Immunization Update: New Vaccine Recommendations

Satellite Conference and Live Webcast
Wednesday, September 23, 2009
10:00 a.m. - 12:00 p.m. Central Time

Produced by the Alabama Department of Public Health
Video Communications and Distance Learning Division

Objectives

• Describe recommendations for seasonal and Novel H1N1 influenza vaccines
• Discuss two upcoming changes in the Imm-50 (blue form)
• Discuss changes in recommendations for polio vaccine

Objectives

• Discuss new Haemophilus influenzae type b vaccine
• Review two rotavirus vaccines
• Discuss new recommendations for pneumococcal vaccine

Seasonal Influenza Vaccine

Impact of Influenza, 1990-1999

• Approximately 36,000 influenza-associated deaths during each influenza season
• Persons 65 years of age and older accounted for more than 90% of deaths
• Deaths of 89 children 0-18 years provisionally reported for 2008-2009
• Average 226,000 hospitalizations during each influenza season

Faculty
Deborah Kilgo, RN
Immunization Manager
Alabama Department of Public Health
### Average Influenza-Associated Illness Rates by Age Group

- Infants (0-2 months) have the highest illness rates, peaking at around 40% for children under 6 months.
- Rates decline for children 6 months to 23 months, but remain elevated.
- For children 24 months to 4 years, illness rates are lower but still significantly higher than in older age groups.
- Rates continue to decline for older children and adolescents, with the lowest rates observed in adults.

### Impact of Influenza on Children
- **School absenteeism**
- **Parental work loss**
- **Medical care visits**
  - 5 to 7 influenza-related outpatient visits per 100 children
  - Children frequently receive antibiotics

### Influenza Vaccines
- **Inactivated subunit (TIV)**
  - Intramuscular
  - Trivalent
  - Contains egg protein
- **Live attenuated vaccine (LAIV)**
  - Intranasal
  - Trivalent
  - Contains egg protein

### 2009-2010 Seasonal Influenza Vaccine Strains
- A/Brisbane/59/2007(H1N1)-like antigen
- A/Brisbane/10/2007(H3N2)-like antigen
- B/Brisbane/60/2008-like antigen

### Trivalent Inactivated Influenza Vaccines (TIV) 2009-2010

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Dose</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluzone (sanofi pasteur)</td>
<td>0.25 mL</td>
<td>6-35 mos</td>
</tr>
<tr>
<td></td>
<td>0.5 mL</td>
<td>&gt;36 mos</td>
</tr>
<tr>
<td>Fluvirin (Novartis)</td>
<td>0.5 mL</td>
<td>&gt;4 yrs</td>
</tr>
<tr>
<td>Fluarix (GSK)</td>
<td>0.5 mL</td>
<td>&gt;18 yrs</td>
</tr>
<tr>
<td>Flulaval (GSK)</td>
<td>0.5 mL</td>
<td>&gt;18 yrs</td>
</tr>
<tr>
<td>Afluria (CSL)</td>
<td>0.5 mL</td>
<td>&gt;18 yrs</td>
</tr>
</tbody>
</table>

### Timing of Influenza Vaccination
- **Influenza activity can occur as early as October**
- In more than 80% of influenza seasons peak activity has not occurred until January or later
- In more than 60% of seasons the peak was in February or later
Timing of Influenza Vaccination

• Immunization providers should begin offering vaccine as soon as it becomes available
• Providers should offer vaccine during routine healthcare visits or during hospitalizations whenever vaccine is available

Timing of Influenza Vaccination

• Continue to offer influenza vaccine in December, especially to healthcare personnel and those at high-risk of complications
• Continue to vaccinate throughout influenza season (December-March)

“Booster” Doses of Influenza Vaccine

• ACIP does not recommend a second dose of influenza vaccine in the same season except for children 6 months through 8 years of age being vaccinated for the first time

2009-2010 Influenza Vaccine Recommendations (Children)

• All children 6 months through 18 years of age receive influenza vaccine annually for the 2009-2010 influenza season

Influenza Vaccine Schedule for Children 6 mos. – 9 yrs.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose</th>
<th># Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-35 mos</td>
<td>0.25 mL</td>
<td>1 or 2*</td>
</tr>
<tr>
<td>3-8 yrs</td>
<td>0.50 mL</td>
<td>1 or 2*</td>
</tr>
<tr>
<td>9 yrs or older</td>
<td>0.50 mL</td>
<td>1</td>
</tr>
</tbody>
</table>

• TIV should only be administered by the intramuscular route
• Separate doses by at least 4 weeks

Influenza Vaccination of Children

• Children 6 months through 8 years of age who did not receive the recommended second dose of influenza vaccine in the initial year that they received influenza vaccine should receive 2 doses during the next influenza season
### Influenza Vaccination of Children

- Children 6 months through 8 years of age who are being vaccinated two or more seasons after receiving an influenza vaccine for the first time should receive a single annual dose, regardless of the number of doses administered previously.

### Influenza Vaccination of Children 6 mos. - 8 yrs.

<table>
<thead>
<tr>
<th>Prior Vaccination</th>
<th>This Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 dose last year (only dose)</td>
<td>2 doses</td>
</tr>
<tr>
<td>1 dose 2 years ago, 1 dose last year</td>
<td>1 dose</td>
</tr>
<tr>
<td>1 dose 2 years ago (only dose)</td>
<td>1 dose</td>
</tr>
</tbody>
</table>

### Inactivated Influenza Vaccine Recommendations, 2009-2010

- Conditions that increase the risk of influenza infection or complications
  - Age
    - 65 years and older
    - 50 through 64 years
    - 6 months through 18 years
  - Pulmonary (emphysema, asthma)

### Inactivated Influenza Vaccine Recommendations, 2009-2010

- Cardiovascular
- Metabolic (diabetes)
- Renal dysfunction
- Hemoglobinopathy
- Immunosuppression, including HIV infection

### Inactivated Influenza Vaccine Recommendations, 2009-2010

- Conditions compromising respiratory function or increase risk of aspiration
- Persons at increased risk of influenza complications
  - Residents of long-term care facilities
  - Persons 6 months to 17 years of age receiving chronic aspirin therapy

### Inactivated Influenza Vaccine Recommendations, 2009-2010

- Pregnant women
  - ACIP recommends vaccination with inactivated influenza vaccine for all women who will be pregnant during influenza season (usually December through March)
Influenza Vaccine
Recommendations, 2009-2010

- Immunization providers should administer influenza vaccine to any person who wishes to reduce the likelihood of becoming ill with influenza or transmitting influenza to others.

Trivalent Inactivated Vaccine (TIV)

- Contraindications and precautions
  - Severe allergic reaction to a vaccine component (e.g., egg) or following a prior dose of vaccine
  - Moderate or severe acute illness (precaution)
  - History of Guillain-Barre’ syndrome within 6 weeks following a previous dose of influenza vaccine (precaution)

Trivalent Inactivated Influenza Vaccine Adverse Events

- Fever
- Malaise
- Myalgia
- Injection site reactions
- Soreness at injection site

(LAIV) Live Attenuated Influenza Vaccine

- Approved only for healthy persons 2 years through 49 years of age who are not pregnant
  - Healthcare personnel
  - Persons in close contact with high-risk groups
  - Persons who want to reduce their risk of influenza

LAIV Vaccination of Children 2-4 Years of Age

- Clinicians and immunization programs should avoid use of LAIV in children with asthma or a recent wheezing episode
- Consult the medical record, when available, to identify children 2 through 4 years of age with asthma or recurrent wheezing that might indicate asthma

Live Attenuated Influenza Vaccination

- Children 2-4 years of age
  - Parents or caregivers of children 2-4 years should be asked
    - “In the past 12 months, has a healthcare provider ever told you that your child had wheezing or asthma?”
**Live Attenuated Influenza Vaccination**
- Children whose parents or caregivers answer "yes" to this question, or whose medical record notes asthma or a wheezing episode within the past 12 months, should not receive LAIV.
- Inactivated influenza vaccine should be administered to children with asthma or possible reactive airways diseases.

**LAIV Influenza Vaccine Schedule**

<table>
<thead>
<tr>
<th>Age Group</th>
<th># Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 though 8 years</td>
<td>2 doses (separated by 4 weeks)</td>
</tr>
<tr>
<td>- No previous influenza vaccine</td>
<td></td>
</tr>
<tr>
<td>- Previously vaccinated</td>
<td></td>
</tr>
<tr>
<td>9 years or older</td>
<td>1</td>
</tr>
</tbody>
</table>

**LAIV Vaccine**

- Contraindications & precautions
  - Children younger than 2 years of age*
  - Persons 50 years of age or older*
  - Persons with underlying medical conditions*
  - Immunosuppression from any cause*

- Children younger than 18 years receiving long-term aspirin therapy*
- Pregnant women*

* These persons should receive inactivated influenza vaccine.

**LAIV Contraindications and Precautions**

- Severe (anaphylactic) allergy to a vaccine component or following a prior dose.
- Children younger than 5 years with wheezing or asthma
  - Should receive inactivated influenza vaccine.

- History of Guillian-Barre’ syndrome within 6 weeks following a previous dose of influenza vaccine (precaution).
- Moderate or severe acute illness (precaution).
**LAIV Adverse Events**
- Runny nose/nasal congestion
- Headache
- Sore throat
- Cough
- Fatigue
- Vomiting
- Myalgias

**Influenza Vaccine Storage and Handling**
- Both TIV and LAIV should be stored at refrigerator temperature (35° - 46° F) at all times
- Neither vaccine should be exposed to freezing temperature

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**Novel H1N1 Influenza Vaccine**

**Novel Influenza A (H1N1) Virus - 2009**
- April 15 - first infection confirmed by CDC
- April 26 - public health emergency declared
- June 11 - World Health Organization raises pandemic alert to Phase 6
  - Pandemic in progress
- June 19 - infections reported by all 50 states

**Novel Influenza A (H1N1) Virus - 2009**
- Virus continues to spread
- Spreading along with seasonal influenza viruses in the southern hemisphere
- Virus transmission has continued into the summer in the United States

**H1N1 Vaccine Target Groups**
- Pregnant women
- Persons who live with or care for infants < 6 months of age
  - Parents, siblings, daycare providers
- Healthcare and emergency services personnel
H1N1 Vaccine Target Groups

• Persons age 6 months-24 years, and
• Persons age 25-64 years who have medical conditions that put them at higher risk for influenza-related complications

Dosing for H1N1 Vaccine

• September 15, 2009
  – Four H1N1 vaccines approved by FDA
• Preliminary data from adults in multiple clinical studies shows that the 2009 H1N1 vaccines induce a robust immune response in most healthy adults eight to 10 days after a single dose

Dosing for H1N1 Vaccine

• Clinical studies underway will provide additional information about the optimal dose in children

Current H1N1 Stats

• Since April 28, 2009, ADPH Bureau of Clinical Laboratories has detected influenza in 2,017 specimens: 1,944 were 2009 H1N1 strain
• Of the positive influenza cases reported to the state in the last 3 weeks, 99% continue to be 2009 H1N1 strain; seasonal A(H3) and B were also detected

Current H1N1 Stats

• ADPH is aware of seven deaths that have occurred in patients testing positive for 2009 H1N1 since July 1, 2009

www.adph.org - Sept. 16, 2009

Imm-50 (Blue Form) Changes
Td/Tdap Requirement

• Effective for students entering 6th grade beginning fall of 2010, a booster dose of Tdap must be given at 11-12 years of age
• This requirement escalates by one successive grade each year to include twelfth grade in the fall of 2016

PCV(Prevnar) Requirements

• The Department of Human Resources has required each child two months of age or older attending any child care center/home daycare to present a valid certificate of immunization, including
  – Age-appropriate immunizations for pneumococcal conjugate vaccine

Polio Recommendations

Poliomyelitis

• First described by Michael Underwood in 1789
• First outbreak described in U.S. in 1843
• 21,000 paralytic cases reported in the U.S. in 1952
• Global eradication in near future

Poliomyelitis - United States, 1950-2007

Poliomyelitis-United States, 1980-2007

*Vaccine-acquired paralytic polio (VAPP) in a U.S. resident acquired outside U.S.
Oral Polio Vaccine
- Highly effective in producing immunity to poliovirus
- 50% immune after 1 dose
- >95% immune after 3 doses
- Immunity probably lifelong

Inactivated Polio Vaccine
- Highly effective in producing immunity to poliovirus
- >90% immune after 2 doses
- >99% immune after 3 doses
- Duration of immunity not known with certainty

Polio Eradication
- Last case in United States in 1979
- Western hemisphere certified polio free in 1994
- Last isolate of type 2 poliovirus in India in October 1999
- Global eradication goal

Wild Poliovirus 1988

Wild Poliovirus 2008

Polio Vaccination Recommendations, 1996-1999
- Increased use of IPV (sequential IPV-OPV schedule) recommended in 1996
- Intended to reduce the risk of vaccine-associated paralytic polio (VAPP)
- Continued risk of VAPP for contacts of OPV recipients
Polio Vaccination Recommendations

- Exclusive use of IPV recommended in 2000
- OPV no longer routinely available in the United States
- Indigenous VAPP eliminated

Polio Vaccination Schedule

<table>
<thead>
<tr>
<th>Age</th>
<th>Vaccine</th>
<th>Minimum Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 months</td>
<td>IPV</td>
<td>---</td>
</tr>
<tr>
<td>4 months</td>
<td>IPV</td>
<td>4 wks</td>
</tr>
<tr>
<td>6-18 months</td>
<td>IPV</td>
<td>4 wks</td>
</tr>
<tr>
<td>4-6 years *</td>
<td>IPV</td>
<td>4 wks</td>
</tr>
</tbody>
</table>

*Fourth dose of IPV may be given as early as 18 weeks of age

Schedules that Include Both IPV and OPV

- Only IPV is available in the United States
- Schedule begun with OPV should be completed with IPV
- Any combination of 4 doses of IPV and OPV by 5 years constitutes a complete series

Factors Affecting the Response to IPV

- Age and dose intervals
- Maternal antibody level at the time of the first dose
  - the lower the maternal antibody level the higher the seroconversion rate

Factors Affecting the Response to IPV

- Longer intervals between doses
  - An interval of at least 6 months between the next to last and last dose provides the best immunologic effect

New IPV Recommendations

- No change in the recommended IPV schedule of four doses at ages 2 months, 4 months, 6 through 18 months, and 4 through 6 years
- Minimum interval between the 3rd and 4th doses is now 6 months
- Minimum age for the final IPV dose is now 4 years
New IPV Recommendations

• When 4 doses of IPV are administered before the 4th birthday, an additional dose of age appropriate IPV should be given on or after the 4th birthday
• Minimum interval from dose 4 to dose 5 should be at least 6 months

New IPV Recommendations

• In the first 6 months of life, the minimum age and minimum intervals are recommended only if the person is at-risk for imminent exposure to circulating poliovirus, such as travel to a polio endemic region or during an outbreak

Combination Vaccines that Contain IPV

• Pediarix
  – DTaP, Hepatitis B and IPV
• Kinrix
  – DTaP and IPV
• Pentacel
  – DTaP, Hib and IPV

Pediarix

• Contains IPV, DTaP, and hepatitis B vaccines
• Minimum age 6 weeks, maximum age 6 years
• Approved by FDA for first 3 doses of the IPV and DTaP series
• Not approved for booster doses

Kinrix

• Contains DTaP (Infanrix) and IPV
• Approved ONLY for the 5th dose of DTaP and 4th dose of IPV in children 4 through 6 years of age
  – Whose previous doses have been with Infanrix and/or Pediarix for the first 3 doses and Infanrix for the 4th doses

Kinrix

• Do NOT use for earlier doses in the DTaP or IPV series
• Use of KINRIX for any dose other than DTaP5 and IPV4 is off-label, and should be considered a medication error
Pentacel
- Contains lyophilized Hib (ActHIB) vaccine that is reconstituted with a liquid DTaP-IPV solution
- Approved for doses 1 through 4 among children 6 weeks through 4 years of age
- The DTaP-IPV solution should not be used separately (i.e., only use to reconstitute the Hib component)

Hiberix - A New Hib Vaccine

Hiberix - Indications
- Approved for the BOOSTER DOSE ONLY in children 15 months through age 4 years
- Child must have received a primary series (3 doses) with a Hib conjugate vaccine

Hiberix Dosage and Administration
- Lyophilized vaccine to be reconstituted with 0.5cc saline diluent in a prefilled syringe and shaken vigorously before administration
- Should be administered promptly after reconstitution

Hiberix - Contraindications
- Severe allergic reaction after a prior dose of any H. flu type b vaccine or tetanus toxoid-containing vaccine or any vaccine component

Hiberix Warnings and Precautions
- Guillain-Barre syndrome within 6 weeks of receipt of a prior vaccine containing tetanus toxoid
- Decision should be made on careful consideration of the potential benefits and possible risks
**Hiberix – Adverse Reactions**

- **Local**
  - Redness, pain, swelling at injection site
- **General**
  - Fever
  - Fussiness/restlessness
  - Loss of appetite
  - Sleepiness
  - Diarrhea/Vomiting

**Rotavirus Vaccine**

**Rotavirus Disease Burden in the United States**

- Estimated 3 million cases per year
  - Pre-vaccine era
- 95% of children infected by 5 years of age
- The most severe disease occurs among children 3-24 months of age

**Rotavirus Disease in the United States**

- Annually* responsible for
  - More than 400,000 physician visits
  - More than 200,000 emergency dept visits
  - 55,000-70,000 hospitalizations
  - 20-60 deaths
  * Pre-vaccine era

**Rotavirus Disease Burden in the United States**

- Highest incidence among children 3 to 35 months of age
- Responsible for 5%-10% of all gastroenteritis episodes among children younger than 5 years of age

**Rotavirus Disease in the United States**

- Annual direct and indirect costs are estimated at approximately $1 billion
**Rotavirus Clinical Features**
- Short incubation period (usually less than 48 hours)
- First infection after age 3 months generally most severe
- May be asymptomatic or result in severe dehydrating diarrhea with fever and vomiting
- Gastrointestinal symptoms generally resolve in 3 to 7 days

**Rotavirus Immunity**
- First infection usually does not lead to permanent immunity
- Reinfection can occur at any age
- Subsequent infections generally less severe

**Rotavirus Complications**
- Severe diarrhea
- Dehydration
- Electrolyte imbalance
- Metabolic acidosis
- Immunodeficient children may have more severe or persistent disease

**Risk Groups for Rotavirus Diarrhea**
- Groups with increased exposure to virus
  - Children in child care centers
  - Children in hospital wards (nosocomial rotavirus)
  - Caretakers, parents of these children

**Risk Groups for Rotavirus Diarrhea**
- Children, adults with immunodeficiency related diseases
  - SCID, HIV, bone marrow transplant

**Rotavirus Vaccines**
- RV5 (RotaTeq®)
  - Contains five reassortant rotaviruses developed from human and bovine parent rotavirus strains
  - Vaccine viruses suspended in a buffer solution
  - Contains no preservatives or thimerosal
Rotavirus Vaccines

- Vaccine tubes with twist-off caps for oral administration

Rotavirus Vaccines

- RV1 (Rotarix®)
  - Contains one strain of live attenuated human rotavirus (type G1P[8])
  - Provided as a lyophilized powder that is reconstituted before administration

Rotavirus Vaccines

- Contains no preservatives or thimerosal
- Should NEVER be injected

Rotavirus Vaccine Effectiveness

<table>
<thead>
<tr>
<th>Condition</th>
<th>Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any rotavirus diarrhea</td>
<td>74%-87%</td>
</tr>
<tr>
<td>Severe diarrhea</td>
<td>95%-98%</td>
</tr>
</tbody>
</table>

Both vaccines significantly reduced physician visits for diarrhea, & reduced rotavirus-related hospitalization

Rotavirus Vaccine Recommendations

- Routine immunization of all infants without a contraindication
- 2 (RV1) or 3 (RV5) oral doses beginning at 2 months of age
- Subsequent doses in the series should be separated from the previous dose by 1 to 2 months

Rotavirus Vaccine Recommendations

- For both rotavirus vaccines
  - Maximum age for first dose is 14 weeks 6 days
  - Minimum interval between doses is 4 weeks
  - Maximum age for any dose is 8 months 0 days
<table>
<thead>
<tr>
<th>Rotavirus Vaccine Recommendations</th>
<th>Rotavirus Vaccine Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• ACIP did not define a maximum interval between doses</td>
<td>• It is not necessary to restart the series or add doses because of a prolonged interval between doses</td>
</tr>
<tr>
<td>• If the interval between doses is prolonged, the child can still receive the vaccine as long as it can be given on or before the child's 8 month birthday</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rotavirus Vaccine Recommendations</th>
<th>Rotavirus Vaccine Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Complete the series with the same product whenever possible</td>
<td>• If any dose in the series was RV5 (RotaTeq) or the vaccine brand used for any prior dose in the series is not known, a total of three doses of rotavirus vaccine should be administered</td>
</tr>
<tr>
<td>• If the product used for a prior dose or doses is not available or is not known continue or complete the series with the product that is available</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rotavirus Vaccine Contraindications</th>
<th>Rotavirus Vaccine Precautions*</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Severe allergic reaction to a vaccine component or following a prior dose of vaccine</td>
<td>• Altered immunocompetence</td>
</tr>
<tr>
<td></td>
<td>• Acute, moderate or severe gastroenteritis or other acute illness</td>
</tr>
<tr>
<td></td>
<td>• History of intussusception</td>
</tr>
<tr>
<td></td>
<td>* The decision to vaccinate if a precaution is present should be made on a case-by-case risk and benefit basis</td>
</tr>
</tbody>
</table>
Rotavirus Vaccine

• Conditions no longer considered to be precautions
  – Pre-existing chronic gastrointestinal conditions
  • No data are available
  • ACIP considers the benefits of vaccination to outweigh the theoretic risks

Rotavirus Vaccine

– Recent receipt of an antibody-containing blood product
  • No data are available
  • ACIP recommends that rotavirus vaccine may be administered at any time before, concurrent with, or after administration of any blood product

Rotavirus Vaccine and Preterm Infants

• ACIP supports vaccination of a preterm infant if
  – Chronological age is at least 6 weeks
  – Clinically stable
  – The vaccine is administered at the time of discharge or after discharge from the neonatal intensive care unit or nursery

Immunosuppressed Household Contacts of Rotavirus Vaccine Recipients

• Infants living in households with persons who have or are suspected of having an immunodeficiency disorder or impaired immune status can be vaccinated
  • Protection provided by vaccinating the infant outweighs the small risk for transmitting vaccine virus

Pregnant Household Contacts of Rotavirus Vaccine Recipients

• Infants living in households with pregnant women should be vaccinated
  – Majority of women of childbearing age have pre-existing immunity to rotavirus
  – Risk for infection by vaccine virus is considered to be very low

Rotavirus Vaccine and Intussusception*

<table>
<thead>
<tr>
<th>No. of Infants</th>
<th>Vaccine Recipients</th>
<th>Placebo Recipients</th>
</tr>
</thead>
<tbody>
<tr>
<td>RV 1</td>
<td>63,225</td>
<td>7 cases</td>
</tr>
<tr>
<td>RV5</td>
<td>69,625</td>
<td>6 cases</td>
</tr>
</tbody>
</table>

*RV1- 0-30 days after either dose
*RV5- 0-42 days after any dose
## Rotavirus Vaccine

### Adverse Reactions

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vomiting</td>
<td>15%-18%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>9%-24%</td>
</tr>
<tr>
<td>Irritability</td>
<td>13%-62%</td>
</tr>
<tr>
<td>Fever</td>
<td>40%-43%</td>
</tr>
<tr>
<td>Serious adverse reactions</td>
<td>None</td>
</tr>
</tbody>
</table>

### Recommendations

- ACIP recommends that providers not repeat the dose if the infant spits out or regurgitates the vaccine
- Any remaining doses should be administered on schedule
- Doses of rotavirus vaccine should be separated by at least 4 weeks

## Rotavirus Vaccine

### Storage and Handling

- Store at 36-46°F (2-8°C) & protect from light
- RV1 diluent may be stored at room temperature
- Do not freeze vaccines or diluent
- Administer RV5 as soon as possible after removing from refrigeration
- RV1 should be administered within 24 hours of reconstitution

## Pneumococcal Disease

- *S. pneumoniae* first isolated by Pasteur in 1881
- Confused with other causes of pneumonia until discovery of Gram stain in 1884
- More than 80 serotypes described by 1940
- First U.S. vaccine in 1977

## Streptococcus Pneumoniae

- Gram-positive bacteria
- 90 known serotypes
- Polysaccharide capsule important virulence factor
- Type-specific antibody is protective
Pneumococcal Disease

- Second most common cause of vaccine-preventable death in the U.S. (after influenza)
- Major clinical syndromes include pneumonia, bacteremia, and meningitis

Pneumococcal Disease Outbreaks

- Outbreaks not common
- Generally occur in crowded environments (jails, nursing homes)
- Persons with invasive disease often have underlying illness
- May have high fatality rate

Pneumococcal Pneumonia

Clinical Features

- Abrupt onset
- Fever
- Shaking chills
- Pleuritic chest pain
- Productive cough
- Dyspnea, tachypnea, hypoxia

Pneumococcal Pneumonia

- 100,000 to 135,000 cases requiring hospitalization per year
- Responsible for up to 1/3 of community-acquired pneumonias and up to 1/2 of hospital-acquired pneumonias
- Common bacterial complication of influenza and measles
- Case-fatality rate 5-7%, higher in elderly

Burden of Pneumococcal Disease in Children*

<table>
<thead>
<tr>
<th>Syndrome</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteremia</td>
<td>13,000</td>
</tr>
<tr>
<td>Meningitis</td>
<td>700</td>
</tr>
<tr>
<td>Death</td>
<td>200</td>
</tr>
<tr>
<td>Otitis media</td>
<td>5,000,000</td>
</tr>
</tbody>
</table>

*Prior to routine use of pneumococcal conjugate vaccine

Pneumococcal Disease Epidemiology

- Reservoir
  - Human carriers
- Transmission
  - Respiratory autoinoculation
- Temporal pattern
  - Winter and early spring
- Communicability
  - Unknown (probably as long as organism in respiratory secretions)
Pneumococcal Vaccines
- 1977
  - 14-valent polysaccharide vaccine licensed
- 1983
  - 23-valent polysaccharide vaccine licensed (PPV23)
- 2000
  - 7-valent polysaccharide conjugate vaccine licensed (PCV7)

Pneumococcal Polysaccharide Vaccine
- Purified capsular polysaccharide antigen from 23 types of pneumococcus
- Accounts for 88% of bacteremic pneumococcal disease
- Cross-reacts with types causing additional 8% of disease

Pneumococcal Conjugate Vaccine
- Pneumococcal polysaccharide conjugated to nontoxic diphtheria toxin (7 serotypes)
- Vaccine serotypes account for 86% of bacteremia and 83% of meningitis among children younger than 6 years of age

Pneumococcal Conjugate Vaccine
- Highly immunogenic in infants and young children, including those with high-risk medical conditions
- 97% effective against invasive disease caused by vaccine serotypes
- 73% effective against pneumonia
- 7% reduction in all episodes of acute otitis media

Invasive Pneumococcal Disease Incidence by Age Group


* Rate per 100,000 population
Children at Increased Risk of Invasive Pneumococcal Disease

- Functional or anatomic asplenia, especially sickle cell disease
- HIV infection
- Recipient of cochlear implant
- Out-of-home group child care
- African American children

Children at Increased Risk of Invasive Pneumococcal Disease

- Alaska Native and American Indian children who live in Alaska, Arizona, or New Mexico
- Navajo children who live in Colorado and Utah

Pneumococcal Conjugate Vaccine Recommendations

- All children 24 months of age
- Unvaccinated children 24-59 months with a high-risk medical condition

Pneumococcal Conjugate Vaccine Recommendations

- Doses at 2, 4, 6, months of age, booster dose at 12-15 months of age
- First dose as early as 6 weeks
- Minimum interval of 4 weeks between first 3 doses
- At least 8 weeks between dose 3 & dose 4

Pneumococcal Conjugate Vaccine Recommendations

- Unvaccinated children 7 months of age or older require fewer doses

PCV7 Vaccine for Children 24-59 Months of Age with a Lapsed Immunization Schedule

<table>
<thead>
<tr>
<th>Group</th>
<th>Previous Vaccination</th>
<th>No. of Doses Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy</td>
<td>Any incomplete schedule</td>
<td>1</td>
</tr>
<tr>
<td>Increased risk*</td>
<td>3 doses</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Fewer than 3 doses</td>
<td>2**</td>
</tr>
</tbody>
</table>

*Due to underlying medical condition
**Separated by at least 8 weeks
PCV7 Vaccine Schedule for Unvaccinated Older Children

<table>
<thead>
<tr>
<th>Age at first dose</th>
<th>Primary Series</th>
<th>Booster</th>
</tr>
</thead>
<tbody>
<tr>
<td>7-11 mos.</td>
<td>2 doses</td>
<td>Yes</td>
</tr>
<tr>
<td>12-23 mos.</td>
<td>2 doses*</td>
<td>No</td>
</tr>
<tr>
<td>24-59 mos. -Healthy</td>
<td>1 dose</td>
<td>No</td>
</tr>
<tr>
<td>-High risk</td>
<td>2 doses*</td>
<td>No</td>
</tr>
</tbody>
</table>

*Separated by at least 8 weeks

Pneumococcal Conjugate Vaccine

- Children aged 24-59 months at high risk and previously vaccinated with PPV23 should receive 2 doses of PCV7
  - Separated by at least 8 weeks
- Children at high risk who previously received PCV7 should receive PPV23 at 2 years of age or older

Direct Benefit of Vaccination: Invasive Pneumococcal Disease (IPD) Among Children

Rate/100,000 children younger than 5 yrs

<table>
<thead>
<tr>
<th></th>
<th>Before vaccine</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>All IPD</td>
<td>100</td>
<td>24</td>
</tr>
<tr>
<td>Vaccine serotypes</td>
<td>80</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Risk Factors for Invasive Pneumococcal Disease (IPD)

- Decreased immune function
- Asplenia (functional or anatomic)
- Chronic heart, pulmonary, liver or renal disease
- Cerebrospinal fluid leak
- Cochlear implant
- Cigarette smoking

Risk Factors for Invasive Pneumococcal Disease (IPD)

- Asthma has now been identified as an independent risk factor for invasive pneumococcal disease
- Adults with asthma had at least double the risk of IPD compared with adults of similar age without asthma

New Pneumococcal Polysaccharide Vaccine (PPSV)

- Recommendation
  - All adults 19 years of age and older with asthma regardless of severity
  - Available data do not support asthma as an indication for PPSV among persons younger than 19 years
Smoking Among Persons with IPD, 2001-2003

Cigarette Smoking and IPD
- Approximately half of adults 65 years of age or younger who develop severe pneumococcal disease are smokers
- Cigarette smoking is a strong risk factor for severe disease
- Many adults who smoke cigarettes also have another condition for which PPSV is already recommended

Cigarette Smoking and IPD
- Cigarette smoking is a risk behavior that is easy to identify among patients in clinical practice
- Smoking cessation should be part of the therapeutic plan regardless of immunization

Pneumococcal Polysaccharide Vaccine Revaccination
- Routine revaccination of immuno-competent persons is not recommended
- Revaccination recommended for persons 2 years of age or older who are at highest risk of serious pneumococcal infection

Pneumococcal Polysaccharide Vaccine Revaccination
- Revaccination is a 1-time event
- 5 years or longer after first dose (interval applies to persons of all ages)

Pneumococcal Polysaccharide Vaccine
- Candidates for revaccination
  - Persons 2 years or older with
    - Asplenia (functional or anatomic)
    - Immunosuppression
    - Chronic renal failure
    - Nephrotic syndrome
  - Persons vaccinated before 65 yrs of age
Pneumococcal Polysaccharide Vaccine Recommendations
• Adults 65 years and older
• Persons 2 years and older with
  – Chronic illness
  – Anatomic or functional asplenia
  – Immunocompromised (disease, chemotherapy, steroids)
  – HIV infection
  – Environments or settings with increased risk

Pneumococcal Polysaccharide Vaccine Coverage
• Healthy People 2010 goal: 90% coverage for persons >65 years
• 2003 BRFSS: 64% of persons >65 years of age ever vaccinated
• Vaccination coverage levels were lower among persons 18-64 years of age with a chronic illness

Pneumococcal Polysaccharide Vaccine
• Missed opportunities
  – >65% of patients with severe pneumococcal disease had been hospitalized within the preceding 3-5 years, yet few had received vaccine
  – May be administered simultaneously with influenza vaccine

PCV7 Vaccine Schedule for Infants and Toddlers
• 2 months
  – May be given as early as 6 weeks
• 4 months
  – 4-8 weeks
• 6 months
  – 4-8 weeks

PCV7 Vaccine Schedule for Infants and Toddlers
• 12-15 months
  – At least 2 months after third dose, not before 12 months of age

PCV7 Schedule for Previously Unvaccinated Older Infants & Children ≥ 7 months of age

<table>
<thead>
<tr>
<th>Age at first dose</th>
<th>Total doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>7-11 months</td>
<td>3 doses*</td>
</tr>
<tr>
<td>12-23 months</td>
<td>2 doses†</td>
</tr>
<tr>
<td>≥ 24 months through 9 years</td>
<td>1 dose</td>
</tr>
</tbody>
</table>

* Two doses at least 4 weeks apart; third dose after 12 months of age, and at least 2 months after second dose
† Two doses at least 2 months apart
Evidence of Measles, Mumps, and Rubella Immunity for Healthcare Personnel (HCP)

- Appropriate vaccination against measles, mumps, and rubella
  - 2 doses of measles and mumps vaccine
  - At least 1 dose of rubella vaccine
- Laboratory evidence of immunity
- Laboratory confirmation of disease

Evidence of Measles, Mumps, and Rubella Immunity for Healthcare Personnel (HCP)

- Physician-diagnosed disease no longer recommended as evidence of measles or mumps immunity

Evidence of Measles, Mumps, and Rubella Immunity for Healthcare Personnel (HCP)

- 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

Vaccine Information Statements

- Every healthcare provider, public or private, who administers a vaccine covered by the National Childhood Vaccine Injury Act is required by law to provide a copy of the most current VIS with EACH DOSE of vaccine
- Not required by Federal law to obtain a signature
**Vaccine Information Statements**

- Must note in each patient’s permanent medical record or permanent office log or file
  - Date the VIS is provided
  - The VIS edition date
- Usually located at the bottom of the second page of the document

**Vaccine Information Statements New Since August 2008**

- Pneumococcal polysaccharide
  - Includes new indications for this vaccine for smokers and adults with asthma
- Combined Td/Tdap

**New VIS Policies**

- Providers can give parents or patients a permanent copy of a VIS to read in the office before the vaccination instead of giving each person their own individual paper copy
  - You should still offer each patient their own copy to take home

**New VIS Policies**

- Persons with a wireless device, such as an iPhone, BlackBerry, or Palm Pre, may now download VISs onto these devices in lieu of taking home a paper copy

**Resources**

- [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)
- [www.adph.org](http://www.adph.org)