the 5th dose is not needed. The 4th dose should be administered a minimum of 6 months after the 3rd dose. However, the 4th dose does not need to be repeated if administered ≥ 4 months after dose 3. Total doses of diphtheria and tetanus toxoids should not exceed 6 before the 7th birthday.

[2] The 3rd dose of Hepatitis B vaccine should be given a minimum of 4 months after the 1st dose and 2 months after the 2nd dose and not before 24 weeks of age.

[3] The number of doses of Hib depends on age at 1st dose and brand of vaccine given. The last dose in the series, whether 3rd or 4th, should be given at least 2 months after the previous dose and not before 12 months of age. Hib is required for children younger than 5 years attending facilities. Hib is not required for admission to kindergarten (5 years) through grade 12 and is not indicated for children who have reached the 5th birthday. One dose is sufficient if it is given at age 15 months or later. Brand names for PRP-T is ActHIB. The brand name for PRP-OMP is Pedvax Hib and the Hib component of Comvax(Hepatitis B-Hib) is Pedvax Hib.

[4] Booster dose must be given on or after the 4th birthday and a 6 month interval is required between the last dose of the primary series and the booster dose. If the 3rd dose of all IPV or all OPV series is given on or after the 4th birthday, a 4th dose is not required provided there is a 6 month interval since the previous dose.

[5] The MMR requirement is 2 doses of measles vaccine, 2 doses of mumps vaccine and 1 dose of rubella vaccine . The vaccines may be given as MMR or MMRV (combined antigens) or as single antigens. single antigens.

[6] The varicella requirement is for 2 doses of varicella-containing vaccine for entry into any level, K-12. (**See Side 2 of REQ, Footnote [4]**).These may be administered as single dose varicella or in combination as MMRV.

[7] The number of doses in the PCV series depends on age at 1st dose. The last dose in the series should be given at least 2 months after the previous dose and not before 12 months of age.

[8] Hepatitis A vaccine should be administered to all children born on or after 1-1-06.

Summary of Georgia Immunization Requirements for Child Care & School Attendance

These charts are based on the ACIP Recommendations and Georgia Requirements; for more detailed information including dose schedules and minimum time intervals; please refer to Georgia Form 3231REQ and Table 1 of the ACIP General Recommendations, *MMWR*, January 28, 2011.

Required Number of Doses for Children Who Started Immunizations before Age 7 Years

Required Vaccines	2 mo	4 mo	6 mo	12 mo	15 mo	18 mo	24 mo	4-6 years	5-6 yrs of age Total Doses Required for School Entry
DTP, DT, DTaP	1	2	3	4				5	4 or 5 (if #4 dose given on or after 4th birthday, #5 not needed)
Hep B	1	2	3						3
Hib (ActhiB) or * Hib (PedvaxHIB or Comvax)	1	2	3	4					Required for Child Care and Pre-K only
	1	2		3					
**Polio	1	2	3					4	3or 4 (4th dose of polio on or after 4th birthday required for children born on or after 1-1-06)
***MMR				1				2	2
Varicella				1				2	2
PCV	1	2	3	4					Required for Child Care & Pre-K only
Hep A				1	2				2 Required for children born on or after 1-1-06

*If PedvaxHIB or Comax is administered at ages 2 and 4 months, a dose at 6 months is not indicated.

**The final dose in the series should be administered on or after the fourth birthday and at least 6 months following the previous dose. If 4 doses are administered prior to age 4 years a fifth dose should be administered at age 4 through 6 years. (MMWR 2009; 58(30) :829-30)

***State requirement is for 2 doses each of measles and mumps, and 1 dose of rubella vaccine. Second dose may be given before age 4 years, provided at least 4 weeks have **elapsed since first dose.**

Required Number of Doses for Children Who Started Immunizations after Age 7 Years

Required Vaccines	First Visit	1 Mo After 1st Dose	1 Mo After 2nd Dose	1 Mo After 3rd Dose	4 Mo After 1st Dose	6 Mo After Previous Dose	Total Doses Required
* Hep B	1	2			3*		3
**Polio	1	2	3			3 or 4	3 or 4
***MMR	1	2					2
**** Varicella	1	2					2
Td/Tdap	1	2				3	3

* If child received 2 doses of adult Recombivax-HB 10 mcg between the ages of 11-15 yrs and the doses are separated by at least 4 months, dose 3 is not needed.

** The final dose in the series should be administered on or after the fourth birthday and at least 6 months following the previous dose. A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.

*** State requirement is for 2 doses each of measles and mumps, and 1 dose of rubella vaccine.

**** If given before age 12, the varicella doses should be separated by 3 months, however, the 2nd dose does not need to be repeated if administered ≥ 1month after first dose.

(Rev. 03/2012)

Immunization Requirements and Recommendations for University System of Georgia Students

Proof of Immunization or Naturally-Acquired Immunity Required for Some or All Students			
Vaccine	**Requirement**	**Required for:**	**Notes**
Measles (Rubeola)	- 2 doses of live measles containing vaccine (combined measles-mumps-rubella or "MMR" meets this requirement), with first dose at 12 months of age or later and second dose at least 28 days after the first dose, **or** - Laboratory/serologic evidence of immunity	Students born in 1957 or later	1) Guidelines exist for vaccination of persons with altered immunocompetence[1]. 2) For students born before 1957, proof of immunity may be required if enrolled in health care curriculum.
Mumps	- 2 doses of live mumps containing vaccine (combined measles-mumps-rubella or "MMR" meets this requirement), with first dose at 12 months of age or later and second dose at least 28 days after the first dose, **or** - Laboratory/serologic evidence of immunity	Students born in 1957 or later	1) Guidelines exist for vaccination of persons with altered immunocompetence[1]. 2) For students born before 1957, proof of immunity may be required if enrolled in health care curriculum.
Rubella (German Measles)	- 1 dose at 12 months of age or later (MMR meets this requirement), **or** - Laboratory/serologic evidence of immunity	Students born in 1957 or later	1) Guidelines exist for vaccination of persons with altered immunocompetence[1]. 2) For students born before 1957, proof of immunity may be required if enrolled in health care curriculum.

Proof of Immunization or Naturally-Acquired Immunity Required for Some or All Students			
Vaccine	**Requirement**	**Required for:**	**Notes**
Varicella (Chicken Pox)	- 2 doses spaced at least 3 months apart if both doses are given before the student's 13th birthday, **or** - 2 doses at least 4 weeks apart, If first dose given after the student's 13th birthday: **or** - Reliable history of varicella disease ("chicken pox"), **or** - Laboratory/serologic evidence of immunity **or** - History of herpes zoster (shingles)	All U.S born students born during or after 1980 All foreign born students regardless of year born	1) Guidelines exist for vaccination of persons with altered immunocompetence[1]. 2) For students born before 1980, proof of immunity may be required if enrolled in health care curriculum.
Tetanus, Diphtheria Pertussis (Whooping Cough)	- One dose of Tdap for persons if they have not previously received Tdap. **or** - One Td **booster** dose if it has been 10 years after receiving Tdap.	All students	1) Tdap can be administered regardless of interval since the last tetanus or diphtheria toxoid-containing vaccine. ~~1)~~2) Tetanus/diphtheria containing boosters are recommended every 10 years throughout adulthood. A single dose of Tdap is recommended to replace a single dose of Td. ~~2)~~3) Students who are unable to document a primary series of 3 doses of tetanus/diphtheria containing vaccine (DTaP, DTP, or Td)are strongly advised to complete a 3-dose primary series.

Proof of Immunization or Naturally-Acquired Immunity Required for Some or All Students			
Vaccine	**Requirement**	**Required for:**	**Notes**
Hepatitis B	- 3 dose hepatitis B series (0, 1-2, and 4-6 months), **or** - 3 dose combined hepatitis A and hepatitis B series (0, 1-2, and 6-12 months), **or** - 2 dose hepatitis B series of Recombivax™ (0 and 4-6 months, given at 11-15 years of age), **or** - Laboratory / serologic evidence of immunity or prior infection	**Required** for all students who will be 18 years of age or less at matriculation. It is **strongly recommended** that all students, regardless of their age at matriculation, discuss hepatitis B immunization with their health care provider.	May be required (along with recommended post-vaccine serologic testing) for students in the health sciences, regardless of age at matriculation.

Signed Documentation Stating that Student Has Received the Vaccine OR Reviewed Information Provided as Required by House Bill 521 Required for Some Students			
Vaccine	**Requirement**	**Required for:**	**Notes**
Meningococcal	- 1 dose meningococcal conjugate vaccine (MCV4) for unvaccinated persons 21 yrs or younger **-or** - 1 **booster** dose of meningococcal conjugate vaccine (MCV4) for persons 21 yrs or younger if received initial MCV4 dose younger than age16 yrs. If initial MCV4 dose given age ≥16 yrs, no booster dose required. **or** Signed documentation that student (or parent or guardian if student <18 years old) has received and reviewed information about the disease as required by O.C.G.A.§ 31-12-3.2	Newly admitted freshmen or matriculated students planning to reside in university managed campus housing	1) Effective January 2004, University System of Georgia institutions are required by O.C.G.A. §31-12-3.2 to obtain signed documentation from newly admitted freshman or matriculated students indicating that they have received the vaccine or have reviewed information about the disease. If a student is a minor, only a parent or guardian may sign such document. 2) Routine vaccination of healthy persons who are not at increased risk for exposure is not recommended after age 21 years.Because of the limited period of increased risk, CDC does not currently recommend that college freshman living in campus housing who are previously vaccinated with MCV4 be revaccinated. However, college freshman living in dormitories who were vaccinated with MPSV4 ≥5years previously are commended to be vaccinated with MCV4.

Immunization Recommended for All Students		
Vaccine	**Recommended Schedule**	**Notes**
Influenza	- Annual vaccination at the start of influenza season (October – March)	**Strongly recommended** for students with medical conditions such as diabetes, asthma, or immunodeficiencies, as well as for students residing in dormitories or other group living situations or who are members of athletic teams.
Human Papillomavirus (HPV)	- 3 dose HPV series. Dose #2 given 4-8 wks after dose #1, and dose #3 is given 6 mos after dose #1 (at least 10 wks after dose #2).	HPV vaccines are licensed for males and females 9 yrs through 26 yrs. Students should discuss with their healthcare provider about their risk for HPV disease and the benefits of HPV vaccination. **Strongly recommended** for all unvaccinated women through age 26 yrs.
Hepatitis A	- 2 dose hepatitis A series (0 and 6-12 months), **or** - 3 dose combined hepatitis A and hepatitis B series (0, 1-2, and 6-12 months)	**Strongly recommended** for: persons traveling to countries where hepatitis A is moderately or highly endemic, men who have sex with men, users of injectable and noninjectable drugs, persons with clotting-factor disorders, and persons with chronic liver disease
Pneumococcal Polysaccharide	- 1 dose for persons < 65 yrs if have chronic illness or other risk factor including but not limited to: diabetes, asthma, asplenia, sickle cell disease, cochlear implant recipient, HIV infection or other immunocompromising condition **or** - 1 dose for unvaccinated persons $\geq$ 65yrs	Revaccination with pneumococcal vaccine every 5 yrs after persons is 65 yrs, is **NOT** recommended[1]
Other Vaccines	- Other vaccines may be recommended for students with underlying medical conditions and students planning international travel. Students meeting these criteria should consult with their physicians or health clinic regarding additional vaccine recommendations.	

References:

1. CDC. General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011;60(RR-2):1-61.

Additional Resources:

American College Health Association (ACHA). Recommendations for Institutional Prematriculation Immunizations. 2011 Update http://www.acha.org/Publications/docs/ACHA_RIPI_Mar2011.pdf

CDC. Recommended Immunization Schedules for Persons aged 0 – 18 yrs- United States, 2011. MMWR 2011;60 (5)

CDC. Recommended Adult Immunization Schedule – United States, 2011. MMWR 2011:60(4).

Pickering LK, Baker CJ, Kimberlin DW, Long SS, eds. Red *Book: 2009 Report of the Committee on Infectious Diseases*. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009.

Georgia Department of Community Health, Division of Public Health, Immunization Program: http://www.health.state.ga.us/programs/immunization

Centers for Disease Control and Prevention (CDC), Vaccines and Immunizations: http://www.cdc.gov/vaccines/

CDC Vaccines for Teenagers and College students: http://www.cdc.gov/vaccines/recs/schedules/teen-schedule.htm

Immunization Action Coalition: http://www.immunize.org/

UNIVERSITY SYSTEM OF GEORGIA

REQUIRED

CERTIFICATE OF IMMUNIZATION

(Return this to the institution)

Return documentation to the college or university that you are applying to. Retain a copy of the completed form for your records.

STUDENT INFORMATION

Social Security Number/Student ID: _____ - _____ - _____

Name: (Last)_____(First)_____(Middle)_____

Address: _____

City: _____ State: _____ Country: _____ Zip Code: _____

Term/Year of Application: _____ Age at time of application: _____ Date of Birth: _____/_____/_____

REQUIRED IMMUNIZATION INFORMATION *(See the Immunization Requirements & Recommendations for USG Students documentation)*

VACCINE	DATE MM/DD/YYYY	DATE MM/DD/YYYY	DATE MM/DD/YYYY	HISTORY	DATE OF POSITIVE LAB/SEROLOGIC EVIDENCE
MMR 1	/ /	/ /			
Measles 1	/ /	/ /			/ /
Mumps 1	/ /	/ /			/ /
Rubella 1	/ /	/ /			/ /
Varicella 3	/ /	/ /		(or history of Varicella) / /	
Tetanus-Diphtheria Pertussis (Whooping Cough)	TDAP / /	Booster / /			
Hepatitis B 2	/ /	/ /	/ /	Type Series: ☐ 2 Dose Series ☐ 3 Dose Series	/ /

1—Not required if born before 1957. 2—Only required of students who are 18 years of age or younger at time of expected matriculation.
3—Required for all US born students born in 1980 or later; all foreign born students regardless of year born.

PERMANENT OR TEMPORARY IMMUNIZATION EXEMPTION

☐ This student is exempt from the above immunizations on the ground of permanent medical contraindication.

☐ This student is temporarily exempt from the above immunization until _____/_____/_____.

CERTIFICATION OF HEALTH CARE PROVIDER *(This information is required)*

Name: _____ Signature: _____

Address: _____

Date of Issue: _____/_____/_____ Telephone: _____

EXEMPTIONS

Check the appropriate box, sign, and date if you are claiming exemption of the immunization requirement for one of the following reasons:

☐ I affirm that Immunization as required by the University System of Georgia is in conflict with my religious beliefs. I understand that I am subject to exclusion in the event of an outbreak of a disease for which immunization is required.

Student Signature: _____ Date: _____/_____/_____

☐ I declare that I will be enrolling in ONLY courses offered by distance learning. I understand that if I register for a course that is offered on-campus or at a campus-managed facility this exemption becomes void and I will be excluded from class until I provide proof of immunization.

Student Signature: _____ Date: _____/_____/_____

UNIVERSITY SYSTEM OF GEORGIA

RECOMMENDED
CERTIFICATE OF IMMUNIZATION
(Return this to the institution)

Return documentation to the college or university that you are applying to. Retain a copy of the completed form for your records.

STUDENT INFORMATION

Social Security Number/Student ID: _____ - _____ - _____

Name: (Last)_____(First)_____(Middle)_____

Address: _____

City: _____ State: _____ Country: _____ Zip Code: _____

Term/Year of Application: _____ Age at time of application: _____ Date of Birth: _____/_____/_____

RECOMMENDED IMMUNIZATION INFORMATION (See the Immunization Requirements & Recommendations for USG Students documentation)

VACCINE	DATE MM/DD/YYYY	DATE MM/DD/YYYY	DATE MM/DD/YYYY	HISTORY	DATE OF POSITIVE LAB/SEROLOGIC EVIDENCE
Human Papillomavirus 4	/ /	/ /	/ /		
Hepatitis A 5	/ /	/ /	/ /	Type Series: ☐ 2 Dose Series ☐ 3 Dose Series	/ /
Meningococcal 6, 7	/ /	Booster / /			
Influenza 5	/ /	/ /			

4 – Strongly recommended for all unvaccinated women through age 26 years.
5 - Strongly recommended but not required.
6 – Strongly recommended if younger than 21 years and unvaccinated.
7 – Booster necessary if younger than 21 years & initial dose was received before age 16 years.

CERTIFICATION OF HEALTH CARE PROVIDER (This information is required)

Name: _____ Signature: _____

Address: _____

Date of Issue: _____/_____/_____ Telephone: _____

Student Signature: _____ Date: _____/_____/_____

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- Polio Fact Sheet and Q & A **(REPLACE)**
- Rubella Fact Sheet and Q & A **(REPLACE)**
- Streptococcus pneumoniae Fact Sheet and Q & A **(REPLACE)**
- Tetanus Fact Sheet **(REPLACE)**
- Neisseria Meningitidis Fact Sheet **(ADD)**
- Varicella Fact Sheet **(ADD)**

Resources for Influenza Prevention and Control **(REPLACE)**
Influenza Outbreak Control in a Long Term Care Facility **(REPLACE)**
Georgia Notifiable Disease Report, Form 3095 (Rev. 8/04) **(REPLACE)**
Diphtheria Worksheet **(REPLACE)**
Measles Surveillance Worksheet **(REPLACE)**
Mumps Surveillance Worksheet **(REPLACE)**
Pertussis Surveillance Worksheet **(REPLACE)**
Rubella Surveillance Worksheet **(REPLACE)**
Tetanus Surveillance Worksheet **(REPLACE)**
Bacteriology Submission Form **(ADD)**
GPHL Microbial Immunology Submission Form **(REPLACE)**
GPHL Molecular Biology Submission Form **(REPLACE)**
Varicella Reporting and Case Investigation Form **(ADD)**
Virology Culture Submission Form (Rev. 1/10) **(REPLACE)**

Procedure for the Investigation and Reporting of Vaccine Preventable Diseases

Surveillance

Each District (or local) Health office must maintain a surveillance system to monitor the incidence of vaccine-preventable diseases (VPD) in their community, especially as immunization rates increase. In most areas of the state, a passive disease surveillance system is used to collect information on vaccine preventable disease. This type of surveillance system is simpler and less burdensome than active surveillance, but is limited by incompleteness of data and a lack of timeliness. Even after efforts are made to publicize the importance of reporting, passive surveillance systems may still not be representative of the disease burden in the community and may fail to identify outbreaks. The quality of surveillance data can be improved through active surveillance, in which public health officials contact providers and/or laboratories regularly to identify cases of reportable disease. This type of surveillance system yields more complete data, and validates the representativeness of the data for vaccine preventable diseases and other notifiable conditions. Active systems require more resources and therefore are generally used for brief periods or discrete purposes (e.g., CDC projects such as the Emerging Infections Program, disease elimination projects, etc.)

Procedure for Reporting

Each and every case of vaccine-preventable disease (confirmed or suspect) must be investigated promptly and thoroughly. All positive and “suspect” cases of vaccine-preventable disease should be reported immediately to the Acute Disease Epidemiology Section, Department of Public Health. District Epidemiologists and Communicable Disease Coordinators will have primary responsibility for VPD case investigations in partnership with the VPD Epidemiologists at DPH. The District Immunization Coordinators and Immunization Field staff will initiate case follow up if the epidemiologist is unavailable. Detailed instructions for case investigation and reporting for each vaccine preventable disease are included in the Disease Fact Sheets in this section. Also included in this section are copies of the Notifiable Disease Reporting Poster, the Notifiable Disease Report Form (#3095), disease worksheets, and lab submission forms, all of which are referenced in the Disease Fact Sheets.

Enclosed is a line listing for the contact persons for VPD surveillance and case investigation at the District Health offices, Immunization Program and the Acute Disease Epidemiology Section (ADES). For questions regarding a specific vaccine preventable disease, please contact the ADES epidemiologist listed for the specific disease. If that person is unavailable, please speak with any ADES epidemiologist for assistance. The Acute Disease Epidemiology Section’s main phone number is (404) 657-2588. Please remember that contact names and numbers may change frequently, therefore call the ADES main number if you are having difficulty reaching a specific individual, or if you have any questions regarding the investigation or reporting of a vaccine preventable disease or any other reportable disease.

Contact Persons For VPD Surveillance at The District Health Office

******Personnel may change frequently. In the event that a specific person listed below, at either the State or District level cannot be reached, please call the main Epidemiology number, (404) 657-2588.**

DISTRICT HEALTH UNIT CONTACT PERSON:								
1-1	Epi. Melissa Atkins Imm. Janet Eberhart Imm. ♦ Tasia Sheppard	(706) 295-6658 (706) 802-5623 (404) 657-3158	**3-5**	Epi. Jessica Grippo Imm. Mia Young Imm. ♦ Jotonna Tulloch	(404) 508-7851 (404) 371-0524 (404) 657-3158	**8-2**	Epi. Jackie Jenkins Imm. Denise Reaves Imm. ♦ Kelly Seegmueller	(229) 430-1858 (229) 430-1738 (404) 657-3158
1-2	Epi. Nancy Loyed Imm. Marie Smith Imm. ♦ Rick Naus	(706) 272-2342 (706) 272-2125 (706) 657-3158	**4-0**	Epi. Amessia Chapman Imm. Amy Fenn Imm. ♦ Tina Dempsey	(706) 845-4294 (706) 298-7712 (770) 657-3158	**9-1**	Epi. Robert Thornton Imm. Elizabeth Hausauer Imm. ♦ Georgia Dittmar	(912) 644-5232 (912) 644-5204 (404) 657-3158
2-0	Epi. Sandy Moore Imm. Connee Martin Imm. ♦ Jan Slaughter	(770) 778-7156 (770) 535-5864 (404) 657-3158	**5-1**	Epi. Jodi Bazemore Imm. Kelly Knight Imm. ♦ DeAnna Brown	(478) 275-6545 (478) 275-6545 (404) 657-3158	**9-2**	Epi. Trevor Thomas Imm. Kay Davis Imm. ♦ Lorie Banks	(912) 285-6022 (912) 557-7172 (912) 657-3158
3-1	Epi. Joy Wells Epi. Rachel Franklin Epi. Elizabeth Bronson Imm. Karen Thomas Imm. ♦ Vacant	(770) 514-2747 (678) 354-5489 (770) 514-2384 (770) 514-2349 (404) 657-3158	**5-2**	Epi. Amber Erikson Epi. Ronnie Boone Imm. Judy McChargue Imm. ♦ Kelly Duke	(478) 751-6034 (478) 751-4151 (478) 751-4175 (404) 657-3158	**10-0**	Epi. Robert Hamilton Epi. Lou Kudon Imm Lindsey Kidd Imm. ♦ Angie Webster	(706) 583-2761 (706) 583-2798 (706) 389-6921 (404) 657-3158
3-2	Epi. Shamim Khan Epi. Priti Kohle Imm. Georgia Goseer Imm. ♦ Janet Kelly ♦ Valerie Pritchett	(404) 730-1336 (404) 730-1330 (404) 612-1677 (404) 657-3158 (404) 657-3158	**6-0**	Epi. Joy Miller Imm. Susan Edmonds Imm. ♦ Natasha Poleate	(706) 667-4263 (706) 667-4286 (404) 657-3158			
3-3	Epi. Olatanwa Adewale Imm. Chishaunna Calhoun Imm. ♦ Vacant	(678) 610-7193 (678) 610-7369 (404) 657-3158	**7-0**	Epi. Eileen Usman Imm. Dianne Robinson Imm. ♦ Libby Massiah	(706) 321-6238 (706) 321-6137 (404) 657-3158			
3-4	Epi. Alana Sulka Epi. Farrah Machida Imm. Gloria Melvin Imm. ♦ Vacant	(678) 442-6918 (678) 442-6886 (770) 227-1235 (404) 657-3158	**8-1**	Epi. January Smith Imm. Deborah Adams Imm. ♦ Jenny Howell	(229) 249-2796 (229) 245-6433 (404) 657-3158			

♦ IPC – Immunization Program Consultant

Contact Persons For VPD Surveillance at The State Health Department

******Personnel may change frequently. If an epidemiologist listed below cannot be reached, please call the main Epidemiology number, (404) 657-2588.**

DISEASE	Epidemiology Contact	Phone
Diphtheria	Ebony Thomas/ Jessica Tuttle	(404) 657-2588

DISEASE	Epidemiology Contact	Phone
Haemophilus Influenzae	Ashley Moore/ Matt Crist	(404) 657-2588

DISEASE	Epidemiology Contact	Phone
Hepatitis A	Lynne Mercedes/ Ami Gandhi	(404) 657-2588

DISEASE	Epidemiology Contact	Phone
Hepatitis B	Lynne Mercedes/ Ami Gandhi	(404) 657-2588

DISEASE	Epidemiology Contact	Phone
Influenza	Delmar Little	(404) 657-2588

DISEASE	Epidemiology Contact	Phone
Measles	Ebony Thomas/ Jessica Tuttle	(404) 657-2588

DISEASE	Epidemiology Contact	Phone
Meningococcal Meningitis	Ashley Moore/ Matt Crist	(404) 657-2588

DISEASE	Epidemiology Contact	Phone
Mumps	Ebony Thomas/ Jessica Tuttle	(404) 657-2588

Contact Persons For VPD Surveillance at The State Health Department

******Personnel may change frequently. If an epidemiologist listed below cannot be reached, please call the main Epidemiology number, (404) 657-2588.**

DISEASE	Epidemiology Contact	Phone
Pertussis	Ebony Thomas/ Jessica Tuttle	(404) 657-2588

DISEASE	Epidemiology Contact	Phone
Pneumococcal Disease	Ashley Moore/ Matt Crist	(404) 657-2588

DISEASE	Epidemiology Contact	Phone
Poliomyelitis	Ebony Thomas/ Jessica Tuttle	(404) 657-2588

DISEASE	Epidemiology Contact	Phone
Rubella	Ebony Thomas/ Jessica Tuttle	(404) 657-2588

DISEASE	Epidemiology Contact	Phone
Congenital Rubella Syndrome	Ebony Thomas/ Jessica Tuttle	(404) 657-2588

DISEASE	Epidemiology Contact	Phone
Tetanus	Ebony Thomas/ Jessica Tuttle	(404) 657-2588

DISEASE	Epidemiology Contact	Phone
Varicella	Ebony Thomas/ Jessica Tuttle	(404) 657-2588

DIPHTHERIA FACT SHEET

Agent: The bacterium, *Corynebacterium diphtheriae*.

Brief Description: In the United States, diphtheria is an uncommon infection of the upper respiratory tract. Initial symptoms of illness include a sore throat and low-grade fever. Nasopharyngitis due to diphtheria commonly presents with patches of adherent, grayish membrane with a surrounding dull red inflammatory zone on the tonsils, soft palate, uvula, and/or back of the pharynx. In severe disease, obstruction of the respiratory tract develops due to extensive membrane formation and there may be marked tenderness and swelling of the neck (Bull Neck). Late effects of diphtheria may include myocarditis and motor and sensory nerve palsy. Most clinical characteristics are caused by the release of a cytotoxin by the bacteria. Asymptomatic nasopharyngeal infection (carriage) occurs in the general population despite vaccination. In the United States, severe diphtheria infection has been documented to occur more frequently in American Indian and homeless populations.

Reservoir: Humans.

Mode of Transmission: Transmission is most often person-to-person via respiratory tract droplets from an infected patient or carrier. Rarely, transmission may occur from skin lesions or articles soiled with discharges from lesions of infected persons.

Incubation Period: Usually 2 to 5 days (range, 1 – 10 days).

Period of Communicability: Variable, until virulent bacilli have cleared from discharges and lesions; shedding is usually 2 weeks or less, and seldom more than 4 weeks. Effective antibiotic therapy promptly terminates shedding within 4 days. Chronic carriers are rare but may shed organisms for 6 months or more.

Clinical Case Definition: An upper-respiratory tract illness characterized by sore throat, low-grade fever, and an adherent membrane of the tonsil(s), pharynx, and/or nose.

Lab Criteria for Diagnosis:

- Isolation of toxin producing *Corynebacterium diphtheriae* from a nasopharyngeal specimen (preferably a culture of membrane tissue or a swab of tissue underlying the membrane), or
- PCR positive for *Corynebacterium diphtheriae* toxin by the CDC Diphtheria Laboratory.

Diagnostic Testing:

A. **Culture (THE LABORATORY MUST BE INFORMED THAT YOU SUSPECT DIPHTHERIA. A SPECIAL MEDIUM IS REQUIRED FOR ISOLATION OF THIS ORGANISM.)**
   1. Specimen: Throat or nasopharyngeal swab.
   2. Outfits: Culture referral outfit, order #505, and Loeffler's slant outfit, order #560.
   3. Lab Form: Culture referral form #3410 and Loeffler's slant form #3415.
   4. Lab Test Performed: Isolation and identification of organism, toxigenicity testing.
   5. Lab: State Bacteriology Laboratory (A REFERENCE LABORATORY IS NEEDED).
   6. Transport requirements: If the duration of transport is < 24hrs, use Amies medium; if duration ≥ 24 hrs, use silica gel sachets. Isolates will be subcultured

DIPHTHERIA FACT SHEET

7. on Loeffler, Pai egg, or cystine blood agar slants. Toxigenicity testing will be performed at CDC. Send suspected isolates in culture referral outfit (#0505).

B. Polymerase Chain Reaction (PCR)

1. Specimen: Throat or nasopharyngeal swab.
2. Outfits: Culture referral outfit, order #505, and Loeffler's slant outfit, order #560.
3. Lab Form: Culture referral form #3410 and Loeffler's slant form #3415.
4. Lab Test Performed: PCR.
5. Lab: CDC Diphtheria Lab – alert lab when Diphtheria is suspected, so that a specific PCR assay can be used.
6. Transport requirements: silica gel sachet, or a sterile dry container at 4 degrees Celsius.

Comment: *C. diphtheria* from non-respiratory sources (e.g. cutaneous, vaginal, otic) should not be reported. All toxin-producing *C. diphtheria* respiratory isolates, regardless of association with disease, should be sent to the Diphtheria Laboratory, National Center for Immunization and Respiratory Diseases, CDC.

Case Classification:

- **Probable:** A clinically compatible case that is not laboratory confirmed and is not epidemiologically linked to a laboratory-confirmed case.
- **Confirmed**: A clinically compatible case that is laboratory confirmed and epidemiologically linked to a laboratory-confirmed case.
- **Carrier:** An asymptomatic person with laboratory confirmed *C. diphtheria* isolated from the nasopharynx.

Vaccination: Primary diphtheria immunization with diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) is recommended for all persons at least 6 weeks old but < 7 years of age and without a history of contraindications. DTaP is the preferred vaccine for all doses in the vaccination series (including completion of the series in children who have received one or more doses of whole-cell DTP). The primary vaccination with DTaP series consists of a three-dose series, administered at ages 2, 4, and 6 months, with a minimum interval of 4 weeks between the first three doses. The fourth dose (first booster) is recommended at 15-18 months of age to maintain adequate immunity during preschool years. The fifth dose (second booster) is recommended for children aged 4-6 years to confer continued protection against disease during the early years of schooling. Routine tetanus booster immunization with Tdap, the adult formulation of tetanus, diphtheria toxoids, and acellular pertussis is recommended for all persons ≥ 10 years of age.

Treatment: Diphtheria antitoxin (of equine origin) should be given when diphtheria is suspected, **without waiting for laboratory confirmation**. Detailed recommendations can be obtained from the Georgia Department of Public Health and CDC. Antitoxin is only available for treatment of clinical cases through CDC. The responsible health-care provider should contact the State Epidemiology Section at (404) 657-2588, or if after hours the State Epidemiologist on call at 1-800 PUB-HLTH, to request antitoxin, obtain authorization for its release and make arrangements for transport.

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Antimicrobial therapy is also required to eradicate the organism and prevent spread, but **it is not a substitute for antitoxin** in clinical cases of diphtheria**.** Either erythromycin or penicillin is recommended to be administered for a 14-day treatment course.

Post-Exposure Prophylaxis: A single dose of benzathine penicillin or a 7-10 day course of erythromycin is recommended for all persons with household exposure to diphtheria, regardless of their immunization status.

Investigation: Guidelines for investigating a suspected case and for managing contacts are published and are referenced below.[2] Management of close contacts of suspected cases should include screening for possible respiratory or cutaneous diphtheria, obtaining nasopharyngeal cultures for *C. diphtheriae*, administering prophylactic antibiotics, treatment and follow-up of carriers, assessing diphtheria vaccination status, and administering any necessary vaccinations. The CDC Diphtheria Worksheet may be used for guidelines in conducting a case investigation.

Reporting: Report all suspect, probable, and confirmed cases **IMMEDIATELY** by phone to the local health department, District Health Office, or the State Epidemiology Section at 404-657-2588. If calling after regular business hours, it is very important to report cases to the Epidemiology Section answering service by calling 1-866-PUB-HLTH. After a verbal report has been made, please transmit the case information electronically through the State Electronic Notifiable Disease Surveillance System (SENDSS) at http://sendss.state.ga.us, or complete and mail a CDC Diptheria Worksheet.

Reported Cases of Diphtheria in Georgia, 2001-2011

Year	Number of Cases
2001	0
2002	0
2003	0
2004	0
2005	0
2006	0
2007	0
2008	0
2009	0
2010	0
2011	0

References:

1. American Academy of Pediatrics. Diphtheria. In: Pickering, LK, Baker CJ, Kimberlin DW, Long SS, eds. 2012 Red Book: Report of the Committee on Infectious Diseases. Elk Grove Village, IL: American Academy of Pediatrics; 2012: 307-311.
2. Centers for Disease Control and Prevention. Diphtheria. Manual for the surveillance of vaccine-preventable diseases. Centers for Disease Control and Prevention, Atlanta, GA, 2012.

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3. Heymann, ed. Diphtheria. In: Control of Communicable Diseases Manual. 18th Ed. Washington, DC: American Public Health Association, 2004: pp. 171-176.
4. Farizo KM, Strebel PM, Chen RT, et al. Fatal respiratory disease due to Corynebacterium diphtheriae: Case report and review of guidelines for management, investigation, and control. Clin Infect Dis 1993; 16:59-68.

Links:

- CDC Diphtheria Fact Sheet – http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/dip.pdf
- CDC National Center for Immunization and Respiratory Diseases – http://www.cdc.gov/vaccines/

HEPATITIS A FACT SHEET

Agent: Hepatitis A virus (HAV)

Brief Description: An acute infectious disease with fever, fatigue, malaise, loss of appetite, nausea, abdominal pain, dark urine and yellowing of the skin and eyeballs. The disease varies widely in severity ranging from asymptomatic to a mild illness without jaundice lasting one to two weeks in children, to severe debilitating illness and lasting several weeks with prolonged convalescence in adults. Fortunately, recovery is generally complete and without complication.

Reservoir: Humans; rarely chimpanzees and other nonhuman primates.

Mode of Transmission: The primary mode of transmission is by the fecal-oral route. This includes ingestion of fecally contaminated water or ice; raw or undercooked shellfish; fruits, vegetables, and other foods eaten uncooked that may have become contaminated during handling. Contact with stool from infected infants and toddlers during diaper changes that is not immediately followed by thorough hand washing is a common means of spread to day care and household contacts. Waterborne transmission of hepatitis A is more common in places with inadequate sewage disposal and water treatment, such as can be found in developing nations. Sexual contact can spread the virus. In rare cases bloodborne transmission occurs.

Incubation Period: Average 28-30 days; Range 15-50 days.

Clinical Case Definition: An acute illness with

- Discrete onset of symptoms, **and**
- Jaundice, dark urine or elevated serum aminotransferase levels (ALT >200 IU/L)

Laboratory criteria for diagnosis:
Immunoglobulin M (IgM) antibody to hepatitis A virus (anti-HAV) positive. Note that a person may remain IgM positive for six months or longer after infection, which makes it difficult to determine the timing of infection in a person who has been asymptomatic.

Diagnostic Testing:
Serology

1. Specimen: Serum/blood, >6 ml
2. Outfits: Outfit 0500
3. Lab Form: Form 3432
4. Lab Tests Performed: Anti-HAV (total) and Anti-HAV IgM
5. Lab: State Immunology Laboratory (GPHL)
6. Transport requirements: All specimens should be transported as soon as possible. Refrigerate if specimen must be held overnight. Specimens >14 days old or hemolyzed will be rejected.

Case Classification:

Confirmed: A case that meets the clinical case definition and is laboratory confirmed
-or-
a case that meets the clinical case definition and occurs in a person who has an epidemiologic link with a person who has laboratory-confirmed hepatitis A (i.e., household or sexual contact with an infected person during the 15-50 days before the onset of symptoms).

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Period of Communicability: Hepatitis A virus is highly infective, requiring only a few virus particles to cause infection. The virus is present in the highest quantity in stool during the latter half of the incubation period (7-14 days prior to onset of illness). Most cases are not infectious after the first week of jaundice.

Vaccine: Three inactivated vaccines are currently available to protect against infection with hepatitis A virus (HAV). Protection begins two to four weeks after the first dose of hepatitis A vaccine. A second dose is considered necessary for long-term protection. Two vaccines, HAVRIX and VAQTA, are currently licensed for persons 12 months of age and older and are available in two formulations based on the recipient's age. The third vaccine, TWINRIX, is a hepatitis A and hepatitis B combination vaccine licensed for persons 18 years of age or older. Pre-exposure hepatitis A vaccine is recommended for all children at 12 months of age, persons traveling to or working in countries that have high or intermediate rates of hepatitis A, persons with chronic liver disease or clotting factor disorders, men who have sex with men, injecting drug users, persons who work with HAV infected primates or with HAV in laboratory settings, and any person who wishes to be immune to hepatitis A. Post-exposure vaccine use is listed below. For more detailed vaccination information, see Hepatitis A Vaccine Guidelines in Chapter 2 of this manual.

Treatment: No specific therapy for HAV infection is available, other than supportive care. Hepatitis A is usually self-limiting.

Post-exposure Prophylaxis of Contacts: Depending on age of contact, immune globulin (IG) or hepatitis A vaccine should be offered after exposure to hepatitis A if it can be given within 14 days of last exposure to the case as indicated below:

- Persons who live in the same household, or who are intimate and/or sex partners of a diagnosed case
- Day care center associated cases as follows:
  - Children who attend the same room as a diagnosed case
  - Workers who change diapers in a day care center with a diagnosed case
- Inmates in the same cell in a detention center
- Foodhandlers who work with the acute case

When a food worker has acute infection, consideration may be given to prophylaxis of patrons if prophylaxis can be given within 14 days of last exposure and the case worked while having diarrhea and/or having questionable hygienic practices, combined with having contact with ready-to-eat foods. **Consult the Epidemiology Section at (404) 657-2588 promptly in these instances.** For contacts younger than 12 months of age, older than 40 years of age, those who are immunocompromised, and persons with chronic liver disease, give IG as a single dose of 0.02 ml per kilogram of body weight within 14 days after exposure to hepatitis A. Immune globulin is **NOT** recommended for hepatitis A exposure for business, office or school contacts, or household visitors (e.g., neighbors and relatives) who do not meet the above criteria. When IG is not readily available, hepatitis A vaccine can be given to contacts older than 40 years of age.

HEPATITIS A FACT SHEET

Investigation: Complete the hepatitis case report in SENDSS (State Electronic Notifiable Disease Surveillance System) at https://sendss.state.ga.us to aid in the investigation. Conduct an assessment of the patient for high-risk activities (food handler, day care attendee/provider, health care provider) and hygienic practices such as hand washing. Determine whether the case worked while experiencing diarrhea. Assess the need for immune globulin (IG) or vaccine as indicated above for contacts of the case patient, and educate case contacts regarding the risk of hepatitis A virus transmission. Investigate the source of the infection. Attention should be paid to sanitation and potential fecal contamination via food or water. Advise hepatitis A vaccine for international travelers, men who have sex with men, persons with chronic liver disease, and others who will be at increased risk of exposure to hepatitis A in the future. **Special evaluation is indicated for outbreaks in institutional settings and hepatitis in food handlers. Consult the Epidemiology Section at (404) 657-2588 promptly in these instances.**

Reporting: Report acute, laboratory-confirmed cases **IMMEDIATELY** by phone to the local health department, District Health Office, or the Epidemiology Section at 404-657-2588. If calling after regular business hours, reports can be made to 1-866-PUB-HLTH (782-4584). After a verbal report has been made, please transmit the case information electronically through the State Electronic Notifiable Disease Surveillance System (SENDSS) at https://sendss.state.ga.us. Please complete all data fields in SENDSS, including the case report form.

Reported Cases of Acute Hepatitis A in Georgia, 2001-2011

Year	Number of Cases
2001	927*
2002	509
2003	776*
2004	318
2005	216
2006	56
2007	67
2008	61
2009	54
2010	38
2011	27

***Note:** Large outbreaks were documented in 2001 and 2003.

References:

1. Centers for Disease Control and Prevention. Prevention of Hepatitis A Through Active or Passive Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2006; 55(RR7): 1-23.
2. Heymann, ed. Hepatitis, Viral. In: Control of Communicable Diseases Manual. 18th ed. Washington, DC: American Public Health Association, 2004: 247-253.
3. Centers for Disease Control and Prevention. Case Definitions for Infectious Conditions Under Public Health Surveillance. *MMWR* Vol. 46(RR10): 1-55.
4. Centers for Disease Control and Prevention. Update: Prevention of Hepatitis A After Exposure to Hepatitis A Virus and in International Travelers. Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2007; 56(41): 1080-1084.

HEPATITIS A FACT SHEET

5. Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book) 12th Edition. Revised May 2012; 101-114.

Links:

- CDC Hepatitis A Fact Sheet – http://www.cdc.gov/hepatitis

HEPATITIS A Q&A

What is hepatitis A?
Hepatitis A is a liver disease caused by a specific virus. The hepatitis A virus (HAV) is one of several viruses known to cause hepatitis (liver inflammation) in humans. Prior to 2006, several hundred cases were reported in Georgia each year.

Who gets hepatitis A?
Anyone who has not previously been infected with or vaccinated against hepatitis A can become infected. Certain persons at increased risk of exposure to hepatitis A include:

- Children and employees of child care centers where a child or employee has hepatitis A
- Persons who share a household or have sexual contact with someone with hepatitis A
- Travelers to developing countries where hepatitis A is common and where clean water and proper sewage disposal are not readily available; and
- Residents and staff of institutions for disabled children where a resident or an employee has hepatitis A.

How is the hepatitis A virus spread?
The hepatitis A virus enters through the mouth, multiplies in the body and is passed in the feces. The virus is fairly hardy and can be carried on an infected person's hands and can be spread by direct contact, or by consuming food or drink that has been handled by the individual. In some cases, consuming untreated or inadequately treated water contaminated with improperly treated sewage can spread it. Eating raw or undercooked shellfish (e.g., mussels, oysters, and clams) is another way one can become infected.

What are the symptoms of hepatitis A?
In outbreak settings, three of every four persons infected with hepatitis A virus have symptoms. When the symptoms are present, they usually develop suddenly and may include fatigue, poor appetite, fever and vomiting. Urine may become darker in color, and then jaundice (a yellowing of the skin and whites of the eyes) may appear. The disease is rarely fatal and most people recover in a few weeks without any complications. Infants and young children tend to be asymptomatic or have very mild symptoms and are less likely to develop jaundice than are older children and adults. Not everyone who is infected will have all of the symptoms, but adults are more likely to have symptoms.

How soon do symptoms appear?
The symptoms usually begin to appear three to four weeks after exposure, but the onset of symptoms may range two to seven weeks after exposure.

When and for how long is an infected person able to spread the virus?
The contagious period begins about a week before the symptoms appear and may extend up to a week after jaundice (a yellow color of the skin and whites of the eyes) begins.

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Does past infection with hepatitis A make a person immune?
Yes. Once an individual recovers from hepatitis A, he or she is immune for life and does not continue to carry the virus. Additionally, vaccination against hepatitis A is thought to provide lifelong protection against infection.

What is the treatment for hepatitis A?
There are no special medicines to treat a person once the symptoms appear. Generally, bed rest is all that is needed. Occasionally an ill person with severe vomiting and/or diarrhea is hospitalized for rehydration.

How can hepatitis A be prevented?
An important way to prevent spread of hepatitis A is careful handwashing after using the toilet. Infected people should not handle foods served to others during the contagious period. Household members or others who have not been immunized, but are in close contact with an infected person, should promptly call a doctor or the health department to determine whether a shot of immune globulin or hepatitis A vaccine can decrease their chances of becoming ill. The FDA has approved two vaccines that very effectively protect against infection with hepatitis A virus. Persons in higher risk groups (e.g. travelers to developing countries) may wish to consider being vaccinated. All children should be vaccinated at 12 months of age. Please contact the Georgia Immunization Program at (404) 657-3158 for current vaccine recommendations.

Where can I get additional information on hepatitis A?
Contact the Georgia Department of Public Health, Epidemiology Section, by email at gaepinfo@dhr.state.ga.us. The following web sites may be useful:

- GDPH hepatitis web page – http://health.state.ga.us/epi/disease/hepatitis/index.asp
- CDC hepatitis web page – http://www.cdc.gov/hepatitis

HEPATITIS B FACT SHEET

Agent: Hepatitis B Virus (HBV)

Brief Description: Exposure to HBV may result in transient or chronic infections, either of which can be asymptomatic. Hepatitis B can present as an acute infectious disease with fever, malaise, loss of appetite, vague abdominal discomfort, nausea and vomiting, sometimes arthralgias and rash, often progressing to jaundice. Liver enzyme levels are markedly elevated. Fever may be absent or mild. Severity ranges from inapparent cases detectable only by liver function tests, to fatal cases of acute hepatic necrosis.

The likelihood of becoming a chronic carrier is affected by age at infection. Fewer than 5% of acutely infected adults in the U.S. become chronic carriers, compared with some 25% (with HBeAg-negative mothers) to 90% (HBeAg-positive mothers) of perinatally infected infants. Chronically infected persons are at increased risk for developing cirrhosis and/or primary hepatocellular carcinoma, leading to end-stage liver disease later in life.

Reservoir: Humans

Mode of Transmission: HBV is usually transmitted by contact with the blood, semen, or vaginal secretions of an infected person. HBV may also be found in saliva and other body fluids. The virus must be introduced through broken skin or come into contact with mucous membranes for infection to occur. In addition, percutaneous transmission of HBV can occur through blood or blood product transfusion, needle sharing, hemodialysis, acupuncture, tattooing, and needlesticks. Indirect inoculation of HBV can also occur via inanimate objects, as the virus can remain viable outside the body for at least 7 days.

Incubation Period: Varies from 45-180 days – usually between 60 and 90 days.

Clinical Case Definition: An acute illness with:

- Discrete onset of symptoms, **and**
- Jaundice or elevated serum aminotransferase levels (ALT >200 IU/L).

Lab Criteria for Diagnosis:

1. IgM antibody to hepatitis B core antigen (anti-HBc) positive and/or hepatitis B surface antigen (HBsAg) positive **and**
2. IgM anti-HAV negative (if done)

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Interpretation of the Hepatitis B Serology Panel

Tests	Results	Interpretation
HBsAg Anti-HBc (IgG + IgM) Anti-HBs	negative negative negative	Susceptible to hepatitis B infection
HBsAg Anti-HBc (IgG + IgM) Anti-HBs	negative negative or positive positive	Immune to hepatitis B infection
HBsAg Anti-HBc (IgG) Anti-HBc (IgM) Anti-HBs	positive positive positive negative	Acutely infected with hepatitis B
HBsAg Anti-HBc (IgG) Anti-HBc (IgM) Anti-HBs	positive positive negative negative	Chronically infected with hepatitis B
HBsAg Anti-HBc (IgG + IgM) Anti-HBs	negative positive negative	Four interpretations possible*

* Interpretations possible for isolated positive Anti-HBc (IgG + IgM)

1. May be recovering from acute HBV infection (in the “core window phase” before anti-HBs appears);
2. May be distantly immune, and the test is not sensitive enough to detect very low levels of anti-HBs in serum;
3. May have a false positive anti-HBc; or
4. May be chronically infected with HBV and have an undetectable level of HBsAg in the serum.

HBeAg is tested in the presence of HBsAg and, if present, is a marker of intense virus production.

Diagnostic Testing:

1. Specimen: Serum/blood, >6 ml.
2. Outfits: Outfit 0500
3. Lab Form: Form 3432
4. Lab Tests Performed: HBsAg, anti-HBs, and total anti-HBc (IgG). Georgia Public Health Lab (GPHL) in Decatur does not currently offer anti-HBc IgM, but this is available through commercial laboratories.
5. Lab: GPHL Immunology Laboratory, hospital laboratories, and private clinic laboratories.
6. Transport requirements: All specimens should be transported as soon as possible. Refrigerate if specimen must be held overnight. Specimens >14 days old or hemolyzed will be rejected.

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Case Classification

- **Confirmed:** A case that meets the clinical case definition, is laboratory confirmed, and is not known to have chronic hepatitis B. Persons who have chronic hepatitis or persons identified as HBsAg positive should not be reported as having acute viral hepatitis unless they have evidence of an acute illness compatible with viral hepatitis or documented seroconversion.

Comment: Also reportable (in addition to acute hepatitis B): (1) all newly identified HBsAg-positive carriers, (2) all HBsAg-positive pregnant women.

Period of Communicability: All persons who are HBsAg positive are potentially infectious. Blood can be infective many weeks before the first onset of symptoms and remain infective through the acute clinical course of the disease. For chronically infected people, the infectivity varies from highly infectious (HBeAg positive) to potentially infectious (anti-HBe positive).

Vaccination: Vaccination is recommended for all infants as part of the routine childhood immunization schedule. Three doses comprise the series:

Dose one: at birth
Dose two: between 1 month and 4 months (but at least 1 month after 1st dose)
Dose three: between 6 months and 18 months (but at least 4 months after 1st dose, and 2 months after 2nd dose, but no earlier than 24 weeks of age). For more detailed vaccination information, see Hepatitis B Vaccine Guidelines in Chapter 2 of this manual.

All children should be vaccinated by 11-12 years of age. Risk of hepatitis B infection increases in the adolescent years, so catch-up vaccination is recommended for children, adolescents and young adults, especially in certain sub-populations, such as Alaska Natives, Asian and Pacific Islanders, and immigrants from countries with high HBV endemicity. In addition, the following categories of high-risk adults should be immunized:

1. Heterosexuals with >1 sex partner in the last 6 months, or who have a sexually transmitted disease
2. Men who have sex with men (MSM)
3. Household contacts and sex partners of HBsAg-positive people
4. Injection drug users (IDU)
5. Healthcare personnel, and others with occupational risk of infection through exposure to blood (including but not limited to public safety workers, trainees in medicine, dentistry, nursing, and laboratory technology)
6. Residents and staff of facilities for developmentally disabled persons.
7. Staff of non-residential child care and school programs attending to HBsAg-positive developmentally disabled children.
8. Hemodialysis patients
9. Patients with bleeding disorders.
10. Household members of adoptees who are HBsAg positive
11. International travelers to areas with high or intermediate rates of HBV infection
12. Inmates of juvenile detention centers or long-term correctional facilities
13. Persons with HIV infection

Note: See Chapter 2 of this Manual for list of persons eligible for state-supplied vaccine in Public Health clinics.

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Although recommended in infancy, the vaccine series can be given at any time. A lapse in immunization does not require restarting the series. Studies have demonstrated vaccine efficacy with one-year intervals between doses. Vaccine is most effective if given intramuscularly. Thus the deltoid (arm) is recommended in persons >18 months old, and antero-lateral thigh for infants and children 18 months or younger.

Treatment: No specific therapy for acute HBV infection is available, other than supportive care. Several drugs are now licensed for treatment of chronic hepatitis B in the USA.

Post-exposure Prophylaxis: Passive immunization with hepatitis B immune globulin (HBIG) and active immunization with hepatitis B vaccine are both used to prevent infection. To be effective, HBIG must be given as soon as possible after exposure (within 7 days after blood exposure and 14 days after sexual exposure). HBIG is available commercially and may be provided by the Georgia Immunization Program under certain specific conditions. (See Chapter 2 for table entitled, "Eligibility Criteria for Vaccines Supplied by the GA Immunization Program for Children, Adolescents, and Adults.")

Post-exposure prophylaxis should be considered in the following situations:

1. Perinatal exposure to HBsAg-positive mother
2. Percutaneous or permucosal exposure to blood
3. Sexual exposure to a HBsAg-positive individual
4. Known exposure to an acute hepatitis B case

Investigation: Collect information about possible exposures, including high-risk behavior during the period 45-180 days before the onset of illness. Particular emphasis should be placed on 60-90 days before symptom onset. Investigators should identify contacts that could benefit from hepatitis B vaccination or HBIG. Special attention should be paid to the presence of hepatitis B among women of childbearing age, since post-exposure prophylaxis with hepatitis B vaccine and HBIG soon after birth is 90-95% effective in preventing infection in the infant with attendant likelihood of chronic disease (see Perinatal Hepatitis B Prevention Guidelines section for complete details).

Follow-up: All new cases of hepatitis B should be re-tested for HBsAg after six months to determine whether infection has cleared or a chronic infection is present. Those persons still HBsAg-positive are considered confirmed chronic carriers, and should be counseled accordingly and referred for maintenance care. Refer to the Perinatal Hepatitis B Prevention Guidelines for detailed follow-up recommendations of HBsAg-positive women, their infants, and sexual and household contacts.

Reporting:

- Report all cases of acute hepatitis B, newly identified HBsAg-positive carriers, and HBsAg-positive pregnant women **WITHIN SEVEN DAYS** electronically through the State Electronic Notifiable Disease Surveillance System (SENDSS) at https://sendss.state.ga.us. Complete all data fields in SENDSS, including the case report form.
- For all cases of acute hepatitis B, complete the hepatitis case report in SENDSS (State Electronic Notifiable Disease Surveillance System) at https://sendss.state.ga.us to aid in the investigation. Chronic hepatitis B infections are also reportable in SENDSS.
- Report all HBsAg-positive prenatal tests and all HBsAg-positive children less than 24 months of age to the state Perinatal Hepatitis B Prevention Program via SENDSS.

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Reported Cases of Acute Hepatitis B in Georgia, 2001-2007

Year	Number of Cases
2001	389
2002	442
2003	512
2004	444
2005	203
2006	198
2007	157
2008	187
2009	142
2010	156
2011	142

References:

1. Pickering L, et al, eds. Hepatitis B. In: 2012 Red Book: Report of the Committee on Infectious Diseases. 29th Ed. Elk Grove Village, IL: American Academy of Pediatrics; 2012: pp. 369-390.
2. Heymann D, ed. Viral Hepatitis B. In: Control of Communicable Diseases Manual. 18th ed. Washington, DC: American Public Health Association, 2004: pp. 253-261.
3. Centers for Disease Control and Prevention. Case Definitions for Infectious Conditions Under Public Health Surveillance. *MMWR* 1997; 46(RR10): 1-55.
4. CDC. Hepatitis B. National Center for Infectious Diseases, Division of Viral and Rickettsial Diseases. 01/01/1996.
5. CDC. Recommendations of the Immunization Practices Advisory Committee. Prevention of Perinatal Transmission of Hepatitis B Virus: Prenatal Screening of all Pregnant Women for Hepatitis B Surface Antigen. *MMWR* 1988; 37(22): 341-6,351.
6. CDC. Notice to Readers: Availability of Hepatitis B Vaccine That Does Not Contain Thimerosal as a Preservative. *MMWR* 1999; 48(35): 780-782.
7. CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP);
   Part 1: Immunization of Infants, Children, and Adolescents. MMWR 2005;54 (No.RR-16)
   Part 2. Immunization of Adults. MMWR 2006:55(No.RR-16)
8. Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book) 12th Edition. Revised May 2012; 115-138.

Links:

- Georgia Immunization Program – http://health.state.ga.us/programs/immunization/index.asp
- CDC National Immunization Program – http://www.cdc.gov/vaccines/vac-gen/safety/default.htm
- CDC Hepatitis Branch – http://www.cdc.gov/hepatitis
- GDPH Acute Disease Epidemiology Section, Hepatitis Program – http://health.state.ga.us/epi/disease/hepatitis/index.asp

HEPATITIS B FACT SHEET

HEPATITIS B Q&A

What is hepatitis B?
Hepatitis B is a liver disease caused by a specific virus. The hepatitis B virus (HBV) is one of several viruses known to cause hepatitis (liver inflammation) in humans. HBV is completely unrelated to the viruses that cause hepatitis A, C, or other non-A, non-B, non-C hepatitis. The HBV may cause mild illness or result in no symptoms, but can also cause lifelong infection, cirrhosis of the liver, liver cancer, liver failure, and death.

Who gets hepatitis B?
All people, regardless of age or residence, may be at risk for hepatitis B. Those at greatest risk include:

- Certain health care workers who have contact with infected blood
- Injecting drug users (IDU) who share needles and drug equipment
- Men who have sex with men (MSM), particularly those with multiple partners
- Other persons with multiple sex partners
- Sex partners of people infected with HBV
- Patients or workers in a residence for the developmentally disabled
- Hemodialysis patients
- Certain household contacts of an infected person
- Infants born to mothers who are carriers of HBV
- Children of individuals born in Southeast Asia, Africa, the Amazon Basin in South America, the Pacific Islands, and the Middle East
- Persons who have spent time in correctional facilities.

If you are at risk for HBV infection, ask your health care provider about hepatitis B vaccine.

How is hepatitis B virus spread?
Hepatitis B virus can be found in the blood, semen and, to a lesser extent, saliva and other body fluids of an infected person. It is spread by direct contact with infected body fluids, usually by needlestick injury or sexual contact. The virus can also be transmitted from mother to baby at birth. HBV is not spread by casual contact.

What are the symptoms of hepatitis B?
The symptoms of hepatitis B include fatigue, poor appetite, fever, vomiting, and occasionally joint pain, hives or rash. Urine may become darker in color, and jaundice (yellowing of the skin and whites of the eyes) may appear. Some individuals may experience few or no symptoms.

How soon do symptoms appear?
The symptoms may appear two to six months after exposure, but usually within three months.

When and for how long is a person able to spread the virus?
The virus can be found in blood and other body fluids several weeks before symptoms appear, and it generally persists for several months afterwards. Some people with HBV infection may become long-term carriers of the virus, and may be able to spread the virus over many years.

What is the hepatitis B carrier state?
Some persons infected with HBV never fully recover and carry the virus for the rest of their lives. These persons have chronic infection and are known as carriers. They can infect other household and sexual contacts throughout their lives. Among adolescents and adults who get hepatitis B, 5%-10% develop a lifelong infection. When young children are infected, the risk of

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lifelong infection is much higher (up to 90%). An estimated one million people have lifelong hepatitis B virus infections in the United States today.

Why is hepatitis B a problem for pregnant women and their babies?
Pregnant women may have HBV in their blood without knowing it and can pass it on to their babies at birth, if their infants are not vaccinated at birth. Many of these babies develop lifelong HBV infections and can pass the virus on to others throughout their lives. At first, babies may not look or feel sick, but as they grow up, they may have liver damage. About 25% of babies who develop lifelong HBV infections die prematurely of liver disease or liver cancer.

What is the treatment for hepatitis B?
There are no special medicines that can be used to treat a person once the symptoms appear. Generally, bed rest as needed is recommended for acute hepatitis B infection.

What precautions should hepatitis B carriers take?
Hepatitis B carriers should follow standard hygienic practices to ensure that their blood and other body fluids do not directly contaminate close contacts. Carriers must not share razors, toothbrushes, insulin needles, or any other object that may become contaminated with blood. Susceptible household members, particularly sex partners, should be immunized with hepatitis B vaccine. It is important for carriers to inform their dentists and health care providers. Medications are available to treat persons with chronic hepatitis B, but they don't work for everyone.

How can hepatitis B be prevented?
Preventing hepatitis B is important because of the risk of lifelong infection leading to serious liver problems. A vaccine has been used since 1982 to prevent hepatitis B. The vaccine is given in a series of three shots. Hepatitis B vaccine is safe, effective and is recommended for

- All babies, beginning at birth
- Everyone 18 years of age and younger
- Adults over 18 years of age who are at risk for HBV infection
- Persons whose jobs expose them to human blood.

Where can I get additional information on hepatitis B?
Contact the Georgia Department of Public Health, Epidemiology Section, by email at gaepinfo@dhr.state.ga.us. The following websites may be useful:

- Georgia Immunization Program – http://health.state.ga.us/programs/immunization/index.asp
- CDC National Immunization Program – http://www.cdc.gov/vaccines/vac-gen/safety/default.htm
- CDC Hepatitis Branch – http://www.cdc.gov/hepatitis
- GDPH Acute Disease Epidemiology Section, Hepatitis Program – http://health.state.ga.us/epi/disease/hepatitis/index.asp

For needlestick accidents and blood exposures, medical providers can call the National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) 24 hours a day, 7 days a week at: 1-888-448-4911

Haemophilus Influenzae Invasive Disease Fact Sheet

Agent: *Haemophilus influenzae* is a bacterium often found in the upper respiratory tract of humans. *H. influenzae* is divided into several strains based on the presence of a polysaccharide capsule virulence factor. Encapsulated strains are considered "typable" (types A, B, C, D, E, and F), while non-encapsulated strains are non-typable.

Brief Description: *H. influenzae* causes a variety of illnesses. Typable strains, especially type B ("Hib") and type F, have been commonly associated with invasive disease, including meningitis, epiglottitis, pneumonia, septic arthritis, cellulitis, osteomyelitis, pericarditis, and bacteremia. Historically, type B was a common, devastating pathogen, especially in children; however, since the widespread use in the U.S. of conjugate vaccines against Hib, cases caused by Hib have decreased drastically. Non-typable *H. influenzae* is occasionally associated with otitis media, pneumonia, sinusitis, conjunctivitis, aggravation of chronic obstructive pulmonary disease, neonatal and maternal sepsis, and bacteremia.

Reservoir: Humans.

Mode of Transmission: Spread occurs through airborne droplets or by direct contact with infectious secretions. Between 30% and 80% of people are carriers of non-typable *H. influenzae*, while approximately 2% are carriers of types A, C, D, E, and F and less than 1% carry type B (in a vaccinated population). Illness may occur in carriers when host immunity is compromised for some reason.

Incubation Period: Unknown, possibly 2-4 days.

Laboratory Criteria for Diagnosis: Isolation of *H. influenzae* from a normally sterile site (e.g., blood or cerebrospinal fluid or, less commonly, joint, pleural, or pericardial fluid).

Diagnostic Testing:

1. Specimen: Blood, CSF, or other sterile site for culture; pure specimen for serotyping.
2. Outfits: Sterile vial for isolation and identification; culture referral order #0505 for serotyping.
3. Lab Form: Form 3410.
4. Lab Test Performed: Bacterial isolation and identification; *H. influenzae* serotyping.
5. Lab Performing Test: Isolation and identification is usually performed at hospital or private labs; serotyping is performed at the GPHL Bacteriology Section in Decatur.

Case Classification:

- Probable: a clinically compatible case with detection of *H. influenzae* antigen in CSF or other sterile site.
- Confirmed: a clinically compatible case that is laboratory confirmed by culture.

Period of Communicability: As long as organisms are present, which may be for a prolonged period even without nasal discharge. Cases are considered non-infectious 24-48 hours after starting effective antibiotic therapy.

Haemophilus Influenzae Invasive Disease Fact Sheet

Vaccination: A conjugate vaccine for Hib has been licensed for use in the U.S. since the mid-1980s. Children should get Hib vaccine at 2, 4, 6, and 12-15 months of age (if PRP-OMP vaccine is used, the dose at 6 months is not required). Children over 5 years of age usually do not need Hib vaccine. Older children or adults with sickle cell disease, HIV/AIDS, removal of the spleen, bone marrow transplant, or undergoing chemotherapy should also receive Hib vaccine. For more detailed vaccination information, see Haemophilus Influenzae Vaccine Guidelines in Chapter 2 of this manual.

Treatment: The 2012 Red Book recommends a third-generation cephalosporin such as ceftriaxone or cefotaxime for initial treatment. Meropenem or chloramphenicol plus ampicillin are alternative treatment regimens. The patient should be given rifampin before discharge from the hospital to ensure elimination of the organism if a regimen other than ceftriaxone or cefotaxime was used to treat illness.

Reporting: Report all confirmed cases of invasive H. influenzae IMMEDIATELY electronically though the State Electronic Notifiable Disease Surveillance System (SENDSS) at http://sendss.state.ga.us . All isolates should be immediately forwarded to the Georgia Public Health Laboratory (GPHL) to determine whether or not the case is Hib.

Investigation: Identification of young children who are close contacts of cases and assessment of their vaccination status may help identify persons who should receive antimicrobial prophylaxis and who need to be immunized. In particular, household and day care classroom contacts should be immediately identified.

Prophylaxis and Follow-Up of Contacts [disease caused by type B (Hib) only]:

- Observe contacts under 6 years old (especially infants) for indications of illness and provide prompt medical attention should signs and symptoms appear.
- Rifampin prophylaxis is warranted for all household contacts, including adults, in households with:
    a. One or more infants <12 months of age who has not received the primary series
    b. A child 1-3 years of age who is unimmunized or incompletely immunized
    c. An immunocompromised child.
- When two or more cases of invasive disease have occurred within 60 days at a day care facility or school which un-immunized or under-immunized children attend, administration of rifampin to all attendees and supervisory personnel is controversial. Efforts should be made to ensure that all day care attendees under 5 years of age are fully vaccinated.
- Dosage of rifampin for prophylaxis:
    a. Age <1 month: 10 mg/kg once daily for 4 days;
    b. Age ≥1 month: 20 mg/kg once daily for 4 days, maximum daily dose 600 mg.
    c. For adults, each dose is 600 mg.
    d. Rifampin can be administered to infants and children suspended in simple syrup or as a dry powder mixed with applesauce.

Haemophilus Influenzae Invasive Disease Fact Sheet

Reported Cases of Invasive *Haemophilus influenzae* in Georgia, 2004-2011 (Source: SENDSS)

Year	Number of Cases
2004	116
2005	113
2006	123
2007	128
2008	151
2009	162
2010	169
2011	140

References:

1. American Academy of Pediatrics. Haemophilus influenzae Infections. In: Pickering, L, Baker CJ, Kimberlin DW, Long SS eds. 2009 Red Book: Report of the Committee on Infectious Diseases. 28th Ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009: 314-321..
2. Case definitions for infectious conditions under public health surveillance. *MMWR* Vol 46(RR-10); 1997: 1-55.
3. Epidemiology and Prevention of Vaccine-Preventable Diseases, 12th edition. Centers for Disease Control and Prevention: Atlanta, GA, 2011.
4. Notice to readers: recommended childhood immunization schedule – United States, 2000. *MMWR* Vol 49(02); 2000: 35-38,47.
5. Manual for the Surveillance of Vaccine-Preventable Diseases. Centers for Disease Control and Prevention: Atlanta, GA, 2009.
6. Heymann, ed. Haemophilus Meningitis. In: Control of Communicable Diseases Manual. 18th ed. Washington, DC: American Public Health Association, 2004: 366-368.
7. Mandell, Bennett, and Dolin. The Principles and Practice of Infectious Diseases. 5th Ed., Philadelphia, PA, 2000:pp. 2369-2376.
8. Urwin G, et al. Invasive disease due to *Haemophilus influenzae* serotype f: clinical and epidemiologic characteristics in the *H. influenzae* serotype b vaccine era. Clin Infect Dis 1996; 22:1069-1076.

Links:

- CDC *Haemophilus influenzae* type b – http://www.cdc.gov/vaccines/vpd-vac/hib/default.htm
- CDC National Center for Immunization and Respiratory Diseases – http://www.cdc.gov/vaccines/
- *Haemophilus influenzae* type B Vaccine – http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hib.pdf

Haemophilus Influenzae Invasive Disease Fact Sheet

What is invasive *Haemophilus influenzae* disease?
Invasive *Haemophilus influenzae* disease is a serious disease caused by bacteria. Before *Haemophilus influenzae* type B (Hib) vaccine, Hib disease was the leading cause of bacterial meningitis among children under 5 years old in the United States. Today invasive disease is less common, and is more often caused by serotypes that are not prevented by the Hib vaccine (types A, C, D, E, F, and non-typable).

Who gets invasive *Haemophilus influenzae* disease?
Before the introduction of the Hib vaccine, almost all invasive infections were among children under 5 years of age and were caused by serotype B. Two-thirds of cases were among children less than 18 months of age. Due to high vaccination rates, Hib invasive disease is now less common among children, although invasive disease due to all serotypes continues to occur at low levels in children and adults, especially those with underlying medical conditions.

How is *Haemophilus influenzae* spread?
The bacteria spread from person to person via airborne droplets or direct contact with respiratory secretions. If the bacteria stay in the person's nose and throat, the person probably will not get sick. Sometimes the bacteria spread into the lungs or the bloodstream, and then *Haemophilus influenzae* can cause serious problems.

What are the symptoms of invasive *Haemophilus influenzae* disease?
Invasive *Haemophilus influenzae* disease can affect different organ systems of the body. The most common types of disease include meningitis (infection of the brain and spinal cord coverings, which can lead to lasting brain damage and deafness); pneumonia; severe swelling in the throat, which makes it difficult to breathe; infections of the blood, joints, bones, and covering of the heart; and death.

How soon after contact could illness develop?
This is uncertain. The period is probably short, from 2-4 days.

When and for how long is a person able to spread *Haemophilus influenzae*?
As long as the bacteria are present, which could be for a prolonged period of time. Within 24-48 hours after beginning treatment with appropriate antibiotics, a person should no longer be able to spread the infection.

How can a person find out if he or she has invasive *Haemophilus influenzae* disease?
A doctor may take a sample of blood or spinal fluid from an ill person to conduct laboratory tests.

What is the treatment for invasive *Haemophilus influenzae* disease?
Hospitalization is generally necessary. A doctor will prescribe antibiotics for treatment.

How can invasive *Haemophilus influenzae* disease be prevented?
For type B *Haemophilus influenzae*, the Hib vaccine can prevent disease. Children should get Hib vaccine at 2, 4, 6, and 12-15 months of age (if the PRP-OMP vaccine is used, the dose at 6 months is not required). If a dose is missed, the next dose should be given as soon as possible; there is no need to start over. Hib vaccine may be given at the same time as other vaccines. Children over 5 years old usually do not need Hib vaccine. Older children or adults with sickle cell disease, HIV/AIDS, removal of the spleen, bone marrow transplant, or undergoing chemotherapy should get the Hib vaccine. Vaccines have not yet been developed to prevent disease caused by other serotypes of *H. influenzae.*

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Other ways to prevent invasive *Haemophilus influenzae* disease include regular handwashing, good hygiene, and disposal of soiled tissues after use.

Where can I get additional information on invasive *Haemophilus influenzae* disease?
Contact the Georgia Department of Public Health, Epidemiology Section, by email at gaepinfo@dhr.state.ga.us or call 404 657-2588. If you have internet access, the following sites may be useful:

- CDC *Haemophilus influenzae* type b – http://www.cdc.gov/vaccines/vpd-vac/hib/default.htm
- CDC National Center for Immunization and Respiratory Diseases – http://www.cdc.gov/vaccines/
- *Haemophilus influenzae* type B Vaccine – http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hib.pdf

MEASLES (RUBEOLA) FACT SHEET

Agent: Measles virus.

Brief Description: An acute, highly communicable, systemic, viral infection characterized by a prodromal period of 2 to 4 days, in which fever and malaise, cough, coryza (profuse amount of clear nasal discharge), and conjunctivitis are observed. Approximately 3 to 4 days later, a characteristic maculopapular (dusky-red blotchy) rash appears on the face and neck. The rash usually starts at the hairline, then spreads downward and outward to the trunk, hands and feet. The rash generally lasts 5 to 6 days. Koplik's spots, characteristic blue-white spots against the bright red background of the buccal (cheek) mucosa, may be observed 1 to 2 days before or 1 to 2 days after the appearance of the maculopapular rash. Complications include diarrhea, otitis media, pneumonia and encephalitis. One or more complications occur in approximately 30% of reported measles cases. In recent years, mortality from measles occurred in roughly 1 to 2 per 1000 reported cases in the United States.

Reservoir: Humans.

Mode of Transmission: Airborne by small droplet spread, direct contact with nasal or throat secretions of an infected person, and less commonly by articles freshly soiled with secretions of nose and throat.

Incubation Period: Commonly10 to 12 days from exposure to prodrome (range, 7 to 21 days). The rash usually appears approximately 14 days after exposure.

Period of Communicability: Measles is highly communicable, with greater than 90% secondary attack rates among susceptible persons. Persons with measles are considered infectious from 4 days before until 4 days after onset of rash. Maximum communicability occurs from the onset of the prodromal period through the first 3-4 days of rash.

Clinical Case Definition:
An illness characterized by all of the following:

- A generalized maculopapular rash lasting 3 or more days.
- A temperature of at least 101.0^{o} F (38.3^{o} C).
- Cough, coryza, and/or conjunctivitis.

Case Classification:

- **Suspected:** Febrile illness accompanied by generalized maculopapular rash.
- **Probable:** a case that meets the clinical case definition, has noncontributory or no serologic or virology testing, and is not epidemiologically linked to a confirmed case.
- **Confirmed:** a case that is laboratory confirmed or that meets the clinical case definition and is epidemiologically linked to a confirmed case. A laboratory-confirmed case does not need to meet the clinical case definition.

  *Comment: Two probable cases that are epidemiologically linked would be considered confirmed cases, even in the absence of laboratory confirmation.

MEASLES (RUBEOLA) FACT SHEET

Confirmed cases should be classified as:

- **Internationally importated case*:*** an internationally imported case is defined as a case in which measles results from exposure to measles virus outside the United States, as evidenced by at least some of the exposure period (7-21 days before rash onset) occurring outside the U.S. and rash onset occurring within 21 days of entering the U.S., and there is no known exposure to measles in the United States during that time. All other cases are considered U.S. acquired

- **U.S.-acquired case:** a U.S.-acquired case is defined as a case in which the patient had not been outside the United States during the 21 days before rash onset or was known to have been exposed to measles within the United States. U.S.-acquired cases are subclassified into four mutually exclusive groups:

    - Import-linked case: any case in a chain of transmission that is epidemiologically linked to an internationally imported case.
    - Imported-virus case: a case for which an epidemiologic link to an internationally imported case was not identified, but for which viral genetic evidence indicates an imported measles genotype, i.e., a genotype that is not occurring within the U.S> in a pattern indicative of endemic transmission. An endemic genotype is the genotype of any measles virus that occurs in an endemic chain of transmission (i.e., lasting ≥12 months). Any genotype that is found repeatedly in U.S.-acquired cases should be thoroughly investigated as potential endemic genotype, especially if the cases are closely related in time or location.
    - Endemic case: a case for which epidemiological or virological evidence indicates an endemic chain of transmission. Endemic transmission is defined as a chain of measles virus transmission that is continuous for ≥ 12 months within the United States.
    - Unknown source case (indigenous): case for which an epidemiological or virological link to importation or to endemic transmission within the U.S. cannot be established after a thorough investigation. These cases must be carefully assessed epidemiologically to assure that they do not represent a sustained U.S.-acquired chain of transmission or an endemic chain of transmission within the U.S.

Note: Internationally imported, import-linked, and imported-virus cases are considered collectively to be import-associated cases.

Note: U.S.-acquired cases may be classified further into two mutually exclusive groups:

- Out-of-state importation: an out-of-state imported case is defined as a case in which measles resulted from exposure to measles virus outside of the state of Georgia, as evidenced by at least some of the exposure period (at least 7-21 days before rash onset) occurring outside of Georgia and rash onset occurring within 21 days of entering Georgia, and there is no known exposure to measles in Georgia

MEASLES (RUBEOLA) FACT SHEET

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- In-state acquired: an in-state case is defined as a case in which measles resulted from exposure to measles virus within the state of Georgia, as evidenced by at least some of the exposure period (at least 7-21 days before rash onset) occurring in Georgia

Laboratory Criteria for Diagnosis:

- Positive serologic test for measles immunoglobulin M (IgM) antibody, or
- Fourfold rise in acute and convalescent-phase measles IgG antibody levels by any standard serologic assay, or
- Isolation of measles virus from a clinical specimen, or
- Detection of measles virus by rt-PCR

Diagnostic Testing: (See Measles Specimen Collection and Submission Guidelines)

A. Serology

1. Specimen Needed: Blood - 5cc collected during acute phase of illness and 5 cc collected 14-30 days later, or two capillary tubes collected during acute phase and convalescent phase.
2. Outfit: Other serology outfit, order #500
3. Form: # 3432
4. Lab Test Performed: Measles IgG (acute and convalescent) **and** IgM titers. Be sure to request the IgM titer with the acute phase draw so that case confirmation can be accomplished in a timely manner. (**Note**: On Form #3432 be sure to request Rubeola (Measles) IgG and IgM AND Rubella IgG and IgM)
5. Lab Performing Test: Immunology Laboratory, Georgia Public Health Laboratory (GPHL) in Decatur.
6. Transport requirements: blood must be non-hemolyzed.

B. Culture or Polymerase Chain Reaction (PCR)

1. Specimen Needed: Urine, heparinized blood, nasopharyngeal aspirates, or throat swabs – collect at same time as samples for serology (best if within 3 days after rash onset).
2. Outfit: Viral transport media – culture: order #575
   PCR: order # 565
3. Form: # 3595R.
4. Lab Test Performed: Culture, PCR.
5. Lab Performing Test: Virology Laboratory, GPHL in Decatur -culture, specimen forwarded to CDC for PCR.
6. Transport: Transport at 4° C if tests are to be performed within 72 hours; otherwise freeze at -70° C.

Immunity:

Evidence of immunity to measles includes:

1. Born in the United States before 1957 (for healthcare providers this does not suffice as evidence of immunity)
2. Laboratory evidence of immunity or laboratory confirmation of disease

MEASLES (RUBEOLA) FACT SHEET

Vaccination: The current recommendation is a two-dose schedule. The first dose should be given at 12 to 15 months of age, the second at school entry (4 to 6 years of age.) Both doses can be given as MMR or MMRV vaccine. For any child older than six who has not received one or both doses, any opportunity to immunize should be utilized.

Post-exposure Prophylaxis: Measles vaccine is effective in preventing infection or modifying the severity of illness if given within 72 hours of exposure. Immune globulin (IG) may prevent or modify disease and provide temporary protection if given within 6 days of exposure. Transmission is likely in households, schools, and other institutions. Immune globulin (IG) may be especially indicated for susceptible contacts in these settings, particularly contacts younger than 1 year of age and immunocompromised contacts.

Treatment: Supportive care only.

Investigation:
Measles and rubella must be ruled out whenever illness involving fever and rash are reported. The investigation must be started immediately when a potential case is identified.
Essential components of the case investigation include the following:

a. Establish a diagnosis by obtaining laboratory specimens for serology, viral isolation and PCR as early as possible.
b. Obtain an accurate and complete immunization history.
c. Identify the source of infection and transmission setting.
d. Assess potential transmission and identify contacts.
e. For symptomatic contacts, obtain specimens for virus isolation and PCR if measles is suspected.
f. Refer to GA Department of Public Health website for measles investigation and outbreak protocol http://health.state.ga.us/epi/vpd/measles.asp

Initial response to the report of suspected measles:

1. Call the State Epidemiology Section (404) 657-2588 **IMMEDIATELY**. If after business hours, report suspect case to 1-866- PUB-HLTH.
2. Contact the parent(s) or guardian and reporting physician immediately to obtain a detailed clinical and exposure history of the patient.
   - Ask parent(s) about any out-of-town travel or visitors during the 7-21 days period prior to rash onset.
   - Identify any person(s) or group(s) exposed by the patient during the period 4 days before to 4 days after rash onset.
3. Complete the Measles Surveillance Worksheet (from the Centers for Disease Control and Prevention's Manual for the Surveillance of Vaccine Preventable Diseases, Appendix 10). Read the instructions carefully and complete as much of the form as possible. Do not leave any item blank. If information is not available, enter "none" or "NA". The following should be collected during case investigations:
   - Demographic information
   - Reporting source
     a. county, district
     b. earliest date reported
     c. date case investigated started

MEASLES (RUBEOLA) FACT SHEET

- Clinical details, including
    a. Date of onset of symptoms
    b. date of rash onset
    c. rash duration and presentation
    d. symptoms
    e. complications
    f. hospitalization
- Outcome (case survived or died)
    a. Date of death
- Laboratory information
    a. serologic test results
    b. date of collection of specimen for virus isolation
- Vaccination status
    a. number of doses of measles vaccine received
    b. date(s) of measles vaccinations
    c. manufacturer name
    d. vaccine lot number
    e. if not vaccinated, reason
- Epidemiologic
    a. transmission setting
    b. source of infection (e.g., age, vaccination status, relationship to case-patient, country/state of residence, laboratory testing, onset dates, etc.)
    c. source of exposure (contact with probable or confirmed case, or contact with immigrants or travelers)
    d. import status (international import, indigenous, out-of-state import, linked or traced to an international importation)
    e. residency (does the patient reside in the U.S.)
    f. travel history
    g. setting (i.e., is case part of an outbreak or is it a sporadic case)

Fax the completed worksheet and any pertinent lab results to the State Epidemiology Section (404) 657-2608. **Do not wait for laboratory confirmation to fax the report.**

Outbreak Control Strategy: <u>All</u> reports of suspected measles cases should be **investigated rapidly.** Control activities should not be delayed until laboratory results on suspected cases are received. A measles outbreak exists in a community whenever there is **one confirmed** case of measles. Once this occurs, preventing dissemination of measles depends on promptly vaccinating susceptible persons and limiting the number of exposures to infectious cases. All persons who cannot readily provide documentation of measles immunity (see ACIP Statement on Measles Prevention, dated 5/22/98) should be vaccinated or excluded from the setting (e.g. school). Documentation of vaccination is adequate only if the date of vaccination is provided. Persons who have been exempted from measles vaccination for medical or religious reasons should be excluded from the outbreak area for at least 2 weeks after the onset of rash in the last case of measles.

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- **Institution-based outbreaks**
  During outbreaks in day care centers, elementary, middle, junior and senior high schools, colleges and other institutions of higher education, a program of mandatory revaccination with MMR vaccine should be conducted in the affected schools. Revaccination should include all students and their siblings and all school personnel born in or after 1957 who cannot provide documentation of receipt of two doses of measles-containing vaccine on or after their first birthday or other evidence of measles immunity. Students and personnel receiving their first dose as part of an outbreak control program may be immediately readmitted to school. A second dose should be given in 28 days. If there is an **unconfirmed** but clinically compatible case in a school, the response should be phased in. Reimmunization should be recommended but not mandatory until the case is confirmed. Proceed with the epidemiologic work on the case. Search for a source, immunize siblings and close contacts when appropriate, ensure an adequate supply of vaccine and begin to prepare for a school-based clinic. At this point it is very important to implement **daily active surveillance** of absenteeism of two or more days and any rashes should be followed up on immediately. New cases signal the immediate need for school-based clinics and the exclusion of children and staff who do not have two documented doses of measles vaccine.

- **Outbreaks among preschool-age children**
  The risk of complications from measles is high among infants less than one (1) year of age. Therefore, considering the benefits and risks, vaccination with monovalent measles vaccine is recommended for infants as young as six (6) months of age when exposure to measles is considered likely. Children less than six months of age do not require measles vaccination because they still have passive antibody passed to them from their mother during gestation. MMR may be used in children before the first birthday if monovalent measles vaccine is not readily available. Infants vaccinated before the first birthday should be revaccinated when they are 12 months old and at school entry to ensure adequate protection.

- **Medical Settings**
  If an outbreak occurs in a healthcare facility, all employees (including volunteers, trainees, nurses, physicians, technicians, receptionists, and other clerical and support staff) are at an increased risk of exposure to measles, and all persons who work in such facilities in any capacity should be immune to measles to prevent any potential outbreak. All employees who were born in or after 1957 who cannot provide documentation of receipt of two doses of measles vaccine on or after their first birthday or other evidence of immunity to measles (see ACIP Statement on Measles Prevention dated 5/22/98) should receive a dose of measles vaccine. Personnel born before 1957 without documentation of measles immunity should receive one dose of MMR. Serologic screening of healthcare workers during an outbreak to

MEASLES (RUBEOLA) FACT SHEET

determine measles immunity is not recommended, because stopping measles transmission requires the rapid vaccination of susceptible healthcare workers, which can be impeded by the need to screen and wait for results. Susceptible personnel who have been exposed should be relieved from direct patient contact from the 5th to the 21st day after the exposure, regardless of whether they received vaccine or immunoglobulin after the exposure. Those who become ill should be relieved from patient contact for seven days after they develop a rash.

Reporting: Report all suspected, probable, or confirmed cases **IMMEDIATELY** by phone to the local health department, District Health Office, or the State Epidemiology Section at 404-657-2588. If calling after regular business hours, it is very important to report cases to 1-866-PUB-HLTH. After verbal report has been made, please transmit the case information electronically through the State Electronic Notifiable Disease Surveillance System (SENDSS) at http://sendss.state.ga.us. Note: Please be sure to complete all data fields in SENDSS,

Reported Cases of Measles in Georgia, 2001-2011

Year	Number of Cases
2001	1
2002	3
2003	1
2004	1
2005	0
2006	0
2007	0
2008	1
2009	1
2010	1
2011	0

References:

2. American Academy of Pediatrics. Measles. In: Pickering, LK, Baker CJ, Kimberlin DW, Long SS, eds. 2012 Red Book: Report of the Committee on Infectious Diseases. Elk Grove Village, IL: American Academy of Pediatrics; 2012: 489-499.
3. Measles --- United States, 2005. *MMWR* Vol. 55(50), 1348-1351.
4. Case Definitions for Infectious Conditions Under Public Health Surveillance. *MMWR* Vol. 46(RR10), 1997: 1-55.
5. Epidemiology of measles – United States, 2001-2003. *MMWR* Vol. 53(31);713-716.
6. Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Hamborsky J, Wolfe S, eds. 12th ed., second printing. Washington DC: Public Health Foundation, 2012: 173-192.
7. Centers for Disease Control and Prevention. Measles Outbreak ---- Netherlands, April 1999--January 2000. *MMWR* Vol. 49(14), 2000: 299-303.
8. Centers for Disease Control and Prevention. Measles. Manual for the surveillance of vaccine-preventable diseases. Centers for Disease Control and Prevention, Atlanta, GA, 2012.

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9. Heymann, ed. Measles. In: Control of Communicable Diseases Manual. 18th ed. Washington, DC: American Public Health Association, 2004: 347-354.
10. Measles – United States. January – May, 2011. MMWR Vol. 60(20);666-668.

Links:

- CDC Measles Fact Sheet – http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/meas.pdf
- CDC National Center for Immunization and Respiratory Diseases – http://www.cdc.gov/vaccines/vpd-vac/measles/default.htm
- GA Public Health, Epidemiology Section Measles Information – http://health.state.ga.us/epi/vpd/measles.asp

MEASLES (RUBEOLA) QUESTIONS & ANSWERS

MEASLES Q&A
(rubeola, hard measles, red measles)

What is measles?
Measles (rubeola) is an acute, highly contagious viral disease capable of producing epidemics. Pneumonia occurs in up to six percent of reported cases and accounts for 60 percent of deaths attributed to measles. Encephalitis (inflammation of the brain) may also occur. Other complications include middle ear infection and convulsions. Measles is more common in winter and spring. Very few, if any, cases of measles occur in Georgia each year.

Who gets measles?
Although measles is usually considered to be a childhood disease, it can be contracted at any age. Generally, inadequately immunized preschool children, adolescents, and young adults comprise the majority of measles cases in the United States.

How is measles spread?
Measles is spread by direct contact with nasal or throat secretions from an infected person or, less frequently, by airborne transmission. Measles is one of the most highly communicable infectious diseases.

What are the symptoms of measles?
Measles symptoms generally appear in two stages. In the first stage, the individual may have a runny nose, cough and a slight fever. The eyes may become reddened and sensitive to light while the fever consistently rises each day. The second stage begins on the third to seventh day and consists of a temperature at or above 101°F, and a red blotchy rash lasting four to seven days. The rash usually begins on the face and then spreads over the entire body. Koplik spots (little white spots) may also appear on the gums and inside of the cheeks.

How soon do symptoms appear?
Symptoms usually appear 10 to 12 days after exposure, although they may occur as early as 7 or as late as 21 days.

When and for how long is a person able to spread measles?
An individual is able to transmit measles from four days before to four days after rash onset.

Does past infection make a person immune?
Yes. Permanent immunity is acquired after contracting the disease.

What is the treatment for measles?
There is no specific treatment for measles.

How can measles be prevented?
Anyone born on or after January 1, 1957, who does not have a history of physician-diagnosed measles or serologic confirmation of measles immunity, should receive two doses of MMR vaccine for maximum protection. The first dose should be given at 12 months of age. The second dose should be given at four to six years of age (school entry) at the same time as the DTaP and polio booster doses. The MMR vaccine is recommended for all routine measles

MEASLES (RUBEOLA) QUESTIONS & ANSWERS

vaccine doses to provide increased protection against all three vaccine-preventable diseases: measles, mumps and rubella. Two doses of measles-containing vaccine are required of all children enrolled in schools, grades K-12. College students also are required to demonstrate immunity against measles. For more detailed vaccination information, see Measles, Mumps, and Rubella Vaccine Guidelines in Chapter 2 of this manual.

Where can I get additional information on measles?
Contact the Georgia Division of Public Health, Epidemiology Branch, by email at gaepinfo@dhr.state.ga.us. If you have Internet access, the following sites may be useful:

- CDC Measles Fact Sheet – http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/meas.pdf
- CDC National Immunization Program – http://www.cdc.gov/vaccines/

MEASLES (RUBEOLA) SPECIMEN COLLECTION & SUBMISSION GUIDELINES

MEASLES: SPECIMEN COLLECTION & SUBMISSION GUIDELINES

A case of measles is a **public health emergency**. Contact public health **immediately** of any suspect cases. A clinical diagnosis of measles is unreliable; suspect cases of measles must be laboratory confirmed. Confirmation of acute infection can be determined by the presence of serum immunoglobulin M (IgM) and a four-fold rise in serum immunoglobulin G (IgG) titer between acute and convalescent phase specimens.

The Georgia Division of Public Health strongly recommends the **collection of serum for measles IgM/IgG and collection of a throat swab and urine specimen for viral isolation/polymerase chain reaction testing (PCR) to confirm a measles case**. To coordinate specimen collection and laboratory submission, call your District or County Health Department. **Please do not send specimens directly to the Georgia Public Health Laboratory (GPHL) or the Centers for Disease Control and Prevention (CDC).**

Specimen Collection Instructions:

Serologic Testing : Collect as soon as possible when measles infection is suspected, preferably at the onset of rash.

- Collect 7-10 ml of blood in a red top or serum separator tube (SST)
  Acute serum (IgM and first IgG) -collect and send immediately
  Convalescent serum (second IgG) -collect 2-4 weeks after rash onset
- SST tubes must be centrifuged and the serum poured into a transport tube for shipment.
- Keep specimens cold (4° C or 39° F) and ship overnight service. **Do not freeze serum samples.**

Viral Testing: Collect a urine and throat swab at the same time as serology. Virus is most frequently recovered within the first 3 days following rash, but up to 7 days after rash onset is acceptable. If it's been a few days since resolution of the rash collect only a urine specimen.

Throat Swabs

- Use a **viral transport kit** if possible (such as what's used to isolate influenza or herpes simplex virus)
- Collect a throat swab by rubbing the posterior nasal passages with a dry sterile cotton swab
- Place swab in a tube containing 2-3 mls of viral transport medium or other sterile isotonic solution (phosphate buffered saline or cell culture medium).
- Keep samples cold (4° C or 39° F)
- Ship the viral specimens using ice packs or dry ice*. Avoid freeze-thaw cycles.

Urine Specimens

- Collect 10-15 ml of urine in a screw top sterile container
- Keep samples cold (4° C or 39° F)
- Ship the viral specimens using ice packs or dry ice*. Avoid freeze-thaw cycles.

*If shipment contains both serum and viral specimens, ship together by overnight service on cold packs (do not freeze serum)

MEASLES (RUBEOLA) SPECIMEN COLLECTION & SUBMISSION GUIDELINES

Laboratory Submission Instructions:

- Notify County or District Public Health Office **immediately** for coordination.
- Label specimen transport tube with the patient name and date of birth
- **UNAPPROVED OR UNLABELED SPECIMENS WILL NOT BE TESTED**
- Complete Immunology, Molecular Biology and Virology lab forms at:
  http://health.state.ga.us/pdfs/lab/manual/Immunology%20Form%203432.pdf

  http://health.state.ga.us/pdfs/lab/manual/Molecular%20Form%203409.pdf
  http://health.state.ga.us/pdfs/lab/manual/Virology%20Form%203595.pdf
  with the following information:
  - Submitter code (if known), address, phone number, and contact name
  - Patient name, address, date of birth, sex, race and ethnicity (if available)
  - Date of specimen collection, type of specimen, reason for testing, date of illness onset
  - Immunology Form: Test requested (NOTE: Be sure to check *Rubeola (Measles) IgG* and *IgM* boxes **AND** *Rubella IgG* and *IgM* boxes)
  - Molecular Biology Form: Test requested (NOTE: Beside *Other* be sure to write in *Measles PCR*)
  - Virology Form: Test requested (NOTE: Beside *Viral Culture/Identification* (Please Specify) be sure to write *Measles Culture*.

- Ship specimen and accompanying lab form to the following address:
  Georgia Public Health Laboratory
  1749 Clairmont Road
  Decatur, GA 30033-4050
  ATTN: Immunology and Virology Laboratories

Contact Information:

- For specimen outfit requests call the Georgia Public Health Laboratory at 404-327-7921
- Additional lab forms available at http://health.state.ga.us/programs/lab/manual.asp in Appendix B
- For questions related to specimen collection and transport contact local public health or the State Epidemiology Unit, 404-657-2588

Interpretation of Measles Laboratory Test Results:

- Serology
  - IgM: Measles infection is confirmed using measles IgM antibody testing of serum samples collected as soon as possible after symptom onset. A positive IgM test result indicates current/very recent infection or reinfection. As with any lab test, there can be false positive test results.

  - IgG: IgG alone is not diagnostic unless you obtain both an acute (can be done as soon after onset as the patient is seen, but ideally four to five days after onset of symptoms) and convalescent (from two to four weeks after onset) blood specimen for serologic tests to determine if a four-fold rise in IgG antibody titer has occurred (e.g., from 1:40 to 1:320). In vaccinated persons it may not be possible to detect a four-fold rise in measles IgG antibody titer in paired serum samples (acute and convalescent). In such persons, the existing IgG will begin to rise soon after exposure and infection. At the time of onset of symptoms and collection of the acute serum, the IgG may already be quite elevated, and obviate the four-fold rise observed in convalescent serum specimen.

MEASLES (RUBEOLA)
SPECIMEN COLLECTION & SUBMISSION GUIDELINES

- PCR
  - Sequence analysis of a RT-PCR product derived from a virus isolate or from a clinical material confirms the presumptive positive PCR results and provides epidemiologically important information

- Viral Culture
  - Isolation of measles virus from any clinical specimen constitutes laboratory confirmation of measles

MUMPS
(INFECTIOUS PAROTITIS)

Agent: Mumps virus.

Brief Description: An illness with acute onset of unilateral or bilateral swelling of the parotid gland or other salivary gland(s) (parotitis), and without other apparent cause. Symptoms such as myalgia, anorexia, malaise, headache, and low-grade fever may precede parotitis by several days. Asymptomatic infections also occur; parotitis is present in only 30-40% of infected persons. Not all cases of parotitis – especially sporadic ones – are due to mumps infection; however, mumps is the only known cause of epidemic parotitis. Complications can include meningitis, arthritis, inflammation of the testicles or ovaries, inflammation of the pancreas and deafness.

Reservoir: Humans.

Mode of Transmission: Airborne, by droplet spread, or by direct contact with saliva of an infected person.

Incubation Period: Commonly 14 to 18 days, range 14 to 25 days.

Period of Communicability: Persons with mumps are usually considered infectious from 2 days before until 4 days after onset of parotitis. Virus has been isolated from saliva from 7 days before parotitis and 9 days after onset of illness.

Clinical Case Definition: An illness with acute onset of unilateral or bilateral tender, self-limited swelling of the parotid or other salivary gland(s), lasting greater than or equal to 2 days, and without other apparent cause.

Lab Criteria for Diagnosis:

- Isolation of mumps virus from clinical specimen, or
- Detection of mumps nucleic acid (e.g. rt-PCR assay), or
- Positive serologic test for mumps immunoglobulin M (IgM) antibody, or
- A fourfold increase between acute- and convalescent-phase titers in serum mumps immunoglobulin G antibody level by any standard serologic assay.

Diagnostic Testing:

A. Serology

1. Specimen needed: Serum/blood - acute and convalescent.
2. Outfit: Other serology, order # 500.
3. Form: # 3432.
4. Lab Test Performed: Mumps serology (IgG and IgM; must write in IgG and IgM on this form).
5. Lab Performing Test: IgG is performed by the State Immunology Laboratory, Georgia Public Health Laboratory (GPHL) in Decatur. IgM is performed by Centers for Disease Control and Prevention (CDC) in Atlanta.
6. Transport Requirements: Acute sera (for IgG and IgM) should be collected as soon as possible after onset of parotitis for examining seroconversion. The convalescent specimen for IgG detection should be drawn about 2 weeks later. IgM antibodies are

MUMPS (INFECTIOUS PAROTITIS)

detectable within a few days after illness onset, peak about a week after onset and remain elevated for several weeks to months.

B. Polymerase Chain Reaction (PCR)

1. Specimen Needed: buccal swab
2. Outfit: # 575
3. Form: # 3409
4. Lab Test Performed: Mumps PCR
5. Lab Performing Test: State Molecular Biology Laboratory, Georgia Public Health Laboratory (GPHL) in Decatur
6. Transport Requirements*: Virus may be isolated from the buccal mucosa from 7 days before, until 9 days after salivary enlargement. Ideally, the specimen should be collected within 72 hours of the onset of illness. Ideally, the specimen should be collected within 72 hours of the onset of illness. If tests are to be performed within 72 hours after collection, transport specimens at 4o Celsius. Otherwise, freeze the specimen at -70oC.

   ***Note**: If specimen is being collected for PCR testing **ONLY** it can be kept and shipped at room temperature. If the specimen is being collected for both PCR and culture testing follow the transport requirements for culture specimens.

C. Culture

1. Specimen Needed: throat swab, urine, or cerebrospinal fluid (CSF).
2. Outfit: Viral culture, order # 575.
3. Form: # 3595.
4. Lab Test Performed: Mumps culture.
5. Lab Performing Test: State Virology Laboratory, GPHL in Decatur.
6. Transport Requirements: Virus may be isolated from the buccal mucosa from 7 days before, until 9 days after salivary enlargement. Ideally, the specimen should be collected within 72 hours of the onset of illness. If tests are to be performed within 72 hours after collection, transport specimens at 4° Celsius. Otherwise, freeze the specimen at -70° Celsius.

Case Classification:

- **Suspect**: a case that meets the clinical case definition or has clinically compatible illness, without laboratory confirmation; or a case without clinical information with laboratory confirmation.
- **Probable**: a case that meets the clinical case definition, without laboratory confirmation, and is epidemiologically linked to a clinically compatible case.
- **Confirmed**: a case that meets the clinical case definition or has clinically compatible illness and is either laboratory confirmed or is epidemiologically linked to a confirmed case.

***Comment**: False-positive IgM results by immunofluorescent antibody assays have been reported. Other serologic tests include Enzyme-Linked Immunosorbent Assay (ELISA or EIA) and Hemagglutination Inhibition (HI).

MUMPS
(INFECTIOUS PAROTITIS)

Vaccination: Live attenuated mumps virus vaccine is recommended for persons ≥ 12 months of age unless medically contraindicated or unless a person is immune as defined by documentation of 1) immunization with at least one dose of live mumps vaccine on or after the first birthday, 2) serological evidence of mumps immunity, 3) physician diagnosis of mumps, or 4) birth before 1957. Under the current 2-dose schedule, most children and adolescents receive two doses of mumps-containing vaccine. Mumps vaccine, as MMR or MMRV, is recommended at 12-15 months of age and 4-6 years of age. For more detailed vaccination information, see Measles, Mumps, and Rubella Vaccine Guidelines in Chapter 2 of this manual.

Post-exposure Prophylaxis: There is no evidence that giving mumps vaccine provides protection to those already exposed. However, in those susceptible persons who were exposed but not infected, the vaccine will provide future immunity, and its use in these situations is not contraindicated.

Treatment: Supportive only.

Investigation:

1. Call the State Epidemiology Section at (404) 657-2588 to report a suspect case. Complete the Mumps Surveillance Worksheet (from the Centers for Disease Control and Prevention's Manual for the Surveillance of Vaccine Preventable Diseases, Appendix 8). Identification of suspected or confirmed cases of mumps is important in the initiation of control measures to prevent the spread of disease among susceptible persons. Essential components of the case investigation include the following:
   a. Establish a diagnosis of mumps (submit specimens for serology, PCR, viral culture).
   b. Obtain accurate and complete immunization histories.
   c. Identify the source of infection.
   d. Assess potential transmission and identify contacts.
   e. Obtain specimens for virus isolation.

2. Fax the completed surveillance worksheet and any pertinent lab results to the Notifiable Disease Epidemiology Section (404) 657-7517.

Outbreak Control: The main strategy for controlling a mumps outbreak is to define the at-risk population and transmission setting, and to rapidly identify and vaccinate susceptible persons or, if a contraindication exists, to exclude susceptible persons from the setting to prevent exposure and transmission.

Reporting: Report all probable or confirmed cases **IMMEDIATELY** by phone to the local health department, District Health Office, or the State Epidemiology Section at 404-657-2588. If calling after regular business hours, it is very important to report cases to the Epidemiology Section answering service or call 1-866 PUB-HLTH. After verbal report has been made, please transmit the case information electronically through the State Electronic Notifiable Disease Surveillance System (SENDSS). Please be sure to complete all data fields in SENDSS including the case report form.

MUMPS
(INFECTIOUS PAROTITIS)

**(Georgia code requires notification of both lab-confirmed and clinical mumps diagnosis within 7 days; however, immediate notification enables a prompt case investigation and public health response.)

Reported Cases of Mumps in Georgia, 2001-2011

Year	Number of Cases
2001	9
2002	2
2003	3
2004	2
2005	2
2006	4
2007	0
2008	4
2009	1
2010	5
2011	5

References:

1. American Academy of Pediatrics. Mumps. In: Pickering, LK, Baker CJ, Kimberlin DW, Long SS, eds. 2012 Red Book: Report of the Committee on Infectious Diseases. Elk Grove Village, IL: American Academy of Pediatrics; 2012: 514-518.
2. Heymann, ed. Mumps. In: Control of Communicable Diseases Manual. 18th ed. Washington, DC: American Public Health Association, 2004: 376-379.
3. Centers for Disease Control and Prevention. Mumps. Manual for the surveillance of vaccine-preventable diseases. Centers for Disease Control and Prevention, Atlanta, GA, 2012.
4. CDC. Case Definitions for Infectious Conditions under Public Health Surveillance. *MMWR* Vol. 46(RR10), 1997: 1-55.
5. MMWR: Updated ACIP Recommmendations for the Control and Elimination of Mumps. Vol 55(22);629-630.
6. Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases.Atkinson W, Hamborsky J, Wolfe S, eds. 12th ed., second printing. Washington DC: Public Health Foundation, 2012:205-214.

Links:

- CDC Mumps Fact Sheet – http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/mumps.pdf
- CDC National Center for Immunization and Respiratory Diseases – http://www.cdc.gov/vaccines/

MUMPS (INFECTIOUS PAROTITIS) SPECIMEN COLLECTION & SUBMISSION GUIDELINES

MUMPS: SPECIMEN COLLECTION & SUBMISSION GUIDELINES

Mumps should be considered in the differential diagnosis of patients presenting with parotitis or swelling of the salivary glands, regardless of vaccination history. Serologic testing (including mumps IgM and acute and convalescent mumps IgG), viral culture, and polymerase chain reaction testing (PCR) are strongly recommended to support the clinical diagnosis.

The Georgia Division of Public Health strongly recommends the **collection of serum for mumps IgM/IgG antibody testing and collection of a buccal swab for viral isolation/PCR testing to confirm a mumps case**. To coordinate specimen collection and laboratory submission, call your District or County Health Department. **Please do not send specimens directly to the Georgia Public Health Laboratory (GPHL) or the Centers for Disease Control and Prevention (CDC).**

Specimen Collection Instructions:

Serologic Testing: Collect as soon as possible when mumps infection is suspected, preferably at the onset of parotid swelling.

- Collect 7-10 ml of blood in a red top or serum separator tube (SST).
  Acute serum (IgM and first IgG): collect preferably 1-2 days after symptom onset
  Convalescent serum (second IgG**):** collect within 2-5 weeks after symptom onset
- SST tubes must be centrifuged and the serum poured into a transport tube for shipment.
- Store specimens cold (using ice packs or dry ice) and ship by overnight service. Do not freeze serum samples.

Viral Testing: Collect a buccal swab* at the same time as serology. Virus is most frequently recovered within the first 3 days following the onset of symptoms. Samples may be positive in unvaccinated persons up to 10 days post onset, however among suspected cases that have received 1 or more doses of MMR, virus may clear much earlier.

* The buccal cavity is the space near the upper rear molars between the cheek and the teeth.

PCR Testing:

- Collect a buccal swab by asking the patient to massage the parotid gland area (buccal cavity) for about 30 seconds
- Use a **synthetic** swab from a **viral transport kit** (such as influenza or herpes simplex viral transport) to collect buccal secretions.
- Place swab in the tube containing 2-3 mls of viral transport medium (e.g., MEM or Hanks Balanced Salt Solution)
- Ship the viral specimens using ice packs or dry ice*. Avoid freeze-thaw cycles
- If there is more than 1 day delay in shipping the samples to the state lab or CDC for testing, the buccal swab or throat swab is best preserved at -70 degrees Celsius or -94 degrees Fahrenheit

MUMPS (INFECTIOUS PAROTITIS) SPECIMEN COLLECTION & SUBMISSION GUIDELINES

Viral Isolation:

- Collect a buccal swab (see instructions above) or throat swab sample (up to 10 days after symptom onset)
- Use a **synthetic** swab from a **viral transport kit** (such as influenza or herpes simplex viral transport) to collect buccal secretions.
- Place swab in the tube containing 2-3 mls of viral transport medium (e.g., MEM or Hanks Balanced Salt Solution)
- Ship the viral specimens using ice packs or dry ice. Avoid freeze-thaw cycles.
- If there is more than 1 day delay in shipping the samples to the state lab or CDC for testing, the buccal swab or throat swab is best preserved at -70 degrees Celsius or -94 degrees Fahrenheit

*If the shipment contains both serum and viral specimens, ship together by overnight service on cold packs (do not freeze serum)

Laboratory Submission Instructions

- Notify County or District Public Health Office **immediately** for coordination.
- Label specimen transport tube with the patient name and date of birth
- **UNLABELED SPECIMENS WILL NOT BE TESTED**)
- Complete Immunology, Molecular Biology and Virology lab forms at:
  http://health.state.ga.us/pdfs/lab/manual/Immunology%20Form%203432.pdf
  http://health.state.ga.us/pdfs/lab/manual/Molecular%20Form%203409.pdf
  http://health.state.ga.us/pdfs/lab/manual/Virology%20Form%203595.pdf
  with the following information:
  - Submitter code (if known), address, phone number, and contact name
  - Patient name, address, date of birth, sex, race and ethnicity (if available)
  - Date of specimen collection, type of specimen, reason for testing, date of illness onset
  - Immunology Form: Under *Miscellaneous Serology* check *Mumps* and *Other*. (NOTE: Beside *Other*, specify *Mumps IgM* **and** *IgG*)
  - Molecular Biology Form: Test requested – *Mumps PC*R
  - Virology Form: Test requested – *Viral Culture/Identification* (NOTE: Specify *Mumps Culture*).

- Ship specimens to the following address :
  Georgia Public Health Laboratory
  1749 Clairmont Road
  Decatur, GA 30033-4050
  ATTN: Immunology and Molecular Biology Laboratories

Contact Information

- Specimen outfit requests: call the Georgia Public Health Laboratory at 404-327-7921
- Additional lab forms available at http://health.state.ga.us/programs/lab/manual.asp in Appendix B
- For questions related to specimen collection and transport contact local public health or the State Epidemiology Unit, 404-657-2588

MUMPS (INFECTIOUS PAROTITIS) SPECIMEN COLLECTION & SUBMISSION GUIDELINES

Interpretation of Mumps Laboratory Test Results

- Serology
  - IgM: Mumps infection is confirmed using mumps IgM antibody testing of serum samples collected as soon as possible after symptom onset. A positive IgM test result indicates current/very recent infection or reinfection. As with any lab test, there can be false positive test results. If the suspected case has received one or more doses of MMR, the IgM response may be missing, delayed, or transient.

  - IgG: IgG alone is not diagnostic unless you obtain both an acute (can be done as soon after onset as the patient is seen, but ideally four to five days after onset of symptoms) and convalescent (from two to four weeks after onset) blood specimen for serologic tests to determine if a four-fold rise in IgG antibody titer has occurred (e.g., from 1:40 to 1:320). In vaccinated persons it may not be possible to detect a four-fold rise in mumps IgG antibody titer in paired serum samples (acute and convalescent). In such persons, the existing IgG will begin to rise soon after exposure and infection. At the time of onset of symptoms and collection of the acute serum, the IgG may already be quite elevated, and obviate the four-fold rise observed in convalescent serum specimen.

- PCR
  - Mumps viral RNA may be detected from viral samples prior to onset of parotitis until 5-9 days after parotitis (1-4 days is optimal for virus collection). Among previously immunized suspected cases, mumps virus detection is an important method of confirming the case.

  - However, the interpretation of a positive RT- PCR result without demonstration of mumps growth in tissue culture must be interpreted carefully, particularly among persons whose symptoms do not meet the clinical definition of mumps

  - Sequence analysis of a RT-PCR product derived from a virus isolate or from clinical material confirms the presumptive positive PCR results and provides epidemiologically important information.

- Viral Culture
  - Isolation of mumps virus from any clinical specimen constitutes laboratory confirmation of mumps infection.

NEISSERIA MENINGITIDIS FACT SHEET (MENINGOCOCCUS)

Brief Description: *Neisseria meningitidis* is a gram-negative diplococcus that can cause a variety of clinical syndromes, but is most often associated with meningitis. Meningococcal serogrouping is based on the antigenic structure of the polysaccharide capsule, with five serogroups causing the majority of disease: A, B, C, Y, and W-135.

Reservoir: Humans

Mode of Transmission: Spread through respiratory droplets, normally requiring direct contact with saliva and respiratory secretions. Up to 5%-10% of people may be asymptomatic carriers with nasopharyngeal colonization.

Incubation Period: 2 to 10 days, commonly 3-4 days

Laboratory Criteria for Diagnosis: Isolation of *N. meningitidis* from a normally sterile site (e.g., blood, cerebrospinal fluid, or less commonly, joint fluid). Invasive disease may take a variety of forms, including septicemia, meningitis, pneumonia, or septic arthritis.

Diagnostic testing:

1. Specimen: Blood, CSF, or other sterile site for culture; pure specimen for typing
2. Outfits: sterile vial for isolation and identification; culture referral order #0505 for serotyping
3. Lab Form: #3410
4. Lab Test Performed: *Neisseria meningitidis* serogrouping
5. Lab Performing Test: Special Bacteriology Laboratory; Georgia Public Health Laboratory (GPHL) in Decatur

Class Classification:

- Suspected: clinical purpura fulminans in the absence of a positive blood culture or gram-negative diplococci (not yet identified) isolated from a normally sterile body site
- Probable: Polymerase chain reaction (PCR) assay detection of *N. meningtidis* in normally sterile site; or detection of N. meningitidis in formalin-fixed tissue by immunohistochemistry (IHC) or in CSF by latex agglutination
- Confirmed: Isolation of *N. meningitidis* from a normally sterile site or from purpuric lesions

Period of Communicability: As long as organisms are present in discharge from the nose and mouth. Cases are considered non-infectious 24 hours after starting effective antibiotic therapy.

NEISSERIA MENINGITIDIS Q&A
(meningococcal disease)

What is meningococcal disease?

Meningococcal disease is caused by the *Neisseria meningitidis* bacteria. These bacteria are found only in humans. These are multiple meningococcal serogroups (types) but the most important of these are A, B, C, Y, & W-135. The two most common forms of meningococcal disease are meningitis, a bacterial infection of the fluid and covering of the spinal cord and brain; and septicemia, an infection of the bloodstream.

Who is at risk?

Risk groups for meningococcal disease include household contacts of case patients, military recruits, college freshmen living in dormitories, persons without a functional spleen or with complement component deficiency (a specific immune system problem), and people exposed to tobacco smoke. Rates of meningococcal disease are highest during infancy, then fall during childhood, and rise again during adolescence.

How are meningococcal bacteria spread?

The bacteria are transmitted from person-to-person in secretions from the nose and throat. They are not spread by casual contact or by simply breathing the air near an infected person, but require close contact. The bacteria can live outside the body for only a few minutes; so, if the germs contaminate a desk or book, they soon die and won't infect a person who touches it later. As many as 2 in 10 people carry the bacteria in the back of the nose and throat at any given time, especially in winter. Why only a very small number of those who have the bacteria in their nose and throat develop disease, while others remain healthy, is not understood.

What are the symptoms?

Meningitis is characterized by high fever, headache, and stiff neck. Other symptoms may include nausea, vomiting, confusion, sleepiness, and sensitivity to light. Sepsis causes high fever, low blood pressure, and severe malaise. Meningococcal sepsis is sometimes associated with a characteristic petechial or purpuric rash. Petechiae are pinpoint spots that do not blanch with pressure, and purpura are patches of bluish discoloration similar to bruises. Both are caused by bleeding into the skin.

Who should be vaccinated?

The Advisory committee on Immunization Practices (ACIP) recommends routine vaccination of all persons aged 11-18 years. College freshmen living in dormitories are also at increased risk for disease and should be vaccinated with MCV4 before college entry if they have not been vaccinated previously, or given a booster dose if they are vaccinated before the age of 16.

ACIP also recommends that persons age 2 to 55 years who are at increased risk for meningococcal disease be vaccinated with MCV4; MPSV4 is recommended for adults 56 years and older who are increased risk. This includes travelers to or residents of countries in which the disease is hyperendemic or epidemic, and individuals who have terminal complement component deficiencies or asplenia.

Does the vaccine prevent all meningococcal disease?

No, currently available vaccines do not protect against serogroup B meningococcal disease.

How can serogroup B meningococcal disease be prevented?

General meningococcal prevention measures include avoiding first and second-hand tobacco smoke, using cough etiquette, and minimizing shared saliva.

Vaccination:

A meningococcal polysaccharide vaccine (MPSV4) was licensed in 1981 to protect against serogroups A, C, Y and W-135, for persons ages 2 years and older. In 2005, a meningococcal conjugate vaccine (MCV4) was licensed for use in persons ages 11 to 55, which protects against the same four serogroups. MCV4 is the preferred product for persons ages 2 through 55, and MPSV4 should be used for adults 56 and older. The first dose of MCV4 is recommended at age 11-12, with a booster dose at 16-18. Only one dose of MCV4 is recommended for adults ages 19-21 who will be attending college, if previously unvaccinated. Persons ages 2 through 55 with persistent complement component deficiency or asplenia should receive an initial series of 2 doses of MCV4, 2 months apart, with a booster every 5 years. Persons with complement component deficiencies or asplenia age 56 and older should receive one dose of MPSV4 and a booster every 5 years. There is no vaccine to prevent serogroup B and non-groupable disease.

Investigation: The Bacterial Meningitis and Sepsis Investigation and Control Manual should be used to investigate suspected, probable, and confirmed cases of *Neisseria meningitidis.* Household members and close contacts in the 7 days before illness onset should be given prophylactic antibiotics; close contact is defined as having direct contact with saliva and respiratory secretions, such as kissing, sharing utensils or beverages, etc. The risk of secondary cases is highest within a few days after the index case occurs, but after 14 days, risk of secondary disease returns to baseline and prophylaxis is of little value.

1. **Prophylaxis and Follow-Up of Contacts:** Prophylaxis should be administered as soon as possible after exposure to a meningococcal disease case, and must occur within 14 days. Ciprofloxacin 500 to 750 mg PO once may be given to adults >18 years of age to eliminate nasopharyngeal carriage of *N. meningitidis*. Do not give to pregnant or lactating women
2. Rifampin is the preferred antibiotic for children and non-pregnant adults:
    - Non-pregnant adults: 600 mg PO q12h for 4 doses
    - Infants and children > 1 months: 10mg/kg (maximum 600mg) PO q12h for 4 doses
    - Infants < 1 month old: Rifampin 5mg/kg PO q12h for 4 doses
3. Ceftriaxone should be given if the client cannot take Rifampin:
    - Adults and children age 15 or older: 250 mg IM, once
    - Children < 15 years old: 125mg IM, once

Immunization with the appropriate meningococcal vaccine should be recommended according to the guidelines above and especially during an outbreak of a vaccine-preventable strain.

Reporting: Report all confirmed cases of invasive *N. meningitidis* IMMEDIATELY electronically through the State Electronic Notifiable Disease Surveillance System (SENDSS) at http://dhr.state.ga.us. All isolates should be forwarded to the Georgia Public Health Laboratory (GPHL) for serotyping.

Reported cases of invasive *Neisseria meningitidis* in Georgia, 2006-2011 (source: SENDSS)

Year	Number of cases
2006	21
2007	26
2008	18
2009	31
2010	12
2011	14

References:

1. Prevention and Control of Meningococcal Disease Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* Vol 54 (RR-7); 2005: 1-21.
2. Heymann, D ed. Meningococcal meningitis. In: Control of Communicable Diseases Manual. 19th ed. Washington, DC: American Public Health Association, 2008:415-421.
3. Americian Academy of Pediatrics. Meningococcal Infections. In: Peter, G. and Pickering, L, eds. 2012 Red Book: Report of the Committee on Infectious Diseases. 29th ed. Elk Grove, IL: American Academy of Pediatrics: 2012: 500-509
4. Case Definitions for infectious conditions under public health surveillance. *MMWR* Vol 46 (RR-10); 1-55.

PERTUSSIS FACT SHEET (WHOOPING COUGH)

Agent: The bacterium *Bordetella pertussis.*

Brief Description: An acute bacterial infection involving the respiratory tract. The initial (catarrhal) stage has insidious onset with irritating cough that can progress to severe paroxysms of cough (paroxysmal stage). Paroxysms are characterized by a series of many coughs without intervening inhalation, often followed by a high-pitched inspiratory "whoop" and vomiting.

Disease in infants younger than 6 months of age may be atypical; apnea is a common manifestation and whoop is often absent. Similarly, older children and adults can have atypical manifestations, with persistent cough and no whoop. In recent years in the United States, pertussis has been recognized with increasing frequency in adolescents and young adults. Many of these cases occur in previously immunized persons and indicate waning immunity following immunization.

Complications of pertussis include seizures, pneumonia, encephalopathy, and death. Disease rates and risk of serious complications, including death, are highest among young children, particularly those younger than 1 year of age.

Reservoir: Humans are believed to be the only host.

Mode of Transmission: By direct contact with discharges from respiratory mucous membranes of infected persons by the airborne route, probably by droplets.

Incubation Period: Commonly 7 to 10 days, range 4 to 21 days

Clinical Case Definition: In the absence of a more likely diagnosis, a cough illness lasting greater than or equal to 2 weeks with one of the following: paroxysms of coughing, inspiratory "whoop," or post-tussive vomiting

Lab Criteria for Diagnosis:

1. Isolation of *B. pertussis* from a clinical specimen
2. Positive polymerase chain reaction (PCR) for *B. pertussis*

Diagnostic Testing:

1. Culture and PCR are recommended for pertussis diagnosis.
2. Specimen needed: Nasopharyngeal (NP) swabs should be collected as soon as possible after illness onset, preferably before antibiotic treatment.
3. See **Appendix 1 for specimen collection and submission details and http://health.state.ga.us/epi/vpd/pertussis.asp**

Case Classification:

- **Probable:** meets the clinical case definition, is not laboratory confirmed, and is not epidemiologically linked to a laboratory-confirmed case
- **Confirmed:** a case that is culture positive and in which an acute cough illness of any duration is present; or a case that meets the clinical case definition and is confirmed by positive PCR; or a case that meets the clinical case definition and is epidemiologically linked directly to a case confirmed by either culture or PCR

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Period of Communicability: Highly communicable in the early catarrhal stage before paroxysmal cough. Thereafter communicability gradually decreases and becomes negligible after about 3 weeks (21 days), despite persisting spasmodic cough. When treated with appropriate antibiotics, the period of infectiousness is usually 5 days after onset of therapy.

Vaccination: Beginning in 1996 acellular pertussis vaccines were recommended for all doses in the pertussis vaccine series, replacing the whole-cell vaccines which previously had been used. All acellular vaccines are combined with diphtheria and tetanus toxoid (DTaP vaccine). Children should receive four doses of vaccine, with the first three doses administered at 4- to 8-week intervals, beginning at 6 weeks to 2 months of age. The fourth dose should be given 6-12 months after the third dose (17-20 months for Daptacel). Children who receive four doses of DTaP before their fourth birthday should receive a booster dose of DTaP at 4 to 6 years of age. In children younger than seven years old, DTaP vaccines efficacy ranges from 71% to 84%. Tdap vaccine is a formulation licensed for use in persons ages 10-64, and should be given as a one-time dose in lieu of a booster dose of Td. For more detailed vaccination information for either Tdap or DTaP, see Diphtheria, Tetanus, and Pertussis Vaccine Guidelines in Chapter 2 of this manual.

Investigation:

I. Obtain the following information immediately in order to perform a risk assessment to gauge index of suspicion.

1. Immunization history
2. Exposure history (any possibility the suspect case was around a confirmed or probable case of pertussis 21 days prior to becoming ill)
3. Obtain detailed description of the clinical presentation:
   - History of cough including onset date
   - Onset of coryza, cyanosis, whoop, post-tussive vomiting or presence of apnea.

II. Confirm the diagnosis. See “Diagnostic Testing” section.

III. Conduct epidemiology investigation*

1. Ensure isolation of case and counsel immediate contacts to avoid contact with high-risk groups until 5 days of antibiotic treatment is completed.
2. Determine period of communicability (one week before to three weeks after cough onset)
3. Interview case to identify possible contacts (i.e. household, school, childcare, work, healthcare facility). Specific definitions of contact will vary according to the situation.

   Transmission occurs by close contact with a case via aerosolized droplets and can be expected with:
   - Direct face-to-face contact for a period (not defined) with a case who is symptomatic (e.g., in the catarrhal or paroxysmal period of illness)
   - Shared confined space in close proximity for a prolonged period of time, such as ≥ 3 hour, with a symptomatic case.
   - **Chemoprophylaxis should be provided to all household contacts regardless of vaccination history; and anyone with prolonged close contact with a case (several hours in a confined space).**

PERTUSSIS FACT SHEET (WHOOPING COUGH)

4. Refer contacts to health department, pharmacy or primary care physician for prophylaxis.
5. If period of prophylaxis has passed (21 days, except in high risk cases), counsel contacts to call their health provider if they develop respiratory symptoms and/or cough.
6. Work with Georgia Department of Public Health and State Pharmacy (District pharmacies in certain Districts) to ensure availability of adequate antibiotics for contacts.

IV. Conduct surveillance for secondary cases and contacts.

* Note that the steps are not ordered by priority since several of these steps are conducted simultaneously.

Treatment and Prophylaxis:

The following treatment/prophylaxis recommendations are from "Recommended Antimicrobial Agents for the Treatment and Postexposure Prophylaxis of Pertussis, 2005 CDC Guidelines" (see citation). The choice of antimicrobial for treatment or prophylaxis should take into account effectiveness, safety (including the potential for adverse events and drug interactions), tolerability, ease of adherence to the regimen prescribed, and cost. All close contacts of cases should receive chemoprophylaxis regardless of their immunization status. Please refer to the article for additional details regarding treatment and prophylaxis (http://www.cdc.gov/pertussis/pubs-tools/pubs-textbooks.html or see citation). Table 4 lists the recommended antimicrobial treatment and postexposure prophylaxis by age group:

TABLE 4. Recommended antimicrobial treatment and postexposure prophylaxis for pertussis, by age group

	Primary agents			Alternate agent*
Age group	Azithromycin	Erythromycin	Clarithromycin	TMP-SMZ
<1 month	Recommended agent. 10 mg/kg per day in a single dose for 5 days (only limited safety data available.)	Not preferred. Erythromycin is associated with infantile hypertrophic pyloric stenosis. Use if azithromycin is unavailable; 40–50 mg/kg per day in 4 divided doses for 14 days	Not recommended (safety data unavailable)	Contraindicated for infants aged <2 months (risk for kernicterus)
1–5 months	10 mg/kg per day in a single dose for 5 days	40–50 mg/kg per day in 4 divided doses for 14 days	15 mg/kg per day in 2 divided doses for 7 days	Contraindicated at age <2 months. For infants aged ≥2 months, TMP 8 mg/kg per day, SMZ 40 mg/kg per day in 2 divided doses for 14 days
Infants (aged ≥6 months) and children	10 mg/kg in a single dose on day 1 then 5 mg/kg per day (maximum: 500 mg) on days 2–5	40–50 mg/kg per day (maximum: 2 g per day) in 4 divided doses for 14 days	15 mg/kg per day in 2 divided doses (maximum: 1 g per day) for 7 days	TMP 8 mg/kg per day, SMZ 40 mg/kg per day in 2 divided doses for 14 days
Adults	500 mg in a single dose on day 1 then 250 mg per day on days 2–5	2 g per day in 4 divided doses for 14 days	1 g per day in 2 divided doses for 7 days	TMP 320 mg per day, SMZ 1,600 mg per day in 2 divided doses for 14 days

* Trimethoprim sulfamethoxazole (TMP–SMZ) can be used as an alternative agent to macrolides in patients aged ≥2 months who are allergic to macrolides, who cannot tolerate macrolides, or who are infected with a rare macrolide-resistant strain of *Bordetella pertussis*.

PERTUSSIS FACT SHEET (WHOOPING COUGH)

Reporting: Report cases **IMMEDIATELY** by phone to the local health department, District Health Office, or the State Epidemiology Section at 404-657-2588. If calling after regular business hours, cases can be reported to 1-866-PUB-HLTH. After a verbal report has been made, please transmit the case information electronically through the State Electronic Notifiable Disease Surveillance System (SENDSS) at http://sendss.state.ga.us. Please be sure to complete all data fields in SENDSS, including the case report form.

Reported Pertussis Cases (Probable and Confirmed) in Georgia, 2001-2011

Year	Number of Cases
2001	23
2002	29
2003	36
2004	71
2005	78
2006	102
2007	37
2008	116
2009	230
2010	247
2011	180

References:

1. American Academy of Pediatrics. Pertussis. In: Pickering, LK, Baker CJ, Kimberlin DW, Long SS, eds. 2009 Red Book: Report of the Committee on Infectious Diseases. Elk Grove Village, IL: American Academy of Pediatrics; 2012: 553-566.
2. Use of diphtheria toxoid-tetanus toxoid-acellular pertussis vaccine as a five-dose series: supplemental recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* Vol. 49(RR-13); 2000: 1-8.
3. Centers for Disease Control and Prevention. Pertussis. Manual for the surveillance of vaccine-preventable diseases. Centers for Disease Control and Prevention, Atlanta, GA, 2012.
4. Heymann, ed. Pertussis. In: Control of Communicable Diseases Manual. 18th Ed. Washington, DC: American Public Health Association, 2004: 399-404.
5. Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Hamborsky J, Wolfe S, eds. 12th ed, second printing. Washington DC: Public Health Foundation; 2012: 215-232.
6. CDC. Recommended Antimicrobial Agents for Treatment and Postexposure Prophylaxis of Pertussis, 2005 Guidelines. *MMWR* Vol. 54(RR-14), 2005:1-16.
7. CDC. Updated Recommendations for the Use of Tetanus Toxoid, Reduced Diptheria Toxoid and Acellular Pertussis (Tdap) Vaccine from the Advisory Committee on Immunization Practices, 2010. *MMWR* 2011;60(01):13-15.

PERTUSSIS FACT SHEET (WHOOPING COUGH)

Links:

- CDC Pertussis – http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/pert.pdf
- CDC National Center for Immunization and Respiratory Diseases – http://www.cdc.gov/vaccines/
- Tetanus, Diptheria or Tetanus, Diptheria, Pertussis Vaccine Information Statement - http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-td-dtap.pdf
- Recommended Antimicrobial Agents for the Treatment and Postexposure Prophylaxis of Pertussis - http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5414a1.htm

PERTUSSIS SPECIMEN COLLECTION & SUBMISSION

APPENDIX 1: PERTUSSIS SPECIMEN COLLECTION AND SUBMISSION

Specimen Collection

A swab of nasopharyngeal secretions is the optimal specimen for confirming a pertussis diagnosis. Specimens should be collected as soon as possible after onset of illness, preferably before antibiotic treatment. Dacron®, rayon, or nylon-flocked (not cotton or calcium alginate) swabs are superior to other types of swabs and are recommended. A culture is the preferred test to confirm pertussis and requires a special transport medium (Regan-Lowe). The State Epidemiology Section currently distributes Regan-Lowe media to the District Health Departments regularly. Alternative diagnostics, such as Polymerase Chain Reaction (PCR) are useful as an adjunct but should not replace culture particularly for definitive diagnosis such as in an outbreak situation. Please consult with the State Epidemiology Section at 404-657-2588 for questions about diagnostics for pertussis.

Regan-Lowe Media

Regan-Lowe medium is used to transport specimens to the laboratory for culture and is available in each District. The medium should be stored in a refrigerator at 2-8 °C. Regan-Lowe medium should be removed from the refrigerator and warmed to room temperature before use. Consult the District Epidemiologist and/or the State Epidemiology Section to obtain Regan-Lowe media.

Nasopharyngeal Swab Procedure and Specimen Preparation

1. Immobilize the patient's head.
2. Pass nasopharyngeal swab very gently into a nostril until the posterior nares is reached.
3. Leave the swab in place for up to 10 seconds (this may induce a cough and in practice only a few seconds may be possible.) If resistance is encountered during insertion of the swab, remove it and attempt insertion on the opposite nostril.
4. **Remove the swab slowly.** Insert and immerse swab into the Regan-Lowe transport medium.
5. Cut the handle end of the swab extending above the transport tube if necessary and cap the container tightly.
6. Label the Regan-Lowe tube with the patient's name and date of specimen collection.
7. A second swab (Dacron, polyester or rayon) must be used for a PCR test. Follow steps 1 – 4 for specimen collection.

PERTUSSIS SPECIMEN COLLECTION & SUBMISSION

Requisition Forms
Use Form #3410 (Bacteriology) to request culture and Form #3409 (Molecular Biology) to request PCR. It is extremely important that the forms are completed entirely. Please include the following information:

1. Patient name
2. Date of specimen collection
3. Test requested (culture for B. pertussis and B. parapertussis and or PCR for B. pertussis)
4. Submitter's name and address
5. Name and telephone number of clinician to contact
6. Source of specimen, such as nasopharyngeal
7. Patient's race, sex, age, and address, if available
8. Brief clinical history, if available

Specimen Transport

Culture and DFA: Place Regan-Lowe media tube in a plastic biohazard bag. Insert requisition form in the front pouch of the bag. Place the bag with form affixed in the orange-labeled cardboard mailing container (Decatur address). Seal the lid of the outside container with tape. The specimens should be transported (room temperature) to the Bacteriology Unit immediately by courier or via Federal Express or UPS. If the shipment is delayed, the specimens should be refrigerated at 2-8 degrees Celsius and then sent the next day on ice packs by first class mail, common carrier, or courier.

Shipping Addresses:
Bacteriology Unit
Georgia Public Health Laboratory
1749 Clairmont Rd.
Decatur, Ga. 30033-4050
Attn: Lynett Poventud

PCR: Place sterile container securely in a plastic biohazard bag. Insert requisition form in the front pouch of the bag. Place the bag with the form affixed in the orange-labeled cardboard mailing container (Decatur address). Seal the lid of the outside container with tape. The specimens should be transported (room temperature) to the Molecular Biology Unit immediately by courier or via Federal Express or UPS. If the shipment is delayed, the specimens should be refrigerated at 2-8 degrees Celsius and then sent the next day on ice packs by first class mail, common carrier, or courier.

Shipping Address:
Molecular Biology Unit
Georgia Public Health Laboratory
1749 Clairmont Rd.
Decatur, Ga. 30033-4050
Attn: Harjinder Ghuman

PERTUSSIS QUESTIONS & ANSWERS

PERTUSSIS Q&A
(Whooping cough)

What is pertussis?
Pertussis, or whooping cough, is a highly contagious disease involving the respiratory tract. It is caused by a bacterium that is found in the mouth, nose and throat of an infected person.

Who gets pertussis?
Pertussis can occur at any age. Seventy-five percent of reported cases occur in children under five years of age and 50 percent of these are in children under one year of age. However, pertussis can occur in adolescents and adults because of waning immunity, and may manifest as milder illness.

How is pertussis spread?
Pertussis is primarily spread by direct contact with discharges from the nose and throat of infected individuals or by contact with airborne droplets of respiratory secretions. Frequently, older siblings who may be harboring the bacteria in their nose and throat can bring the disease home and infect an infant in the household.

What are the symptoms of pertussis?
Pertussis begins as a mild upper respiratory infection. Initially, symptoms resemble those of a common cold, including sneezing, runny nose, low-grade fever and a mild cough. Within two weeks, the cough becomes more severe and is characterized by episodes of numerous rapid coughs followed by a high-pitched whoop. These episodes may recur for one to two months, and are more frequent at night. Older people or partially immunized children generally have milder symptoms.

How soon after infection do symptoms appear?
The incubation period is usually 7 to 10 days but can be anywhere from 4 to 21 days.

When and for how long is a person able to spread pertussis?
A person can transmit pertussis from seven days following exposure to three weeks after the onset of coughing episodes. The period of communicability is reduced to five days once antibiotic therapy is begun.

Does past infection with pertussis make a person immune?
No. Immunity from disease or vaccination is not lifelong but lasts approximately 7-10 years.

What are the complications associated with pertussis?
Complications of pertussis may include pneumonia, middle ear infection, dehydration, loss of appetite, seizures, encephalopathy (disorders of the brain), apneic episodes (brief cessation of breathing) and death.

What is the treatment for pertussis?
Antibiotics may be given to shorten the period of time that an infected person can transmit the infection to others, but antibiotics do not reduce symptoms except when given before or shortly after symptoms develop.

PERTUSSIS QUESTIONS & ANSWERS

How can pertussis be prevented?
The single most effective control measure is maintaining the highest possible level of immunization in the community. The vaccine for pertussis is usually given in combination with diphtheria and tetanus. For more detailed vaccination information for either Tdap or DTaP, see Diphtheria, Tetanus, and Pertussis Vaccine Guidelines in Chapter 2 of this manual.

Treatment of cases with certain antibiotics such as azithromycin can shorten the contagious period. People who have or may have pertussis should stay away from young children and infants until properly treated.

Where can I get additional information on pertussis?
Contact the Georgia Division of Public Health, Epidemiology Branch, by email at gaepinfo@dhr.state.ga.us. The following web sites may be useful:

- CDC Pertussis – http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/pert.pdf
- National Center for Immunization and Respiratory Diseases – http://www.cdc.gov/pertussis/index.html
- Diphtheria, Tetanus, and Pertussis Vaccine Information Statement - http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-dtap.pdf
- Georgia Division of Public Health, Epidemiology Section – http://health.state.ga.us/epvpd/

POLIOMYELITIS FACT SHEET
(INFANTILE PARALYSIS, POLIO)

Agent: Poliovirus serotypes 1, 2, and 3.

Brief Description: A highly contagious viral infection with manifestations ranging from inapparent infection to non-specific febrile illness, aseptic meningitis, paralytic disease and death. Symptoms include fever, headache, sore throat, gastrointestinal upset, malaise, and stiffness of neck and back. In approximately 0.1% to 2% of cases, symptoms include a flaccid paralysis typified by absent deep tendon reflexes; in approximately 1 out of 250 cases, residual neurologic symptoms occur, including paralysis.

Reservoir: Humans.

Mode of Transmission: Primarily person-to-person spread, principally through the fecal-oral route but also by the respiratory route; fecal-oral transmission occurs in situations where sanitation is poor. However, where sanitation is good, pharyngeal spread may be more apparent. In rare instances, milk, foodstuffs and other materials contaminated with feces have been incriminated as vehicles. There is no reliable evidence of spread by insects; sewage and water are rarely implicated.

Incubation Period: Usually 6 to 20 days, with a range of 3 to 35 days.

Clinical Case Definition: Acute onset of a flaccid paralysis of one or more limbs with decreased or absent tendon reflexes in the affected limbs, without other apparent cause, and without sensory or cognitive loss.

Laboratory Criteria for Diagnosis: Case confirmation is based on a clinical definition. However, a probable case can be supported by laboratory information. Diagnosis is made by isolation of the organism from throat, stool, rectum, cerebrospinal fluid (CSF), or blood. The highest probability of isolation is achieved when two stool and throat specimens are obtained twenty-four hours apart. These should be sent to the Georgia Public Health Laboratory for primary isolation. The state laboratory will forward isolates to the Centers for Disease Control and Prevention (CDC) for Polymerase Chain Reaction (PCR) and antibody blocking testing to determine intratypic variation. This will determine whether a paralytic polio case is derived from wild-type or vaccine related virus.

Diagnostic Testing:

A. Culture
   1. Specimen Needed: Stool, throat swab, rectal swab, CSF, or blood.
   2. Outfit: Viral culture outfit, order #575.
   3. Form: 3595.
   4. Lab Test Performed: Isolation and identification of poliovirus.
   5. Lab Performing Test: State Virology Laboratory, Georgia Public Health Laboratory (GPHL) in Decatur, followed by intratypic differentiation performed at the CDC.
   6. Transport Requirements: Collect within 72 hours of onset of symptoms; specimens should be frozen immediately and shipped on dry ice.

POLIOMYELITIS FACT SHEET
(INFANTILE PARALYSIS, POLIO)

Comment: Isolation of wild-type virus constitutes a public health emergency and appropriate control measures must be initiated immediately (in consultation between health care providers, state and local health departments, and CDC).

B. Serology

1. Specimen Needed: Acute and convalescent sera, or whole blood.
   a. Acute sera: 2-3 cc collected as soon as possible after onset of illness.
   b. Convalescent sera: 2-3 cc whole blood collected 14-21 days after acute phase of illness.
2. Outfit: Serology, order #504.
3. Form: 3432.
4. Lab Test Performed: Neutralizing antibody titers to poliovirus serotype 1, 2, and 3.
5. Lab Performing Test: CDC with prior arrangement by the Georgia Public Health Laboratory. Do not submit specimens directly to CDC. All specimens must be submitted to the Georgia Public Health Laboratory.

Case Classification:

- **Probable:** A case that meets the clinical case definition.
- **Confirmed:** A case that meets the clinical case definition and in which the patient has a neurologic deficit 60 days after onset of initial symptoms, has died, or has unknown follow-up status.

Vaccination: There are two types of polio vaccine: the Inactivated Polio Vaccine (IPV) and the Oral Polio Vaccine (OPV). The IPV is given intramuscularly or subcutaneously, and OPV, a live attenuated virus, is given orally. The Advisory Committee for Immunization Practices (ACIP) recommends a four-dose schedule of IPV for routine immunization of infants and children. The first three are given at two-month intervals beginning at 2 months of age (the third dose can be given between 6 and 18 months.) The fourth dose is given at age 4 to 6 years, before entering school. For more detailed vaccination information see Polio Vaccine Guidelines in Chapter 2 of this manual.

Oral polio vaccine (OPV) is no longer routinely recommended in the United States because of the continued risk for vaccine-associated paralytic poliomyelitis (VAPP), the absence of indigenous disease, and the low risk for wild poliovirus importation into the United States. OPV is no longer available for routine vaccination in the U.S.

Most adults in the United States are at low risk for polio due to immunizations received in childhood. Certain adults are at high risk however, and should be vaccinated. These adults are:

1. Travelers to areas or countries where polio may be epidemic or endemic.
2. Members of communities with disease caused by wild-type polio.
3. Laboratory workers handling specimens that may contain wild-type polio.
4. Health-care personnel in close contact with patients who may be excreting wild-type polio.
5. Unvaccinated adults whose children will be receiving oral poliovirus vaccine.

POLIOMYELITIS FACT SHEET
(INFANTILE PARALYSIS, POLIO)

Period of Communicability: Not accurately known, but transmission is possible as long as virus is excreted. Virus is demonstrable in the throat as early as 36 hours after exposure and in the feces 72 hours after exposure to infection in both clinical and inapparent cases. Virus persists in the throat for approximately 1 week and in the feces for 3 to 6 weeks or longer. Cases are most infectious during the first few days before and after onset of symptoms.

Treatment: None except attention during the acute illness to the complications of paralysis.

Investigation: The State Epidemiology Section will give instructions regarding investigation when a case is reported by phone. The following information should be collected as part of the investigation:

1. Demographic Information: The name, age, sex, race, occupation, and address (county, city and zip code) of the patient.

2. Immunization History: The number, dates and lot numbers of previous doses of inactivated polio vaccine (IPV) and the number, dates, type (monovalent versus trivalent) and lot numbers of previous doses of oral polio vaccine (OPV). Information on the number, site and types of injections given at either the time of vaccination or within 30 days after vaccination should also be collected.

3. Clinical Information: A brief description of the patient's illness including the date of onset of paralysis. Information should include the course of the illness and the sites of paralysis or other complications.

4. Immunologic Status: Since persons with some immune deficiency diseases are at increased risk of paralytic poliomyelitis, known immune deficiency either in the patient or patient's family should be documented. If any doubt exists, an immunologic evaluation (quantitative immunoglobulins, T and B cell quantitation, lymphocyte transformation, etc.) should be considered.

5. Exposure History:
    a. History of recent travel of the patient or a close contact outside of the United States to an endemic or epidemic area for poliomyelitis.
    b. History of contact with any known cases of poliomyelitis and the date of contact, if applicable.
    c. History of receipt of OPV by the patient within 30 days prior to onset, including the date of receipt and the lot number of the vaccine.
    d. History of contact within 30 days prior to onset of symptoms with any person who received OPV within the last 60 days prior to onset, including the date of contact, the nature of the contact, the date the contact received OPV, the lot number of the vaccine, the age of the contact, and the relationship to the patient. Information regarding the contact's prior history of immunization with IPV should also be collected.

POLIOMYELITIS FACT SHEET
(INFANTILE PARALYSIS, POLIO)

6. Laboratory Data: For the diagnosis of suspected cases, original specimens are most desirable because special methods are used to determine if viruses other than polioviruses are present. Types of laboratory tests are described above in "Diagnostic Testing."

Reporting: Report cases **IMMEDIATELY** by phone to the local health department, District Health Office, or the State Epidemiology Section at 404-657-2588. If calling after regular business hours, it is very important to report cases to the Epidemiology Section answering service, or call 1-800 PUB-HLTH. After a verbal report has been made, please transmit the case information electronically through the State Electronic Notifiable Disease Surveillance System (SENDSS) at http://sendss.state.ga.us.
Please be sure to complete all data fields in SENDSS including the case report form.

Reported Cases of Poliomyelitis in Georgia, 2001-2010

No cases of polio have been reported in Georgia between 2001 and 2010.

References:

1. American Academy of Pediatrics. Polio. In: Pickering, LK, Baker CJ, Kimberlin DW, Long SS, eds. 2009 Red Book: Report of the Committee on Infectious Diseases. Elk Grove Village, IL: American Academy of Pediatrics; 2012: 588-592..
2. CDC. Case Definitions for Infectious Conditions Under Public Health Surveillance. *MMWR* Vol. 46(RR10); 1997: 1-55.
3. Centers for Disease Control and Prevention. Manual for the surveillance of vaccine-preventable diseases. Centers for Disease Control and Prevention, Atlanta, GA, 2012.
4. Centers for Disease Control and Prevention. Poliomyelitis Prevention in the United States. Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* Vol. 49(RR-5); 2000: 1-22.
5. CDC: Updated Recommendations of the ACIP Regarding Routine Poliovirus Vaccination. *MMWR* Vol. 58(30); 829-830.
6. Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Hamborsky J, Wolfe S, eds. 12th ed., second printing. Washington DC: Public Health Foundation, 2012:249-262
7. Heymann, ed. Poliomyelitis, Acute. In: Control of Communicable Diseases Manual. 18th ed. Washington, DC: American Public Health Association, 2004: 399-404.
8. Edwards E, Grant C, Huang Q, Powell K, Croxson M. A case of vaccine-associated paralytic poliomyelitis. J Paediatr Child Health Vol. 36(4); 2000: 408-11.

Links:

- CDC National Center for Immunization and Respiratory Diseases - http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/polio.pdf

POLIOMYELITIS QUESTIONS AND ANSWERS (INFANTILE PARALYSIS, POLIO)

POLIOMYELITIS Q&A
(Infantile paralysis, Polio)

What is polio?
Polio is a viral disease that may affect the central nervous system. Complications include paralysis (most commonly of the legs). Paralysis of the muscles of respiration and swallowing can be fatal. Since polio immunization has become widespread, cases of polio are very rare.

Who gets polio?
Polio is more common in infants and young children and occurs under conditions of poor hygiene. However, paralysis is more common and more severe when infection occurs in older individuals. In exceedingly rare cases, oral polio vaccine can cause paralytic polio in a person who receives the vaccine (one in every 2.4 million doses).

How is polio spread?
Polio is predominately spread from person to person through the fecal-oral route when community or personal hygiene is imperfect.

What are the symptoms of polio?
Infection with poliovirus can range from inapparent to a severe paralytic disease that may result in death. Symptoms include fever, malaise, headache, nausea and vomiting, excruciating muscle pain and stiffness in the neck and back.

How soon after infection do symptoms appear?
The incubation period is usually 6 to 20 days, with a range of 3 to 35 days.

When and for how long is a person able to spread the poliovirus?
Patients are most infectious from 7 to 10 days before and after the onset of symptoms. However, patients are potentially contagious as long as the virus is present in the throat and feces. The virus persists in the throat for approximately one week after onset of illness and is excreted in feces for several weeks or, occasionally, months.

Does past infection with polio make a person immune?
There are three types of poliovirus. Lifelong immunity usually depends on which type of virus one is infected with. Second attacks are rare and result from infection with a poliovirus of a different type than the first attack.

What is the treatment for polio?
There is presently no cure for polio. Treatment involves supportive care.

How can polio be prevented?
Maintaining high levels of polio immunization in the community is the single most effective preventive measure. Two types of polio vaccine are available: trivalent oral polio vaccine (OPV) and inactivated polio vaccine (IPV). However, in the United States IPV is the vaccine of choice and OPV is not readily available. Contact the Georgia Immunization Program at 404-657-3158 for current vaccine recommendations.

POLIOMYELITIS QUESTIONS AND ANSWERS
(INFANTILE PARALYSIS, POLIO)

Where can I get additional information on polio?
Contact the Georgia Division of Public Health, State Epidemiology Section, by email at gaepinfo@dhr.state.ga.usor by calling 404 657-2588. If you have Internet access, the following web site may be useful:

CDC National Immunization Program–
http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/polio.pdf

RUBELLA FACT SHEET
(German Measles)

Agent: Rubella virus.

Brief Description: A mild febrile viral disease with a diffuse punctate (pinpoint) and maculopapular rash sometimes resembling that of measles or scarlet fever. Children usually present few or no constitutional symptoms, but adults may experience a 1 to 5 day prodrome of low grade fever, headache, malaise, mild coryza, and conjunctivitis. Rubella is important because of its ability to produce anomalies in the developing fetus. These abnormalities are termed Congenital Rubella Syndrome (CRS). Congenital rubella syndrome occurs when a pregnant mother becomes infected and passes the virus to her fetus. The primary congenital defects are ophthalmologic (cataracts, glaucoma, retinopathy), cardiac (patent ductus arteriosus, peripheral pulmonary artery stenosis), auditory (sensorineural deafness) and neurologic (behavioral disorders, meningoencephalitis, mental retardation). Other congenital defects include radiolucent bone disease and growth retardation. The occurrence of these defects is 50% if the mother is infected in the first month of pregnancy, 20% to 30% if infected in the second month and 5% if infected in the third to fourth month. Defects are rare when maternal infection occurs after the 20th week.

Reservoir: Humans.

Mode of Transmission: Contact with nasopharyngeal secretions of infected persons. Infection is transmitted by droplet spread or direct contact with patients. Infants with congenital rubella syndrome shed large quantities of virus from body secretions for up to one year, and can therefore serve as a source of infection for susceptible persons caring for them. Rubella may also be transmitted by sub-clinical cases (approximately 30% to 50% of all rubella infections).

Incubation Period: 14 days, with a range of 12 to 23 days.

Period of Communicability: Rubella is moderately contagious. The disease is most contagious as the rash is erupting, but can be transmitted about 1 week before to 5-7 days after onset of rash. Infected children should be excluded from school until 7 days after rash onset.

Clinical Case Definition: An illness with ALL of the following characteristics:

- Acute onset of generalized maculopapular rash, and
- Temperature > 37.2° C (99° F), if measured, and
- Arthralgia, arthritis, lymphadenopathy, or conjunctivitis.

Lab Criteria for Diagnosis:

- Isolation of rubella virus, or
- Positive serologic test for rubella IgM antibody, or
- Significant rise in rubella IgG antibody level by any standard serologic assay, or
- PCR positive for rubella virus

Diagnostic Testing:

A. Serology

1. Specimen: Blood - acute sera (at least 5cc whole blood) for IgM and IgG titers collected at the onset of illness and convalescent sera (IgG) collected 14-21 days later. Please note that a single IgM test will confirm the diagnosis. False-positive

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(German Measles)

rubella IgM tests have been found in persons with parvovirus infections, a positive heterophile test for infectious mononucleosis, or a positive rheumatoid factor.

2. Outfits: Other serology outfit, order #504.
3. Form: 3432.
4. Lab Test Performed: Titers for Rubella - IgG and IgM (must write IgM request on the form).
5. Lab Performing Test: Immunology Laboratory, Georgia Public Health Laboratory (GPHL) in Decatur.
6. Transport Requirements: Sera can be kept at ambient temperature, refrigerated, or frozen. Specimen should be non-hemolyzed.

B. Culture / Polymerase Chain Reaction (PCR)

1. Specimen: Nasopharyngeal swab/aspirate, throat, urine, or cerebrospinal fluid (CSF).
2. Outfit: Viral transport media.
3. Form: #3595.
4. Lab Test Performed: Culture or PCR.
5. Lab Performing Test: Virology Laboratory, GPHL in Decatur.
6. Transport Requirements: Specimen should be kept in viral transport medium.

Case Classification:

- **Suspect**: any generalized rash illness of acute onset.
- **Probable**: a case that fits the clinical case definition, has no or noncontributory serologic or virologic testing, and is not epidemiologically linked to a laboratory-confirmed case.
- **Confirmed**: a case that is laboratory confirmed or that meets the clinical case definition and is epidemiologically linked to a laboratory-confirmed case.

Note: Cases meeting the measles case definition are excluded. Also excluded are cases with serology that is compatible with recent measles virus infection. All rubella cases should be confirmed by a laboratory test (serology).

Vaccination: Children should receive rubella vaccine at 12-15 months of age, and 4-6 years of age. It is usually given combined with measles and mumps vaccine as MMR or MMRV. Adults born in 1957 or later should receive at least one dose of MMR vaccine unless they have documentation of vaccination with at least one MMR, or other acceptable evidence (laboratory results) of immunity to measles, mumps, and rubella. Efforts should be made to identify and vaccinate susceptible adolescents and adults, particularly women of childbearing age who are not pregnant. Women who are pregnant or who plan to become pregnant within one month should not receive the vaccine, due to the theoretical risk for causing birth defects in the developing fetus. Emphasize vaccinating susceptible males and females in colleges, employment and health care settings. For more detailed vaccination information, see Measles, Mumps, and Rubella Vaccine Guidelines in Chapter 2 of this manual.

RUBELLA FACT SHEET
(German Measles)

Post-exposure Prophylaxis: Live attenuated vaccine given after exposure **has not** been demonstrated to prevent illness. However, non-pregnant people exposed to rubella may still theoretically benefit from the vaccine if given up to three days after exposure. Immunization of a person who is incubating natural rubella or who already is immune is not associated with increased risk of adverse effects. The risk of congenital rubella when a pregnant woman is exposed is significant. Exposed pregnant women **should not** be given live virus vaccine. An intramuscular dose of 20 ml of immune globulin (IG) may decrease clinically apparent infection, but no studies show that such a dose protects the fetus. It should only be used in cases where therapeutic abortion is not an option.

Treatment: None.

Investigation:

Case Investigation:

1. **Establish a diagnosis**: Because the clinical diagnosis of rubella is unreliable, cases **must** be confirmed by a laboratory test.
2. **For adult women, obtain accurate pregnancy status**: All women of childbearing age should be evaluated for pregnancy status. If a pregnant woman is infected, immediate referral to her medical care provider is necessary.
3. **Obtain an accurate and complete immunization history**.
4. **Identify the source of infection**: Case-patients and their caregivers should be asked about contact with other known cases. Since 20%-50% of cases are asymptomatic, identification of a source will not always be possible.
5. **Assess potential for transmission and identify contacts**: Contacts of case-patients during the infectious period (7 days before to 7 days after rash onset) should be identified. Transmission can occur in households, communities, workplaces, and prisons.
6. **Obtain specimens for virus isolation**: Nasopharyngeal swabs and urine should be collected within 4 days after rash onset and submitted for virus isolation. Isolates are essential to identify virus types and track the epidemiology of rubella in the United States, especially as we progress towards elimination of the virus in geographical regions.
7. **Laboratory evaluation of exposed pregnant women**: Pregnant women who have been exposed should have serologic testing (an IgG and IgM test) at the time of exposure, an IgG titer 2 to 3 weeks later, and another IgG titer 6 weeks after exposure. If the first IgG test is positive, the woman is immune. If the first test is negative, the second and third test will determine whether infection has occurred in the absence of an IgM test. A positive IgM indicates a recent or acute infection.
8. **Pregnancy Outcome Registry for women diagnosed with rubella during pregnancy**: All pregnant women infected with rubella during pregnancy should be monitored to document the pregnancy outcome (e.g., termination, CRS, or normal infant) on Centers for Disease Control and Prevention (CDC) Form 71.17, “Congenital Rubella Case Report Form,” and forward to the State Epidemiology Section.

RUBELLA FACT SHEET
(German Measles)

Outbreak Investigation:

Strategies to control rubella outbreaks include defining at-risk populations, ensuring susceptibles are rapidly vaccinated, and maintaining active surveillance for new cases. Outbreak control measures should be implemented immediately when **one case of rubella is confirmed** in a community.

Reporting: Report all suspect, probable or confirmed cases **IMMEDIATELY** by phone to the local health department, District Health Office, or the State Epidemiology Section at 404-657-2588. If calling after regular business hours, report cases to 1-866- PUB-HLTH. After a verbal report has been made, please transmit the case information electronically through the State Electronic Notifiable Disease Surveillance System (SENDSS) at http://sendss.state.ga.us. Please complete all data fields in SENDSS including the case report form. Additionally, Districts should report all congenital rubella cases on CDC Form 71.17, "Congenital Rubella Case Report Form," and forward to the State Epidemiology Section.
**(Georgia code requires notification of rubella diagnosis within 7 days; however, immediate notification enables a prompt case investigation and public health response.)

Reported Cases of Rubella in Georgia, 2001-2011

Year	Number of Cases
2001	1
2002	0
2003	0
2004	1
2005	0
2006	0
2007	0
2008	0
2009	0
2010	0
2011	0

References:

1. American Academy of Pediatrics. Rubella. In: Pickering, LK, Baker CJ, Kimberlin DW, Long SS, eds. 2009 Red Book: Report of the Committee on Infectious Diseases. Elk Grove Village, IL: American Academy of Pediatrics; 2012: 629-634.
2. CDC. Case Definitions for Infectious Conditions Under Public Health Surveillance. *MMWR* Vol. 46(RR10), 1997: 1-55.
3. Centers for Disease Control and Prevention. Rubella. Manual for the surveillance of vaccine-preventable diseases. Centers for Disease Control and Prevention, Atlanta, GA, 2012.
4. Heymann, ed. Rubella. In: Control of Communicable Diseases Manual. 18th ed. Washington, DC: American Public Health Association, 2004: 464-469.

Links:

- CDC National Center for Immunizations and Respiratory Diseases Information – http://www.cdc.gov/vaccines/vpd-vac/rubella/in-short-adult.htm
- CDC's Epidemiology and Prevention of Vaccine-Preventable Diseases – http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/rubella.pdf

RUBELLA QUESTIONS & ANSWERS (German Measles)

RUBELLA Q&A
(German measles)

What is rubella?
Rubella is a viral disease characterized by slight fever, rash and swollen glands. Very few to no cases are reported in Georgia each year.

Who gets rubella?
In unvaccinated populations, rubella is primarily a childhood disease. Where children are well immunized, adolescent and adult infections become more evident. Rubella occurs more frequently in winter and spring.

How is rubella spread?
Rubella is spread by direct contact with nasal or throat secretions of infected individuals.

What are the symptoms of rubella?
Rubella is a mild illness that may present with few or no symptoms. Symptoms may include a rash, slight fever, joint aches, headache, discomfort, runny nose and reddened eyes. The lymph nodes just behind the ears and at the back of the neck may swell causing some soreness and/or pain. The rash, which may be itchy, first appears on the face and progresses from head to foot, lasting about three days. As many as half of all rubella cases occur without a rash.

How soon do symptoms appear?
The incubation period for rubella ranges from 12 to 23 days. However, in most cases symptoms appear within 14 days.

When and for how long is a person able to spread rubella?
Rubella may be transmitted from seven days before to four days after the onset of rash.

Does past infection with rubella make a person immune?
Yes. Immunity acquired after contracting the disease is usually permanent.

When is the vaccine for rubella needed?
Rubella vaccine is given on or after a child's first birthday, but is recommended at 12 months of age when given in combination with measles vaccine. The vaccine can be given alone or in a one-shot combination vaccine that protects against measles, mumps and rubella (MMR) or measles, mumps, rubella, and varicella (MMRV). A second dose of MMR is recommended at age 4 to 6 years, to produce immunity in those who failed to respond to the first dose.

What can be the effect of not being immunized against rubella?
Rubella infection is serious due to its potential to cause birth defects. Infection in a pregnant woman may result in miscarriage, stillbirth, or the birth of an infant with abnormalities that may include deafness, cataracts, heart defects, liver and spleen damage, and mental retardation. These abnormalities are defined as “congenital rubella syndrome” (CRS) and occur in at least 25 percent of infants born to women who have had rubella during the first trimester of pregnancy.

RUBELLA QUESTIONS & ANSWERS (German Measles)

What can be done to prevent the spread of rubella?
Maintaining high levels of rubella immunization in the community is critical to controlling transmission of the virus when sporadic cases or outbreaks occur. Prevention of rubella is especially important in susceptible pregnant women to prevent the birth defects caused by CRS. Therefore, women of childbearing age who have not been vaccinated should receive one rubella vaccine. **Women known to be pregnant or attempting to become pregnant should not receive rubella vaccine.** Although there is no evidence that rubella vaccine causes birth defects, pregnancy should be avoided for 1 month after rubella or MMR vaccine. Infected children should not attend school when they are infectious; infected children may return to school 7 days after rash onset.

Where can I get additional information on rubella?
Contact the Georgia Division of Public Health, Epidemiology Section, by email at gaepinfo@dhr.state.ga.us or by calling 404 657-2588. The following web sites may be useful:

- CDC National Center for Immunization and Respiratory Diseases Rubella Information – http://www.cdc.gov/vaccines/vpd-vac/rubella/in-short-adult.htm
- CDC's Epidemiology and Prevention of Vaccine-Preventable Diseases – http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/rubella.pdf
- Georgia Department of Public Health, Vaccine-Preventable Diseases Epidemiology Unit - http://health.state.ga.us/epi/vpd/

STREPTOCOCCUS PNEUMONIAE FACT SHEET
(Invasive Disease, Reported Syndrome and Susceptiblility Information)

Agent: *Streptococcus pneumoniae* (Pneumococcus)

Brief Description: *Streptococcus pneumoniae* causes many clinical syndromes, depending on the site of infection (e.g., acute otitis media, pneumonia, bacteremia, or meningitis). Pneumococci are increasingly likely to be resistant to one or several antibiotics, including penicillin, doxycycline, erythromycin, azithromycin, trimethoprim-sulfamethoxazole, and cephalosporins. Invasive disease caused *S. pneumoniae* is notifiable with microbial susceptibility information requested.

Reservoir: Humans. The pneumococcus asymptomatically colonizes the nasopharynx of 5-40% of healthy people.

Mode of Transmission: By droplet spread, direct oral contact, or through contact with articles freshly soiled with respiratory discharges. Person-to-person transmission of the organism is common, but illness among casual contacts and attendants is infrequent. Disease results when the organism multiplies locally (e.g., otitis media), multiplies after aspiration (pneumonia) or invades a sterile site (e.g., central nervous system or bloodstream).

Incubation Period: Variable. For pneumococcal pneumonia, approximately 1 to 3 days.

Laboratory Criteria for Diagnosis:
For invasive disease:

- Isolation of *S. pneumoniae* from a normally sterile site (e.g., blood, cerebrospinal fluid, or, less commonly, joint, pleural, or pericardial fluid)

Case Classification:

- Probable: a clinically compatible case without laboratory confirmation or with isolation of *S. pneumoniae* from a non-sterile site.
- Confirmed: a clinically compatible case with a laboratory confirmed isolation of *S. pneumoniae* from a normally sterile site.

Period of Communicability: Presumably until discharges of mouth and nose no longer contain virulent pneumococci in significant numbers. This can be a prolonged period among immunocompromised persons.

Vaccine: The polyvalent pneumococcal polysaccharide vaccine (PPSV) is recommended for all adults over age 65 and any individuals 2 years of age or older with chronic medical conditions that place them at high risk for pneumococcal disease. PPSV is not effective in children under age 2. The 13-valent pneumococcal conjugate vaccine (PCV13) was licensed for use in February 2010 and is recommended for infants and young children up to five years of age. Children who have begun their immunization series with the 7-valent pneumococcal conjugate vaccine (PCV7) should complete the series with PCV13 when available. PPV23, PCV7, and PCV13 provide protection against commonly resistant pneumococcal strains. For more detailed vaccination information, see Pneumococcal Vaccine Guidelines in Chapter 2 of this manual.

Treatment: Sensitivities of strains isolated from normally sterile sites should be determined because of increasing prevalence of drug-resistant pneumococci. Where diagnostic facilities are limited and delay in treatment could prove fatal, antibiotic treatment should be started presumptively based on clinical signs.

STREPTOCOCCUS PNEUMONIAE FACT SHEET
(Invasive Disease, Reported Syndrome and Susceptiblility Information)

Reporting: Report all confirmed cases of invasive *Streptococcus pneumoniae* WITHIN 7 DAYS electronically though the State Electronic Notifiable Disease Surveillance System (SENDSS) at http://sendss.state.ga.us. Please be sure to complete all data fields. Antibiotic susceptibilities are also reportable though SendSS for *S. pneumoniae*.

References and Further Reading:

1. Preventing Pneumococcal Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2000; 49 (No. RR-9): 1-38.
2. Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1997; 46 (No. RR-8): 1-24.
3. Geographic Variation in Penicillin Resistance in *Streptococcus pneumoniae* -- Selected Sites, United States, 1997. *MMWR* 1999; 48(30): 656-661.
4. Outbreaks of Pneumococcal Pneumonia Among Unvaccinated Residents in Chronic-Care Facilities—Massachusetts, October 1995, Oklahoma, February 1996, and Maryland, May-June 1996. *MMWR* 1997; 46(03): 60-62.
5. Defining the Public Health Impact of Drug-resistant *Streptococcus pneumoniae*: Report of a Working Group. *MMWR* 1996; 45 (No. RR-1): 1-14.
6. Case Definitions for Infectious Conditions under Public Health Surveillance. *MMWR* 1997; 46(RR10): 1-55.
7. Heymann, ed. Pneumonia. In: Control of Communicable Diseases Manual. 19th ed. Washington, DC: American Public Health Association, 2008:
8. National Committee for Clinical Laboratory Standards. Performance standards for antimicrobial susceptibility testing. Villanova, PA: National Committee for Clinical Laboratory Standards, 1994; 14(16).
9. Mandell, Bennett, and Dolin. The Principles and Practice of Infectious Diseases. 5th Ed., Philadelphia, PA, 2000:pp. 2128-2147.
10. Licensure of a 13-Valent Pneumococcal Conjugate Vaccine (PCV13) and Recommendations for Use Among Children – Advisory Committee on Immunization Practices (ACIP), 2010. *MMWR* 2010:59(09):258-261.

Links:

- CDC *Streptococcus pneumoniae* Fact Sheet – http://www.cdc.gov/ncidod/dbmd/diseaseinfo/streppneum_t.htm
- National Foundation for Infectious Diseases Drug-resistant *Streptococcus pneumoniae* Fact Sheet – http://www.nfid.org/factsheets/drsp.html
- CDC Antimicrobial Resistance Web Site – http://www.cdc.gov/drugresistance/
- Alliance for the Prudent Use of Antibiotics --- http://www.tufts.edu/med/apua/
- Vaccine Information Statement – Pneumococcal Conjugate Vaccine – http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-pcv.pdf

STREPTOCOCCUS PNEUMONIAE FACT SHEET
(Invasive Disease, Reported Syndrome and Susceptiblility Information)

STREPTOCOCCUS PNEUMONIAE Q&A
(Pneumococcal disease)

What is invasive *Streptococcus pneumoniae*?
Streptococcus pneumoniae (also called pneumococcus) is a bacterium that frequently causes pneumonia (lung infection), otitis media (ear infection), bloodstream infection, and meningitis. Invasive *S. pneumoniae* infections affect body sites that normally contain no bacteria at all, such as blood, spinal fluid, joint, pleural, or pericardial fluid.

Who gets pneumococcal infections?
Pneumococcal disease is most common at the extremes of age. Infections are also more common and severe in people with weakened immune systems such as persons undergoing chemotherapy or with HIV infection, or people with chronic diseases such as sickle cell disease, diabetes, chronic lung disease, or congestive heart failure. Blacks, American Indians and Alaska Natives are also at higher risk.

What are the symptoms of a pneumococcal infection?
Symptoms of pneumococcal pneumonia include abrupt onset of fever, shaking chills, chest pain, productive cough, shortness of breath, and weakness. Signs of pneumococcal meningitis include headache, drowsiness, vomiting, irritability, fever, stiff neck, and seizures. Ear infection can cause fever and ear pain or discharge.

How soon do symptoms appear?
Symptoms of infections caused by pneumococcus take a minimum of 1 to 3 days to develop after exposure.

When and for how long is a person able to spread *S. pneumoniae*?
A person can spread the organism as long as the pneumococci are present in the discharges from the nose and mouth. Illness among casual contacts of a person with pneumococcal disease is infrequent.

How can pneumococcal disease be prevented?
Three pneumococcal vaccines are available. PPV23 protects against infections caused by common strains of *S. pneumoniae*. It is recommended for everyone age 65 and older, and for people age 2 years and older with underlying health conditions making them more susceptible to *S. pneumoniae* infections. The other two pneumococcal vaccines, PCV7 and PCV13, prevent disease in infants and young children. PCV13 is newly licensed and is effective against more strains of *S. pneumoniae* than PCV7. PCV7 and PCV13 are recommended for use in children under 5 years old.

What is drug-resistant *Streptococcus pneumoniae*?
Drug-resistant *Streptococcus pneumoniae* (DRSP) are strains of the common bacterium *S. pneumoniae* (also called pneumococcus) that have become resistant to a variety of antibiotics. Some strains are resistant to only one antibiotic, while other strains are resistant to many antibiotics, making infection with these strains more difficult to treat.

STREPTOCOCCUS PNEUMONIAE FACT SHEET
(Invasive Disease, Reported Syndrome and Susceptiblility Information)

How common is DRSP?
Surveillance studies by the Centers for Disease Control and Prevention have shown that in the U.S., DRSP strains have been increasing in frequency since 1987. In some communities, 40% of *S. pneumoniae* isolates are resistant to at least one drug, and strains causing infections may be resistant to several antibiotics. DRSP strains in Georgia are more common than in many other parts of the U.S.

What caused these strains of bacteria to become resistant to antibiotics?
Many experts believe that overuse of antibiotics contributes to the development of DRSP strains. Antibiotics are sometimes used to treat infections caused by viruses (such as colds and bronchitis), which are not killed by antibiotics. Once DRSP is in the community, use of antibiotics may "select" the resistant strains for survival.

Where can I get additional information on pneumococcal disease?
Contact the Georgia Division of Public Health, Epidemiology Section, by email at gaepinfo@dhr.state.ga.us or call 404 657-2588. The following web sites may also be useful:

- CDC *Streptococcus pneumoniae* Fact Sheet – http://www.cdc.gov/ncidod/dbmd/diseaseinfo/streppneum_t.htm
- National Foundation for Infectious Diseases Drug-Resistant *Streptococcus pneumoniae* Fact Sheet – http://www.nfid.org/factsheets/drsp.html
- CDC Antimicrobial Resistance Web Site – http://www.cdc.gov/drugresistance/

TETANUS FACT SHEET
(LockJaw)

Agent: The bacterium, *Clostridium tetani*.

Brief Description: Tetanus is an acute, often fatal disease caused by an exotoxin produced by the anaerobic organism C. tetani in a contaminated wound. Increased muscle rigidity and severe muscle spasms characterize tetanus. The muscle stiffness usually first involves the jaw (lockjaw) and neck, and later becomes generalized. Muscle spasms may continue for 3-4 weeks or more. Other symptoms include fever, sweating, elevated blood pressure, and rapid heart rate.

Reservoir: Intestines of humans, as well as the intestines of horses and other animals, in which the organism is a normal inhabitant. Tetanus spores are ubiquitous in the environment and can contaminate wounds of all types. Soil or fomites contaminated with animal and human feces can also be reservoirs.

Mode of Transmission: Tetanus spores are introduced into the body through: (1) puncture wounds; (2) lacerations, burns, trivial or unnoticed wounds in which fecally-contaminated soil containing C. tetani spores penetrates body tissues; or (3) by injected contaminated street drugs.

Incubation Period: Usually 3 to 21 days, although it may range from 1 day to several months, depending on the wound. The average is 8 days, and most cases occur within 14 days. Shorter incubation periods have been associated with more heavily contaminated wounds, more severe disease, and a worse prognosis.

Period of Communicability: Not transmitted from person-to-person.

Clinical Case Definition: Acute onset of hypertonia and/or painful muscular contractions (usually of the muscles of the jaw and neck) and generalized muscle spasms without other apparent medical cause.

Laboratory Criteria for Diagnosis: Attempts at laboratory confirmation are of little help. The organism is rarely recovered from the site of infection, and there is usually no detectable antibody response. The diagnosis is entirely clinical and does not depend upon bacteriologic confirmation.

Diagnostic Testing: Not indicated.

Case Classification:

- **Confirmed:** A clinically compatible case, as reported by a health-care professional.

Vaccination: Primary tetanus immunization with diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) is recommended for all persons at least 6 weeks old, but < 7 years of age, for whom the vaccine is not contraindicated. For those with allergies to pertussis vaccine, a diphtheria and tetanus toxoid vaccine is available (DT). The primary vaccination consists of a three-dose series, administered at ages 2, 4, and 6 months. The fourth dose (first booster) is recommended at 15-18 months of age to maintain adequate immunity during preschool years. The fifth dose (second booster) is recommended for children aged 4-6 years to confer continued protection against disease during the early years of schooling. Routine tetanus booster immunization, with tetanus toxoid usually combined with adult-diphtheria toxoid (Td), is recommended for all persons ≥ 7 years of age every 10 years. Persons aged 10-64 years may get a one-time dose of Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis)

TETANUS FACT SHEET
(LockJaw)

in lieu of one booster dose of Td. For more detailed vaccination information, see Diphtheria, Tetanus, and Pertussis Vaccine Guidelines in Chapter 2 of this manual.

Treatment: Tetanus Immune Globulin (TIG) IM, in doses of 3,000-6,000 IU. The wound should be properly cleaned, debrided, and excised if necessary. Metronidazole (30 mg/kg per day, given at 6-hour intervals) is the antibiotic of choice and should be given for 7-14 days. Active immunization should be initiated concurrently with therapy. Tetanus clinical disease does not confer immunity because of the small amount of toxin required to produce illness.

Post-exposure Prophylaxis: For routine wound management, wounds that are "dirty" should be treated with TIG IM unless the patient has had three or more doses of the tetanus vaccine. "Dirty" wounds include those contaminated with dirt, feces, soil, or saliva, puncture wounds, avulsions, and wounds resulting from missiles, crushing, burns, or frostbite. For all wounds, clean or dirty, a dose of Td should be given if the patient has had less than three doses of the vaccine. If patients have had three or more doses, the decision to give Td should be based on the amount of time since the last vaccine was given. If the wound is clean, the patient should receive Td unless he or she has had the vaccine within the last ten years. If the wound is dirty, give Td unless he or she has had the vaccine within the last five years. The wound should be cleaned and debrided as described under "Treatment."

Investigation: The Tetanus Surveillance Worksheet may be used as a guideline. The investigation should include identification of age at onset, the circumstances of any previous injury, tetanus toxoid vaccination history, and determination of the patient's status (alive, dead) at one-month after onset of disease.

Reporting: Report all cases **WITHIN 7 DAYS** electronically through the State Electronic Notifiable Disease Surveillance System (SENDSS) at http://sendss.state.ga.us. Please complete all data fields in SENDSS including the case report form.

Reported Cases of Tetanus in Georgia, 2001-2011

Year	Number of Cases
2001	0
2002	0
2003	0
2004	2
2005	0
2006	0
2007	2
2008	0
2009	0
2010	0
2011	0

TETANUS FACT SHEET
(LockJaw)

References:

1. American Academy of Pediatrics. Tetanus. In: Pickering, LK, Baker CJ, Kimberlin DW, Long SS, eds. 2012 Red Book: Report of the Committee on Infectious Diseases. Elk Grove Village, IL: American Academy of Pediatrics; 2012: 707-712.
2. Case Definitions for Infectious Conditions under Public Health Surveillance. *MMWR* 1997; 46(No. RR-10): 39-40.
3. Tetanus among injecting drug users – California, 1997. *MMWR* 1998; 47(08): 149-151.
4. Centers for Disease Control and Prevention. Tetanus. Manual for the surveillance of vaccine-preventable diseases. Centers for Disease Control and Prevention, Atlanta, GA, 2012.
5. Heymann, ed. Tetanus. In: Control of Communicable Diseases Manual. 18th ed. Washington, DC: American Public Health Association, 2004: 528-534.
6. Tetanus Surveillance – United States, 2001-2008. MMWR, April 1, 2011, vol 60(12)365-9.

Links:

1. CDC Tetanus Fact Sheet - http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/tetanus.pdf
2. CDC National Center for Immunization and Respiratory Diseases – http://www.cdc.gov/vaccines/vpd-vac/tetanus/default.htm

VARICELLA FACT SHEET

Agent: Varicella zoster virus (VZV)

Brief Description: Primary varicella infection is characterized by a generalized, pruritic, vesicular rash typically consisting of 250 to 500 lesions in varying stages of development and resolution (crusting). In some infected individuals a low-grade fever may precede the rash. Varicella severity and complications are increased among immunocompromised persons, children younger than 1 year of age, and adults. Adults and immunocompromised persons are most at risk for developing serious complications. Complications can include bacterial superinfection of skin lesions, pneumonia, encephalitis, cerebellar ataxia, Reye syndrome, and death.

Breakthrough varicella is a case of wild-type varicella infection that occurs more than 42 days after an individual is vaccinated with varicella vaccine. This disease is usually mild with a shorter duration of illness, absence of fever, and fewer than 50 skin lesions. The rash may not become vesicular (fluid-filled blister) or itchy.

Reservoir: Humans

Mode of Transmission: Airborne, by droplet spread, or by direct contact with secretions from the nose, throat or vesicular lesions of an infected person. Spread may also occur by contact with articles that have been soiled by fluid from lesions.

Incubation Period: Commonly 14 to 16 days, range 10 to 21 days

Period of Communicability: Persons with varicella are considered infectious from 1 to 2 days before rash onset until all lesions are crusted (usually about 5 days). Varicella is one of the most readily communicable diseases, especially just before and in the early stages of eruption. Breakthrough cases may sometimes be as infectious as natural varicella, particularly if the rash is extensive and contains vesicles.

Exposure: In general, exposure to varicella is defined as contact with nasopharyngeal secretions or vesicular lesions, face-to-face interaction, or sharing indoor airspace with an infectious person.

Clinical Case Definition: An illness with acute onset of diffuse (generalized) maculopapulovesicular rash without other apparent cause.

Note: In vaccinated persons who develop breakthrough varicella more than 42 days after vaccination, the disease is almost always mild with fewer than 50 skin lesions and shorter duration of illness. The rash may also be atypical in appearance (maculopapular with few or no vesicles).

VARICELLA FACT SHEET

Case Classification:

- **Probable**: A case that meets the clinical case definition, is not laboratory confirmed, and is not epidemiologically linked to another probable or confirmed case.

- **Confirmed**: A case that is laboratory confirmed or that meets the clinical case definition and is epidemiologically linked to a confirmed or probable case.

Note: Two probable cases that are epidemiologically linked are considered confirmed cases

Lab Criteria for Diagnosis:
- Positive polymerase chain reaction (PCR) for VZV

Note: Routine laboratory testing to diagnose varicella in each case is not generally recommended, but testing may be useful in special circumstances to confirm the diagnosis or to determine varicella susceptibility.

Diagnostic Testing: P

A. Polymerase Chain Reaction
   a. Specimen needed: crusts (scab), vesicular fluid or cells from the base of a lesion (**See Appendix 1 for specimen collection and submission details**)
   b. Outfit: n/a
   c. Form: #3409
   d. Lab Test Performed: VZV (rt-PCR)
   e. Lab Performing Test: State Molecular Biology Laboratory, Georgia Public Health Laboratory (GPHL), in Decatur
   f. Transport Requirements: The specimen can be submitted dry, preferably in a sterile container. Please notify the Epidemiology Section at 404-657-2588 before sending the specimen, as PCR testing is available by request only from the state office.

Immunity:
Evidence of immunity to varicella includes:
1. Documentation of age-appropriate vaccination
2. Laboratory evidence of immunity or laboratory confirmation of disease
3. Born in the United States before 1980 (for healthcare providers and pregnant women, this does not suffice as evidence of immunity)
4. A healthcare provider diagnosis of varicella or verification of history of varicella disease

5. History of herpes zoster based on healthcare provider diagnosis

Vaccination: A vaccine for varicella was licensed in 1995. It is recommended that all children without contraindications be vaccinated between 12 and 15 months of age and receive a second dose between 4 and 6 years of age. The second dose may be administered earlier than 4 through 6 years of age if at least 3 months have elapsed following the first dose. However, if the second dose is administered at least 28 days following the first dose, the second dose does

VARICELLA FACT SHEET

not need to be repeated. Healthy people over the age of 13 who have no history of chickenpox and have never been vaccinated against the disease should get two doses of the vaccine four to eight weeks apart.

Post-exposure Prophylaxis: Varicella vaccine is effective in preventing infection or modifying the severity of illness if given within 72 hours and possibly up to 120 hours after varicella exposure. Antiviral drugs are not typically recommended for prophylaxis.

Varicella zoster immune globulin (VZIG) is no longer available. An investigational product (VariZIG) can be given under an investigational new drug protocol within 96 hours of exposure to susceptible persons at high risk for developing severe varicella. The patient groups recommended by the ACIP to receive VariZIG include immunocompromised persons, pregnant women, and neonates whose mothers have varicella 5 days before to 2 days after delivery, and certain preterm infants.

Treatment: Supportive.

Note: Acyclovir and similar agents can reduce the duration and severity of illness if given within 24 hours of rash onset. These drugs should be considered for treatment of immunocompromised persons and other persons at high risk for severe varicella. (See 2009 AAP Red Book)

Investigation:

1. Establish a diagnosis of varicella
2. Obtain an accurate and complete immunization history
3. Identify the source of infection
4. Assess potential transmission and identify contacts
5. Identify persons at high risk for developing severe disease (e.g., immunocompromised persons, pregnant women)
6. Complete the varicella case report form

Outbreak Control:

1. Notify the Epidemiology Section by calling 404-657-2588
2. Collect specimens to confirm the outbreak. (See Diagnostic Testing Section above and Appendix)
3. Identify transmission setting
4. Use the diagram below to help determine cases' period of infection and communicability

Incubation: 2 to 3 weeks; commonly 14 – 16 days			**Rash**	**Communicability**
-3 weeks	-2 weeks	-1 week	Rash Onset	+ 5 days
Onset of rash minus 14 (10-21) days is probable exposure. Date: / /		May have no prodrome before rash, but infectious period still begins 2 days prior to rash. Date: / /	Rash emerges in 2-4 crops over 3-4 days, vesicles in each crop need up to 24 hours to become crusted. Date: / /	Until all lesions have crusted (typically up to 5 days after rash onset) Date: / /

VARICELLA FACT SHEET

5. Obtain accurate and complete immunization histories for those exposed
6. Identify those most at-risk for developing severe disease (e.g. unvaccinated individuals, immunocompromised persons and pregnant women)
7. Vaccinate susceptible persons.
8. Consider VariZIG for susceptible persons for whom vaccination is contraindicated – refer to physician
9. Exclude susceptible persons from the setting

Note: Exclusions of susceptible persons should be considered on a case-by-case basis.

For further information on varicella case investigation and outbreak control please see the Varicella Outbreak and Control Manual at:

http://health.state.ga.us/pdfs/epi/vpd/Varicella%20Outbreak%20Recommendations%20Protocol.pdf

Reporting: Single cases of wild-type varicella and breakthrough varicella are reportable within 7 days.

References:

1. American Academy of Pediatrics. Varicella. In: Pickering, LK, Baker CJ, Kimberlin DW, Long SS, eds. 2009 Red Book: Report of the Committee on Infectious Diseases. Elk Grove Village, IL: American Academy of Pediatrics; 2012: 774-789.
2. Centers for Disease Control and Prevention. Varicella. Manual for the surveillance of vaccine-preventable diseases. Centers for Disease Control and Prevention, Atlanta, GA, 2012.
3. CDC. General recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2011; 60 (No. RR-2): 1-64.
4. Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Hamborsky J, Wolfe S, eds. 12th ed., second printing. Washington DC: Public Health Foundation, 2012: 301-324.
5. Grossman, L, Eds. Varicella-Zoster Virus. In: Infection Control in the Child Care Center and Preschool. 6th Ed. Philadelphia, PA: Lippincott, Williams and Wilkins; 2003: 317-323.

Links:

- CDC Pink Book: Varicella Chapter — http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/varicella.pdf
- CDC VPD Surveillance Manual, 5th Ed.: Varicella Chapter — http://www.cdc.gov/vaccines/pubs/surv-manual/chpt17-varicella.pdf
- GDPH Varicella webpage — http://health.state.ga.us/epi/vpd/varicella.asp
- GDPH Varicella Outbreak and Control Manual — http://health.state.ga.us/pdfs/epi/vpd/Varicella%20Outbreak%20Recommendations%20Protocol.pdf

VARICELLA QUESTIONS & ANSWERS

What is varicella (chickenpox)?
Varicella (chickenpox) is a contagious, vaccine-preventable disease caused by the varicella zoster virus (VZ).

Who gets varicella?
Before the vaccine became available, almost everyone got varicella. Anyone who has not had the disease and has not received the varicella vaccine can get varicella. However, no vaccine is 100% effective and some individuals who have been vaccinated can still get varicella, although it is usually much milder.

How is varicella spread?
Varicella is spread through the respiratory tract. The most common mode of transmission is by person to person from infected respiratory tract secretions. Transmission may also occur by respiratory contact with airborne droplets or by direct contact or inhalation of aerosols from skin lesions of acute disease.

What are the symptoms of varicella?
In children, the first sign of varicella is often a rash, though adults may have 1-2 days of fever and fatigue before the rash begins. The rash is itchy, and usually appears first on the head, followed by the trunk and then the limbs. Initially maculopapular, it evolves into fluid-filled vesicles which last 3-4 days before crusting. There may be 2-4 successive crops of lesions. Children often also develop fever and fatigue, which last 2-3 days.

How soon do symptoms appear?
Symptoms usually appear in 14 to 16 days, although they may occur as early as 10 or as late as 21 days after exposure.

How long is a person with varicella contagious?
Varicella is most contagious two days before the rash appears until all blisters are crusted over (typically 5 days).

What complications are associated with getting varicella?
Varicella is usually mild and self-limited, but it may be associated with complications. Secondary bacterial infections of skin lesions with *Staphylococcus* or *Streptococcus* and pneumonia are the most common causes of hospitalization. Complications from varicella are higher in infants, persons older than 15 years of age, unvaccinated pregnant women and in immunocompromised persons such as those with HIV infection, leukemia and lymphoma.

Does past infection make a person immune?
No. The varicella vaccine is 70 to 90% effective in preventing disease and being vaccinated with 2 doses can prevent severe disease in 95% of persons. There is still a small chance of getting the disease even after vaccination, but it is infrequent and usually a much milder illness.

Is there treatment for varicella?
The treatment for varicella is primarily supportive. Treatment depends on a person's age, health and severity of illness. A primary care physician should be seen to discuss treatment options.

VARICELLA QUESTIONS & ANSWERS

Is there a vaccine for varicella?
A vaccine for varicella is available. It is recommended that all children be routinely vaccinated between 12 and 18 months of age and receive a second dose between 4 and 6 yrs. of age. Healthy people over the age of 13 who have no history of varicella and have never been vaccinated against the disease should get two doses of the vaccine four to eight weeks apart.

Since varicella is usually not serious, why not let people get the disease?
It is never possible to predict who will have a mild case of varicella and who will have a serious or even deadly case of the disease. Now that a safe and effective vaccine is available, it is not worth taking a chance.

Where can I get additional information on varicella?
Contact the Georgia Department of Public Health, Epidemiology Section by email at gaepinfo@dhr.state.ga.us or call 404 657-2588.. The following web sites may be useful:

- CDC National Center for Immunizations and Respiratory Diseases – http://www.cdc.gov/vaccines/vpd-vac/varicella/dis-faqs-gen.htm
- GDPH Varicella webpage — http://health.state.ga.us/epi/vpd/varicella.asp

VARICELLA SPECIMEN COLLECTION AND SUBMISSION

APPENDIX 1: VARICELLA SPECIMEN COLLECTION AND SUBMISSION

Routine laboratory testing to diagnose varicella in each case is not generally recommended, but testing may be useful in special circumstances to confirm the diagnosis or to determine varicella susceptibility. To coordinate specimen collection and laboratory submission, call your District or County Health Department. **Please do not send specimens directly to the Georgia Public Health Laboratory (GPHL) or the Centers for Disease Control and Prevention (CDC).**

Specimen Collection Instructions:

Viral Testing: To make a laboratory diagnosis of VZV infection using the polymerase chain reaction (PCR) method, the presence of viral DNA should be demonstrated in tissues, vesicular fluid or crusts from lesions. We recommend the following methods for the collection of specimens for PCR testing. As noted below, scabs generally contain sufficient viral DNA for amplification and as such are also useful specimens.

Polyester Swab Method

- Use a sterile needle to unroof the top of the vesicle
- Use a **synthetic,** sterile swab to vigorously swab the base of the lesion, applying enough pressure to collect epithelial cells without causing bleeding, and collect vesicular fluid (collection of infected epithelial cells at the base of the lesion is important because they usually contain a significant amount of virus).
- Place swab into empty tube, breakage-resistant snap-cap, or screw top tube
- DO NOT PLACE TRANSPORT MEDIUM INTO THE TUBE; THE SPECIMEN MUST BE KEPT DRY
- Specimen can remain at room temperature

Glass Slide Method

- Rake the edge of the glass slide over the selected lesion to disrupt it
- Press the flat surface of the slide against the opened lesion, rocking it back and forth several times (with young children it may be less stressful if you ask them to help with this)
- Air-dry the specimen
- Place glass slide in a container that protects against breakage. Cardboard mailers work well
- Specimen can remain at room temperature

Crusts (Scabs)

- Remove a scab from the patient
- Place specimen into empty tube, breakage-resistant snap cap, or screw top tube
- Specimen can remain at room temperature

Laboratory Submission Instructions

- Notify County or District Public Health Office **immediately** for coordination.
- Label specimen transport tube with the patient name and date of birth
- **UNLABELED SPECIMENS WILL NOT BE TESTED**
- Complete the Molecular Biology lab submission form: http://health.state.ga.us/pdfs/lab/manual/Molecular%20Form%203409.pdf

VARICELLA SPECIMEN COLLECTION AND SUBMISSION

with the following information:

- Submitter code (if known), address, phone number, and contact name
- Patient name, address, date of birth, sex, race and ethnicity (if available)
- Date of specimen collection, type of specimen, reason for testing, date of illness onset
- Molecular Biology Form: Test requested – VZV (PCR)

- Ship specimens to the following address :
  Georgia Public Health Laboratory
  1749 Clairmont Road
  Decatur, GA 30033-4050
  ATTN: Molecular Biology Laboratories

Interpretation of Results

Sequence analysis of a RT-PCR product derived from a virus isolate or from clinical material confirms the presumptive positive PCR results and provides epidemiologically important information

Influenza Resources

RESOURCES FOR INFLUENZA PREVENTION AND CONTROL

PREVENTING INFLUENZA

Vaccination remains the primary method of preventing influenza infection or lessening the severity of influenza. Because circulating influenza strains change from year to year, a new vaccine is manufactured each year. For complete protection individuals must receive a new influenza vaccine annually. October to November is the ideal time for influenza vaccination, especially for persons at higher risk of developing complications from influenza, such as residents of long-term care facilities (LTCF). Persons who did not receive an influenza vaccine during the ideal time should still be immunized throughout the influenza season to achieve some protection. **Employees of LTCF are also strongly advised to be vaccinated to reduce the chance of their spreading influenza to residents.** LTCF visitors should be encouraged to receive influenza vaccine. In fact, given that influenza vaccine is more effective at preventing disease among young, healthy adults than among the elderly, vaccination of workers and visitors may be more effective in preventing disease among LTCF residents than vaccination of the residents themselves.

Listed below are the three manufacturers of influenza vaccine with contact information for ordering. The ideal time to order influenza vaccine for the upcoming flu season is in the spring, as most manufacturers' stocks are pre-booked by May.

- sanofi pasteur (www.sanofipasteur.com) 1-800-822-2463
- Novartis (www.chiron.com) 1-800-244-7668
- Medimmune (www.medimmune.com) 1-877-633-4411
- GlaxoSmithKline (www.gskvaccines.com) 1-866-475-8222

DIAGNOSING INFLUENZA

Numerous infectious agents cause flu-like symptoms, making influenza diagnosis difficult on clinical grounds. A verified diagnosis of influenza requires a positive real-time polymerase chain reaction (RT-PCR) test, which may take up to 4 hours. Several rapid tests for influenza have been developed with variable sensitivities and specificities. Some of these rapid tests can provide results as fast as 10 minutes and may be useful in a LTCF setting to attempt to quickly document the cause of an outbreak of influenza-like illness. While negative rapid test results **do not** rule out influenza virus as the causative agent, a single positive test result in a LTCF setting strongly indicates an outbreak is due to influenza. If rapid tests are being used, PCR tests **should still** be done for confirmation and to identify the strain and antigenic characteristics of the virus. Public health officials can provide molecular specimen submission kits to an LTCF during an outbreak and arrange for viral testing at the Georgia Public Health Laboratory. Call your local health department **immediately** if an influenza outbreak is suspected in a LTCF. Public health does not supply rapid tests for influenza.

Influenza Resources

Table 1 describes the various laboratory tests available for documenting influenza infection[1]. Long-term care facilities might consider stocking some of the rapid tests available for point-of-care use.

Table 1. Laboratory Diagnostic Procedures for Influenza

Procedure	Influenza Virus Types Detected	Acceptable Specimens	Test Time	Point-of-care Market
Viral culture	A and B	NP[2] swab/aspirate, nasal swab/aspirate/wash, throat swab, bronchioalveolar lavage	3-10 days[3]	NO
Immunofluorescence [Direct Fluorescent Antibody (DFA) or Indirect Fluorescent Antibody (IFA) Staining]	A and B	NP[2] swab/aspirate, nasal swab/aspirate/wash, throat swab,	2-4 hours	NO
RT-PCR[5]	A and B	NP[2] swab/aspirate, nasal swab/aspirate/wash, throat swab, bronchioalveolar lavage sputum	2-4 hours	NO
Serology*	A and B	paired acute and convalescent serum samples[6]	2 weeks or more	NO
Enzyme Immuno Assay (EIA)	A and B	NP[2] swab/aspirate, nasal swab/aspirate/wash, throat swab,	2 hours	NO
Rapid Influenza Diagnostic Tests				
3M™ Rapid Detection Flu A+B Test[7,9](3M)	A and B	NP[2] swab/aspirate; Nasal wash/aspirate	15 minutes	YES
Directigen™ Flu A+B[7,9] (Becton-Dickinson)	A and B	NP[2] wash/aspirate/swab; lower nasal swab; throat swab; bronchioalveolar lavage	Less than 15 minutes	YES
Directigen™ EZ Flu A+B[7,9] (Becton-Dickinson)	A and B	NP[2] wash/aspirate/swab; throat swab	15 minutes	YES
BinaxNOW® Influenza A&B[7,8,9] (Alere)	A and B	NP[2] swab Nasal wash/aspirate/swab	15 minutes	YES
Clearview Exact® II Influenza A &B[7,9](Alere)	A and B	Nasal swab	15 minutes	YES
OSOM® Influenza A&B[7,9] (Genzyme)	A and B	Nasal swab	10 minutes	YES
QuickVue® Influenza Test[4,8] (Quidel)	A or B	Nasal wash/aspirate/swab	10 minutes	YES
QuickVue® Influenza A+B Test,[8,9] (Quidel)	A and B	NP[2] swab, nasal wash/ aspirate/swab	10 minutes	YES
SAS™ FluAlert A&B[8,9] (SA Scientific)	A and B	Nasal wash/aspirate	15 minutes	YES

Influenza Resources

SAS™ FluAlert A[4,8] (SA Scientific)	A only	Nasal wash/aspirate	15 minutes	YES
SAS™ FluAlert B[4,8] (SA Scientific)	B only	Nasal wash/aspirate	15 minutes	YES
TRU FLU®[7,9] (Bioscience)	A and B	NP[2] aspirate/swab Nasal wash	15 minutes	YES
XPECT™ Flu A&B[7,9] (Remel/Thermofisher)	A and B	Nasal wash/swab, throat swab	15 minutes	YES

Serology is not recommended for routine diagnostic testing, only for research purposes or sero-eepidemiological investigations, and cannot produce timely results for clinical decision-making

1. List may not include all test kits approved by the U.S. Food and Drug Administration
2. NP = nasopharyngeal
3. Shell vial culture, if available, may reduce time for results to 2 days.
4. Does not distinguish between influenza A and B virus infections when used alone.
5. RT–PCR = reverse transcription polymerase chain reaction.
6. A fourfold or greater rise in antibody titer from the acute– (collected within the 1st week of illness) to the convalescent-phase (collected 2-4 weeks after the acute sample) sample is indicative of recent infection.
7. Moderately complex test – requires specific laboratory certification.
8. CLIA–waived test. Can be used in any office setting. Requires a certificate of waiver or higher laboratory certification.
9. Distinguishes between influenza A and B virus infections.

Disclaimer: Use of trade names or commercial sources is for identification only and does not imply endorsement by the Georgia Department of Public Health.

TREATING INFLUENZA

Two antiviral drugs are currently approved for influenza treatment: oseltamivir (Tamiflu®) and zanamivir (Relenza®). Oseltamivir and zanamivir have also been approved for prophylaxis against influenza. Oseltamivir and zanamivir may be used for influenza A or B. Influenza A virus resistance to amantadine and rimantadine can emerge rapidly during treatment. On the basis of antiviral testing results conducted at CDC and in Canada indicating high levels of resistance, CDC and ACIP recommend that neither amantadine nor rimantadine be used for the treatment or chemoprophylaxis of influenza A in the United States until susceptibility to these antiviral medications has been re-established among circulating influenza A viruses.

Zanamivir and oseltamivir are chemically related antiviral drugs known as neuraminidase inhibitors that have activity against both influenza A and B viruses. Both zanamivir and oseltamivir were approved in 1999 for treatment of uncomplicated influenza virus infections.

Zanamivir, an inhaled drug, may aggravate existing chronic respiratory illnesses. Table 2 describes medication dosage and duration for all age groups with normal renal function[2]. Each medication should be administered within 48 hours of symptom onset.

Influenza Resources

INFLUENZA PROPHYLAXIS

In 2000, oseltamivir was approved for chemoprophylaxis of influenza among persons aged >13 years and was approved for chemoprophylaxis of children aged >1 year in 2005. In 2006, zanamivir was approved for chemoprophylaxis of children aged >5 years. Once a cluster of influenza-like illness has been identified in a long-term care facility, chemoprophylaxis of all residents should begin immediately, regardless of whether they received vaccine. Chemoprophylaxis of staff should also be considered.

Table 2 describes dosage and duration for persons 65 years and older with normal renal function[2].

Table 2. Antiviral Medications for Treatment and Prophylaxis of Influenza

TABLE 2. Recommended dosage and schedule of influenza antiviral medications* for treatment† and chemoprophylaxis§						
Antiviral agent		**Age group (yrs)**				
		1--6	**7--9**	**10--12**	**13--64**	**≥65**
Zanamivir	Treatment, influenza A and B	NA	10 mg (2 inhalations) twice daily	10 mg (2 inhalations) twice daily	10 mg (2 inhalations) twice daily	10 mg (2 inhalations) twice daily
	Chemoprophylaxis, influenza A and B	NA for ages 1--4	Ages 5--9 10 mg (2 inhalations) once daily	10 mg (2 inhalations) once daily	10 mg (2 inhalations) once daily	10 mg (2 inhalations) once daily
Oseltamivir¶	Treatment,** influenza A and B	Dose varies by child's weight**	Dose varies by child's weight**	Dose varies by child's weight** >40 kg = adult dose	75 mg twice daily	75 mg twice daily
	Chemoprophylaxis, influenza A and B	Dose varies by child's weight††	Dose varies by child's weight††	Dose varies by child's weight†† >40 kg = adult dose	75 mg once daily	75 mg once daily

Influenza Resources

Abbreviation: NA = not approved

* Zanamivir is manufactured by GlaxoSmithKline (Relenza --- inhaled powder). Zanamivir is approved for treatment of persons aged ≥7 years and approved for chemoprophylaxis of persons aged ≥5 years. Zanamivir is administered through oral inhalation by using a plastic device included in the medication package. Patients will benefit from instruction and demonstration of the correct use of the device. Zanamivir is not recommended for those persons with underlying airway disease. Oseltamivir is manufactured by Roche Pharmaceuticals (Tamiflu --- tablet). Oseltamivir is approved for treatment or chemoprophylaxis of persons aged ≥1 year. Oseltamivir is available for oral administration in 30 mg, 45 mg, and 75 mg capsules and liquid suspension. No antiviral medications are approved for treatment or chemoprophylaxis of influenza among children aged <1 year. This information is based on data published by the Food and Drug Administration (FDA).

† Recommended duration for antiviral treatment is 5 days. Longer treatment courses can be considered for patients who remain severely ill after 5 days of treatment.

§ Recommended duration is 10 days when administered after a household exposure and 7 days after the most recent known exposure in other situations. For control of outbreaks in long-term care facilities and hospitals, CDC recommends antiviral chemoprophylaxis for a minimum of 2 weeks and up to 1 week after the most recent known case was identified

¶ See Table 4 for information about use of oseltamivir for infants aged <1 year. A reduction in the dose of oseltamivir is recommended for persons with creatinine clearance <30 mL/min.

** The treatment dosing recommendation for oseltamivir for children aged ≥1 year who weigh ≤15 kg is 30 mg twice a day. For children who weigh >15 kg and up to 23 kg, the dose is 45 mg twice a day. For children who weigh >23 kg and up to 40 kg, the dose is 60 mg twice a day. For children who weigh >40 kg, the dose is 75 mg twice a day.

†† The chemoprophylaxis dosing recommendation for oseltamivir for children aged ≥1 year who weigh ≤15 kg is 30 mg once a day. For children who weigh >15 kg and up to 23 kg, the dose is 45 mg once a day. For children who weigh >23 kg and up to 40 kg, the dose is 60 mg once a day. For children who weigh >40 kg, the dose is 75 mg once a day.

REIMBURSEMENT FOR INFLUENZA AND PNEUMOCOCCAL VACCINATION

Influenza and pneumococcal vaccines are a Medicare benefit, so long-term care facilities can bill Medicare for these immunizations. *Frequently, nursing homes in Georgia are not billing Medicare and are losing this revenue.*

- One of the most effective strategies for increasing influenza and pneumococcal immunizations involves the health care provider. Medicare beneficiaries are more likely to get immunized when their physician specifically recommends vaccination.
- Medicare Part B began paying for influenza vaccine on May 1, 1993.

Influenza Resources

- Medicare Part B began paying for pneumococcal polysaccharide vaccine (PPV) on July 1, 1981.
- Coverage of the vaccines and their administration is available under Medicare Part B regardless of the setting in which they are administered.

- If a beneficiary at high risk of pneumococcal disease (i.e., aged 65 or older) is unsure about his or her PPV vaccination status, Medicare will cover re-vaccination.

Roster bills can be submitted so that only one bill is needed per facility (although influenza and pneumococcal vaccines must be on separate roster claim forms).

Billing Code	Description
90658	Influenza split-virus vaccine (Only split virus vaccines are available in the U.S.)
90732	Pneumococcal polysaccharide vaccine
G0008	Administration of influenza vaccine
G0009	Administration of pneumococcal vaccine
V04.81	Diagnosis code for influenza vaccine
V03.82	Diagnosis code for pneumococcal polysaccharide vaccine

References:

1. Centers for Disease Detection and Control of Influenza Outbreaks in Acute Care Facilities. Control and Prevention. Available at http://www.cdc.gov/flu/professionals/infectioncontrol/ltc-facility-guidance.htm; 2011.
2. Kingston BJ and Wright CV. Influenza in the Nursing Home. Am Fam Physician 2002;65:75-78.
3. Centers for Disease Control and Prevention. Prevention and Control of Influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2010;59 (No. RR-3):1-62.

Other Resources:

- Georgia Division of Public Health Influenza Web Site – http://health.state.ga.us/epi/flu
- Centers for Disease Control and Prevention, National Center for Infectious Diseases Influenza Web Site - http://www.cdc.gov/ncidod/diseases/flu/fluvirus.htm
- Centers for Disease Control and Prevention, National Immunization Program Influenza Web Site - http://www.cdc.gov/vaccines/vpd-vac/flu/default.htm
- Georgia Adult Immunization Coalition - http://www.immunizeadultga.org/
  Medicare Preventive Services, Adult Immunization Overview – http://www.cms.hhs.gov/AdultImmunizations/

Influenza Outbreak Control In A Long-Term Care Facility

Influenza vaccination remains the primary method of preventing illness and death associated with influenza. Among elderly persons residing in nursing homes, influenza vaccine can be 50-60% effective in preventing hospitalization or pneumonia and 80% effective in preventing death. However, the vaccine may be less effective in preventing milder illness. If an outbreak of influenza-like illness (defined as fever ≥ 100˚F oral (≥ 101˚F rectal) AND cough and/or sore throat) occurs in a long-term care facility, please immediately contact the local county health department or the Georgia Department of Public Health Epidemiology Section at 404-657-2588 for assistance in outbreak investigation and control. Public health can help you confirm the diagnosis and prevent spread.

A. Confirmation of Influenza and Determination of the Outbreak Strain

- Early in the outbreak, obtain viral throat swab specimens from up to 10 patients with symptoms suggestive of influenza for viral culture and antigen detection. Viral specimen kits can be obtained through the health department, which can also arrange testing at the Georgia Public Health Laboratory.
- Because viral culture results may not be available for up to 10 days, facilities may also consider using rapid flu tests. While a negative rapid test result does not rule out influenza, a single positive result strongly indicates that influenza is causing the outbreak. Please see **RESOURCES FOR INFLUENZA PREVENTION AND CONTROL** for more information about rapid flu tests. Rapid flu tests are not available through public health.

B. Vaccination of Patients and Personnel

- Even during an outbreak, administer current influenza vaccine to unvaccinated patients and staff, especially if the outbreak occurs early in the influenza season.
- The local county health department may have vaccine available during flu season. See **RESOURCES FOR INFLUENZA PREVENTION AND CONTROL** for information on how to order influenza vaccine prior to flu season.
- For more detailed vaccination information, see Influenza Vaccine Guidelines in Chapter 2 of this manual.

C. Treatment and Prophylaxis

- Certain rapid tests are able to differentiate between influenza A and B which can help guide which antiviral medication can be used. Even in the absence of viral strain confirmation, the Georgia Department of Public Health advises long-term care facilities to begin treatment and prophylaxis of residents and staff with antiviral medications. *If influenza is suspected, treatment and prophylaxis should **not** be delayed until viral culture results are available.*

Influenza Outbreak Control In A Long-Term Care Facility

- Two antiviral drugs are currently approved for influenza treatment: oseltamivir and zanamivir. Oseltamivir and zanamivir have also been approved for prophylaxis against influenza. Oseltamivir and zanamivir may be used for influenza A or B. Influenza A virus resistance to amantadine and rimantadine can emerge rapidly during treatment. On the basis of antiviral testing results conducted at CDC and in Canada indicating high levels of resistance, CDC and ACIP recommend that neither amantadine nor rimantadine be used for the treatment or chemoprophylaxis of influenza A in the United States until susceptibility to these antiviral medications has been re-established among circulating influenza A viruses.

- Zanamivir and oseltamivir are chemically related antiviral drugs known as neuraminidase inhibitors that have activity against both influenza A and B viruses. Both zanamivir and oseltamivir were approved in 1999 for treatment of uncomplicated influenza virus infections. In 2000, oseltamivir was approved for chemoprophylaxis of influenza among persons aged >13 years and was approved for chemoprophylaxis of children aged >1 year in 2005. In 2006, zanamivir was approved for chemoprophylaxis of children aged >5 years.
- Please see **RESOURCES FOR INFLUENZA PREVENTION AND CONTROL** for information regarding medication dosage and therapy duration.

D. Interruption of Person-to-Person Transmission

- Keep residents known or suspected to have influenza in a private room or in a room with other residents with documented influenza unless there are medical contraindications.
- If feasible, place persons with influenza-like illness together in an area with an independent air supply and exhaust system.
- Implement respiratory droplet precautions, including requiring all staff that have contact with ill residents to wear masks and gloves, and to wash hands frequently and thoroughly. Consider using hand sanitizers in areas where hand washing is difficult.
- Restrict visitors who have a febrile respiratory illness.
- Do not allow staff to work while ill.
- Consider temporarily closing the facility to new admissions while the outbreak continues.

Preventing Influenza Outbreaks in Long-Term Care Facilities

Morbidity and mortality from influenza can be greatly reduced if long-term care facilities follow these guidelines for influenza prevention:

- Develop an influenza control plan incorporating vaccination, surveillance, diagnosis, treatment, and prophylaxis activities. Ensure all staff are familiar with the plan's components.

Influenza Outbreak Control In A Long-Term Care Facility

- Plan an annual vaccination campaign targeting all residents, staff, volunteers, and visitors for flu vaccination. Ideally, vaccination should occur in October or early November, but the facility should also have methods in place to ensure that all staff and residents who enter the facility after the mass vaccination campaign are also vaccinated. Standing orders by the facility medical director may make this process more convenient.
- Review residents' immunization histories and administer pneumococcal vaccine to those who are eligible. This should be done on a regular basis, and especially during the annual flu vaccine campaign. If a pneumococcal vaccination history is unknown, it is safe and preferable to give another dose.
- During flu season, post signs asking visitors with flu-like symptoms, such as fever, cough, sore throat, or muscle aches, to refrain from visiting.
- Train staff at the beginning of each flu season on the proper respiratory secretion precautions, hand-washing procedures, and surveillance activities. Have a mechanism to ensure all new employees who are hired during flu season receive the training as well.
- Establish and post a definition of flu-like illness. The Centers for Disease Control and Prevention (CDC) defines flu-like illness as fever $\geq$100˚F oral or $\geq$101˚F rectal and at least one of the following: cough, runny nose, nasal congestion, or sore throat. Be aware that influenza symptoms are sometimes different in elderly persons or persons with chronic medical conditions. Staff should be alert for residents who have fever with lethargy or delirium, or changes in their functional status.
- Monitor influenza activity in the community. The Georgia Department of Public Health posts influenza information at http://health.state.ga.us/epi/flu. You may also receive periodic influenza activities during flu season by subscribing to the public health flu email list (sign up by sending an email to flu@dhr.state.ga.us with the word "subscribe" in the subject line). Knowledge of influenza activity in the community can assist in making a clinical diagnosis.
- Consider stocking rapid flu tests and antiviral medications for immediate detection and response to outbreaks. If you do not stock rapid tests, have a plan in place for quickly obtaining laboratory confirmation of influenza. There should also be a method to quickly obtain physician orders for antiviral medication.
- Post the county, district, or state health department phone number for reporting a cluster of influenza-like illness. A cluster is defined as 3 or more cases of illness among residents and/or staff within a 72-hour period. *By law, any cluster of illness must be reported to Georgia public health authorities immediately*.

  (DHR Rule 290-5-3-.02(2))

NOTIFIABLE DISEASE / CONDITION REPORTING

All Georgia physicians, laboratories, and other health care providers are required by law to report patients with the following conditions. Both lab-confirmed and clinical diagnoses are reportable within the time interval specified below.

Reporting enables appropriate public health follow-up for your patients, helps identify outbreaks, and provides a better understanding of disease trends in Georgia. For the latest information from the DPH, Department of Public Health, visit their web site at: www.health.state.ga.us

District Health Office Contact Information

Northwest Health District
Epidemiology Section
1309 Redmond Road
Rome, GA 30165-1391
Phone (706) 295-6656
FAX (706) 802-5342

North Georgia Health District
Infectious Disease Department
100 West Walnut Ave., Suite 92
Dalton, GA 30720-8417
Phone (706) 272-2342
FAX (706) 272-2929

North Health District
1280 Athens Street
Gainesville, GA 30507-7000
Phone (770) 535-5743
FAX (770) 535-5958

Cobb and Douglas Public Health
Center for Health Assessment
1650 County Services Pkwy., SW
Marietta, GA 30008-4010
Phone (770) 514-2432
FAX (770) 514-2313

Fulton Health District
Fulton County Department of
Health and Wellness
Office of Epidemiology
99 Jesse Hill Jr. Dr., SE
Atlanta, GA 30303-3030
Phone (404) 730-1391
FAX (404) 730-1326

Clayton County Board of
Health District
Administrative Office
1117 Battlecreek Road
Jonesboro, GA 30236-2407
Phone (678) 610-7199
FAX (770) 603-4873

East Metro Health District
Office of Infectious Diseases
2570 Riverside Parkway
P.O. Box 897
Lawrenceville, GA 30046-0897
Phone (770) 339-4260
After hours (404) 323-1910
FAX (770) 339-5971

DeKalb Health District
Office of Infectious Diseases
445 Winn Way
P.O. Box 987
Decatur, GA 30031-1701
Phone (404) 508-7851
FAX (404) 508-7813

LaGrange Health District
122 Gordon Commercial Dr.
Suite A
LaGrange, GA 30240-5740
Phone (706) 845-4035
FAX (706) 845-4038

South Central Health District
2121-B Bellevue Road
Dublin, GA 31021-2998
Phone (478) 275-6545
FAX (478) 275-6575

North Central Health District
Infectious Disease Unit Supervisor
811 Hemlock Street
Macon, GA 31201-2198
Phone (478) 751-6214
FAX (478) 752-1710

East Central Health District
1916 North Leg Rd. Bldg. B
Augusta, GA 30909-4437
Phone (706) 667-4260
FAX (706) 667-4792

West Central Health District
Epidemiology Unit
2100 Comer Ave.
P.O. Box 2299
Columbus, GA 31902-2299
Phone (706) 321-6300
FAX (706) 321-6155

South Health District
Epidemiology
325 West Savannah Ave.
Valdosta, GA 31601-5901
Phone (229) 333-5290
FAX (229) 259-5003
Toll Free 866-801-5360

Southwest Health District
1109 N. Jackson Street
Albany, GA 31701-2022
Phone (229) 430-4599
FAX (229) 430-7853

Coastal Health District
Epidemiology
24 Oglethorpe Professional Blvd.
P.O. Box 14257
Savannah, GA 31406
PHONE (912) 644-5232
FAX (912) 644-5230

Southeast Health District
Office of Infectious Diseases
1115 Church Street, Suite C
Waycross, GA 31501-3525
Phone (912) 285-6022
FAX (912) 338-5309

Northeast Health District
Epidemiology Section
220 Research Drive
Athens, GA 30605-2738
Phone (706) 583-2868
FAX (706) 369-5640

State Contact Information

Department of Public Health
2 Peachtree Street, N.W.
14th Floor
Atlanta, GA 30303-3142
Phone (404) 657-2588
FAX (404) 657-2608

Legal Authority: O.C.G.A. §§ 31-12-2, 31-22-7;DHR Rules and Regulations, Notification of Disease, Chapter 290-5-3 and Chapter 290-9-8.

NOTIFIABLE DISEASE/CONDITION REPORT FORM

All Georgia physicians, laboratories, and other health care providers are required by law to report patients with conditions of public health concern listed on the reverse of the enclosed form. Both lab-confirmed and clinical diagnoses are reportable within the time interval specified.

Reporting enables appropriate public health follow-up for your patients, helps identify outbreaks, and provides a better understanding of disease trends in Georgia. For the latest information from the DPH, Department of Public Health, visit their web site at: www.health.state.ga.us.

Instructions:

1. Report cases for all diseases, except those noted below, electronically through the State Electronic Notifiable Disease Surveillance System at: http://sendss.state.ga.us
   OR
   Complete reverse of this Notifiable Disease/Condition Report Form and mail, in an envelope marked CONFIDENTIAL, to: District Health Office (see cover for contact information)
   OR
   Fax to: District Health Office (see cover for contact information).

2. Fill out the form as completely and as timely as possible, including laboratory submissions.

3. Include treatment information for sexually transmitted diseases.

4. Report symptoms and tests needed to establish the diagnosis for viral hepatitis and Lyme disease and other tick-borne diseases.

5. If you mail the form, photocopy the form as your record of reported disease/condition.

6. Report a suspect case of hearing impairment (under age 5) by completing the Children 1st Screening and Referral Form. Report a confirmed case of hearing impairment (under age 5) by completing the Surveillance of Hearing Impairment in Infants and Young Children Form (both forms available at: http://health.state.ga.us/programs/unhs/reporting.asp)

7. For Birth Defects, DO NOT USE THIS FORM,
   Refer to the Georgia Birth Defects Reporting and Information System (GBDRIS) Reporting Guidelines (available at: http://health.state.ga.us/epi/mch/birthdefects/gbdris/publications.asp).

8. For Cancer and Benign Brain Tumor, DO NOT USE THIS FORM,
   Refer to the GCCR Policy and Procedure Manual (available at: http://health.state.ga.us/programs/gccr/reporting.asp)
   AND
   Call the Georgia Comprehensive Cancer Registry at 404-463-8919 for how and what to report.

9. For HIV infections and AIDS, DO NOT USE THIS FORM,
   Complete the Georgia HIV/AIDS Confidential Case Report Form (available at: http://health.state.ga.us/epi/hivaids or by calling 1-800-827-9769) and mail in an envelope marked CONFIDENTIAL to:

   Georgia Department of Public Health, Epidemiology Section
   P.O. Box 2107
   Atlanta, GA 30301

GEORGIA NOTIFIABLE DISEASE/CONDITION REPORT FORM

REPORT CASES BY MAIL, FAX OR PHONE TO DISTRICT HEALTH OFFICE
OR TO SENDSS (http://sendss.state.ga.us)

Disease/Condition _____ Medical Record Number _____

PATIENT DEMOGRAPHICS

Patient's Name

Last Name First Name MI

Patient's Address

Street

City State Zip+4 County

( ) Patient's Home Phone ( ) Patient's Work Phone ( ) Patient's Other Phone

Date of Birth / /

Age

Age Type
- ☐ Yrs
- ☐ Mos
- ☐ Weeks
- ☐ Days
- ☐ Unk

Ethnicity
- ☐ Hispanic
- ☐ Non-Hispanic
- ☐ Unknown

Sex
- ☐ Male
- ☐ Female
- ☐ Unknown

Race
- ☐ Asian
- ☐ Black/African-American
- ☐ Native American or Alaska Native
- ☐ Multiracial
- ☐ Native Hawaiian or Pacific Islander
- ☐ Other
- ☐ Unknown
- ☐ White

CLINICAL INFORMATION

Illness Onset Date / /

	Y	N	UNK		Y	N	UNK
Hospitalized	☐	☐	☐	Outpatient	☐	☐	☐
Emergency Rm	☐	☐	☐				

Died? Y ☐ N ☐ UNK ☐
Date of Death: / /

If hospitalized, complete:

Hospital Name	Admit Date	Discharge Date

LABORATORY INFORMATION

Report Hepatitis information in Viral Hepatitis box below

Specimen Collection Date	Test Name (ex. Culture, IFA, IGM, EIA)	Specimen Type (ex. Stool, Blood, CSF)	Result (ex. +/-, titer, Presumptive)	Species / Serotype	Lab Name

ADDITIONAL INFORMATION

	Yes	No	UNK
Pregnant	☐	☐	☐
Nursing Home or other Chronic Care Facility	☐	☐	☐
Child In Daycare	☐	☐	☐
Daycare Worker	☐	☐	☐
Prisoner/Detainee	☐	☐	☐
Food Handler	☐	☐	☐
Health Care Worker	☐	☐	☐
Outbreak Related	☐	☐	☐
Travel in Last 4 Weeks	☐	☐	☐

*VIRAL HEPATITIS Test Results

Date of test(s) _____

		Pos	Neg	UNK
Hepatitis A	Total anti-HAV	☐	☐	☐
	IgM anti-HAV	☐	☐	☐
Hepatitis B	HBsAg	☐	☐	☐
	Total anti-HBc	☐	☐	☐
	IgM anti-HBc	☐	☐	☐
Hepatitis C	anti-HCV (EIA)	☐	☐	☐
	anti-HCV signal to cut-off ratio	_____		
	RIBA	☐	☐	☐
	HCV RNA (PCR, bDNA)	☐	☐	☐
All	ALT(SGPT) _____ AST (SGOT) _____			

REPORTER INFORMATION

Report Date / /

Reporter Name _____

Reporter Phone ( ) _____

Reporter Institution _____

Physician Name _____

Physician Phone ( ) _____

☐ Need More 3095 Forms

☐ Entered into SENDSS

Comments/Symptoms/Treatment:

Local Use Only

☐ Additional form completed

Name: _____

State Use Only

CONFIDENTIAL

NOTIFIABLE DISEASE / CONDITION REPORTING

All Georgia physicians, laboratories, and other health care providers are required by law to report patients with the following conditions. Both lab-confirmed and clinical diagnoses are reportable within the time interval specified below.

Reporting enables appropriate public health follow-up for your patients, helps identify outbreaks, and provides a better understanding of disease trends in Georgia. For the latest information from the Department of Public Health, visit their web site at: www.health.state.ga.us

REPORT IMMEDIATELY

To Report Immediately
Call: District Health Office or 1-866-PUB-HLTH (1-866-782-4584)

any cluster of illnesses
animal bites
▶ anthrax
all acute arboviral infections:
- -Eastern Equine Encephalitis (EEE)
- -LaCrosse Encephalitis (LAC)
- -St. Louis Encephalitis (SLE)
- -West Nile Virus (WNV)

▶ botulism
▶ brucellosis
cholera
diphtheria
E. coli O157
*Haemophilus influenzae (invasive)**
hantavirus pulmonary syndrome
hemolytic uremic syndrome (HUS)
hepatitis A (acute)
measles (rubeola)
meningitis (specify agent)
meningococcal disease
novel influenza A virus infections
pertussis
▶ plague
poliomyelitis
▶ Q fever
rabies (human & animal)
severe acute respiratory syndrome (SARS)
shiga toxin positive tests
S. aureus with vancomycin MIC ≥ 4μg/ml
▶ smallpox
syphilis (congenital & adult)
tuberculosis
latent TB infection in children<5 years old
▶ tularemia
▶ viral hemorrhagic fevers

▶ Potential agent of bioterrorism.
* Invasive = isolated from blood, bone, CSF, joint, pericardial, peritoneal, or pleural fluid.

REPORT WITHIN 7 DAYS

To Report Within 7 Days
Report cases electronically through the State Electronic Notifiable Disease Surveillance System at **http://sendss.state.ga.us (SEE REPORTING FOOTNOTES BELOW.)**

AIDS#
aseptic meningitis
blood lead level (all)
campylobacteriosis
chancroid
Chlamydia trachomatis (genital infection)
Creutzfeldt-Jakob Disease (CJD), suspected cases, under age 55
cryptosporidiosis
cyclosporiasis
ehrlichiosis
giardiasis
gonorrhea
HIV#
hearing impairment† (permanent, under age 5)
hepatitis B
- -acute hepatitis B
- -newly identified HBsAg+ carriers**
- -HBsAg+ pregnant women

hepatitis C virus infection (past or present)
influenza-associated death (all ages)
legionellosis
leptospirosis
listeriosis***
leprosy or Hansen's disease (*Mycobacterium leprae*)
Lyme disease
lymphogranuloma venereum
malaria
maternal death##
methicillin-resistant *S. aureus* (*community-associated*)♦
mumps
psittacosis
Rocky Mountain spotted fever
rubella (including congenital)
salmonellosis
shigellosis
streptococcal disease, Group A or B (invasive)*
Streptococcus pneumoniae (invasive)*
- report with antibiotic-resistance information

tetanus
toxic shock syndrome
toxoplasmosis
typhoid
Varicella (Chickenpox)
Vibrio infections
yersiniosis

* Invasive = isolated from blood, bone, CSF, joint, pericardial, peritoneal, or pleural fluid.
** HBsAg+ = hepatitis B surface antigen positive.
*** *L. monocytogenes* isolated from blood, bone, CSF, joint, pericardial, peritoneal, or pleural fluid, or other normally sterile site; or from placenta or products of conception in conjunction with fetal death or illness. Infant mortality is reportable to Vital Records.
♦ Resulting in severe illness or death

REPORTING HIV/AIDS:
\# Report forms and reporting information for HIV/AIDS available by telephone (1-800-827-9769) OR at http://health.state.ga.us/epi/hivaids/reportinginformation.asp. For mailing HIV/AIDS reports, please use double envelopes marked "confidential", addressed to Georgia Department of Public Health Epidemiology Section, P.O.Box 2107, Atlanta, GA 30301
† Report forms and reporting information for **hearing impairment** available at http://health.state.ga.us/programs/unhs/reporting.asp

REPORT WITHIN 1 MONTH

birth defects (under age 6)
maternal deaths (during pregnancy or within 1 year of delivery)

Report forms and reporting information for **birth defects and maternal deaths** available at http://health.state.ga.us/epi/mch/publications.asp

REPORT WITHIN 6 MONTHS

benign brain and central nervous system tumors
cancer

Report forms and reporting information for **tumors and cancer** found at http://health.state.ga.us/programs/gccr/reporting.asp

CDC Diphtheria Worksheet

PATIENT INFORMATION

Date of Request (Month Day Year)

Name (Last, First)

Birth Date (Month Day Year)

Age (Unk=999)

Age Type
0 = 0-120 years
1 = 0-11 months
2 = 0-52 weeks
3 = 0-28 days
9 = Age unknown

Sex
M = Male
F = Female
U = Unknown

Pregnant?
Y = Yes
N = No
U = Unknown

Race
N = Native Amer./Alaskan Native
A = Asian/Pacific Islander
B = African American
W = White
O = Other
U = Unknown

Ethnicity
H = Hispanic
N = Not Hispanic
U = Unknown

Address (Street and No.)

County

State

Zip

Phone

Date Symptom Onset (Month Day Year)

Date First Diagnosis (Month Day Year)

Date Hospitalized (Month Day Year)

History of Immunization Against Diphtheria

Childhood Primary Series?
Y = Yes
N = No
U = Unknown

Boosters as Adult?
Y = Yes
N = No
U = Unknown

Date of Last Dose (Month Day Year) OR U = Unknown

Description of Clinical Picture

Outcome
N = Recovered, No Residua
R = Recovered, Residua
D = Died
U = Unknown

CLINICAL INFORMATION

Enter Y = Yes, N = No, or U = Unknown in the Boxes Below Unless Otherwise Indicated

Symptoms

- Fever?
- Sore Throat?
- Difficulty Swallowing?
- Change in Voice?
- Shortness of Breath?
- Weakness?
- Fatigue?
- Other?

Signs

- Fever?
- If Yes, Temp ___.___ °C
- Membrane?
- If Yes, Site(s)
  - Tonsils
  - Soft Palate
  - Hard Palate
  - Larynx
  - Nares
  - Nasopharynx
  - Conjunctiva
  - Skin
- Soft Tissue Swelling? (Around Membrane)
- Neck Edema?
- If Yes
  - B = Bilateral
  - L = Left Side Only
  - R = Right Side Only
- If Yes, Extent
  - S = Submandibular Only
  - M = Midway to Clavicle
  - C = To Clavicle
  - B = Below Clavicle
- Stridor?
- Wheezing?
- Palatal Weakness?
- Tachycardia?
- EKG Abnormalities?

Complications

- Complications?
- Airway Obstruction?
- Date of Onset (Month Day Year)
- Intubation Required?
- Myocarditis?
- Date of Onset (Month Day Year)
- (Poly)neuritis?
- Date of Onset (Month Day Year)
- Other?
- Describe:

LABORATORY

Specimen for Diphtheria Culture Obtained?
Y = Yes
N = No
U = Unknown

If Yes, Obtained on (Month Day Year) OR U = Unknown

Culture Result
P = Positive
N = Negative
U = Unknown

Specify Lab Performing Culture:

If Culture Positive, Biotype
M = Mitis
G = Gravis
I = Intermedious
B = Belfanti

If Culture Positive, Results of Toxigenicity Testing
X = Not Done
P = Positive
N = Negative
U = Unknown

Specimen Sent to CDC Diphtheria Lab for Confirmation/Molecular Typing?
Y = Yes
N = No
W = Will be Sent

Type of Specimen (Check All That Apply)
- Clinical Swab
- Piece of Membrane
- *C. diphtheria* Isolate

Serum Specimen for Diphtheria Antitoxin Antibodies Obtained?
Y = Yes
N = No
W = Will be Obtained Prior to DAT

PCR Result
P = Positive
N = Negative
U = Unknown
X = Not Done

ANTIBIOTICS

Treated with Antibiotics?
Y = Yes
N = No

As an Outpatient

If Yes, Date Initiated (Month Day Year)

Antibiotic (See Codes Below)

Duration of Therapy (Days)

As an Inpatient

Antibiotic Therapy in Hospital?
Y = Yes
N = No

If Yes, Date Initiated (Month Day Year)

Antibiotic (See Codes Below)

Duration of Therapy (Days)

Were Antibiotics Given in the 24 Hours Before Culture?
Y = Yes
N = No
U = Unknown

Antibiotic Codes
1 = Erythromycin (incl. Pediazole, ilosone)
2 = Penicillin (Bicillin, Pfizerpen-AS, Wycillin)
3 = Amoxicillin/Ampicillin/Augmentin/Ceclor/Cefixime
4 = Clarithromycin/azithromycin
5 = Cotrimoxazole (bactrim/septra)
6 = Tetracycline/Doxycycline
7 = Other
9 = Unknown

Note: This Form Has 2 Sides

EXPOSURE

Country of Residence
U = US
O = Other

If Other, Country Name:

Date of US Arrival
Month Day Year OR U = Unknown

History of International Travel?
(2 Weeks Prior to Onset)
Y = Yes
N = No
U = Unknown

Country(s) Visited

	From Month	From Day	From Year	To Month	To Day	To Year

History of Interstate Travel?
(2 Weeks Prior to Onset)
Y = Yes
N = No
U = Unknown

State(s) Visited

	From Month	From Day	From Year	To Month	To Day	To Year

Known Exposure to Diphtheria Case or Carrier?
Y = Yes
N = No
U = Unknown

Known Exposure to International Travelers?
Y = Yes
N = No
U = Unknown

Known Exposure to Immigrants?
Y = Yes
N = No
U = Unknown

REPORTING INFORMATION

Has This Suspected Case Been Reported to The State or Local Health Department?
Y = Yes
N = No
U = Unknown

Date Reported to State or Local Health Department
Month Day Year

Person Informed:
Phone - -
Fax - -

Reporting Physician:
Phone - -
Fax - -

REQUESTING PHYSICIAN

Name

Institution

Street

City | State | Zip

Phone - -

Fax - -

Name of Investigator Under the IND (If Different From Requesting Physician)

Phone - -

Fax - -

SEND DRUG TO

Name

Attn.

Institution

Street

City | State | Zip

Phone - -

Fax - -

DOSE

Amount of DAT Administered: , IU DAT

DISPOSITION

Final Diagnosis:

How Was the Final Diagnosis Confirmed?

Final Case Disposition
C = Confirmed
P = Probable
N = Not a Case

Measles Surveillance Worksheet

Appendix 8

NAME (Last, First)				Hospital Record No.
Address (Street and No.)	City	County	Zip	Phone
Reporting Physician/Nurse/Hospital/Clinic/Lab	Address			Phone

---------- DETACH HERE and transmit only lower portion if sent to CDC ----------

Measles Surveillance Worksheet

County | State | Zip

Birth Date (Month Day Year)

Age (Unk = 999)

Age Type
0 = 0-120 years
1 = 0-11 months
2 = 0-52 weeks
3 = 0-28 days
9 = Age unknown

Ethnicity
H = Hispanic
N = Not Hispanic
U = Unknown

Race
N = Native Amer./Alaskan Native
A = Asian/Pacific Islander
B = African American
W = White
O = Other
U = Unknown

Sex
M = Male
F = Female
U = Unknown

Event Date (Month Day Year)

Event Type
1 = Onset Date
2 = Diagnosis Date
3 = Lab Test Done
4 = Reported to County
5 = Reported to State or MMWR Report Date
9 = Unknown

Outbreak Associated (Unk = 999)

Reported (Month Day Year)

Imported
1 = Indigenous
2 = International
3 = Out of State
9 = Unknown

Report Status
1 = Confirmed
2 = Probable
3 = Suspect
9 = Unknown

CLINICAL DATA

Any Rash? Y = Yes, N = No, U = Unknown

Rash Onset (Month Day Year)

Rash Duration 0 - 30 Days, 99 = Unknown

Rash Generalized? Y = Yes, N = No, U = Unknown

Fever? Y = Yes, N = No, U = Unknown

If Recorded, Highest Measured Temp. 36.0 - 110.0 degrees, 999.9 = Unknown

Cough? Y = Yes, N = No, U = Unknown

Coryza? Y = Yes, N = No, U = Unknown

Conjunctivitis? Y = Yes, N = No, U = Unknown

COMPLICATIONS

Otitis? Y = Yes, N = No, U = Unknown

Diarrhea? Y = Yes, N = No, U = Unknown

Pneumonia? Y = Yes, N = No, U = Unknown

Encephalitis? Y = Yes, N = No, U = Unknown

Thrombocytopenia? Y = Yes, N = No, U = Unknown

Death? Y = Yes, N = No, U = Unknown

Other Complications? Y = Yes, N = No, U = Unknown

Hospitalized? Y = Yes, N = No, U = Unknown

Days Hospitalized 0 - 998, 999 - Unknown

If Yes, Please Specify:

LABORATORY

Was Laboratory Testing For Measles Done? Y = Yes, N = No, U = Unknown

Date IgM Specimen Taken (Month Day Year)

Result
P = Positive
N = Negative
I = Indeterminate
E = Pending
X = Not Done
U = Unknown

Date IgG Acute Specimen Taken (Month Day Year)

Date IgG Convalescent Specimen Taken (Month Day Year)

Result
P = Significant Rise in IgG
N = No Significant Rise in IgG
I = Indeterminate
E = Pending
X = Not Done
U = Unknown

Other Lab Result
P = Positive
N = Negative
I = Indeterminate
E = Pending
X = Not Done
U = Unknown

Specify Other Lab Method:

VACCINE HISTORY

Vaccinated? (Received measles-containing vaccine?) Y = Yes, N = No, U = Unknown

If Not Vaccinated, What Was The Reason? (See Reason Codes Below)

Vaccination Date (Month Day Year)	Vaccine Type	Vaccine Manuf	Lot Number

(See Type and Manuf. Codes Below)

Number of doses received BEFORE 1st birthday

Number of doses received ON or AFTER 1st birthday

If vaccinated BEFORE 1st birthday, but no doses given ON or AFTER 1st birthday, what was the reason?

If received one dose after 1st birthday, but never received 2nd dose after 1st birthday, what was the reason?

Reason Codes
1 = Religious Exemption
2 = Medical Contraindication
3 = Philosophical Objection
4 = Lab. Evidence of Previous Disease
5 = MD Diagnosis of Previous Disease
6 = Under Age For Vaccination
7 = Parental Refusal
8 = Other
9 = Unknown

Vaccine Type Codes
A = MMR
B = Measles
O = Other
U = Unknown

Vaccine Manuf. Codes
M = Merck
O = Other
U = Unknown

EPIDEMIOLOGIC INFORMATION

Date First Reported to a Health Department (Month Day Year)

Date Case Investigation Started (Month Day Year)

Transmission Setting (Where did this case acquire measles?)
1 = Day Care
2 = School
3 = Doctor's Office
4 = Hospital Ward
5 = Hospital ER
6 = Hospital Outpatient Clinic
7 = Home
8 = Work
9 = Unknown
10 = College
11 = Military
12 = Correctional Facility
13 = Church
14 = International Travel
15 = Other

Outbreak Related? Y = Yes, N = No, U = Unknown

If Yes, Outbreak Name

Source of Exposure For Current Case (Enter State ID if source was an in-state case; enter Country if source was out of US; enter State if source was out-of-state)

Were Age and Setting Verified? (Is age appropriate for setting, i.e. aged 49 years and in day care, etc.) Y = Yes, N = No, U = Unknown

If Transmission Setting Not Among Those Listed And Known, What Was The Transmission Setting?

Epi-Linked to Another Confirmed or Probable Case? Y = Yes, N = No, U = Unknown

Is Case Traceable Within 2 Generations to an International Import? Y = Yes, N = No, U = Unknown

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Indicates epidemiologically important items not yet on NETSS screen

Contact Information: (For statistical health department use)

Mother's Name	Father's Name
Phone	

---------- DETACH HERE ----------

The information below is epidemiologically important, but not included on NETSS screens

Activity History For 18 Days Before Rash Onset and 7 Days After Rash Onset
Day -18
Day -17
Day -16
Day -15
Day -14
Day -13
Day -12
Day -11
Day -10
Day -9
Day -8
Day -7
Day -6
Day -5
Day -4
Day -3
Day -2
Day -1
Day 0 (Rash Onset)
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Clinical Case Definition*: A generalized rash lasting ≥ 3 days, a temperature ≥ 101.0° F (≥38.3° C), and cough, coryza, or conjunctivitis.
Case Classification*: Suspected: Any febrile illness accompanied by rash. Probable: A case that meets the clinical case definition, has noncontributory or no serologic or virologic testing, and is not epidemiologically linked to a confirmed case. Confirmed: A case that is laboratory confirmed or that meets the clinical case definition and is epidemiologically-linked to a confirmed case. A laboratory-confirmed case does not need to meet the clinical case definition.

Mumps Surveillance Worksheet

Name (Last, First)					Hospital Record Number
Address (Street and Number)	City	County	State	Zip Code	Phone
Reporting Physician/Nurse/Hospital/Clinic/Lab	Address				Phone

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Mumps Surveillance Worksheet

County	State	Zip Code

Birth Date — Month ☐☐ Day ☐☐ Year ☐☐☐☐

Age — ☐☐☐ 999 = Unknown

Age Type — ☐ 0 = 0-120 years; 1 = 0-11 months; 2 = 0-52 weeks; 3 = 0-28 days; 9 = Age unknown

Ethnicity — ☐ H = Hispanic; N = Not Hispanic; U = Unknown

Race — ☐ N = Native American / Alaskan Native; A = Asian / Pacific Islander; B = African American; W = White; O = Other; U = Unknown

Sex — ☐ M = Male; F = Female; U = Unknown

Event Date — Month ☐☐ Day ☐☐ Year ☐☐☐☐

Event Type — ☐ 1 = Onset Date; 2 = Diagnosis Date; 3 = Lab Test Date; 4 = Reported to County; 5 = Reported to State or *MMWR* Report Date; 9 = Unknown

Reported — Month ☐☐ Day ☐☐ Year ☐☐☐☐

Import Status — ☐ 1 = U.S.-acquired; 2 = International Import ☐ 1 = Import-linked; 2 = Imported Virus; 3 = Endemic; 4 = Unknown Source

Report Status — ☐ 1 = Confirmed; 2 = Probable; 3 = Suspect; 4 = Unknown

CLINICAL DATA

Parotitis (opposite 2nd molars)? ☐ Y = Yes; N = No; U = Unknown ☐ Unilateral ☐ Bilateral

Jaw Pain? ☐ Y = Yes; N = No; U = Unknown

Salivary Gland Swelling (including parotitis)

Onset — Month ☐☐ Day ☐☐ Year ☐☐☐☐

Duration — ☐☐☐ 1-998 = Number of Days; 999 = Unknown

Submandibular? ☐ Y = Yes; N = No; U = Unknown

Sublingual? ☐ Y = Yes; N = No; U = Unknown

Notes

COMPLICATIONS

Meningitis? ☐ Y = Yes; N = No; U = Unknown

Deafness? ☐ Y = Yes; N = No; U = Unknown

Orchitis? ☐ Y = Yes; N = No; U = Unknown

Encephalitis? ☐ Y = Yes; N = No; U = Unknown

Death? ☐ Y = Yes; N = No; U = Unknown

Other Complications? ☐ Y = Yes; N = No; U = Unknown

If Yes, please specify

Hospitalized? ☐ Y = Yes; N = No; U = Unknown

Days Hospitalized ☐☐☐ 999 = Unknown

LABORATORY

Was Laboratory Testing Done for Mumps? ☐ Y = Yes; N = No; U = Unknown

Date Serologic (IgG) Specimens Taken

IgG (acute) — Month ☐☐ Day ☐☐ Year ☐☐☐☐

Test Used _____

Units Reported _____

IgG (convalescent) — Month ☐☐ Day ☐☐ Year ☐☐☐☐

Test Used _____

Units Reported _____

Result ☐

Result Codes
P = Significant rise in IgG
I = Indeterminate
N = No significant rise in IgG
E = Pending
X = Not Done
U = Unknown

Single IgG Specimen Only — Month ☐☐ Day ☐☐ Year ☐☐☐☐

Test Used _____

Units Reported _____

Result ☐

Date Serologic (IgM) Specimens Taken

IgM (1) — Month ☐☐ Day ☐☐ Year ☐☐☐☐ ☐

IgM (2) — Month ☐☐ Day ☐☐ Year ☐☐☐☐ ☐

Result Codes
P = Positive
I = Indeterminate
N = Negative
E = Pending
X = Not Done
U = Unknown

Other Lab Results — Result

PCR — Month ☐☐ Day ☐☐ Year ☐☐☐☐ ☐

Culture — Month ☐☐ Day ☐☐ Year ☐☐☐☐ ☐

EPIDEMIOLOGIC

Date First Reported to a Health Department — Month ☐☐ Day ☐☐ Year ☐☐☐☐

Date Case Investigation Started — Month ☐☐ Day ☐☐ Year ☐☐☐☐

Outbreak Related? ☐ Y = Yes; N = No; U = Unknown

If Yes, Outbreak Name

Transmission Setting (Where did this person acquire mumps?) ☐

1 = Day Care
2 = School
3 = Doctor's Office
4 = Hospital Ward
5 = Hospital ER
6 = Hospital Outpatient Clinic
7 = Home
8 = Work
9 = Unknown
10 = College
11 = Military
12 = Correctional Facility
13 = Church
14 = International Travel
15 = Other

If Other, Specify Transmission Setting _____

Were Age and Setting Verified? (Is age appropriate for setting?) ☐ Y = Yes; N = No; U = Unknown

Source of Exposure for Current Case (Enter State ID if source was an in-state case; enter Country if source was out of U.S.; enter State if source was out-of-state)

Epi-linked to Another Confirmed or Probable Case? ☐ Y = Yes; N = No; U = Unknown

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VACCINE HISTORY

Vaccinated? (Received mumps-containing vaccine?)	Notes (History of natural mumps disease?)
☐ Y = Yes N = No U = Unknown	

Vaccination Date	Vaccine Type	Manufacturer	Lot Number
☐☐ ☐☐ ☐☐☐☐	☐	☐	☐☐☐☐☐☐☐☐☐☐
☐☐ ☐☐ ☐☐☐☐	☐	☐	☐☐☐☐☐☐☐☐☐☐
☐☐ ☐☐ ☐☐☐☐	☐	☐	☐☐☐☐☐☐☐☐☐☐
☐☐ ☐☐ ☐☐☐☐	☐	☐	☐☐☐☐☐☐☐☐☐☐

Vaccine Type Codes
A = MMR
B = Mumps
O = Other
U = Unknown

Vaccine Manufacturer Codes
M = Merck
O = Other
U = Unknown

Number of Doses Received After 1st Birthday	If Not Vaccinated, What Was the Reason?
☐ 9 = Unknown	☐ 1 = Religious Exemption 2 = Medical Contraindication 3 = Philosophical Objection 4 = Lab. Evidence of Previous Disease 5 = MD Diagnosis of Previous Disease 6 = Under Age for Vaccination 7 = Parental Refusal 8 = Other 9 = Unknown

Notes/Other information

Clinical Case Definition (2008)

An illness with acute onset of unilateral or bilateral tender, self-limited swelling of the parotid and or other salivary gland(s), lasting at least 2 days, and without other apparent cause.

Case Classification (2008)

Suspected: a case with clinically compatible illness or that meets the clinical case definition without laboratory testing or a case with laboratory tests suggestive of mumps without clinical information.

Probable: a case that meets the clinical case definition without laboratory confirmation and is epidemiologically linked to a clinically compatible case.

Confirmed: a case that: 1) meets the clinical case definition or has clinically compatible illness, and 2) is either laboratory confirmed or is epidemiologically linked to a confirmed case.

Pertussis Surveillance Worksheet

NAME (Last, First) | Hospital Record No.

Address (Street and No.) | City | County | Zip | Phone

Reporting Physician/Nurse/Hospital/Clinic/LabPhone | Address | Phone

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CDC NETSS id | **County** | **State** | **Zip**

Birth Date Month Day Year

Age Unk= 999

Age Type
0 = 0-120 years
1 = 0-11 months
2 = 0-52 weeks
3 = 0-28 days
9 = Age Unknown

Race
N = Native Amer./Alaskan Native
A = Asian/Pacific Islander
B = African American
W = White
O = Other
U = Unknown

Ethnicity
H = Hispanic
N = Not Hispanic
U = Unknown

Sex
M = Male
F = Female
U = Unknown

Event Date Month Day Year

Event Type
1 = Onset Date
2 = Diagnosis Date
3 = Lab Test Done
4 = Reported to County
5 = Reported to State or MMWR Report Date
9 = Unknown

Outbreak Associated
999 = Unknown

Reported Month Day Year

Report Status
1 = Confirmed
2 = Probable
3 = Suspect
9 = Unknown

CLINICAL DATA

Any Cough? Y = Yes, N = No, U = Unknown

Cough Onset Month Day Year

Paroxysmal Cough? Y = Yes, N = No, U = Unknown

Whoop? Y = Yes, N = No, U = Unknown

Posttussive Vomiting? Y = Yes, N = No, U = Unknown

Apnea? Y = Yes, N = No, U = Unknown

Final Interview Date Month Day Year

Cough at Final Interview? Y = Yes, N = No, U = Unknown

Duration of Cough at Final Interview Days
0–150
999 = Unknown

COMPLICATIONS

Chest X-ray for Pneumonia
P = Positive
N = Negative
X = Not Done
U = Unknown

Seizures Due to Pertussis Y = Yes, N = No, U = Unknown

Acute Encephalopathy Due to Pertussis Y = Yes, N = No, U = Unknown

Hospitalized? Y = Yes, N = No, U = Unknown

Days Hospitalized? 0-998, 999 = Unknown

Died? Y = Yes, N = No, U = Unknown

TREATMENT

Were Antibiotics Given? Y = Yes, N = No, U = Unknown

1 = Erythromycin (incl. pediazole, ilosone)
2 = Cotrimoxazole (bactrim/septra)
3 = Clarithromycin/azithromycin
4 = Tetracycline/Doxycycline
5 = Amoxicillin/Penicillin/Ampicillin/Augmentin/Cector/Cefixime
6 = Other
9 = Unknown

Date Started First Antibiotic Month Day Year

Days First Antibiotic Actually Taken
0-998
999 = Unknown

Second Antibiotic Received See Choices for First Antibiotic Given

Date Started Second Antibiotic Month Day Year

Days Second Antibiotic Actually Taken
0-998
999 = Unknown

LABORATORY

Was Laboratory Testing for Pertussis Done? Y = Yes, N = No, U = Unknown

	Result	Date Specimen Taken (Month Day Year)
Culture		
DFA		
Serology 1		
Serology 2		
PCR		

RESULT CODES
P = Positive
N = Negative
E = Pending
I = Indeterminate
X = Not Done
S = Parapertussis
U = Unknown

VACCINE HISTORY

Vaccinated? (Received any doses of diphtheria, tetanus, and/or pertussis-containing vaccines) Y = Yes, N = No, U = Unknown

Vaccination Date (Month Day Year)	Vaccine Type*	Vaccine Manuf*	Lot Number

Vaccine Type Codes
W = DTP Whole Cell
A = DTaP
H = DTaP-Hib
D = DT or Td
T = DTP-Hib
P = Pertussis Only
X = Tdap
V = DTaP-IPV-Hep B
N = DTaP-IPV-Hib
K = DTaP-IPV
O = Other
U = Unknown

Vaccine Manufacturer Codes
C = Sanofi Pasteur
L = Wyeth
S = GlaxoSmithKline
M = Massachusetts Health Department
I = Michigan Health Department
N = North American Vaccine
O = Other
U = Unknown

*Record for each dose

Date of Last Pertussis-Containing Vaccine Prior to Illness Onset Month Day Year

Number of Doses of Pertussis-Containing Vaccine Prior to Illness Onset
0-6
9 = Unknown

Reason Not Vaccinated With ≥ 3 Doses of Pertussis Vaccine
1 = Religious Exemption
2 = Medical Contraindication
3 = Philosophical Exemption
4 = Previous Pertussis Confirmed by Culture or MD
5 = Parental Refusal
6 = Age Less Than 7 Months
7 = Other
9 = Unknown

EPIDEMIOLOGIC INFORMATION

Date First Reported to a Health Department Month Day Year

Date Case Investigation Started Month Day Year

Outbreak Related? Y = Yes, N = No, U = Unknown

Epi-Linked? Y = Yes, N = No, U = Unknown

Outbreak Name (Name of outbreak this case is associated with)

If patient <12 months old:

What was the mother's age at infant's birth: _____

What was the weight of the infant at birth:

_____ lb _____ oz *OR* _____ kg _____ g

Transmission Setting (Where did this patient acquire pertussis)?
1 = Day Care
2 = School
3 = Doctor's Office
4 = Hospital Ward
5 = Hospital ER
6 = Hosp. Outpatient Clinic
7 = Home
8 = Work
9 = Unknown
10 = College
11 = Military
12 = Correctional Facility
13 = Church
14 = International Travel
15 = Other

Setting (Outside Household) of Further Documented spread From This Case
Use same codes as for Transmission Settings, except:
7 = >1 Setting Outside Household
16 = No Documented Spread Outside Household

Number of Contacts in Any Setting Recommended Antibiotics
0-998
999 = Unknown

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The information below is epidemiologically imporant, but not included on NETSS screens.

Age of the person from whom this patient contracted pertussis	Age	Age Type
	☐☐☐ 999 = Unknown	☐ 0 = 0-120 years 1 = 0-11 months 2 = 0-52 weeks 3 = 0-28 days 9 = Age unknown

Setting	In which setting was pertussis acquired? (Please specify)	In which setting was there secondary spread? (Please specify)
Day Care		
School		
Doctor's Office		
Hospital (Ward/Outpatient/Clinic)		
Home		
Travel (International/ Domestic)		
Other		
Unknown		

Name of Contact	Birthdate	Relation to Case-Patient	Case?	Case ID#	Cough Onset Date (If Present)	# of PCVs*	Date of Last PCV	Parent's Name and Phone # (If Applicable)

**PCV=Pertussis-Containing Vaccine*

Comments

Clinical Case Definition*:
A cough illness lasting ≥ 2 weeks with one of the following: paroxysms of coughing, inspiratory "whoop", or posttussive vomiting, without apparent cause

Case Classification*:

Probable: **A case that meets the clinical cas definition, is not laboratory confirmed, and is not epidemiologically linked to a laboratory-confirmed case.**

Confirmed: **1) A case that is culture positive, and in which an acute illness of any duration is present, or**
2) a case that meets the clinical case definition and is confirmed by PCR, or
3) a case that meets the clinical case definition and is epidemiologically linked directly to a case confirmed by either culture or PCR.

***CDC Case Definitions for Infectious Conditions Under Public Health Surveillance. MMWR 1997;46 (No. RR-10):39**

Rubella Surveillance Worksheet

NAME (Last, First)				Hospital Record No.
Address (Street and No.)	City	County	Zip	Phone
Reporting Physician/Nurse/Hospital/Clinic/Lab	Address			Phone

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Rubella Surveillance Worksheet

County | State | Zip | Country of Birth

Birth Date (Month Day Year)

Age (Unk = 999)

Age Type
0 = 0-120 years
1 = 0-11 months
2 = 0-52 weeks
3 = 0-28 days
9 = Age unknown

Ethnicity
H = Hispanic
N = Not Hispanic
U = Unknown

Race
N = Native Amer./Alaskan Native
A = Asian/Pacific Islander
B = African American
W = White
O = Other
U = Unknown

Sex
M = Male
F = Female
U = Unknown

Event Date (Month Day Year)

Event Type
1 = Onset Date
2 = Diagnosis Date
3 = Lab Test Date
4 = Reported to County
5 = Reported to State or MMWR Report Date
9 = Unknown

Outbreak Associated (Unk = 999)

Reported (Month Day Year)

Imported
1 = Indigenous
2 = International
3 = Out of State
9 = Unknown

Report Status
1 = Confirmed
2 = Probable
3 = Suspect
9 = Unknown

CLINICAL DATA

Any Rash? Y = Yes, N = No, U = Unknown

Rash Onset (Month Day Year)

Rash Duration (0 - 30 Days, 99 = Unknown)

Fever? Y = Yes, N = No, U = Unknown

If Recorded, Highest Measured Temp. (36.0 - 110.0 Degrees, 999.9 = Unknown)

Arthralgia/ Arthritis? Y = Yes, N = No, U = Unknown

Lymphadenopathy? Y = Yes, N = No, U = Unknown

Conjunctivitis? Y = Yes, N = No, U = Unknown

COMPLICATIONS

Encephalitis? Y = Yes, N = No, U = Unknown

Arthralgia/Arthritis? Y = Yes, N = No, U = Unknown

Thrombocytopenia? Y = Yes, N = No, U = Unknown

Death? Y = Yes, N = No, U = Unknown

Other Complications? Y = Yes, N = No, U = Unknown

If Yes, Please Specify:

Hospitalized? Y = Yes, N = No, U = Unknown

Days Hospitalized (0 - 998, 999 - Unknown)

LABORATORY

Was Laboratory Testing For Rubella Done? Y = Yes, N = No, U = Unknown

Date IgM Specimen Taken (Month Day Year)

Result
P = Positive
E = Pending
N = Negative
X = Not Done
I = Indeterminate
U = Unknown

Date IgG Acute Specimen Taken (Month Day Year)

Date IgG Convalescent Specimen Taken (Month Day Year)

Result
P = Significant Rise in IgG
N = No Significant Rise in IgG
I = Indeterminate
E = Pending
X = Not Done
U = Unknown

Other Lab Result
P = Positive
N = Negative
I = Indeterminate
X = Not Done
E = Pending
U = Unknown

Specify Other Lab Method:

VACCINE HISTORY

Vaccinated? (Received rubella-containing vaccine?) Y = Yes, N = No, U = Unknown

Vaccination Date (Month Day Year)	Vaccine	Vaccine Type	Manuf.	Lot Number

Vaccine Type Codes
A = MMR
B = Rubella
O = Other
U = Unknown

Vaccine Manufacturer Codes
M = Merck
O = Other
U = Unknown

Number of doses received ON or AFTER 1st birthday

If Not Vaccinated, What Was The Reason?
1 = Religious Exemption
2 = Medical Contraindication
3 = Philosophical Objection
4 = Lab. Evidence of Previous Disease
5 = MD Diagnosis of Previous Disease
6 = Under Age For Vaccination
7 = Parental Refusal
8 = Other
9 = Unknown

EPIDEMIOLOGIC

Date First Reported to a Health Department (Month Day Year)

Date Case Investigation Started (Month Day Year)

Outbreak Related? Y = Yes, N = No, U = Unknown

If Yes, Outbreak Name

Transmission Setting (Where did patient acquire rubella?)
1 = Day Care
2 = School
3 = Doctor's Office
4 = Hospital Ward
5 = Hospital ER
6 = Hospital Outpatient Clinic
7 = Home
8 = Work
9 = Unknown
10 = College
11 = Military
12 = Correctional Facility
13 = Church
14 = International Travel
15 = Other

If Other, Specify Transmission Setting:_____

Were Age and Setting Verified? (Is age appropriate for setting) Y = Yes, N = No, U = Unknown

Source of Exposure For Current Case (Enter State ID if source was an in-state case; enter Country if source was out of U.S.; enter State if source was out-of-state)

Epi-Linked to Another Confirmed or Probable Case? Y = Yes, N = No, U = Unknown

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Indicates epidemiologically important items not yet on NETSS screen

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PREGNANT WOMEN

Was Patient Pregnant?

☐ Y = Yes
N = No
U = Unknown

Number of Weeks Gestation (or Trimester) at Onset of Illness ☐☐☐

1st = First Trimester
2nd = Second Trimester
3rd = Trimester

Or

1 = 1 Week
2 = 2 Weeks
3 = 3 Weeks
Etc. – continue up to 45 weeks

Prior Evidence of Serological Immunity?

☐ Y = Yes
N = No
U = Unknown

Year of Test ☐☐☐☐

OR

Age of Patient at Time of Test ☐☐

0 -50
99 - Unknown

Was Previous Rubella Serologically Confirmed?

☐ Y = Yes
N = No
U = Unknown

Year of Disease ☐☐☐☐

OR

Age of Patient at Time of Disease ☐☐

0 -50
99 - Unknown

The information below is epidemiologically important but not included on NETSS screens

Exposure Period — **Period of Communicability**

21 Days	14 Days	7 Days	Rash Onset	7 Days
Month ☐☐ Day ☐☐ Year ☐☐	Month ☐☐ Day ☐☐ Year ☐☐	Month ☐☐ Day ☐☐ Year ☐☐	Month ☐☐ Day ☐☐ Year ☐☐	Month ☐☐ Day ☐☐ Year ☐☐

Contacts of patient during infectious period (7 days before to 7 days after rash onset) who are in 1st 5 months of pregnancy

Name	Address/Phone	Documented Prior Rubella Immunization?	If Yes, Date	Documented Rubella Seropositivity Before Or Within 7 Days After First Exposed	If No or Unknown, Action Taken – Rubella Serology, etc.
		☐ Y = Yes N = No U = Unknown	Month ☐☐ Day ☐☐ Year ☐☐	☐ Y = Yes N = No U = Unknown	
		☐ Y = Yes N = No U = Unknown	Month ☐☐ Day ☐☐ Year ☐☐	☐ Y = Yes N = No U = Unknown	
		☐ Y = Yes N = No U = Unknown	Month ☐☐ Day ☐☐ Year ☐☐	☐ Y = Yes N = No U = Unknown	

Group contacts of patient during infectious period (7 days before to 7 days after rash onset), i.e., households, child care center, school, college, workplace, jail/prison, physician's office/clinic/hospital/emergency room, etc.

Name of Group/Site	Address/Phone	Notes

Clinical Case Definition:
An illness that has all of the following characteristics: acute onset of generalized maculopapular rash, temperature > 99° F (> 37° C), if measured, and arthralgia/arthritis, lymphadenopathy, or conjunctivitis.

Case Classification:
***Suspected*: any generalized rash illness of acute onset**
***Probable*: a case that meets the clinical case definition, has no or noncontributory serologic or virologic testing, and is not epidemiologically linked to a laboratory-confirmed case**
***Confirmed*: a case that is laboratory confirmed or that meets the clinical case definition and is epidemiologically linked to a laboratory-confirmed case**

Tetanus Surveillance Worksheet

NAME (Last, First)				Hospital Record No.
Address (Street and No.)	City	County	Zip	Phone
Reporting Physician/Nurse/Hospital/Clinic/Lab Phone	Address			Phone

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CDC NETSS ID [ ]

County

State

Zip

Birth Date Month [ ] Day [ ] Year [ ]

Age [ ] Unknown= 999

Age Type [ ]
0 = 0-120 years
1 = 0-11 months
2 = 0-52 weeks
3 = 0-28 days
9 = Unknown

Race [ ]
N = Native Amer./Alaska Native
A = Asian/Pacific Islander
B = African American
W = White
O = Other
U = Unknown

Ethnicity [ ]
H = Hispanic
N = Not Hispanic
U = Unknown

Sex [ ]
M = Male
F = Female
U = Unknown

Event Date Month [ ] Day [ ] Year [ ]

Event Type [ ]
1 = Onset Date
2 = Diagnosis Date
3 = Lab Test Done
4 = Reported to County
5 = Reported to State or MMWR Report Date
6 = Unknown

Reported Month [ ] Day [ ] Year [ ]

Imported [ ]
1 = Indigenous
2 = International
3 = Out of State
9 = Unknown

Report Status [ ]
1 = Confirmed
2 = Probable
3 = Suspect
9 = Unknown

HISTORY

Date Year of Onset Month [ ] Day [ ] Year [ ]

Occupation

History of Military Service (Active or Reserve)? [ ]
Y = Yes
N = No
U = Unknown

Year of Entry into Military Service [ ]

Tetanus Toxoid Vaccination History Prior to Tetanus Disease
(Exclude Doses Received Since Acute Injury) [ ]
0 = Never
1 = 1 dose
2 = 2 doses
3 = 3 doses
4 = 4+ doses
9 = Unknown

Years Since Last Dose [ ]
0 - 98
99 = Unknown

CLINICAL DATA

Acute Wound Identified? [ ]
Y = Yes
N = No
U = Unknown

Date Wound Occurred Month [ ] Day [ ] Year [ ]

Principal Anatomic Site [ ]
1 = Head
2 = Trunk
3 = Upper Extremity
4 = Lower Extremity
9 = Unspecified

Work Related? [ ]
Y = Yes
N = No
U = Unknown

Environment [ ]
0 = Home
1 = Other Indoors
2 = Farm / Yard
3 = Automobile
4 = Other Outdoors
9 = Unknown

Circumstances

Principal Wound Type [ ]
1 = Puncture
2 = Stellate Laceration
3 = Linear Laceration
4 = Crush
5 = Abrasion
6 = Avulsion
7 = Burn
8 = Frostbite
9 = Compound Fracture
10 = Other (e.g. with cancer) Specify: _____
11 = Surgery
12 = Animal Bite
13 = Insect Bite/Sting
14 = Dental
15 = Tissue Necrosis
99 = Unknown

Wound Contaminated? [ ]
Y = Yes
N = No
U = Unknown

Depth of Wound [ ]
1 = 1 cm. or less
2 = more than 1 cm.
9 = Unknown

Signs of Infection? [ ]
Y = Yes
N = No
U = Unknown

Devitalized, Ischemic, or Denervated Tissue Present? [ ]
Y = Yes
N = No
U = Unknown

MEDICAL CARE PRIOR TO ONSET

Was Medical Care Obtained For This Acute Injury [ ]
Y = Yes
N = No
U = Unknown

Tetanus Toxoid (TT/Td/Tdap) Administered Before Tetanus Onset [ ]
Y = Yes
N = No
U = Unknown

If Yes, How Soon After Injury? [ ]
1 = < 6 Hours
2 = 7 - 23 Hours
3 = 1 - 4 Days
4 = 5 - 9 Days
5 = 10 - 14 Days
6 = 15+ Days
9 = Unknown

Wound Debrided Before Tetanus Onset [ ]
Y = Yes
N = No
U = Unknown

If Yes, Debrided How Soon After Injury [ ]
1 = < 6 Hours
2 = 7 - 23 Hours
3 = 1 - 4 Days
4 = 5 - 9 Days
5 = 10 - 14 Days
6 = 15+ Days
9 = Unknown

Tetanus Immune Globulin (TIG) Prophylaxis Received Before Tetanus Onset [ ]
Y = Yes
N = No
U = Unknown

If Yes, TIG Given How Soon After Injury? [ ]
1 = < 6 Hours
2 = 7 - 23 Hours
3 = 1 - 4 Days
4 = 5 - 9 Days
5 = 10 - 14 Days
6 = 15+ Days
9 = Unknown

Dosage (Units) [ ]
0 - 998
999 = Unknown

Associated Condition (If no Acute Injury) [ ]
1 = Abscess
2 = Ulcer
3 = Blister
4 = Gangrene
5 = Cellulitis
6 = Other Infection
7 = Cancer
8 = Gingivitis
88 = None
99 = Unknown

Describe Condition:

Diabetes? [ ]
Y = Yes
N = No
U = Unknown

If Yes, Insulin-Dependent? [ ]
Y = Yes
N = No
U = Unknown

Parenteral Drug Abuse? [ ]
Y = Yes
N = No
U = Unknown

Describe Condition:

CLINICAL COURSE

Type of Tetanus Disease [ ]
1 = Generalized
2 = Localized
3 = Cephalic
4 = Unknown

TIG Therapy Given After Tetanus Onset [ ]
Y = Yes
N = No
U = Unknown

If Yes, How Soon After Illness Onset? [ ]
1 = < 6 Hours
2 = 7 - 23 Hours
3 = 1 - 4 Days
4 = 5 - 9 Days
5 = 10 - 14 Days
6 = 15+ Days
9 = Unknown

Dosage (Units) [ ]
0 - 998
999 = Unknown

Days Hospitalized [ ]
0 - 998
999 = Unknown

Days In ICU [ ]
0 - 998
999 = Unknown

Days Received Mechanical Ventilation [ ]
0 - 998
999 = Unknown

Outcome One Month After Onset? [ ]
R = Recovered
C = Convalescing
D = Died

If Died, Date of Death Month [ ] Day [ ] Year [ ]

CS106190 02/09

Tetanus Surveillance Worksheet

NAME (Last, First)				Hospital Record No.
Address (Street and No.)	City	County	Zip	Phone
Reporting Physician/Nurse/Hospital/Clinic/Lab Phone	Address			Phone

DETACH HERE and transmit only lower portion if sent to CDC

NEONATAL (<28 DAYS OLD)

Mother's Age in Years
99 = Unknown

Mother's Birth Date
Month Day Year

Date Mother's Arrival in U.S.
Month Day Year

Mother's Tetanus Toxoid Vaccination History PRIOR to Child's Disease
(Known Doses Only)
0 = Never
1 = 1 dose
2 = 2 doses
3 = 3 doses
4 = 4+ doses
9 = Unknown

Years Since Mother's Last Dose
0 - 98
99 = Unknown

Child's Birthplace
1 = Hospital
2 = Home
3 = Other
9 = Unknown

Birth Attendant(s)
1 = Physician
2 = Nurse
3 = Licensed Midwife
4 = Unlicensed Midwife
5 = Other
9 = Unknown

Other Birth Attendant(s)
(If Not Previously Listed)

Other Comments?
Y = Yes
N = No
U = Unknown

Reporter's Name

Title

Institution Name

Phone Number

Date Reported
Month Day Year

Clinical Case Definition*:
Acute onset of hypertonia and/or painful muscular contractions (usually of the muscles of the jaw and neck) and generalized muscle spasms

Case Classification*:
Confirmed: A clinically compatible case, as reported by a health-care professional.

Notes/Other Information:

*CDC. Case Definitions for Infectious Conditions Under Public Health Surveillance. MMWR 1997;46(No. RR-10):39

GEORGIA DEPARTMENT OF PUBLIC HEALTH
PUBLIC HEALTH LABORATORY

BACTERIOLOGY SUBMISSION FORM

SUBMITTER INFORMATION

SUBMITTER CODE: ☐☐☐☐☐☐

CLINIC NAME: _____

STREET: _____

CITY: _____

STATE _____ ZIP CODE: _____

PHONE NO: _____

FAX NO: _____

CONTACT NAME: _____

PATIENT INFORMATION

PATIENT ID: _____ DOB: ____/____/____

NAME: _____
Last First Middle

RESIDENCE: _____
Street City State Zip

_____ PHONE: _____
County Home Work Cell/other

RACE:
- ☐ American Indian/Alaska Native
- ☐ Asian
- ☐ Black/African-American
- ☐ Native Hawaiian/Pacific Islander
- ☐ Other
- ☐ Unknown
- ☐ White

ETHNICITY:
- ☐ Hispanic or Latino
- ☐ Non-Hispanic or Latino
- ☐ Unknown

GENDER:
- ☐ Male
- ☐ Female
- ☐ Unknown

SPECIMEN INFORMATION

Date of Collection:

_____/_____/_____

Source:
- ☐ Blood
- ☐ Cervix
- ☐ CSF
- ☐ Nasopharyngeal
- ☐ Skin
- ☐ Sputum
- ☐ Stool/Feces
  - ☐ First
  - ☐ Repeat
- ☐ Throat
- ☐ Urethra
- ☐ Urine
- ☐ Wound
- ☐ Other: _____

Specimen Type:
- ☐ Isolated organism
- ☐ Culture
- ☐ Slide/ Smear
- ☐ Other: _____

Special instructions:

_____

_____

_____

_____

Clinical Information:

Date of Onset: _____

Incubation period: _____

Antibiotics: _____

Collected before antibiotic Rx ☐Yes ☐ No

Outbreak related: ☐ Yes ☐ No
If Yes, name of outbreak:
_____

Travel outside US: ☐ Yes ☐ No
If Yes, where? :
_____

Symptoms:
- ☐ Diarrhea
- ☐ Vomiting
- ☐ Blood/mucus
- ☐ Not Ill
- ☐ Other: _____

Please select ONLY one TEST per SPECIMEN per FORM

ENVIRONMENTAL/FOOD
(Epidemiology use only)

Source:
- ☐ Environmental
- ☐ Food

Type (Please specify):

_____

Shipped:
- ☐ Refrigerated
- ☐ Frozen
- ☐ Room Temperature

Test requested:
- ☐ B. cereus
- ☐ Campylobacter
- ☐ C. perfringens
- ☐ Listeria
- ☐ STEC / SLT
- ☐ Salmonella
- ☐ Shigella
- ☐ S. aureus / Toxin
- ☐ Other: _____

BACTERIOLOGY

☐ **Enteric Pathogens**
- ☐ Campylobacter
- ☐ STEC
- ☐ Salmonella
- ☐ Shigella
- ☐ Yersinia

☐ **Stool Culture** Suspected Agent: _____
- ☐ Preserved stool (Para-Pak C&S, Room Temp)
  - ☐ Routine (Salmonella, Shigella, Campylobacter, Aeromonas, STEC, and Yersinia)
  - ☐ S. aureus (Submit within 24h after onset)*
- ☐ Fresh stool (Refrigerated)
  - ☐ B. cereus (Submit within 48h after onset)*
  - ☐ C. perfringens (Submit within 48h after onset)*
  - ☐ C. botulinum (Epidemiology approval required CALL 404-657-2588) *

☐ **Reference ID/Special Bacteriology**
- ☐ *Neisseria meningitidis*
- ☐ *Haemophilus infuenzae*
- ☐ *Listeria monocytogenes*
- ☐ *Vibrio sp*.
- ☐ Other (**Specific Agent Suspected**):_____

☐ **Pertussis (Whooping cough)**
- ☐ Direct Fluorescent Antibody (DFA)
- ☐ Culture

☐ **Group A Streptococcus**

☐ **Forward to CDC* (Please specify):** _____

*Special arrangement required CALL 404-327-7997

GEORGIA DEPARTMENT OF PUBLIC HEALTH
PUBLIC HEALTH LABORATORY

IMMUNOLOGY SUBMISSION FORM

SUBMITTER INFORMATION

SUBMITTER CODE:

CLINIC NAME:_____

_____

STREET: _____

_____

CITY:_____

STATE _____ ZIP CODE: _____

PHONE NO: _____

FAX NO: _____

CONTACT NAME: _____

PATIENT INFORMATION

PATIENT ID: _____

NAME: _____
Last First Middle

RESIDENCE:_____
Street City State Zip

_____ PHONE:_____
County Home Work Cell/other

DOB: _____/_____/_____ Medicaid #_____

RACE:
- ☐ American Indian/Alaska Native
- ☐ Asian
- ☐ Black/African-American
- ☐ Native Hawaiian/Pacific Islander
- ☐ Other
- ☐ Unknown
- ☐ White

ETHNICITY:
- ☐ Hispanic or Latino
- ☐ Non-Hispanic or Latino
- ☐ Unknown

GENDER:
- ☐ Male
- ☐ Female
- ☐ Unknown

SPECIMEN INFORMATION

Date of Collection:

_____/_____/_____

Source/Type:
- ☐ Blood
- ☐ CSF
- ☐ Plasma
- ☐ Serum
- ☐ Serum/Acute
- ☐ Serum/Convalescent
- ☐ Other: _____

Reason for Testing:
- ☐ Contact to STD
- ☐ Court Ordered
- ☐ Diagnosis
- ☐ Repeat testing
- ☐ Other: _____

Shipped:
- ☐ Refrigerated
- ☐ Room Temperature

Please complete:
Pregnant ☐ Yes ☐ No ☐ Unknown

Prenatal (Hepatitis B) EDC date_____

Clinical Information:

Date of Onset: _____

Previous Lab Results, if any: _____

Travel outside US: Yes No
If Yes, where? : _____

Symptoms: (check all that apply)
- ☐ fever
- ☐ rash
- ☐ stiff neck
- ☐ headache
- ☐ other_____

Please submit a separate form and specimen for each <u>Test Panel</u>

Routine Syphilis

- ☐ Routine RPR
- ☐ VDRL(spinal fluid)

Special RPR testing request:

- ☐ Quantitative(Titer) and Confirmatory even if screening test (RPR) negative
- ☐ No Confirmatory Test needed even if screening test (RPR) is positive
- ☐ Quantitative (Titer) RPR
- ☐ List test for CDC referrals _____
- ☐ Special test requests_____

Arbovirus/WNV panel

- ☐ Arbo IgG & IgM panel
- ☐ WNV IgG & IgM
- ☐ WNV IgM (CSF)

Hepatitis Testing

- ☐ Hep B (Prenatal)
- ☐ Hep B (Routine Screen)
- ☐ Anti-HAV Total Antibody
- ☐ Anti-HAV-IgM
- ☐ Anti-HCV

Miscellaneous Serology

- ☐ Toxoplasmosis IgG
- ☐ Toxoplasmosis IgM
- ☐ Rubella IgG
- ☐ Rubella IgM
- ☐ CMV IgG
- ☐ CMV IgM
- ☐ HSV1/HSV2
- ☐ Rubeola IgG
- ☐ Rubeola IgM
- ☐ Mumps
- ☐ Varicella Zoster
- ☐ Rocky Mountain Spotted Fever
- ☐ Murine Typhus
- ☐ Torch Panel**
- ☐ Other _____

** **TORCH panel** includes Toxoplasmosis, Rubella, CMV, HSV1/2

GEORGIA DEPARTMENT OF PUBLIC HEALTH
PUBLIC HEALTH LABORATORY

MOLECULAR BIOLOGY SUBMISSION FORM

SUBMITTER INFORMATION

SUBMITTER CODE:

☐☐☐☐☐☐

NAME:_____

_____

STREET: _____

CITY: _____

STATE _____ ZIP CODE_____

PHONE NO: _____

FAX NO: _____

CONTACT NAME::

_____

PATIENT INFORMATION

PATIENT ID: _____

NAME: _____
Last First Middle

RESIDENCE:_____
Street City State Zip

_____ PHONE:_____
County Home Work Cell/Other

DOB: _____/_____/_____ Medicaid #_____

RACE:
- ☐ American Indian/Alaska Native
- ☐ Asian
- ☐ Black/African-American
- ☐ Native Hawaiian/Pacific Islander
- ☐ Other
- ☐ Unknown
- ☐ White

ETHNICITY:
- ☐ Hispanic or Latino
- ☐ Non-Hispanic or Latino
- ☐ Unknown

GENDER:
- ☐ Male
- ☐ Female
- ☐ Unknown

SPECIMEN/CLINICAL INFORMATION

Date of collection:

_____/_____/_____

Time of collection: _____

Source: _____

Specimen type:
- ☐ Clinical _____
- ☐ Culture
- ☐ Other

Specimen shipped:
- ☐ Frozen
- ☐ Refrigerated
- ☐ Room Temperature

Special instructions (if any):

_____

Clinical information:

Date of onset: _____/_____/_____

Patient location at time of collection:
- ☐ Inpatient
  Hospital name _____
- ☐ Outpatient
- ☐ Long term care

Patient receiving antivirals ☐Yes ☐ No

Patient receiving antibiotics: ☐Yes ☐ No

Outbreak related: ☐ Yes ☐ No
If Yes, Name/ID# of outbreak:

_____

Travel outside US (within last 10 days):
☐ Yes ☐ No
If yes, where? _____

Symptoms:
(check all that apply):

- ☐ Backache
- ☐ Blurred vision
- ☐ Chest pain
- ☐ Constipation
- ☐ Cough
- ☐ Diarrhea
- ☐ Difficulty swallowing
- ☐ Disordered speech
- ☐ Fatigue
- ☐ Fever
- ☐ Headache
- ☐ Hemorrhage
- ☐ Joint pain
- ☐ Myalgia
- ☐ Nausea
- ☐ Necrosis
- ☐ Vomiting
- ☐ Rash
- ☐ Sore throat
- ☐ Stiff neck
- ☐ Swollen lymph nodes
- ☐ Watery/red/itchy eyes
- ☐ Weight loss
- ☐ Other_____

Influenza rapid test results (if performed):

_____

Please select <u>ONLY</u> one TEST per SPECIMEN per FORM

Test requested

- ☐ BT agent rule out*_____
- ☐ Bordetella pertussis (PCR)*
- ☐ Influenza panel (rRT-PCR)*
- ☐ Mumps (PCR)*
- ☐ Norovirus (rRT-PCR)*
- ☐ Rash illness panel (PCR)*
- ☐ VZV (PCR)*
- ☐ Refer to CDC*
- ☐ Other: _____

* Research use only procedure- requires epidemiology consultation

Results

Date reported: _____

Reported by: _____

Georgia Department of Public Health

Pertussis Reporting and Case Investigation Form

PATIENT DEMOGRAPHICS

Patient name: Last, First M.I.	Date of birth (mm/dd/yy): ____/____/____	Age *(enter age and check one):* _____ □ Days □ Weeks □ Months □ Years		Gender: □ Male □ Female
Address: Number, Street	City:	State:	ZIP code:	County:

Telephone number:

Home ( ) – Work ( ) –

Ethnicity (check one):	Race (check all that apply):		
□ Hispanic/Latino	□ Black/African-American	□ Asian /Pacific Islander	□ Unknown
□ Non-Hispanic/Latino	□ Native American/Alaskan Native	□ Multiracial	
□ Unknown	□ White	□ Other (please specify)_____	

Country of birth:

TRACKING DATA

Medical record no. or client no.:			State Case ID ***(For state use only)***
Date reported to health department (mm/dd/yy): ____/____/____	Date investigation started: ____/____/____	Person/clinician reporting:	Reporter telephone: ( ) –
Case investigator completing form:	Investigator telephone: ( ) –	Investigator's organization:	

Is this case epi-linked to another confirmed or probable case? □ Yes □ No □ Unknown

SIGNS AND SYMPTOMS

Any cough? □ Yes □ No □ Unknown	Cough onset date ____/____/____	Cough 14 days after cough onset? □ Yes □ No □ Unknown	Paroxysmal cough? □ Yes □ No □ Unknown
Whoop? □ Yes □ No □ Unknown	Post-tusive vomiting? □ Yes □ No □ Unknown	Apnea? □ Yes □ No □ Unknown	
Number of physician visits prior to diagnosis _____ days □ Unknown		Final interview date ____/____/____	Cough at final interview □ Yes □ No □ Unknown
Duration of cough at final interview (days) _____ days		DOES CASE MEET CLINICAL CRITERIA □ Yes □ No □ Unknown ***(For state use only)***	

COMPLICATIONS AND OTHER SYMPTOMS

Hospitalized? □ Yes □ No □ Unknown	Admission date ____/____/____	Discharge date ____/____/____	No. of days hospitalized _____days	Facility
X-ray for pneumonia? □ Pos □ Neg □ Not done □ Unknown		Seizures? □ Yes □ No □ Unknown	Acute encephalopathy? □ Yes □ No □ Unknown	
Died? □ Yes □ No □ Unknown	Date of death ____/____/____	**If case died, please complete and attach pertussis death worksheet**		

TREATMENT

Antibiotics given? □ Yes □ No □ Unknown	1st antibiotic received □ Erythromycin (1) □ Clarithromycin/Azithromycin (2) □ Tetracycline/Doxycycline (3) □ Cotrimoxazole (4) □ Amoxicillin/Penicillin/Ampicillin/ Augmentin/Ceclor/Cefixime (5) □ Other (6) □ Unknown (9)		Date 1st antibiotic started ____/____/____
No. of days 1st antibiotic actually taken _____ days	2nd antibiotic received See choices for 1st antibiotic received _____	Date 2nd antibiotic started ____/____/____	No. of days 2nd antibiotic actually taken _____ days

Georgia Department of Public Health
Varicella Reporting and Case Investigation Form

PATIENT DEMOGRAPHICS

Patient name: Last, First M.I.	Date of birth (mm/dd/yy): ____/____/____	Age *(enter age and check one)*: _____ □ Days □ Weeks □ Months □ Years		Gender: □ Male □ Female
Address: Number, Street	City:	State:	ZIP code:	County:

Telephone number:
Home ( ) – Work ( ) –

Ethnicity (check one):	Race (check all that apply):		
□ Hispanic/Latino	□ Black/African-American	□ Asian /Pacific Islander	□ Unknown
□ Non-Hispanic/Latino	□ Native American/Alaskan Native	□ Multiracial	
□ Unknown	□ White	□ Other (please specify)_____	

Country of birth:

TRACKING DATA

Medical record no. or client no.:		State Case ID ***(For state use only)***	
Date reported to health department (mm/dd/yy): ____/____/____	Date investigation started: ____/____/____	Person/clinician reporting:	Reporter telephone: ( ) –
Case investigator completing form:	Investigator telephone: ( ) –	Investigator's organization:	

Is this case epi-linked to another confirmed or probable case? □ Yes □ No □ Unknown

SIGNS, SYMPTOMS AND COMPLICATIONS

Diagnosis date: ____/____/____	Illness onset date: ____/____/____	Rash: □ Yes □ No □ Unknown	Rash onset date: ____/____/____	Estimated number of lesions:
Rash location: □ Generalized □ Focal □ Unknown	If focal, specify area(s) of body:	Where on body did rash 1st occur? (check all that apply) □ Face/Head □ Legs □ Trunk □ Arms □ Inside mouth □ Other (please specify)_____		□ < 50 □ 50-249 □ 250-500 □ > 500

Character of lesions :			
Macules (flat) present	□ Yes	□ No	□ Unknown
Papules (raised) present	□ Yes	□ No	□ Unknown
Vesicles (fluid) present)	□ Yes	□ No	□ Unknown
Hemorrhagic	□ Yes	□ No	□ Unknown
Itchy	□ Yes	□ No	□ Unknown
Scabs/crusting	□ Yes	□ No	□ Unknown
Crops/waves	□ Yes	□ No	□ Unknown

Did the rash crust over?
□ Yes □ No □ Unknown

If yes, how many days until all the lesions crusted over?
_____ days

If no, how many days did the rash last? _____ days

Fever? (T ≥38.5 C or 101.3°F)
□ Yes □ No □ Unknown

Date of fever onset: ____/____/____

Highest measured temperature: _____ °F

Total number of days with fever: _____ days

VACCINATION AND DISEASE HISTORY

Ever received one or more doses of varicella containing vaccine?
□ Yes □ No □ Unknown

Number of doses **on** or **after** first birthday: _____ doses

Dose	Vaccination date	Vaccine type	Vaccine manufacturer	Lot number
Dose 1	____/____/____			
Dose 2	____/____/____			

Has this patient ever been diagnosed with varicella before?
□ Yes □ No □ Unknown

If previously diagnosed, age at previous diagnosis:
_____ □ Days □ Weeks □ Months □ Years

Previous diagnosis made by:
□ Physician/heatlthcare provider
□ Parent
□ Other _____

Reason for not receiving varicella containing vaccine(s) (check all that apply):

□ Born outside the U.S. **(1)**
□ Lab evidence of previous disease **(2)**
□ MD diagnosis of previous disease **(3)**
□ Medical contraindication **(4)**
□ Never offered vaccine **(5)**
□ Parent/patient forgot to vaccinate **(6)**
□ Parent/patient refusal **(7)**
□ Philosophical objection **(8)**
□ Religious exemption **(9)**
□ Under age for vaccination **(10)**
□ Other **(11)** (specify) _____
□ Unknown **(12)**

If patient is ≥ 6 yrs. old and received one dose **on** or **after** 6th birthday but never received second dose, what is the reason? ***(Use number codes from question to the left)*** ←
_____

CLINICAL COURSE AND COMPLICATIONS

Did the patient visit a healthcare provider during this illness? □ Yes □ No □ Unknown

Hospitalized:	Dates hospitalized:	Total # days hosp:	Facility name:
□ Yes □ No □ Unknown	____/____/____ to ____/____/____		

Did the patient develop any complications that were diagnosed by a healthcare provider? □ Yes □ No □ Unknown

If "yes":
(Check all that apply)

□ Skin/soft tissue infection
□ Cerebellitis/ataxia
□ Encephalitis
□ Dehydration
□ Hemorrhagic condition
□ Pneumonia

Death:	If yes, date of death:	**If case died, please complete and attach varicella death worksheet**
□ Yes □ No □ Unknown	____/____/____	

LABORATORY TESTS

Was laboratory testing for varicella done?	Case lab confirmed ***(For state use only)***
□ Yes □ No □ Unknown	□ Yes □ No □ Unknown

	Result	Date Specimen Taken	Lab Name
PCR	_____	____/____/____	_____
DFA	_____	____/____/____	_____
IgM	_____	____/____/____	_____
IgG (acute)	_____	____/____/____	_____
IgG (convalescent)	_____	____/____/____	_____
Other (specify)	_____	____/____/____	_____

Result Codes
P:Positive
X:Not done
N:Negative
I:Indeterminate
E:Pending
U:Unknown

EPIDEMIOLOGIC INFORMATION

Where did this patient acquire varicella?

□ Athletics
□ College
□ Community
□ Hospital ER
□ Daycare
□ Unknown
□ Doctor's office
□ International travel
□ Correctional facility
□ Hospital outpatient clinic
□ Hospital ward
□ Other (specify)_____
□ Home
□ Military
□ Place of worship
□ School
□ Work

Is the patient:

Pregnant? □ Y□ N □ Unk
A healthcare worker? □ Y□ N □ Unk
In daycare? □ Y□ N □ Unk
Incarcerated? □ Y□ N □ Unk
Institutionalized? □ Y□ N □ Unk
(nursing home or chronic care facility)

2010 CASE DEFINITION

Case definition

An illness with acute onset of diffuse (generalized) maculopapulovesicular rash without other apparent cause.

Breakthrough disease: A case of wild-type varicella infection occuring more than 42 days after vaccination. Such disease is usually mild with a shorter duration of illness, fewer constitutional symptoms, and fewer than 50 skin lesions.

Case classification:

Probable: A case that meets the clinical case definition, is not laboratory confirmed, and is not epidemiologically linked to another probable or confirmed case.

Confirmed: A case that is laboratory confirmed or that meets the clinical case definition and is epidemiologically linked to a confirmed or a probable case.

Note: Two probable cases that are epidemiologically linked are considered confirmed, even in the absence of laboratory confirmation.

Varicella death case classification:

Probable: A probable case of varicella that contributes directly or indirectly to acute medical complications that result in death.

Confirmed: A confirmed case of varicella that contributes directly or indirectly to acute medical complications that result in death.

LABORATORY TESTS

Was laboratory testing for pertussis done?
□ Yes □ No □ Unknown

Case lab confirmed ***(For state use only)***
□ Yes □ No □ Unknown

	Result	Date specimen taken	Lab name
Culture	_____	____/____/____	_____
PCR	_____	____/____/____	_____
Serology 1	_____	____/____/____	_____
Serology 2	_____	____/____/____	_____
DFA	_____	____/____/____	_____

Result codes
P:Positive
X:Not done
N:Negative
I:Indeterminate
E:Pending
U:Unknown
S:*B.parapertussis*
B:*B.bronchiseptica*
H:*B.holmseii*

VACCINATION HISTORY

Vaccinated? (Received any doses of pertussis-containing vaccines)
□ Yes □ No □ Unknown

Number of doses of pertussis-containing vaccine received prior to illness onset? ————

Dose	Vaccination date	Vaccine type*	Vaccine manufacturer†	Lot number
Dose 1	____/____/____			
Dose 2	____/____/____			
Dose 3	____/____/____			
Dose 4	____/____/____			
Dose 5	____/____/____			
Dose 6	____/____/____			

***Vaccine type codes:**
W:DTP
A: DTap
H: DTaP-Hib
D: DT or Td
T: DTP-Hib
P: Pertussis Only
U: Unknown
B: DTP-Hib-HepB
X: Tdap (Adacel, Boostrix)
V: DTaP-IPV-HepB (Pediarix)
N: DTaP-IPV-Hib (Pentacel)
K: DTaP-IPV (Kinrex)
O: Other

†Vaccine manufacturer codes:
C: Sanofi Pasteur
L: Wyeth
S: Glaxo Smith Kline
M: Mass. Health Dept
I: Michigan Health Dept
N: North American Vaccine
O: Other
U: Unknown

(If available) Reason for inadequate vaccination coverage (check all that apply)
□ Religious exemption
□ Medical contraindication
□ Philosophical exemption
□ Previous culture/MD confirmed pertussis
□ Parental refusal
□ Age < 7 months
□ Other
□ Unknown

EPIDEMIOLOGIC INFORMATION

Epi-linked?
□ Yes □ No □ Unknown

Outbreak related?
□ Yes □ No □ Unknown

Outbreak name or location

Employed at or attends daycare ?
□ Yes □ No □ Unknown

Employed at or attends school?
□ Yes □ No □ Unknown

PATIENT SETTING (EXPOSURE AND CONTACT)

Transmission setting (Where did this case acquire pertussis?)
□ Daycare (1)
□ School (2)
□ Doctor's Office (3)
□ Hospital Ward (4)
□ Hospital ER (5)
□ Outpatient clinic (6)
□ Home (7)
□ Work (8)
□ Unknown (9)
□ College (10)
□ Military (11)
□ Correctional facility (12)
□ Church (13)
□ International travel (14)
□ Other (15)

Number of contacts recommended antibiotics

Setting of further documented spread from case (outside of household) **(use number codes from transmission setting question above)** _____ *(no documented spread = 16)*

Suspected source of infection (if case < 1 year, is another person with suspected pertussis known?) □ Yes □ No □ Unknown

Source's relationship to case (if patient <12 months old)
□ Mother □ Brother □ Grandparent
□ Father □ Friend □ Neighbor □ Daycare
□ Sister □ Other □ Baby Sitter □ Unknown

Source's current age (if patient < 12 months old)
_____

Mother's age at infant birth
_____

Number of residents in case household(s)
_____

Weight of infant at birth (if patient <12 months old) _____ lb _____oz

Comments:

GEORGIA DEPARTMENT OF PUBLIC HEALTH
PUBLIC HEALTH LABORATORY

VIROLOGY SUBMISSION FORM

SUBMITTER INFORMATION

SUBMITTER CODE:

☐☐☐☐☐☐

CLINIC NAME: _____

_____

STREET: _____

CITY: _____

STATE _____ ZIP CODE: _____

PHONE NO: _____

FAX NO: _____

CONTACT NAME:

_____

PATIENT INFORMATION

PATIENT ID: _____ CTS#: _____

NAME: _____
Last First Middle

RESIDENCE: _____
Street City State Zip

_____ PHONE: _____
County Home Work Cell/other

DOB: _____/_____/_____ Medicaid # _____

RACE:
- ☐ American Indian/Alaska Native
- ☐ Asian
- ☐ Black/African-American
- ☐ Native Hawaiian/Pacific Islander
- ☐ Other
- ☐ Unknown
- ☐ White

ETHNICITY:
- ☐ Hispanic or Latino
- ☐ Non-Hispanic or Latino
- ☐ Unknown

GENDER:
- ☐ Male
- ☐ Female
- ☐ Unknown

SPECIMEN INFORMATION

Date of Collection:

_____/_____/_____

Source/Type:
- ☐ Blood
- ☐ CSF
- ☐ Lesion/General Swab
- ☐ Lesion/Genital Swab
- ☐ Nasopharyngeal Aspirate
- ☐ Nasopharyngeal Swab
- ☐ Plasma
- ☐ Rectal Swab
- ☐ Serum
- ☐ Stool
- ☐ Throat Swab
- ☐ Urine
- ☐ Other: _____

Reason for Testing:
- ☐ Court Ordered
- ☐ Diagnosis
- ☐ Outbreak
- ☐ Rapid Test Confirmation
- ☐ Routine Screening
- ☐ HIV Viral Load
- ☐ Other: _____

Shipped:
- ☐ Frozen
- ☐ Refrigerated
- ☐ Room Temperature

Special Instructions:

_____

_____

Forward to CDC**

Clinical Information:

Date of Onset: _____

Previous Lab Results, if any: _____

Outbreak Related: ☐ Yes ☐ No
If Yes, Name/ID# of outbreak:

_____

Travel Outside US: Yes No
If Yes, where? : _____

Symptoms: (check all that apply)
- ☐ chills/body aches
- ☐ diarrhea
- ☐ headache
- ☐ stiff neck
- ☐ watery/red/itchy eyes
- ☐ cough
- ☐ fever
- ☐ rash
- ☐ vomiting
- ☐ other_____

Please select <u>ONLY</u> one TEST per SPECIMEN per FORM

HIV

Test requested:

- ☐ HIV 1/2 plus O EIA
- ☐ HIV-1 Ab WB
- ☐ HIV-2 Ab

Ryan White Care Act Clients Only
- ☐ HIV-1 Viral Load

- ☐ Other: _____

VIRAL CULTURE

Test requested:

- ☐ CMV Culture/IFA
- ☐ Enterovirus Culture/IFA
- ☐ Gastrointestinal Outbreak Investigation
  - ☐ Norovirus Panel (EM/PCR)
  - ☐ Rotavirus EIA
- ☐ Herpes Culture/ELVIS
- ☐ Respiratory Panel/IFA
  - ☐ Adenovirus Culture/IFA
  - ☐ Influenza Culture/IFA
  - ☐ Parainfluenza Culture/IFA
  - ☐ RSV Culture/IFA
  - ☐ Other respiratory_____/IFA
- ☐ VZV Culture/IFA
- ☐ Viral Culture/Identification (Please specify):

_____

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Perinatal Hepatitis B Prevention Program Guidelines

Georgia Perinatal Hepatitis B
Prevention Program
2 Peachtree Street, NW, 14-263
Atlanta, Georgia 30303
404-651-5196
Fax: 404-657-2608

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Perinatal Hepatitis B Prevention Program Guidelines
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A. **Background**

In the United States, over 24,000 pregnant women test positive for hepatitis B virus (HVB) each year. In Georgia, the Centers for Disease Control and Prevention (CDC) estimates between 516-849 births to hepatitis B surface antigen (HBsAg) positive women should be reported annually. Aside from antiviral treatment, there is currently no cure for hepatitis B infection; however, there are methods to prevent perinatal exposure. Administering the hepatitis B vaccine to the infant within 12 hours of birth has shown to be 85-95 percent effective in preventing acute and chronic HBV infection in infants born to women who are positive for both HBsAg and HBeAg.

The purpose of Georgia's Perinatal Hepatitis B Prevention Program is to ensure that babies born to hepatitis B surface antigen (HBsAg) positive women are given the opportunity to live their lives free of hepatitis B disease. Infants born to HBsAg-positive women are exposed to the virus through contact with their mother's blood during delivery. Infants and children who become infected with the hepatitis B virus have a 90 percent chance of becoming chronic carriers. These children are more likely to die prematurely from end-stage liver disease (hepatocellular carcinoma or cirrhosis) as adults. Immunizing babies born to HBsAg-positive women with hepatitis B immune globulin (HBIG) and the hepatitis B vaccine series can prevent this tragic outcome.

Identification of the hepatitis B virus (HBV) in pregnant women occurs through prenatal screening and reporting of positive HBsAg results from the laboratory and/or physician to the state or local health department. To prevent perinatal transmission of hepatitis B, health district case managers and staff follow HBsAg-positive pregnant women during gestation and track their infants through completion of the post-vaccination serologic testing. Infants born to HBsAg-positive women should be administered HBIG and hepatitis B vaccine at birth, followed by hepatitis B vaccine at 1-2 months and 6 months of age. Vaccination of sexual and household contacts of HBsAg-positive pregnant women also prevents transmission to susceptible individuals who are at high risk for the disease. Infected women should be informed by the provider that antiviral treatment for chronic hepatitis B does exist and encouraged to follow up with a provider after delivery.

The Perinatal Hepatitis B Prevention Program is funded through the CDC's National Center for Immunization and Respiratory Disease, Immunization Services Division, with technical support from CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Since 1991, every state has received federal funding to support the Perinatal Hepatitis B Prevention Program. Separate funding from the state has been allocated to each district to assist with case management.

These guidelines are to be used as a reference for the case management of HBsAg-positive pregnant women, their infants, and sexual/household contacts. Emphasis is placed upon infant prophylaxis and post-vaccination testing. The appendix contains several forms and tools that can be used during the case management process. Please adapt these materials to suit the needs of your Health District's perinatal hepatitis B prevention program.

Perinatal Hepatitis B Prevention Program Guidelines
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B. **Program Goals**

The goals of the Georgia Perinatal Hepatitis B Prevention Program are to:

- Ensure that all pregnant women are screened for HBsAg as part of the initial prenatal screening panel.
- Assure that all local health departments perform case investigations on all positive HBsAg-pregnant women reported to their jurisdiction.
- Confirm that infants born to HBsAg-positive women receive HBIG and the first dose of hepatitis B vaccine within twelve (12) hours of birth.
- Ensure that infants born to HBsAg-positive women receive the second dose of vaccine at 1-2 months of age, and the third dose of vaccine at six (6) months of age.
- Ensure that infants born to HBsAg-positive women in the U.S. and residing in Georgia are tested at nine (9) months to eighteen (18) months of age for HBsAg and hepatitis B surface antibody (anti-HBs) after completing the hepatitis B vaccination series.

C. **Georgia Perinatal Hepatitis B Program Eligibility Requirements**

Eligibility requirements for enrollment into Georgia's Perinatal Hepatitis B Prevention Program include:

- All pregnant women who test positive for HBsAg
- All infants born to HBsAg-positive women
- All sexual and household contacts of HBsAg-positive pregnant women

D. **Universal Prenatal Screening for Hepatitis B**

The Advisory Committee on Immunization Practices (ACIP), The American College of Obstetrics and Gynecologists (ACOG), and The American Academy of Pediatrics (AAP) recommend that ***all pregnant women be routinely tested for HBsAg at an early prenatal visit in each pregnancy.*** The Georgia Perinatal Hepatitis B Prevention Program encourages all prenatal health providers to follow this recommendation. An additional test for HBsAg can be ordered later in the pregnancy (approximately 34 weeks gestation) if the mother is at high risk for acquiring HBV infection (e.g., more than one sex partner during the past six (6) months, recent history of STD, intravenous drug use, household contact of a chronically HBV infected person). **Pregnant women susceptible to hepatitis B virus (i.e., have never been infected) can and should be vaccinated against the disease during pregnancy,** especially if they are at high risk for infection (see CDC "Guidelines for Vaccinating Pregnant Women" at http://www.cdc.gov/nip/publications/preg_guide.htm). Chapter 2 in this manual also addresses the hepatitis B vaccine schedule and age appropriate dosage information. Appendix H-1, "Hepatitis B Facts: Testing and Vaccination," will provide a concise interpretation of the hepatitis B serology profile.

Perinatal Hepatitis B Prevention Program Guidelines
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E. **General Management of HBsAg-Positive Pregnant Women**
The following guidelines are recommended by the Georgia Perinatal Hepatitis B Prevention Program and follow the recommendations of the Centers for Disease Control and Prevention (CDC) and the ACIP for managing an HBsAg-positive pregnant woman.

1. The client's physician should draw a prenatal serologic panel at the time pregnancy is confirmed. While there is no law in Georgia mandating prenatal HBsAg testing, it is considered a standard of care for prenatal screening panels to include HBsAg serology. One of the following two scenarios may occur after the laboratory performs the test:

    a. If the HBsAg test is **NEGATIVE,** the laboratory will report the results to the physician. The physician files the results in the client's records and sends the information with the rest of her prenatal records to the hospital before delivery.

    b. If the HBsAg test is **POSITIVE**, the laboratory reports the results to the physician **AND** the Epidemiology Section at the State Health Department. The physician should inform the pregnant woman of her HBsAg-positive status, file the results in the client's record, and send the information with the rest of her prenatal records to the hospital prior to delivery.

NOTE: All HBsAg-positive test results for pregnant women must be reported to either the Local Health Department or the state Department of Public Health Epidemiology Section by the laboratory and health care provider within seven (7) days of receiving positive results. Reporting is required by authority of the Official Code of Georgia Section 31-12-2, Official Code of Georgia Section 31-22-7, Rules of the Department of Human Resources, chapter 290-5-3-02.

2. The Epidemiology Section sends HBsAg-positive laboratory reports on all females between age 10 and 50 years to the Perinatal Hepatitis B Prevention Program.

3. The Perinatal Hepatitis B Prevention Program reviews the laboratory reports for females ages 10 to 50 years that are positive for HBsAg. The program then contacts the physician and inquires of pregnancy status, estimated date of confinement (EDC), and delivery hospital of each reported case.

4. All pregnant HBsAg-positive women are then entered in the Web-based tracking system (Perinatal SENDSS) where it is available to the district perinatal hepatitis B case manager for case management.

5. All **PREGNANT** clients are contacted by the Health District for counseling about their infection and interviewed for sexual and household contacts. The message is then reinforced that the client must also alert medical personnel attending her baby's birth that she is positive for HBsAg.

Perinatal Hepatitis B Prevention Program Guidelines
Georgia Immunization Office

NOTE: ***Communicating the woman's HBsAg status to the birthing hospital's department of labor and delivery should be the responsibility of her healthcare provider***. It is strongly recommended that the Health District make efforts to remind the healthcare provider and the hospital of the woman's impending delivery at least four weeks before her EDC. An alert letter should be sent to the hospital's labor & delivery unit and/or provider. See Appendix B-2 for a sample fax to use when notifying the hospital for this purpose.

6. The hepatitis B counseling interview should be performed in the client's own language. Each district has a Limited English Proficient/Sensory Impaired (LEP/SI) Program Coordinator. This coordinator can assist the district with the utilization of the language line. It is critical that she is aware of self-care and disease transmission in order to protect her own health and that of others. See the Example Interviewing/Counseling Format for assistance (Appendix D-1).
7. Any client who is chronically infected with hepatitis B should be encouraged to seek care with her physician so that her condition can be monitored routinely. Advise the client to discuss possible treatment options with her physician that may improve her health outcome and overall quality of life.

F. **General Management of Infants Born to HBsAg-Positive Women**

1. Babies born to women who are HBsAg positive must receive HBIG and the appropriate dose of hepatitis B vaccine (see Section 2, "Recommended Schedule and Guidelines, Hepatitis B") within twelve (12) hours of birth.

***NOTE*:** There is a window of **seven (7) days** to administer HBIG if an infant born to an HBsAg-positive woman did not receive HBIG within twelve (12) hours of delivery. Every effort should be made to locate the infant and administer HBIG within seven (7) days, if the baby was released from the hospital before receiving this important prophylactic component.

2. The Health District should contact either the client or the delivery hospital close to the date of delivery to learn:
   a. Infant's name, birth date and sex, and
   b. If the infant received HBIG and hepatitis B vaccine within twelve (12) hours of birth.

   After obtaining this information, the Health District should update the Perinatal SENDSS case management event screen, where it will be available to the Perinatal Hepatitis B Prevention Program.

3. The Health District will notify the pediatric care provider and/or mother that the baby should receive the second dose of vaccine, consult GRITS for verification that the vaccine was administered, and update Perinatal SENDSS.

4. The Health District will notify the mother to take the baby for the third dose of vaccine, verify that vaccine was given, and update Perinatal SENDSS for further tracking.

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5. District perinatal hepatitis B case managers will document updated infant information in Perinatal SENDSS for each subsequent dose of vaccine and monitor for when any dose of hepatitis B vaccine is overdue.

6. The hepatitis B post-vaccination serologic testing (PVT) should be obtained when the child is 9-18 months old. If the third dose of hepatitis B vaccine is given late, the child must have received the third dose a minimum of one month before obtaining the PVT. When the test results (HBsAg and anti-HBs) are known, the Health District will update Perinatal SENDSS and document the case as complete.

Note: The health district has the discretion to send the parent/guardian and baby to a local public health clinic for the (HBsAg and anti-HBs) PVT, if testing is not otherwise affordable to the family. The local health department, Health District or private physician can send the blood sample to the Georgia Public Health Laboratory where specimen processing will be performed at no charge to the baby's parents/guardians.

7. If the test is **NEGATIVE for HBsAg** and **POSITIVE for anti-HBs**, the baby is considered **IMMUNE** to hepatitis B and the perinatal case is closed.

8. If the test is **NEGATIVE for BOTH HBsAg and Anti-HBS,** the baby is considered **SUSCEPTIBLE** to hepatitis B infection, and should be immunized again with the complete 3-dose series of hepatitis B vaccine. The baby should be retested one (1) month after the sixth dose of hepatitis B vaccine. In the rare instance the child tests negative for HBsAg and anti-HBs after completion of the second series, no additional hepatitis B vaccine is to be given. The mother should be counseled regarding her child's negative results and susceptible status. The perinatal hepatitis B case is closed for the infant after the initial PVT is completed.

9. If the test is **POSITIVE for HBsAg** and **NEGATIVE for anti-HBs**, the baby is **INFECTED** and should be referred to the pediatrician for subsequent follow-up and specialist referrals. This infection is a notifiable disease that should be reported as a perinatal hepatitis B infection through SENDSS and will be reported to the CDC by the Epidemiology Section. The perinatal hepatitis B case is then considered closed.

G. **Management of Infants Born to Women with Unknown HBsAg Status**

1. Infants born to women whose HBsAg status is unknown at the time of delivery should receive hepatitis B vaccine at the appropriate dosage per manufacturer (see Section 2, "Recommended Schedule and Guidelines, Hepatitis B") within twelve (12) hours of delivery. The woman should be tested in the hospital at the time of delivery and an expedited HBsAg test should be run to determine her status. If the mother's test is positive, the baby should receive HBIG as soon as possible, preferably before hospital discharge.

Perinatal Hepatitis B Prevention Program Guidelines
Georgia Immunization Office

REMINDER: There is a window of **seven (7) days** to administer HBIG if an infant born to an HBsAg-positive woman did not receive HBIG within twelve (12) hours of delivery. Every effort should be made to locate the infant and administer HBIG within this seven (7) days if the baby was released from the hospital without it.

2. The hospital laboratory and physician are required by law (see Note under Section E, 1-b) to report the positive HBsAg test within seven (7) days to the Georgia Department of Public Health, Epidemiology Section.

3. Upon receipt of a maternal HBsAg-positive serology report from the hospital, the Perinatal Hepatitis B Prevention Program (state Coordinator or Health District) will obtain the baby's vaccination history and enter the infant into the Perinatal SENDSS tracking system to be followed as indicated in Section F, "General Management of Infants Born to HBsAg-positive Women." If the mother is determined to be HBsAg negative, the baby should receive the hepatitis B vaccine according to the schedule recommended by the ACIP for infants born to HBsAg-negative women, that is, first dose at birth, second dose at 1 to 2 months and third dose at 6 to18 months of age.

NOTE: When the mother is HBsAg-negative but is at high risk for hepatitis B infection, she should be vaccinated as soon as possible. Hepatitis B vaccine is not contraindicated during pregnancy.

4. Upon completion of the three-dose vaccination series, infants born to HBsAg-positive mothers need to undergo post-vaccination serologic testing (PVT), in order to document immunity or infection status. If the baby does not have insurance to cover the PVT expense or the pediatric provider refuses to do the PVT, the district case manager should assist with arrangements to refer the baby to a nearby public health clinic for the blood test. (See Appendix K-2 for GPHL sample submission form.)

H. **Management of Sexual/Household Contacts of HBsAg-Positive Pregnant Women**

1. When Health Districts receive Perinatal Hepatitis B Prevention Program referrals of HBsAg-positive pregnant women, appropriate District personnel should make every effort to interview these women for household and sexual contacts. The contact interview should take place during the initial counseling session with the woman. It is imperative to identify younger contacts of the HBsAg-positive client due to the high risk for chronic infection in children aged five (5) years and younger. (See Section III, "Example Interviewing/Counseling Format", Appendix D-1, for further information.)

Perinatal Hepatitis B Prevention Program Guidelines
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2. Household and sexual contacts to HBsAg-positive women are at increased risk of infection; therefore, it is important to test contacts for HBsAg and anti-HBs (See Appendix H-1, "Hepatitis B Facts: Testing and Vaccination"). Order these tests at the same visit when the contact receives the first dose of hepatitis B vaccine, but **draw the blood for serology before administering vaccine**. The test can be sent to the Georgia Public Health Laboratory using Form 3432: http://health.state.ga.us/pdfs/lab/manual/2012/lsm2012.pdf

   ***NOTE*:** Post-vaccination testing is **NOT** recommended for sexual or household contacts of HBsAg-positive pregnant women.

3. Sexual and household contacts should be vaccinated during their first visit to a medical provider with the age-appropriate dose of hepatitis B vaccine. Vaccine must be given according to the ACIP recommended schedule. See Section 2, "Recommended Schedule and Guidelines, Hepatitis B" of this manual for information on the hepatitis B vaccine dosage and scheduling for infants, children and adults.

4. HBIG can be given to sexual contacts of pregnant women diagnosed with acute hepatitis B infection (e.g., HBV infection of less than six (6) months duration with or without symptoms of hepatitis and/or positive anti-HBc IgM), when the last sexual exposure occurred within fourteen (14) days of administration. Administer HBIG and vaccine during the same visit, in two different body sites. HBIG can also be given to those household contacts that have not had sexual exposure, but have had known blood exposure to an acute case of hepatitis B within the past seven (7) days.

5. To calculate HBIG dosage for persons one (1) year of age through adulthood, use 0.06 mL per kilogram of body weight or 0.06 mL per 2.2 pounds of body weight. For example, for an adult weighing 140 pounds, the weight would be divided by 2.2 to obtain the equivalent in kilograms, then multiplied by 0.06 to obtain the HBIG dosage.

   Example: 140 lbs. ÷ 2.2 = 63.636 kg, rounded up to 64 kg
   64 kg x 0.06 mL = 3.84 mL of HBIG

6. If it is determined that the contact is **infected** (HBsAg positive) or has **immunity** (HBsAg negative and anti-HBs positive) to infection, no <u>further doses of vaccine are to be given</u>. If the contact is susceptible to infection, that is, HBsAg and anti-HBs negative, then complete the vaccine series. (See Appendix H-4 for hepatitis B serology interpretations.)

7. Each susceptible contact must be followed and reminded to complete the hepatitis B vaccine series at the appropriate intervals (See Section 2, "Recommended Schedule and Guidelines, Hepatitis B"). The Health District is responsible for tracking perinatal hepatitis B sexual and household contacts, documenting tests and vaccinations in Perinatal SENDSS, and reporting the information to the Grant-in-Aid monthly report.

8. Contacts that are infected with hepatitis B should be counseled about the disease and its transmission. The "Example Interviewing/Counseling Format" is a useful guide for this situation. (See Appendix D-1)

Perinatal Hepatitis B Prevention Program Guidelines
Georgia Immunization Office

I. **Finding Clients That are Lost to Follow Up**

- Ask if provider received request to transfer records to another provider (there may be a fax number available for the new provider).
- Call telephone information 411 to see if you can locate the lost contact.
- Use Internet search engines (e.g. Google), white pages, and United States Postal Service online (USPS.com) to search for contact information.
- Try old telephone numbers. Relatives/friends with information on the patient might still be reached at those numbers.
- Look in directories that list occupants of each household in the city. Most sexually transmitted disease (STD) programs have such directories.
- Transpose digits in telephone numbers and addresses.
- Try “Street” instead of “Avenue” and vise versa.
- Ask neighbors, landlords, and apartment rental offices.
- Ask mail carriers; they cannot give you addresses, by law, but might confirm whether or not the patient lives at the address.
- Ask the post office for the forwarding address. You may have to complete a justification form provided by the postal service and show your health department identification. The STD case manager may have local procedures.
- Search health department records.
- Ask other state and local agencies and programs (e.g. Medicaid, WIC programs, Department of Family and Child Services, parole and probation offices) for contact information.

J. **Required Reports and Case Updates for Perinatal Hepatitis B Prevention in Georgia**

Each month, the Perinatal Hepatitis B Prevention Program will review case information about any cases that are due for activity during that month, such as vaccination, blood tests, deliveries, etc. Health District case management staff are expected to update Perinatal SENDSS at least monthly and alert the Perinatal Hepatitis B Prevention Program to any questionable or concerning information about a case.

Prompt documentation of case information in Perinatal SENDSS allows for efficient maintenance of the tracking system and thus timely disease prevention. The updates will be used to complete state and federal annual reports including the Perinatal Hepatitis B Prevention Report requested biannually by the CDC. If timely case management is not being performed over a period of several months, a letter of concern may be sent to the District Clinical Coordinator and District Health Director for assistance with problem solving future Perinatal Hepatitis B case management within that district.

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K. Glossary of Terms

EDC	Estimated date of confinement or the approximate day that a woman's baby is expected to be born *(aka:* due date).
Viral Hepatitis	Inflammation of the liver as a result of viral infection.
HBV	Hepatitis B virus, the agent that causes hepatitis B virus infection**.**
HBsAg	Hepatitis B surface antigen found on the surface of the hepatitis B virus. HBsAg is detected in serum thirty (30) to sixty (60) days after HBV exposure and persists for variable periods**.**
HBeAg	Hepatitis B "e" antigen is associated with active HBV replication, high concentrations of HBV in serum, and high infectivity (increased risk of transmission); appears in early infection and persists for variable length of time (from weeks to years).
Anti-HBs	Antibody to HBsAg is associated with long-term protection against reinfection and, in most persons, persists for many years after natural infection. Anti-HBs is also produced as an immune response to hepatitis B vaccine or is passively transferred when HBIG is administered. Anti-HBs is currently measured by radioimmunoassay (RIA) or enzyme-linked immunosorbent assay (ELISA).
Anti-HBc	Antibody to HBcAg is produced in all HBV infections; it indicates infection at some undefined time and persists indefinitely; sometimes appears as a false-positive result when other HBV tests are negative
IgM Anti-HBc	IgM class antibody to HBcAg indicates recent infection with HBV and is positive for approximately six (6) months after infection.
HBsAg Chronic Carriage	Through serologic testing, a person is confirmed as an HBsAg carrier (chronic infection) when: 1) HBsAg is detected on at least two tests, spaced a minimum of six (6) months apart; or 2) the results of a single serum specimen are HBsAg positive and IgM anti-HBc negative. Carriers may be asymptomatic and unaware that they are infected with HBV. Because they carry HBsAg in their blood, they are capable of infecting others.
HBIG	Hepatitis B immune globulin is a preparation obtained from the blood plasma from donor pools selected for a high antibody content of anti-HBs. In some situations, HBIG is administered post-exposure with hepatitis B vaccine to provide additional protection against HBV infection.

Perinatal Hepatitis B Prevention Program Guidelines
Georgia Immunization Office

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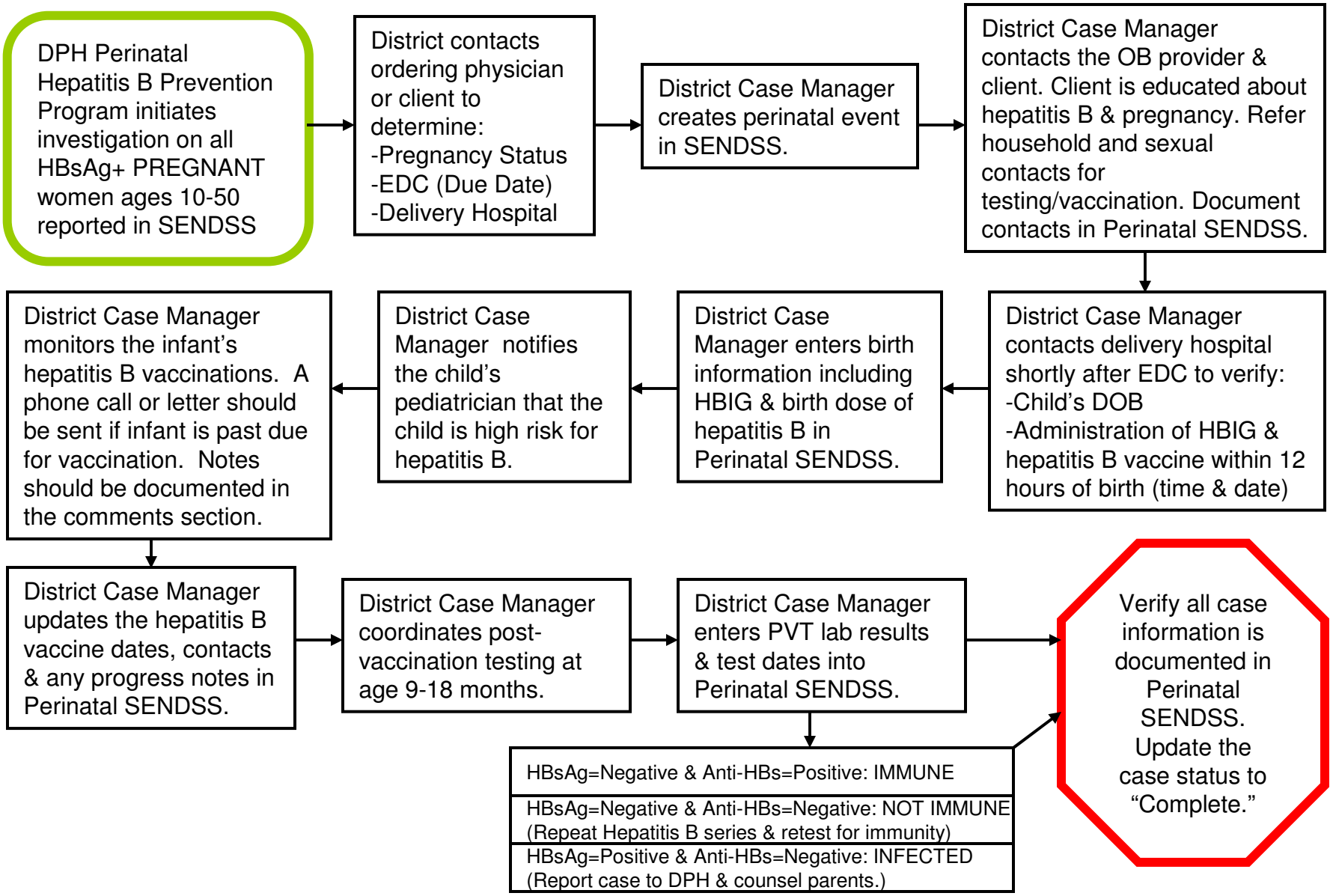
Georgia Perinatal Hepatitis B Prevention Program

Perinatal Hepatitis B Case Management Flow Chart



INSERT YOUR HEALTH DEPARTMENT'S LETTERHEAD

Sample Letter for Medical Providers with HBsAg-Positive Pregnant Patients

Medical Alert

Today's Date

Name of Practice
Attention: Clinic Manager
Street Address
City, State Zip Code

Dear Medical Provider,

The County Name Health Department was notified that your patient, **Mother's Name (DOB: ## / ## /####)**, had a reactive Hepatitis B Surface Antigen (HBsAg) test during a recent prenatal exam. Hepatitis B is reportable to the health department in Georgia.

The County Name Health Department's Perinatal Hepatitis B Program tracks Hepatitis B Surface Antigen-positive mothers to ensure that their infants receive Hepatitis B Immune Globulin (HBIG) and the first dose of hepatitis B vaccine within 12 hours of birth. We also track the infant until the child completes the hepatitis B vaccination series and post-vaccination testing to ensure that they are immune to the hepatitis B virus.

We ask that you notify the patient of her results and explain that hepatitis B virus can be transmitted to her infant at birth. Also, please notify the delivering hospital of your patient's Hepatitis B Surface Antigen test result to ensure the infant receives HBIG and hepatitis B vaccine at birth.

Thank you in advance for your attention to this matter. Protecting your patient's infant from hepatitis B is our number one priority! Please contact me with any questions or concerns at (###) ### - ####.

Sincerely,

Case Manager's Name
Title

INSERT YOUR HEALTH DEPARTMENT'S LETTERHEAD

Hepatitis B Alert

Please flag this patient's medical record or electronic record.

This pregnant patient has been identified as having a positive Hepatitis B Surface Antigen (HBsAg) blood test.

Patient's Name:	Name
Patient's DOB:	## / ## / ####
Patient's EDC:	## / ## / ####
Patient's HBsAg Result:	## / ## / ### = Reactive

Medical Provider's Role:

- ☐ Notify the patient of her result and explain that hepatitis B virus can be transmitted to her infant(s) during delivery
- ☐ Notify the delivering hospital of the patient's positive HBsAg blood test result
- ☐ Administer Hepatitis B Immune Globulin (HBIG) and the first dose of hepatitis B vaccine to the infant within the first 12 hours of birth
- ☐ Notify the Specific County Perinatal Case Manager of the patient's delivery date, infant's name, and date HBIG/vaccine was administered

Immunizing babies born to HBsAg-positive mothers with HBIG and hepatitis B vaccine, followed by vaccine at 1-2 months and 6 months of age, results in 85% to 95% efficacy in preventing perinatal hepatitis B transmission.

Please contact Case Manager's Name, Specific County/District Perinatal Hepatitis B Program Coordinator, with any questions or concerns at (###) ### - ####.

County/District Logo & Contact Info

INSERT YOUR HEALTH DEPARTMENT'S LETTERHEAD

Perinatal Hepatitis B Report Form

(Infants born to HBsAg-positive Mothers)

Please complete form after patient has delivered infant. Fax or mail completed form to the Specific County Health Department / District. Contact Case Manager's Name with questions at (###) ### - ####.

MOTHER'S INFORMATION

Patient Name:_____ **DOB**:_____
Last First Maiden

Current Address:_____ **City:**_____ **Zip:**_____

Phone Number(s):_____

Delivering Hospital:_____ **Physician:**_____

Mother's HBsAg Result at Delivery: ☐ Reactive ☐ Negative ☐ Not Done

Collection Date: _____

INFANT'S INFORMATION

Infant Name:_____
Last First

Date of Birth:_____ **Time of Birth:**_____

Birth Weight:_____ **Alive?** ☐ **Yes** ☐ **No**

POST EXPOSURE INFORMATION

Hepatitis B Immune Globulin (HBIG) Given: ☐ **Yes**

Time Administered:_____

Date Administered:_____

☐ **Not Administered**

Hepatitis B Vaccine – Dose #1 Given: ☐ **Yes**

Time Administered:_____

Date Administered:_____

☐ **Not Administered**

Mail or Fax Completed Form to:

County Health Department / District
Attention: Perinatal Hepatitis
Mailing Address
City, State Zip Code

OR

Fax form to: (###) ### - ####

INSERT YOUR HEALTH DEPARTMENT'S LETTERHEAD

Sample Letter for HBsAg-Positive Pregnant Women

Today's Date

Mother's Name
Address
City, State Zip Code

Dear Ms. Mother's Last Name,

During your pregnancy you tested positive for the hepatitis B virus. Hepatitis B can be a serious disease. Not only does this virus affect your liver, but also it can be passed to your baby at the time of birth. To be protected from this disease, your baby will need to get several shots. **The first two (2) shots are given within a few hours after birth.** They are hepatitis B immune globulin (HBIG) and dose 1 of hepatitis B vaccine.

Your baby will later need **dose 2 of hepatitis B vaccine at one or two months of age** and **dose 3 at six months of age.** After completing these shots, your baby's doctor will do some blood tests to see if your baby is protected. The blood test should be done when the baby is between 9 and 18 months of age. In some cases, the baby may need more shots to prevent infection.

It is possible that your sexual partner and other people living in your household could get infected. We recommend that they be tested and vaccinated for hepatitis B also, if they haven't been already. It is important that you discuss with your doctor whether you need further follow up for your infection. Your doctor may refer you to a gastroenterologist (GI doctor) who specializes in liver diseases.

We encourage you to show this letter to your doctor and later to your baby's doctor. If you have any questions, please call me at (###) ###-####. Protecting your child from hepatitis B is our number one priority!

Sincerely,

Case Manager Name
Title

INSERT YOUR HEALTH DEPARTMENT'S LETTERHEAD HERE

Sample Letter for Foster Parents of Infants born to HBsAg-positive Women

Date

Name
Address
City/State/Zip

Dear Legal Guardian's Name:

Thank you for making the decision to care for BABY FIRST/LAST NAME (DOB) in your home. As the foster parent(s), it is important that you know BABY FIRST NAME may have been exposed to the hepatitis B virus during childbirth. Hepatitis B is a serious disease that affects the liver. To be protected from the disease, the baby will need to get several shots. **The first two (2) shots should have been given within a few hours after birth**. They are hepatitis B immune globulin (HBIG) and dose 1 of hepatitis B vaccine.

The baby will later need **dose 2 of hepatitis B vaccine at one month of age** and **dose 3 at six months of age**. After completing these shots, the baby's doctor will do some blood tests to see if the baby is protected. The two tests that are needed are called HBsAg and anti-HBs. The blood test should be done when the baby is between 9 and 18 months of age. When the test results are back, please ask the doctor to call our office to report them to us. In some cases, the baby may need more shots to prevent hepatitis B infection.

We encourage you to show this letter to the baby's doctor. If you have any questions or concerns, please feel free to call me at XXX-XXX-XXXX.

Sincerely,

Your Name
Job Title

Protect yourself and your baby with the first "anti-cancer vaccine"

If you have not been infected, get vaccinated

Hepatitis B can still be transmitted through unprotected sex and contaminated blood (sharing toothbrushes, razors, or needles for tattoos/piercings).

The 3 shots given over 6 months are safe, even during pregnancy. The hepatitis B vaccine is so effective in preventing HBV and liver cancer that it is known as the first "anti-cancer vaccine."

Make sure your baby is vaccinated at birth

Since 1991, U.S. national guidelines have recommended that all newborns be vaccinated against HBV. The 3 shots can protect your baby for life against hepatitis B, reducing the risk of liver cancer and liver damage in the future.

Time	Infant should receive
At birth	birth dose of hepatitis B vaccine
1-2 months	2nd dose of hepatitis B vaccine
6 months	3rd dose of hepatitis B vaccine

The vaccine is safe, even for premature babies.

Unite against HBV.

人

The **Jade Ribbon** is folded like the Chinese character for people "人" to symbolize the united voices of those fighting hepatitis B and liver cancer worldwide.

Asian Liver Center
at Stanford University
300 Pasteur Drive, H3680
Stanford, CA 94305-5655
Tel: (650) 72-LIVER
1-888-311-3331
Fax: (650) 723-0006
http://liver.stanford.edu

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Hepatitis B & Moms-to-Be

HBV and Moms-to-Be

- Hepatitis B (HBV) is the most common serious viral infection of the liver, and can lead to premature death from liver cancer or liver failure.
- In the U.S., approximately 10-15 people die every day as a result of HBV infection.
- Hepatitis B can be transmitted from an infected mother to her child during the birthing process.
- Newborns who become infected with HBV have a 90% chance of developing chronic (lifelong) infection.

Fortunately, HBV can be prevented with a very safe and effective vaccine.

Ask your doctor for the results of your HBV test

Most people with chronic HBV infection have no symptoms. As an expecting mother, you should have already been tested for HBV with the following blood test:

- **Hepatitis B surface antigen (HBsAg):**
  Tells if you have chronic hepatitis B (also known as being a hepatitis B carrier).

Take extra precautions if you are a mom with HBV

During pregnancy:

Currently, antiviral HBV treatments are not recommended during pregnancy. If you are already on treatment, talk to your doctor.

At time of birth:

In addition to the first shot of the hepatitis B vaccine, make sure your newborn receives the hepatitis B immunoglobulin (HBIG) shot.

Time	Infant born to mother with HBV should receive
At birth	birth dose of hepatitis B vaccine **and hepatitis B immunoglobulin (HBIG)**
1-2 months	2nd dose of hepatitis B vaccine
6 months	3rd dose of hepatitis B vaccine
9-18 months	**HBsAg and anti-HBs* tests to confirm that your child is protected**

* The hepatitis B surface antibody (anti-HBs) blood test checks for protection against HBV.

Cesarean sections (C-sections) have not been found to prevent HBV transmission from mother to child. Hepatitis B vaccination along with the HBIG shot is the best way to protect your newborn against HBV infection.

In the first 6 months:

It is critical for your child to complete the hepatitis B vaccine series on time. This will be more than 95% effective in protecting your newborn against HBV infection.

Breastfeeding is safe for your baby. HBV is not transmitted through breast milk.

Moms with HBV
You're important too!

Remember to get screened for liver disease

You probably have no symptoms and feel healthy, but are still at increased risk for liver damage or liver cancer. However, regular screening and appropriate treatment can reduce this risk and help you lead a normal, healthy life. Ask your doctor for the following tests:

Every	Test	Screens for
6 months	ALT blood test	liver damage
	AFP blood test	liver cancer
1 year	ultrasound	liver cancer

Don't rush into treatment

Not every person with chronic HBV infection needs treatment. But if your ALT level is elevated, treatment with antiviral medication may be appropriate.

Be sure to review all medications with your doctor. Even some over-the-counter or herbal medications can injure your liver.

Get the hepatitis A vaccine

Avoid drinking alcohol

Protect your loved ones

Make sure your family and partner are tested for HBV, and vaccinated if they are not already protected.

Your local health department may contact you to ensure your baby is fully protected against HBV.

Interviewing/Counseling Format Hepatitis B

Example
Interviewing/Counseling Format
Hepatitis B

I. Introduction, professional role, and purpose

Purpose: To let the patient know what is going to take place is to his/her benefit, that he /she is going to be dealing with a competent person, and that there should be no fears about discussing otherwise personal information.

A. Introduce yourself and anyone else present to the patient.
B. Tell the patient that you have been trained and have experience in helping people who have hepatitis B to understand and manage their disease.
C. Inform the patient that part of your job is to ensure that no one else find out about the patient's infection and that problems are minimized for everyone who may be involved.

II. Patient Assessment

Purpose: To establish rapport, get the patient accustomed to talking, reduce the possibility of patient concerns interfering with the rest of the process, gather information that can be used in later sections, and give the patient sufficient information to be able to understand and support disease intervention behaviors. Targeted medical information can preempt inappropriate strategies that the patient may be developing to take care of the problem. By getting the patient to talk during this section, issues may arise that can be used as motivations or as benchmarks against inconsistencies later on in the interview/counseling session.

A. Patient Concerns
   1. Ask the patient about problems or questions regarding the disease and how it has been handled thus far.
   2. Address concerns even if they are involved in other elements of the format.

B. Socio-sexual Information
   1. Question patient conversationally about where he/she lives, telephone number, alternate locating information, who living with, employment, travel, recreation social groups.
   2. Question the patient about current employment and/or past jobs where they may have had to handle blood or other body fluids.
   3. Explain reasons for questions if patient shows signs of concern.

C. Medical History and Disease Comprehension
   1. Ask what patient knows about the disease.
   2. Compliment correct responses, tactfully correct any misconceptions, and add any information that directly supports disease intervention behaviors.
   3. Ask about past hepatitis/liver problems.
   4. Impress upon the patient that the disease is serious, people usually don't know that they have it until it is too late, that routine tests may not discover the disease, and that it is often passed unintentionally.

Interviewing/Counseling Format Hepatitis B

III. Disease Intervention Behaviors

A. Assure examination of household, sexual, and needle-sharing contacts

1. Explain that the medical facts just discussed clearly show that the patient's household contacts, sexual contacts, and needle-sharing contacts are in need of an exam as soon as possible.
2. Ask for the names and birthdays of all the children in the home.
3. Explain that other adults in the household need to be notified that they have been exposed to someone with a serious disease. This has to be done so that they can be tested for the infection and given vaccine as necessary.
4. Ask for the names and birthdays of all the adults in the house besides the husband/boyfriend.
5. Explain that the sex partners and needle-sharing partners (sex/NS partners) need to be notified privately that they have been exposed to someone with a serious disease. This has to be done in a way that doesn't embarrass them or the patient, but ensures that the examination takes place immediately by someone who knows enough about the circumstances to do the right things medically.
6. Tell the patient that you can work together to come up with the plan for notifying the sex/NS partners, and that you have to know about each of the sex/NS partners since a certain date in order to do that.
7. If the patient seems hesitant about talking about sex/NS partners, problem solve and explain the different plans and give different examples of how you would handle referrals.
8. Ask for the names of each of the sex/NS partners since the significant date you have established for the interview period. Do not be concerned if the patient doesn't supply the whole name, but emphasize that you want to discuss every partner during that period, regardless of how much they know about them. Continue to probe for partners even after the patient has indicated there are no more. Use some other identifier for sex/NS partners if the patient can't remember a name or nickname.
9. When further probing fails to produce other sex/NS partners, ask and record the last date of exposure beside each person's name.
10. Confront problems indicated by exposure gaps and conflicts with previously gathered information.
11. If you have not already done so, explain referral methods.
12. Gather locating information including full name, nicknames, address, telephone numbers, living-with status, employment, age, race, sex, marital status, physical descriptions, directions to home, description of home, etc.
13. Determine methods of sex/NS partner referral for each partner and agree to best approaches.
14. Coach patient on any contact referrals (referrals they prefer to make, themselves) and give guidelines and deadlines.

Interviewing/Counseling Format Hepatitis B

B. Reduce Risk
Purpose: This section is important for all patients to hear, but is especially important for those who appear to have contracted the infection sexually. The information should be tailored to each patient.

1. The patient should be instructed that it is possible for her to spread the hepatitis B virus to others. She should be told of ways to prevent this spread:
   a. Household articles that could become contaminated with blood (such as toothbrushes and razors) should not be shared.
   b. Cuts or skin lesions should be covered to prevent the spread of infectious secretions or blood.
   c. When seeking medical or dental care, those responsible for care should be informed of HbsAg status.
   d. If sexual partner(s) are not immune to hepatitis B, the partner should be advised to take precautions, including "safer sex" and vaccination, if warranted.
   e. "Safer sex" should be practiced for the prevention of many sexually transmitted diseases, including hepatitis B, syphilis, gonorrhea, Chlamydia infection, and HIV/AIDS.
   f. Blood, plasma, body organs, other tissue or sperm should not be donated.
   g. Enroll or stay in a drug treatment program if using illicit drugs.

2. Medical follow-up is needed for evaluation of chronic hepatitis B. Patients with progressive liver disease may need to be referred to a liver specialist for consideration of interferon therapy.

3. Other recommendations include:
   a. Limiting the number of sex partners.
   b. Limiting anonymous sex.
   c. Routine checkups for STDs and liver function.

C. Respond to Disease Suspicion
Purpose: In spite of current status, the patient should understand how to respond to signs that the infection has worsened.

1. Discuss clinical symptoms of hepatitis B.
2. Tell patient to return to provider immediately if symptoms appear.

D. Complete Vaccine Series for All Exposed
Purpose: The understanding of the multi-dose regimen is particularly important and these messages should be delivered in concert with individualized pamphlets. The case manager should be reinforcing messages expressed by the provider and verifying that the patient understands and intends to comply with the plan.

1. Emphasize the need for all exposed to complete the series, especially the baby and children of the household. Remind the patient that she is directly responsible for her baby's and other children's health. She should remind the nurses and her baby's doctor that she is a carrier of hepatitis B virus and her baby needs to complete the high-risk vaccine series.
2. Establish a specific schedule so that the patient is aware when the vaccine is due to be given to her baby.
3. Discuss contraindications and potential side effects.
4. Identify and discuss potential compliance problems.

Interviewing/Counseling Format Hepatitis B

IV. Conclusion

A. Ask what questions or problems remain.

B. Review and reinforce all components of compliance plan.

C. Reinforce commitments to communicate information.

D. Make arrangements for the next visit, if indicated.

Centers for Disease Control and Prevention. Managing a Hepatitis B Prevention Program: A Guide to Life as a Program Coordinator. [manual] April 2007.

Perinatal Hepatitis B Interview Questions

Patient's Name:

Case Number:

Interview Date:

1. OB/GYN?

2. EDC?

3. Delivering hospital?

4. History of hepatitis?

5. Country of birth?

6. Household members?
   (Name & DOB)

7. Sex partners?

8. Pediatrician?

9. Verify address:

INSERT YOUR HEALTH DEPARTMENT'S LETTERHEAD

Sample Letter for Pediatricians caring for infant born to HBsAg-positive mother

Today's Date

Medical Alert

Pediatrician
Street Address
City, State Zip Code

Dear Medical Provider,

The Specific County Health Department / District is responsible for tracking high risk infants to ensure they complete hepatitis B vaccination. Infants are indentified as high risk based on their mother's positive HBsAg status at the time of birth. Your patient, **Child's Name (DOB: ## / ##/ ####)**, is being tracked by Specific County Health Department / District Perinatal Hepatitis B program.

The Centers for Disease Control and Prevention recommend that all newborns be vaccinated at birth against the hepatitis B virus. It is important for this child to receive the hepatitis B vaccine at the recommended age intervals.

RECOMMENDED AGE	INTERVENTION
Birth	Hepatitis B Vaccine Dose #1 **AND** Hepatitis B Immune Globulin (HBIG)
1-2 Months	Hepatitis B Vaccine Dose #2
6 Months	Hepatitis B Vaccine Dose #3
9 Months	Post-vaccination Serologic Testing (HBsAg and anti-HBs)

After the child has completed the hepatitis B vaccine series and is at least 9 months old, he/she should have a post-vaccination serologic test. Post-vaccination testing consists of two blood tests called hepatitis B surface antigen (HBsAg) and hepatitis B surface antibody (anti-HBs). These tests help confirm that the hepatitis B vaccine has provided adequate protection for the child against the hepatitis B virus. Testing is recommended at age 9 through 18 months, but is generally done at the child's next well visit (no earlier than 9 months of age). A copy of the labs should be forwarded to the health department via mail or by fax to (###) ###-####.

Thank you in advance for your attention to this matter. Protecting your patient from hepatitis B is our number one priority! Please contact me with any questions or concerns at (###) ###-####.

Sincerely,

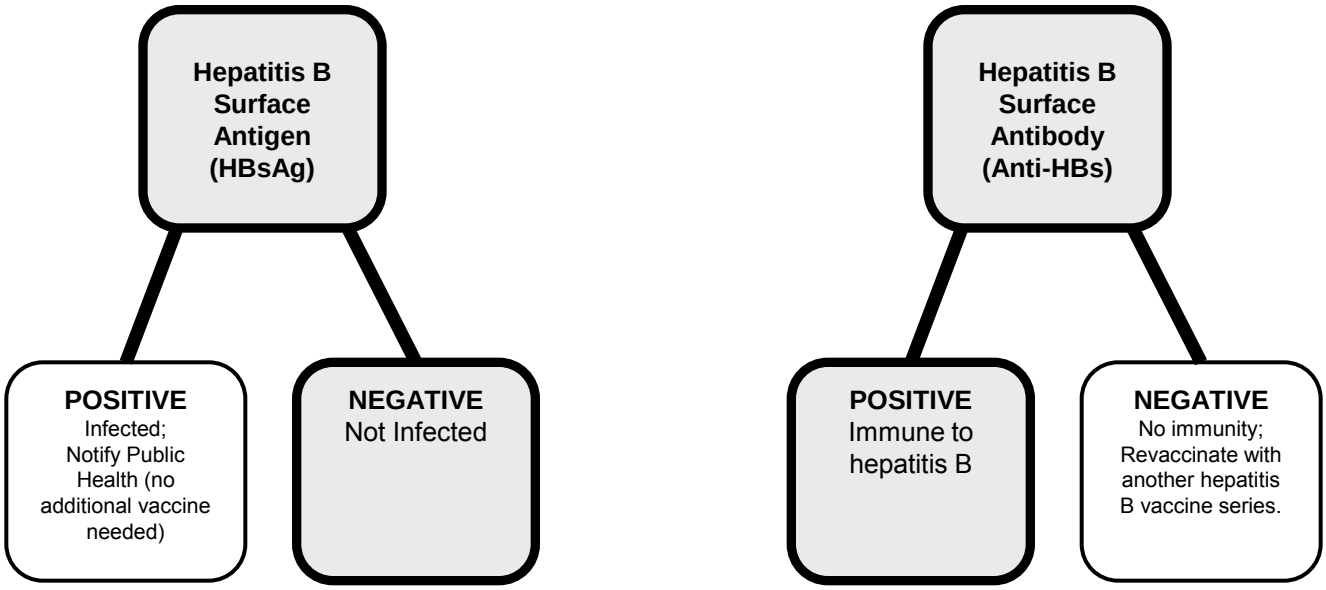
Case Manager Name
Title

Quick Reference
For Care of Infants born to Hepatitis B Infected Mothers

AGE	INTERVENTION
Birth	**Hepatitis B Vaccine #1 (within 12 hours of birth)** **AND** **Hepatitis B Immune Globulin (HBIG)** HBIG can be given up to 7 days after birth
1-2 Months	**Hepatitis B Vaccine #2***
6 Months	**Hepatitis B Vaccine #3**
9-18 Months	**Post Vaccination Serologic Test (PVT)** **(HBsAg and Anti-HBs)** Blood for PVT must be drawn no earlier than 9 months of age and must be a minimum of one month after final hepatitis B vaccine dose.

***Low Birth Weight Infants (less than 4.4 lbs or 2,000 grams) should receive HBIG and 4 doses of vaccine at birth, 1, 2, and 6 months.**

Interpretation of PVT



Send all PVT results to District Perinatal Hepatitis B Case Manager

For more information, please call the state Perinatal Hepatitis B Coordinator at (404) 651-5196

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention (CDC)
Atlanta, GA 30333
June 21, 2005

Re: Public Health Implications of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

Dear Colleague:

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule has been in effect since April 14, 2003. The intent of HIPAA is to establish national standards for consumer privacy protection and insurance market reform. Initially, a lack of information and misinterpretation of some HIPAA provisions had a negative impact on the conduct of some time-honored public health activities. In some instances, confusion about the intent and implementation of the rules resulted in health-care providers refusing access by public health officials to patient records for immunization assessment and surveillance purposes. The National Immunization Program (NIP) of the Centers for Disease Control and Prevention (CDC) recognizes that providers are concerned about compliance, and they need clear and accurate information about the practical application of the HIPAA Privacy Rule on public health practices.

NIP has worked closely with Health and Human Services (HHS) Office for Civil Rights, which is the lead agency for interpreting and enforcing HIPAA, and the CDC legal counsel to clarify public health provisions of the Privacy Rule and to disseminate information to our partners at the state and local levels. In August 2003, NIP sent the first of a series of guidance statements to Immunization Program Managers and State Epidemiologists in response to states' requests for clarification regarding access to patient records to conduct VFC and AFIX site visits. The mailing included a one-page *HIPAA and Public Health Fact Sheet* that provided a brief summary of HIPAA and Privacy Rule definitions, and *HIPAA and Public Health Site Visits: Access to Patient Records during AFIX and VFC Visits*, a short document containing responses to specific questions asked by the states regarding disclosure of patient health information without prior authorization during VFC and AFIX provider site visits. The CDC Office of General Counsel, which provides legal advice for CDC programs on issues such as implementation of HIPAA, prepared the responses to these questions. These materials have been very effective in addressing providers' concerns about HIPAA and facilitating traditional public health practice.

Almost two years after the effective date of the Privacy Rule, several states have requested written materials clarifying other questions and concerns about HIPAA. Enclosed is the second in the series of guidance statements, *HIPAA and Perinatal Hepatits B Prevention*. The original *HIPAA and Public Health Fact Sheet* is also enclosed. Additional information is available on the Office for Civil Rights website at http://www.hhs.gov/ocr/hipaa and in the MMWR, HIPAA Privacy Rule and Public Health: http://www.cdc.gov/mmwr/pdf/other/m2e411.pdf. We hope you will find this information helpful as you educate your provider groups and work with your respective legal offices on HIPAA issues.

Sincerely,

Stephen L. Cochi

Stephen L. Cochi, M.D., M.P.H.
Captain, United States Public Health Service
Acting Director
National Immunization Program

Enclosures

cc:
President, Association of State and Territorial Health Officials
President, Association of Immunization Managers
President, Council of State and Territorial Epidemiologists

Centers for Disease Control and Prevention
National Immunization Program

HIPAA and Perinatal Hepatitis B Prevention

Responses to Frequently Asked Questions about Perinatal Hepatitis B Prevention

This guidance is intended to give health care providers and public health agencies specific information regarding the HIPAA Privacy Rule and how it impacts perinatal hepatitis B prevention. Several frequently asked questions posed to the CDC legal counsel for interpretation are presented below. Additional sources of information and reference materials available on the internet are also included.

Q. 1. Does HIPAA permit providers, hospitals, and laboratories to report HBsAg-positive women to state and local health departments (including local health agencies and local boards of health) without the authorization of the individual, regardless of whether the state has a reporting law?

A. 1. Yes. Under 45 CFR §164.512(b)(1)(i) of the HIPAA Privacy Rule, covered entities may disclose protected health information without authorization to public health authorities that are authorized by law to collect such information for public health purposes. In addition, under 45 CFR §164.512(a), covered entities may disclose protected health information to public health authorities if the disclosure is required by law. A specific mandate to report is not required for disclosure. In states that do not have a law that specifically mandates the reporting of maternal HBsAg status, notifiable disease reporting laws mandate reporting of hepatitis B.

Q. 2. Does HIPAA permit providers and hospitals to disclose patient information to state and local health departments ((including local health agencies and local boards of health) without the authorization of the individual, for perinatal case management (e.g. immunization, prophylaxis, and post vaccination serology)?

A. 2. Yes. Under 45 CFR §164.512(b)(1)(i) of the HIPAA Privacy Rule, covered entities may disclose protected health information without authorization to public health authorities that are authorized by law to collect such information for public health purposes including disease prevention or control.

Q. 3. Can patient records be reviewed by state and local health department staff and their contractual agents when conducting quality assurance activities (e.g. chart reviews to assess HBsAg screening rates and appropriate prophylaxis), case investigations and/or disease outbreak activities?

A. 3. Yes. As explained above, under 45 CFR §164.512(b)(1)(i) of the HIPAA Privacy Rule, covered entities may disclose protected health information without authorization to public health authorities that are authorized by law to collect such information for public health purposes.

Q. 4. Does the HIPAA Privacy Rule apply to Indian Health Services and tribal clinics?

A. 4. Yes. The HIPAA Privacy Rule governs the use and disclosure of protected health information by covered entities (health plans, clearinghouses, and providers who transmit specified transactions electronically). The definition of health plans (45 CFR §160.103) includes the Indian Health Service (IHS) and programs under the Indian Health Care Improvement Act, 25 U.S.C. 1601 et seq. (45 CFR 160.103(1)(xii)).

Resources

Office for Civil Rights (responsible for enforcing the Privacy Rule) website: (www.hhs.gov/ocr/hipaa)

CDC/DHHS guidance on the Privacy Rule and Public Health, available at http://www.cdc.gov/mmwr/pdf/other/m2e411.pdf.

Centers for Disease Control and Prevention
National Immunization Program

Health Insurance Portability and Accountability Act and Public Health

Fact Sheet

What is HIPAA?

The Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) established a national floor of consumer privacy protection and marketplace reform. Some key provisions include: insurance reforms, privacy and security, administrative simplification, and cost savings.

What is the HIPAA Privacy Rule?

HIPAA required Congress to enact privacy legislation by August 1999 or the Secretary of DHHS was to develop regulations protecting privacy. The HIPAA Privacy Rule (Standards for Privacy of Individually Identifiable Health Information) sets national minimal standards for protected health information.

Implications for Public Health

The Privacy Rule strikes a balance between protecting patient information and allowing traditional public health activities to continue. Disclosure of patient health information without the authorization of the individual is permitted for purposes including but not limited to 1) disclosures required by law (45 CFR § 164.512(a)) or 2) for "public health activities and purposes." This includes disclosure to "a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to, the reporting of disease, injury, vital events. . ., and the conduct of public health surveillance,. . . investigations, and. . . interventions." (45 CFR § 164.512(b)(i))

Definition of Public Health Authority

Defined as "an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandates." (45 CFR § 164.501)

Centers for Disease Control and Prevention
National Immunization Program

Health Insurance Portability and Accountability Act and Public Health

Factsheet

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Admission Orders for Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus (HBV) Transmission

The guidelines in this 2-page document were developed to help hospitals establish policies and standing orders in their labor and delivery and newborn units.

During 2005, the Centers for Disease Control and Prevention (CDC) published updated recommendations of the Advisory Committee on Immunization Practices (ACIP) for prevention of hepatitis B virus (HBV) infections in children which includes the recommendation to administer hepatitis B vaccine to ***all newborns before hospital discharge.*** *The American Academy of Pediatrics, American Academy of Family Physicians, and American College of Obstetricians and Gynecologists have all endorsed the birth dose recommendation. To obtain a copy, go to* www.cdc.gov/mmwr/PDF/rr/rr5416.pdf.

To protect infants from HBV infection, CDC recommends that all delivery hospitals institute standing orders or admission orders, and protocols to ensure healthcare professionals do the following:

1. *Administer hepatitis B vaccine to* ***all newborns*** *before they are discharged from the hospital.*
2. *Identify all infants born to mothers who are hepatitis B surface antigen (HBsAg) positive or to mothers with unknown HBsAg status. Administer appropriate immunoprophylaxis to these infants.*

Admission orders / procedures for birthing mothers

For pregnant women who have a HBsAg lab report included in their prenatal records, do the following:

1. Examine a copy of the *original* laboratory report of the pregnant woman's HBsAg[1] test result to verify that the correct test (i.e., HBsAg) was performed and to verify that the testing date was during *this* pregnancy not a previous one. *Do not rely on a handwritten or transcribed HBsAg test result!*
2. Place a copy of the original HBsAg lab report into (1) the pregnant woman's L&D record and (2) the infant's hospital record.
3. If the pregnant woman is HBsAg positive, alert the nursery staff that the newborn is high risk and will need postexposure prophylaxis —both HBIG and hepatitis B vaccine—within 12 hours of birth.
4. Perform a repeat blood test for HBsAg[1] if the pregnant woman was HBsAg negative during a prenatal visit but was at risk for acquiring HBV infection during this pregnancy (e.g., not in a long-term, mutually monogamous relationship; had an HBsAg-positive sex partner; had evaluation or treatment for a sexually transmitted disease; currently uses or recently used injection drugs).
5. Instruct the laboratory to call L&D and the nursery with the HBsAg test result ASAP.

For pregnant women who do not have an HBsAg lab report on their prenatal record, do the following:

1. Perform HBsAg[1] testing ASAP on women who do not have a copy of an original HBsAg laboratory report from the current pregnancy included in their prenatal record.
2. Instruct the lab to call L&D and the nursery units with the newly obtained HBsAg test result ASAP.

Admission orders / procedures for newborns

Hospital procedures to follow for ALL newborns

1. Review a copy of the mother's *original* HBsAg[1] lab report to ensure that the correct serologic test was ordered and that it was ordered during this pregnancy.
2. Determine if the newborn needs immediate postexposure prophylaxis within 12 hours of birth. To do this you must know the mother's HBsAg status and the newborn's birth weight. If the newborn weighs less than 2kg, see the descriptions below and footnotes 2, 5, 6.

For newborns of HBsAg-negative mothers

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) before hospital discharge to <u>all</u> newborns weighing 2 kg or more at birth.[2, 3, 4]
2. Document the hepatitis B vaccine dose in the newborn's medical record, including date, time, site of administration, and lot number.
3. Give the mother an immunization record card that includes the hepatitis B vaccination date. Explain the need for the complete hepatitis B vaccine series to protect her baby. Remind her to bring the card with her each time her baby sees a provider.

For newborns of mothers with unknown HBsAg status, do the following:

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 12 hours of birth.[3, 5] Do not wait for test results to return before giving this dose of vaccine.
2. Document the hepatitis B vaccine dose in the newborn's medical record, including date, time, site of administration, and lot number.
3. Give the mother an immunization record card that includes the hepatitis B vaccination date. Explain the need for the complete hepatitis B vaccine series to protect her baby. Remind her to bring the card with her each time her baby sees a provider.
4. Confirm that the laboratory has received blood for the mother's HBsAg[1] test.
5. Verify when the mother's HBsAg result will be available and that it will be reported to L&D and the newborn unit ASAP.
6. If the nursery does not receive the report of the mother's HBsAg test at the expected time, call the laboratory for the result.
7. If the laboratory test indicates the mother's HBsAg[1] test result is positive, do the following:
   a. Administer hepatitis B immune globulin (HBIG 0.5 mL, IM) to the newborn ASAP. (Hepatitis B vaccine should have been given within 12 hours of birth.)

(continued on next page)

 continued from page 1

b. Document the HBIG dose appropriately in the newborn's medical record. There is little benefit in giving HBIG if more than 7 days have elapsed since birth.
c. Alert the mother's and newborn's physician(s) of the test result.
d. Follow the instructions below "For newborns of HBsAg-positive mothers," steps 3–7.

8. If the newborn must be discharged before the mother's HBsAg result is known:
   a. Document contact information for the parents (e.g., addresses, telephone numbers, emergency contacts) in case further treatment is needed.
   b. Obtain the name, address, and phone number of the mother's and the newborn's healthcare providers.
   c. Notify the mother's and newborn's healthcare providers that the mother's HBsAg test result is pending.

For newborns of HBsAg-positive mothers

1. Administer HBIG (0.5 mL, IM) and single-antigen hepatitis B vaccine[3, 6] (0.5 mL, IM) at separate injection sites within 12 hours of birth.
2. Document the hepatitis B vaccine and HBIG dose in the newborn's medical record, including date, time, site of administration, and lot number.
3. Give the mother an immunization record card that includes the hepatitis B vaccination and HBIG dates. Explain the need for the complete hepatitis B vaccine series to protect her baby. Remind her to bring the card with her each time her baby sees a provider.
4. Notify the local or state health department of the infant's birth and the date and time of administration of HBIG and hepatitis B vaccine doses.
5. Obtain the name, address, and phone number of the newborn's primary care provider.
6. Notify the provider of the newborn's birth, the date and time of HBIG and hepatitis B vaccine doses administered, and the importance of additional on-time vaccination and postvaccination testing of the infant for HBsAg and antibody to HBsAg after completion of the hepatitis B vaccine series.
7. Provide advice to the mother. Tell her the following:
   a. That she may breast-feed her infant upon delivery, even before hepatitis B vaccine and HBIG are given;
   b. That it is critical for her infant to complete the full hepatitis B vaccine series on the recommended schedule;
   c. That blood will need to be drawn from the infant after completion of at least 3 doses of the hepatitis B vaccine series at age 9–18 months (usually done at a well-child visit) to determine if the infant developed a protective immune response to vaccination or needs additional management;
   d. About modes of HBV transmission and the need for testing and vaccination of susceptible household, sexual, and needle-sharing contacts;
   e. That she needs to have a medical evaluation for chronic hepatitis B, including an assessment of whether she is eligible for antiviral treatment.

Footnotes

1. Be sure the correct test for HBsAg (hepatitis B surface antigen) was/is ordered. The HBsAg test should not be confused with other hepatitis B serologic tests, including antibody to HBsAg (anti-HBs or HBsAb) and antibody to hepatitis B core antigen (anti-HBc or HBcAb).
2. Infants weighing less than 2 kg at birth and whose mothers are documented to be HBsAg negative should receive the first dose of vaccine 1 month after birth or at hospital discharge, whichever comes first. The mother's HBsAg test result must be part of the infant's medical record.
3. Federal law requires that you give parents a Hepatitis B Vaccine Information Statement (VIS) before vaccine administration. To obtain a VIS, download it from the IAC website at www.immunize.org/vis or call your state health department.
4. According to the CDC recommendations, exceptions to administering the birth dose of hepatitis B vaccine are allowed on a case-by-case basis and only in rare circumstances. If a birth dose is not administered, a copy of the mother's negative HBsAg test result from the current pregnancy must be placed in the infant's medical record and the attending physician must write a specific order directing staff not to administer the birth dose in the hospital. Infants who do not receive the first dose of hepatitis B vaccine before hospital discharge should receive the first dose no later than age 2 months.
5. An infant weighing less than 2 kg whose mother's HBsAg status is unknown should receive HBIG and hepatitis B vaccine within 12 hours of birth. Do not count the hepatitis B vaccine dose as the first dose in the vaccine series. Reinitiate the full hepatitis B vaccine series at age 1–2 months.
6. An infant weighing less than 2 kg whose mother is HBsAg positive should receive the first dose of hepatitis B vaccine and HBIG within 12 hours of birth. Do not count the hepatitis B vaccine dose as the first dose in the vaccine series. Reinitiate the full hepatitis B vaccine series at age 1–2 months.

SAMPLE TEXT

Admission Order for Routine Newborn Hepatitis B Vaccination (to include in the standard admission orders)

☐ **Hepatitis B Vaccine (RECOMBIVAX HB or Engerix-B) IM**
ONE TIME, Intramuscular, Dose: 0.5 mL. Give within 12 hours of birth to all infants who weigh 2 kg (4.4 lb) or more. Bathe the newborn, washing the site well with soap and water, cleanse the injection site with alcohol prior to IM administration. *Obtain verbal consent from the parent prior to administration. Give the hepatitis B Vaccine Information Statement (VIS) to the parent and document the vaccine's administration in the hospital medical record. If the parent is unwilling to give verbal consent, notify physician by morning rounds or prior to 12 hours of age.*

Give the birth dose . . .

Hepatitis B vaccine at birth saves lives!

*By **Deborah L. Wexler, MD,** Executive Director, Immunization Action Coalition*

*In December 2005, CDC issued updated recommendations on hepatitis B vaccination (HepB) for infants. The recommendations strongly support (1) giving the HepB birth dose to every newborn prior to hospital discharge and (2) using standardized admission orders for administering the birth dose. In addition, it is recommended that a copy of the **original** maternal hepatitis B lab report be sent to the hospital—**not** a transcribed result. The recommendations also state that the HepB birth dose may be delayed until after hospital discharge only "in rare circumstances." When doing so, a physician's order to withhold the birth dose and a copy of the original lab report indicating that the mother was HBsAg negative during this pregnancy should be placed in the infant's medical record. The latest CDC estimates indicate only 55% of newborns receive the HepB birth dose by 3 days of age. Clearly, there is much work left to do to fully protect newborns.*

Healthcare professionals!

Urge your patients to protect their newborns with hepatitis B vaccine before hospital discharge. Your recommendation to vaccinate is a strong patient motivator!

The HepB birthdose saves lives!

To obtain CDC's recommendations for hepatitis B immunization of infants, children, and adolescents, go to: www.cdc.gov/mmwr/pdf/rr/rr5416.pdf

Leading health organizations—CDC, AAP, AAFP, and ACOG—recommend that all hospitals and healthcare professionals protect newborns from hepatitis B virus (HBV) infection by administering the first dose of hepatitis B vaccine (HepB) to every baby at birth, no later than hospital discharge.

Approximately 24,000 women with chronic HBV infection give birth in the U.S. each year, and many do not know they are infected. Up to 95% of perinatal infections can be prevented by postexposure prophylaxis given within 12 hours of birth. Tragically, many babies are exposed to HBV at birth and do not receive appropriate postexposure prophylaxis. Infants infected at birth have a greater than 90% chance of becoming chronically infected with HBV. Chronic HBV infection in infants leads to liver cancer, cirrhosis, and liver failure in 25% of these infants when they become adults.

Why is a universal birth dose policy necessary in hospitals?

Following are some of the ways newborns can be infected if they do not receive a dose of hepatitis B vaccine, ideally within 12 hours of birth:

- The pregnant woman is tested and found to be hepatitis B surface antigen (HBsAg) positive, but her "infected" status is not communicated to the newborn nursery. The infant receives neither HepB nor HBIG protection at birth.
- A chronically infected pregnant woman receives the wrong test. For example, antibody to hepatitis B surface antigen (antiHBs) is ordered in error, instead of HBsAg. This can happen because some labs use the confusing abbreviation HBsAb instead of anti-HBs. This misordering of a test is relatively common since the two abbreviations (HBsAg and HBsAb) differ by only one letter. However, when her incorrectly ordered test comes back "negative," the woman may actually be HBsAg positive and her infant would not receive appropriate postexposure prophylaxis.
- The pregnant woman is HBsAg positive, but her test results are misinterpreted or mistranscribed into her prenatal record or her infant's chart. As a result, her infant does not receive HBIG or HepB.
- The pregnant woman is not tested for HBsAg either prenatally or in the hospital at the time of delivery. In one study, women who didn't receive prenatal care were eight times more likely to be HBsAg positive than women who received prenatal care. When a woman does not receive prenatal care and is not tested at the time of delivery, her infant is in danger of being infected with HBV at birth—unless he or she is born in a hospital that adheres to a policy of administering HepB within 12–24 hours of birth to every newborn ***without fail.*** This provides the greatest effectiveness in preventing HBV infection.
- She develops HBV infection later in pregnancy, but it is not clinically detected. Because her initial HBsAg test result is negative, she is not retested later in pregnancy as CDC recommends for high-risk women, and her infant does not receive HepB or HBIG at birth.
- The mother is HBsAg negative, but the infant is exposed to HBV postnatally from another family member or caregiver. This occurs in two-thirds of the cases of childhood transmission.

State perinatal hepatitis B coordinators provided hundreds of reports of newborns who were unprotected or inadequately protected because of medical errors.

In 2001, 2002, and 2008, the Immunization Action Coalition surveyed perinatal hepatitis B coordinators at every state health department, as well as at city and county CDC projects to assess their views about providing hepatitis B vaccine in the hospital. Their responses contained hundreds of reports of newborns who were unprotected or inadequately protected because healthcare professionals failed to order or misordered hepatitis B blood tests or misinterpreted, mistranscribed, or miscommunicated the test results of the children's mothers (see www.immunize.org/catg.d/p2062.pdf).

These state coordinators' reports tell us that no matter how well healthcare providers think they are doing in screening all pregnant women for HBsAg, mistakes continue to occur. Newborns are are unnecessarily being exposed without the benefit of postexposure prophylaxis. At least one baby has died of fulminant hepatitis B; hundreds have become chronically infected and are doomed to preventable hepatocellular carcinoma or cirrhosis later in life. To overcome these failures, perinatal hepatitis B coordinators overwhelmingly endorse providing a HepB birth dose as the first step in developing a safety net to protect all infants from HBV infection, regardless of the circumstances.

To maximally protect every newborn, CDC, AAP, AAFP, and ACOG recommend ***all*** infants be vaccinated with a HepB birth dose prior to hospital discharge. Delaying hepatitis B vaccination until a follow-up office visit will be too late to prevent perinatal HBV transmission.*

State perinatal hepatitis B coordinators surveyed overwhelmingly endorsed providing the birth dose.

HepB is a highly effective vaccine. Studies have shown that infants of the most highly infectious mothers (women who are both HBsAg and HBeAg positive) who receive postexposure prophylaxis with HepB alone (without HBIG) at birth are protected in 70%–95% of cases. Please read the hepatitis coordinators' survey results (www.immunize.org/birthdose), including descriptions of their experiences with failures of the system—failures that largely will be prevented by administering HepB to infants before they go home from the hospital, ideally within 12 hours of birth.

Your support for providing a birth dose to newborns while they are still in the hospital will protect and save lives that are now being put at risk. ♦

*For subsequent doses of hepatitis B vaccine (HepB) in infants, use monovalent HepB or hepatitis B-containing combination vaccines. If using hepatitis B-containing combination vaccines, you will be giving 3 more doses of HepB. Giving a total of 4 doses of HepB to infants is acceptable practice to CDC, AAP, and AAFP. These vaccine doses are covered under the Vaccines For Children (VFC) program for VFC-eligible children.

www.immunize.org/catg.d/p2125.pdf • Item #P2125 (9/09)

Hepatitis B Facts: Testing and Vaccination

Who should be vaccinated?

The following persons should receive routine hepatitis B vaccination, according to the Centers for Disease Control and Prevention (CDC):

Routine vaccination:
- All newborns at birth prior to hospital discharge
- All children and teens ages 0 through 18 years
- All persons who wish to be protected from hepatitis B virus (HBV) infection. CDC states it is not necessary for the patient to disclose a risk factor to receive hepatitis B vaccine.

Persons who are at risk for sexual exposure:
- Sexually active persons who are not in long-term, mutually monogamous relationships
- Sex partners of HBsAg-positive persons
- Persons seeking evaluation or treatment for an STD
- Men who have sex with men

Persons at risk for infection by percutaneous or mucosal exposure to blood:
- Injection-drug users, current or past
- Household contacts of HBsAg-positive persons
- Residents and staff of facilities for developmentally challenged persons
- Healthcare and public safety workers with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids
- Persons with end-stage renal disease and those receiving dialysis

Others:
- Travelers to areas with moderate or high rates of HBV infection
- Persons with chronic (life-long) liver disease
- Persons with HIV infection

Refugees, immigrants, and adoptees from countries where HBV infection is endemic should have hepatitis B testing. Adults should discuss their need or desire for hepatitis B vaccination with their healthcare providers.

For certain people at risk, postvaccination testing is recommended. Consult ACIP recommendations for details (see references).

Hepatitis B lab nomenclature

HBsAg: *Hepatitis B surface antigen* is a marker of infectivity. Its presence indicates either acute or chronic HBV infection.

Anti-HBs: *Antibody to hepatitis B surface antigen* is a marker of immunity. Its presence indicates an immune response to HBV infection, an immune response to vaccination, or the presence of passively acquired antibody. (It is also known as ***HBsAb,*** but this abbreviation is best avoided since it is often confused with abbreviations such as HBsAg.)

Anti-HBc (total): *Antibody to hepatitis B core antigen* is a nonspecific marker of acute, chronic, or resolved HBV infection. It is *not* a marker of vaccine-induced immunity. It may be used in prevaccination testing to determine previous exposure to HBV infection. (It is also known as ***HBcAb,*** but this abbreviation is best avoided since it is often confused with other abbreviations.)

IgM anti-HBc: *IgM antibody subclass of anti-HBc.* Positivity indicates recent infection with HBV (within the past 6 mos). Its presence indicates acute infection.

HBeAg: *Hepatitis B "e" antigen* is a marker of a high degree of HBV infectivity, and it correlates with a high level of HBV replication. It is primarily used to help determine the clinical management of patients with chronic HBV infection.

Anti-HBe: *Antibody to hepatitis B "e" antigen* may be present in an infected or immune person. In persons with chronic HBV infection, its presence suggests a low viral titer and a low degree of infectivity.

HBV-DNA: *HBV Deoxyribonucleic acid* is a marker of viral replication. It correlates well with infectivity. It is used to assess and monitor the treatment of patients with chronic HBV infection.

About hepatitis B serologic testing

Serologic testing prior to vaccination may be undertaken based on your assessment of your patient's level of risk and your or your patient's need for definitive information (see information in the left column). If you decide to test, draw the blood first, and then give the first dose of vaccine at the same office visit. Vaccination can then be continued, if needed, based on the results of the tests. If you are not sure who needs hepatitis B testing, consult your state or local health department.

Tests	Results	Interpretation	Vaccinate?
HBsAg anti-HBc anti-HBs	negative negative negative	susceptible	vaccinate if indicated
HBsAg anti-HBc anti-HBs	negative negative positive with ≥10mIU/mL	immune due to vaccination	no vaccination necessary
HBsAg anti-HBc anti-HBs	negative positive positive	immune due to natural infection	no vaccination necessary
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive positive negative	acutely infected	no vaccination necessary
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive negative negative	chronically infected	no vaccination necessary (may need treatment)
HBsAg anti-HBc anti-HBs	negative positive negative	four interpretations possible*	use clinical judgment

*1. May be recovering from acute HBV infection
2. May be distantly immune, but the test may not be sensitive enough to detect a very low level of anti-HBs in serum
3. May be susceptible with a false positive anti-HBc
4. May be chronically infected and have an undetectable level of HBsAg present in the serum

Managing chronic HBV infection

When you identify a patient who is chronically infected with HBV, make sure you consult a specialist knowledgeable in the treatment of liver disease so your patient's care is optimized. Chronically infected persons need medical evaluation every 6–12 months to assess the status of their liver health and their need for antiviral therapy, as well as to screen for liver cancer. In addition, persons with chronic HBV infection should be educated about their disease and how to protect others.

Household members and sex partners should be tested for HBV infection (HBsAg and antiHBs) and given the first dose of hepatitis B vaccine at the same visit. (Vaccinating a person who has already been infected will do no harm). If testing indicates HBV susceptibility, complete the hepatitis B vaccination series. If testing indicates the presence of HBV infection, consultation and further care with a physician knowledgeable about chronic hepatitis B is needed.

References

1. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the U.S.: Recommendations of the ACIP, Part 1: Immunization of Infants, Children and Adolescents, *MMWR,* Dec. 23, 2005, Vol. 54(RR-16)
2. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the U.S.: Recommendations of the ACIP, Part II: Immunization of Adults, *MMWR,* Dec. 8, 2006, Vol. 55(RR-16)

www.immunize.org/catg.d/p2110.pdf • Item #P2110 (6/10)

Patient notification letter regarding hepatitis B test results

Dear _____ , Date of birth:_____Today's date:_____

Your hepatitis B test results are recorded here and the explanation checked below.

Date of testing: _____ HBsAg: _____ anti-HBs: _____ anti-HBc: _____ IgM anti-HBc: _____

[ ] **Susceptible:** (HBsAg, anti-HBs, and anti-HBc are negative)
Your test results show that you have never been infected with the hepatitis B virus. This means that you could develop hepatitis B virus infection in the future. You should receive the three doses of hepatitis B vaccine to protect yourself from this disease. After the 1st dose, the 2nd dose is usually given one month later and the 3rd dose is usually given five months after that. Please call the clinic to make an appointment to start your hepatitis B vaccination series.

[ ] **Immune due to past infection:** (HBsAg is negative; anti-HBs and anti-HBc are positive)
Your results show that you had hepatitis B virus infection in the past but that the disease is gone and you will not get the disease again. You do not need the shots to protect you. You are already protected.

[ ] **Immune due to vaccination:** (HBsAg and anti-HBc are negative; anti-HBs is positive)
Your results indicate that you are protected from hepatitis B virus infection because you most likely received the hepatitis B vaccine. You are immune or safe from hepatitis B.

[ ] **Acutely infected with hepatitis B:** (HBsAg, anti-HBc, and IgM anti-HBc are positive; anti-HBs is negative)
Your results show that you have recently developed hepatitis B virus infection and that you are infectious. Please contact the clinic to discuss what further evaluation needs to be done.

[ ] **Resolving hepatitis B virus infection:** (HBsAg is negative; anti-HBc and IgM anti-HBc are positive; anti-HBs is negative)
Your results show that you were recently infected with hepatitis B virus, but that your infection is resolving. You are no longer infectious to others.

[ ] **Chronically infected with hepatitis B virus:** (HBsAg and anti-HBc are positive; IgM anti-HBc and anti-HBs are negative)
Your test results show that you are infected with the hepatitis B virus. It is important for you to come into the clinic *soon* for further evaluation and to receive additional information about hepatitis B. It is also important for you to learn how to take care of yourself and how to protect others from this infection. Hepatitis B can cause serious liver damage in some people, *even if they feel fine*. Call us now to make an appointment for further evaluation and education about hepatitis B.

[ ] **Indeterminate results:** (only anti-HBc is positive)
Your test results suggest that you may have been in contact with the hepatitis B virus at some time in the past. You may not be protected from this disease. Please make an appointment to come to discuss the meaning of your hepatitis B tests and what plan of action needs to be taken.

Please call the clinic if you have questions about this information or to schedule the appointment(s) indicated above.

Sincerely,

_____ _____
Clinician's signature Clinician's name (print or type)

Item #P4140 (4/02)

What the Physician Can Do to Help the Child with Chronic Hepatitis B Virus Infection

Sarah Jane Schwarzenberg, M.D.
Division of Pediatric Gastroenterology, Hepatology and Nutrition
University of Minnesota

Although children with chronic hepatitis B virus (HBV) infection may follow many different clinical courses, these recommendations will help all of them maintain good health.

1. **A yearly physical**
   Every child with hepatitis B needs a yearly check-up with his/her primary physician to make sure the child is healthy and growing normally.

2. **Laboratory studies to monitor liver health**
   At the first clinical visit, liver enzymes (ALT and AST), INR, a complete blood count, alpha-fetoprotein (AFP) and ultrasound are usually obtained. Thereafter, liver enzymes should be checked yearly in the healthy child with HBV.

3. **Screening for hepatocellular carcinoma**
   There are no definitive guidelines for screening children with HBV for hepatocellular carcinoma. AFP is a tumor marker and is increased in 85% of individuals with hepatocellular carcinoma, often before clinical evidence of cancer is present. It may be elevated at a time when the tumor can be resected completely. We recommend yearly AFP in the child with HBV, and twice yearly testing with hepatic ultrasound in the child with cirrhosis and HBV. It should be noted that even close monitoring of these tests does not guarantee early diagnosis of hepatocellular carcinoma.

4. **Hepatitis B testing every 3-5 years**
   Few children convert from HBsAg to anti-HBs (HBsAb), especially if they acquired the disease in the perinatal period. It is important to occasionally check to see if the patient is still infected.

5. **Referral to a pediatric gastroenterologist**
   Any child with an AST >2 times the upper limit of normal, evidence of hepatic dysfunction, failure to thrive, an elevated AFP, a need for family counseling, or abnormalities on hepatic ultrasound should be referred to a pediatric gastroenterologist for evaluation.

6. **Treatment**
   Although medications are available to treat hepatitis B, they are generally useful only in patients with on-going hepatic injury (active hepatitis). Consultation with a pediatric gastroenterologist will help identify those patients who would benefit from medical therapy.

7. **Vaccination of household members**
   All members of the child's household and caregivers who have close contact with the child should be vaccinated against hepatitis B, even if pregnant.

8. **Hepatitis B education**
   Each child with hepatitis B and his/her parents should receive age-appropriate hepatitis B education. This should include methods for prevention of transmission of the virus and assistance for the child in dealing with his/her positivity throughout the school years and as a teenager. Older children should receive counseling on the use of condoms to prevent viral transmission to their sexual partners.

9. **Maintaining personal health**
   Immunization against hepatitis A is recommended to prevent a second injury to the liver. Ethanol should be avoided. When prescribing other medications, care must be taken to avoid or monitor those with known hepatotoxicity.

For more information regarding the child with hepatitis B, please contact Dr. Sarah Jane Schwarzenberg in the division of Pediatric Gastroenterology, Hepatology and Nutrition, University of Minnesota, Department of Pediatrics, 420 Delaware Street SE, Minneapolis, Minnesota 55455; Telephone (612) 624-1133.

www.immunize.org/catg.d/p2170.pdf • Item #P2170 (7/08)

Interpretation of Hepatitis B Serologic Test Results

Hepatitis B serologic testing involves measurement of several hepatitis B virus (HBV)-specific antigens and antibodies. Different serologic "markers" or combinations of markers are used to identify different phases of HBV infection and to determine whether a patient has acute or chronic HBV infection, is immune to HBV as a result of prior infection or vaccination, or is susceptible to infection.

HBsAg **anti-HBc** **anti-HBs**	negative negative negative	Susceptible
HBsAg **anti-HBc** **anti-HBs**	negative positive positive	Immune due to natural infection
HBsAg **anti-HBc** **anti-HBs**	negative negative positive	Immune due to hepatitis B vaccination
HBsAg **anti-HBc** **IgM anti-HBc** **anti-HBs**	positive positive positive negative	Acutely infected
HBsAg **anti-HBc** **IgM anti-HBc** **anti-HBs**	positive positive negative negative	Chronically infected
HBsAg **anti-HBc** **anti-HBs**	negative positive negative	Interpretation unclear; four possibilities: 1. Resolved infection (most common) 2. False-positive anti-HBc, thus susceptible 3. "Low level" chronic infection 4. Resolving acute infection

Adapted from: A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. Part I: Immunization of Infants, Children, and Adolescents. MMWR 2005;54(No. RR-16).

- **Hepatitis B surface antigen (HBsAg):** A protein on the surface of hepatitis B virus; it can be detected in high levels in serum during acute or chronic hepatitis B virus infection. The presence of HBsAg indicates that the person is infectious. The body normally produces antibodies to HBsAg as part of the normal immune response to infection. HBsAg is the antigen used to make hepatitis B vaccine.
- **Hepatitis B surface antibody (anti-HBs):** The presence of anti-HBs is generally interpreted as indicating recovery and immunity from hepatitis B virus infection. Anti-HBs also develops in a person who has been successfully vaccinated against hepatitis B.
- **Total hepatitis B core antibody (anti-HBc):** Appears at the onset of symptoms in acute hepatitis B and persists for life. The presence of anti-HBc indicates previous or ongoing infection with hepatitis B virus in an undefined time frame.
- **IgM antibody to hepatitis B core antigen (IgM anti-HBc):** Positivity indicates recent infection with hepatitis B virus (≤6 mos). Its presence indicates acute infection.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention
Division of Viral Hepatitis

CDC
Centers for Disease Control and Prevention

www.cdc.gov/hepatitis

Hepatitis B
COALITION
Immunization Action Coalition

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www.immunize.org • www.vaccineinformation.org

QUESTIONS FREQUENTLY ASKED ABOUT HEPATITIS B

What is hepatitis B?

Hepatitis B is a serious public health problem that affects people of all ages in the U.S. and around the world. In 2006, an estimated 46,000 people contracted hepatitis B virus (HBV) infection in the U.S. Hepatitis B is caused by a highly infectious virus that attacks the liver and can lead to severe illness, liver damage, and in some cases, death.

The best way to be protected from hepatitis B is to be vaccinated with hepatitis B vaccine, a vaccine used in the U.S. for more than two decades and proved safe and effective.

Who is at risk for HBV infection?

About 5% of people in the U.S. will get infected with HBV sometime during their lives if they are not vaccinated. You might be infected with HBV and not even know it. If you engage in certain activities, your risk might be much higher. You might be at risk if you

- have a job that exposes you to human blood
- share a household with someone who has chronic (lifelong) HBV infection
- inject drugs
- have sex with a person infected with HBV
- are sexually active but not in a long-term, mutually monogamous relationship
- are a man who has sex with men
- received a blood transfusion before 1975, when excellent blood testing became available
- are a person who was born, or who has a parent born, in Asia, Africa, the Amazon River Basin in South America, the Pacific Islands, Eastern Europe, or the Middle East
- were adopted from Asia, Africa, the Amazon River Basin in South America, the Pacific Islands, Eastern Europe, or the Middle East
- have hemophilia
- are a patient or worker in an institution for developmentally challenged people
- are an inmate of a correctional facility
- travel internationally to areas with moderate or high rates of HBV infection

How is HBV spread?

HBV is found in the blood of people infected with the virus and certain of their body fluids, such as serum, semen, and vaginal secretions. HBV is not found in sweat, tears, urine, or respiratory secretions. Contact with microscopic amounts of infected blood can cause infection.

Hepatitis B virus can be spread by

- unprotected sex
- injection drug use
- an HBV-infected mother to her child during birth
- contact with blood or open sores of an HBV-infected person
- human bites from an HBV-infected person
- sharing a household with a person with chronic (lifelong) HBV infection
- sharing items such as razors, toothbrushes, or washcloths
- pre-chewing food for babies or sharing chewing gum
- using unsterilized needles in ear- or body-piercing, tattooing, or acupuncture
- using the same immunization needle on more than one person

Hepatitis B virus IS NOT spread by

- casual contact, like holding hands
- eating food prepared by an infected person
- kissing or hugging
- sharing silverware, plates, or cups
- visiting an infected person's home
- sneezing or coughing
- breastfeeding

What are the symptoms of hepatitis B?

Most babies and young children who get HBV infection don't look or feel sick at all. About half of adults who get infected don't have any symptoms or signs of the disease. If people do have signs or symptoms, they might experience any or all of the following:

- loss of appetite
- nausea, vomiting
- fever
- weakness, fatigue, inability to work for weeks or months
- abdominal pain
- yellowing of skin and eyes (jaundice)
- joint pain
- cola-colored urine
- clay-colored stools

I'm not in a risk group. How did I get HBV infection?

Many people don't know when or how they got the infection. When they get the results of a blood test indicating they've been infected with HBV, they are taken by surprise. Studies have demonstrated that about 15% of people who acquire hepatitis B are unable to identify a risk factor that explains why they have the disease.

(continued on next page)

Technical content reviewed by the Centers for Disease Control and Prevention, Aug. 2007.

Do people usually recover from HBV infection?

About 95% of adults recover after several months. They clear the infection from their bodies and become immune. This means they won't get infected with HBV again. They are no longer contagious and cannot pass HBV to others.

Unfortunately, about 5% of adults and up to 90% of children under age 5 years are unable to clear the infection from their bodies and develop chronic HBV infection.

How do I know if I have or have had HBV infection?

The only way to know if you are currently infected with HBV, have recovered, are chronically infected, or could become infected, is by having blood tests. The three standard blood tests are the following:

HBsAg (hepatitis B surface antigen): when this is "positive" or "reactive," it means the person is currently infected with HBV and is able to pass the infection on to others.

Anti-HBs [sometimes written as HBs-Ab] (antibody to hepatitis B surface antigen): when this is "positive" or "reactive," it means the person is immune to HBV infection, either from vaccination or from past infection. (This test is not done routinely by most blood banks on donated blood.)

Anti-HBc [sometimes written as HBc-Ab] (antibody to hepatitis B core antigen): when this is "positive" or "reactive," it might mean the person has had contact with HBV. This is a very complicated test to explain because the "anti-HBc" can possibly be a "false-positive" test result. Blood banks routinely run an "anti-HBc" on donated blood. The interpretation of this test result, if it is positive, depends on the results of the other two blood tests previously described.

A fourth blood test that is sometimes done is **IgM anti-HBc (IgM class antibody to hepatitis B core antigen).** When this is positive or "reactive," it means that the person has had HBV infection in the past six months, indicating acute (recently acquired) HBV infection.

Interpretation of the hepatitis B blood test results

Tests	Results	Interpretation	Vaccination Needed
HBsAg anti-HBc anti-HBs	negative negative negative	susceptible	Yes, for all people who want protection
HBsAg anti-HBc anti-HBs	negative negative positive with ≥10mIU/mL*	immune due to vaccination	no
HBsAg anti-HBc anti-HBs	negative positive positive	immune due to natural infection	no
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive positive negative	newly infected	no
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive negative negative	chronically infected	no (may need treatment)
HBsAg anti-HBc anti-HBs	negative positive negative	four interpretations possible†	possibly†

*Postvaccination blood testing, when it is recommended, should be done 1–2 months after the final vaccine dose.

†1. May be recovering from acute HBV infection.
2. May be distantly immune, and the test is not sensitive enough to detect a very low level of anti-HBs in serum.
3. May be susceptible with a "false positive" anti-HBc.
4. May be chronically infected and have an undetectable level of HBsAg present in the serum.

What does it mean if my blood bank said I tested positive for hepatitis B and can no longer donate blood?

If the blood bank told you your test was "positive," it is important to find out which test was positive. If the "HBsAg" was positive, this means that you are either chronically infected with HBV or were recently infected. If only the "anti-HBc" was positive, it is most likely that you either had a "false-positive" test or are immune to HBV infection (had HBV infection sometime in the past). It is important that you understand the full meaning of your test results. If you are not sure how to interpret these test results, call your blood bank for an explanation or have the blood bank send the test results to your healthcare provider. You may need to provide written permission for the blood bank to release these results to your healthcare provider. Your healthcare provider may want to repeat the blood tests or perform additional tests such as an "anti-HBs." Bring this information sheet along with you on your visit to your healthcare provider. The blood bank does not usually test for anti-HBs or IgM anti-HBc.

And remember, you cannot get HBV from donating blood because the equipment used during blood donation is sterile.

CHRONIC HEPATITIS B VIRUS INFECTION

What does it mean to be chronically infected with HBV?

People who do not recover from HBV infection are chronically infected, usually for life. There are over one million chronically infected people in the U.S. today. A chronically infected person is someone who has had HBV in her/his blood for more than 6 months. While approximately 5% of adults who acquire HBV infection become chronically infected, children younger than age 5 years have a greater risk (up to 90%). The younger the child is at the time of infection, the greater the risk that the child will develop chronic infection. Many babies born to chronically infected mothers will also become chronically infected with HBV unless the babies are given two shots in the hospital immediately after birth—the first dose of hepatitis B vaccine and a dose of hepatitis B immune globulin [HBIG])—and at least two doses of hepatitis B vaccine during the 6 months after

(continued on next page)

birth to protect them from the infection. The final dose should not be given before 24 weeks of age.

A chronically infected person might have no signs or symptoms of HBV infection but usually remains infected for years or for a lifetime and is capable of passing HBV on to others. Sometimes chronically infected people will spontaneously clear the infection from their bodies, but most will not. Although most chronically infected people have no serious problems with hepatitis B and lead normal, healthy lives, some develop liver problems later. Chronically infected people are at significantly higher risk than the general population for liver failure or liver cancer.

How can I take care of myself if I am chronically infected with HBV?

A person with HBV infection should see a physician knowledgeable about the management of liver disease every 6–12 months. The physician will do blood tests to check the health of the liver, as well as test for evidence of liver cancer. It is best for chronically infected people to avoid alcohol because alcohol can injure the liver. Additionally, your physician should know about all the medicines you are taking, even over-the-counter drugs, because some medicines can hurt the liver. If the result of any liver test is abnormal, it's important that you consult a liver specialist.

If your liver disease has progressed...

If your physician tells you your liver disease has progressed, read the following for some extra precautions you should take.

- Avoid alcohol and medicine that has not been prescribed by your doctor—even over-the-counter medicines.
- Get vaccinated against hepatitis A. Hepatitis A virus infection can further damage your liver.
- Get a yearly influenza (flu) vaccination. Patients with severe liver disease (cirrhosis) should also receive pneumococcal vaccine.
- Don't eat raw oysters. They may carry the bacteria *Vibrio vulnificus,* which can cause serious blood infections in people with liver disease. Approximately 50% of people with this blood infection die from it.

What can I do to protect others from HBV infection?

People with HBV infection might feel healthy but are still capable of passing the infection on to other people. To protect others from getting HBV infection, it is important to protect them from contact with your infected blood and other infectious body fluids, including semen and vaginal secretions. Sweat, tears, urine, and respiratory secretions do not contain HBV. Transmission of HBV by saliva has only been documented through biting.

Important DOs and DON'Ts for people with chronic HBV infection

DO:

- Cover all cuts and open sores with a bandage.
- Discard used items such as bandaids and menstrual pads carefully so no one is accidentally exposed to your blood.
- Wash your hands well after touching your blood or infectious body fluids.
- Clean up blood spills. Then reclean the area with a bleach solution (one part household chlorine bleach to 10 parts water).
- Tell your sex partner(s) you have hepatitis B so they can be tested and vaccinated (if not already infected). Sex partners should be tested for anti-HBs 1–2 months after the three doses are completed to be sure the vaccine worked.
- Use condoms (rubbers) during sex unless your sex partner has had hepatitis B or has been vaccinated and has had the anti-HBs blood test demonstrating immunity. (Condoms may also protect you from other sexually transmitted diseases.)
- Tell household members to see their healthcare providers for testing and vaccination for hepatitis B.
- Tell your healthcare providers that you are chronically infected with HBV.
- See your healthcare provider every 6–12 months to check the health of your liver with blood tests and liver scanning.
- If you are pregnant, tell your healthcare provider that you have HBV infection. It is critical that your baby is started on the hepatitis B shots (both vaccine and HBIG) within 12 hours of birth.

DON'T:

- Don't share chewing gum, toothbrushes, razors, washcloths, needles for ear or body piercing, or anything that might have come in contact with your blood or infectious body fluids
- Don't pre-chew food for babies.
- Don't share syringes and needles.
- Don't donate blood, plasma, body organs, tissue, or sperm.
- Don't take any medicines not prescribed by your doctor, even over-the-counter medicines.

What are the long-term effects of HBV infection?

Each year, approximately 3,000–5,000 people in the U.S. die of HBV-related chronic liver disease. HBV infection is the most common cause of liver cancer worldwide and ranks second only to tobacco as the world's leading cause of cancer.

Is there a cure for hepatitis B?

As of this writing, there are several drugs used for the treatment of people with chronic hepatitis B. These drugs usually don't get rid of the virus completely, but may reduce your risk for serious liver disease such as cirrhosis and liver cancer. Check with your doctor to find out if treatment with medication is the right choice for you. Researchers continue to find additional treatments and look for cures for hepatitis B.

(continued on next page)

Why is hepatitis B so serious in pregnant women?

Pregnant women who are infected with HBV can transmit the disease to their babies. If babies aren't protected with vaccinations, many of them develop lifelong HBV infections, and up to 25% of those who become infected will develop liver failure or liver cancer later in life. All pregnant women should be tested early in every pregnancy to determine if they are infected with HBV. If the blood test is positive, the baby should be vaccinated within 12 hours of birth with two shots, one of HBIG and the other the first dose of hepatitis B vaccine. The infant will need at least two more doses of hepatitis B vaccine by age 6 months. The final dose should not be given before age 24 weeks.

How can hepatitis B be prevented?

Hepatitis B vaccine can provide protection in 90%–95% of healthy young adults. The vaccine can safely be given to infants, children, and adults, including pregnant women. Usually, three doses of vaccine are given over a 6-month period. Hepatitis B vaccine is very safe, and side effects are rare. Since 1982, more than 100 million children, teens, and adults in the U.S. have been vaccinated. Hepatitis B vaccine is our first vaccine that prevents cancer—liver cancer.

At what age are hepatitis B vaccines given routinely?

The hepatitis B vaccine series can begin at any age. For newborns, it's recommended that the first dose be given in the hospital at birth. Hepatitis B vaccine is recommended routinely for all children age 0–18 years living in the U.S. Older children and teens should be vaccinated at the earliest opportunity. Any adult who is at risk for HBV infection or who simply wants to be protected from HBV infection should start the vaccine series right away.

Where can I get hepatitis B vaccine?

Check with your healthcare provider's office first. Children's health insurance usually covers the cost of this vaccine since it is routinely recommended for all children in the U.S. If your child is uninsured, ask your local health department for assistance. The federal Vaccines For Children (VFC) program helps families by providing free vaccines to healthcare providers who serve eligible children. VFC is administered at the national level by the Centers for Disease Control and Prevention (CDC), which contracts with vaccine manufacturers to buy vaccines at reduced rates. For adults, contact your healthcare provider to find out if the vaccine is available and how much it costs. If you are uninsured or don't have a healthcare provider, call your local health department for advice.

How many doses of vaccine are needed?

Three doses are needed usually for the best protection against HBV infection, but protection is sometimes provided from receiving as little as one dose. Hepatitis B vaccine is usually given on a schedule of 0, 1, and 6 months, but there is flexibility in the timing of these injections. As with all other vaccines, if you fall behind on the schedule, you just continue from where you left off. Hepatitis B vaccine will not help or cure a person who is already infected with HBV.

What should I do if I'm in a risk group and am not infected with HBV?

If you are in a risk group for hepatitis B, be sure to get vaccinated! All people in risk groups (risk groups are listed in the second question on this question-and-answer series) should protect themselves from HBV infection. You don't have to "admit" that you have a risk factor to be vaccinated. You simply need to ask to be vaccinated. Every day you delay getting vaccinated increases your chances of being in contact with this highly contagious liver disease. The problems caused by hepatitis B—liver cancer and liver failure—are too great to take a chance. See your healthcare provider or visit your health department.

How does hepatitis B differ from hepatitis A and C?

Hepatitis A, B, and C are all different viruses that attack and injure the liver, and all can cause similar symptoms. Usually, people get hepatitis A virus (HAV) infection from household or sexual contact with a person who has the infection. Hepatitis C is caused by the hepatitis C virus (HCV) and is spread through HCV-infected blood. Both HCV- and HBV- infections are spread by blood through some of the same activities (e.g., injection drug use). Both HBV- and HCV- infections can cause lifelong liver problems. HAV infection does not. Vaccines to prevent HAV infection are also available. Hepatitis A vaccine won't protect you from HBV or HCV infection, nor will hepatitis B vaccine protect you from HAV or HCV infection. There is no vaccine yet for hepatitis C. If you've been infected with HAV or HCV in the past, it is still possible to get infected with HBV.

Where can I receive more information about hepatitis B?

Contact your local and state health departments for more information. You can also contact the following organizations:

Immunization Action Coalition
Hepatitis B Coalition
(651) 647-9009
www.immunize.org
www.vaccineinformation.org
www.hepprograms.org

American Liver Foundation
(212) 668-1000
www.liverfoundation.org

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Asian Liver Center
(888) 311-3331
http://liver.stanford.edu

Centers for Disease Control and Prevention
(800) 232-4636 (800) CDC-INFO
www.cdc.gov/hepatitis
www.cdc.gov/vaccines

Hepatitis B Foundation
(215) 489-4900
www.hepb.org

Hepatitis Foundation International
(800) 891-0707
www.hepfi.org

Parents of Kids with Infectious Diseases (PKIDS)
(877) 557-5437
www.pkids.org

What is the Immunization Action Coalition (IAC)?

The Immunization Action Coalition is a nonprofit organization that works to prevent hepatitis B and all other vaccine-preventable diseases in people of all ages. IAC promotes hepatitis B vaccination, screening for all pregnant women, testing and vaccination for risk groups, and education and treatment for people with chronic HBV infection.

IAC relies on financial support from the CDC, corporations, foundations, health-care providers, and individuals to maintain its activities. Financial contributions are always needed, greatly appreciated, and tax-deductible. You can send your check to IAC at the address below or donate online at www.immunize.org/support.

Immunization Action Coalition
1573 Selby Ave., Suite 234
St. Paul, MN 55104
(651) 647-9009
admin@immunize.org
www.immunize.org
www.vaccineinformation.org
www.hepprograms.org

If you have chronic hepatitis B virus (HBV) infection . . .

If you have chronic hepatitis B virus infection (HBV), you are not alone. Today, approximately one million people in the United States are chronically infected with HBV. The majority of infected people feel healthy for their entire lives and do not demonstrate any evidence of ongoing liver damage. Other people progress to levels of more severe disease. Some people ultimately develop liver scarring (cirrhosis), liver failure, or liver cancer. It is important that you take care of yourself. And because it is possible to spread HBV to others, you have to know how to protect your family, friends, and others from this disease.

How you can take care of yourself

People who have chronic HBV infection need regular monitoring of their liver condition to determine whether their disease is progressing, whether treatment is needed, or whether a liver cancer is developing. Make sure you do the following:

- See your doctor for evaluation of your liver's condition once or twice a year. Certain blood tests need to be performed periodically to monitor your liver's health. Discuss with your doctor if you are a candidate for antiviral medication. These medicines are given to certain people with chronic liver disease.
- Discuss with your doctor about getting periodic ultrasounds, alpha-fetoprotein blood tests, or other studies to make sure there is no evidence of a developing liver cancer. Physicians may recommend different schedules for ultrasounds and blood tests depending on the patient's age, sex, ethnicity, age at which the infection was initially acquired, family history, HBeAg status, and liver enzymes. Usually, ultrasounds and blood tests are recommended every six to 12 months.
- Review with your physician *all* medications you take. Even some "over-the-counter" medications can injure your liver.
- If you are pregnant, tell your physician that you have chronic HBV infection. It is essential that your baby be given an injection of hepatitis B immune globulin (HBIG) and started on the hepatitis B vaccine series within 12 hours of birth.
- Avoid alcoholic beverages. Alcohol can damage your liver.

If your doctor tells you your liver disease has progressed...

If your liver disease progresses, here are some extra precautions you should take:

- Get your yearly influenza vaccine. Patients with severe liver disease should also receive pneumococcal polysaccharide vaccine.
- Get vaccinated against hepatitis A. Hepatitis A can further damage your liver.
- Don't eat raw oysters. Raw oysters may carry the bacteria *Vibrio vulnificus* which can cause a serious blood infection in individuals with liver disease. Approximately 40% of these cases are fatal.

How to protect others from HBV infection

People can get HBV infection from you by coming in contact with your blood, serum, semen, or vaginal fluids. HBV has also been transmitted by human bites. Although HBV has been detected in low concentrations in other body fluids, including tears, sweat, urine, feces, and breast milk, these fluids have not been associated with any documented transmission. Fortunately, HBV is *not* transmitted by sneezing or coughing, or from casual contact such as holding hands. Here are some important guidelines for you to follow so that others are protected:

- Tell your sex partner(s) that you are infected with HBV. Your sex partner(s) must see a physician for hepatitis B blood testing and should receive the first dose of hepatitis B vaccine at this same visit. If, according to the blood tests, your partner has never had hepatitis B, he or she should complete the vaccination series. One to two months after the series of three shots is completed, your partner needs to return to the doctor for blood testing to make sure the vaccine protected him or her. Use condoms until your partner is proven to be protected from HBV.
- Make sure *all* your household members see their physicians for hepatitis B testing and vaccination.
- Tell your healthcare providers that you are infected with HBV.
- Cover all cuts and open sores with a bandage.
- Throw away used personal items such as tissues or menstrual pads in a bag that does not leak so others will not be exposed to your blood.
- Wash your hands well after touching your blood or body fluids.
- Clean up your blood spills. Then reclean the area with bleach solution (one part regular household bleach to 10 parts water).
- Do not share toothbrushes, razors, needles for ear piercing, nail files, clippers, nail scissors, washcloths, or anything that may have come in contact with your blood or body fluids.
- Do not share food that has been in your mouth (e.g., chewing gum) and do not pre-chew food for babies.
- Do not share syringes, needles, or drugs.
- Do not donate blood, plasma, body organs, tissue, or sperm.
- Know that if someone is exposed to your blood—be it a family member, a friend, or even a stranger—*preventive treatment is available* for that person. If the exposed person receives HBIG and starts the hepatitis B vaccine series right away, that person has an excellent chance of being protected from HBV!
- Learn more about hepatitis B so you can make the best decisions for yourself and provide the best protection for your family and friends.

More resources...

If you have further questions, contact one of these trusted resources:

Immunization Action Coalition
(651) 647-9009
www.immunize.org

American Liver Foundation
(212) 668-1000
www.liverfoundation.org

Asian Liver Center, Stanford University
(888) 311-3331
http://liver.stanford.edu/

Centers for Disease Control and Prevention
(800) 232-4636
www.cdc.gov/hepatitis

Hepatitis B Foundation
(215) 489-4900
www.hepb.org

Hepatitis Foundation International
(800) 891-0707
www.hepfi.org

National Digestive Diseases Information Clearinghouse
(301) 496-3583
www2.niddk.nih.gov

Parents of Kids with Infectious Diseases (PKIDS)
(877) 557-5437
www.pkids.org

www.immunize.org/catg.d/p4120.pdf • Item #P4120 (6/10)

2011 Recommended Immunizations for Children from Birth Through 6 Years Old

Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
HepB	HepB			HepB						
		RV	RV	RV						
		DTaP	DTaP	DTaP		DTaP				DTaP
		Hib	Hib	Hib	Hib					
		PCV	PCV	PCV	PCV§					
		IPV	IPV	IPV	IPV	IPV	IPV	IPV		IPV
				Influenza (Yearly)*	Influenza (Yearly)*	Influenza (Yearly)*	Influenza (Yearly)*	Influenza (Yearly)*	Influenza (Yearly)*	Influenza (Yearly)*
					MMR	MMR	MMR	MMR		MMR
					Varicella	Varicella	Varicella	Varicella		Varicella
					HepA, 2 doses§	HepA, 2 doses§	HepA, 2 doses§	HepA, 2 doses§		

Shaded boxes indicate the vaccine can be given during shown age range.

NOTE: If your child misses a shot, you don't need to start over, just go back to your child's doctor for the next shot. The doctor will keep your child up-to-date on vaccinations. Talk with your doctor if you have questions.

FOOTNOTES

§ HepA vaccination is recommended for high-risk children older than 2 years. Children with certain medical conditions may also need a dose of meningococcal vaccine (MCV4) and pneumococcal vaccine (PPSV). HepA vaccination may be administered to any child older than 2 years for whom immunity is desired. See vaccine-specific recommendations at http://www.cdc.gov/vaccines/pubs/ACIP-list.htm.

* Two doses given at least four weeks apart are recommended for children aged 6 months through 8 years of age who are getting a flu vaccine for the first time. Children who only got one dose in their first year of vaccination should get two doses the following year.

See back page for more information on vaccine-preventable diseases and the vaccines that prevent them.

For more information, call toll free
1-800-CDC-INFO (1-800-232-4636)
or visit
http://www.cdc.gov/vaccines

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

AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Vaccine-Preventable Diseases and the Vaccines that Prevent Them

Disease	Vaccine	Disease spread by	Disease symptoms	Disease complications
Chickenpox	Varicella vaccine protects against chickenpox.	Air, direct contact	Rash, tiredness, headache, fever	Infected blisters, bleeding disorders, encephalitis (brain swelling), pneumonia (infection in the lungs)
Diphtheria	DTaP* vaccine protects against diphtheria.	Air, direct contact	Sore throat, mild fever, weakness, swollen glands in neck	Swelling of the heart muscle, heart failure, coma, paralysis, death
Hib	Hib vaccine protects against *Haemophilus influenzae* type b.	Air, direct contact	May be no symptoms unless bacteria enter the blood	Meningitis (infection of the covering around the brain and spinal cord), mental retardation, epiglottis (life-threatening infection that can block the windpipe and lead to serious breathing problems) and pneumonia (infection in the lungs), death
HepA	HepA vaccine protects against hepatitis A.	Personal contact, contaminated food or water	May be no symptoms, fever, stomach pain, loss of appetite, fatigue, vomiting, jaundice (yellowing of skin and eyes), dark urine	Liver failure
HepB	HepB vaccine protects against hepatitis B.	Contact with blood or body fluids	May be no symptoms, fever, headache, weakness, vomiting, jaundice (yellowing of skin and eyes), joint pain	Chronic liver infection, liver failure, liver cancer
Flu	Flu vaccine protects against influenza.	Air, direct contact	Fever, muscle pain, sore throat, cough, extreme fatigue	Pneumonia (infection in the lungs)
Measles	MMR** vaccine protects against measles.	Air, direct contact	Rash, fever, cough, runny nose, pinkeye	Encephalitis (brain swelling), pneumonia (infection in the lungs), death
Mumps	MMR**vaccine protects against mumps.	Air, direct contact	Swollen salivary glands (under the jaw), fever, headache, tiredness, muscle pain	Meningitis (infection of the covering around the brain and spinal cord) , encephalitis (brain swelling), inflammation of testicles or ovaries, deafness
Pertussis	DTaP* vaccine protects against pertussis (whooping cough).	Air, direct contact	Severe cough, runny nose, apnea (a pause in breathing in infants)	Pneumonia (infection in the lungs), death
Polio	IPV vaccine protects against polio.	Through the mouth	May be no symptoms, sore throat, fever, nausea, headache	Paralysis, death
Pneumococcal	PCV vaccine protects against pneumococcus.	Air, direct contact	May be no symptoms, pneumonia (infection in the lungs)	Bacteremia (blood infection), meningitis (infection of the covering around the brain and spinal cord), death
Rotavirus	RV vaccine protects against rotavirus.	Through the mouth	Diarrhea, fever, vomiting	Severe diarrhea, dehydration
Rubella	MMR** vaccine protects against rubella.	Air, direct contact	Children infected with rubella virus sometimes have a rash, fever, and swollen lymph nodes.	Very serious in pregnant women—can lead to miscarriage, stillbirth, premature delivery, and birth defects
Tetanus	DTaP* vaccine protects against tetanus.	Exposure through cuts in skin	Stiffness in neck and abdominal muscles, difficulty swallowing, muscle spasms, fever	Broken bones, breathing difficulty, death

* DTaP is a combination vaccine that protects against diphtheria, tetanus, and pertussis.
** MMR is a combination vaccine that protects against measles, mumps, and rubella.

Last updated on 4/26/2011 • *CS220486-B*

HEPATITIS B VACCINE

WHAT YOU NEED TO KNOW

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

1 What is hepatitis B?

Hepatitis B is a serious disease that affects the liver. It is caused by the hepatitis B virus (HBV). HBV can cause:

Acute (short-term) illness. This can lead to:
- loss of appetite
- diarrhea and vomiting
- tiredness
- jaundice (yellow skin or eyes)
- pain in muscles, joints, and stomach

Acute illness is more common among adults. Children who become infected usually do not have acute illness.

Chronic (long-term) infection. Some people go on to develop chronic HBV infection. This can be very serious, and often leads to:
- liver damage (cirrhosis)
- liver cancer
- death

Chronic infection is more common among infants and children than among adults. People who are infected can spread HBV to others, even if they don't appear sick.

- In 2005, about 51,000 people became infected with hepatitis B.
- About 1.25 million people in the United States have chronic HBV infection.
- Each year about 3,000 to 5,000 people die from cirrhosis or liver cancer caused by HBV.

Hepatitis B virus is spread through contact with the blood or other body fluids of an infected person. A person can become infected by:
- contact with a mother's blood and body fluids at the time of birth;
- contact with blood and body fluids through breaks in the skin such as bites, cuts, or sores;
- contact with objects that could have blood or body fluids on them such as toothbrushes or razors;
- having unprotected sex with an infected person;
- sharing needles when injecting drugs;
- being stuck with a used needle on the job.

2 Hepatitis B vaccine: Why get vaccinated?

Hepatitis B vaccine can prevent hepatitis B, and the serious consequences of HBV infection, including liver cancer and cirrhosis.

Routine hepatitis B vaccination of U.S. children began in 1991. Since then, the reported incidence of acute hepatitis B among children and adolescents has dropped by more than 95% – and by 75% in all age groups.

Hepatitis B vaccine is made from a part of the hepatitis B virus. It cannot cause HBV infection.

Hepatitis B vaccine is usually given as **a series of 3 or 4 shots**. This vaccine series gives long-term protection from HBV infection, possibly lifelong.

3 Who should get hepatitis B vaccine and when?

Children and Adolescents

- All children should get their first dose of hepatitis B vaccine **at birth** and should have completed the vaccine series by 6-18 months of age.
- Children and adolescents through 18 years of age who did not get the vaccine when they were younger should also be vaccinated.

Adults

- All unvaccinated adults **at risk for HBV infection** should be vaccinated. This includes:
  - sex partners of people infected with HBV,
  - men who have sex with men,
  - people who inject street drugs,
  - people with more than one sex partner,
  - people with chronic liver or kidney disease,
  - people with jobs that expose them to human blood,
  - household contacts of people infected with HBV,
  - residents and staff in institutions for the developmentally disabled,
  - kidney dialysis patients,

- people who travel to countries where hepatitis B is common,
- people with HIV infection.

- Anyone else who wants to be protected from HBV infection may be vaccinated.

4 Who should NOT get hepatitis B vaccine?

- Anyone with a life-threatening allergy to **baker's yeast**, or to **any other component of the vaccine,** should not get hepatitis B vaccine. Tell your provider if you have any severe allergies.
- Anyone who has had a life-threatening allergic reaction to a **previous dose of hepatitis B vaccine** should not get another dose.
- Anyone who is **moderately or severely ill** when a dose of vaccine is scheduled should probably wait until they recover before getting the vaccine.

Your provider can give you more information about these precautions.

Pregnant women who need protection from HBV infection may be vaccinated.

5 Hepatitis B vaccine risks

Hepatitis B is a very safe vaccine. Most people do not have any problems with it.

The following **mild problems** have been reported:

- Soreness where the shot was given (up to about 1 person in 4).
- Temperature of 99.9°F or higher (up to about 1 person in 15).

Severe problems are extremely rare. Severe allergic reactions are believed to occur about once in 1.1 million doses.

A vaccine, like any medicine, ***could*** cause a serious reaction. But the risk of a vaccine causing serious harm, or death, is extremely small. More than 100 million people have gotten hepatitis B vaccine in the United States.

6 What if there is a moderate or severe reaction?

What should I look for?

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

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

  Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

  VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

In the event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at **www.hrsa.gov/vaccinecompensation**.

8 How can I learn more?

- Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)**
  - Visit CDC websites at:
    www.cdc.gov/ncidod/diseases/hepatitis
    www.cdc.gov/vaccines
    www.cdc.gov/travel

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

Vaccine Information Statement (Interim)
Hepatitis B (7/18/07) 42 U.S.C. § 300aa-26

INFECTIOUS DISEASE SEROLOGY
404-327-7970

INTRODUCTION

The **Microbial Immunology Unit** performs infectious disease serology. Serology for HIV (Human Immunodeficiency Virus), is performed in the Virology Unit. Various serologic procedures are performed for a variety of bacterial, parasitic, and viral agents. Hepatitis serology is performed for county health departments, and Georgia Department of Public Health agencies, only. Tests not performed in the Public Health Laboratory are forwarded to CDC, if they provide the requested testing.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

Collection Using Universal Precautions, and standard venipuncture technique, collect approximately six milliliters of whole blood (for serum) in a red top tube (no additive), labeled with patient's identifier (name, first and last, or number), date, and name of the submitter. Use a marker that will not fade, smear, or run during transportation. Use proper size needle (large enough to prevent hemolysis of the red blood cells) for the vein location and age of the patient. Allow blood specimen to clot, at least 30 minutes undisturbed, at room temperature, and transport, or place in the refrigerator for transporting. Collect blood specimens in, or transfer them to, non-breakable, leak resistant tubes. Specimens should be transported as soon as possible, do not hold over 7 days. Specimens over 14 days old are unacceptable. Many of the procedures we perform are not approved for use with plasma. Therefore, please submit only serum or whole blood without anticoagulants, not plasma.

Collect cerebrospinal fluids (CSF) according to proper hospital procedure. CSF contaminated with blood or grossly contaminated with bacteria is unacceptable.

Labeling All specimens must be labeled with patient identification (name or number), in acceptable testing condition, and accompanied by a completed requisition form. If the form is not specific for one test or a set of tests, the specific testing requested must be hand-written in the proper area, e.g., "viral serology" is not acceptable, the specific agent, e.g., "CMV", must be clearly requested. Failure to provide proper patient information may result in testing delays.

Requisition Form Use Form #3432 for all tests performed by the Microbial Immunology Unit. There is a single requisition form for all serological tests performed, including the RPR and EIA tests for syphilis, Hepatitis B (DCH facilities and county health departments only), and other Serology. Completely fill out the form and include the following information:

1. Unique patient identifier (name or number).
2. **TEST(S) REQUESTED (Please check <u>only</u> the corresponding box for test(s) requested).**

3. Date specimen collected.
4. Submitter's name, address, and code number, where applicable.
5. For hepatitis the reason for testing, e.g., routine, or prenatal.
6. Any information the submitter needs for patient identification, e.g., chart number, address.
7. The date of onset of illness, if applicable.
8. Race, sex, and age, where applicable, e.g., hepatitis testing.

SHIPMENT OF SPECIMENS

Use outfit #0500, available from Laboratory Services and Supply, 404-327-7920, and follow the specific instructions below. Specimens may be mailed or delivered to the laboratory by courier.

Shipping Instructions for USPS and Couriers:
Place the tubes of blood in protective, leak resistant, double-walled containers, e.g., aluminum and cardboard box, for transport. Wrap the requisition form around the inner (aluminum) can, secure with a rubber band and place in the outer container. If a screw-cap outer container is used, the screw-cap must be secured with tape or the Postal Service will return it for taping. Up to 50 milliliters of blood may be transported in one package (U.S. postal regulations). Therefore, an individual tube of blood may be placed in the metal can, with the requisition form secured to the outside by a rubber band, and several aluminum cans placed in one cardboard box for transporting.

Shipping Instructions for Courier Services Only:
Tubes of blood may be placed in leak proof biohazard bags. Wrap brown absorbent material around the tube, then secure with a rubber band. Place the requisition form in the sleeve located on the outside of the bag.

REPORTING AND INTERPRETATION OF RESULTS

Table 1 (pages IV-61 through IV-63) summarizes the interpretation of results for all serological tests performed in the Microbial Immunology Unit. Table 2 (page IV-64) gives the turnaround times for all of the same serological tests. The turnaround time after receipt of the specimen depends on the testing methodology and the frequency of testing. The frequency of testing depends on the demand for a specific test. Several tests are performed daily, while others are performed weekly. The turn-around time for specimens referred to CDC depends on CDC's schedule, which varies from laboratory to laboratory.

UNACCEPTABLE SPECIMENS

1. Spinal fluid obviously contaminated with bacteria or blood;
2. All specimens:

Not approved for testing by the indicated method, e.g., plasma for RPR.
Grossly hemolyzed, lipemic, turbid, or contaminated.
Over 14 days old.
Broken in transit.
Insufficient quantity for testing.
No identification on specimen.
Name on tube and form does not match.

The submitter will be notified of all rejected specimens. Most serologic services are available to both the public and private sectors. However, hepatitis B testing is limited to the public health care providers, and not available to the private providers.

Test Result Interpretation[1]						
Agent	**Test**	**Method**	**Negative**	**Positive[2]**	**Diagnostic**	**Presumptive[3]**
California Encepha-litis	IgG[1] IgM[1]	IFA[1]	IgG <1:16 IgM <1:16	IgG ≥1:16 IgM ≥ 1:16	Four-fold rise in titer between paired sera[4]	≥ 1:16
Cytome-galovirus (CMV)	IgG IgM	EIA[1]	No IgG Detected No IgM Detected	IgG Detected IgM Detected	IgM detected and/or significant rise in titer between paired sera[4,5]	IgM Equivocal
Eastern Equine Encephalitis	IgG IgM	IFA	IgG <1:16 IgM <1:16	IgG ≥1:16 IgM ≥ 1:16	Four-fold rise in titer between paired sera[4]	≥ 1:16
Hepatitis A Total	IgG	EIA	Negative	Positive		
	IgM	EIA	Negative	Positive	Presumptive evidence of IgM antibodies to HAV	
Hepatitis C		EIA	Negative	Positive	s/co>/=10; samples confirm >/=95% positive. <10; confirm with Riba positive 2 or more 1+ bands.	
Hepatitis B Virus (HBV)[6]	HBs[1] ← HBsAg	EIA	Negative	Positive	Positive HBs	None
	Hbe[1] ← HBeAg		Negative	Positive		
	Anti-HBs[1]		Negative	Positive		
	Anti-HBc[1]		Negative	Positive		
Herpes Simplex Virus (HSV)	Type 1 Type 2	EIA	No IgG Detected	IgG Detected	Significant difference between paired sera[4,5]	None

Test Result Interpretation[1]						
Agent	**Test**	**Method**	**Negative**	**Positive[2]**	**Diagnostic**	**Presumptive[3]**
Mumps	IgG	EIA	No IgG Detected	IgG Detected	Significant difference between paired sera[4,5]	None
Murine typhus	IgG	IFA	<1:16	≥ 1:16	Four-fold rise in titer between paired sera[4]	≥ 1:128
Rocky Mountain Spotted Fever (RMSF)	IgG	IFA	< 1:16	≥ 1:16	Four-fold rise in titer between paired sera[4]	≥ 1:128
Rubeola (Measles)	IgG	EIA	No IgG Detected	IgG Detected	IgM detected and/or significant increase between paired sera[4,5]	IgM Equivocal
	IgM		No IgM Detected	IgM Detected		
Rubella (German Measles)	IgG	EIA	No IgG Detected	IgG Detected	IgM detected and/or significant increase between paired sera[4,5]	Not Applicable
	IgM		No IgM Detected	IgM Detected		
St. Louis Encepha-litis	IgG IgM	IFA	IgG <1:16 IgM <1:16	IgG ≥1:16 IgM ≥ 1:16	Four-fold rise in titer between paired sera[4]	≥ 1:16
Syphilis	RPR[1]	Agg[1].	Non-Reactive	Reactive ≥ 1:1	RPR and EIA Reactive	Reactive RPR and Equivocal EIA
	Confir-matory EIA	EIA	Non-Reactive	Reactive		
	FTA	IFA	Non-Reactive	Reactive	RPR, EIA, FTA	Equivocal EIA
Syphilis	VDRL (CSF[1])	Agg[1]	Non-Reactive	Reactive	VDRL Reactive	Reactive VDRL
Toxoplas-	IgG	EIA	No IgG Detected	IgG Detected	IgM detected and/or significant increase	IgM Equivocal

mosis	IgM		No IgM Detected	IgM Detected	between paired sera[4,5]	
Varicella Zoster		EIA	No IgG Detected	IgG Detected	Significant increase between paired sera[4,5]	None
Agent	**Test**	**Method**	**Negative**	**Positive[2]**	**Diagnostic**	**Presumptive[3]**
West Nile Virus	IgG IgM	EIA	No IgG Detected No IgM Detected	IgG Detected IgM Detected	IgM detected and/or significant increase between paired sera[4,5]	IgM Equivocal
Western Equine Encephalitis	IgG IgM	IFA	IgG <1:16 IgM <1:16	IgG ≥1:16 IgM ≥ 1:16	Four-fold rise in titer between paired sera[4]	≥ 1:16

Abbreviations (in alphabetical order)[1]

Agg.	Agglutination
Anti-HBs	Hepatitis B surface antibody
CSF	Cerebrospinal Fluid
Anti-HBc	Hepatitis B core antibody
EIA	Enzyme Immunoassay
IgM	Immunoglobulin M
IgG	Immunoglobulin G
FTA	Fluorescent treponemal antibody
IFA	Indirect Fluorescent Antibody
RPR	Rapid Plasma Reagin
HBs	Hepatitis B surface antigen
VDRL	Venereal Disease Research Laboratory
HBe	Hepatitis B e antigen

[2]A positive result indicates natural or acquired immunity, especially for vaccine-preventable diseases
[3]Presumptive results identify a significant result for a single (not paired) serum, and need confirmation by clinical symptoms, recollection of specimen for retesting, or if applicable, submission of a convalescent specimen.
[4]Paired sera (acute and convalescent) dates of collection and date of onset of illness are needed for proper interpretation of results.
[5]A significant difference is determined by instructions given in individual enzyme immunoassay procedures, and may differ between manufacturers.
[6]Performed for county health departments and DCH facilities only.

FOR ADDITIONAL INFORMATION REGARDING TEST INTERPRETATION
CALL THE MICROBIAL IMMUNOLOGY LABORATORY
AT (404) 327-7970

Table 2. Turnaround Times

Agent	Turnaround Time Working Days[1]
California Encephalitis IgG[2]/IgM[2]	10-12 days
Cytomegalovirus IgG/IgM	7-14 days
Eastern Equine Encephalitis IgG/IgM	10-12 days
Hepatitis A	5-7 days
Hepatitis C	5-7 days
Hepatitis C (Confirmation)	7-14 days
Hepatitis B Diagnosis	
Surface antigen	5-7 days
Total antibody	5-7 days
core antibody	5-7 days
e-antigen (performed on surface antigen-	7-14 days
(positive specimens only)	
(positive HBs specimens)	7-14 days
Herpes simplex 1& 2	7-14 days
Mumps	7-14 days
Murine typhus	7-14 days
Rocky Mountain Spotted Fever	5-7 days
(Misc. Serology)	
Rubella IgG / IgM	5-7 days
Rubeola IgG/IgM	7-14 days
St. Louis Encephalitis IgG/IgM	10-12 days

Syphilis	
RPR[2] Non-Reactive	3-5 days
RPR Reactive	5-7 days
Confirmatory Non-Reactive	5-7 days
Confirmatory Reactive	5-7 days
FTA[2] Non-Reactive	5-7 days
FTA Reactive	5-7 days
FTA Repeats	7-14 days
Toxoplasmosis IgG /IgM	7-14 days
West Nile Virus IgG/IgM	10-12 days
Western Equine Encephalitis IgG/IgM	10-12 days
Varicella zoster	7-14 days
VDRL[2] (CSF[2] only)	5-7 days

[1] Special arrangements may be made in the case of an emergency.
[2] Abbreviations: IgG, Immunoglobulin; G; IgM, Immunoglobulin M; EIA, Enzyme Immunoassay; RPR, Rapid Plasma Reagin; FTA, Fluorescent treponemal antibody; VDRL, Veneral Disease Research Laboratory; CSF, Cerebrospinal Fluid.

GEORGIA DEPARTMENT OF PUBLIC HEALTH
PUBLIC HEALTH LABORATORY

IMMUNOLOGY SUBMISSION FORM

SUBMITTER INFORMATION

SUBMITTER CODE: ☐☐☐☐☐☐

CLINIC NAME: _____

_____

STREET: _____

_____

CITY: _____

STATE _____ ZIP CODE: _____

PHONE NO: _____

FAX NO: _____

CONTACT NAME: _____

PATIENT INFORMATION

PATIENT ID: _____

NAME: _____
Last First Middle

RESIDENCE: _____
Street City State Zip

_____ PHONE: _____
County Home Work Cell/other

DOB: _____/_____/_____ Medicaid # _____

RACE:
- ☐ American Indian/Alaska Native
- ☐ Asian
- ☐ Black/African-American
- ☐ Native Hawaiian/Pacific Islander
- ☐ Other
- ☐ Unknown
- ☐ White

ETHNICITY:
- ☐ Hispanic or Latino
- ☐ Non-Hispanic or Latino
- ☐ Unknown

GENDER:
- ☐ Male
- ☐ Female
- ☐ Unknown

SPECIMEN INFORMATION

Date of Collection:

_____/_____/_____

Source/Type:
- ☐ Blood
- ☐ CSF
- ☐ Plasma
- ☐ Serum
- ☐ Serum/Acute
- ☐ Serum/Convalescent
- ☐ Other: _____

Reason for Testing:
- ☐ Contact to STD
- ☐ Court Ordered
- ☐ Diagnosis
- ☐ Repeat testing
- ☐ Other: _____

Shipped:
- ☐ Refrigerated
- ☐ Room Temperature

Please complete:
Pregnant ☐ Yes ☐ No ☐ Unknown

Prenatal (Hepatitis B) EDC date_____

Clinical Information:

Date of Onset: _____

Previous Lab Results, if any: _____

Travel outside US: Yes No
If Yes, where? : _____

Symptoms: (check all that apply)
- ☐ fever
- ☐ rash
- ☐ stiff neck
- ☐ headache
- ☐ other_____

Please submit a separate form and specimen for each <u>Test Panel</u>

Routine Syphilis

- ☐ Routine RPR
- ☐ VDRL(spinal fluid)

Special RPR testing request:

- ☐ Quantitative(Titer) and Confirmatory even if screening test (RPR) negative
- ☐ No Confirmatory Test needed even if screening test (RPR) is positive
- ☐ Quantitative (Titer) RPR
- ☐ List test for CDC referrals _____
- ☐ Special test requests_____

Arbovirus/WNV panel

- ☐ Arbo IgG & IgM panel
- ☐ WNV IgG & IgM
- ☐ WNV IgM (CSF)

Hepatitis Testing

- ☐ Hep B (Prenatal)
- ☐ Hep B (Routine Screen) ←
- ☐ Anti-HAV Total Antibody
- ☐ Anti-HAV-IgM
- ☐ Anti-HCV

Note: Panel includes HBsAg, anti-HBs and anti-HBc; *ignore anti-HBc result for PVT*

Miscellaneous Serology

- ☐ Toxoplasmosis IgG
- ☐ Toxoplasmosis IgM
- ☐ Rubella IgG
- ☐ Rubella IgM
- ☐ CMV IgG
- ☐ CMV IgM
- ☐ HSV1/HSV2
- ☐ Rubeola IgG
- ☐ Rubeola IgM
- ☐ Mumps
- ☐ Varicella Zoster
- ☐ Rocky Mountain Spotted Fever
- ☐ Murine Typhus
- ☐ Torch Panel**
- ☐ Other _____

** **TORCH panel** includes Toxoplasmosis, Rubella, CMV, HSV1/2

State Hepatitis Program

Background:

The State Hepatitis Program provides hepatitis B vaccine when indicated to eligible children and adults through the Perinatal Hepatitis B Prevention Program, the Vaccines for Children (VFC) Program, and the STD/HIV Program and Family Planning Program. Hepatitis A vaccine is provided to eligible children through the Vaccines for Children Program, high-risk adults, and to both children and adults in outbreak situations.

Groups recommended for routine vaccination:

Hepatitis B

Hepatitis B vaccine is recommended for all persons aged zero through 18 years, and adults at highest risk for the hepatitis B virus. These high-risk groups are as follows:

- Persons with occupational risk
- Clients and staff of institutions for the developmentally disabled
- Hemodialysis patients
- Recipients of certain blood products
- Household contacts and sexual partners of HBV carriers
- Adoptees from countries where HBV infection is endemic
- International travelers who plan to spend more than 6 months in areas with high rates of HBV infection and who will have close contact with the local population
- Injecting drug users (IDU)
- Sexually active men who have sex with men (MSM)
- Sexually active heterosexual men and women who are diagnosed as having recently acquired other sexually transmitted diseases, and for persons who have a history of sexual activity with more than one partner in the previous 6 months. *NOTE:* Persons seen for evaluation of sexually transmitted diseases should be considered candidates for vaccination
- Inmates of long-term correctional facilities
- Diabetics (type 1 or type 2)

Hepatitis A

Hepatitis A vaccine is recommended for persons aged $\geq$ 12 months of age who are at increased risk for infection or severe outcomes from the disease. These groups include the following:

- Travelers to countries where hepatitis A is endemic
- Close contacts of an international adoptee from a country of high or intermediate endemicity
- Men who have sex with men (MSM)
- Users of illegal injecting and non-injecting drugs
- Persons with clotting-factor disorders
- Persons with chronic liver disease
- Persons with occupational risk (working with nonhuman primates)

State Hepatitis Program

Provision of vaccine for routine vaccination by the State Hepatitis Program:

The State Immunization Program provides hepatitis B vaccine to VFC and PeachCare eligible children aged birth through 18 years, household and sexual contacts to acute and chronic hepatitis B cases (which includes perinatal cases), and persons seeking evaluation for an STD at a public STD/HIV or Family Planning Clinic.

Serologic testing:

Prevaccination serology for hepatitis B:
Prevaccination serology is not indicated before routine vaccination of infants, children and adults. Prevaccination serology should be performed on persons who are at highest risk for infection with the hepatitis B virus (HBV). Those clients at highest risk are defined as:

- Injecting drug users (IDU)
- Sexually active men who have sex with men (MSM)
- Sexually active heterosexual men and women with more than one sex partner within a 6 month period
- Alaska Natives
- Pacific Islanders
- Children of immigrants from endemic countries
- Family members of hepatitis B surface antigen (HBsAg) positive persons

Persons being evaluated in STD/ HIV and Family Planning clinics should first be assessed for risk factors and serologic testing performed if indicated. The first dose of hepatitis B vaccine should be administered at the same visit as serologic testing. **Draw the blood *before* administering vaccine.** After the results of the serologic tests are received and the client is found to be susceptible, the second and third doses should be administered according to the client's age as specified in the ACIP recommended schedule.

Prevaccination Serology for Hepatitis A:
Prevaccination serology for hepatitis A is not indicated for routine vaccination of children and adults. Antibody production in response to HAV infection results in lifelong immunity to hepatitis A infection. Vaccination of persons who are immune because of prior infection does not increase the risk for adverse events. In populations that have expected high rates of prior HAV infection, prevaccination testing may be considered to reduce costs by not vaccinating persons who have prior immunity. Testing of children is not indicated because of their expected low prevalence of infection. For adults, the decision to test should be based upon the following information:

a) the expected prevalence of immunity;
b) the cost of vaccination compared with the cost of serologic testing (including the cost of an additional visit); and
c) the likelihood that testing will not interfere with initiating vaccination.

State Hepatitis Program

Persons for whom prevaccination testing will likely be most cost-effective include:

- Adults who were either born in or lived for extensive periods in geographic areas that have a high endemicity of HAV infection;
- Older adolescents and adults in certain population groups (i.e., American Indians, Alaska Natives, and Hispanics);
- Adults in certain groups that have a high prevalence of infection (e.g., injecting drug users).

Post-vaccination serology for Hepatitis B
Testing for immunity to hepatitis B following vaccination is not routinely recommended but should be considered for persons whose subsequent management depends on knowing their immune status. This would include:

- Infants born to HBsAg-positive women
- Dialysis patients, persons with weakened immune systems and health care workers who have direct contact with blood or body fluids

When indicated, post-vaccination testing for children and adults should be done 1 to 2 months after completion of the vaccine series to provide definitive information on response to the vaccine. Infants born to HBsAg-positive women should be tested 3 to 9 months after the third dose of hepatitis B vaccine.

Post-vaccination serology for Hepatitis A
Post-vaccination serology is not indicated in persons receiving hepatitis A vaccine due to the high rate of response among children and adults. No test sensitive enough to detect low anti-HAV concentrations is approved for routine diagnostic use in the United States.

NOTE: Please refer to Chapter 2, "Vaccines to Prevent Hepatitis B" for specific vaccine administration guidelines for hepatitis B vaccines.

State Hepatitis Program

Resources

1. Centers for Disease Control and Prevention. Protection Against Viral Hepatitis. Recommendations of the Immunization Practices Advisory Committee. *MMWR*, February 09, 1990, Vol. 39 (RR-2).
2. Centers for Disease Control and Prevention. Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission In the United States Through Universal Childhood Vaccination. Recommendations of the Advisory Committee on Immunization Practices. *MMWR*, November 22, 1991, Vol. 40(RR-13); 1-19.
3. Centers for Disease Control and Prevention. Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices and the Hospital Infection Control Practices Advisory Committee (HICPAC), *MMWR,* December 26, 1997, Vol.46 (RR-18).
4. Centers for Disease Control and Prevention. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States. Recommendations of the Immunization Practices Advisory Committee, Part 1: Immunization of Infants, Children, and Adolescents. *MMWR*, December 23, 2005, Vol. 54 (RR-16).
5. Centers for Disease Control and Prevention. Prevention of Hepatitis A Through Active or Passive Immunization. Recommendations of the Immunization Practices Advisory Committee. *MMWR*, May 19, 2006, Vol. 55 (RR-7).
6. Centers for Disease Control and Prevention. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States. Recommendations of the Immunization Practices Advisory Committee, Part II: Immunization of Adults. *MMWR*, December 8, 2006, Vol. 55 (RR-16).
7. Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine Preventable Diseases (Pink Book), CDC, 12th Edition, (2011) Washington, D.C.: Public Health Foundation.

Hepatitis B Vaccination in STD, HIV and Family Planning Clinics Guidelines for Public Health

Background

The goal of hepatitis B immunization is to prevent transmission of chronic HBV infection, which in turn prevents chronic liver disease and liver cancer. While routine vaccination of infants in the United States will eventually produce a population highly immune to hepatitis B, further efforts must be extended to prevent transmission among groups at highest risk for infection (see list below). Healthy People 2020 goals state that "viral hepatitis can be prevented, yet health care systems often do not make the best use of their available resources to support prevention efforts." To reach the Healthy People 2020 target for adults (1.5 cases per 100,000), hepatitis B vaccination programs must continue to focus on susceptible persons at the highest risk of infection. In 2010, there were 1.6 cases per 100,000 reported in Georgia, with individual county rates ranging from 0.7 to 16.1 cases per 100,000 population. Of the data collected on risk factors, the majority of newly acquired cases of hepatitis B are associated with high-risk sexual activity or injection-drug use. It is important to provide prevention and healthy lifestyles information. This includes advancing effective and evidence-based viral hepatitis prevention priorities and interventions. Vaccinating susceptible persons attending public Sexually Transmitted Disease (STD), HIV, and Family Planning clinics in Georgia will reduce the transmission of HBV to sexually active adolescents and adults. Measures should be taken at the district and county levels to avoid missed opportunities to vaccinate high-risk patients, especially those referred by Perinatal Hepatitis B Case Managers and other Public Health staff.

High-risk Groups for whom Hepatitis B Vaccination is Recommended

1. **Persons with occupational risk.** Any healthcare or public-safety worker may be at risk for HBV exposure, depending on the tasks performed. Workers who perform tasks involving contact with blood or blood-contaminated body fluid should be vaccinated. For persons in health-care fields, vaccination should be completed during training in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions, before trainees have their first contact with blood.
2. **Clients and staff of institutions for the developmentally disabled.** Susceptible clients in institutions for the developmentally disabled, as well as staff who work closely with clients, should be vaccinated. Susceptible clients and staff who live or work in smaller residential settings with known HBV carriers should also receive hepatitis B vaccine. Clients discharged from residential institutions into community programs should be screened for HBsAg so that appropriate measures can be taken to prevent HBV transmission. These measures should include both environmental controls and appropriate use of vaccine.

   Staff of nonresidential day-care programs for the developmentally disabled (e.g., schools, sheltered workshops) attended by known HBV carriers have a risk of infection comparable with that of health-care workers and therefore should be vaccinated. The risk of infection for other clients appears to be lower than the risk for staff. Vaccination of clients in day care programs may be considered. Vaccination of classroom contacts is strongly encouraged if a classmate who is an HBV carrier behaves aggressively or has special medical problems (e.g., exudative dermatitis, open skin lesions) that increase the risk of exposure to his or her blood or serous secretions.

Hepatitis B Vaccination in STD, HIV and Family Planning Clinics Guidelines for Public Health

3. **Hemodialysis patients.** Hepatitis B vaccination is recommended for susceptible hemodialysis patients. Vaccinating patients early in the course of their renal disease is encouraged because patients with uremia who are vaccinated before they require dialysis are more likely to respond to the vaccine. Although their seroconversion rates and anti-HBs titers are lower than those of healthy persons, patients who respond to vaccination will be protected from infection, and the need for frequent serologic testing will be reduced.

4. **Recipients of certain blood products.** Patients who receive clotting-factor concentrates have an increased risk of HBV infection and should be vaccinated as soon as their specific clotting disorder is identified. Prevaccination testing is recommended for patients who have already received multiple infusions of these products.
5. **Household contacts and sex partners of HBV carriers.** All household and sexual contacts of persons identified as HBsAg positive should be vaccinated. Hepatitis B vaccine should be administered at the age-appropriate dose to those determined to be susceptible or judged likely to be susceptible to infection.
6. **Adoptees from countries where HBV infection is endemic.** Adopted or fostered orphans or unaccompanied minors from countries where HBV infection is endemic should be screened for HBsAg. If the children are HBsAg positive, other family members should be vaccinated.
7. **International travelers.** Vaccination should be considered for persons who plan to spend *more than 6 months in areas with high rates of HBV infection and who will have close contact with the local population.* Short-term travelers who are likely to have contact with blood (e.g., in a medical setting) or sexual contact with residents of areas with high or intermediate levels of endemic disease should be vaccinated. Vaccination should begin at least 6 months before travel to allow for completion of the full vaccine series, although a partial series will offer some protection. The alternate four-dose schedule should provide protection if the first three doses can be delivered before departure.
8. **Injecting drug users (IDU).** All injecting drug users who are susceptible to HBV should be vaccinated as soon as their drug use begins. Because of the high rate of HBV infection in this population, prevaccination screening should be considered.
9. **Men who have sex with men (MSM).** Susceptible MSM should be vaccinated. Because of the high rate of HBV infection in this population, prevaccination screening should be considered. Men known to have HIV infection should be tested for anti-HBs response after completion of the vaccine series.
10. **Sexually active heterosexual men and women.** Vaccination is recommended for men and women who are diagnosed as having recently acquired other sexually transmitted diseases, for prostitutes, and for persons who have a history of sexual activity with more than one partner in the previous 6 months. Most patients seen in clinics for sexually transmitted diseases should be considered candidates for vaccination.
11. **Inmates of long-term correctional facilities**. Prison officials should consider undertaking screening and vaccination programs directed at inmates with histories of high-risk behaviors.

Hepatitis B Vaccination in STD, HIV and Family Planning Clinics Guidelines for Public Health

Eligibility for Hepatitis B Vaccination in STD/HIV and Family Planning Clinics in Georgia

The following persons **ARE ELIGIBLE** to receive state-supplied hepatitis B vaccine if screened in any Public Health clinic and are Medicare covered, Medicaid covered, underinsured, or uninsured:

1. Men having sex with men (MSM)
2. Injecting drug users (IDU)
3. Individuals with multiple sex partners (more than 1 partner in the past six months)
4. Homeless Adults
5. Persons seeking STD/HIV screening services including HIV testing and counseling
6. HIV infected persons
7. Persons recently diagnosed with a sexually transmitted disease (STD)
8. Persons seeking Family Planning clinic services
9. Sexual partners of persons with acute or chronic hepatitis B virus infection
10. Household contacts of persons with acute or chronic HBV infection
11. Hemodialysis and transplant patients
12. Persons who began the series using state-supplied vaccine and still need to complete the series, regardless of insurance status
13. Refugees ≥ 19 years of age
14. Diabetics (Type 1 or Type 2)

Persons **NOT ELIGIBLE** to receive state-supplied hepatitis B vaccine for routine immunizations include:

1. Public safety workers
2. Health care workers
3. International travelers
4. Inmates
5. Staff of institutions for developmentally disabled

Postexposure Prophylaxis for Hepatitis B with Vaccine and HBIG

Recommendations on postexposure prophylaxis are based on available efficacy data and on the likelihood of future HBV exposure of the person requiring treatment. In all exposures, a regimen combining HBIG with hepatitis B vaccine will provide both short- and long-term protection and is the treatment of choice. Please refer to Chapter 2, “Eligibility Criteria for Vaccines Supplied by the Georgia Immunization Program for Adult Populations (age ≥19 years)” in this manual for the eligibility requirements for persons to receive state-supplied HBIG.

Immunization Consent Requirements

Vaccination against viral hepatitis for persons under the age of 18 years without parental/guardian consent can occur in conjunction with STD/HIV examinations due to already existing laws and legal precedent relating to STD/HIV examination and treatment of minors (O.C.G.A. 31-17-7). In these instances, a minor is considered to be receiving hepatitis B vaccine as prophylaxis for STD, and therefore is covered under the aforementioned section of the Official Code of Georgia. Conversely, persons less than 18 years of age cannot be vaccinated without parental/guardian consent in any other vaccination setting, including school vaccination programs, outbreak control settings where mass vaccinations are being given, and other clinic settings where STD/HIV evaluations and treatments *are **not*** conducted.

Hepatitis B Vaccination in STD, HIV and Family Planning Clinics Guidelines for Public Health

Serology Testing

Prevaccination serologic testing for susceptibility
Pre-vaccination serology is cost effective and should be considered in persons who are at high risk for hepatitis B infection. Due to higher seroprevalence, the following high-risk groups should receive pre-vaccination testing:

1. Men having sex with men (MSM)
2. Intravenous drug users (IDU)
3. Sexual/household contacts of persons infected with HBV

Prevaccination testing should not interfere with administering vaccine during the visit for which immunization against hepatitis B is requested. To test high-risk patients for history of disease and the need for vaccine, order HBsAg and anti-HBs tests. **Draw the blood before administering vaccine.** The first dose of vaccine should be given at the same visit as the blood test. If the client is found susceptible to HBV (via negative serology), then doses 2 and 3 should be administered at the appropriate intervals. It is not cost-effective for groups with a low expected prevalence of HBV serologic markers, to receive prevaccination testing. Therefore, pre-vaccination serologies are ***not indicated*** before routine vaccination of infants, children and adults.

The Georgia Public Health Laboratory hepatitis serology consists of HBsAg, total anti-HBc, HBeAg, and anti-HBs. Specific guidelines for ordering hepatitis B serologies can be found in the Georgia Public Health Laboratory Service Manual in the "Microbial Immunology Laboratory, Infectious Disease Serology section." (See Appendix to this chapter.) For additional information regarding the interpretation of hepatitis B serologies, please see Appendix H4 of the Perinatal Hepatitis B Prevention Program Guidelines.

Postvaccination Testing

Hepatitis B vaccine, when given at the correct anatomic site produces protective antibody (anti-HBs) in greater than 90% of healthy persons. Testing for immunity after vaccination is not recommended routinely but is advised for persons whose subsequent management depends on knowing their immune status (such as dialysis patients, other immunocompromised patients, and health care workers with direct contact to blood and body fluids). Testing for immunity is also advised for persons for whom a suboptimal response may be anticipated, such as those who have received vaccine in the buttock, persons greater than or equal to 50 years of age, and persons known to have HIV infection. Post-vaccination testing should also be considered for persons at occupational risk who may have needle-stick exposures necessitating postexposure prophylaxis. When indicated, post-vaccination testing should be done between 1-3 months after completion of the vaccine series to provide definitive information on response to the vaccine.

> **Note:** The post-vaccination serology recommendation for infants born to HBsAg-positive women is 3-9 months after the third dose of hepatitis B vaccine.

Persons who do not respond to the first series of hepatitis B vaccine should complete a second three-dose series. Revaccination of persons who do not respond to the primary series produces adequate antibody in 15%-25% after one additional dose and in 30%-50% after three additional doses when the primary vaccination has been given in the deltoid. For persons who did not respond to a primary vaccine series given in the buttock, data suggest that revaccination in the arm induces adequate antibody in greater than 75%.

Hepatitis B Vaccination in STD, HIV and Family Planning Clinics Guidelines for Public Health

Sexual Partners of Persons with Acute HBV Infection

Sexual partners of HBsAg-positive persons are at increased risk of acquiring HBV infection, and HBIG has been shown to be 75% effective in preventing such infections. Data about the efficacy of HBIG beyond the 14-day cutoff is limited and the period after sexual exposure during which HBIG is effective is unknown; however, it is unlikely that this period would exceed 14 days. Testing of sexual partners for susceptibility is recommended at the same visit as the first dose of vaccine. If a sexual partner is found susceptible after serology, then administer doses 2 and 3 at the appropriate dosage and time intervals.

Household Contacts of Persons with Acute HBV Infection

Since infants have close contact with primary care givers and they have a higher risk of becoming HBV carriers after acute HBV infection, prophylaxis of an infant less than 12 months of age with HBIG (0.5 mL) and hepatitis B vaccine is indicated if the mother or primary care giver has acute HBV infection. Prophylaxis with HBIG for other household contacts of persons with acute HBV infection is not indicated unless they have had identifiable blood exposure to the index patient, such as by sharing toothbrushes or razors, within the past 7 days. Hepatitis B vaccine is recommended for household contacts and the first dose should be administered at the same visit as the prevaccination serology. **Be sure to draw blood for the serology before administering the vaccine.** If the household contact is found susceptible after serology, then administer doses 2 and 3 at the appropriate dosage and time intervals. Such exposures should be treated similarly to sexual exposures. If the index patient becomes an HBV carrier, all household contacts should be given hepatitis B vaccine.

> **NOTE**: Administering even one dose of hepatitis B vaccine allows seroconversion for 40% to 50% of persons receiving vaccine. Always encourage clients to complete the series, but do not withhold vaccine if uncertain that the client will return for the subsequent doses.

General Hepatitis B Vaccination Requirements

Please see Chapter 2, "Vaccines to Prevent Hepatitis B", for specific vaccine administration guidelines.

Reporting Requirements

All Georgia physicians, laboratories, and other health care providers are required by the authority of the Official Code of Georgia (Sections 31-12-2 and 31-22-7, Rules of the Department of Human Resources, chapter 290-5-3.02) to report persons with acute hepatitis B disease or persons who are HBsAg positive within 7 days to their County Health Department or District Health Office. Hepatitis B cases may also be reported to the Epidemiology Section. The preferred method of reporting is through the State Electronic Notifiable Disease Surveillance System (SENDSS), available at http://sendss.state.ga.us/ .
In addition, positive serologies and acute cases received by the County Health Department or Health District are to be reported via SENDSS.

Hepatitis B Counseling Interview

Each person infected with HBV should be counseled regarding the infection and interviewed for household and sexual contacts. For more specific information, please refer to “Example

Interviewing/Counseling Format (for) Hepatitis B,” found in the Appendix section of the Perinatal Hepatitis B Prevention Guidelines in this chapter.

Hepatitis B Vaccination in STD, HIV and Family Planning Clinics Guidelines for Public Health

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9. VACCINE DISTRIBUTION AND STORAGE
Distribution of Vaccines **(REPLACE)**
Temperature Log Sheet **(REPLACE)**
PH Provider Agreement **(REPLACE)**
Accountability Policy **(ADD)**
Vaccine Loss Policy For Public Health Providers **(REPLACE)**
Fraud and Abuse Policy **(REPLACE)**
Handling Of Vaccine During Inclement Weather Conditions **(REPLACE)**
Temperature Conversion Chart **(REPLACE)**
Vaccine Storage & Handling Guide (December 2011) **(REPLACE)**
Vaccine Storage and Handling Interim Guidance **(ADD)**
Chart of Refrigerated /Frozen Pack Needs **(REPLACE)**
Transporting Refrigerated Vaccine **(ADD)** (This replaces Maintaining the Cold Chain during Transport)
McKesson Vaccine Return Instructions **(REPLACE)** (This replaces the Guidelines for Returning Vaccine Products to the Manufacturer for Disposal)
McKesson Form for Return of Outdated, Unused, or Overstocked Drugs **(REPLACE)**
Title X Unaccompanied Minor without Insurance Information VFC Vaccine Log **(REPLACE)**
Centralized Distribution Information and Instruction for VFC Providers **(REPLACE)**
Routine and Emergency Vaccine Handling Plans **(ADD)**
Vaccine Incident Report **(ADD)**

DISTRIBUTION OF VACCINES

1. The State Immunization Office will utilize comprehensive reports, submitted by individual clinics each month to evaluate current vaccine inventory and historical usage. Shipments of vaccines, sufficient to bring vaccine inventories to the level of a three-month supply, will be made if vaccine is available.

2. Comprehensive reports are to be submitted monthly via GRITS.

3. All vaccine shipments will be sent directly to Clinic/County offices.

4. Short dated vaccines MUST be reported a minimum of 90 days before the date of expiration to the State Immunization Office, via phone (404) 657-5013 or e-mail: crrobinson@dhr.state.ga.us. The GRITS pre-populated report form will not generate this information for you.

5. State supplied vaccines lost due to expiration or spoilage must be returned to McKesson. Instructions are available on the GRITS home page under the "Additional Resources" section.

6. When vaccine shortages occur nationally, it may be necessary to move vaccine within the district. It also may be necessary to move vaccine from one district to another. It is the responsibility of the Immunization Office to evaluate total state needs and authorize movement of vaccine when necessary.

7. Details of all vaccine transfers must be reported to the state office via email at gavfc@dhr.state.ga.us and crrobinson@dhr.state.ga.us . The following information must be included in the email: date of transfer, GIP ID numbers for sending and receiving sites, vaccine name, lot number, expiration date, and number of doses.

Each facility that stores vaccine must have AST or NIST certified thermometers in both the refrigerator section and in the freezer section of the unit used for vaccine storage. Temperature readings must be taken and recorded twice daily; once in the morning and once in the evening (see sample temperature log). If temperatures fall outside the acceptable range, the cause **must** be determined and corrected immediately. Failure to have thermometers and to record temperatures will jeopardize your status to receive vaccine and may result in counties/districts having to purchase replacement vaccine.

Each facility that stores vaccine must have adequate storage to assure vaccine integrity. Dormitory type refrigerators are not acceptable. Routinely placing vaccine in portable coolers during the clinic day is also unacceptable. Refrigerators must have externally separate sealed doors for the refrigerator and freezer compartments. Dual thermostats/temperature controls for each compartment are also strongly required. An emergency plan must be developed by each facility for handling vaccine storage in the event of a power outage. This plan must be reviewed and updated annually, at minimum, to determine if all parties listed in the plan are aware of their responsibilities (see sample "Routine and Emergency Vaccine Handling Plans" form).

Providers are encouraged to visit the CDC's storage and handling toolkit for additional resources at http://www2a.cdc.gov/vaccines/ed/shtoolkit/

Document temperatures twice daily, and keep temp logs on file for at least 3 years!

Fahrenheit (^{o}F)Temperature Log

MONTH/YEAR:_____

REFRIGERATOR 35-46 ^{o}F																				FREEZER ≤ 5 ^{o}F						ROOM TEMP
Day of Month	Time	Staff Initials		≥49	48	47	46	45	44	43	42	41	40	39	38	37	36	35	34	33	≤32	≥8	7	6	5	4	≤3	
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Instructions: Place an "X" in the box that corresponds with the temperature (columns), day of the month, and am or pm (rows) for your temperature check. Then enter your initials and the time you monitored the temperature in the appropriate boxes.

If the temperature is in the gray range:

1. Store the vaccine under proper conditions as quickly as possible-do not discard.
2. Call the Georgia Immunization Office at (404)657-5013 or the vaccine manufacturers to determine whether the potency of the vaccine has been affected.
3. Document action taken on the *"Provider Temperature Excursion Form"* .

2/13/12

SEE REVERSE SIDE FOR DOCUMENTATION

State of Georgia Immunization Office
Georgia Department of Public Health

VACCINES FOR CHILDREN (VFC) PROGRAM

PROVIDER TEMPERATURE EXCURSION FORM

VFC PIN #

When temperatures are outside the acceptable ranges, please contact the Georgia VFC Program at (800) 372-3627 or (404) 657-5013 to determine appropriate actions to take. If after normal business hours, please follow instructions as listed on your clinic's Emergency Plan. Common actions are:

1. Move Vaccines and other biological an alternate controlled storage unit
2. Notify Supervisor
3. Attempt to adjust thermostat of malfunctioning storage unit
4. Check condition of storage unit (i.e electricity supply, seals, lint on coils)
5. Check temperatures every two hours
6. Call clinic's designated repair company if problem persists

DATE	TIME	TEMP	PROBLEM	ACTION TAKEN	RESULTS	STAFF INITIAL

Multiple reports of unit malfunction may require replacement of the unit at the clinic expense.

Document temperatures twice daily, and keep temp logs on file for at least 3 years!

Celsius (^{o}C)Temperature Log

MONTH/YEAR:_____

REFRIGERATOR 2-8 ^{o}C															FREEZER ≤ -15 ^{o}C									ROOM TEMP
Day of Month	Time	Staff Initials		≥11	10	9	8	7	6	5	4	3	2	1	0	≤-1	≥-12	-13	-14	-15	-16	-17	-18	-19	≤-20	
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Instructions: Place an "X" in the box that corresponds with the temperature (columns), day of the month, and am or pm (rows) for your temperature check. Then enter your initials and the time you monitored the temperature in the appropriate boxes.

If the temperature is in the gray range:

1. Store the vaccine under proper conditions as quickly as possible - do not discard.
2. Call the Georgia Immunization Office at (404)657-5013 or the vaccine manufacturers to determine whether the potency of the vaccine has been affected and
3. Document action taken on the *"Provider Temperature Excursion Form"*.

2/13/2012

SEE REVERSE SIDE FOR DOCUMENTATION

State of Georgia Immunization Office
Georgia Department of Public Health

VACCINES FOR CHILDREN (VFC) PROGRAM

PROVIDER TEMPERATURE EXCURSION FORM

VFC PIN #

When temperatures are outside the acceptable ranges, please contact the Georgia VFC Program at (800) 372-3627 or (404) 657-5013 to determine appropriate actions to take. If after normal business hours, please follow instructions as listed on your clinic's Emergency Plan. Common actions are:

1. Move Vaccines and other biological an alternate controlled storage unit
2. Notify Supervisor
3. Attempt to adjust thermostat of malfunctioning storage unit
4. Check condition of storage unit (i.e electricity supply, seals, lint on coils)
5. Check temperatures every two hours
6. Call clinic's designated repair company if problem persists

DATE	TIME	TEMP	PROBLEM	ACTION TAKEN	RESULTS	STAFF INITIAL

Multiple reports of unit malfunction may require replacement of the unit at the clinic expense.

State of Georgia Immunization Office
Georgia Department of Public Health

Public Health Provider Agreement

This document is the Georgia Department of Public Health (DPH), Division of Health Protection, Immunization Office (GIO) policy for program compliance. Noncompliance is defined as any intentional deviation from the signed Provider Agreement with GIO. Each enrolled County Nurse Manager must sign a Provider Agreement stating that he/she agrees to the following conditions:

1. **I agree that vaccine supplied by GIO will be administered <u>only</u> to Vaccines for Children (VFC)-eligible children ≤ 18 years of age who meet one of the following 4 eligibility criteria:**
   a) **Is covered by Medicaid (or qualifies through a Medicaid waiver).**
   b) **Has no health insurance (uninsured).**
   c) **Is American Indian or an Alaska Native.**
   d) **Has health insurance that does not pay for the vaccine (underinsured) seen in a FQHC/RHC or deputized clinical settings.**

   Definitions for VFC eligible children:
   a) Medicaid – has a current Medicaid card or Medicaid waiver at the time of service.
   b) Uninsured - has no health insurance.
   c) American Indian/Alaska Native – self-reported by the patient.
   d) Underinsured - has insurance but vaccines are not a covered benefit.
      - Example: An insurance company may not cover certain immunizations, such as the Pneumococcal Conjugate vaccine. The child will qualify for VFC for those particular vaccines.
      - Example: An insurance company may cover immunizations up to a certain age. Until that age, the child is fully insured. After that age, the child is considered underinsured (has insurance but vaccines are not a covered benefit) and is then eligible to receive VFC vaccines.
      - Example: An insurance company may only provide $100.00 per year to cover the costs of immunizations. The child is fully insured up to $100.00. Once this amount is exhausted, the child is then eligible to receive VFC vaccines.

   Program Violations (examples should not be considered all-inclusive)
   a) A provider administers VFC supplied vaccine, then bills the recipient's insurance for the cost of the vaccine.
   b) A provider charges a patient who is eligible for VFC supplied vaccine for the cost of the vaccine.
   c) A provider charges a Medicaid recipient any fee at all.
   d) A provider fails to purchase private stock vaccine for patients who are ineligible for state supplied vaccine, and gives a patient VFC supplied vaccine, whether they are eligible or not.
   e) A provider administers VFC supplied vaccine to a child who has private insurance with a high deductible.
      - Example: Parent has a policy with a $1,000.00 deductible. The child is still considered fully insured and privately purchased vaccine should be administered.
   f) A provider 'borrows' VFC vaccine to administer to a privately insured patient. Providers are required to purchase vaccine for non VFC-eligible patients.

   Actions
   a) Educational training and follow-up visits will be conducted by an Immunization Program Consultant (IPC).

b) Vaccine shipments will be suspended until VFC supplied vaccine is replaced by the provider. **See Appendix A, Georgia Immunization Office Vaccine Loss Policy**.
c) Program violations will result in a provider's ineligibility to receive VFC supplied vaccines.

2. **I agree that vaccine supplied by GIO will be provided to the following non-VFC eligible categories. Immunization Office (GIO) supplies vaccines to the following special populations :**
   a) **PeachCare kids with coverage provided by Amerigroup, WellCare, and Peach State.**
   b) **Patients deemed otherwise eligible for state supplied vaccine in public health departments as defined in the current eligibility criteria table.**
   c) **Has health insurance that does not pay for the vaccine (underinsured) seen in non FQHC/RHC and non-deputized clinical settings.**

   Program Violations (examples should not be considered all-inclusive)
   a) A provider administers state supplied vaccine, then bills the recipient's insurance for the cost of the vaccine.
   b) A provider charges patients who are eligible for state supplied vaccine for the cost of the vaccine.
   c) A provider fails to purchase private stock vaccine for patients who are ineligible for state supplied vaccine, and gives a patient seen in the clinic state-supplied vaccine, whether they are eligible or not.
   d) A provider administers state supplied vaccine to a patient who has private insurance with a high deductible.
      - Example: Parent has a policy with a $1,000.00 deductible. The child is still considered fully insured and privately purchased vaccine should be administered.
   e) A provider 'borrows' state vaccine to administer to a privately insured patient. Providers are required to purchase vaccine for non state-eligible patients.

   Actions
   a) Educational training and follow-up visits will be conducted by an Immunization Program Consultant (IPC).
   b) Vaccine shipments will be suspended until state supplied vaccine is replaced by the provider. **See Appendix A, Georgia Immunization Office Vaccine Loss Policy**.
   c) Program violations will result in a provider's suspension of vaccine shipments from GIO.

3. **The following applies to FQHC/RHC Deputized Providers only:**
   a) Agree to vaccinate "walk-in" VFC-eligible underinsured children as defined under subsection 1928(b)(2)(A)(iii) of the Social Security Act;.
   b) Screen for VFC eligibility, including for underinsured status, at every visit by any child less than 19 years of age;
   c) Report to GIO, in manner and time as decided by GIO, all requirements set forth in the guidance; and
   d) Comply with any additional VFC requirements as GIO or CDC may from time to time impose.

4. **I will screen and document eligibility status for each patient during each immunization encounter. I will maintain Eligibility Screening Records for a period of three years. If requested, I will make such records available to the Georgia Department of Public Health (DPH), the United States Department of Health and Human Services (DHHS) or as required by law.**

   Program Violation
   a) Failure to maintain records of patient eligibility for at least three years.
   b) Failure to properly enter patient eligibility in GRITS.
   c) Failure to share records with DPH or DHHS.

   Actions
   a) Educational training and follow-up visits will be conducted by an IPC.
   b) Excessive violations will result in termination from the VFC Program.

5. **All clinic sites within my district will participate in a quality assurance site visit conducted a minimum of once per year by an IPC.**

Program Violation

a) Provider does not allow a site visit.

Actions

a) If a site visit is not allowed within 60 calendar days of request, then vaccine shipments may be suspended.
b) Additional time may be allowed due to justifiable and extenuating circumstances.

6. **I will comply with the appropriate immunization schedule, dosage and contraindications that are established by the DHHS Advisory Committee on Immunization Practices (ACIP), unless (a) in making a medical judgment in accordance with accepted medical practice, I deem such compliance to be medically inappropriate, or (b) the particular requirement is not in compliance with state laws, including laws relating to religious or other exemptions.**

Program Violations

a) Inappropriate administration of vaccine.
   - Example: Mixing two vaccines in the same syringe (e.g., MMR and DTaP) for the purpose of reducing the number of injections needed.
   - Example: Administering pneumococcal conjugate vaccine to a 12 year old, when VFC guidelines allow for administration to children less than 5 years of age.

b) Non-compliance with ACIP recommendations for age and dose intervals.
   - Example: Administering vaccines before the proper age (e.g., vaccinating a child with MMR and Varicella vaccine before the age of one year).

c) Provider fails to assess for immunization status and immunize children at the time they are seen.
   - Example: Provider sees child for well-child visits but does not review immunization status and/or simply refers child to another facility for immunizations.
   - Example: Provider sees child for sick visit but does not review immunization status to be administered once child is well.

Actions

a) Mandatory participation in educational training provided by an IPC.
b) Program violations may result in suspension of vaccine shipments from GIO.

7. **I will provide Vaccine Information Statements and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).**

Program Violation

a) Failure to provide and document distribution of current Vaccine Information Statements (VIS) to patients.
b) Failure to document VAERS.
c) Failure to report VAERS.

Actions

a) Educational training and follow-up visits will be conducted by an IPC.
b) Program violations may result in suspension of vaccine shipments from GIO.

8. **I will not impose a charge for the cost of any state supplied vaccine.**

Program Violation

a) Imposing a charge for the cost of vaccine

- Example: An office visit fee and administration fee can be charged to the patient, but a fee **cannot** be charged for the cost of the vaccine.

Actions

a) Educational training and follow-up visits will be conducted by an IPC.
b) Program violations may result in suspension of vaccine shipments from GIO.

9. I will not impose a charge to the patient for administration of any vaccine purchased by the state in any amount higher than the current state fee cap of $21.93 per injection. (Health departments <u>may</u> charge less than $21.93 per injection.)

Program Violation

a) Imposing a charge greater than $21.93 per injection

Actions

a) Educational training and follow-up visits will be conducted by an IPC.
b) Program violations may result in suspension of vaccine shipments from GIO.

10. I will not deny administration of a state supplied vaccine to any eligible client due to the inability of the client or child's parent/guardian/individual of record to pay an administration fee. If the parent/guardian/individual of record is unable to pay, the administration fee must be waived. Other visit or office fees may be charged as applicable.

Program Violations

b) Denying vaccine to an adult who is eligible for state supplied vaccine due to inability to pay the administration fee.
c) Denying vaccine to a VFC-eligible child due to inability to pay the administration fee.
d) Denying a child/parent/guardian access to vaccine administration records due to an outstanding bill on the part of the parent/guardian.
e) Carrying a balance for unpaid administration fees.

Actions

a) Educational training and follow-up visits will be conducted by an IPC.
b) Program violations may result in suspension of vaccine shipments from GIO.

11. I will comply with GIO requirements for ordering vaccine, for reporting vaccine usage, spoilage, expiration, physical inventories, and all other requirements as outlined on the monthly reporting forms.

Program Violation

a) Failure to submit Comprehensive Report detailing vaccine usage, inventory, short dated vaccines, and wastage on a monthly basis.
b) Failure to report short dated vaccines 90 days prior to expiration. **See Appendix A, Georgia Immunization Office Vaccine Loss Policy**.

Actions

a) Educational training and follow-up visits will be conducted by a GIO Representative.
b) Non-reporting of vaccine usage, inventory, short dated, wasted, and returned vaccines may result in termination from the program. **See Appendix A, Georgia Immunization Office Vaccine Loss Policy**.
c) Non-reporting of vaccine usage, inventory, expired, spoiled and returned vaccine may result in suspension of vaccine shipments from GIO. **See Appendix A, Georgia Immunization Office Vaccine Loss Policy**.

12. Maintain separation between public funded vaccine and privately purchased vaccine inventory.

Program Violation

a) Failure to store VFC stock, adult stock, and private stock separately; even if stored in the same unit.
b) Non-VFC approved vaccine "borrowing" with the intent to re-pay doses.

Actions

a) Educational training and follow-up visits will be conducted by an IPC.
b) Provider will be required to replace doses administered to non-eligible patients at provider expense. **See Appendix A, Georgia Immunization Office Vaccine Loss Policy**.

13. I am not prohibited by Georgia law or any other applicable law from possessing dangerous drugs (i.e., vaccines). See Official Code of Georgia Annotated, Title 16, Chapter 13; Title 26, Chapter 4; Title 43, Chapter 34.

Program Violations

a) Drug Enforcement Agency number has been revoked.
b) License to practice medicine has been revoked, suspended, or annulled.

Action

a) Immediate suspension of vaccine shipments from GIO and termination from the VFC Program.

14. I will accept the responsibility to maintain the integrity of the drugs (i.e., vaccines) in accordance with all laws, regulations, and GIO recommendations pertaining to vaccine storage and handling procedures.

Program Violations

a) Failure to properly store vaccine in accordance with CDC guidelines. As of 1/1/2010, VFC-supplied vaccines may not be stored in a dorm-style refrigerator, even for short periods of time. VFC-supplied vaccines must be moved to CDC-approved storage unit (stand alone refrigerator or freezer unit; household style unit with separate refrigerator and freezer doors). **See Appendix A, Georgia Immunization Office Vaccine Loss Policy for Public Health Providers**.
b) Failure to identify a primary and backup staff member responsible for vaccine storage and handling.
c) Failure to monitor and document temperatures a minimum of twice daily.
d) Failure to complete and utilize the Routine and Emergency Vaccine Handling Plans.

Actions

a) Educational training and follow-up visits will be conducted by an IPC.
b) As of 1/1/2010, providers storing vaccine in a dorm-style refrigerator will have vaccine shipment suspended until vaccines are moved to an approved unit.
c) Vaccine replacement by provider. **See Appendix A, Georgia Immunization Office Vaccine Loss Policy**.

15. I will complete and submit the annual Provider Profile Update within 30 days of receipt to the VFC office. I understand that not submitting this update can lead to suspension of vaccine shipments.

Program Violation

a) Failure to complete the annual Provider Profile Update within 30 days of receipt.

Action

a) Termination from the VFC Program.

16. I will comply with all requirements of VFC's Vaccine Tracking System (VTrckS). (VTrckS is schedule to replace our current CDC software referred to as VACMAN in December 2012)

a) Should my staff, representative, or I access VTrckS, I agree to be bound by CDC's terms of use for interacting with the online ordering system. I further agree to be bound by any applicable federal laws, regulations or guidelines related to accessing a CDC system and ordering publically funded vaccines.

b) In advance of any VTrckS access by my staff, representative or myself, I will identify each member of my staff or representative who is authorized to order vaccines on my behalf. In addition, I will maintain a record of each staff member who is authorized to order vaccines on my behalf. If changes occur, I will inform VFC and CDC within 24 hours of any change in status of current staff members or representatives who are no longer authorized to order vaccines, or the addition of any new staff authorized to order on my behalf. I certify that my identification is represented correctly on this provider enrollment form.

Program Violations

a) Provider fails to designate a primary and backup staff member responsible for vaccine management in VTrckS.
b) Provider fails to notify VFC of staff changes within 24 hours.

Actions
a) Vaccine shipments may be suspended until a new staff person has been certified.
b) May result in termination from the program**.**

17. Pursuant to O.C.G.A.§31-12-3, the vaccination data for every dose of vaccine administered by the clinic will be entered into the Georgia Registry of Immunization Transactions and Services (GRITS) within **30** business days of the service being rendered. See Appendix B, Georgia Immunization Registry Law – O.C.G.A. §31-12-3.1.

Program Violations
a) Provider fails to enter vaccination data into GRITS within 30 business days.

Actions
a) Provider order may be suspended until all shot data has been submitted into GRITS
b) Failure to comply may result in termination from the program.

18. I understand that this agreement may be terminated by either party at any time for any reason. GIO has the discretion to terminate this agreement for failure of the provider to comply with all requirements.

a) Termination by either party must be in writing, at least 30 calendar days prior to termination.
b) If I am terminating the agreement, I will notify GIO for vaccine pickup.
c) If GIO is terminating the agreement, GIO staff will contact the provider to arrange for vaccine pickup.

State of Georgia Immunization Office
Georgia Department of Public Health

Public Health Provider Agreement Signature Page

In order to receive state or federally funded vaccine at no cost from Georgia Immunization Office (GIO), each clinic site must agree to the following conditions which are further defined in the enclosed Provider Agreement Policy document:

1. Vaccine supplied by GIO will be administered only to a child ≤18 years of age who: (a) is enrolled in the Georgia Medicaid Program , (b) has no health insurance, (c) who is an American Indian or Alaskan native, or (d) has health insurance that does not pay for the vaccine (underinsured) seen in a FQHC/RHC or deputized clinical setting.
2. I agree that vaccine supplied by GIO will be provided to the following non-VFC eligible categories. GIO supplies vaccines to the following special populations: (a) PeachCare for Kids® with coverage provided by Amerigroup, WellCare, and Peach State. (b) Patients deemed otherwise eligible for state supplied vaccine in public health departments as defined in the current eligibility criteria table, or (c) has health insurance that does not pay for the vaccine (underinsured) seen in a non-FQHC/RHC or non-deputized clinical setting.
3. **The following applies to FQHC/RHC Deputized Providers only:** (a) Agree to vaccinate "walk-in" Vaccines for Children (VFC)-eligible underinsured children as defined under subsection 1928(b)(2)(A)(iii) of the Social Security Act; (b) Screen for VFC eligibility, including for underinsured status, at every visit by any child less than 19 years of age; **(**c) Report to GIO, in manner and time as decided by GIO, all requirements set forth in the guidance; and (d) Comply with any additional VFC requirements as GIO or CDC may from time to time impose.
4. I will screen and document eligibility status for each patient during each immunization encounter. I will maintain Eligibility Screening Records for a period of three years. If requested, I will make such records available to the Georgia Department of Public Health (DPH), the United States Department of Health and Human Services (DHHS) or as required by law.
5. All clinic sites within its district will participate in a Quality Assurance Site Visit conducted a minimum of once per year by an Immunization Program Consultant (IPC).
6. Comply with the appropriate immunization schedule, dosage, and contraindications that are established by the DHHS Advisory Committee on Immunization Practices unless (a) in making a medical judgment in accordance with accepted medical practice, the practitioner deems such compliance to be medically inappropriate, or (b) the particular requirement is not in compliance with state laws, including laws relating to religious or other exemptions.
7. Provide Vaccine Information Statements (VIS) and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
8. Not impose a charge for the cost of any state supplied vaccine.
9. Not impose a charge to the patient for administration of any vaccine purchased by the state in any amount higher than the current state fee cap of $21.93 per injection.
10. Not deny administration of a state supplied vaccine to any eligible client due to the inability of the client or child's parent/guardian/individual of record to pay an administration fee. If the parent/guardian/individual of record is unable to pay, the administration fee must be waived. Other visit or office fees may be charged as applicable.
11. Comply with GIO's requirements for ordering vaccine, for reporting vaccine usage, spoilage, expiration, physical inventories, and all other requirements as outlined on the monthly reporting forms.
12. Maintain separation between public/VFC and privately purchased vaccine inventory.
13. Clinic is not prohibited by Georgia law or any other applicable law from possessing dangerous drugs (i.e., vaccines). See Official Code of Georgia Annotated, Title 16, Chapter 13; Title 26, Chapter 4; Title 43, Chapter 34.
14. Accept the responsibility to maintain the integrity of the drugs (i.e., vaccines) in accordance with all laws, regulations, and GIO recommendations pertaining to vaccine storage and handling procedures.
15. Complete and submit to the VFC office the annual Provider Profile Update within 30 days of receipt. Failure to submit this update can lead to suspension of vaccine shipments.
16. Comply will all requirements of VFC's Vaccine Tracking System (VTrckS).
    a) Should clinic staff, or its representatives, access VTrckS each user agrees to be bound by CDC's terms of use for interacting with the online ordering system. Each user further agrees to be bound by any applicable federal laws, regulations, or guidelines related to accessing a CDC system and ordering publically funded vaccines.

b) Upon execution of this contract, the name of each member of the clinic's staff or any person representing the clinic that will access VTrckS to order vaccines on behalf of the clinic will be submitted to GIO. In addition, the clinic will maintain a record of each staff member authorized to order vaccines on behalf of the clinic. The clinic will designate a contact person responsible for informing the CDC of changes in the status of current staff members or representatives who are no longer authorized to order vaccines, or the addition of any new staff authorized to order on my behalf within 24 hours of such change.

17. Pursuant to O.C.G.A.§31-12-3, the vaccination data for every dose of vaccine administered by the clinic will be entered into the Georgia Registry of Immunization Transactions and Services (GRITS) within **30** business days of the service being rendered. See Appendix B, Georgia Immunization Registry Law – O.C.G.A. §31-12-3.1.
18. Understand that this agreement may be terminated by either party at any time for any reason. DCH has the discretion to terminate this agreement for convenience or for the clinic's failure to comply with all requirements. A written notice will be provided by the party initiating termination 30 calendar days prior to the effective date of such termination.

Clinic Name _____

Mailing Address _____
Street Address and/or P.O. Box Number

_____
City State Zip Code

I, _____, (advanced nurse practitioner/physician), am executing this agreement on behalf of _____ [enter clinic name]. I understand that by signing this agreement I am primarily responsible for ensuring that the clinic meets all 18 conditions of participation listed in this Provider Agreement and agrees to adhere to the guidelines provided in the GIO Accountability Policy, Vaccine Loss Policy and the Fraud and Abuse Policy. **Further I understand that the failure to abide by any of these conditions may result in termination of enrollment and applicable professional license review.** Also, in order to prevent fraud, abuse, and for other related purposes, a copy of my valid professional license is submitted with this enrollment package.

_____

Name (Please print or type) **Title**

_____

Signature **Date**

<u>Enrollment cannot be processed without completion of the signature page</u>

State of Georgia Immunization Office
Georgia Department of Public Health

Georgia Immunization Office Vaccine Accountability Policy

This document will serve as the Georgia Department of Public Health, Immunization Office Vaccine Accountability Policy. This policy is designed to ensure:

1. Vaccine purchased with Vaccines for Children (VFC), federal and state funds are administered only to VFC-eligible and state-eligible recipients;
2. Vaccine loss and waste are minimized and measured;
3. The Georgia Immunization and VFC Programs are protected against fraud and abuse;
4. State, VFC and other federally purchased vaccines are ordered appropriately based on a provider's VFC-eligible and state-eligible populations.

The increase in the number of ACIP recommended vaccines and a rise in their associated costs has prompted a renewed emphasis on program accountability at all levels. As part of the enrollment and annual recertification processes for VFC and state vaccine programs, providers agree to comply with VFC and Georgia Immunization Office (GIO) requirements for ordering, storage, handling and accountability of vaccine to avoid vaccine loss as outlined in the Georgia Vaccine Loss Policy (Appendix A). Providers also agree to operate in a manner intended to avoid vaccine fraud and abuse as outlined in the Georgia Vaccine Fraud and Abuse policy (Appendix B).

Georgia will help ensure vaccine accountability in provider offices by:

1. Using provider profiles to monitor provider orders;
2. Monitoring provider vaccine inventory levels to ensure adequate supplies of public and privately purchased vaccine for the population size served in provider offices;
3. Monitoring vaccine wastage and loss that occur in provider offices;
4. Monitoring provider activities to prevent and/or identify fraud and abuse against the VFC and state vaccine programs.
5. Providing clear guidance to providers regarding the return of expired and wasted public vaccine for excise tax credit.

Using Provider Profiles to Monitor Provider Orders

VFC Providers are required to submit supporting documents for the enrollment estimates produced during VFC enrollment, re-enrollment, or annual re-certification with the VFC Program. Documentation is required to verify that submitted estimates are based on the previous year's:

1. Doses administered, benchmarking, Medicaid and/or other billing data; or
2. IIS (GRITS) data.

The VFC Logistics Associate will review a random provider sample on a monthly basis for accountability review purposes. Doses administered data will be reviewed over a 6 month span and data will be compared to the providers submitted profile estimates. Aggregate vaccine data exceeding annual profile estimates identified during this will result in corrective action development and implementation as necessary, including vaccine replacement for unaccounted for doses.

1. GIO staff contact providers that exceed profile amounts to determine if distribution of additional vaccine is justified, or if adjustments to the profile are needed.
2. Future vaccine orders are adjusted appropriately to ensure providers receive sufficient supply to serve their VFC or State-eligible population without creating an increase risk for vaccine loss, fraud, and/or abuse.

VFC providers who submit their *Monthly Comprehensive Report"* through GRITS are also required to manage their inventory and doses administered data in GRITS. Effective January 1, 2012:

1. Newly enrolled VFC providers are required to report via GRITS.
2. All currently enrolled active VFC providers must transition to 100% GRITS reporting by October 31, 2012.

VFC staff, the GRITS Help Desk, and the IPC staff will be available to assist with the transition to total GRITS reporting. This requirement in preparation for VTrckS implementation will assist with accountability of doses as the monthly report generates a monthly statement of vaccine accountability and replacement cost when necessary.

Monitoring of Provider Inventory Levels (Public vs. Private Supply)
In order to receive vaccine from Georgia's VFC program, VFC-enrolled providers must comply with reporting requirements for vaccine usage including: doses administered by eligibility category, wastage, and inventory. Georgia uses the following methods as ways to monitor provider inventory levels for both public and private vaccine supply:

1. VFC Program Representatives have been trained to routinely review monthly comprehensive reports for excessive use, underreporting, over reporting and anything that may look out of the ordinary.
2. Vaccine over- and under-reporting will be reviewed with provider(s) and unexplained amounts above the 5% allowance will be reported to the Deputy Director, who will respond accordingly.

Monitoring Vaccine Wastage and Loss
The *Georgia Department of Public Health - Immunization Office Vaccine Loss Policy* (Appendix A) details the action taken by the Georgia VFC Program for identifying, monitoring and management of incidents that result in loss of public vaccine. The action taken by the Georgia VFC Program will depend on the category of the vaccine loss. For this policy, lost vaccines fall under three categories: 1) negligence, 2) non-preventable loss, and 3) noncompliance.

VFC staff use the *CDC Non-compliance with VFC Provider Requirement Protocol (algorithm)* to address all vaccine loss policy violations. Continued violation of any section of this policy will result in termination from the VFC Program.

Prevention and Detection of Fraud and Abuse in Provider Offices
The *Georgia Department of Public Health - Immunization Office Fraud and Abuse Policy* (Appendix B) details the action taken by the Georgia VFC Program to provide programmatic direction for the prevention of fraud and abuse in the utilization of state-supplied and/or VFC-funded vaccine. The Fraud and Abuse Policy is reviewed annually and updated, as necessary. Training on fraud and abuse takes place as part of new employee orientation. Additionally, program staff (VFC staff and Immunization Program Consultants [IPCs]) receives annual educational updates, led by the Deputy Director .

Georgia uses the following methods as ways to detect and/or prevent fraud and abuse of public vaccine supply:

1. Upon enrollment and on a monthly basis thereafter, provider information is cross-checked against the List of Excluded Individuals/Entities on the Department of Health and Human Services (HHS) Office of Inspector General website. If located in the Exclusion database, providers are not allowed to participate in VFC.
2. VFC Program staff has been trained to routinely review monthly comprehensive reports for excessive use, underreporting, and anything that may look out of the ordinary.
3. Georgia Immunization Representatives are required to review with the provider a vaccine accountability statement representative of at least six (6) months, which can help identify areas of potential fraud and/or abuse.
4. Vaccine over- and under-reporting will be reviewed with provider, and unexplained amounts above the 5% allowance will be reported to the Deputy Director, who will respond accordingly.

5. Any individual, group, or practice who wants to report a suspected case of fraud and/or abuse, a dedicated Fraud and Abuse Hotline has been implemented and is monitored by the Deputy Director. The Fraud and Abuse hotline number is (404) 657-5950. Reports must include (as applicable):
    1. Provider name and address;
    2. Source of the allegation;
    3. Source's name, address, and telephone number (if available)
    4. A description of the reason for the report (suspected misconduct/violation)
    5. Specific VFC requirements violated;
    6. Value of vaccine involved (if available);
    7. If the report was initiated in response to a complaint, a copy and/or summary of the complaint and the complainant's name, address and telephone number;
    8. Success of educational intervention; and
    9. A summary of the result of any preliminary investigation conducted by GIO staff regarding allegations or suspicions of fraud or abuse.

Once a report is received, the Non-compliance with VFC Provider Requirements Protocol will be used to determine the appropriate follow up action.

At the GIO, the Deputy Director is the person with primary responsibility for responding to suspected fraud and/or abuse. The Deputy Director will have authority to make decisions, referrals, and notifications when appropriate. In the event that the Deputy Director is not available, the VFC Coordinator will assume responsibility. In the event that neither of these individuals is available, the Program Director will assume responsibility.

The Deputy Director (or designated respondent) will review all information submitted and initiate an internal investigation on all cases reported without sufficient evidence of fraud and abuse within five days of the report. All suspected cases of VFC fraud and abuse will be forwarded electronically to the Centers for Medicare & Medicaid Services (CMS), Medicaid Integrity Group (MIG) Field Office and CDC within ten (10) business days following disposition. MIG will conduct preliminary investigations and, as warranted, transmit the referral to the appropriate oversight entity and will monitor the handling of the referral by entity.

Process for Returning Expired and/or Wasted Public Vaccine

All vaccine received from the GIO must always be accounted for. This includes doses administered and inventory as well as wasted and expired vaccine. Providers are required to report doses wasted or expired on the Federal Return of Vaccine Form which begins the processing of their return request and our excise tax credit process. Vaccine returns are approved by the Vaccine Logistics Associate. The Vaccine Logistics Associate submits requests to McKesson monthly for UPS return labels. Once returns are approved and McKesson has received the label request from VFC, McKesson will ship UPS return label(s) directly to the provider site.

Providers are asked to box returns properly to ensure safe transit of the vials. Providers submit return request every quarterly or bi-annually unless a vaccine incident or temperature excursion requires an immediate return. The Vaccine Logistics Associate processes and screens each return to ensure returned vaccines have been accounted for in our Vaccine Loss Database and determine if replacement of the loss vaccine(s) are required according to Georgia's Vaccine Loss Policy. Providers are reminded to mark expired or wasted vaccine(s) **"DO NOT USE"** and store it securely and outside of the refrigerator to avoid accidental administration of non-viable vaccine.

Vaccine return boxes should include:

1. At least one full shipping box of vaccines (use McKesson shipping boxes as a size gauge)
2. Full vials of unused vaccine
3. Appropriate padding to protect vials from breaking
4. Federal Return Form (copy faxed to the VFC office)

Vaccine return boxes should **not** include:

1. Needles or syringes with needles (vaccine that has been drawn into a syringe should be wasted on-site, not returned.)
2. Broken or partially used vials (including partially used multi-dose vials)
3. Paperwork or other reports intended for VFC
4. Any other objects

Deputy Director will review CDC distributed Quarterly Vaccine Monitoring Reports to determine the amount of excise tax credit allocated to Georgia for returned vaccines. Excise tax credit is used to purchase vaccines in order to replenish or stock state/local vaccine supply for Georgia at McKesson.

State of Georgia Immunization Office
Georgia Department of Public Health

Vaccine Loss Policy (Appendix A)

This document will serve as the Georgia Department of Public Health - Immunization Office's policy for management of incidents that result in loss of state supplied vaccines. The action taken by the Georgia VFC Program will depend on the category of the vaccine loss. For this policy, lost vaccines fall under three categories: 1) negligence, 2) non-preventable loss, and 3) noncompliance.

Category 1

Vaccine loss due to **negligence** is defined as, but not limited to, the following:

a) Vaccines stored improperly (i.e., refrigerating vaccine that should have been frozen, freezing vaccine that should have been refrigerated, or storing any vaccine in a dormitory style refrigerator even for day use).
b) Vaccines left out of refrigerator or freezer.
c) Refrigerator or freezer unplugged.
d) Door of refrigerator or freezer left ajar resulting in unit temperatures outside the acceptable range.
e) Improper maintenance of recommended refrigerator and freezer temperatures resulting in vaccine spoilage, including prolonged storage of vaccines when out of range temperatures are recorded. *(Note: Temperatures recorded on temperature logs will be considered official in making vaccine viability decisions. Also, a thermometer's margin of error will not be considered when temperatures are recorded at or below 35°F/2°C.)*
f) Pre-drawing or premixing vaccine, then not administering.
g) Discarding vaccine prior to the manufacturer's stated expiration date (e.g., discarding vaccine in a multi-dose vial 30 days after the vial is first used).
h) Transporting/shipping vaccine with lack of or inappropriate coolants (e.g., packing refrigerated vaccines with dry ice or frozen vaccines with ice packs only).
i) Failure to notify the VFC Program when provider office hours change or the practice moves, resulting in vaccines being undeliverable and consequently spoiled.
j) Failure to notify the VFC Program Vaccine expired due to failure of the provider to notify the VFC Program three months prior to expiration date so that vaccine might be transferred.

Action Plan

If the provider discovers: vaccine not refrigerated or frozen within the recommended temperature range, vaccine left outside the refrigerator or freezer, the refrigerator or freezer door left ajar, continued documentation of temperatures outside the recommended range, vaccine lost in transit to a satellite facility, or vaccine undeliverable and spoiled due to a change in office hours, the incident must be reported to VFC immediately. **Vaccines should be kept in the appropriate storage environment (refrigerator or freezer) until a decision is made concerning their viability.**

Call 404-657-5013 and explain the circumstances to the Vaccine Logistics Associate. The Vaccine Logistics Associate will send the provider a copy of the *Vaccine Incident Report* form to complete and return for further review of the incident. Be prepared to furnish the following information:

a) Last known temperature of the refrigerator and freezer;
b) Current temperature of the refrigerator and freezer;
c) Duration of time the vaccines were stored out of recommended temperature range; and
d) Lot numbers, expiration dates, and number of doses of all vaccines in question.

Upon receipt of the Vaccine Incident Report, the Vaccine Logistics Associate will contact the vaccine manufacturers and determine if the vaccines in question are salvageable. **If they are not, the provider may be required to purchase replacement vaccines. This decision will be made by the Vaccine Logistics Associate and the Deputy Director based on past vaccine loss history and the number of vaccine doses lost. The provider will be required to replace VFC vaccine losses due to negligence when those losses are valued at more than 5 percent of the number of doses of VFC vaccines available to be administered by the provider in the past 12 months.** For example, VFC MMR shipped to a provider in the past 12 months totals 1,000 doses. A vaccine loss of 75 doses of MMR occurs. A 5% loss would equal 50 doses. In this case, the provider would be required to purchase and replace 25 doses of MMR to be administered to VFC-eligible children.

When replacement of lost vaccine is required:

a) The provider must mail or fax invoices for replacement vaccine to the VFC Program within 10 business days;
b) The assigned Immunization Program Consultant (IPC) will verify, by site visit, the replacement of the lost vaccines within 30 days of the incident; and
c) The provider will submit a description of the incident in writing within 10 business days that discusses the circumstances of the loss and the steps taken to ensure that vaccine is protected in the future.

When replacement of vaccine is not required:

a) The provider will submit a letter describing the incident within 10 business days that discusses the circumstances of the loss and the steps taken to ensure that vaccine is protected in the future; and
b) Vaccine shipments will be resumed upon receipt of the aforementioned letter.

Any vaccine that is deemed not usable due to negligent circumstances should be returned to McKesson using the VFC-issued McKesson Return of Federal Vaccine Form. For more information, please call 404-657-5013. Information and instructions on returning wasted/expired vaccine (as well as the return form) can be found via the web at **http://health.state.ga.us/programs/immunization/vfc/**, or on the GRITS home page in the 'Resources' section.

Category 2

Vaccine loss due to **non-preventable** circumstances, such as:

a) Area power outages due to severe weather or other unavoidable and unanticipated causes.
b) Refrigerator failure.
c) Transport company error (i.e., FedEx or Drug Transport, Inc.) Failure of the provider to notify VFC of a change in office hours or address will not be considered a transport company error.

Action Plan
If the provider discovers a power outage has occurred or the refrigerator storing vaccines has malfunctioned, the VFC program should be notified immediately by calling 404-657-5013. **Vaccines should be kept in the appropriate storage environment (refrigerator or freezer) until a decision is made concerning their viability (provider should enact their Vaccine Disaster Recovery Plan immediately if necessary).** The Vaccine Logistics Associate will send the provider a copy of the *Vaccine Incident Report* form to complete and return for further review of the incident. The provider should be prepared to supply the following information to the Vaccine Logistics Associate:

a) Last known temperature of the refrigerator and freezer;
b) Current temperature of the refrigerator and freezer;
c) Duration of time the vaccines were stored out of recommended temperature range; and
d) Lot numbers, expiration dates, and number of doses of all vaccines in question.

Upon receipt of the Vaccine Incident Report, the Vaccine Logistics Associate will contact the vaccine manufacturers and determine the status of the vaccines. **If the vaccines are determined to be viable, but the power to the office has not been restored or the refrigerator is still in disrepair, vaccines must be transported immediately to an alternate refrigerator/freezer and steps followed as noted in the provider's Vaccine Disaster Recovery Plan. If no plan is in place, the Vaccine Logistics Associate will assist the provider in determining a plan of action. Providers without a Vaccine Disaster Recovery Plan will be required to develop and submit a copy of their Vaccine Disaster Recovery Plan within 10 business days to prevent interruption in shipment of public vaccine supply from VFC.**

Any vaccine that is deemed not usable due to negligent circumstances should be returned to McKesson using the VFC-issued McKesson Return of Federal Vaccine Form. For more information, please call 404-657-5013. Information and instructions on returning wasted/expired vaccine (as well as the return form) can be found via the web at **http://health.state.ga.us/programs/immunization/vfc/** or on the GRITS home page in the 'Resources' section.

As soon as power is restored or a replacement refrigerator is acquired, the provider should:

a) Monitor and document temperatures of the refrigerator and freezer for 5 days.
b) The assigned IPC will verify, by site visit, that the storage unit is functioning properly and is adequate in size to accommodate safe storage of public supply within 10 days following provider's notification that the above step has been completed.
c) If adequate temperatures are maintained, replacement vaccines will be shipped to the provider from VFC.

Category 3
Vaccine loss due to **noncompliance** with VFC written policies, such as:

a) VFC vaccine not accounted for by monthly usage and inventory reports. This can be reflected by usage data or inventory discrepancies that reflect lost vaccine supply. Examples include the following:
    - Failure to document doses administered on usage log;
    - Failure to document patient eligibility on usage log;
    - Failure to report inventory;
    - Inaccurate reporting of inventory;
    - Failure to report expired/wasted vaccine; or
    - Failure to report short dated vaccines 90 days prior to expiration

b) VFC vaccine knowingly administered to children who are not eligible for the VFC program, including the following:
   - Administration of VFC vaccine to patients who are over 18 years of age;
   - Administration of VFC to every patient in the practice whether eligible or not (i.e., a provider discontinues purchasing private stocks of vaccine for administration to patients whose insurance covers immunizations or to patients who can afford vaccine);
   - Administration of VFC vaccine because the reimbursement rate of the child's insurance company is low;
   - Administration of VFC vaccine to a child who is fully insured (has insurance and vaccines are a covered benefit), including administration of VFC vaccine to a child who has not met their deductible in order to save the parent the cost of the deductible (a child is considered fully insured until the deductible has been met); or
   - Administration of VFC vaccine to a child even though the insurance company provides a flat rate of coverage for immunization for the year (upon exhaustion of flat rate coverage, the child is then eligible for VFC vaccine).
   - Failure to maintain separate inventories for VFC, Adult (state supplied if applicable), and privately purchased vaccine doses resulting in possible administration of state supplied vaccines to privately insured children.

c) Accepting reimbursement from insurance companies or patients for VFC vaccine as evidenced by:
   - Administering VFC vaccine to a child and subsequently billing the child's insurance for the cost of the vaccine;
   - Charging the patient for the cost of the vaccine; or
   - Charging a Medicaid recipient any fee at all.

Action Plan

If a provider is found to be in violation of written VFC policies, the action taken will depend upon the policy violated, as follows:

a) Vaccine unaccounted for in usage reports:
   - Vaccine usage and inventory must be reported to the VFC office monthly. Vaccine accountability statements will be processed and remitted to the provider. These accountability statements tell the provider what their vaccine losses have been over the current reporting period.
   - If accountability statements indicate unaccounted for VFC vaccine in excess of 5% for any vaccine for 3 consecutive reporting periods:
     1. The assigned IPC will be informed; and
     2. A site visit will be conducted before the next reporting period to investigate possible reasons for the vaccine inventory discrepancies.
   - Future vaccine accountability statements must reflect 5% or less of vaccine loss. Possible consequences include, but are not restricted to:
     1. A decrease in shipment of VFC vaccine; or
     2. Providers replacing unaccounted for vaccines exceeding 5% of the total number of doses of vaccine available to be administered by the provider in the past 12 months.

For example, if 10% of the provider's VFC provided Varicella vaccine is unaccounted for, then the provider may be asked to purchase 5% of the Varicella lost as replacement vaccine, or future shipments of Varicella will be decreased so that only the vaccine accounted for is replaced.

Decisions concerning the consequences of having unaccounted for vaccine will be made after receiving input from the IPC, the Vaccine Logistic Associate, VFC Coordinator, and the Deputy Director.

b) VFC supplied vaccines knowingly administered to children not eligible for VFC.
The VFC Coordinator or Vaccine Logistics Associate will notify the provider by letter detailing the following (when available):

- Name of child vaccinated;
- Date vaccine given;
- Each vaccine administered;
- Deadline for replacement of vaccine;
- Request for invoices for replacement vaccine;
- Request for action plan to prevent further misuse of VFC supplied vaccine; and
- Notification of future chart reviews by assigned Immunization Program Consultant.

VFC staff will use the *CDC Non-compliance with VFC Provider Requirement Protocol (algorithm)* to address future infractions. Upon receipt of written notification, any infractions or continued administration of VFC supplied vaccine to children not eligible for VFC will result in termination from the VFC.

c) Accepting reimbursement from insurance companies or patients for VFC supplied vaccine.
Providers found billing insurance companies or charging patients for state supplied vaccine will be notified of the infraction by letter from the VFC Coordinator or Vaccine Logistics Associate. The letter will include the following:

- Name of child vaccinated;
- Date vaccine given;
- Each vaccine administered and billed;
- Deadline for replacement of vaccine;
- Request for invoices for replacement vaccine;
- Request for action plan to prevent further fraudulent billing; and
- Notification of future chart reviews by assigned Immunization Program Consultant.

VFC staff will use the *CDC Non-compliance with VFC Provider Requirement Protocol (algorithm)* to address future infractions. Continued acceptance of reimbursement from insurance companies or patients for VFC supplied vaccine after receiving notification by letter will result in termination from the VFC Program.

Reports from outside sources of fraudulent use of VFC supplied vaccine will be referred to the Deputy Director immediately. The assigned IPC will be asked to perform a site visit and chart review within 5 business days of the report. Findings will be reviewed with the provider and reported to the Deputy Director. Any action to be taken will be decided after receiving input from the IPC, the VFC Coordinator, the Vaccine Logistics Associate and the Deputy Director.

Fraud and Abuse Policy (Appendix B)

I. Background

The purpose of this policy is to provide programmatic direction for the prevention of fraud and abuse in the utilization of public (state-supplied and/or Vaccines for Children [VFC]) funded vaccine. The Georgia Immunization Office (GIO) is required by federal granting authorities to implement vaccine fraud and abuse prevention policies.

Vaccines supplied through GIO are funded through several federal sources. For simplification purposes, those funding sources can be divided into two primary groups: VFC and non-VFC funds. VFC funds may be used to purchase vaccine for children and adolescents who are birth through 18 years of age (less than 19), and who are:

- Medicaid eligible
- Uninsured (have no health insurance)
- American Indian/Alaskan Native
- Underinsured (have health insurance that does not pay for vaccinations), seen in Federally Qualified Health Centers (FQHC), or Rural Health Centers (RHC)

Non-VFC funds are utilized to purchase vaccines for children and adolescents who are birth through 18 years of age (less than 19), and who are:

- Underinsured, seen in their medical home
- PeachCare for Kids™

Georgia VFC providers must adhere to the vaccine usage constraints relative to vaccine funding. Providers must administer this vaccine only to the aforementioned categories of adolescents and children. Misuse of state/VFC-funded vaccine may result in civil or criminal penalties.

The Fraud and Abuse Policy will be reviewed annually and updated, if necessary. Training on fraud and abuse will take place as part of new employee orientation. Additionally, program staff (VFC staff and Immunization Program Consultants [IPCs]) will receive annual educational updates, led by the Deputy Director.

II. Definitions

Fraud is defined by Medicaid as "an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law."

Abuse is defined by Medicaid as "provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program, [and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient]; or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program."

Examples of fraud and abuse include, but are not limited to, the following:

- Providing VFC vaccine to non VFC non-VFC-eligible children;
- Selling or otherwise misdirecting VFC vaccine;

- Billing a patient or third party for VFC vaccine;
- Charging more than the established maximum regional charge ($14.81) for administration of a VFC-funded vaccine to a federally vaccine-eligible child;
- Not providing VFC-eligible children VFC-funded vaccine because of inability to pay for the administration fee;
- Not implementing provider enrollment requirements of the VFC program;
- Failing to screen patients for VFC eligibility at every visit;
- Failing to maintain VFC records for a minimum of three (3) years or comply with other requirements of the VFC program;
- Failing to fully account for VFC-funded vaccine through required monthly reporting of doses administered, doses wasted, and inventory on hand;
- Failing to properly store and handle VFC vaccine;
- Ordering VFC vaccine or reporting vaccine usage in quantities or patterns that do not match provider profile or otherwise involve over-ordering of VFC doses;
- Waste of VFC vaccine due to negligence.

III. Compliance Assessment

In order to receive vaccine from Georgia's VFC program, VFC-enrolled providers must comply with reporting requirements for vaccine usage including: doses administered by eligibility category, wastage, and inventory. Every vaccine order submitted is compared to the most recent provider profile estimates, calculated by GIP, and approved by the provider. The provider profile is an estimate of the number of VFC-eligible children the provider expects to see in a given year by eligibility category. These estimates are entered into the Centers for Disease Control and Prevention (CDC)-developed Vaccine Management System (VACMAN). Aggregate vaccine orders exceeding annual profile data are identified by VACMAN. GIO staff contact providers that exceed profile amounts to determine if distribution of additional vaccine is justified, or if adjustments to the profile are needed.

Upon enrollment and on a monthly basis thereafter, provider information is cross-checked against the List of Excluded Individuals/Entities on the Department of Health and Human Services (HHS) Office of Inspector General website. If located in the Exclusion database, providers are not allowed to participate in VFC.

VFC Program staff has been trained to routinely review monthly comprehensive reports for excessive use, underreporting, and anything that may look out of the ordinary. In addition, IPCs are required to review with the provider a vaccine accountability statement representative of at least six (6) months, which can help identify areas of potential fraud and/or abuse. Vaccine over- and under-reporting will be reviewed with provider, and unexplained amounts above the 5% allowance will be reported to the Deputy Director, who will respond accordingly.

VFC fraud or abuse determination is not a responsibility of GIO. However, GIO is required to report suspected VFC fraud and abuse to state and federal authorities. Unjustified, excessive, and/or repeated discrepancies between provider profile data, vaccine orders, and vaccine usage will be referred for further investigation as is required of the program.

IV. Referrals

The GIO Deputy Director is the person with primary responsibility for responding to suspected fraud and/or abuse. The Deputy Director will have authority to make decisions, referrals, and notification when appropriate. In the event that the Deputy Director is not available, the VFC Coordinator will assume responsibility. In the event that neither of these individuals is available, the Program Director will assume responsibility.

Should any individual, group, or practice want to report a suspected case of fraud and/or abuse, a dedicated Fraud and Abuse Hotline has been implemented and is monitored by the Deputy Director. The Fraud and Abuse hotline number is (404) 657-5950. Reports must include (as applicable):

1. Provider name and address;
2. Source of the allegation;
3. Source's name, address, and telephone number (if available)
4. A description of the reason for the report (suspected misconduct/violation)

5. Specific VFC requirements violated;
6. Value of vaccine involved (if available);
7. If the report was initiated in response to a complaint, a copy and/or summary of the complaint and the complainant's name, address and telephone number;
8. Success of educational intervention; and
9. A summary of the result of any preliminary investigation conducted by GIO staff regarding allegations or suspicions of fraud or abuse.

Once a report is received, the Non-compliance with VFC Provider Requirements Protocol will be used. This protocol has two levels of formal education – secondary and tertiary. Each level requires a minimum amount of education intervention and follow-up. For a provider to successfully complete the Secondary Education process, the provider must have corrected the situation. Tertiary Education requires a full VFC compliance site visit, and the compliance issue must be resolved for the provider to be released from the educational intervention. For example, if an employee from a practice calls to report that the practice is failing to properly store vaccine, the IPC assigned to the provider will be notified that a storage and handling visit needs to be made. It is expected that the IPC will enter the provider into secondary education and take steps to resolve the issue, which may involve suspending vaccine shipment until the situation is resolved. If the issue is not resolved the provider will be entered into Tertiary Education. If the issue remains unresolved, the provider has more than three instances with the same issue, or any allegation where it is discovered that a provider is billing Medicaid inappropriately (inaccurate services, ineligible clients, etc.), then the IPC will notify the Deputy Director immediately and provide the following information (as applicable):

1. Provider name and address;
2. Specific VFC requirements violated;
3. Value of vaccine involved (if available);
4. If the report was initiated in response to a complaint, a copy or summary of the complaint and the complainant's name, address and telephone number;
5. Success of educational intervention; and
6. A summary of the result of any preliminary investigation conducted by GIO staff regarding allegations or suspicions of fraud or abuse.

The Deputy Director will review all information submitted. The Deputy Director will initiate an internal investigation on all cases reported with sufficient evidence of fraud and abuse within five days of the report. All suspected cases of VFC fraud and abuse will be forwarded electronically to the Centers for Medicare & Medicaid Services (CMS), Medicaid Integrity Group (MIG) Field Office and CDC within ten (10) business days following disposition. MIG will conduct preliminary investigations and, as warranted, transmit the referral to the appropriate oversight entity and will monitor the handling of the referral by entity.

V. <u>Allegation and Referral Database</u>

GIO will maintain a database to monitor and document all actions taken on allegations related to fraud and abuse of the VFC program requirements, including actions taken to address identified situations. As requested, database will be made available to CDC. The following data will be collected for the database:

1. Provider's name (Medicaid ID if known);
2. Address;
3. Source of allegation;
4. Date allegation reported to program;
5. Description of suspected misconduct;
6. Specific VFC requirements violated;
7. Value of vaccine involved if available;
8. Success of educational intervention;
9. Disposition (closed, referred, entered into educational process) of case; and
10. Date of disposition

V. Resolution

Determination of fraud or abuse is made by the appropriate oversight entity. Providers identified to be engaged in VFC fraud or abuse will be suspended from the VFC program. Reinstatement to the VFC program will be contingent on the outcome of proceedings conducted by the appropriate oversight entity. Final resolution may include the following (not all-inclusive) interventions: remedial education, recoupment of funds, reinstatement without penalty, or referral for criminal prosecution or civil resolution.

Providers who have been cleared of suspected fraud due to excusable lack of knowledge will be required to work with IPC staff to complete corrective action training sessions prior to reinstatement to the program. Trainings may include: Provider Refresher, Vaccine Storage and Handling, and Vaccine Administration. IPC will be required to document all steps taken and will have authority to reinstate providers, which will then be reviewed by the Deputy Director. In all cases, providers will be required to submit a corrective action plan in which the practice will be expected to outline how to avoid a similar situation in the future.

In those instances where provider activities do not involve Medicaid or billing agencies, GIO will work with the provider directly within the VFC policy guidelines. This may include requiring education, suspending vaccine shipments until corrective actions are taken, or termination from the VFC program. In any event that a provider's activities violate Medicaid requirements, the abovementioned notification steps will be taken to inform

Georgia Immunization Office
Handling of Vaccine During Inclement Weather Conditions

To protect vaccine and to minimize the potential monetary loss from inclement weather conditions such as tornadoes; hurricanes; and tropical, ice, snow, rain, lightening, or wind storms, etc., emergency procedures at the provider level should be implemented immediately. A part of this implementation should include communication to all providers who receive publicly purchased vaccines, or at least to those in the geographic areas of highest risk.

When the state/local officials or a provider has reasonable cause to believe that weather conditions have the potential to disrupt power and/or flood any office where vaccine is stored, emergency procedures should be implemented IN ADVANCE OF THE EVENT.

In advance of the emergency, all providers should ensure the following:

A. Identification of an alternative storage facility (hospital, packing plant, state depot, etc.), with back-up power (generator), where the vaccine can be properly stored and monitored for the duration of the storm (provider needs to ensure that the receiving site is able to store multiple sites, if they have signed agreements with multiple sites). A written agreement (updated annually) is strongly advised;

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

C. The use of appropriate packing containers, certified thermometers, and cold packs; and

D. The transport of the vaccine to the secure storage facility.

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 can adversely affect 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 INFORMATION.

EMERGENCY PROCEDURES

A. List emergency phone numbers, companies, and points of contact for:
    1. Electrical power company:
    2. Refrigeration repair company:
    3. Temperature alarm monitoring company:
    4. Perimeter alarm repair company:
    5. Perimeter alarm monitoring company:
    6. Backup storage facility:

7. Transportation to backup storage:
8. Emergency generator repair company:
9. National Weather Service:
   Satellite tracking of significant weather is also available at http://www.goes.noaa.gov/ .
10. Manufacturers:
    a. Merck Vaccines: 800-672-6372
    b. Aventis Pasteur: 800-VACCINE (800-822-2463)
    c. GlaxoSmithKline: 800-366-8900
    d. Pfizer: 800-879-3477
    e. Med Immune: 877-633-4411
    f. Novartis: 800-244-7668

B. Providers may contact the Georgia Immunization Office (GIO) for assistance in identifying 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 district or county level and/or with assistance from the Office of Emergency Preparedness. The GIO will prioritize assistance and communication to target providers in areas at highest risk, e.g., low lying coastal or floodplain areas.

C. Entering vaccine storage spaces: 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. Doors
   2. Flash lights
   3. Spare batteries
   4. Light switches
   5. Keys
   6. Locks
   7. Alarms
   8. Circuit breakers
   9. Packing materials

D. Identify whom to call for the following items:
   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 and certified thermometer(s).
   2. Remove and pack the varicella vaccines, using cold packs and certified thermometer(s), immediately prior to transport

F. Pack and transport all vaccine or if that is not possible, determine the types and amount 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. Priority should be given to those vaccines which would be the most expensive to replace (pneumococcal conjugate, varicella, DTaP/HepB/IPV, Hep B/Hib, MMR).

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. Do not place vaccines that cannot be frozen directly against cold packs. (Note: MMR can be stored frozen or refrigerated.)
   4. Follow vaccine handling guidelines. The following are important tips to remember:

      --Varicella vaccine is fragile and should be used within 72 hours of placing on wet ice or in a refrigerated environment.

      --MMR vaccine can be refrigerated or frozen, but should be kept out of direct light.

      --All other vaccines should be maintained at refrigerator temperature.

H. Move vaccine to backup storage according to pre-arranged plans. Pre-arranged plans should take into consideration the following:

   1. How to load the transportation vehicle
   2. Routes to take
   3. Time enroute
   4. Temperature monitoring (maintenance of temperature log with temperatures checked twice daily) while vaccine is in backup storage

I. On returning inventory to the clinic/practice/pharmacy, vaccines should be checked carefully and placed in the appropriate refrigerator or freezer compartments. **If the provider is not able to assure viability, GIO should be contacted before using any vaccines that may not be effective for protecting children and/or adults against disease.**

Fahrenheit to Celsius and Celsius to Fahrenheit Conversion

ºF	ºC
-22	-30.0
-21	-29.4
-20	-28.9
-19	-28.3
-18	-27.8
-17	-27.2
-16	-26.7
-15	-26.1
-14	-25.6
-13	-25.0
-12	-24.4
-11	-23.9
-10	-23.3
-9	-22.8
-8	-22.2
-7	-21.7
-6	-21.1
-5	-20.6
-4	-20.0
-3	-19.4
-2	-18.9
-1	-18.3
0	-17.8
1	-17.2
2	-16.7
3	-16.1
4	-15.6
5	-15.0
6	-14.4
7	-13.9
8	-13.3
9	-12.8
10	-12.2
11	-11.7
12	-11.1
13	-10.6
14	-10.0
15	-9.4
16	-8.9
17	-8.3
18	-7.8
19	-7.2
20	-6.7
21	-6.1
22	-5.6
23	-5.0
24	-4.4
25	-3.9
26	-3.3
27	-2.8
28	-2.2
29	-1.7

ºF	ºC
30	-1.1
31	-0.6
32	0.0
33	0.6
34	1.1
35	1.7
36	2.2
37	2.8
38	3.3
39	3.9
40	4.4
41	5.0
42	5.6
43	6.1
44	6.7
45	7.2
46	7.8
47	8.3
48	8.9
49	9.4
50	10.0
51	10.6
52	11.1
53	11.7
54	12.2
55	12.8
56	13.3
57	13.9
58	14.4
59	15.0
60	15.6
61	16.1
62	16.7
63	17.2
64	17.8
65	18.3
66	18.9
67	19.4
68	20.0
69	20.6
70	21.1
71	21.7
72	22.2
73	22.8
74	23.3
75	23.9
76	24.4
77	25.0
78	25.6
79	26.1
80	26.7
81	27.2

ºF	ºC
82	27.8
83	28.3
84	28.9
85	29.4
86	30.0
87	30.6
88	31.1
89	31.7
90	32.2
91	32.8
92	33.3
93	33.9
94	34.4
95	35.0
96	35.6
97	36.1
98	36.7
99	37.2
100	37.8
101	38.3
102	38.9
103	39.4
104	40.0

ºC	ºF
-30	-22.0
-29	-20.2
-28	-18.4
-27	-16.6
-26	-14.8
-25	-13.0
-24	-11.2
-23	-9.4
-22	-7.6
-21	-5.8
-20	-4.0
-19	-2.2
-18	-0.4
-17	1.4
-16	3.2
-15	5.0
-14	6.8
-13	8.6
-12	10.4
-11	12.2
-10	14.0
-9	15.8
-8	17.6
-7	19.4
-6	21.2
-5	23.0
-4	24.8
-3	26.6
-2	28.4
-1	30.2
0	32.0
1	33.8
2	35.6
3	37.4
4	39.2
5	41.0
6	42.8
7	44.6
8	46.4
9	48.2
10	50.0
11	51.8
12	53.6
13	55.4
14	57.2
15	59.0
16	60.8
17	62.6
18	64.4
19	66.2
20	68.0
21	69.8

ºC	ºF
22	71.6
23	73.4
24	75.2
25	77.0
26	78.8
27	80.6
28	82.4
29	84.2
30	86.0
31	87.8
32	89.6
33	91.4
34	93.2
35	95.0
36	96.8
37	98.6
38	100.4
39	102.2
40	104.0

Vaccine Storage & Handling Guide

Protect your vaccine ~ Protect your patients

December, 2011

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

CDC

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Information contained in this document is based on the recommendations of the Advisory Committee on Immunization Practices (ACIP) and the manufacturer's product information.

A combination vaccine is defined as a product containing components that can be divided equally into independently available routine vaccines. A dash (-) between vaccine products indicates that products are supplied in their final form by the manufacturer and do not require mixing or reconstitution by the user. A slash (/) indicates that the products must be mixed or reconstituted by the user.

Vaccine Storage and Handling Best Practices

Vaccines must be stored properly from the time they are manufactured until they are administered. Immunization providers are responsible for proper storage and handling from the time vaccine arrives at the facility until the vaccine is given. Below is an outline of vaccine storage and handling best practices. CDC's Storage and Handling Toolkit contains detailed information on vaccine management. Immunization providers and staff are strongly encouraged to review the Storage and Handling Toolkit annually. Educate all staff, including temporary staff, as part of new staff orientation. In addition, Vaccines for Children (VFC) providers should follow VFC policy and work with their immunization program.

- **Vaccine Management** includes, but is not limited to, these three components.
  1. The **equipment** used for vaccine storage and temperature monitoring is **reliable and appropriate.**
  2. **Staff is knowledgeable** regarding proper vaccine storage and handling. At least 2 staff members should be responsible for vaccine management.
  3. Written storage and handling plans are updated at least annually for:
     - **routine storage and handling** of vaccines; and
     - **emergency vaccine retrieval and storage**.

Routine Vaccine Storage and Handling Plan should include the following four elements.

1. **Ordering and Accepting Vaccine Deliveries**
   - Store vaccines at the recommended temperatures IMMEDIATELY upon arrival.
     - Store refrigerated vaccines between 35°F and 46°F (2°C and 8°C).
     - Store frozen vaccines between -58°F and +5°F (-50°C and -15°C).
   - Ensure vaccines are delivered when the facility is open. Vaccine shipments should be delivered when staff is available to unpack and store the vaccine properly. Inform manufacturer/distributor when vaccine shipments can be delivered. VFC providers should also notify the immunization program. Consider holidays, vacations, changes in hours of operation, and staff schedules when ordering vaccines.
   - Educate all facility staff about vaccine storage. Vaccine shipments are often accepted by nonmedical staff. They should be aware that vaccine needs to be stored according to the manufacturer's guidelines immediately upon delivery.

- Order vaccines to maintain an adequate amount to meet the needs of the facility's patients. The amount of vaccine needed can vary throughout the year. Anticipate peak periods such as back-to-school appointments or influenza season and order accordingly.
- Order the vaccines and presentations that are appropriate for the ages and types of patients the facility serves. Influenza vaccine, for example, is available from many manufacturers with differing indications.
- Maintain a vaccine inventory log including:
  1. vaccine name and number of doses received;
  2. date vaccine received;
  3. condition of vaccine on arrival;
  4. vaccine manufacturer and lot number; and
  5. vaccine expiration date.

2. **Storing and Handling Vaccines**
   - Store vaccines in refrigerator and freezer units which can maintain the appropriate temperature range and are large enough to maintain the year's largest inventory without crowding. Stand alone units are preferred but household combination units with separate exterior doors and thermostats can be used. Dormitory-style refrigerators should not be used. A dormitory-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door with an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.
   - Store vaccine in storage units designated specifically for biologics. If biologic specimens must be stored in the same unit, these should be stored on a lower shelf to prevent contamination. Food and drinks should never be stored in the same unit with vaccines.
   - Keep a calibrated thermometer with a Certificate of Traceability and Calibration* in the refrigerator and freezer. These thermometers should be recalibrated as recommended by the manufacturer.
   - Post "Do Not Unplug" signs next electrical outlets and "Do Not Stop Power" signs near circuit breakers to maintain a consistent power source.
   - Read and document refrigerator and freezer temperatures at least twice each workday- in the morning and before the end of the workday. Keep temperature logs for at least 3 years.

*Certificate of Traceability and Calibration thermometer with calibration measurements traceable to a testing laboratory accredited by the International organization of Standardization, to the standards of the National Institute of Standards and Technology, or to another internationally recognized standards agency

- Store vaccine according to the manufacturer's instructions. Aim to maintain storage unit temperatures within the middle of the acceptable temperature range. This allows for the small temperature fluctuations that can occur in refrigerators and freezers without exposing vaccines to unacceptable temperatures.
- Ensure good air circulation around the vaccine in the storage unit. Proper air circulation is essential to maintaining the correct storage temperatures. Bins, baskets, or some other type of uncovered containers that allow for air circulation should be used to store the vaccines. There should be space between the containers to promote air flow.
- Store vaccines on the shelves away from the walls, and vents in the part of the unit best able to maintain the required temperature. Vaccines should never be stored in the door of the freezer or refrigerator. The temperature here is not stable.
- Place frozen packs in the door of the freezer and water bottles in the door of the refrigerator to help the storage unit maintain a constant temperature. Frozen packs or water bottle should be placed securely so they do not dislodge and prevent the door from closing. In addition, caution must be taken to avoid weighing down the door so much that the seal is compromised when the door is closed.
- Store unopened and opened vaccines in their original box with the lid in place until administration. Several vaccines must be protected from light. This practice also helps to ensure different vaccines are not stored together in the same bins or containers which can lead to vaccine administration errors. And in the event of a power failure, studies have shown storing vaccines in the box helps to maintain the vaccine at the appropriate temperature.
- Prepare vaccines at the time the vaccine is administered. This includes reconstituting or "mixing" vaccine, if indicated. Use only the diluent supplied by the vaccine manufacturer. Store diluent according to the manufacturer's instructions.

3. **Managing Inventory**
   - Rotate stock so vaccine and diluent with the shortest expiration date is used first. Place vaccine with the longest expiration date behind the vaccine that will expire the soonest. Remove expired vaccine and diluent from usable stock.
   - Keep vaccine stock well organized. VFC providers should separate and identify VFC and other vaccines purchased with public funds within the storage unit. In addition, clearly label the space where the vaccine is placed to help staff choose the appropriate vaccine.

- Inspect the storage unit daily. A physical inspection helps to ensure vaccines and thermometers are placed appropriately within the unit. During a busy work day, vaccines and thermometers can be easily moved or displaced to an area inappropriate for vaccine storage.
- Dispose of all vaccine materials using medical waste disposal procedures. Contact the immunization program for details and state specific guidance.

4. **Managing Potentially Compromised Vaccines**
   - Identify and isolate all potentially compromised vaccines and diluents. Label these "DO NOT USE". Store separately from uncompromised vaccines and diluents in the recommended temperature range. A clearly labeled paper bag can be used for this purpose. Do not automatically discard the vaccine or diluent.
   - Contact vaccine manufacturers and/or state immunization program for appropriate actions that should be followed for all potentially compromised vaccines and diluents.
   - Educate staff administering vaccines on correct handling and preparation procedures to decrease the likelihood of vaccine or diluent inadvertently being compromised. For example, each vaccine should be prepared just prior to administration.

Emergency Vaccine Retrieval and Storage Plan should include the following components.

1. Designate an alternate site where vaccines and diluents can be safely stored. Considerations when choosing a site include types of storage unit(s) available, temperature monitoring capabilities, and back-up generator. Potential back-up locations include local hospitals, another provider's facility, retail or clinic pharmacies, long-term care facilities, or the Red Cross. Identify procedures that allow 24-hour access to alternate facilities.
2. Obtain and store an adequate number/amount of appropriate packing containers and materials (e.g., frozen and refrigerated gel packs, bubble wrap) in the facility that will be needed to pack vaccines for safe transport. Acceptable packing containers are described in the *Storage and Handling Toolkit*. Consider the year's largest inventory when stocking supplies. Store these supplies with a copy of the emergency vaccine retrieval and storage plan. Communicate to staff where everything is kept.
3. Include written directions for packing vaccines and diluents for transport. A calibrated thermometer should be placed in each packing container near the vaccine or refrigerated diluent.

4. Develop a plan in which vaccine coordinators will be notified of power outages at the facility. Include instructions for gaining 24-hour access to where the vaccines are stored.
5. Incorporate written procedures for managing potentially compromised vaccines.
6. Include contact information for vaccine manufacturers and/or the immunization program.

For more detailed information on proper vaccine storage and handling please refer to CDC's *Vaccine Storage and Handling Toolkit*.

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Diphtheria Toxoid-, Tetanus Toxoid- and acellular Pertussis-Containing Vaccines

DTaP: DAPTACEL, Infanrix, Tripedia
DTaP-HepB-IPV: Pediarix
DTaP-IPV: KINRIX
DTaP-IPV/Hib: Pentacel

Condition upon Arrival

Diphtheria toxoid-, tetanus toxoid- and acellular pertussis-containing vaccines (DTaP, DTaP-HepB-IPV, DTaP-IPV, DTaP-IPV/Hib) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

- **DTaP-IPV/Hib (Pentacel) has 2 components.** The lyophilized Hib vaccine (ActHIB) and DTaP-IPV diluent vials should arrive packaged together in the same shipping container.

Storage Requirements

Refrigerate vaccine and diluent, if applicable, immediately upon arrival. Do not freeze or expose to freezing temperatures.

- **DTaP, DTaP-HepB-IPV (Pediarix), DTaP-IPV (KINRIX): Refrigerate between 35°F* and 46°F (2°C and 8°C).**

- **DTaP-IPV/Hib (Pentacel): Refrigerate the lyophilized Hib vaccine (ActHIB) and the vaccine diluent (DTaP-IPV) together between 35°F* and 46°F (2°C and 8°C). Do not store them separately.**

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe of the vaccine AND diluent, if applicable. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. DTaP, DTaP-HepB-IPV (Pediarix), DTaP-IPV (KINRIX), DTaP-IPV/Hib (Pentacel) vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **DTaP, DTaP-HepB-IPV (Pediarix), DTaP-IPV (KINRIX):** Just before use, shake vial or manufacturer-filled syringe well. After shaking, the vaccine should be a cloudy, white colored liquid. Do not use vaccine if it cannot be resuspended with thorough agitation.
- **DTaP-IPV/Hib (Pentacel):** This vaccine is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute DTaP-IPV/Hib (Pentacel) prior to administering it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for an example of a label and the educational handout "Vaccines with Diluents: How to Use Them".
  1. Just before use, shake the vial of DTaP/IPV diluent.
  2. Withdraw the entire contents of the diluent vial (blue capped vial) and inject it into the vial containing the lyophilized vaccine component (green capped vial).
  3. Shake the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.

4. The reconstituted vaccine is a cloudy, uniform, white to off-white (yellow tinged) liquid.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.
DTaP-IPV/Hib (Pentacel): All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted DTaP-IPV/Hib may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 30 minutes. Do not freeze or expose reconstituted vaccine to freezing temperatures. Agitate stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted DTaP-IPV/Hib (Pentacel) vaccine if it is not used within 30 minutes.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

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

Special Instructions

Diphtheria toxoid-, tetanus toxoid- and acellular pertussis-containing vaccines are easily confused increasing the risk for error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

Haemophilus influenzae type b-Containing Vaccines

Hib: ActHIB, Hiberix, PedvaxHIB

Hib-HepB: Comvax

Note: Information pertaining to DTaP/IPV-Hib (Pentacel) can be found on page 11

Condition upon Arrival

Haemophilus influenzae type b-containing vaccines (Hib, Hib-HepB) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

- **ActHIB and Hiberix vaccines each have 2 components.** The lyophilized Hib vaccine and diluent vials should arrive packaged together in the same shipping container.

Storage Requirements

Store the vaccine and diluent, if applicable, according to the manufacturer’s guidelines immediately upon arrival. Do not freeze or expose to freezing temperatures.

- **PedvaxHIB and Comvax vaccines: Refrigerate vaccine between 35°F* and 46°F (2°C and 8°C).**

- **ActHIB vaccine: Refrigerate lyophilized vaccine and diluent between 35°F and 46°F (2°C and 8°C).** Do not store them separately.
- **Hiberix vaccine:** If space allows, store the lyophilized vaccine and diluent together in the refrigerator.
  Vaccine: Refrigerate the lyophilized vaccine between 35°F* and 46°F (2°C and 8°C). Protect vaccine from light at all times by storing in the original box.
  Diluent: Store in the refrigerator between 35°F* and 46°F (2°C and 8°C) or at room temperature between 68°F and 77°F (20°C and 25°C).

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe of the vaccine AND diluent, if applicable. Do not use vaccine or diluent after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at end of this document for information on vaccine administration.

- **PedvaxHIB and Comvax vaccines:** Just before use, shake the vial. The vaccine should be a slightly opaque, white liquid. Do not use vaccine if it cannot be resuspended with thorough agitation.
- **ActHIB and Hiberix vaccines:** These vaccines must be reconstituted before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute these vaccines. ActHIB and Hiberix diluents are not the same and they are NOT interchangeable. ActHIB is reconstituted with 0.4% sodium chloride diluent. Hiberix is reconstituted with 0.9% sodium chloride diluent. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for examples of labels and the educational handout "Vaccines with Diluents: How to Use Them".
  1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized Hib vaccine.

2. Shake the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
3. The reconstituted vaccine should be a clear and colorless liquid.

Beyond Use Date*: Shelf Life after Opening

PedvaxHIB and Comvax vaccines: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
ActHIB and Hiberix vaccines: All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted ActHIB or Hiberix may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 24 hours. Do not freeze or expose reconstituted vaccines to freezing temperatures. Protect reconstituted Hiberix from light. Agitate stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted ActHIB or Hiberix vaccine if it is not used within 24 hours.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

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

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. For example, single antigen and combination vaccines. Vaccine products and presentations often have different approved indications (e.g., ages). Storing multiple products and presentations can be confusing to staff and increases the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

Hepatitis-Containing Vaccines

HepA: Havrix, VAQTA
HepB: Engerix-B, Recombivax HB
HepA-HepB: Twinrix

Note: Information pertaining to DTaP-IPV-HepB (Pediarix) can be found on page 11
Information pertaining to Hib-HepB (Comvax) can be found on page 15

Condition upon Arrival

Hepatitis-containing vaccines (HepA, HepB, HepA-HepB) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or manufacturer-filled syringe well. Do not use vaccine if it cannot be resuspended with thorough agitation. After shaking, the vaccine should be white, slightly cloudy in color. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

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

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). For example, single antigen HepA and HepB vaccines have different formulations based on age. Storing multiple products and presentations can be confusing to staff and increases the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

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Human Papillomavirus Vaccines

HPV2: Cervarix
HPV4: Gardasil

Condition upon Arrival

Human papillomavirus vaccine (HPV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

- **HPV4 (Gardasil):** Protect vaccine from light at all times by storing in the original box.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or manufacturer-filled syringe well. After shaking, HPV vaccine is a white, cloudy liquid. Through agitation immediately before administration is needed to maintain suspension. Do not use vaccine if it cannot be resuspended with thorough agitation. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **HPV2 (Cervarix):** May separate to a fine, white deposit on the bottom of the vial with a clear, colorless liquid above during storage. This does not indicate deterioration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.

4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

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

Special Instructions

Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. There are two HPV products available from different manufacturers with different indications. HPV4 can be administered to males and females. HPV2 is approved for use in females only. Consider indications and the facility's patient population when ordering HPV vaccine.

Vaccines that sound alike are often confused. For example, HPV, HepB and Hib vaccines are often confused, increasing the risk for an error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Label the space where HPV is stored with name, gender and age indications to help decrease the likelihood of a vaccine administration error. Refer to the Resources section at the end of this document for examples of labels.

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Influenza Vaccines

LAIV: FluMist

Condition upon Arrival

Live, attenuated influenza vaccine (LAIV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

Shelf Life

Influenza vaccine is formulated for use during the current influenza season. Check expiration date on the nasal sprayer. Do not use after the expiration date shown on the label.

Preparation

This vaccine should not be combined or mixed with any other vaccines. Each nasal sprayer contains a single dose of LAIV. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Sprayer: The nasal sprayer should be removed from the refrigerator at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer

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

Special Instructions

Often providers have different influenza presentations in the same storage unit. Influenza products and presentations have different approved indications (e.g., ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications, and route of administration can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

Influenza Vaccines

TIV: Afluria, Fluarix, FluLaval, Fluvirin, Fluzone, Fluzone High-Dose, Fluzone Intradermal

Condition upon Arrival

Trivalent influenza vaccine (TIV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

- **Afluria, Fluarix, FluLaval, and Fluvirin:** Protect vaccine from light at all times by storing in the original box.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Influenza vaccine is formulated for use during the current influenza season. Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Shake multidose vials each time before withdrawing a dose. Do not use vaccine if it cannot be resuspended with thorough agitation. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration. .

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed or needle attached) at the time the vaccine is administered.
Intradermal Microinjection Syringe: Manufacturer-filled microinjection syringe should be activated (i.e., needle cap removed) at the time the vaccine is administered.
Multidose Vials: Shake vial well prior to withdrawing each dose. Withdraw a single age-appropriate dose of vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).** A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

- **Once entered, a multidose vial of Afluria or FluLaval should be discarded after 28 days.**

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

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

Special Instructions

Vaccines, including TIV, should be drawn from the vial into the syringe at the time of administration. CDC strongly discourages providers from prefilling syringes in advance. If more than one dose of vaccine must be predrawn, only draw up a few syringes (no more than 10 doses or the contents of one multidose vial).

Provider prefilled syringes should be administered by the person who filled them. Any syringes prefilled by the provider must be stored within the recommended temperature range and used or discarded by the end of the workday.

CDC recommends manufacturer-filled syringes for large immunization events, such as community influenza vaccination clinics. Once a manufacturer-filled syringe is activated (e.g., syringe cap removed or needle attached) it must be stored within the recommended temperature range and used or discarded by the end of the workday.

Often providers have different TIV presentations in the same storage unit. Influenza products and presentations have different approved indications (e.g., ages, route). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications, dosage and route of administration can help prevent vaccine administration errors. Refer to the Resources section of this document for examples of labels.

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Measles-, Mumps- and Rubella-Containing Vaccine

MMR: M-M-RII

Note: Information pertaining to MMRV (ProQuad) can be found on page 69

Condition upon Arrival

Measles, Mumps, Rubella vaccine (MMR) has 2 components: lyophilized vaccine and diluent. Both components should arrive together in the same shipping container. The vaccine and diluent should be in separate compartments. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the recommended storage between -58°F and +46°F (-50°C and +8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Store lyophilized vaccine and diluent according to the manufacturer’s guidelines immediately upon arrival.

Lyophilized vaccine: Store MMR lyophilized vaccine in the refrigerator or freezer between -58°F and +46°F (-50° and +8°C). Protect vaccine from light at all times by storing in the original box.

Diluent: Store diluent in the refrigerator between 35°F* and 46°F (2°C and 8°C) or at room temperature between 68°F and 77°F (20°C and 25°C). Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container or vial of the vaccine AND diluent. Do not use after the expiration date shown on the label.

Preparation

MMR is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for an example of a label and the educational handout "Vaccines with Diluents: How to Use Them". This vaccine should not be combined or mixed with any other vaccines. The Resources section at the end of this document also includes vaccine administration information.

1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized vaccine component.
2. Shake the vial now containing the lyophilized vaccine and diluent to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
3. The reconstituted vaccine should be a yellow, clear liquid. Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used.

Beyond Use Date*: Shelf Life after Opening

All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted MMR may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 8 hours. Do not freeze or expose reconstituted vaccine to freezing temperatures. Protect reconstituted vaccine from light at all times. Agitate stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted MMR vaccine if it is not used within 8 hours.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between -58°F and +46°F (-50°C and +8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

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

Special Instructions

MMR vaccine can be stored in the refrigerator or freezer. Consider storing MMR in the freezer between -58°F and +5°F (-50°C and -15°C).

- Storing MMR in the freezer can free up storage space in the refrigerator. More vaccines must be stored in the refrigerator than in the freezer. Storing MMR in the freezer increases the space available for vaccines that should be stored in the refrigerator.
- In addition, storing MMR in the freezer can decrease confusion when stocking both MMR and MMRV (ProQuad). MMRV must be stored in the freezer. MMRV has been inadvertently moved to the refrigerator storage because staff confused it with MMR. Storing MMR and MMRV in the freezer decreases the likelihood of this happening.

MMR may be stored and/or transported in an insulated container between 35°F and 46°F (2°C and 8°C). Place a calibrated thermometer in the container with the vaccine. Monitor and record the temperature. **Use of dry ice is not recommended**, even for temporary storage. Dry ice may subject MMR vaccine to temperatures colder than -58°F (-50°C).

Providers can have different products or presentations containing the same vaccine in the storage unit, for example, MMR and MMRV (ProQuad) vaccines. Vaccine

products and presentations often have different approved indications and uses (e.g., ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

Meningococcal Vaccines

MCV4: Menactra, Menveo

Condition upon Arrival

Meningococcal conjugate vaccine (MCV4) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from other uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

- **Menveo has 2 components.** The lyophilized Men A vaccine and the diluent (Men C, Y, W-135) vials should arrive packaged together in the same shipping container.

Storage Requirements

Refrigerate vaccine and diluent, if applicable, immediately upon arrival. Do not freeze or expose to freezing temperatures.

- **Menactra: Refrigerate between 35°F and 46°F (2°C and 8°C).**
- **Menveo: Refrigerate the lyophilized Men A vaccine and vaccine diluent (Men C, Y, W-135) together between 35°F* and 46°F (2°C and 8°C)**. Do not store them separately. Protect Menveo from light at all times by storing in the original box.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe of the vaccine AND diluent, if applicable. Do not use vaccine or diluent after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **Menactra:** This vaccine is a clear to slightly cloudy liquid.
- **Menveo:** This vaccine is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine**. Refer to the Resources section at the end of this document for an example of a label and the educational handout “Vaccines with Diluents: How to Use Them”.
  1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized vaccine component.
  2. Shake the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation
  3. The reconstituted vaccine should be a clear, colorless liquid.

Beyond Use Date*: Shelf Life after Opening

Menactra: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
Menveo: All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted Menveo may be stored at or below 77°F (25°C) for up to 8 hours. Do not freeze or expose reconstituted vaccine to freezing temperatures. Protect from light. Agitate any stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted Menveo vaccine if it is not used within 8 hours.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer

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

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). For example, meningococcal vaccines (MCV4 and MPSV4) can be confused when stored in the same storage unit. Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications, and/or route of administration can help prevent vaccine administration errors. Refer to the Resources sections at the end of this document for examples of labels.

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Meningococcal Vaccines

MPSV4: Menomune

Condition upon Arrival

Meningococcal polysaccharide vaccine (MPSV4) has 2 components: lyophilized vaccine and diluent. MPSV4 should arrive packed in an insulated container. Both components should arrive packaged together in the same shipping container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine and diluent in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from other uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate the lyophilized vaccine and diluent immediately upon arrival. **Store the lyophilized vaccine and diluent between 35°F and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container or vial of the vaccine AND diluent. Do not use vaccine or diluent after the expiration date shown on the label.

Preparation

MPSV4 is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute

it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for an example of a label and the educational handout "Vaccines with Diluents: How to Use Them". This vaccine should not be combined or mixed with any other vaccines. The Resources section at the end of this document also includes vaccine administration information.

1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized vaccine component.
2. Swirl the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
3. The reconstituted vaccine should be a clear, colorless liquid. Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted MPSV4 vaccine may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 30 minutes. Agitate any stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted MPSV4 vaccine if it is not used within 30 minutes.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

Multidose Vials: Shake well prior to withdrawing each dose. Withdraw a single dose (0.5 mL) of vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).**

- **Once entered, the multidose vial of MPSV4 should be discarded after 35 days.**

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer

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

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages, route). For example, meningococcal vaccines (MCV4 and MPSV4) can be confused when stored in the same storage unit. Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications and route of administration can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

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Pneumococcal Vaccines

PCV13: Prevnar 13
PPSV23: Pneumovax 23

Condition upon Arrival

Pneumococcal vaccines (PCV13, PPSV23) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C)**. Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **PCV13:** During storage, the aluminum phosphate particles may settle, and this can result in a clear liquid solution above the aluminum phosphate particles. Just before use, shake VIGOROUSLY. After shaking, PCV13 is a white liquid. Do not use the vaccine if it cannot be resuspended with thorough agitation.
- **PPSV23:** Just before use, shake vial well. After shaking, PPSV23 should be a clear, colorless liquid. Do not use the vaccine if it cannot be resuspended with thorough agitation.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time of administration.
Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.
PPSV23 Multidose Vials: Shake vial well prior to withdrawing each dose. Withdraw a single dose (0.5 mL) vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).** A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

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

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). For example, pneumococcal vaccines (PCV13 and PPSV23) can be confused when stored in the same storage unit. Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section of this document for examples of labels.

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Poliovirus-Containing Vaccine

IPV: IPOL

Note: Information pertaining to DTaP-IPV (KINRIX) can be found on page 11
Information pertaining to DTaP-IPV/HepB (Pediarix) can be found on page 11
Information pertaining to DTaP-IPV-Hib (Pentacel) can be found on page 11

Condition upon Arrival

Inactivated polio vaccine (IPV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C)**. Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. This vaccine should not be

combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed or needle attached) at the time the vaccine is administered. **Multidose Vials:** Withdraw a single dose (0.5 mL) of vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C)**. A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

*The date or time after which the vaccine should not be used; determined from the date (time) the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

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

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. For example, single antigen and combination vaccines. Vaccine

products and presentations often have different approved indications and uses (e.g. ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

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Rotavirus Vaccines

RV1: ROTARIX
RV5: RotaTeq

Condition upon Arrival

Rotavirus vaccines (RV1, RV5) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

- **RV1 (ROTARIX) has 2 components.** The lyophilized vaccine and diluent should arrive packaged together in the same shipping container.

Storage Requirements

Store the vaccine and diluent, if applicable, according to the manufacturer's guidelines immediately upon arrival. Do not freeze or expose to freezing temperatures. Protect vaccine from light at all times by storing in the original box.

- **RV1 (ROTARIX): Refrigerate lyophilized vaccine between 35°F and 46°F (2°C and 8°C). Store diluent separately at room temperature between 68°F and 77° F (20°C and 25°C).**
- **RV5 (RotaTeq): Refrigerate between 35°F* and 46°F (2°C and 8°C).**

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container or vial of vaccine AND diluent. Do not use vaccine or diluent, if applicable, after the expiration date shown on the label.

Preparation

RV1 and RV5 should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **RV1 (ROTARIX):** This vaccine is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Reconstituted vaccine is a cloudy, white liquid. Refer to the Resources section at the end of this document for an educational handout "Vaccines with Diluents: How to Use Them".
- **RV5 (RotaTeq):** This vaccine is supplied in a single dose squeezable plastic, latex-free dosing tube with a twist off cap. The dosing tube is contained in a pouch

Beyond Use Date*: Shelf Life after Opening

RV1 (ROTARIX): After reconstitution, **administer immediately**. Store unused, reconstituted RV1 in the oral applicator between 35°F and 46°F (2°C and 8°C) or at room temperature up to 77°F (25°C) for up to 24 hours. Agitate any stored, reconstituted vaccine prior to administration. Do not freeze reconstituted vaccine.

- **Do not administer reconstituted RV1 vaccine if it is not used within 24 hours.** Follow the immunization program guidance before discarding VFC or other publicly purchased vaccines. Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

RV5 (RotaTeq): This vaccine should be removed from the refrigerator and the screw cap removed at the time the vaccine is administered. Once the screw cap has been removed, the dosing tube should not be returned to the refrigerator. **Administer immediately.**

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

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

Special Instructions

Providers may have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications and route of administration can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

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Tetanus Toxoid Vaccine

TT: Tetanus Toxoid

Condition upon Arrival

Tetanus toxoid vaccine (TT) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C)**. Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container or vial. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial well. Do not use vaccine if it cannot be resuspended with thorough agitation. This vaccine should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Multidose Vials: Shake vial well prior to withdrawing each dose. Withdraw a single dose (0.5 mL) of vaccine into a sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).** A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

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

Special Instructions

TT vaccine should only be used for tetanus immunization if the person has a severe, life-threatening allergy to the diphtheria component in other tetanus-containing vaccines. For persons 11 years of age and older who need a tetanus toxoid-containing vaccine, the Advisory Committee on Immunization Practices recommends the following:

- Tdap vaccine, if available, is preferred to TT or Td for those not previously vaccinated with Tdap.

- Td vaccine, if available, is preferred to TT for those previously vaccinated with Tdap.
- Tdap or Td vaccines, if neither available, TT should be administered.

Tetanus toxoid-containing vaccines are easily confused increasing the risk for a vaccine administration error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

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Tetanus Toxoid- and diphtheria toxoid-Containing Vaccines

Td: DECAVAC
DT: Diphtheria and Tetanus Toxoid

Condition upon Arrival

Tetanus toxoid- and diphtheria toxoid-containing vaccines (Td; DT) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C)**. Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or

manufacturer-filled syringe well. Do not use vaccine if it cannot be resuspended after thorough agitation. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- After shaking, Td vaccine is a cloudy, whitish-gray colored liquid.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

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

Special Instructions

Diphtheria toxoid- and tetanus toxoid-containing vaccines are easily confused increasing the risk for a vaccine administration error. Consider organizing vaccines

in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

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Tetanus Toxoid-, diphtheria toxoid-, and acellular pertussis- Containing Vaccines

Tdap: Adacel, Boostrix

Condition upon Arrival

Tetanus toxoid-, diphtheria toxoid- and acellular pertussis-containing vaccine (Tdap) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or manufacturer-filled syringe well. Do not use vaccine if it cannot be resuspended after thorough agitation. After shaking, Tdap should be a cloudy, white colored liquid. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.
Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

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

Special Instructions

Diphtheria toxoid- and tetanus toxoid-containing vaccines are easily confused increasing the risk for a vaccine administration error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

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Varicella-Containing Vaccines

VAR: Varivax (chickenpox)
ZOS: Zostavax (herpes zoster/shingles)
MMRV: ProQuad

Condition upon Arrival

Varicella-containing vaccines (VAR, MMRV and ZOS) have 2 components: lyophilized vaccine and diluent. Both components should arrive together in the same shipping container. The vaccine and diluent should be in separate compartments. Examine the shipping container and contents for damage during transport. If the interval between shipment from the manufacturer and arrival of the vaccine at the facility has been more than 3 days or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the freezer between -58°F and +5°F (-50°C and -15°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the manufacturer and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Store the lyophilized vaccine and diluent according to the manufacturer’s guidelines immediately upon arrival. Do not store lyophilized vaccine and diluent together.

Lyophilized vaccine: Store lyophilized vaccine in the freezer between -58°F and +5°F (-50°C and -15°C). Protect vaccine from light at all times by storing in the original box. Vaccine should only be stored in freezers or refrigerator/freezer units with separate compartments and exterior doors.

Diluent: Store separately from lyophilized vaccine in the refrigerator between 35°F* and 46°F (2°C and 8°C) or at room temperature between 68°F and 77°F (20°C and 25°C). Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2˚C is exactly converted to 35.6˚F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container or vial of the vaccine AND diluent. Do not use after the expiration date shown on the labels.

Preparation

These vaccines must be reconstituted before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for examples of labels and the educational handout "Vaccines with Diluents: How to Use Them". These vaccines should not be combined or mixed with any other vaccines. The Resources section at the end of this document also includes vaccine administration information.

1. Just before use, withdraw the entire contents of the diluent vial and inject it slowly into the vial containing the lyophilized vaccine vial.
2. Gently shake or agitate the vial now containing the lyophilized vaccine and diluent to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
3. Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Reconstituted vaccine should have the following appearance:
   - VAR: Clear, colorless to pale yellow liquid.
   - ZOS: Semi-hazy to translucent, off white to pale, yellow liquid.
   - MMRV: Pale yellow to light pink, clear liquid.

Beyond Use Date*: Shelf Life after Opening

All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted varicella and MMRV vaccines may be stored at room temperature between 68°F and 77°F (20°C and 25°C) for up to 30 minutes. Protect from light. Do not freeze or exposed reconstituted vaccine to freezing temperatures. Agitate any stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted varicella-containing vaccine (VAR, ZOS, MMRV) if it is not used within 30 minutes.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Varicella-containing vaccines exposed to temperatures outside the recommended range **require immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the freezer between -58°F and +5°F (-50°C and -15°C). Any freezer that has a separate sealed freezer door and reliably maintains a temperature between -58°F and +5°F (-50°C and -15°C) is acceptable for storage of varicella-containing vaccines.
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

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

Special Instructions

In order to maintain temperatures between -58°F and +5°F (-50°C and -15°C), it will be necessary in most combination 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 will be necessary to avoid freezing vaccines stored in the refrigerator.

"Dormitory-style" refrigerator/freezer is not appropriate for the storage of varicella-containing vaccines. A dormitory-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

CDC and the vaccine manufacturer do not recommend transporting varicella-containing vaccines. If varicella-containing vaccines must be transported, CDC recommends transport with a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C). Portable freezers may be available

for rent in some places. If varicella-containing vaccines must be transported and a portable freezer unit is not available complete the following actions:

Varicella-containing vaccines may be transported at refrigerator temperature between 36°F and 46°F, (2°C and 8°C) for up to 72 continuous hours prior to reconstitution.

1. Place a calibrated thermometer in the container used for transport as close as possible to the vaccine.
2. Record:
   a. the time the vaccine was removed from the storage unit and placed in the container
   b. temperature during transport
   c. document the time and temperature at the beginning and end of transport
3. According to the vaccine manufacturer, **immediately** upon arrival at the alternate storage facility:
   a. **place the vaccine in the freezer between -58°F and +5°F (-50°C and -15°C)**. Any freezer that has a separate sealed freezer door and reliably maintains a temperature between -58°F and +5°F (-50°C and -15°C) is acceptable for storage of varicella-containing vaccines.
   b. document the time the vaccine was removed from the container and placed in the alternate storage unit.
   c. note that this is considered a temperature excursion, so **contact the manufacturer at 1-800-637-2590 for further guidance**.
4. Do not discard vaccine without contacting the manufacturer and/or the immunization program for guidance.

Use of dry ice is not recommended, even for temporary storage or emergency transport. Dry ice may subject varicella-containing vaccine to temperatures colder than -58°F (-50°C).

Providers can have different products or presentations containing the varicella-containing vaccines in the storage unit. For example, single antigen and combination vaccines. Vaccine products and presentations often have different approved indications and uses (e.g., ages, route). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors.

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CDC Resources

Advisory Committee on Immunization Practices U.S. VACCINE ABBREVIATIONS
http://www.cdc.gov/vaccines/recs/acip/downloads/vac-abbrev.pdf

Epidemiology and Prevention of Vaccine-Preventable Diseases 12th Edition Storage and Handling Chapter 5
http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/vac-storage.pdf
Storage and Handling Resources Appendix C
http://www.cdc.gov/vaccines/pubs/pinkbook/pink-appendx.htm#appc
Vaccine Administration Appendix D
http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-d.pdf

Epidemiology and Prevention of Vaccine-Preventable Disease Course Session 2 includes vaccine storage and handling information
http://www.cdc.gov/vaccines/ed/epivac/default.htm

General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)
http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf

Storage and Handling web page
http://www.cdc.gov/vaccines/recs/storage/default.htm

Storage and Handling ToolKit
http://www2a.cdc.gov/vaccines/ed/shtoolkit/

Vaccine Label Examples
http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-labels.pdf

Vaccine Administration web page
http://www.cdc.gov/vaccines/recs/vac-admin/default.htm

Other Resources

Alliance for Immunization in Michigan (AIM) Provider ToolKit
www.aimtoolkit.org

Storage and Handling Materials
http://www.aimtoolkit.org/vaccine.php
Vaccine Administration Materials
Children
http://www.aimtoolkit.org/children.php
Adolescents
http://www.aimtoolkit.org/adolescents.php
Adults
http://www.aimtoolkit.org/adults.php

EZIZ- California Vaccines for Children (VFC) Program
www.eziz.org

Storage and Handling Educational Video
http://eziz.org/eziz-training/
Storage and Handling Job Aides
http://eziz.org/resources/materials_storageandhand.html
Vaccine Administration Educational Video
http://eziz.org/eziz-training/
Vaccine Administration Job Aides
http://eziz.org/resources/vaccine-admin-job-aids/

Immunization Action Coalition (IAC)
www.immunize.org

Handling and Storage Resources
http://www.immunize.org/handouts/vaccine-storage-handling.asp
Handling and Storage FAQ's
http://www.immunize.org/askexperts/experts_general.asp
Checklist for Safe Vaccine Storage and Handling
http://www.immunize.org/catg.d/p3035.pdf
Don't be Guilty of These Errors in Vaccine Storage and Handling
http://www.immunize.org/catg.d/p3036.pdf
Emergency Response Worksheet
http://www.immunize.org/catg.d/p3051.pdf

Skills Checklist for Immunization
http://www.immunize.org/catg.d/p7010.pdf
Temperature Logs for Refrigerator and Freezer:
Celsius http://www.immunize.org/catg.d/p3039a.pdf
Fahrenheit http://www.immunize.org/catg.d/p3039.pdf
Vaccines with Diluents: How to Use Them
http://www.immunize.org/catg.d/p3040.pdf
Vaccine Handling Tips
http://www.immunize.org/catg.d/p3048.pdf
Vaccine Administration Resources
http://www.immunize.org/clinic/administering-vaccines.asp
Vaccine Administration FAQ's
http://www.immunize.org/askexperts/experts_general.asp#admin
Administering Vaccines: Dose, Route, Site, and Needle Size
http://www.immunize.org/catg.d/p3085.pdf
How to Administer IM and SC Injections
http://www.immunize.org/catg.d/p2020.pdf
Manufacturer's Product Information
http://www.immunize.org/packageinserts/

Thermal Analysis of Refrigeration Systems Used for Vaccine Storage
http://www.nist.gov/customcf/get_pdf.cfm?pub_id=904574

State Immunization Program Information

State Immunization Program Websites
http://www.cdc.gov/vaccines/spec-grps/prog-mgrs/grantee-imz-websites.htm

Manufacturer / Distributor Websites	Telephone Number/E-mail	Products
Centers for Disease Control and Prevention www.cdc.gov/ncidod/srp/drugs/drug-service.html http://www.cdc.gov/laboratory/drugservice/index.html	404-639-3670/ drugservice@cdc.gov	Distributor for diphtheria antitoxin, VIG, smallpox vaccine
GlaxoSmithKline (GSK) http://www.gskvaccines.com/	866-475-8222	DTaP, DTaP-HepB-IPV, DTaP-IPV, HepA, HepB, HepA-HepB, HPV2, RV1, Tdap, TIV
Massachusetts Biological Labs http://www.umassmed.edu/massbiolabs/index.aspx	617-474-3000	IGIM, Td, TT
MedImmune http://www.medimmune.com/	877-633-4411 medinfo@medimmune.com	LAIV
Merck & Co., Inc https://www.merckvaccines.com/	800-637-2590	HepA, HepB, Hib, Hib-HepB, HPV4, MMR, MMRV, PPSV23, Td, TIV, VAR, ZOS
Biotest Pharmaceuticals http://www.biotestpharma.com/products/nabiHB.html	800 458-4244 ma@biotestpharma.com	HBIG
Novartis http://www.novartisvaccines.com/us/index.shtml	877 683-4732 Vaccineinfo.us@novartis.com	TIV
Pfizer/Wyeth http://pfizerpro.com/	800-438-1985	PCV13
Sanofi Pasteur https://www.vaccineshoppe.com/	800-822-2463	DT, DTaP, DTaP-IPV/Hib, Hib, IPV, MCV4, MPSV4, Rabies, RIG, Td, Tdap, TIV, TT
Talecris Biotherapeutics http://www.talecris.com/talecris-biotherapeutics-us-home.htm	800-520-2807 talecris@medcomsol.com	HBIG, IGIM, RIG, TIG

Vaccine Storage and Handling

INTERIM GUIDANCE

Introduction

In response to recent scientific studies[i] on equipment used for vaccine storage and a better understanding of best practices for vaccine storage and handling, the Centers for Disease Control and Prevention (CDC) is providing interim guidance on appropriate vaccine storage and handling practices. This guidance is intended for use by all public and private sector providers and, while recognizing that cost may be a barrier, we encourage practices to move toward implementing these recommendations as soon as possible. CDC is currently evaluating the most efficient and cost effective method to phase these recommendations in and more guidance is forthcoming.

With the goal of improving the way providers store and handle vaccines nationwide, several important changes have been made to previous recommendations issued by CDC, including:

1. Use of a biosafe glycol-encased probe or a similar temperature buffered probe rather than measurement of ambient air temperatures, and;
2. Use of digital data loggers with detachable probes that record and store temperature information at frequent programmable intervals for 24 hour temperature monitoring rather than non-continuous temperature monitoring, and;
3. Use of stand-alone refrigerator and stand-alone freezer units suitable for vaccine storage rather than combination (refrigerator+freezer) or other units not designed for storing fragile biologics, such as vaccines, and;
4. Discontinuing use of dorm-style or bar-style refrigerator/freezers for ANY vaccine storage, even temporary storage, and;
5. Weekly review of vaccine expiration dates and rotation of vaccine stock.

More detail regarding these changes and the rationale behind them is included below.

Biosafe Glycol-Encased Probes or Similar Temperature Buffered[1] Probes

CDC recommends use of a digital thermometer with a biosafe glycol-encased probe or a similar temperature buffered probe that will more closely approximate the measure of liquid temperature. A temperature buffer enables a thermometer probe to more closely match the temperature changes experienced by stored vaccine. Examples of temperature buffers are a probe inserted into a glycol-filled vial or one inserted into glass beads. CDC recommends this type of probe because studies by the National Institutes of Standards and Technology (NIST), U .S. Dept of Commerce [i] conducted in 2009 showed that compared to temperature monitors that measure ambient air temperature, the digital thermometer with glycol-encased probe more accurately reflects the temperature of the vaccine vial and does not register normal air temperature fluctuations which do not significantly impact vaccine temperature. Because the main factor affecting potency of refrigerated vaccines is exposure to freezing temperatures, it is important that glycol-encased or similar temperature buffered probes be placed among the vaccines instead of on a wall, and at least for refrigerated vaccines, in the part of the refrigerator unit where manufacturer recommended vaccine storage temperatures can best be maintained. To ensure validity of temperature measurements, only calibrated thermometers with a certificate of Traceability and Calibration should be used. Calibrated thermometers will continue to be a requirement for providers who receive VFC vaccine.

Digital Data Loggers for Temperature Monitoring

In addition to the use of a digital thermometer with a biosafe glycol-encased or similar temperature buffered probe, the thermometer should also be able to provide and store data monitoring information set at programmable intervals in an active display that allows for reading temperatures without opening the unit door. This means that the digital data logging thermometer probe should be able to remain in place and not be disturbed during data reading and recording. A detachable probe facilitates downloading temperature data without removing the probe from the storage unit, and should simplify daily use and minimize operator cause of temperature variability. The digital data logger should also include the following:

- Hi/Lo alarm for out-of-range temperatures;
- Current temperature, as well as minimum and maximum temperatures;
- Reset button ;

[1] The purpose of a temperature buffer is to slow the response time of the probe to temperature changes so that it matches the temperature changes experienced by the vaccine.

- Low battery indicator;
- Accuracy of +/- 1°F (0.5°C);
- Memory storage of at least 4000 readings, device will not rewrite over old data and stops recording when memory is full;
- User programmable logging interval (or reading rate).

These changes in the use of systems for continuous temperature monitoring mean more accurate and comprehensive monitoring of any temperature excursions to which vaccines may have been exposed, and diminish the need for opening the unit door while conducting this routine monitoring. Finally, it is a requirement for VFC providers and a recommendation for all providers that storage unit temperatures continue to be read and documented twice each workday. It is recommended that minimum/maximum temperatures be checked and documented once per day preferably in the morning. Reviewing the minimum/maximum temperatures helps to ensure that temperature excursions will be identified more quickly and corrections made that can prevent vaccine loss, as well as minimize the inaccuracy of generalizing twice daily measurements.

Stored temperature monitoring data should be downloaded and reviewed at least weekly by providers, both to ensure the timely review of the data and the appropriate response to issues. When the data is downloaded, the data logger should be reset so there is sufficient memory available. The downloaded information should be kept for a minimum of 3 years or according to individual state record retention requirements. These practices ensure that the data logger will continue to function properly with sufficient memory for accurate monitoring and that problems with storage equipment can be identified and corrected early.

Stand-Alone Refrigerator and Stand-Alone Freezer Units

CDC strongly recommends the use of stand-alone refrigerator and stand-alone freezer units, meaning a self-contained unit that only refrigerates or freezes and is suitable for vaccine storage. These units can vary in size, from a compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit. CDC does not recommend use of dormitory[2] or bar-style refrigerator/freezers for ANY vaccine storage. The use of these specific refrigerator/freezers is not allowed at any time for Vaccines for Children (VFC) program providers.

[2] Dormitory-style or bar-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. Please note that there are compact, purpose-built storage units for biologics that are not considered to be dormitory-style or bar style.

The characteristics of a recommended storage unit include: 1) enough room to store the year's largest inventory without crowding and 2) sufficient room to store water bottles in the refrigerator and frozen coolant packs in the freezer to stabilize the temperature and minimize temperature excursions that can impact vaccine potency. The addition of water bottles (not gel packs) reduces the risk of freezing due to the tremendous latent heat released from water prior to freezing. In addition, frost-free or automatic defrost cycle units are preferred. Because freezing of refrigerated vaccines affects vaccine potency more than other exposure problems, it is especially important that refrigerators be selected and set up in a way that eliminates the chance of freezing vaccine. Use of stand-alone units is a best practice. Studies by NIST[i] show that 1) dormitory-style or bar-style combination units pose a significant risk of freezing vaccine even when used for temporary storage, and 2) the usual house-hold single-condenser combination refrigerator/freezer units are less capable of simultaneously maintaining proper storage temperatures in the refrigerator and freezer compartments. These refrigerators are cooled by venting cold freezer air into the refrigerated section – thus a real risk of freezing vaccine near the cooling vents. An alternative to stand-alone units is to use only the refrigerator compartment of a combination household refrigerator/freezer unit to store refrigerated vaccines and to be very careful not to use the top shelf if the vent from the freezer opens there. A separate stand-alone freezer should then be used to store frozen vaccines; this is because the freezer compartment of a combined house-hold unit should not be used for vaccine storage if the refrigerator unit is being used for that purpose.

Procedures for Efficient Management of Vaccines

Each provider practice (each location) should have written storage and handling plans, updated annually, both for routine storage and handling of vaccines, and for emergency vaccine retrieval and storage. Plans for routine storage and handling of vaccines should include detailed descriptions of the procedures for: 1) ordering and accepting vaccine deliveries; 2) storing and handling vaccines (e.g., ensuring that refrigerated vaccines are stored between 35°F and 46°F [2°C and 8°C] and frozen vaccines between -58°F and +5°F [-50°C and -15°C]); 3) managing potentially compromised vaccines (i.e., vaccine that has been exposed to temperatures outside of the recommended range defined above); 4) managing vaccine inventory (e.g., checking vaccine and diluent expiration dates weekly and removing expired items from usable stock); and 5) downloading and reviewing electronic monitoring data weekly.

Another necessary component of good practice is ensuring adequately trained vaccination personnel at all levels. This includes personnel that can serve as designated primary and back-up vaccine coordinators, both permanent and temporary staff who are familiar with proper storage and handling policies and procedures, comprehensive storage and handling training for both new staff and maintaining competence of current staff, and accountability checks to ensure protocols are followed. It is also important that a physician partner or member of management is directly involved with the responsible clinical staff – someone with a clear understanding of the vaccine replacement costs of miss-managed refrigerators and vaccine.

Frequently Asked Questions (FAQs) regarding this Interim Guidance are available on our website. The changes summarized in this Interim Guidance will also be reflected in a comprehensive update of CDC's Vaccine Storage and Handling Toolkit (target date for publication Fall 2012). In addition, CDC's posted guidance will continue to be updated as necessary to reflect best practices on vaccine storage and handling. For example, ongoing and planned studies with NIST, U.S. Department of Commerce are being conducted to better understand areas such as optimizing frequency of checking temperature recording by data loggers and packing of vaccine vial boxes for transport.

Thank you and please direct any questions to NIPINFO@cdc.gov

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[i] NISTIR 7656 "Thermal Analysis of Refrigeration Systems Used for Vaccine Storage", Michal Chojnacky, Wyatt Miller, Dean Ripple, Gregory Strouse CSTL November 2009
NISTIR 7753 Michal Chojnacky, Wyatt Miller, Gregory Strouse. Thermal Analysis of Refrigeration Systems Used for Vaccine Storage, PML, September 2010

Chart of Refrigerated/Frozen Pack Needs for Different Climates

Outside Temperature	Number of Faces* Covered with Packs	Temperature of Packs	Comment**
Greater than 75°F to 110°F (greater than 24°C to 43°C)	2***	23°F (-5°C)	Up to 48 hours delivery with 10 hours at 110°F (43°C)
32°F to 75°F (0°C to 24°C)	2***	23°F (-5°C)	Up to 48 hours delivery
	4	41°F (+5°C)	Up to 24 hours delivery
Colder than 32°F (°C)	4 to 6****	50°F (+10°C)	About 24 hours exposure to mix of outdoors and heated areas
0°F (-18°C) or colder	6****	68°F (+20°C)	Prolonged, 24 to 48 hours continuous exposure to 0°F (-18°C)

* Faces would include the interior surfaces of the box, including the walls, floor and lid (above the vaccines and insulating material).

** Applies when high quality insulated boxes with walls of 1¾ inches to 2¼ inches expanded polystyrene, 1 inch isocyanurate, or 3 inches polyurethane insulation were used.

*** 3 for the medium-sized box tested by CDC (10x10x7 inches—interior dimensions).

**** Essentially the entire surface area is covered with packs.

Refrigerated/Frozen Packs.

Transporting Refrigerated Vaccine

Guidelines for vaccine transport and short-term storage

- The procedure below for packing vaccine will keep all vaccines (**except varicella vaccine**) within recommended temperatures for 12 hours during transport and/or storage at room temperatures (inside a car, building, etc.). It will also maintain recommended temperatures if the cooler is exposed to outside temperatures as low as -4°F for one of those 12 hours.
- If the vaccine will be stored in refrigerators after transport, be sure those refrigerators have maintained temperatures between 35°F and 46°F for at least 3 to 5 days.

Assemble packing supplies

1. **Cooler.** Use hard plastic Igloo-type coolers.
   Attach a "Vaccines: Do Not Freeze" label to the cooler.
2. **"Conditioned" cold packs.** Condition frozen gel packs by leaving them at room temperature for 1 to 2 hours until the edges have defrosted and packs look like they've been "sweating." Cold packs that are not conditioned can freeze vaccine. **Do not use dry ice.**
3. **Thermometer.** Prepare the thermometer by placing it in the refrigerator at least 2 hours before you pack the vaccine.
4. **Packing material.** Use two 2-inch layers of bubble wrap.
   Not using enough bubble wrap can cause the vaccine to freeze.

Pack vaccine

1. Cold packs

Spread conditioned cold packs to cover only half of the bottom of the cooler.

2. Bubble wrap & Thermometer

Completely cover the cold packs with a 2-inch layer of bubble wrap.
Then, place the thermometer/probe on top of the bubble wrap directly above a cold pack.

3. Vaccine

Stack layers of vaccine boxes on the bubble wrap. Do not let the boxes of vaccine touch the cold packs.

4. Bubble wrap

Completely cover the vaccine with another 2-inch layer of bubble wrap.

5. Cold packs

Spread "conditioned" cold packs to cover only half of the bubble wrap. Make sure that the cold packs do not touch the boxes of vaccine.

6. Form & display

Fill the cooler to the top with bubble wrap. Place the thermometer's digital display and the *Return or Transfer of Vaccines Report* form on top. It's ok if temperatures go above 46°F while packing.

As soon as you reach the destination site, check the vaccine temperature. If the vaccine is:

- Between 35°F and 46°F, put it in the refrigerator.
- Below 35°F or above 46°F, contact your VFC Rep or the VFC program immediately **(800) 848-3868**
  Then label the vaccine "Do Not Use" and put it in the refrigerator.

Georgia Department of Public Health
Brenda Fitzgerald, MD, Commissioner Nathan Deal, Governor
2 Peachtree St. NW, 15th Floor
Atlanta, Georgia 30303-3142
www.health.state.ga.us

Dear Vaccines for Children (VFC) Provider,

All vaccine received from the Vaccines for Children Program must always be accounted for. This includes doses administered and inventory as well as wasted and expired vaccine. Your office is required to report doses wasted or expired on the Federal Return of Vaccine Form which begins the processing of your return request. Once returns have been approved, McKesson will ship your site a return UPS return label. Returns should be boxed properly to ensure safe transit of the vials. Since the doses are no longer viable, ice packs and dry ice are unnecessary. Simply, box up the vaccine to be returned, place the return label on top of the box, and give it to the UPS driver the next time s/he is in your office. There is no need to schedule a pickup. If you would specifically like a pickup scheduled, please call our office at (404) 657-5013.

You are encouraged to send returns every three to six months. Return requests are processed and screened to ensure that your office has collected a large amount of vaccines prior to approval of the return request. Until you are ready to return vaccines, remember to clearly label wasted or expired vaccine **"DO NOT USE"** and store it securely and outside of the refrigerator to avoid accidental administration of non-viable vaccine.

What should be included in the return?

- At least one full shipping box of vaccines (use McKesson shipping boxes as a size gauge)
- Full vials of unused vaccine
- Appropriate padding to protect vials from breaking
- Federal Return Form (also fax to the VFC office)
-

What should not be included in the return

- Needles or syringes with needles
  (vaccine that has been drawn into a syringe should be wasted on-site, not returned.)

- Broken or partially used vials (including partially used multi-dose vials)
- Paperwork or other reports intended for VFC
- Any other objects

Remember –NEEDLES should NEVER be returned to McKesson!

Contact VFC with questions at (404) 657-5013

GEORGIA IMMUNIZATION PROGRAM
McKesson Return of Federal Vaccine Form

Date: _____ VFC PIN: _____

Contact Person _____

Provider Name _____

Address _____

_____

Phone # _____

Fax # _____

All nonviable vaccines must be returned to McKesson for excise tax credit processing.

To return wasted/expired vaccine to McKesson, follow these steps:

1. Fax a copy of the completed McKesson Return of Federal Vaccine Form to VFC at (404) 657-5736 or outside Metro Atlanta at (800) 372-3627. **Faxing this form will initiate a request for a return label.**

If you call UPS or FedEx directly, you will be charged for the retrieval of the box(es).

2. Returns can be sent in the McKesson shipping container or a container of your own. If you use your own container, ensure that vials are secure (so that they don't break during transport).

3. You must include a copy of the completed McKesson Return of Federal Vaccine Form in the box with the non-viable vaccines that are to be returned to McKesson.

4. Keep a copy of this form for your records.

* Do not return H1N1 vaccine to McKesson. All H1N1 vaccine must be disposed of locally/at your clinic site.

** UPS will pick up all boxes to return to McKesson, even when packages are shipped to you via Fed Ex or DHL.

*** Once you have the label and affix it to the box, simply give to your UPS driver the next time s/he is in your office. A specific pickup is not necessary.

All columns below are required.

NDC # *	Vaccine	# Doses	Manufacturer	Lot #	Expiration Date	Reason Code

* The NDC Number can be found on each individual vaccine vial.

Return Reason Codes:

3 - Spoilage (e.g., Refused or not needed after prepared)
4 - The expiration date has passed
5 - Damaged in transit from McKesson
6 - Failure to store or handle properly (e.g., Vaccine left out overnight)
7 - Refrigeration failure (report to VFC immediately!!!)
11 - Lost or unaccounted for in inventory

This form is for return purposes only.
All wasted/expired/spoiled doses must be listed on the monthly Comprehensive Report.

Rev. 1/2010

Directions: This form must be completed and submitted to the Georgia Immunization Program on a monthly basis. The log must document only the administration of any VFC vaccine to **unaccompanied minors** (through age 18 years of age) because they present **without insurance information**. Please remember that an unaccompanied minor younger than 18 may only independently sign for Hep A, Hep B, and HPV. 18-year olds may sign for all vaccines on their own.

Please keep one copy for your clinic's records and send one to the State Immunization Program to the address or fax number below:

By mail:
Georgia Immunization Program
2 Peachtree St, NW
Suite 13-233
Atlanta, GA 30303
Attention: Crystal Robinson

By email:
crrobinson@dhr.state.ga.us

By FAX:
(404) 657-5736

Title X Unaccompanied Minor without Insurance Information
VFC Vaccine Log

Month: _____ Year: 2012 Site Name: _____ GIP/VFC ID #: _____

Date Administered	Patient's Age	Mark VFC Vaccines Administered											
					age 18 only								
		HPV	Hep A	Hep B	Flu	Hep AB	MCV4	MMR	Pneumo	Td	Tdap	Varicella	
TOTALS													

(enter total number of patients seen in first box)

Georgia Immunization Office

Centralized Distribution Information and Instructions for Public Health Providers

Revised 2/2012

Troubleshooting Problems / Issues	Instructions
You have a change in your vaccine delivery address, days, and/or hours available for vaccine deliveries. Your office/clinic will be closed for an extended period of time. Your office hours change at all (this includes unscheduled days that the office is closed or you are unable to receive vaccines).	Notify your **PPOC (Project Point of Contact)** prior to placing you vaccine order. **Your PPOC is: Crystal Robinson** **Vaccines for Children Program** **(404) 657-5013** **crrobinson@dhr.state.ga.us**
You receive a partial vaccine shipment. (i.e.; missing doses, vaccine, or diluent – MMR/Varicella)	Notify your PPOC on Day 1 of the partial shipment.
You receive more vaccines than were ordered. You received vaccines that you did not order.	Notify your PPOC who will arrange for vaccine transfer between providers. **Viable vaccine cannot be returned to McKesson.**
The temperature monitor is tripped, or you suspect the vaccine shipment was compromised in any way.	Follow the instructions for the interpretation of the temperature monitors. The instructions will be attached to the **two** temperature monitors located in each vaccine shipment box. If there are any questions about how to interpret the temperature monitor readings or you suspect the shipment is compromised in any way: 1. Label the vaccines "Do Not Use" and continue to store them at recommended temperatures until a final determination is made. 2. Immediately contact the VFC Vaccine Logistics Associate, Shelena King, for further instructions. McKesson must be contacted by VFC within 2 hours of vaccine receipt.
You have nonviable vaccines that need to be returned.	**1.** Fax a copy of the completed McKesson Return of Federal Vaccine Form to VFC at (404) 657-5736 or outside Metro Atlanta at (800) 372-3627. **2.** Returns can be sent in the McKesson shipping container or a container of your own. If you use your own container, ensure that vials are secure (so that they don't break during transport). **3.** You must include a copy of the completed McKesson Return of Federal Vaccine Form in the box with the non-viable vaccines that are to be returned to McKesson. **4.** Keep a copy of this form for your records. * UPS will pick up all boxes to return to McKesson, even when packages are shipped to you via Fed Ex

	or DHL. ** Once you have the label and affix it to the box, simply give to your UPS driver the next time s/he is in your office. Scheduling a specific pickup is not necessary. Your UPS driver can pick up the return during their regular visit(s) to your practice. **If you call UPS directly to schedule a pick up, you may be charged.**

Other Important Information

- **McKesson is no longer accepting returns of vaccine shipping cartons.** Providers are encouraged to keep one or two cartons on hand in the event an emergency occurs or vaccine needs to be transferred. Please check to see if there is a local recycling program in your area.

- It is imperative that you continue to submit monthly comprehensive reports. Make sure to notify your PPOC of any changes to hours, address, contact, etc.

- You must immediately open all vaccine packages, check the temperature monitor devices, inspect the vaccines and store them at the appropriate temperatures once the package is delivered.

- Direct-ship vaccines, such as varicella, will continue to be shipped by the manufacturer, not McKesson.

- Influenza vaccine may arrive in separate shipments.

- During periods of vaccine shortage, vaccine may be shipped incrementally throughout the month and may arrive in separate shipments.

Vaccine Shipping Timeframes

Vaccine deliveries may take from one to two weeks to arrive at your location. At the time your order is placed, please ensure that your available delivery times are up to date and that you have at least 2-3 month's supply of vaccine on hand to decrease the likelihood of running out of vaccine in the event of a prolonged delivery time.

State of Georgia Immunization Office
Georgia Department of Public Health

VACCINES FOR CHILDREN (VFC) PROGRAM

Routine and Emergency Vaccine Handling Plans

Practice Name:		VFC PIN/GIP ID #	
Effective Date		Annual Review Date	
Approved By		Date Approved	

These are guidelines to follow in developing routine and emergency vaccine handling plans. They should be posted near your storage unit or where they can be easily accessed in case of an emergency. All office staff, including the janitor and security guard, should know the standard procedure to follow and where/how the individual vaccines are to be stored.

☐ Designate two people responsible for routine vaccine storage and security (keep current as staff changes):

Primary Person: _____ Title: _____

Secondary Person: _____ Title: _____

☐ Vaccine Ordering will be done **monthly** on the _____ day of each month.

Primary Person: _____ Title: _____

Secondary Person: _____ Title: _____

☐ Maintain proper temperature for storage of vaccine of vaccine:

Unit	Fahrenheit (F)	Celsius (C)
Refrigerator	35° - 46°F	2° - 8°C
Freezer	5° or colder	-15°C or colder

☐ Monitor temperatures and record twice a day: morning and evening. (See Temperature Log)
☐ Maintain ongoing file of temperature logs. Keep for at least three years. Immediately take action if temperatures are out of range. Document what was done to ensure vaccine viability as well as action taken to establish proper temperatures on the Provider Temperature form. Complete the "Vaccine Incident Report" and fax to the VFC office at: (800) 372-3627 or (404) 657-5736
☐ Immediately unpack received vaccines and store at proper temperature.
☐ Label VFC/State Supplied vaccines and store separately from private supply.
☐ Store and rotate vaccines according to expiration dates and use vaccines with the shortest expiration dates first.
☐ Conduct monthly inventory count.
☐ Vaccines expiring within 90 must be reported to the VFC Program via e-mail at: gavfc@dhr.state.ga.us to avoid possible replacement according to the VFC Loss Policy.
☐ Check the unit doors to ensure they are closed and, if possible, locked.
☐ Place "DO NOT UNPLUG" stickers/notices next to outlet and circuit breaker.
☐ Use safety outlet covers where possible.
☐ Advise maintenance and cleaning personnel not to unplug refrigerator/freezer units.
☐ If public (VFC/State Supplied) vaccine is expired, wasted or spoiled: complete the Georgia Immunization Office "McKesson Return of Federal Vaccine Form" and fax to the VFC office at: (800) 372-3627 or (404) 657-5736.

Emergency Vaccine Handling/Storage Plan – Notify VFC Office and/or IPC of emergency situations ASAP

☐ Designate two people responsible for emergency vaccine storage and security (keep current as staff changes):

☐ How will designated personnel be contacted in vaccine storage emergency? (i.e. phone, alarm, email, etc)

☐ Staff listed below have 24-hour access to storage units storing vaccines:

#	Name	Title	Phone	E-Mail
1.				
2.				
3.				

☐ Designate alternative storage units and facilities (back-up refrigerator, fire dept., hospital, another provider location).

☐ Written directions for packing vaccines and diluents for transport are located: _____

#	Alternate Location	Contact Person	Phone	Address
1.				
2.				

☐ Procedures the designated personnel should follow to access alternative units and facilities.

1. _____
2. _____
3. _____

☐ Designate a refrigerator/freezer repair company to contact for equipment problems.

Company Name: _____

Phone Number: _____

☐ Procedures the designated personnel should follow to access alternative units and facilities.

Brand: _____

Model #: _____

Serial #: _____

NOTE: Georgia Immunization Program Consultant (IPC) staff will ask for a copy of the clinic's vaccine storage & handling plans during on-site visits.

****CDC and the vaccine manufacturer do not recommend transport of varicella-containing vaccines. If varicella-containing vaccines must be transported, CDC recommends transport with a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C). Portable freezers may be available for rent in some places. Contact VFC or your assigned Immunization Program Consultant, prior to transport of Varicella-containing vaccines for specific instructions.***

State of Georgia Immunization Office
Georgia Department of Public Health

Vaccine Incident Report

Follow the procedures below when your publicly purchased vaccine has experienced out-of-range storage temperatures. Use a separate report for each affected storage appliance.

1. Do not use or discard the affected vaccine.
2. Contact the Vaccine Manager or Georgia VFC Staff at 404-657-5013.
3. Isolate the affected vaccine, mark the boxes with an **"X"**, and post a clear **"Do Not Use"** sign.
4. If the situation is temporary or quickly remedied (w/in 3 hours), keep the vaccine in its original storage unit with the door closed.
5. If necessary, move the vaccine to a working storage unit or your emergency storage location. Be sure to monitor temperatures at this location.
6. Contact the Georgia VFC Program (404) 657-5013.
7. Record the following information about the incident:

Facility Name: _____**VFC #**_____

Reported by: _____ **Telephone #**_____**Date Reported**_____

Storage Unit Involved: _____

(Use a separate report for each affected storage appliance.)

- When was the incident discovered? Date_____ Time_____am/pm (circle one)
- Room Temperature at time of discovery: _____C / F
- Temperature of storage unit at time of discovery: Refrigerator_____C / F Freezer_____ C / F
  (Record temperature for refrigerator and freezer if a combined unit.)
- Last known temperature recording prior to incident: Date_____ Time_____am/pm (circle one)
- Temperature at last known recording: Refrigerator_____C or F Freezer_____C or F
  (Record temperature for refrigerator and freezer if a combined unit.)
- Time interval vaccine was exposed to out-of-range temperatures: _____ day's _____hrs_____minutes
  (Estimate the worst case scenario based on last recorded temperatures. If using a data logger, use the graphing function to determine the exact interval.)
- Has the affected vaccine experienced previous temperature excursions? _____Yes _____No

8. Inventory the affected vaccine in columns 1–5 of the Vaccine Inventory Table on page 2 of this form.
9. Contact the manufacturer of the affected vaccine to determine its viability. Use the contact information on page 2. The manufacturer will need the information recorded above to determine vaccine viability. Record the information from the manufacturer in columns 6–8 of the Vaccine Inventory Table.

Vaccine Inventory Table (Copy this page if you need more rows in the table.)

Vaccine Name	Manufacturer	Lot #	Expiration Date	# of Doses	Disposition per Manufacturer (i.e., viable, wasted, exp date changed, etc.)	Call Ref# or Representative's Name	Date of Call

10. If the manufacturer determines the vaccine is viable: a) Mark the date of this report next to the "X" on the package. This indicates that the vaccine has experienced a temperature excursion and references this report; b) If the expiration date of the vaccine has changed, clearly indicate the new expiration date on the package; and c) Return the vaccine to your inventory. Do not return vaccine to a malfunctioning storage unit until it can reliably maintain vaccine storage temperatures.
11. If the manufacturer determines that the vaccine is wasted: a) Fill out a Federal Vaccine Return Form, place a copy of the form in the return box, and fax a copy to the Georgia Immunization VFC Program (404)-657-5736 for processing and to receive a shipping label; c) Account for the vaccine on your Monthly Comprehensive Report.
12. To finish this report, provide the following information: Briefly describe the incident:

    _____

    _____

    _____

    What steps will be taken to prevent this from happening in the future?

    _____

    _____

    _____

13. Once completed, Fax or e-mail this report to the GA Vaccine Manager (Sheila Lovett) at szlovett@dhr.state.ga.us, Fax (404) 657-5736. This report serves as a record of the incident, the steps taken to determine vaccine viability, and the disposition of the affected vaccine.
    Keep a copy for your records.

Vaccine Manufacturer Contact Information

GlaxoSmithKline	866-475-8222	MedImmune	877-633-4411
Merck	800-637-2590	Novartis	800-244-7668
Sanofi Pasteur	800-822-2463	Pfizer	800-879-3477

GA Immunization Office use only

Reviewer's initials/date_____

Corrective Action required _____Yes _____No

Completed initials/date_____

Vaccine Manager sign-off _____

TABLE OF CONTENT

12. TRAVEL INFORMATION*

Foreign Travel Information
Travel and Yellow Fever Vaccination Clinics in Georgia **(REPLACE)**
Vaccines and Biologics Used in U.S. and Foreign Markets (**REMOVE**)
Translation of Foreign Vaccine-Related Terms into English **(REPLACE)**

FOREIGN TRAVEL INFORMATION

In general, U.S. citizens who are up-to-date with regard to the ACIP recommendations do not need any additional immunizations. When advising individuals regarding foreign travel, recommend they check their immunization record to see if they are due to receive any of the vaccines routinely recommended by the ACIP.

The ACIP may recommend other vaccines and prophylaxis with regard to specific itineraries. Therefore, it is important that if you administer vaccines for travel purposes, you have a system for keeping current information regarding travel requirements for specific countries. The ACIP Recommendations notebook provides reasonably detailed information about the vaccines that might be indicated for foreign travel. These recommendations should be referred to for specific vaccine dosage and administration information and guidelines. Additional information resources are included under the Travel Resource Information section.

Certification for International Travel

- The International Health Regulations adopted by the World Health Organization only addresses requirements for Yellow Fever Vaccine.
- Smallpox was deleted as a required vaccine in 1982.
- Many adults are not up-to-date for Tetanus/diphtheria (Td/Tdap) and should consider getting this vaccine for travel anywhere.
- Prophylaxis against malaria is recommended for travel to many parts of the world.
- **Meningococcal vaccination is required by the government of Saudi Arabia for annual travel during the Hajj**
- **International Certificate of Vaccination or Prophylaxis (ICVP):**
  Individual copies are not available. To order, please visit http://bookstore.gpo.gov/collections/vaccination.jsp or call toll-free (866) 512-1800. Packages of 25 are available for $23 and packages of 100 are available for $51.

  Delivery time for orders varies based on shipping options. To have orders shipped via FedEx, please place your order by phone.

For direct travel from the United States only a few countries require certificates. No vaccinations are required for return to the United States.

Certification Requirements for Yellow Fever:

- When Yellow Fever Vaccine is required for travel, an immunization certificate that has been stamped with an official stamp should be issued after the traveler receives his vaccination.

- Certification for Yellow Fever requires one dose of vaccine and is valid for 10 years beginning 10 days after primary vaccination.

Georgia Requirements to Administer Yellow Fever Vaccine

- The Immunization Program of the Georgia Department of Public Health designates sites which may administer Yellow Fever Vaccines.

- To apply to become a designated Yellow Fever site and receive the official stamp for Yellow Fever Vaccination send a request to:

  Georgia Department of Public Health
  2 Peachtree Street, NW, Suite 13.285
  Atlanta GA 30303-3142
  Attention: Yellow Fever Program

FOREIGN TRAVEL INFORMATION

You may also fax a letter of request to: (404) 657-1463. Additional information about the application and stamp can be obtained from Jeanette Ivey at (404) 657-3158.

- Travel vaccine clinics and designated Yellow Fever Vaccination Centers for Georgia are listed in this section and on the Immunization Program website at http://health.state.ga.us/programs/immunization/travel.

How to Obtain Travel Vaccines

The state pharmacy does not purchase and distribute any vaccines or preventive medications that might be recommended for travel. Providers must obtain these from the drug manufacturer.

Travel Resource Information

Travelers and immunization travel clinics may refer to the following resources when seeking information about recommendations and requirements:

- Centers for Disease Control and Prevention
  Fax Information Service.....1-888-232-3299
  Malaria Hotline..... 770-488-7788 **or 1-855-856-4713**
  Internet Address: http://www.cdc.gov (click on Travelers' Health)

- Health Information for International Travel ("The Yellow Book").
  This book is published every 2 years (most recent edition is **2012.)** It contains all immunization requirements, disease risk and precautions, and prevention information for travel to other countries. The book should be used in conjunction with updated sources of information available through the CDC's Fax Information services. It can also be accessed online at http://wwwnc.cdc.gov/travel/page/yellowbook-2012-home.htm

- Epidemiology and Prevention Branch
  Department of Public Health
  Georgia Department of Public Health
  (404) 657-2588

- Immunization Program
  Department of Public Health
  Georgia Department of Public Health
  (404) 657-3158

- The embassies and consulates of the countries to be visited may be of some assistance, as well, especially if certain vaccines are required prior to entry.

Routine Childhood Vaccines by Country

- This information may be accessed from the World Health Organization (WHO) website at http://www.who.int/countries/en
- Select a country, then "Immunization Profile."

Designated Yellow Fever Vaccination Clinics in Georgia

Designated Yellow Fever Vaccination Clinics

International Hot Line for Yellow Fever 1-888-332-4559
CDC Travel Information

- YF — Yellow Fever Vaccine Only---these offices will not be able to offer any travel vaccines except yellow fever vaccine
- O — These offices can offer other travel vaccines in addition to the yellow fever vaccine
- S — Students only---these offices can only offer yellow fever vaccine to the students at this particular school or institution
- E — Employees only---these offices only offer yellow fever vaccine to their employees

City & County	Services	Address	Phone
City-Albany CO-Dougherty	YF	Jacqueline H. Grant, M.D. Dougherty County Health Department 1710 South Slappey Boulevard Albany, Georgia 31706	229-430-6225
City-Albany CO-Dougherty	O	Bruce Houston, M.D. Phoebe North 2000 Palmyra Road Albany, Georgia 31701-1528	229-434-2173
City-Albany CO-Dougherty	O	Kevin M. Smith, M.D., M.P.H. Barry L. Barker, DO Phoebe Corporate Health 2410 Sylvester Road Albany, Georgia 31705	229-312-9220
City-Albany CO-Dougherty	O	Carlos Ernesto Franco-Paredes, M.D. Phoebe Infectious Diseases & Travel Medicine 507 Third Avenue, Suites 2-3 Albany, Georgia 31701	229-312-1680
City-Alpharetta CO-Forsyth	O	Mariam Labib Latif, M.D. Alphacare Medical Center 1865 Lockeway Drive, Suite 603 Alpharetta, Georgia 30004	770-752-8440

Designated Yellow Fever Vaccination Clinics in Georgia

City-Alpharetta CO-Fulton	O	Matthew McKenna, M.D. Fulton County Dept. of Health and Wellness North Fulton Regional Health Center 3155 Royal Drive, Suite 125 Alpharetta, Georgia 30022	404-612-1876
City-Alpharetta CO-Fulton	O	David Perkins, M.D. Doctors Express of Alpharetta 12315 Crabapple Road, Suite 108 Alpharetta, Georgia 30004	678-762-9292
City-Americus CO-Sumter	O	Michael S. Busman, M.D. Brett Law, M.D. David Khan Vay Taing, M.D. Sumter Family Medicine & Sports Medicine Center, P.O. Box 6815 922 East Jefferson Street, Suite B Americus, Georgia 31709	229-924-2383
City-Athens CO-Clarke	O	Ronald L. Forehand, M.D. University Health Center University of Georgia 55 Carlton Street Athens, Georgia 30605	706-542-5575
City-Athens CO-Clarke	O	Claude A. Burnett III, M.D., M.P.H. Clarke County Health Department 345 North Harris Street Athens, Georgia 30601-2470	706-389-6921
City-Athens CO- Clarke	O	Leigh M. Howell, RPh. Village Drug Shop of Athens, Inc. 740 Prince Avenue Athens, Georgia 30606	706-548-4444
City-Atlanta CO-Fulton	O	Crawford F. Barnett, Jr., M.D. Travel Immunization Center Paces Pavillion 3193 Howell Mill Road N.W. Suite 302 Atlanta, Georgia 30327-2100	404-262-1414
City-Atlanta CO-Fulton	O	Howard J. Cohen, M.D. Atlanta Infectious Disease Specialist 960 Johnson Ferry Road, Suite 500 Atlanta, Georgia 30342	404-851-0081

Designated Yellow Fever Vaccination Clinics in Georgia

City-Atlanta CO-Fulton	S	Frank M. Pickens, M.D. Georgia Tech. Student Health Services 740 Ferst Drive Atlanta, Georgia 30332	404-894-0248
City-Atlanta CO-Fulton	O	Steven I. Marlow, M.D. Atlanta Travel Medicine &Clinical Care 5673 Peachtree Dunwoody Rd., Suite 330 Atlanta, Georgia 30342	404-459-0002
City-Atlanta CO-Fulton	O	Scott D. Henderson, M.D. Family Practice Associates of Atlanta, PC 1776 Old Spring House Lane, Suite 200 Atlanta, Georgia 30338	770-454-0091
City-Atlanta CO-Fulton	O	Charles H. Taylor, M.D. Perimeter North Family Medicine 960 Johnson Ferry Road, Suite 300 Atlanta, Georgia 30342	404-255-7325
City-Atlanta CO-Fulton	O	Matthew McKenna, M.D. Fulton County Health & Wellness Center The Center for Health & Rehabilitation 265 Boulevard Dr, N.E., Third Floor Atlanta, Georgia 30312	404-612-1613
City-Atlanta CO-Fulton	O	Christine Zurawski, M.D., M.P.H. Ronald Devine, M.D. Atlanta Infectious Disease Group Piedmont Professional Bldg. 275 Collier Road, Suite 450-A Atlanta, Georgia 30309	404-351-2572
City-Atlanta CO-Fulton	O	John Ralph Destito, M.D. Doctors Express 1800 Howell Mill Road, NW, Suite 130 Atlanta, Georgia 30318	404-355-8775
City-Atlanta CO-Fulton	O	Phyllis E. Kozarsky, M.D. The Emory Travelwell Clinic 550 Peachtree Street, Suite 7000 Medical Office Tower 7th Floor Atlanta, Georgia 30308-2246	404-686-5885 404-686-8114
City-Atlanta CO-Fulton	E	Susana A. Alfonso, M.D.,M.H.C.M. The Emory Clinic at Delta 1030 Delta Boulevard Atlanta, Georgia 30354	404-778-8281

Designated Yellow Fever Vaccination Clinics in Georgia

City-Atlanta CO-Fulton	O	Alex E. Rikhter, M.D., P.C. Perimeter Clinic 1140 Hammond Drive, Suite G-7105 Atlanta, Georgia 30328	770-351-0900
City-Atlanta CO-Fulton	S	Joseph W. Williams, M.D. Morehouse College Student Health Services 830 Westview Drive, SW Atlanta, Georgia 30314	404-215-2637
City-Atlanta CO-Fulton	O	Jalola Zuberi, M.D. Morehouse Medical Associates 75 Piedmont Rd, Suite 700 Atlanta, Georgia 30303	404-756-1430
City-Atlanta CO-Fulton	O	Maria L. Walker, M.D. Piedmont Minor Emergency Clinic/Piedmont Travel Clinic 3108 Piedmont Road, N.E. Atlanta, Georgia 30305-2790	404-237-1755
City-Atlanta CO-Fulton	O	Mitchell A. Blass, M.D. World Travel Care 5673 Peachtree Dunwoody Rd, Suite 600 Atlanta, Georgia 30342-1701	404-459-4393
City-Atlanta CO-Fulton	O	Nicholas J.Beaulieu, M.D. Highland Travel Medicine of Atlanta 920 Ponce De Leon, Suite B Atlanta, Georgia 30306	404-815-1913
City-Atlanta CO-Fulton	O	Liza Chapman, Pharm.D. Kroger Pharmacy # 298 1700 Monroe Drive Atlanta, Georgia 30324	404-872-0785
City-Atlanta CO-Fulton	O	Amina S.Hassanali, M.D. Global Medical Clinical/Amina Consultant 2840 N.E. Expressway, Suite 116 Access Road, NE Atlanta, Georgia 30345	404-929-1402

Designated Yellow Fever Vaccination Clinics in Georgia

City-Atlanta CO-Fulton	O	Joseph G. Saulsbury II, M.D. Concentra Medical Center – Midtown 688 Spring Street, NW Atlanta, Georgia 30308	404-881-1155
City-Atlanta CO-Fulton	O	Janet Anne Dey, M.D. Piedmont Health Center 1830 Piedmont Road, Suite C Atlanta, Georgia 30324	404-874-1111
City-Atlanta CO-Fulton	O	Larry W. Anderson, DO Passport Health 3006 Clairmont Road, Suite 115 Atlanta, Georgia 30329	770-649-1675
City-Atlanta CO-Fulton	O	Sophie A. Lukashok, M.D. Intown Infectious Diseases, LLC 619 Rankin Street Atlanta, Georgia 30308	404-874-3102
City-Augusta CO-Richmond	O	David R. Haburchak, M.D. MCG Travel Advisory Clinic Inpatient Pharmacy 1120 15th Street, Room BP 2511 Augusta, Georgia 30912-3130	706-721-8888
City-Augusta CO-Richmond	O	Ketty Gonzalez, M.D. Richmond County Health Dept. 950 Laney Walker Boulevard Augusta, Georgia 30901	706-721-5827 706-721-5808
City-Augusta CO-Richmond	O	Doctor's Hospital Ctr. For Occup. Medicine Jayant Eldurkar, M.D. 2215 Tobacco Road, # F Augusta, Georgia 30906	706-396-1140
City-Augusta CO-Richmond	O	Jack H. Austin, Jr., M.D. Gweneth M. Francis, M.D. MedEx Associates 811 13th Street, Suite 10, POB 13 Augusta, Georgia 30901	706-434-1590
City-Brunswick CO-Glynn	O	Diane Z. Weems, M.D. Glynn County Health Department 2747 4th Street Brunswick, Georgia 31520	912-264-3961

Designated Yellow Fever Vaccination Clinics in Georgia

City-Buford CO-Gwinnett	O	Lloyd M. Hofer, M.D. Buford Health Center 2755 Sawnee Avenue Buford, Georgia 30518	770-614-2401
City-Carrollton CO-Carroll	O	G. Nicole Haynes, M.D. Carroll County Health Dept. 1004 Newnan Road Carrollton, Georgia 30116	770-836-6667
City-Cartersville CO-Bartow	O	Aman Mongia, M.D. Center for Infectious Diseases 100 Market Place Blvd. Suite 207 Cartersville, Georgia 30152	678-721-6971
City-Cave Spring CO-Floyd	O	Susan M. Butler-Sumner, M.D. Cave Spring Medical Center 28 Rome Road Cave Spring, Georgia 30124	706-777-8775
City-Chamblee CO-DeKalb	O	Nipun Patel, M.D. Premier Family Clinic 3646-D Chamblee Tucker Road Chamblee, Georgia 30341	770-493-6767
City-Chamblee CO-DeKalb	O	S. Elizabeth Ford, M.D., MBA, F.A.A.P. District Health Director North DeKalb Health Center 3807 Clairmont Road, N.E. Chamblee, Georgia 30341-4911	770-454-1144 Ext. 4602
City-Chatsworth CO-Murray	O	Russell B. Minor, M.D. Corner Drugs, Inc. 430 North 3rd Avenue Chatsworth, Georgia 30705	706-695-0444
City-Clarkston CO-DeKalb	O	Joyce R. Lewis, M.D. Greater Atlanta Family Healthcare 3700 Market Street, Building C Clarkston, Georgia 30021	404-298-9333
City-College Park CO-Fulton	O	Matthew McKenna, M.D. College Park Regional Health Center Fulton County Health Department 1920 John E. Wesley Avenue College Park, Georgia 30337	404-765-4155

Designated Yellow Fever Vaccination Clinics in Georgia

City-Columbus CO-Muscogee	O	Prima Rao Foster, M.D. Carl Andrew Foster, M.D. Capri Medical Group 6400 Flat Rock Road Columbus, Georgia 31907	706-478-5858
City-Columbus CO-Muscogee	O	David McMicken, M.D. Ace Acute Care Express 7901 Veterans Parkway Columbus, Georgia 31909	706-321-1223
City-Columbus CO-Muscogee	O	Lori A.Kingsley, DO Concentra Health Services 1051 Talbotten Road Columbus, Georgia 31904	706-322-2511
City-Columbus CO-Muscogee	O	Beverley A. Townsend, M.D. West Central Health District P.O. Box 2299 2100 Comer Avenue Columbus, Georgia 31902-2299	706-321-6300
City-Columbus CO-Muscogee	O	Kevin Donald Lokkesmoe, M.D. Urgent Care and Occupational Medicine 4328 Armour Road Columbus, Georgia 31904	706-507-1213
City-Columbus CO-Muscogee	O	Kenneth D. Gordon, M.D. Comprehensive Contingency Task Force “Rapid Ready” 3649 Victory Drive Columbus, Georgia 31903	706-221-5025
City-Conyers CO-Rockdale	O	Lloyd M. Hofer, M.D. Rockdale County Health Department 985 Taylor Street Conyers, Georgia 30012	770-785-4345
City-Covington CO-Newton	O	Lloyd M. Hofer, M.D. Newton County Health Department 8203 Hazelbrand Road Covington, Georgia 30014	770-786-9086
City-Cumming CO-Forsyth	O	Priya Vamsi Bayyapureddy, M.D. Windermere Medical Clinic 3850 Windermere Parkway, Suite 105 Cumming, Georgia 30041	678-455-2800

Designated Yellow Fever Vaccination Clinics in Georgia

City-Dawsonville CO-Dawson	O	Larry W. Anderson, DO Passport Health 400 Dawson Commons Circle, Suite 410 Dawsonville, Georgia 30534	770-649-1675
City-Decatur CO-DeKalb	S	Mark Mulligan, M.D. Carlos Del Rio, M.D. Hope Clinic of Emory Vaccine Resource Center 603 Church Street Decatur, Georgia 30030	404-712-9046
City-Decatur CO-DeKalb	O	S. Elizabeth Ford, M.D., MBA, F.A.A.P. District Health Director Central Health Center 440 Winn Way Decatur, Georgia 30030	404-294-3762
City-Decatur CO-DeKalb	O	Chad Donald Costley, M.D. Ponce Preventive Care, LLC 402 W. Ponce de Leon Avenue Decatur, Georgia 30030	404-537-2521
City-Decatur CO-DeKalb	O	Adam Matthew Bressler, M.D. Safe Passage Travel Medicine, PC/Infectious Disease Specialists of Atl.,PC 2665 North Decatur Road, Suite 330 Decatur, Georgia 30033	404-297-9755 or 404-304-9855
City-Douglas CO-Coffee	O	George D. Zoret, M.D. CRH Industrial Medicine, LLC 100 Doctors Drive, Suite 102 Douglas, Georgia 31533	912-260-5400
City-Duluth CO-Gwinnett	YF	Young W. Kang, M.D. River Parc Internal Medicine 4855 River Green Parkway #140 Duluth, Georgia 30096	678-417-0077
City-Dunwoody CO-DeKalb	O	Charles W. Wilson, Jr., RPh. The Medicine Shoppe of Dunwoody 4675 North Shallowford Rd., Suite 101 Dunwoody, Georgia 30338	770-455-1144
City-East Point CO-Fulton	O	H. Stacy Vereen, M.D. Senior Aviation Medical Examiner Flight Health, Inc. 1603 Ware Avenue, East Point, Georgia 30344	404-761-2166

Designated Yellow Fever Vaccination Clinics in Georgia

City-Ellijay CO-Gilmer	O	Harold Wendell Pitts, M.D. Gilmer County Health Department International Travel Clinic 28 Southside Church Street Ellijay, Georgia 30540	706-635-4363
City-Evans CO-Columbia	O	Jayant Bhaskar Eldurkar, M.D. Doctors Hospital Center for Occup. Medicine 635 Ronald Reagan Drive Evans, Georgia 30809	706-922-5056
City-Fayetteville CO-Fayette	O	G. Nicole Haynes, M.D. Fayette County Health Dept. 140 Stonewall Avenue West, Suite 107 Fayetteville, Georgia 30214	770-305-5416
City-Fayetteville CO-Fayette	O	Ronald Eugene Devine, M.D. Infectious Disease Solutions/P'tree Travel 1265 Highway 54, Suite 201 Fayetteville, Georgia 30214	678-435-3040
City-Fort Benning CO-Muscogee	E	Robert J. Pawloski, PA Readiness Processing Center MEDDAC 7950 Martin Loop, Building 9224 Fort Benning, Georgia 31905-5637 Military Staff Only	706-544-3912
City-Gainesville CO-Hall	O	David N. Westfall, M.D. Hall Co. Health Dept. Travel Clinic 1290 Athens Street Gainesville, Georgia 30507	770-531-5657
City-Greensboro CO-Greene	O	James Edward Southerland, M.D. TenderCare Clinic 803 South Main Street Greensboro, Georgia 30642	706-453-1201
City-Hapeville CO-Fulton	O	Oclla Michele Fletcher, M.D. Concentra Medical-Airport #1121 3580 Atlanta Avenue Hapeville, Georgia 30354	404-768-3351

Designated Yellow Fever Vaccination Clinics in Georgia

City-Hapeville CO-Fulton	O	Donovan W. Christie, M.D. Anwan Wellness Medical Center 725 North Central Avenue Hapeville, Georgia 30354	404-761-2766
City-Johns Creek CO-Fulton	O	Rajender Singh, M.D. Sohum Medicenter 9995 Jones Bridge Road Johns Creek, Georgia 30022	678-366-1200
City-Kennesaw CO-Cobb	S	Kathleen Marie Desire Gunchick, M.D. Kennesaw State University Student Health Services 1000 Chastain Road, MD 5200, House 52 Kennesaw, Georgia 30144-5591	770-423-6642
City-LaGrange CO-Troup	O	Warren Henderson, M.D. Emory Clark Holder Clinic 303 Smith Street LaGrange, Georgia 30240	706-812-4293
City-Lawrenceville CO-Gwinnett	O	Lloyd M. Hofer, M.D. Gwinnett County Public Health Services *(formerly Lawrenceville Health Center)* 455 Grayson Hwy, Suite 300 Lawrenceville, Georgia 30093	770-339-4283
City-Lawrenceville CO-Gwinnett	YF	Daniel Henson, M.D. Care Here Clinic, Group 3001 1600 North Brown Road Lawrenceville, Georgia 30043	678-710-6872
City-Lawrenceville CO-Gwinnett	O	Philip Norton Henderson, M.D. Premier Immediate Care 289 Grayson Highway Lawrenceville, Georgia 30045	678-376-1300
City-Lawrenceville CO-Gwinnett	O	Larry W. Anderson, DO Passport Health 5415 Sugarloaf Parkway, Suite 1107 Lawrenceville, Georgia 30043	770-649-1675
City-Lawrenceville CO-Gwinnett	O	Afroz Rahman, M.D. Urgent & Family Care Clinic 325 Lester Road, NW, Suite C Lawrenceville, Georgia 30044	770-935-1515

Designated Yellow Fever Vaccination Clinics in Georgia

City-Loganville CO-Walton	O	Constance O. George-Adebayo, M.D. Christ the King Medical Center 3531-3533 Highway 81 South Loganville, Georgia 30052	770-554-8015
City-Macon CO-Bibb	O	David N. Harvey, M.D. Macon-Bibb County Health Dept. 171 Emery Highway Macon, Georgia 31217	478-745-0411
City-Macon CO-Bibb	O	Ritu A. Kumar, M.D. Mercer Medicine 707 Pine Street Macon, Georgia 31201	478-301-5801
City-Marietta CO-Cobb	O	John (Jack) Kennedy, M.D. Cobb County Public Health (East Cobb Ctr.) 4938 Lower Roswell Road Marietta, Georgia 30068	678-784-2180
City-Marietta CO-Cobb	O	John (Jack) Kennedy, M.D. Cobb County Public Health 1650 County Services Parkway Marietta,.Georgia 30008	770-514-2300
City-Marietta CO-Cobb	O	Thomas Gary Sheftel, M.D. Kenmar Pharmacy 833 Campbell Hill Street Marietta, Georgia 30060	770-427-0202
City-Marietta CO-Cobb	O	Larry W. Anderson, DO Passport Health 2759 Delk Road, Suite 1075 Marietta, Georgia 30067	770-649-1675
City-McDonough CO-Henry	E	Jorge L. Moreno, Jr., M.D. Family Medical Clinic 1631 Highway 20W West McDonough, Georgia 30253	770-288-2822
City-McDonough CO-Henry	O	G. Nicole Haynes, M.D. Henry County Health Department McDonough Center 135 Henry Parkway McDonough, Georgia 30253	770-288-6136

Designated Yellow Fever Vaccination Clinics in Georgia

City-Monroe CO-Walton	O	Alice Louise Edwards, M.D. Head to Toe Research & Wellness, LLC 150-C Martin Luther King Jr. Boulevard Monroe, Georgia 30655	678-325-0241
City-Newnan CO-Coweta	O	Gaye Nicole Haynes, M.D. Coweta County Health Department 70 Hospital Road Newnan, Georgia 30263	770-254-7400
City-Norcross CO-Gwinnett	O	Lloyd M. Hofer, M.D. Norcross Health Center 5030 Georgia Belle Court Suite 2071 Norcross, Georgia 30093	770-638-5700
City-Norcross CO-Gwinnett	O	Jane T. St. Clair, M.D. WellBeings Occupational Healthcare 3300 Holcomb Bridge Road Suite 110 Norcross, Georgia 30092	770-449-5161
City-Peachtree City CO-Fayette	O	Jeffery Van Curtis, M.D. The Doctor's Office, LLC 3000 Shake Rag Hill Peachtree City, Georgia 30269	770-631-9999
City-Riverdale CO-Clayton	O	Richard C. Prokesch, M.D. Infectious Diseases Associates, PC 6285 Garden Walk Blvd, Suite A Riverdale, Georgia 30274	770-991-1500
City-Rome CO-Floyd	O	John S. Hostetler, M.D. The Harbin Clinic Travel Medicine 1825 Martha Berry Blvd. Rome, Georgia 30165-1698	706-236-6460
City-Roswell CO-Fulton	O	Larry W. Anderson, DO Passport Health 990 Holcomb Bridge Rd. - Suite 4 Roswell, Georgia 30076	770-649-1675
City-Roswell CO-Fulton	E	Thomas L. Fariss, M.D. Kimberly-Clark Corp.(Employees Only) 1400 Holcomb Bridge Road Roswell, Georgia 30076	770-587-8286

Designated Yellow Fever Vaccination Clinics in Georgia

City-Roswell CO-Fulton	O	Michael P. Dailey, M.D. Infectious Disease Services Of Georgia 11660 Alpharetta Highway, Suite 430 Roswell, Georgia 30076	770-255-1069
City-Roswell CO-Fulton	O	Howard J. Cohen, M.D. Atlanta Infectious Disease Specialist 1350 Upper Hembree Road, Suite A Roswell, Georgia 30076	770-442-1990
City-Sandy Springs CO-Fulton	O	Matthew McKenna, M.D. North Fulton Service Center 7741 Roswell Road Sandy Springs, Georgia 30350	404-612-0312
City-Savannah CO-Chatham	O	Diane Z. Weems, M.D. Chatham County Health Department 1395 Eisenhower Drive Savannah, Georgia 31406	912-356-2441
City-Savannah CO-Chatham	O	George G. Haberman, M.D. Industrial Medicine 1903 Abercorn Street Savannah, Georgia 31401	912-232-5169
City-Savannah CO-Chatham	O	Richard S. Roth, M.D. Nenad Avramovski, M.D. Travel Medicine Consultants 5354 Reynolds Street, Suite 421 Savannah, Georgia 31405	912-354-5543
City-Suwanee CO-Gwinnett	O	James Louis Roth, M.D. Vaccines On The Go 4255 Johns Creek Parkway – Suite A Suwanee, Georgia 30024	770-896-8284
City-Suwanee CO-Gwinnett	O	Philip Norton Henderson, M.D. Premier Immediate Care 2696 Lawrenceville-Suwanee Road Suwanee, Georgia 30024	678-376-1300
City-Thomaston CO-Upson	O	G. Nicole Haynes, M.D. Upson County Health Dept. 314 East Lee Street Thomaston, Georgia 30286-34256	706-647-7148

Designated Yellow Fever Vaccination Clinics in Georgia

City-Tifton CO-Tift	O	Marcy Corkern, R.Ph. Samuel W. Lokey, R.Ph. Moon's Pharmacy 717 Second Street West Tifton, Georgia 31794	229-382-3711
City-Tucker CO-DeKalb	O	Donovan W. Christie, M.D. Anwan Wellness Medical Center 2227 Idlewood Road, Suite 1 Tucker, Georgia 30084	678-205-2039
City-Valdosta CO-Lowndes	O	William Roy Grow, M.D. Lowndes County Health Dept. 206 South Patterson St., 1st. Fl. Valdosta, Georgia 31603-5619	229-333-5257
City-Warner Robins CO-Houston	O	David N. Harvey, II, M.D. Houston County Health Dept. 98 Cohen Walker Drive Warner Robins, Georgia 31088-2729	478-218-2000
City-Waycross CO-Ware	O	Rosemarie Parks, M.D. Ware County Health Department 604 Riverside Avenue Waycross, Georgia 31501	912-283-1875
City-Woodstock CO-Cherokee	O	Jackie L. Williamson, M.D. Piedmont Physicians at Woodstock 9766 Highway 92, Suite 200 Woodstock, Georgia 30188	770-926-8717

Foreign Language Terms

Table 2: Product Names

Trade Name	Antigen(s)	Manufacturer, Country
6 in 1	Diphtheria, tetanus, pertussis, polio, Hib, hepatitis B	GSK, Ireland
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, Y, W135)	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	Novartis
AH	Hepatitis B	(Romania)
Aimmugen	Hepatitis A (inactivated)	Chemo-Sero-Therapeutic Resh Inst. Japan
Aldiana	Diphtheria (adsorbed)	Sevac, Czech Republic
Alditeana	Diphtheria, tetanus (adsorbed)	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
AM-BC	Meningococcal B & C	Cuba
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
AP	Polio	(Romania)
AS	Measles	Cuba
Arilvax	Yellow fever	MEDI, UK
ATPA	Tetanus toxoid	(Romania)
AVAC-1, AVA	Anthrax	(for U.S. military use)
AVAXIM	Hepatitis A	Aventis Pasteur, France
B-Hepavac II	Hepatitis B	Merck, Singapore

Trade Name	Antigen(s)	Manufacturer, Country
Begrivac	Influenza (split virus)	Novartis
Betagen	Hepatitis B	Sanofi Pasteur
Biaflu Zonale	Influenza (whole virus)	Farmabiagini, Italy
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
Chiromas	Influenza (same as Fluad)	Novartis, Spain
Cinquerix	Diphtheria, tetanus, pertussis, Hib, polio	GSK, Europe
Cocquelucheau	Pertussis (adsorbed)	Sanoti Pasteur, France
Cuadruple	Diphtheria, tetanus, pertussis, Hib	Mexico
D-Immun	Diphtheria	Osterreichisches Institut, Austria
D.S.D.P.T.	Diphtheria, tetanus, pertussis (adsorbed)	Dong Shit 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
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 (Sii)
Dultavax	Diphtheria, tetanus, polio	Aventis Pasteur, France
Dupla	Diphtheria, tetanus	Instituto Butantan, Brazil
Duplex	Diphtheria, tetanus	Sweden
Easyfive	DTwP-Hib-HepB	India
Ecolarix	Measles, rubella (Schwarz & RA 27/3)	GSK, Europe

Trade Name	Antigen(s)	Manufacturer, Country
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
Enzira	Influenza	CSL
Eolarix	Measles, rubella (Schwartz & 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	(Hexavalent) 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	Influenza (adults ≥65)	Novartis, Europe, Asia, NZ
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
Funed-CEME	Diphtheria, tetanus, pertussis	Belo Horizonte, Brazil
Gen H-B-Vax	Hepatitis B	Merck-Behringwerke
GenHevac B Pasteur	Hepatitis B	Sanofi Pasteur
Gene Vac-B	Hepatitis B	Serum Institute of India (Sii)
Gripax	Influenza (whole virus)	Hebrew University
Gripe	Influenza (whole virus)	Spain
Gripguard	Influenza (same as Fluad)	Novartis, France
Gripovax	Influenza (whole virus)	GSK
Gunevax	Rubella	Chiron, Italy
H-Adiftal	Diphtheria	Ism, Italy
H-Adiftetal	Diphtheria, tetanus	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
HDCV	Human Diploid Cell Rabies Vaccine	
Heberbiovac HB	Hepatitis B	Heberbiotec, Cuba
Hepabest	Hepatitis A	Sanofi Pasteur, Mexico

Trade Name	Antigen(s)	Manufacturer, Country
Hepacare	Hepatitis B (recombinant)	Chiron, Europe
Hepaccine-B	Hepatitis B (plasma derived)	Chiel Jedang, South Korea
Hepagene	Hepatitis B	Chiron, Europe
Hepativax	Hepatitis B	Sanofi Pasteur, Mexico
Hepatyrix	Hepatitis A, typhoid	GSK
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 or Mexico
Hiberix	Hib conjugate	GSK
HIBest	Hib	Sanofi Pasteur
Hinkuys karokoe	Pertussis (adsorbed)	Natl. Public Health Institute, Finland
HIS	Influenza	Serbian Institute, Yugoslavia
IBV	Polio (inactivated)	Statens Seruminstitut, Denmark
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
Imovas D.T.	Diphtheria, tetanus (adult)	Sanofi Pasteur, Europe
Imovas Gripe	Influenza	Sanofi Pasteur, Europe
Imovax D.P.T.	Diphtheria, tetanus, pertussis	Sanofi Pasteur Mexico
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	Sanofi Pasteur, Europe
Imovax Tetano	Tetanus	Sanofi Pasteur, Europe
Infanrix Hexa	Diphtheria, tetanus, pertussis, polio, Hib, hepatitis B	GSK, France
Infanrix Penta	Diphtheria, tetanus, pertussis, hepatitis B, polio	GSK, Europe
Infanrix Quinta	Diphtheria, tetanus, pertussis, polio, Hib	GSK, Europe
Infanrix Tetra	Diphtheria, tetanus, pertussis, 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

Trade Name	Antigen(s)	Manufacturer, Country
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
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
M-Vac	Measles (live)	Serum Institute of India (Sii)
Massern-Impfstoff SSW	Measles (live)	Chiron, Germany
Massling	Measles	Sweden
MDPH-PA	Anthrax	
Measavac	Measles (Edmonston strain)	Pfizer, UK
MenAfriVac	Meningococcal A Conjugate	Africa
Mencevax A	Meningococcal Group A (polysaccharide)	SmithKline/RIT, Belgium
Mencevax ACWY	Meningococcal quadravalent	GSK
Mengivax A/C	Meningococcal Groups A & C (conjugate)	Sanofi Pasteur, Europe
Meningitec	Meningococcal Group C (conjugate)	Wyeth, UK, Australia
Meningtec	Meningococcal Group C (conjugate)	Wyeth, Canada
Meninvact	Meningococcal Group C (conjugate)	Sanofi Pasteur
Menjugate	Meningococcal Group C (conjugate)	Novartis
Menpovax 4	Meningococcal Groups A, C, Y & W135 (polysaccharide)	Chiron, Europe
Menpovax A+C	Meningococcal Groups A & C	Chiron, Italy
MeNZB	Meningococcal Group B	Novartus, New Zealand
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 17-valent (polysaccharide)	GSK, Europe
Monovax / Monovac	BCG	Sanofi Pasteur, France
Mopavac	Measles, mumps (live)	Sevac, Czech Republic
Morbilvax	Measles (live)	Chiron, Italy
Morubel	Measles, rubella (live)	Chiron, Italy
Moruman Berna	Measles immunoglobulin	Berna, Switzerland
Morupar	Measles, mumps, rubella (live)	Chiron, Italy
Movivac	Measles (live)	Sevac, Czech Republic
Mumaten	Mumps (live)	Berna Biotech, Switzerland
Munevan	Influenza (whole virus)	Medeva
Mutagrip	Influenza	Sanofi Pasteur, Germany
Nasoflu	Influenza	GSK, Europe
Neis Vac-C	Meningococcal Group C (conjugate)	Baxter, Europe & Canada
Neumo Imovax	Pneumococcal 23-valent (polysaccharide)	Sanofi Pasteur, Mexico
Neotyf	Typhoid (live, oral)	Chiron, Italy
Nilgrip	Influenza	CSL
Nivgrip	Influenza (whole virus)	Nicolau Institute of Virology, Romania
NorHOMHerHTA	Polio (inactivated)	Russia
Nothav	Hepatitis A	Chiron, Italy
Okavax	Varicella (live)	Biken / Sanofi Pasteur, Japan & Europe
Optaflu	Influenza (cell culture-based)	Novartis, Europe, Iceland, Norway
Oral Virelon	Polio (oral)	Chiron, Germany
Pariorix	Mumps (live)	GSK, Mexico & Europe
Pavivac	Mumps (live)	Sevac, Czech Republic
Pediacel	Diphtheria, tetanus, acellular pertussis, Hib, polio	Europe
Penta	Diphtheria, tetanus, acellular pertussis, Hib, polio	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
Pentavalenti	Diphtheria, tetanus, pertussis, polio, Hib ***OR*** Diphtheria, tetanus, pertussis, polio, hepatitis B	Italy
Pentaxim	Diphtheria, tetanus, pertussis, polio, Hib	Aventis Pasteur, France
Pluserix	Measles, rubella	GSK, Mexico & Europe
Pneumopur	Pneumococcal 23-valent (polysaccharide)	Chiron, Europe
POLIAcel	Diphtheria, tetanus, pertussis, polio, Hib	Sanofi Pasteur, Argentina
Poliomyelite	Polio (inactivated)	France
Polioral	Polio (live, oral, trivalent)	Novartis
Polio Sabin	Polio (oral)	GSK, Europe

Trade Name	Antigen(s)	Manufacturer, Country
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 (live)	GSK, Europe
Probivac-B	Hepatitis B	Probiomed, Mexico
Procomvax	Hib, hepatitis B	Sanofi Pasteur, Europe
PRS	MMR	Cuba
Pulmovax	Pneumococcal 23-valent (polysaccharide)	Merck
Q-Vac	Diphtheria, tetanus, pertussis, hepatitis B	Serum Institute of India (Sii)
Quadracel	Diphtheria, tetanus, acellular pertussis, polio	Sanofi Pasteur, Mexico
QUADRAcel/Hibest	Diphtheria, tetanus, acellular pertussis, polio, Hib	Sanofi Pasteur, Argentina
Quadravax	Diphtheria, tetanus, pertussis, polio	GSK
Quadruple	Diphtheria, tetanus, pertussis, Hib	Mexico
Quatro-Virelon	Diphtheria, tetanus, pertussis, polio	Chiron, Europe
Quinivax-IN	Diphtheria, tetanus, pertussis, polio, Hib	Valda Laboratori, Europe
Quintuple	Diphtheria, tetanus, pertussis, polio, Hib	GSK, Mexico
Quinvaxem	Diphtheria, tetanus, pertussis, Hib, Hepatitis B	Novartis/Crucell
R-HB Vaccine	Hepatitis B (recombinant)	Mitsubishi Chem Corp, Japan
R-Vac	Rubella (live)	Serum Institute of India (Sii)
Rabdomune	Rabies	Impdfstofwerke, Germany
Rabipur	Rabies	Chiron, Germany
Rabivac	Rabies	Chiron, Germany
Rasilvax	Rabies	Chiron, Italy
RDCV	“Rabies Diploid Cell Vaccine”	
Refortrix	Diphtheria, tetanus (adult)	GSK
Repevax	Diphtheria, tetanus, pertussis, polio	Sanofi Pasteur
Revaxis	Tetanus, diphtheria, polio (adult)	Sanofi Pasteur (Europe)
Rimevax	Measles (live, Schwarz strain)	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
Rouvax	Measles (live)	Sanofi Pasteur, Europe
Rubavax	Rubella (live)	Sanofi Pasteur, UK
Rubeaten	Rubella (live)	Berna Biotech, Europe
Rubellovac	Rubella (live)	Chiron, Germany
Rubilin	Rubella (live)	Chiron, UK
Rudi-Rouvax	Measles, rubella (live)	Sanofi Pasteur, France
Rudivax	Rubella (live)	Sanofi Pasteur, France
Sahia	Polio (live oral)	Multiple manufacturers
Sampar	Plague	Sanofi Pasteur, Indonesia

Trade Name	Antigen(s)	Manufacturer, Country
Sandovac	Influenza	Sandoz, Austria
Serap	Diphtheria, tetanus, pertussis	Perum Bio Farma, Indonesia
Shanvac-B	Hepatitis B	Shantha, India
SMBV	Rabies	Sanofi Pasteur, Europe
Sii Rabivax	Rabies	Serum Institute of India (Sii)
Sii Triple Antigen	Diphtheria, tetanus, pertussis	Serum Institute of India (Sii)
Stamaril	Yellow fever (live)	Sanofi Pasteur, Europe
Streptopur	Pneumococcal 23-valent (polysaccharide)	Chiron, Europe
Subinvira	Influenza (split virus)	Imuna, Czech Republic
Synflorix	Pneumococcal (10-valent, conjugate)	GSK, Europe, Australia
T. Polio	Tetanus, polio	SP (Canada)
T.A.B.	Typhoid, paratyphoid (A & B)	- Institute Pasteur, Tunisia - Egypt - Pharmaceutical Industries Corp., Burma
T-Immun	Tetanus (adsorbed)	Baxter, Germany
T-Vaccinol	Tetanus	Roehm Pharma, Germany
T-Wellcovax	Tetanus	Wellcopharm, Germany
Tanrix	Tetanus	GSK, Europe
Td-Pur	Tetanus, diphtheria (adult)	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
Tetano-difter	Tetanus, diphtheria	Celltech Pharma
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, acellular 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 paratyphoid	Italy
TOPV	Polio (oral, trivalent)	Multiple manufacturers
Trenin DPT Behring	Diphtheria, tetanus, pertussis	Chiron Behring GmbH, Germany

Trade Name	Antigen(s)	Manufacturer, Country
Tresivac	Measles, mumps, rubella (live)	Serum Institute of India (Sii)
Triacel	Diphtheria, tetanus, acellular pertussis	Sanofi Pasteur, Europe & Mexico
Triacelluvax	Diphtheria, tetanus, acellular pertussis	Chiron, Europe
Trimovax	Measles, mumps, rubella (live)	Sanofi Pasteur,
Tripacel	Diphtheria, tetanus, acellular pertussis	Sanofi Pasteur, Europe
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	Diphtheria, tetanus, whole-cell pertussis	GSK
Tritanrix-HB	Diphtheria, tetanus, whole-cell pertussis, hepatitis B	GSK, Mexico
Tritanrix-HB-Hib	Diphtheria, tetanus, whole-cell pertussis, 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)	Berna Biotech, Switzerland
Trivivac	Measles, mumps, rubella (live)	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 paratyphoid	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 (adsorbed)	Cantacuzino Institute, Romania
Vaccin Rabique Pasteur	Rabies	Pasteur Vaccins
Vaccin Combinat Diftero-Tetanic	Diphtheria, tetanus (adsorbed)	Cantacuzino Institute, Romania
Vaccin tuberculeux attenue lyophilize	BCG	Sanofi Pasteur, France

Trade Name	Antigen(s)	Manufacturer, Country
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
Vacuna Doble	Tetanus, diphtheria	Instituto Biologico Argentino
Vacunol	Tetanus	Temis-Lostato, Brazil
Vaksin Sampar	Plague	Perum Bio Farma, Indonesia
Vaksin Cacar	Smallpox	Indonesia
Vaksin Serap	Diphtheria, tetanus, pertussis	Perum Bio Farma, Indonesia
Vaksin Campak Kerig	Measles (live)	Perum Bio Farma, Indonesia
Vaksin Kotipa	Cholera, typhoid, paratyphoid A, B & C	Perum Bio Farma, Indonesia
Vamoavax	Measles, mumps (live)	Institute of Immunology, Croatia
Varicella-RIT	Varicella	GSK, Europe
Varicellon	Zaricella zoster immunoglobulin	Behringwerke Aktiengesellischaft, Germany
Varie	Smallpox (lyophilized)	Institute of sera and Vaccine, Czech Republic
Varilrix	Varicella (live, Oka strain)	GSK, Australia, New Zealand
Varirix	Varicella (live, Oka strain)	GSK, Europe & Mexico
Vax-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 Institute, Romania
Verorab	Rabies (purified vero cell)	Sanofi Pasteur, France
ViATIM	Hepatitis A, typhoid	Sanofi Pasteur, UK
Vibriomune	Cholera	Duncan Flockhart, UK
Viralinte	Hepatitis B	Ivax Pharmaceuticals, Mexico
Virelon C	Polio (inactivated)	Chiron, Germany
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	Polio (oral)	PT Biofarma, Indonesia
VPH	Human Papillomavirus	Spanish
V T (Vacine Triplice)	Diphtheria, tetanus, pertussis	Instituto Butantan, Brazil
V T V (Vacina Triplice Viral)	Measles, mumps, rubella	Brazil
V V R	Measles (live)	Cantucuzino Institute, Romania
Welltrivax Trivalente	Diphtheria, tetanus, pertussis	Spain
X-Flu	Influenza	CSL

Trade Name	Antigen(s)	Manufacturer, Country
Zaantide	Diphtheria antitoxin	Imunoloski Zavod, Croatia
Zaantite	Tetanus antitoxin	Imunoloski Zavod, Croatia
Zaditeadvax	Diphtheria, tetanus	Imunoloski Zavod, Croatia
Zaditevax	Diphtheria, tetanus	Imunoloski Zavod, Croatia
Zamevax A+C	Meningococcal Groups A & C (polysaccharide)	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, mumps, rubella (live)	Imunoloski Zavod, Croatia

February 2012

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13. QUALITY ASSURANCE
Quality Assurance/Quality Improvement for Immunization Practice for Public Health Nurses and Immunization Support Staff

Appendices
Attachment A - Immunization Reference Video Information and Resources, Training Sessions **(REPLACE)**
Attachment B - Post Test **(REPLACE)**
Attachment C - Post Test Answers **(REPLACE)**
Attachment D – Injections: IM/SC (Intramuscular),(Subcutaneous) Injections **(REPLACE)**
Attachment E - Vaccine Administration Techniques Post Test **(REPLACE)**
Attachment F - Vaccine Administration Techniques Post Test Answer Key **(REPLACE)**
Attachment G - Clinical Skills Checklist **(REPLACE)**
Attachment H - QA/QI Review Assessment Tool **(REPLACE)**
Attachment I - Influenza Vaccine Administration Routes **(ADD)**

Quality Assurance/Quality Improvement (QA/QI) for Public Health Nurses

Immunization

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Section II: Training/Education 3
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Section IV: Clinical Practice 13
Section V: Storage, Handling and Labeling of Drugs 14
Section VI: Management of Drug Reactions 15
Summery Page 17

Review Date: _____

Review Site(s): _____

REVIEW TEAM MEMBERS:

1.

2.

3.

4.

5.

6.

QUALITY ASSURANCE /QUALITY IMPROVEMENT FOR IMMUNIZATION PRACTICE FOR PUBLIC HEALTH NURSES

INTRODUCTION

The **Georgia Immunization Office**, under the **Department of Public Health**, produces both an **Immunization Office Manual** and an Advisory Committee on Immunization Practices (ACIP) Recommendations Notebook that outline the recommended Policies and Procedures for administering vaccines by registered nurses and for providing immunization services. An advisory committee consisting of district immunization coordinators and pediatricians, a state pharmacist and the Immunization Program management team, review and update these manuals on an ongoing basis. Each district is responsible for having written policies and procedures for the administration of vaccines that have been reviewed and signed annually by the health director or their designee. Districts are encouraged to either utilize the Policies and Procedures outlined in the **Georgia Immunization Office Manual** and the ACIP Recommendations Notebook, or to write their own which should be consistent with those outlined in these two references.

PURPOSE

The purpose of this quality assurance tool is to document the training /education expectations and the parameters of clinical practice immunization services. Use of this tool will help promote consistency in practice across programs on a statewide basis. Quality assurance will provide an opportunity to identify excellence in practice, as well as opportunities for improvement. The components of this tool may be used to conduct QA reviews of training programs, administration of vaccines by registered nurses. These reviews may be done by Public Health staff from either the local and/or state level. **The credentialing, training, and education expectations, as well as the parameters of clinical practice for Licensed Practical Nurses in immunization services are located in Chapter 13 of the Georgia Immunization Office Manual. This tool may be used when evaluating immunization services provided by Licensed Practical Nurses.**

Nurse or Site: _____ Date: _____

SECTION I - CREDENTIALING

EXPECTATIONS	DOCUMENTATION Yes	DOCUMENTATION No	COMMENTS
1. Professional Licensure for RN's:			
Each Registered Professional Nurse (RN) and **each Advanced Practice Registered Nurses (APRN)** practicing under the District's Policies and Procedures is currently licensed**/authorized** by the Georgia Board of Nursing. Documentation shall include verification of license(s) per internet (www.sos.state.ga.us). **A hardcopy of the Internet verification should be documented in the supervisory personnel file prior to employment and at least once annually thereafter.**			
2. Scope of Practice for RN's:			
The district's written P&P for the administration of vaccines and provision of immunization services are consistent with the **Department of Public Health's** Scope of Practice Guidelines for Expanded Role of RNs and Advanced Practice Registered Nurse.			
3. Clinical Preceptorship/Peer Review for RN's:			
Prior to practicing under P&P, written documentation of completion of a clinical preceptorship, consistent with the recommended Policies & Procedures outlined in Section II of this document must be on file.			

Nurse or Site: _____ Date: _____

SECTION II — TRAINING/EDUCATION

FOR REGISTERED NURSES (RN's):

NOTE: This section may be used to review an individual nurse's (RN) training and preparation for practicing under Immunization Policies & Procedures (P&P). A copy may be placed in the nurse's personnel file. It may also be used to review the training and preparation of a group of nurses who are practicing under Immunization Policies and Procedures. The self-study and didactic training sections should be completed and documented prior to completing the preceptorship. Each nurse should complete the following:

	DOCUMENTATION		
EXPECTATIONS	**Yes** (Date completed/ Reviewers Initial)	**No**	**COMMENTS**

INITIAL TRAINING – REQUIRED

The nurse has completed the following:

A. SELF-STUDY (Nurse is to read the following documents): Familiar with and has access on-site to:			
▪ ***Georgia Immunization Program Manual*** **∗+ (Also available on line)**			
▪ ***Advisory Committee on Immunization Practices (ACIP) Recommendations Manual*** **∗+ (Also available on line)**			

II — TRAINING/EDUCATION, continued

EXPECTATIONS	DOCUMENTATION Yes (Date completed/ Reviewers Initial)	No	COMMENTS
▪ *Health District Policies & Procedures for Vaccine Administration∗* ▪ *(Signed annually by the District Health Director or his/her designee)*			
▪ *Health District Policies & Procedures for Administration of Travel* ▪ *Vaccines∗ (If district administers travel vaccines)*			
▪ *Health District Emergency Policies & Procedures∗*			
▪ ***Georgia Notifiable Disease Fact Sheets*∗+ (District must be able to access on line)**			
▪ ***Manual for the Surveillance & Reporting of Vaccine Preventable Diseases Manual*,** ▪ ***CDC*+∗ (District must be able to access on line)**			
▪ *Vaccine package inserts.*			
+ See Attachment A for detailed information on these references ∗ Most Current version			

II — TRAINING/EDUCATION, continued

EXPECTATIONS	DOCUMENTATION Yes (Date Completed/ Reviewers Initial)		No	COMMENTS
B. DIDACTIC/CLASSROOM TRAINING COMPLETED:				
▪ **Basic Epidemiology: Prevention of Vaccine Preventable Diseases: (VPD's)** - Attend or view and complete and pass post tests for the CDC Satellite Immunization Training Sessions **(webcast, or taped session)** on: *Epidemiology & Prevention of Vaccine Preventable VPD's* +* (includes basic vaccine pharmacology).				
▪ **Storage and Handling:** - **View all components of the CDC's Storage and Handling Tool Kit +*(DVD or webcast)**and complete and pass post tests for: o *How to Handle Your Vaccine Supply* (See attachments A,B & C) **or** - Attend Vaccine Storage & Handling training session provided by the **GA Immunization Office** +*				
▪ **Vaccine Administration Techniques** - Vaccine Administration Techniques training session **+* (Contact GA Immunization Program consultant (IPC)** or District Immunization Coordinator) **or** - View Immunization Techniques Video**/DVD** +* and pass post test. **(see attachments A,D, E, and F)**				

II — TRAINING/EDUCATION, continued

EXPECTATIONS	DOCUMENTATION Yes (Date Completed/ Reviewers Initial)		No	COMMENTS
▪ **GA Requirements for Day Care and School Attendance:** Attend Training Session on GA Requirements for Attending Day Care & School **(Provided by District "Certified Trainer" or Georgia IPC- see attachment A)**				
▪ Complete CPR Certification Class **provided by the district or other entity** (must be currently certified).				
▪ Forms, Reports, & Records - Instructed in purpose of and has access to the following forms, reports, **and records:**				
+ See Attachment A for detailed information on these references ∗ Most Current version				
a. Patient Record (written and computerized) and how to access 1. Immunization status.				
b. Vaccine Information Statements*				
c. Certificates and Statements for School and Day Care Attendance*				
d. Determination of Coverage and Fees (VFC Eligibility, Medicaid, PeachCare, Private Insurance, HMO coverage) and how to apply for Medicaid and PeachCare.				
e. Informed Consent				
f. Vaccine Adverse Event Reporting System (VAERS)				
g. Tracking and Follow up Moved or Gone Elsewhere (MOGE)				

II— TRAINING/EDUCATION, continued

EXPECTATIONS	DOCUMENTATION Yes (Date Completed/ Reviewers Initial)		No	COMMENTS
h. Notifiable Disease Reports				
i. Vaccine Preventable Disease (VPD) worksheets*				
j. Immigration Forms*				
k. Employee Immunization Record				
l. District Immunization documentation forms and charting process*				
m. Pre-call and Recall process and related forms and letters				
n. Clinical Assessment Software Application (**CoCASA)** report*				
o. GA Registry of Immunization Transactions & Services (GRITS) (Knows how to access and query for an existing immunization record to determine current immunization status and need for vaccinations)				
p. Current population based immunization study and child care and school audit results				
▪ Tour of Immunization clinic, including information about where vaccine emergency cart trays and immunization forms are stored.				
▪ Informed how to access district immunization coordinator and the **GA Immunization Office** "On-Call" resource phone line and area **IPC** .				
▪ Attend at least one (1) training on cultural competencies.				
+ See Attachment A for detailed information on these sessions or videos. * Most current version				

II — TRAINING/EDUCATION, continued

EXPECTATIONS	DOCUMENTATION YES (Dated Completed/ Reviewer's Initial)		NO	COMMENTS
C. PRECEPTORSHIP / CLINICAL:				
The extent and duration of the preceptorship/clinical may vary according to the needs of each individual nurse. However, there shall be documentation that the nurse can satisfactorily perform the required clinical skills on the attached check list **(Attachment G)** and that the preceptor has observed the required encounters prior to the nurse being allowed to administer vaccines without direct supervision. The minimum number of observed encounters should be two per age group indicated.				
D. HAVE ACCESS ON-SITE TO REFERENCE MATERIALS & RECORDS:				
▪ *Epidemiology & Prevention of Vaccine Preventable Diseases. CDC+**				
▪ *Red Book, AAP,+∗ (vaccine recommendations section) (at least 1copy at district)*				
▪ *Current Guide to Vaccine Contraindications and Precautions, CDC+∗*				
▪ *Control of Communicable Diseases in Manual,* ***Heymann,*** *A.S.,+∗*				
▪ ***Current Year Drug Reference (refer to current Nurse Protocol Manual, Drug Dispensing Procedure, for list of acceptable drug references)***				
▪ ***GA Registry of Immunization Transactions & Services (GRITS)*** **(Needs to be able to access and query for an existing immunization record to determine current immunization status and need for vaccinations)**				
+ See Attachment A for detailed information on these sessions or videos * Most current version				

II — TRAINING/EDUCATION, continued

EXPECTATIONS	DOCUMENTATION Yes (Date Completed/ Reviewer's Initial)	No	COMMENTS

INITIAL TRAINING – REQUIRED

The nurse has completed the following:

Each Nurse should annually complete the following:				
A. SELF-STUDY (Nurse is to read the following documents)::				
▪ Review of current year's District Policies and Procedures for Administration of Vaccines (if separate from the **GA Immunization Office Manual**)				
▪ Review of current **GA Immunization Office Manual** and current updates for the ACIP Recommendations Notebook				
B. DIDACTIC/CLASSROOM TRAINING				
Participation in at least one training per year to keep updated on current policies and procedures concerning administration of vaccines. Recommended training sessions could include but are not limited the following: (Multiple presenter topics available from GA Immunization Program and **CDC National Center for Immunization and Respiratory Diseases-Immunization Services** +) ▪ CDC Immunization Training Sessions +∗ (live, webcast, or recorded): - **Vaccine Safety** - **Immunization Updates (Childhood or Adult)** - Surveillance & Prevention of Vaccine Preventable Diseases - International Travel ▪ Immunization Office training sessions+∗ **(Provided by GA Immunization Office staff or District "Certified Trainer")** ▪ **Cultural Competency Update**				
+ See Attachment A for detailed information on these sessions or videos * Most current version				

II — TRAINING/EDUCATION, continued

EXPECTATIONS	DOCUMENTATION Yes (Date Completed/ Reviewer's Initial)		No	COMMENTS
C. PEER REVIEW/CLINICAL:				
▪ At least once annually, a supervisor or peer shall observe, evaluate, and document on skills checklist **(Attachment G)** the nurse assess, prepare, administer vaccines, and document information provided to infants and children, adolescents and adults (at least one encounter for each).				
D. OTHER:				
a. Have Access On-Site to: ▪ District Policies and Procedures for Administration of Vaccines.+∗ (if separate from the GA Immunization Office Manual) ▪ *GA Immunization Office Manual* .∗ ▪ *ACIP Recommendations Notebook.*∗ ▪ *Epidemiology & Prevention of Vaccine Preventable Diseases. CDC+*∗ ▪ *Red Book, AAP+*∗*, (Vaccine Recommendations section) (at least one copy at district)* ▪ *Current Guide to Vaccine Contraindications and Precautions, CDC+*∗ ▪ *Control of Communicable Diseases in Manual,* ***Heymann,*** *A.S., +*∗ ▪ **Current year drug reference (refer to current Nurse Protocol Manual, Drug Dispensing Procedure, for list of acceptable drug references)** ▪ Health District's P&P for Administrating Travel vaccines∗ (If applicable) ▪ ***GA Notifiable Disease Fact Sheets (available at district and in Chapter 6 of GA Immunization Program Manual)∗***				

II — TRAINING/EDUCATION, continued

EXPECTATIONS	DOCUMENTATION Yes (Date Completed/ Reviewer's Initial)	No	COMMENTS
▪ ***Manual for Surveillance & Reprinting of VPD Manual CDC+∗ (available at district)∗*** ▪ Vaccine Package Inserts∗ ***GA Registry of Immunization Transactions & Services (GRITS)*** **(Needs to be able to access and query for an existing immunization record to determine current immunization status and need for vaccinations)**			
+See Attachment A for detailed information on these sessions or videos. * Most current version			

SECTION III — POLICIES & PROCEDURES

EXPECTATIONS	DOCUMENTATION YES (Date Completed/ Reviewer's Initial)	NO	COMMENTS
▪ The district utilizes the Policies & Procedures in the GA Immunization Office Manual and the ACIP Recommendations Manual and both manuals are current.			
▪ The District writes their own Policies and Procedures (P&P) for the Administration of Vaccines and Provision of Immunization Services. The P&P are consistent with the recommendations outlined in the GA Immunization Office Manual and the ACIP Recommendations Manual.			
▪ Are available upon request in the setting where RN practices under the Policies and Procedures.			
▪ Are reviewed, revised or updated annually, or as GA Immunization Office recommends change.			
▪ Are signed by licensed Physician.			
▪ Bear a current review date.			
▪ Include a provision for immediate consultation with a physician or designee.			
▪ Include a provision for the supervision of the LPN by a RN, Physician, Dentist, and/or Podiatrist.			
+ See Attachment A for detailed information on these references * Most Current Version			

SECTION IV –– CLINICAL PRACTICE

	DOCUMENTATION		
EXPECTATIONS	**YES** (Date Completed/ Reviewer's Initial)	**NO**	**COMMENTS**
Direct observations of clinical nursing practice will be documented on the Clinical Skills Checklist (see Attachment G) for each nurse administering vaccines.			
+ See Attachment A for detailed information on these references * Most Current Version			

SECTION V — VACCINE STORAGE, HANDLING , ETC.

This section will be documented on a separate report (see Attachment H). This document is updated annually based on CDC requirements. Please check with your Immunization Program Consultant {IPC} for current version)

SECTION VI — MANAGEMENT OF DRUG REACTIONS

EXPECTATIONS	DOCUMENTATION			COMMENTS
	YES (Date Completed/ Reviewer's Initial)	NO	Incomplete	
A. Clinic site has most current written, Policies and Procedures for handling anaphylactic (allergic) reactions and/or blood drawing.				
B. Clinic site has appropriate emergency equipment and supplies are readily available.				
C. Clinic site has an emergency alert communication system that is known by all staff.				
D. Clinic site has posted local emergency telephone numbers, (i.e., EMS, Hospital, etc.) for easy access.				
E. Each RN has current CPR certification.				
F. Each RN has received orientation/training updates in emergency procedures within one (1) month of employment.				
G. Each RN has participated in training updates as needed and in mock emergency drills at least once a year.				
H. There must be at least one annual mock emergency drill which includes infants, toddlers, children and adults.				
I. One person (designee) coordinates training and scheduling, implementation and evaluation of the mock emergency drills.				
J. Copies of records on anaphylactic reactions are distributed as follows:				
• Sent with patient to emergency room, if applicable;				
• Retained by the clinic for patient record; and				
• Sent to District Office with incident report.				

SECTION VI — MANAGEMENT OF DRUG REACTIONS (continued)

EXPECTATIONS	DOCUMENTATION			COMMENTS
	YES (Date Completed/ Reviewer's Initial)	NO	Incomplete	
K. Review of emergency preparedness for drug reactions is conducted at least once annually.				
L. Each RN is familiar with the Vaccine Adverse Event Reporting System (VAERS) and the policies and procedures for reporting vaccine adverse events following immunizations.				
+ See Attachment A for detailed information on these references * Most Current Version				

Support Staff or Site: _____ Date: _____

Summary

FINDINGS:

RECOMMENDATIONS:

Immunization Resources

Publications:

Name	Ordering Information	Approximate Cost
Georgia Immunization Program Manual	Can be downloaded from program website *http://health.state.ga.us/programs/immunization/index.asp*	
Advisory Committee on Immunization Practices (ACIP) Recommendations Manual	No longer available as a complete manual. Single copies of each report may be ordered from the National Immunization Program, CDC; or can be viewed and downloaded at *http://www.cdc.gov/vaccines/pubs/ACIP-list.htm*	
Georgia Notifiable Disease Fact Sheets	Disease-specific fact sheets are available online: *http://health.state.ga.us/siteindex/d.asp#diseases* and click on specific disease to view fact sheet (i.e. Notifiable Disease: xxxxxx)	
GA VFC Provider Operations Guide	Available for private VFC providers. Contact VFC Program Office or Immunization Program Consultant	Free
Manual for the Surveillance of Vaccine Preventable Diseases, CDC	Available only on CDC website at *www.cdc.gov/vaccines/pubs/surv-manual/default.htm*	
The Red Book 29th Edition - Report of the Committee on Infectious Diseases, American Academy of Pediatrics, 2012	American Academy of Pediatrics 141 Northwest Point Blvd. Elk Grove Village, IL 60007-1098 1-847-434-4000 1-847-434-8000 (Fax) Elk Grove, Illinois (Published every 3 years) *www.aap.org*	$114.95

Immunization Resources

Name	Ordering Information	Approximate Cost
Current Guide to Vaccine Contraindications and Precautions, CDC, 2009	Access from CDC's website at *http://www.cdc.gov/vaccines/recs/vac-admin/downloads/contraindications_guide.pdf*	
The Pink Book – Epidemiology & Prevention of Vaccine Preventable Diseases, CDC, 12th edition 2nd printing, 2012	One copy provided for each public health facility; or Order from Public Health Foundation 1-877-252-1200 (toll free) Access from CDC's website: *http://www.cdc.gov/vaccines/pubs/pinkbook/default.htm*	$35.00+ shipping from Public Health Foundation at *http://bookstore.phf.org*
Control of Communicable Diseases Manual, 19th edition, 2008	Engineer's Book Store 748 Marietta St., NW Atlanta, GA 30318 404-221-1669	$27.00 + tax + shipping from Public Health Foundation at http://bookstore.phf.org/
IAC Express – Internet news service of the Immunization Action Coalition	Order from: Immunization Action Coalition *http://www.immunize.org/subscribe/*	Free
Immunize Georgia, (newsletter) Georgia Immunization Office **Electronic Version On Immunization Website**	**Sent to local health departments & Field Representatives** **http://health.state.ga.us/programs/immunization/index.asp**	Free

Immunization Resources

Name	Ordering Information	Approximate Cost
Morbidity & Mortality Weekly Report (MMWR)	Order electronic subscription: *http://www.cdc.gov/mmwr* To order paper copy, contact: Superintendent of Documents P.O. Box 371954 Pittsburgh, PA 15250-7954 202-512-1800	Free
IAC Express NEEDLETIPS & Vaccinate Adults	**Order from:** **Immunization Action Coalition at** ***http://www.immunize.org/subscribe/nt.asp***	**Free**

Training Tools

Vaccine Storage and Handling Toolkit (Under Revision) **Vaccine Storage and Handling Guide**	**http://www.2a.cdc.gov/vaccines/ed/shtoolkit/** ***http://www.cdc.gov/vaccines/recs/storage/guide/default.htm***	
Immunization Administration	View Attachment D of the Georgia Immunization Program Manual Can be downloaded at http://health.state.ga.us/programs/immunization/index.asp Or view appendix D of the Pink book online at http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-d.pdf	Free
Copies of the CDC Satellite Immunization Training Courses	View webcasts at: *http://www2a.cdc.gov/phtn/calendar.asp* or order the DVD using the CDC online order form at: *https://www2.cdc.gov/nchstp_od/PIWeb/niporderform.asp*	One DVD available free
Immunization: You Call the Shots--- web-based training course	Access from the CDC website at *http://www.cdc.gov/vaccines/ed/youcallthesshots.htm*	Free

Immunization Resources

Telephone and Fax:

- GA Immunization Program "On Call" Phone Line
  404-657-3158
- GA Vaccines for Children Program
  800-848-3868, 800-372-3627 (Fax)
- CDC Immunization Information Hotline (English & Spanish)
  800-232-4636
- Public Health Foundation
  202-218-4400
- GA Chapter, American Academy of Pediatrics
  404-881-5020
- GA Chapter, American Academy of Family Physicians
  404-321-7445 or (800) 392-3841

Affiliated Computer Services (ACS) Georgia Health Partnership Customer Interaction Center
Providers:……...…....…….. 1-800-766-4456
…….. 404-298-1228
For claim status, eligibility verification, provider enrollment, Electronic Manual Claims (EMC) assistance (GA Better Health and Health Check Services)., and to reach your ACS Field Representative - *www.ghp.georgia.gov*

Members:……1-866-211-0950
TDD/TTY……..……..……1-866-211-0951

Health Check Services...…….....…404-656-6679
http://health.state.ga.us/programs/family/healthcheck.asp

Vaccine Manufacturers

Bayer Pharmaceutical ……1-800-842-2937
Merck National Service Center.....…...1-800-672-6372
Merck Vaccine Customer Help Line..…. 1-800-982-7482
Sanofi Pasteur……..1-800-822-2463
GlaxoSmithKline….....…. ..1-800-366-8900
Wyeth-Lederle Laboratories……. 1-800-666-7248

Immunization Resources

Internet Addresses:

- GA Immunization Program
  http://health.state.ga.us/programs/immunization/index.asp
- CDC Home Page Immunization
  www.cdc.gov
- CDC Travel Information
  www.cdc.gov/travel/destinat.htm
- All Kids Count
  www.allkidscount.org
- Immunofacts
  www.immunofacts.com
- GA Chapter, American Academy of Pediatrics
  www.gaaap.org
- Immunization Action Coalition
  www.immunize.org
- Every Child by Two
  www.ecbt.org
- American Academy of Pediatrics
  www.aap.org
- GA Academy of Family Physicians
  www.gafp.org
- **Georgia Health Partnership**
  https://www.mmis.georgia.gov/portable/default.aspx
- National Vaccine Program Office
  www.hhs.gov/nvpo

Education Presentations:

- Georgia Immunization Program Presentations[1]
- CDC Satellite Training Programs[2]
- Educating Physicians In Your Community (EPIC)[3]

[1]Contact your Immunization Office Consultant to schedule (see page 6 for program offerings)
[2]Contact your Immunization Office Consultant for dates and locations
[3]Contact GA Chapter: Academy Of Pediatrics to schedule

Georgia Immunization Office
Educational Training Presentations

Georgia Department of Public Health is an approved provider of continuing nursing education by the Georgia Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

Title of Presentation	Length of Presentation	Certification Credits Awarded if given by GA Immunization Office Staff Contact Hours= CH
Adolescent and Adult Immunizations	1.5 Hours	CH 1.5 Hours
Childhood Immunization Update (Combination review of the immunization schedule and GA requirements for daycare & school attendance)	1.5 Hours	CH 1.5 Hours
Childhood Immunization Requirements (for WIC and Clerical Personnel)	1 Hour	
Epidemiology & Prevention of Viral Hepatitis From A-E (Contact Lynne Mercedes (404) 657-3171)*	3 Hours	CH 3.0 Hours
GA Requirements for School and Child Care Attendance (presentation for health care providers, day care, and school personnel)	1.5 Hours	CH 1.5 Hours
GRITS (GA Registry of Immunization Transaction and Services) Overview	1 Hour	
GRITS Train-The-Trainer Training	3-5 Hours	
Perinatal Hepatitis B Prevention (Inservice for Birthing Hospital) (Contact Tracy Kavanaugh (404) 651-5196)*	1 Hour	
Review Of The Recommended Immunization Schedule	1.5 Hour	CH 1.5 Hours
Vaccine Administration Techniques (Contact Nurse Consultant (404)-657-3158)*	1.5 Hour	CH 1.5 Hours
Vaccine Storage & Handling	1.66 Hours	CH 1.66 Hours

To schedule a training session:
Contact your Georgia Immunization Office Consultant at 404-657-3158
*** Contact the appropriate Coordinator or Consultant**

POST TEST

"How to Protect Your Vaccine Supply"

Please mark one correct answer for each question. Each question counts 10 points.
A passing score is 80%.

1. The type of refrigerator/freezer utilized to store vaccine should be:

   A. Standard refrigerator with separate freezer door and seal
   B. Dormitory type refrigerator with small hanging freezer inside
   C. Dormitory type refrigerator and separate dormitory type freezer

2. Which vaccines go in the freezer?

   A. IPV & DTaP
   B. Td, Hib
   C. Varicella-Containing Vaccines
   D. DT and Pneumococcal

3. The temperature in the refrigerator and freezer should be checked:

   A. Once a day
   B. Twice a day
   C. Once a week
   D. Once a month

4. To stabilize temperature in the refrigerator it is helpful to keep the following in there:

   A. All vaccine diluents
   B. Large plastic containers filled with water
   C. Lunch

5. Vaccine should never be stored in which part of the refrigerator?

   A. Floor
   B. Door
   C. Lower right-hand corner

6. You can tell if the temperature in your freezer does not go above freezing if :

   A. A penny on top of a cup of ice does not become covered with ice.
   B. The cola you put in there at 7:00AM explodes by lunch time.
   C. The freezer needs to be defrosted.

7. When handling varicella vaccine, which of the following is **not** recommended?

   A. Keep at 5°F or below and protect it from light.
   B. Dry ice must be present for temporary storage or emergency transport.
   C. Discard reconstituted vaccine if not used within 30 minutes.
   D. None of the above

8. The expiration date on the vial of vaccine you are holding is today's date. This vaccine is ok to use.

   A. True
   B. False

9. When rotating the vaccine stock,

   A. Use short dated vaccine first.
   B. Use the longest date vaccine first as this is the "freshest."
   C. Rotating stock is not that important as long as you don't use anything outdated.
   D. Always over-order to make sure nothing out dates.

10. You should have a sign "Do Not Unplug" near your refrigerator/freezer electrical outlet to prevent accidental unplugging.

    A. True
    B. False

POST TEST

Answers

"How to Protect Your Vaccine Supply"

Please mark one correct answer for each question. Each question counts 10 points.
A passing score is 80%.

1. The type of refrigerator/freezer utilized to store vaccine should be:

   A. Standard refrigerator with separate freezer door and seal
   B. Dormitory type refrigerator with small hanging freezer inside
   C. Dormitory type refrigerator and separate dormitory type freezer

2. Which vaccines go in the freezer?

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   B. Td, Hib
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   C. The freezer needs to be defrosted.

7. When handling varicella vaccine, which of the following is **not** important?

   A. Keep at 5°F or below and protect it from light.
   B. Dry ice must be present for temporary storage or emergency transport.
   C. Discard reconstituted vaccine if not used within 30 minutes.
   D. None of the above

8. The expiration date on the vial of vaccine you are holding is today's date. This vaccine is ok to use.

   A. True
   B. False

9. When rotating the vaccine stock,

   A. Use short dated vaccine first.
   B. Use the longest date vaccine first as this is the "freshest."
   C. Rotating stock is not that important as long as you don't use anything outdated.
   D. Always over-order to make sure nothing out dates.

10. You should have a sign "Do Not Unplug" near your refrigerator/freezer outlet to prevent accidental unplugging.

    A. True
    B. False

How to Administer Intramuscular (IM) Vaccine Injections

Administer these vaccines by the intramuscular (IM) route: diphtheria-tetanus-pertussis (DTaP, Tdap); diphtheria-tetanus (DT, Td); *Haemophilus influenzae* type b (Hib); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus (HPV); inactivated influenza (TIV); quadrivalent meningococcal conjugate (MCV4); and pneumococcal conjugate (PCV). Administer inactivated polio (IPV) and pneumococcal polysaccharide (PPSV23) either IM or SC.

Patient age	Injection site	Needle size
Newborn (0–28 days)	Anterolateral thigh muscle	⅝"* (22–25 gauge)
Infant (1–12 months)	Anterolateral thigh muscle	1"* (22–25 gauge)
Toddler (1–2 years)	Anterolateral thigh muscle	1–1¼" (22–25 gauge)
	Alternate site: Deltoid muscle of arm if muscle mass is adequate	⅝–1"* (22–25 gauge)
Children (3–18 years)	Deltoid muscle (upper arm)	⅝–1"* (22–25 gauge)
	Alternate site: Anterolateral thigh muscle	1–1¼" (22–25 gauge)
Adults 19 years and older	Deltoid muscle (upper arm)	1–1½"*† (22–25 gauge)
	Alternate site: Anterolateral thigh muscle	1–1½" (22–25 gauge)

*A ⅝" needle usually is adequate for neonates (first 28 days of life), preterm infants, and children ages 1 through 18 years if the skin is stretched flat between the thumb and forefinger and the needle is inserted at a 90° angle to the skin.

†A ⅝" needle is sufficent in adults weighing less than 130 lbs (<60 kg) if the subcutaneous tissue is not bunched and the injection is made at a 90-degree angle; a 1" needle is sufficient in adults weighing 130–152 lbs (60–70 kg); a 1–1½" needle is recommended in women weighing 152–200 lbs (70–90 kg) and men weighing 152–260 lbs (70–118 kg); a 1½" needle is recommended in women weighing more than 200 lbs (>90 kg) or men weighing more than 260 lbs (>118 kg).

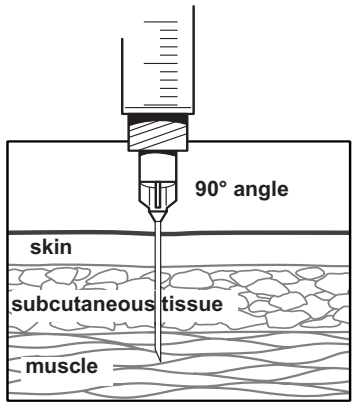
Needle insertion

Use a needle long enough to reach deep into the muscle.

Insert needle at a 90° angle to the skin with a quick thrust.

(Before administering an injection of vaccine, it is not necessary to aspirate, i.e., to pull back on the syringe plunger after needle insertion.¶)

Multiple injections given in the same extremity should be separated by a minimum of 1", if possible.

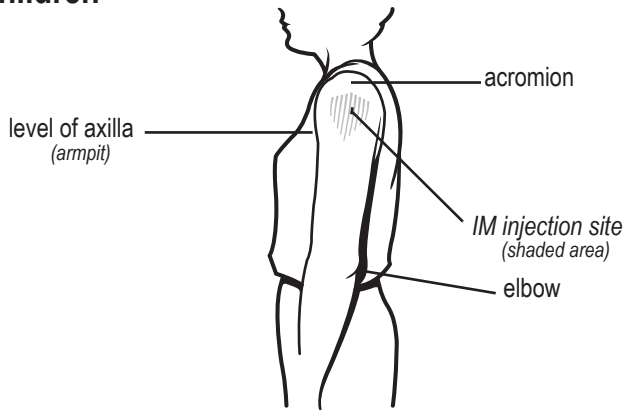


¶CDC. "ACIP General Recommendations on Immunization" at www.immunize.org/acip

IM site for infants and toddlers

Insert needle at a 90° angle into the anterolateral thigh muscle.

IM site for children and adults



Insert needle at a 90° angle into thickest portion of deltoid muscle — above the level of the axilla and below the acromion.

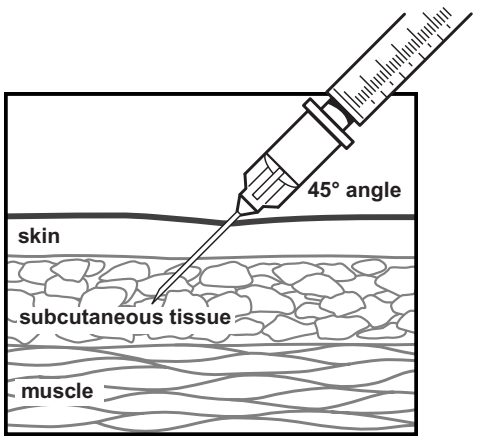
Technical content reviewed by the Centers for Disease Control and Prevention.

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

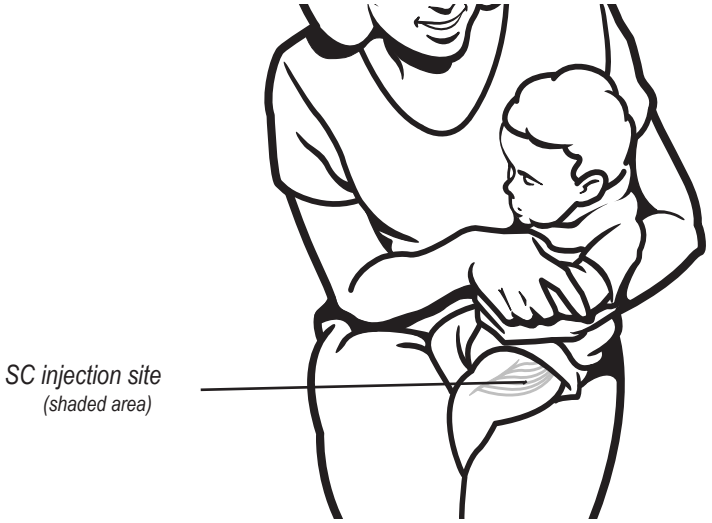
How to Administer Subcutaneous (SC) Vaccine Injections

Administer these vaccines by the subcutaneous (SC) route: measles, mumps, and rubella (MMR), varicella (VAR), meningococcal polysaccharide (MPSV4), and zoster (shingles [ZOS]). Administer inactivated polio (IPV) and pneumococcal polysaccharide (PPSV23) vaccines either SC or IM.

Patient age	Injection site	Needle size	Needle insertion
Birth to 12 mos.	Fatty tissue over the anterolateral thigh muscle	⅝" needle, 23–25 gauge	Pinch up on subcutaneous (SC) tissue to prevent injection into muscle. Insert needle at 45° angle to the skin. (Before administering an injection of vaccine, it is not necessary to aspirate, i.e., to pull back on the syringe plunger after needle insertion.*) Multiple injections given in the same extremity should be separated by a minimum of 1". *CDC. "ACIP General Recommendations on Immunization" at www.immunize.org/acip
12 mos. and older	Fatty tissue over anterolateral thigh or fatty tissue over triceps	⅝" needle, 23–25 gauge	

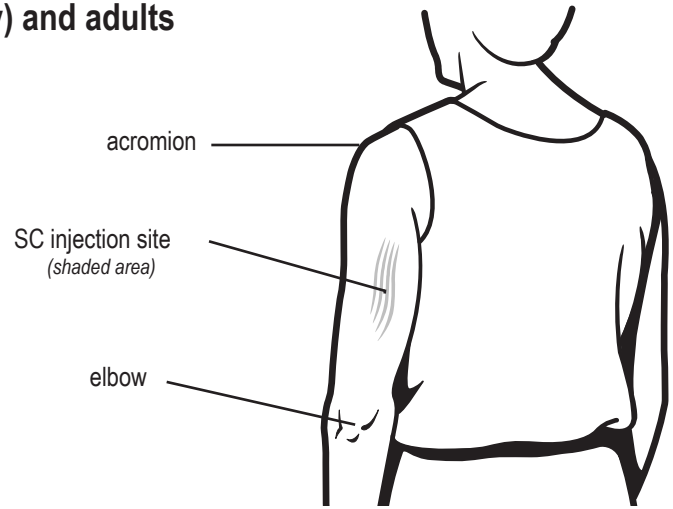


SC site for infants



Insert needle at a 45° angle into fatty tissue of the anterolateral thigh. Make sure you pinch up on SC tissue to prevent injection into the muscle.

SC site for children (after the 1st birthday) and adults



Insert needle at a 45° angle into the fatty tissue over the triceps muscle. Make sure you pinch up on the SC tissue to prevent injection into the muscle.

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

www.immunize.org/catg.d/p2020.pdf • Item #P2020 (10/12)

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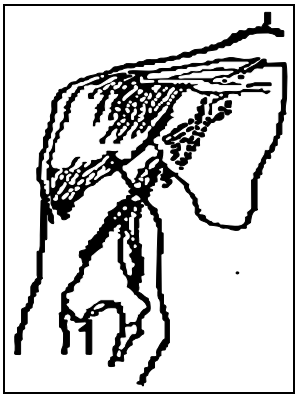
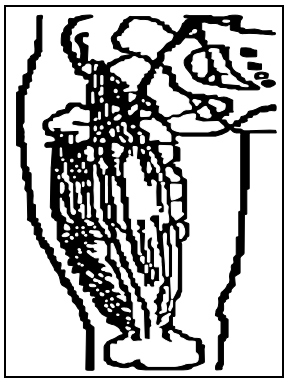
Vaccine Administration Techniques

POST-TEST





1. Indicate the site for (**a**) an intramuscular, and (**b**) a subcutaneous immunization on an adult.

2. Please mark the site for an infant or toddler's **DTaP** immunization.

3. Please indicate above with arrows the angle of the needle used for **(a)** an intramuscular and **(b)** a subcutaneous immunization.

4. If the following three vaccines were to be administered simultaneously to an adult, which site(s) and method(s) of immunization would be used for each:

Type of Vaccine	Route(s) of Injection/administration	Site(s)
Influenza	_____	_____
Pneumococcal	_____	_____
Td/Tdap	_____	_____

5. What factors should be considered when determining the needle size and site for an intramuscular injection?
   a. Patient's age
   b. Volume of material to be administered
   c. Size of the muscle
   d. Depth below muscle surface into which the material is to be injected
   e. All of the above

6. Circle the site which is **never** recommended for immunizations.
   a. Deltoid b. Vastus Lateralis
   c. Anterolateral Thigh d. Gluteus Maximus

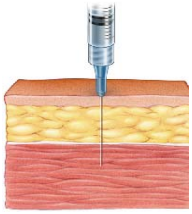
7. Check the pediatric vaccines which may be given to a child on the same visit as a TB skin test:
   __Varicella __DTaP __Hib __MMR

8. Vaccines can be mixed in a single syringe when:
   a. Vaccines are licensed and labeled to be mixed
   b. There is need to decrease the number of injections to be given
   c. Giving all live or all inactivated vaccines.

NAME _____DATE _____SCORE _____

9. Which of the following is not a route of vaccine administration?
   a. IM
   b. IT
   c. SC
   d. Nasal

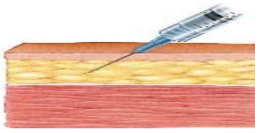
10. Which type of injection is this?
   a. SL
   b. SC
   c. IM
   d. IV



11. When administering intranasal influenza vaccine it is necessary to re-administer vaccine if client sneezes immediately following administration?
   a. True b. False

12. You must re-administer rotavirus if the infant spits or regurgitates following administration.
   a. True b. False

13. The needle angle is correct for an SC injection.
   a. True b. False



14. Never recap or clip needles prior to disposal.
   a. True b. False

15. If both hepatitis A and B vaccines are indicated, it is acceptable to mix the two vaccines together in one syringe.
   a. True b. False

16. When more than two IM vaccines are given to an infant at one visit, the gluteal (buttock) muscle should be used.
   a. True b. False

17. A new needle and syringe must be used for each vaccination.
   a. True b. False

18. MMR and varicella vaccines are both given subcutaneously.
   a. True b. False

19. The proper needle length for an SC injection in a child or adult is 5/8inch.
   a. True b. False

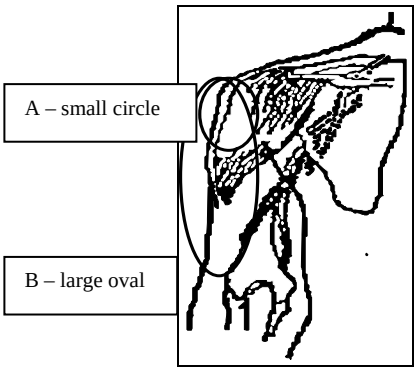
20. No vaccine should be injected unless epinephrine is immediately available.
   a. True b. False

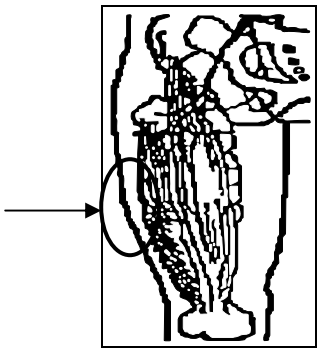
NAME _____DATE _____SCORE _____

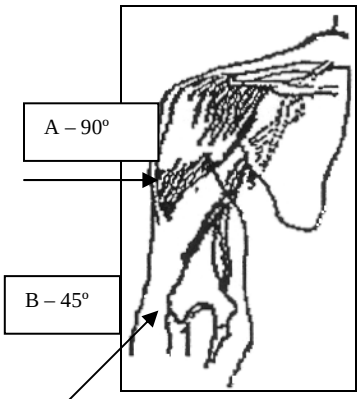
8 Vaccine Administration Techniques

POST-TEST ANSWER KEY

Score 5 points for correct answers. Passing score = 80%







1. Indicate the sites for (a) an intramuscular, and (b) a subcutaneous immunization on an adult.
2. Please mark the site for an infant or toddler's DTaP immunization.
3. Please indicate above with arrows the angle of the needle used for (a) an intramuscular and (b) a subcutaneous immunization.

4. If the following three vaccines were to be administered simultaneously to an adult, which site and method of immunization would be used for each:

Type of Vaccine	Route(s) of Injection	Site(s)
Influenza	***IM***, ***ID***, ***Intranasal***	***IM***, ***ID*** *deltoid*, nostrils*
Pneumococcal	*Either* ***SC*** *or* ***IM***	***SC*** *upper arm;* ***IM*** *deltoid**
Td	***IM***	*Either deltoid**

****Note: Different arms preferred. Separate sites required****.*

5. What factors should be considered when determining the needle size and site for an intramuscular injection?
   a. Patient's age
   b. Volume of material to be administered
   c. Size of the muscle
   d. Depth below muscle surface into which the material is to be injected
   e. All of the above

6. Circle the site which is never recommended for immunizations.
   Deltoid — Vastus Lateralis
   Anterolateral Thigh — Gluteus Maximus

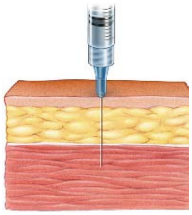
7. Check below the pediatric vaccines which may be given to a child on the same visit as a TB skin test:
   Varicella √ — DTaP √
   Hib √ — MMR √

8. Vaccines can be mixed in a single syringe when:
   a. Vaccines are licensed and labeled to be mixed
   b. There is need to decrease the number of injections to be given
   c. Giving all live or all inactivated vaccines.

NAME _____ DATE _____ SCORE _____

9. Which of the following is not a route of vaccine administration?
   a. IM
   b. IT
   c. SC
   d. Nasal

10. Which type of injection is this?



   a. SL
   b. SC
   c. IM
   d. IV

11. When administering intranasal influenza vaccine it is necessary to re-administer vaccine if client sneezes immediately following administration?
   a. True b. False

12. You must re-administer rotavirus if the infant spits or regurgitates following administration.
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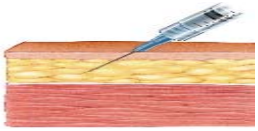
13. The needle angle is correct for an SC injection.



   a. True b. False

14. Never recap or clip needles prior to disposal.
   a. True b. False

15. If both hepatitis A and B vaccines are indicated, it is acceptable to mix the two vaccines together in one syringe.
   a. True b. False

16. When more than two IM vaccines are given to an infant at one visit, the gluteal (buttock) muscle should be used.
   a. True b. False

17. A new needle and syringe must be used for each vaccination.
   a. True b. False

18. MMR and varicella vaccines are both given subcutaneously.
   a. True b. False

19. The proper needle length for an SC injection in a child or adult is 5/8inch.
   a. True b. False

20. No vaccine should be injected unless epinephrine is immediately available.
   a. True b. False

NAME _____DATE _____SCORE _____

CLINICAL SKILLS CHECKLIST
Support Staff

Clinic site_____ Name and title of person being reviewed_____
Program/type of client visit_____Date_____Time_____Reviewer_____

To assure the quality of client services, this form is used to record the findings from observation of support staff performance. For each line, mark under the number that most closely fits the consistency of the support staff's performance with programmatic standards and policies and procedures. Comments must be specific and objective. This form may be used for one observation per age group indicated. A minimum of two observations per age group are required for completion of ***preceptorship****. A minimum of one observation per age group is required annually.*

RATING CODE: (1) = Unsatisfactory (2)= Needs improvement (3)= Satisfactory (4) = Not applicable

STANDARDS	Infant				Child				Adolescent				Adult			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Support Staff: Interview Process/Application																
Cordial during interview and immunization fee assessment and collection process																
Introduces self and observer																
Is wearing a clearly visible ID badge (designating professional licensure)																
Uses explicit terminology to explain immunization status																
Accurately acquires and documents appropriate demographic data and insurance coverage (Medicaid, PeachCare, VFC, etc.)																
Demonstrates appropriate use of current immunization schedule to obtain prior immunization history and enters information into client's immunization record accurately. Process includes accessing, querying, and reviewing records in GRITS.																

STANDARDS	Infant				Child				Adolescent				Adult			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Provides appropriate type, translation, and most current Vaccine Information Statements (VIS) for patient or caregiver to review prior to receiving immunizations																
Issues immunization certificates for school and day care attendance in accordance with Georgia laws and rules and regulations																
Demonstrates appropriate vaccine coding, including hepatitis B coding, according to district and state policies																
Demonstrates appropriate use of "next immunization date due" and understanding of the relationship of "next immunization date due" to pre-call/recall activities																
Demonstrates knowledge of Clinical Assessment Software Application (WinCASA/ CoCASA)																
Demonstrates knowledge and appropriate use of MOGE and documents records accordingly																
Demonstrates coordination of other programs (ex: Child Health, WIC, FP, STD, etc.) with immunizations by reviewing and entering immunization history and referring for immunizations as needed																
Demonstrates coordination of visits involving other programs (ex: Child Health, WIC, etc.) with immunizations by scheduling appointments according to due date of next Health Check, WIC re-certification or certification, etc., when feasible																
Provides client with current immunization record and next immunization date due when indicated																
Vaccine Storage and Handling:																
Demonstrates appropriate Vaccine Storage and Handling techniques according to Georgia Immunization Office standards.																
Transporting Dangerous Drugs:																

STANDARDS	Infant				Child				Adolescent				Adult			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
If applicable, complies with the parameters, accountability standards, and training defined in the *Protocol for Transporting Dangerous Drugs*.																
Computer/Automation:																
Computer security procedure followed																
Data and/or billing system correctly entered																
Computer screen turned away from clients																

SUMMARY

FEEDBACK/STRATEGIZING_____

_____

_____

_____

_____

FOLLOW-UP PLAN_____

_____

_____

_____

Signature of person being reviewed:_____ Signature of Clinician:_____

Date:_____ Date:_____

CLINICAL SKILLS CHECKLIST
Nursing

Clinic site_____ Name and title of person being reviewed_____
Program/type of client visit_____Date_____Time_____Reviewer_____

To assure the quality of client services, this form is used to record the findings from observation of a nurse performance. For each line, mark under the number that most closely fits the consistency of the nurses' performance with programmatic standards and policies and procedures. Comments must be specific and objective.

RATING CODE: (1) = Unsatisfactory (2)= Needs improvement (3)= Satisfactory (4) = Not applicable

	Infant				Child				Adolescent				Adult			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Nursing																
Interview Process																
Cordial with client displaying excellent customer service																
Uses simple, explicit immunization terminology																
Introduces self and observer.																
Is wearing a clearly visible ID badge																
Listens attentively																
Conducts session in language participant speaks/understands under supervision of the preceptor.																
Reviews appropriate immunization-screening questions prior to administration according to district and state policies and procedures (allergies, fever, immunocompetence, previous reactions, blood products, etc.) and counsels client appropriately under the supervision of the preceptor.																
Demonstrates appropriate knowledge of where to find information pertaining to true contraindications and precautions when assessing and administering vaccines																
Assists in evaluating immunizations from computer and or personal immunization record and accurately determines immunizations needed. Process includes accessing, querying, and reviewing records in GRITS.																

STANDARDS	Infant				Child				Adolescent				Adult			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Explains to client/parent/caregiver appropriate immunizations needed in a accurate and professional manner under the supervision of the preceptor.																
Has client/caregiver review current, appropriately translated, Vaccine Information Statement (VIS) for each vaccine to be administered and answers questions or concerns prior to administering vaccine with preceptor present.																
Administration Techniques																
Uses immunization resources appropriately (Georgia Immunization Program Manual, ACIP Manual, District Policies and Procedures (P&P), CDC's Recommendations for Travel, CDC's Epidemiology and Prevention of Vaccine Preventable Diseases, The Red Book , etc.) to assess and administer vaccine indicated for age																
Utilizes current recommended schedule and recommendations and district policies and procedures to assess and administer adult and childhood vaccines																
Understands use of accelerated vaccination schedule when appropriate																
Checks expiration date and lot number of each vaccine before administering																
Follows universal precautions and appropriate hand washing techniques during immunization administration																
Appropriately prepares site for administration																
Uses appropriate needle length and gauge for type of injection																
Uses appropriate route of administration for each vaccine (IM, SQ, PO, ID, intranasal)																
Administers vaccine in appropriate site																
Uses correct technique for administering injectable vaccines																
Uses correct technique for administering oral vaccines																
Utilizes appropriate positioning techniques to administer vaccine																
Documentation:																
Documents according to P&P, the type of vaccine administered, date of administration, manufacturer, lot number, site, route, nurse's' initials, observer's initials, and VIS publication date																

STANDARDS	Infant				Child				Adolescent				Adult			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Demonstrates knowledge of informed request policy. Reviews current VIS for each vaccine, answers questions, and has client sign appropriate consent under supervision of preceptor.																
Demonstrates knowledge of VAERS (Vaccine Adverse Event Reporting System) reporting system according to Georgia Immunization Office regulations																
Appropriately accounts for vaccine wasted																
Accurately documents immunizations administered and next due date on clinic record																
Accurately documents next vaccine due and “date next immunization due” on client’s personal immunization record																
Documents certificates issued in accordance with district P&P																
Demonstrates knowledge of MOGE (Moved or Gone Elsewhere) criteria according to Georgia Immunization Office standards																
Follows hepatitis B guidelines according to Georgia Immunization Office recommendations (also correctly determines High Risk or VFC eligibility)																
Counseling/Education																
Informs client/parent of any immunization problem (delinquent immunization status, screening for private provider use/MOGE status) under supervision of preceptor.																
Assists with scheduling follow-up as indicated (return visit coordinated with other clinics, labs, voucher pick-ups, etc.)																
Demonstrates knowledge of procedure for referrals (to private providers, Children First, CMS, etc.)																
Provides "After the Vaccines" document (in most appropriate translation) explaining side effects for any vaccine administered																
Provides client with appropriate immunization certificate(s) according to the GA laws and rules and regulations for school and day care attendance, and an updated immunization history, including next immunization “due date”																
Computer/Automation																

STANDARDS	Infant				Child				Adolescent				Adult			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Computer security procedure followed per district policy																
Correct immunization procedure codes, lot numbers, etc. entered correctly according to Georgia Immunization Office standards under supervision of preceptor.																
Demonstrates basic knowledege of GRITS (what is it used for, what information is gained from the program)																
Demonstrates knowledge of Clinic Assessment Software Application (WinCASA/ CoCASA) criteria.																
Storage and Handling																
Demonstrates appropriate Vaccine Storage and Handling techniques according to Georgia Immunization Office standards																
Other (specify)																

SUMMARY

Description of Nurse Performance _____

_____

_____

_____

_____

Signature of Nurse being reviewed:_____ Signature of Observer/Clinician:_____

Date:_____ Date:_____

2012 GIP Provider Site Visit Questionnaire
(Public Health Department Sites)

☐ GIP QA Site Visit/AFIX visit ☐ GIP QA Site Visit Only

Date: _____

GIP ID Number: _____ GRITS Org ID: _____

Facility Name: _____

Address: _____

City: _____ State: GA Zip: _____

Telephone: _____ Fax Number: _____

District: _____ County: _____

Reviewer's (IPC) Name: _____

Contact Person for Immunization: _____

Email: _____

Type of Clinic:

☐ General Health Dept (Multi-Program)

☐ Family Planning or STD/HIV Only

☐ Teens Only

! = An inappropriate or incorrect response to any question marked with this icon automatically requires that a corrective action be recommended.

SECTION I. VFC/GIP COMPLIANCE

Questions (1-8) should be answered by interviewing the provider.

1. (A) ! What is the vaccine administration fee charged to non-Medicaid VFC eligible children (uninsured, American Indian/Alaska Native, underinsured)? _____

   (B) ! What is the vaccine administration fee charged to adults who receive state-supplied vaccine? _____ (Cap for both adults and children = $14.81 per injection)

2. Under what circumstances would a client be referred to another facility for immunization services?
   - ☐ Not applicable, clients are never referred
   - ☐ Vaccine is unavailable
   - ☐ Client is under-insured
   - ☐ Client/parent is unable to pay administration fee
   - ☐ Client/parent is unable to pay office visit fee
   - ☐ Other (specify)

3. Which of the following vaccines are **NOT** routinely recommended for clients in this facility (including adults)?
   - ☐ DTaP
   - ☐ Influenza (during flu season)
   - ☐ Pneumococcal Polysaccharide*
   - ☐ Hepatitis A
   - ☐ Meningococcal Conjugate
   - ☐ Polio
   - ☐ Hepatitis B
   - ☐ MMR
   - ☐ Rotavirus
   - ☐ HIB
   - ☐ MMR-V
   - ☐ Td
   - ☐ Human Papillomavirus
   - ☐ Pneumococcal Conjugate
   - ☐ Tdap
   - ☐ Other: _____
   - ☐ Varicella

   **High-risk adults, adults over age 65 years, and high risk children ≥ 2 years of age.*

4. ! When does this clinic provide patients with copies of the Vaccine Information Statements (VIS) to keep?
   - ☐ Every time the patient receives a vaccination
   - ☐ When the client receives the first dose of vaccine within a particular series (e.g. 1st dose of DTaP)
   - ☐ Does not provide
   - ☐ Other (specify)_____

5. In order to complete the annual provider profile, how does this clinic determine the number of VFC-eligible patients in this clinic? *Note: "Provider profile" is the number of children (not doses) by age category that the provider expects to immunize within a 12-month period. The VFC Program requires annual updates of this information.*
   - ☐ Use doses administered data
   - ☐ Use benchmarking data
   - ☐ Use Medicaid and billing data
   - ☐ Immunization Information System (GRITS)
   - ☐ Other (please describe): _____

6. ! When does the clinic screen children for VFC eligibility?
   - ☐ First immunization visit to the office only
   - ☐ Every immunization visit
   - ☐ Does not screen for VFC eligibility
   - ☐ Not applicable, clinic serves 100% VFC eligible children and has appropriate Comprehensive Certification form with up-to-date signature on file.
   - ☐ Other (specify) _____

7. (A) ! Does this clinic always notify the Immunization Program when publicly purchased vaccine has been involved in a cold chain failure, has expired or been wasted?
☐ Yes ☐ No

(B) *Does this clinic always notify the Immunization/VFC Program of short-dated vaccine at least three months prior to the date of expiration so that vaccine may be transferred to another provider?
☐ Yes ☐ No

(C) *When did the clinic last submit a VFC/State-Supplied comprehensive report? _____
***Program use only**

8. ! When does this clinic prepare vaccine for administration to patient?
☐ Immediately before administration ☐ Other: specify process_____

Questions 9-10 should be answered based on a physical review of clinic's written plan and VISs.

9. ! Does the clinic have a **written plan** for vaccine management including the following (review for accuracy):

	Yes	No
Designation of primary vaccine coordinator and at least one back-up staff		
Proper vaccine storage and handling		
Vaccine shipping (includes receiving & transport)		
Procedures for vaccine relocation in the event of a power failure or mechanical difficulty or emergency situation (emergency plan)		
Has the emergency plan been reviewed or updated annually or since change in responsible staff?		
Vaccine ordering and reporting (i.e., should be **monthly**)		
Inventory control (e.g., stock rotation)		
Vaccine wastage		

10. ! Please identify the publication date for each of the VIS currently being used in this clinic/practice and then check the appropriate status for each VIS. *(If not using VISs or using outdated VISs, leave current VISs.*

VACCINE*	VIS VERSION BEING USED IN THIS FACILITY			
	Current	Outdated	None Used	Does Not Administer
DTaP (05/17/2007) E & S	☐	☐	☐	☐
Polio **(11/08/2011)** E & S	☐	☐	☐	☐
MMR **(03/13/2008)** E & S	☐	☐	☐	☐
Hepatitis B **(02/02/2012)** E & S	☐	☐	☐	☐
Varicella **(3/13/2008)** E & S	☐	☐	☐	☐
Hepatitis A **(10/25/2011)** E & S	☐	☐	☐	☐
Hib (12/16/1998) E & S	☐	☐	☐	☐
Pneumococcal Conjugate **(PCV13) (04/16/2010)** E & S	☐	☐	☐	☐
Inactivated Influenza **(07/26/2011)** E & S	☐	☐	☐	☐
Live, Intranasal Influenza **(07/26/2011)** E & S	☐	☐	☐	☐
Pneumococcal Polysaccharide **(PPSV23) (10/06/09)** E&S	☐	☐	☐	☐
Meningococcal **(MCV4) (MPSV4) (10/14/2011)** E&S	☐	☐	☐	☐
Td/Tdap **(01/24/2012)** E&S	☐	☐	☐	☐
Rotavirus **(12/06/2010)** E & S	☐	☐	☐	☐
Human Papillomavirus **(05/3/2011) or (02/22/2012)**	☐	☐	☐	☐
Multiple Vaccines (09/18/2008) E & S	☐	☐	☐	☐
Zoster **(10/06/2009)** E & S	☐	☐	☐	☐
Other _____	☐	☐	☐	☐

VIS website: http://cdc.gov/vaccines/pubs/vis/default.htm Current VIS publication dates as of 02/22/2012

Questions (11-28) should be answered based on a physical review of clinic's refrigerator(s) and freezer(s).

11. ! What type of storage units does this clinic use to store vaccines, including varicella? Check all that apply.

(Dual thermostats/temperature controls are preferred if using household unit.)

Varicella Vaccine	All Other Vaccines
☐ Stand alone freezer	☐ Stand alone freezer
☐ Stand alone refrigerator	☐ Stand alone refrigerator
☐ Dormitory style refrigerator/freezer	☐ Dormitory style refrigerator/freezer
☐ Combined refrigerator/freezer with separate refrigerator and freezer doors (e.g. household style appliance)	☐ Combined refrigerator/freezer with separate refrigerator and freezer doors (e.g. household style appliance)
☐ Combined refrigerator/freezer with a single door	☐ Combined refrigerator/freezer with a single door
☐ Does not administer vaccines requiring freezer storage	

12. ! Are working thermometers placed in a central area of each refrigerator and freezer?

	Refrigerator					Freezer				
	#1.	#2.	#3.	#4.	#5.	#1.	#2.	#3.	#4.	#5.
Yes										
Have thermometer but not placed properly										
No thermometer										

13. (A) What type of thermometer is used by the clinic (check all that apply)?

	Refrigerator					Freezer				
	#1.	#2.	#3.	#4.	#5.	#1.	#2.	#3.	#4.	#5.
Standard Fluid Filled										
Continuous Recording										
Min-Max										
Dial										
Digital										
Other (specify)										

(B) ! For each type of thermometer used by the clinic, indicate if thermometer is **certified** (check all that apply).

	Refrigerator					Freezer				
	#1.	#2.	#3.	#4.	#5.	#1.	#2.	#3	#4	#5
Standard Fluid Filled	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**
Continuous Recording	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**
Min-Max	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**
Dial	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**
Digital	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**
Other (specify)	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**	**YES___ NO ___**

14. ! For each refrigerator and freezer, indicate how often temperatures are recorded. (check all that apply)

	Refrigerator					Freezer				
	#1.	#2.	#3.	#4.	#5.	#1.	#2.	#3.	#4.	#5.
Once a day										
Less than once a day										
Twice a day										
More than twice a day										

15. Record the highest and lowest temperatures logged in the last 3 months, and indicate if recordings are Celsius (°C) or Fahrenheit (°F). *(If no log is available, record current temperatures and select "no." If log is not available for full 3 months, record the highest and lowest temperatures from available logs and select "partial.")*

	Refrigerator (2-8°C / 35-46°F)					**Freezer**(-15°C / 5°F or lower)				
	#1.	#2.	#3.	#4.	#5.	#1.	#2.	#3.	#4.	#5.
Lowest	____'C ____'F	____'C ____'F	____'C ____'F	____'C ____'F	____'C ____'F	____'C ____'F	____'C ____'F	____'C ____'F	____'C ____'F	____'C ____'F
Highest	____'C ____'F	____'C ____'F	____'C ____'F	____'C ____'F	____'C ____'F	____'C ____'F	____'C ____'F	____'C ____'F	____'C ____'F	____'C ____'F
Log available for last 3 months?	**YES** **NO** **Partial**	**YES** **NO** **Partial**	**YES** **NO** **Partial**	**YES** **NO** **Partial**	**YES** **NO** **Partial**	**YES** **NO** **Partial**	**YES** **NO** **Partial**	**YES** **NO** **Partial**	**YES** **NO** **Partial**	**YES** **NO** **Partial**

16. ! During past 3 months, how many times were the temperatures outside the recommended range? If no logs are available, select "unknown."

	Refrigerator (2-8°C / 35-46°F)					**Freezer** (-15°C / 5°F or lower)				
	#1.	#2.	#3.	#4.	#5.	#1.	#2.	#3.	#4.	#5.
Below Guidelines										
Above Guidelines										
Unknown: No Log Available										

17. ! When the temperatures were outside the recommended range, what action did the provider take? *(✓all that apply)*

- ☐ **Adjusted thermostat in refrigerator/freezer**
- ☐ **Measured temperature with different thermometer to check accuracy of original reading**
- ☐ **Moved vaccine to a different refrigerator/freezer maintained at proper temperature**
- ☐ **Called the vaccine manufacturer to determine the potency of the vaccine**
- ☐ **Called the local/state immunization program for assistance**
- ☐ Did not do anything
- ☐ Unable to answer, no log available
- ☐ Not applicable, temps never out of range

18. ! Does the clinic have written documentation of the action taken when the temperatures were outside the recommended range?

☐ Yes ☐ No ☐ Not Applicable – No temperatures outside range ☐ Unable to answer, no log available

19. Record the current temperatures. **(THIS IS NOT OPTIONAL.)**

	Refrigerator (2-8°C / 35-46°F)					**Freezer** (-15°C / 5°F or lower)				
	#1.	#2.	#3.	#4.	#5.	#1.	#2.	#3.	#4.	#5.
Practice Thermometer	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**
Reviewer's Thermometer	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**	____**'C** ____**'F**

20. ! Are current temperatures within the guidelines according to the **reviewer's** thermometer?
(Refrigerator: 2-8°C / 35-46°F, Freezer: -15°C / 5°F or lower)

Refrigerator					**Freezer**				
#1.	#2.	#3.	#4.	#5.	#1.	#2.	#3.	#4.	#5.
YES	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**
NO	NO	NO	NO	NO	NO	NO	NO	NO	NO

21. ! Is food stored with vaccines in the refrigerator and freezer?

Refrigerator					**Freezer**				
#1.	#2.	#3.	#4.	#5.	#1.	#2.	#3.	#4.	#5.
YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
NO	**NO**	**NO**	**NO**	**NO**	**NO**	**NO**	**NO**	**NO**	**NO**

22. ! Are vaccines stored in the doors of the refrigerator and freezer?

Refrigerator					**Freezer**				
#1.	#2.	#3.	#4.	#5.	#1.	#2.	#3.	#4.	#5.
YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
NO	**NO**	**NO**	**NO**	**NO**	**NO**	**NO**	**NO**	**NO**	**NO**

23. ! Is vaccine stored in the middle of the storage unit and stacked with air space between the stacks and side/back of the unit to allow cold air to circulate around the vaccine?

Refrigerator					**Freezer**				
#1.	#2.	#3.	#4.	#5.	#1.	#2.	#3.	#4.	#5.
YES	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**
NO	NO	NO	NO	NO	NO	NO	NO	NO	NO

24. ! Is there a "DO NOT DISCONNECT" sign on the refrigerator/freezer electrical outlet?

Refrigerator					Freezer				
#1.	#2.	#3.	#4.	#5.	#1.	#2.	#3.	#4.	#5.
YES	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**
NO	NO	NO	NO	NO	NO	NO	NO	NO	NO

25. ! Is there a "DO NOT DISCONNECT" sign on the circuit breaker?

☐ **Yes** ☐ No ☐ Don't Know

26. ! Are short-dated vaccines stored in front and used first, rotating stock effectively?

Refrigerator					Freezer				
#1.	#2.	#3.	#4.	#5.	#1.	#2.	#3.	#4.	#5.
YES	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**	**YES**
NO	NO	NO	NO	NO	NO	NO	NO	NO	NO

27. ! Can the clinic physically differentiate privately purchased vaccine from publicly purchased vaccine? To answer yes, clinic must be able to demonstrate how this is done.

☐ **Yes, clinic can physically differentiate public vaccine from private vaccine.**
☐ **No, clinic cannot physically differentiate public vaccine from private vaccine.**
☐ Not applicable, clinic has no private stock.
☐ Other method (please specify)_____

*(*Should investigate if this clinic vaccinates fully insured children or provides adult immunizations for employment purposes, such as Hepatitis B for public safety workers. If so, private stock is required.)*

28. ! Upon checking the provider's vaccine supply, did you find any unreported wasted or expired vaccine?

☐ Yes ☐ **No**

Questions (29-31) should be answered based on a review of patient charts, electronic medical records, patient log (electronic or manual), or GRITS, all of which record VFC eligibility status.

29. What is the VFC eligibility screening coverage in this clinic/practice? *(Screening of children for eligibility for VFC or state-supplied vaccine, not immunization coverage rates.)*

☐ VFC screening coverage of 100% ☐ VFC screening coverage of at least 95%
☐ VFC screening coverage of at least 90% ☐ VFC screening coverage below 90%

30. What methodology was used to determine VFC eligibility screening coverage during this site visit?

☐ CDC Lot Quality Assurance (LQA) Protocol
(*Review of at least 10 randomly selected records, or ALL records if 10 not available. Records may be client charts or in clinic's information system.*)
☐ CoCASA

31. Do all immunization records contain the following documentation required by statute 42 US Code 300aa-25 and 300aa-26?

(✓ one box per item)

Required Documentation	Yes	No
Name of vaccine given	☐	☐
Date vaccine was given	☐	☐
Date VIS was given	☐	☐
Name of vaccine manufacturer	☐	☐
Lot number	☐	☐
Name and title of person who gave the vaccine	☐	☐
Address of clinic where vaccine was given	☐	☐
Publication date of VIS	☐	☐

Questions 32-33 should be answered based on results of the site visit.

32. (A) Are corrective actions recommended for this VFC enrolled site?

☐ Yes ☐ No *(SKIP to SECTION II)*

(B) Please indicate which corrective actions regarding vaccine practices were recommended for this site.

(✓ all that apply and specify problem and actions taken, especially on questions marked ❗)

☐ Administrative practices _____

_____

_____

_____

☐ Vaccine storage and handling _____

_____

_____

_____

☐ Other: _____

33. Please indicate your plan for following-up with the site to ensure recommendations were implemented.

☐ Provided technical assistance at time of site visit, no further follow-up is needed

☐ Telephone call ☐ Site visit ☐ F/U letter

☐ Suspended delivery of VFC vaccine until storage/handling problems resolved

☐ Other: _____

SECTION II. Standards for Pediatric & Adolescent Immunization Practices

Vaccine Administrative Policy

1. How does the clinic offer immunization services to patients? (Check all that apply)

☐ During well-child visits ☐ Immunization-only appointments

☐ Walk-in immunizations ☐ Dedicated days/times for immunizations

☐ Off-site immunizations ☐ During other visits such, as STD, FP, WIC or SHAPP (*circle all that apply*)

☐ Other (specify)_____

2. Is an office visit fee charged in addition to any vaccine administration fees for an imm-only visit?

☐ Yes ☐ No

If yes, what is the amount of the office visit fee if immunization is the only service? _____

3. Is a physical exam required before immunizations are given?
   ☐ Yes ☐ No

Assessment of Vaccination Delivery *(Share information re: Valid Contraindications to Immunization)*

4. Does the clinic routinely immunize when the client has:

	Yes	No	Situational
A "cold"	☐	☐	☐
Low grade fever (e.g. 100.4°F [38°C] or lower)	☐	☐	☐
Recently been exposed to infectious illness	☐	☐	☐
Mild diarrhea	☐	☐	☐
Convalescing from an acute illness	☐	☐	☐

Effective Communication about Vaccine Benefits and Risks

5. Does the clinic staff know how to obtain foreign-language Vaccine Information Statements (VIS) for patients/families whose first language is not English?
   ☐ Yes ☐ No

Proper Storage and Administration of Vaccines and Documentation of Vaccinations

6. Does the clinic have a copy or have access to a copy of the most recent version of the following documents? *(If no, leave current copy.)*

	Yes	No
Recommended Childhood Immunization Schedule	☐	☐
Revised Standards for Child and Adolescent Immunization Practices	☐	☐
Current Guide to Contraindications to Childhood Vaccines, CDC	☐	☐
Vaccine Storage and Handling Guide (December, 2011) *http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-handling.pdf*	☐	☐
2009 Red Book, AAP **(District)**	☐	☐
Standards for Adult Immunization Practices	☐	☐
Georgia Immunization Program Manual	☐	☐
Epidemiology & Prevention of VPD's (Pink Book) 12th edition, May 2011, CDC *http://www.cdc.gov/vaccines/pubs/pinkbook/pink-chapters.htm*	☐	☐
Current ACIP (Advisory Committee of Immunization Practices) Manual (available online) *http://www.cdc.gov/vaccines/pubs/ACIP-list.htm*	☐	☐
Health District's P&P for Administration of Vaccines	☐	☐
Health District's Policies and Procedures for Administration of Travel Vaccines	☐	☐
Health District's Management of Adverse Drug Reactions	☐	☐
Communicable Diseases in Man; 19th edition, Heymann **(District)**	☐	☐
Manual for Surveillance of Vaccine-Preventable Diseases, CDC (only available online) *http://www.cdc.gov/vaccines/pubs/surv-manual/default.htm*	☐	☐

7. Are up-to-date, written vaccination protocols accessible at all locations where vaccines are administered?
   ☐ Yes ☐ No (Ask to see a copy.)

8. Who gives immunization injections? (Check all that apply)
   ☐ MD ☐ NP ☐ PA ☐ RN ☐ LPN ☐ MA

9. How do persons who administer vaccines and staff who manage or support vaccine administration receive ongoing education regarding immunization? (Check all that apply.)
   - ☐ No ongoing training
   - ☐ In-house training by staff at least once a year
   - ☐ Distribution of written materials
   - ☐ Other (specify) _____
   - ☐ In-house training by health dept./professional organization at least once a year
   - ☐ Off-site conferences or workshops at least once a year
   - ☐ Web-based training or satellite broadcasts

10. Does the clinic document ongoing education regarding immunization for persons who administer vaccines and staff who manage or support vaccine administration?

    ☐ Yes ☐ No

11. Does the clinic simultaneously administer all vaccines for which the client is eligible?

    ☐ Yes ☐ No

12. What size needles are generally used for <u>intramuscular</u> injections? (Check **<u>ONE</u>** only)

    ☐ 5/8 "(inch) ☐ 1 " (inch) ☐ 7/8 " (inch)
    ☐ Depends on age/size ☐ Other (specify)_____

13. Does the clinic have VAERS forms and know how to report to VAERS? *(If not, leave copy.)*
    ☐ Yes ☐ No

14. Does the clinic require staff who have contact with patients to be immunized or show proof of immunity against the following vaccine-preventable diseases? (Check all that apply)
    - ☐ None required
    - ☐ Hepatitis A
    - ☐ Td/Tdap
    - ☐ Measles/Mumps/Rubella
    - ☐ Varicella
    - ☐ Other (specify)_____
    - ☐ Hepatitis B
    - ☐ Influenza

<u>Implementation of Strategies to Improve Vaccination Coverage</u>

15. How does the clinic remind patients of their next appointment? (Check all that apply)
    - ☐ Mail
    - ☐ Telephone
    - ☐ Verbally at last visit
    - ☐ Written appointment slip given at last visit
    - ☐ Does not remind patients of next appointment
    - ☐ Other (specify)_____

16. How does the clinic contact patients who miss their appointments? (Check all that apply)
    - ☐ Mail
    - ☐ Telephone
    - ☐ Does not contact patients who miss their appointments
    - ☐ Other (specify)_____

17. How does the clinic identify patients if no appointment is made and immunizations are due/overdue? (Check all that apply)
    - ☐ Cannot identify patients due/overdue for immunizations
    - ☐ Computer (office-based, not connected to a registry)
    - ☐ Other (specify)_____
    - ☐ Immunization registry
    - ☐ Paper-based "tickler" system or chart review

18. How frequently does the clinic generate reminder/recall notices (or phone calls) to patients who are due/overdue for a vaccination? (Check all that apply)
    - ☐ Quarterly
    - ☐ Monthly
    - ☐ No regular schedule
    - ☐ Weekly
    - ☐ Clinic/practice does not distribute recall notices to patients

19. (A) Is a district- or clinic-based patient record review and vaccination coverage assessment performed at least once a year (check all that apply)?
    - ☐ No
    - ☐ Yes
    - If Yes,
      - ☐ By clinic/district staff
      - ☐ By immunization/VFC program
      - ☐ By other external reviewer

    When was the most recent district- or clinic-based patient record review and vaccination coverage assessment? Date:_____(month/day/year)

    (B) *How often does the clinic generate CoCASA reports?
    - ☐ Monthly
    - ☐ Bi-monthly
    - ☐ Quarterly
    - ☐ Other: explain_____

    ***Program Use Only**

20. (A) Does the clinic participate in GRITS?
    - ☐ Yes
    - ☐ No

    (B) *If yes, give date shots last entered/uploaded: _____

    (C) *Does the clinic submit a monthly VFC/State-Supplied comprehensive report through GRITS?
    - ☐ Yes
    - ☐ No

    ***Program Use Only**

21. What community-based approaches does the clinic use to increase immunization coverage? (Check all that apply)
    - ☐ No community-based approaches used
    - ☐ Participates in health fairs
    - ☐ Provides off-site immunization services
    - ☐ Conducts community-based outreach/education
    - ☐ Partners schools/school nurses
    - ☐ Other (specify)_____

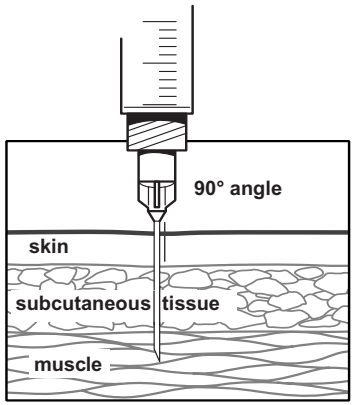
How to administer intramuscular, intradermal, and intranasal influenza vaccines

Intramuscular injection

Trivalent Inactivated Influenza Vaccines (TIV)

1. Use a needle long enough to reach deep into the muscle. Infants age 6 through 11 mos: 1"; 1 through 2 yrs: 1–1¼"; children and adults 3 yrs and older: 1–1½".
2. With your left hand*, bunch up the muscle.
3. With your right hand*, insert the needle at a 90° angle to the skin with a quick thrust.
4. Push down on the plunger and inject the entire contents of the syringe. There is no need to aspirate.
5. Remove the needle and simultaneously apply pressure to the injection site with a dry cotton ball or gauze. Hold in place for several seconds.
6. If there is any bleeding, cover the injection site with a bandage.
7. Put the used syringe in a sharps container.

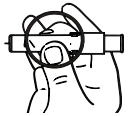
*Use the opposite hand if you are left-handed.



Intradermal administration

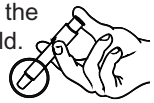
Trivalent Inactivated Influenza Vaccine (TIV)

1. Gently shake the microinjection system before administering the vaccine.
2. Hold the system by placing the thumb and middle finger on the finger pads; the index finger should remain free.



3. Insert the needle perpendicular to the skin, in the region of the deltoid, in a short, quick movement.
4. Once the needle has been inserted, maintain light pressure on the surface of the skin and inject using the index finger to push on the plunger. Do not aspirate.

5. Remove the needle from the skin. With the needle directed away from you and others, push very firmly with the thumb on the plunger to activate the needle shield. You will hear a click when the shield extends to cover the needle.



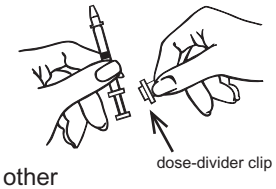
6. Dispose of the applicator in a sharps container.

Intranasal administration

Live Attenuated Influenza Vaccine (LAIV)

1. FluMist (LAIV) is for intranasal administration only. Do not inject FluMist.
2. Remove rubber tip protector. Do not remove dose-divider clip at the other end of the sprayer.
3. With the patient in an upright position (i.e., head not tilted back), place the tip just inside the nostril to ensure LAIV is delivered into the nose. The patient should breathe normally.

4. With a single motion, depress plunger as rapidly as possible until the dose-divider clip prevents you from going further.
5. Pinch and remove the dose-divider clip from the plunger.



6. Place the tip just inside the other nostril, and with a single motion, depress plunger as rapidly as possible to deliver the remaining vaccine.
7. Dispose of the applicator in a sharps container.

Technical content reviewed by the Centers for Disease Control and Prevention, October 2011.

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