Polio and *Haemophilus influenzae* type b

**Pink Book Webinar Series**

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ACIP Recommendations: Polio and Polio Vaccines
Poliomyelitis Disease

- First outbreak described in the U.S. in 1843
- Polio epidemics were reported each summer and fall
- More than 21,000 paralytic cases reported in the U.S. in 1952
Poliovirus

- Three serotypes of wild poliovirus:
  - WPV1
  - WPV2
  - WPV3
- Minimal heterotypic immunity between serotypes
- Rapidly inactivated by heat, chlorine, formaldehyde, and ultraviolet light
Poliomyelitis Pathogenesis

- Enters into mouth
- Replicates in pharynx and GI tract
- Hematologic spread to lymphatics and central nervous system
- Viral spread along nerve fibers
- Destruction of motor neurons

Racaniello VR. One hundred years of poliovirus pathogenesis. *Virology* 2006;344:9-16
Outcomes of Poliovirus Infection

- Asymptomatic
- Minor non-specific illness
- Aseptic meningitis
- Flaccid paralysis

- 0%
- 10%
- 20%
- 30%
- 40%
- 50%
- 60%
- 70%
- 80%
Asymmetric paralysis
# Poliovirus Epidemiology

<table>
<thead>
<tr>
<th>Reservoir</th>
<th>Human</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmission</td>
<td>Fecal-oral</td>
</tr>
<tr>
<td></td>
<td>Oral-oral possible</td>
</tr>
<tr>
<td>Communicability</td>
<td>Most infectious: 7–10 days before onset</td>
</tr>
<tr>
<td></td>
<td>Virus present in stool 3–6 weeks</td>
</tr>
</tbody>
</table>
Poliomyelitis—United States, 1950–2011

Cases

- Inactivated vaccine
- Live oral vaccine
- Last indigenous case

Source: National Notifiable Disease Surveillance System, CDC
Poliomyelitis—United States, 1980–2010

Vaccine-associated paralytic polio = VAPP
Poliovirus Vaccines

- 1955–Inactivated vaccine
- 1963–Live, attenuated vaccine (OPV)
- 1987–Enhanced-potency, inactivated vaccine (IPV)
Enhanced Inactivated Polio Vaccine

- Highly effective in producing immunity to poliovirus
  - ≥90% of recipients immune after 2 doses
  - ≥99% of recipients immune after 3 doses

- Duration of immunity not known with certainty
<table>
<thead>
<tr>
<th>Product</th>
<th>ACIP Abbreviation</th>
<th>Age Indications</th>
<th>IPV Series</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPOL</td>
<td>IPV</td>
<td>6 weeks and older</td>
<td>Any dose in the series</td>
</tr>
<tr>
<td>Pediarix</td>
<td>DTaP-IPV-HepB</td>
<td>6 weeks through 6 years</td>
<td>Doses 1 through 3</td>
</tr>
<tr>
<td>Pentacel</td>
<td>DTaP-IPV/Hib</td>
<td>6 weeks through 4 years</td>
<td>Doses 1 through 4</td>
</tr>
<tr>
<td>Kinrix</td>
<td>DTaP-IPV</td>
<td>4 through 6 years</td>
<td>Dose 4</td>
</tr>
<tr>
<td>Quadracel</td>
<td>DTaP-IPV</td>
<td>4 through 6 years</td>
<td>Dose 4 or 5</td>
</tr>
</tbody>
</table>
ACIP Polio Immunization Recommendations
Routine Schedule

<table>
<thead>
<tr>
<th>IPV Dose</th>
<th>Routinely Recommended Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 months</td>
</tr>
<tr>
<td>2</td>
<td>4 months</td>
</tr>
<tr>
<td>3</td>
<td>6–18 months</td>
</tr>
<tr>
<td>4</td>
<td>4–6 years</td>
</tr>
</tbody>
</table>
ACIP Polio Immunization Recommendations

Catch-Up Schedule

- Infants 6 months of age and younger, follow the recommended schedule intervals
- If accelerated protection is needed (e.g., travel to polio-endemic area), minimum age and intervals may be followed

<table>
<thead>
<tr>
<th>Dose</th>
<th>Minimum Age</th>
<th>Minimum Interval to the Next Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose 1</td>
<td>6 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Dose 2</td>
<td>10 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Dose 3</td>
<td>14 weeks</td>
<td>6 months</td>
</tr>
<tr>
<td>Dose 4</td>
<td>4 years</td>
<td>--------</td>
</tr>
</tbody>
</table>
ACIP Polio Immunization Recommendations
4th Dose and the Catch-Up Schedule

- A 4th dose is not necessary if the 3rd dose was administered:
  - At age 4 years or older AND
  - At least 6 months after the previous dose

- Children who have received 4 doses (or more) before 4 years of age need an additional dose
  - There should be at least 6 months between last and next-to-last dose
Schedules that Include Both IPV and OPV

- Mixed-product series containing both OPV and IPV is acceptable
  - Only trivalent OPV (tOPV) counts toward completing the series

- Children with an incomplete series:
  - Administer IPV to complete a series that includes doses of OPV
  - Ensure doses met minimum ages and intervals

- Administer 1 dose of IPV to children who received 4 doses of OPV (or more) before 4 years of age
  - There should be at least 6 months the last dose of OPV and the IPV dose
OPV Administered Outside the U.S.

- Use the date of administration to make a presumptive determination of what type of OPV was received.
- Trivalent OPV was used throughout the world prior to April 2016.
- Persons 18 years of age and younger with doses of OPV that do not count towards the U.S. vaccination requirements should receive IPV.
ACIP Polio Immunization Recommendations
Adolescents and Adults

- Routine vaccination of U.S. residents 18 years of age or older is not necessary or recommended

- May consider vaccination of travelers to polio-endemic countries and selected lab workers
ACIP Polio Immunization Recommendations
Unvaccinated Adults

- Use routine IPV schedule if possible
  - 0, 1–2 months, 6–12 months intervals

- If accelerated protection is needed (e.g., travel to polio-endemic area), use the minimum intervals

<table>
<thead>
<tr>
<th>Minimum Intervals to the Next Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose 1</td>
</tr>
<tr>
<td>Dose 2</td>
</tr>
<tr>
<td>Dose 3</td>
</tr>
</tbody>
</table>
ACIP Polio Immunization Recommendations
Previously Vaccinated Adults

- **Previously completed series**
  - Administer 1 dose of IPV to those at risk

- **Incomplete series**
  - Administer remaining doses in series based on immunization history
  - No need to restart a valid, documented series
    - Valid = minimum intervals met
Contraindications and Precautions

- Severe allergic reaction to a vaccine component or following a prior dose of vaccine

- Moderate to severe acute illness
IPV Adverse Reactions

- Local reactions: 2.8% (pain, redness, swelling)
- Severe reactions: rare
Polio Eradication

- Last case in the United States in 1979
- Western Hemisphere certified polio-free in 1994
- Last isolate of WPV2 was in India in October 1999
- Global eradication goal
Global Polio Eradication Efforts

Polio Global Eradication Initiative website, accessed on 8/20/2018  http://polioeradication.org/polio-today/polio-now/

YEAR-TO-DATE 2018
Jan 1 - Aug 21, 2018
13 WPV 24 cVDPV

2017 TOTAL
Jan 1 - Dec 31, 2017
22 WPV 96 cVDPV

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.
Clinical Considerations for IPV-Containing Vaccines

- **Storage:** Refrigerate between 2°C and 8°C (36°F and 46°F)
- **Preparation:** Prepare the vaccine just prior to administration
  - Pentacel requires reconstitution
  - Reconstitute the lyophilized vaccine with the DTaP-IPV liquid diluent supplied by the manufacturer. Do NOT use Kinrix or Quadracel
- **Route:** IM injection*
- **Site:**
  - 11 months and younger: Anterolateral thigh muscle
  - 12 months and older: Anterolateral thigh muscle or deltoid muscle of arm
- **Needle:**
  - Children: 22–25 gauge, 1-inch needle
  - Adults: 22–25 gauge, length varies by weight

*IPV may be administered by subcutaneous injection using a 5/8-inch needle given in the fatty tissue over the upper, outer triceps or anterolateral thigh
Polio: Vaccine Administration Errors

- **Schedule errors: Dose 4 administered too soon**
  - Doses administered 5 or more days before the minimum age and/or interval do not count and should be repeated when age-appropriate
  - Wait the minimum interval from the invalid dose before giving the repeat dose
  - Minimum age/interval: At/after age 4 AND 6 months after dose 3

- **Age/dose errors: Kinrix or Quadracel for doses 1 through 3**
  - If the minimum age and interval from the last dose of polio vaccine has been met, the dose can count and does not need to be repeated

- **Preparation errors: Wrong diluent to reconstitute DTaP-IPV/Hib (Pentacel)**
  - Do not use Kinrix or Quadracel to reconstitute Pentacel
ACIP Recommendations:

*Haemophilus influenzae* type b and Hib Vaccine
Haemophilus influenzae type b

- Severe bacterial infection, particularly among infants
- Aerobic gram-negative bacteria
- Polysaccharide capsule
- 6 different serotypes (a–f) of polysaccharide capsule
- 95% of invasive disease caused by type b (prevaccine era)
Impact of *Haemophilus influenzae* type b Disease

- Formerly the leading cause of bacterial meningitis among children younger than 5 years of age
- Approximately 1 in 200 children developed invasive Hib disease
- Almost all infections among children younger than 5 years
Haemophilus influenzae type b
Clinical Manifestations*

- Bacteremia: 2%
- Cellulitis: 6%
- Arthritis: 8%
- Osteomyelitis: 2%
- Pneumonia: 15%
- Epiglottitis: 17%
- Meningitis: 50%

*Prevaccine era
Facial cellulitis or infection of the soft tissues of the face, caused by Hib
Haemophilus influenzae type b Epidemiology

Reservoir
Human asymptomatic carriers

Transmission
Respiratory droplets presumed

Temporal pattern
Peaks in Sept–Dec and March–May

Communicability
Generally limited but higher in some circumstances (e.g., household, child care)
Estimated Annual Incidence (per 100,000) of Invasive *Haemophilus influenzae* type b (Hib) Disease in Children Aged <5 Years—U.S., 1980–2012

MMWR 2014;63(RR1):1–14
Haemophilus influenzae, Invasive Disease Incidence of Reported Cases (per 100,000), by serotype Among Children aged <5 years—U.S., 2000–2013
Haemophilus influenzae type b Polysaccharide Vaccine

- Not effective in children younger than 18 months of age
- Efficacy in older children varied
- Age-dependent immune response
- Not consistently immunogenic in children 2 years of age and younger
- No booster response
Haemophilus influenzae Type b Conjugate Vaccines

- Conjugation improves immunogenicity
  - Immune response with booster doses
- Same polysaccharide capsule linked to different carrier proteins
- 3 single-component conjugate Hib vaccine products
- 1 combination vaccine products available that contain Hib conjugate vaccine
## Hib-Containing Vaccine Products

<table>
<thead>
<tr>
<th>Product</th>
<th>ACIP Abbreviation</th>
<th>Age Indications</th>
<th>Approved for</th>
</tr>
</thead>
<tbody>
<tr>
<td>ActHIB Hib</td>
<td></td>
<td>6 weeks and older</td>
<td>Primary series (3 doses)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Booster dose (1)</td>
</tr>
<tr>
<td>Hiberix Hib</td>
<td></td>
<td>6 weeks and older</td>
<td>Primary series (3 doses)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Booster dose (1)</td>
</tr>
<tr>
<td>PedvaxHIB Hib</td>
<td></td>
<td>6 weeks and older</td>
<td>Primary series (2 doses)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Booster dose (1)</td>
</tr>
<tr>
<td>Pentacel DTaP-IPV/Hib</td>
<td></td>
<td>6 weeks through 4 years</td>
<td>Primary series (3 doses)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Booster dose (1)</td>
</tr>
</tbody>
</table>
ACIP Hib Immunization Recommendations
Routine Schedule

- Routinely recommended for all infants beginning at 2 months of age*
- Schedule varies based on the product used
  - ActHib, Pentacel, Hiberix: Follow the 4-dose schedule at 2, 4, 6, and 12–15 months of age
  - PedvaxHIB: Follow the 3-dose schedule at 2, 4, and 12–15 months of age
- If any dose in the series is ActHIB, Pentacel, Hiberix or the product is not known, follow the 4-dose schedule

*Minimum age for the 1st dose is 6 weeks
Unvaccinated Healthy Children 7 months of Age and Older

- Children starting late may not need entire 3- or 4-dose series
- Number of doses child requires depends on current age
- Resources:
  - 2018 catch-up schedule
  - Catch-up guidance for healthy children
  - Detailed schedule p. 128 of Pink Book

[Image: Catch-Up Guidance for Healthy Children 4 Months through 4 Years of Age]

ACIP Hib Immunization Recommendations
Older Children and Adults

- Generally not recommended for healthy persons older than 59 months of age
- Vaccinate high-risk older children and adolescents if incompletely or previously unvaccinated
  - Asplenia
  - Immunodeficiency
  - HIV infection
  - Receipt of chemotherapy or radiation therapy
# ACIP Hib Immunization Recommendations

## High-Risk Children and Adults

<table>
<thead>
<tr>
<th>High-Risk Children and Adults</th>
<th>Hib Vaccine Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective splenectomy</td>
<td>If unvaccinated: 1 dose prior to procedure</td>
</tr>
<tr>
<td>Asplenic patient</td>
<td>If unvaccinated: 1 dose</td>
</tr>
<tr>
<td>HIV-infected children</td>
<td>If unvaccinated: 1 dose</td>
</tr>
<tr>
<td>Hematopoietic cell transplant</td>
<td>3 doses (at least 4 weeks apart) beginning 6–12 months after transplant</td>
</tr>
<tr>
<td>HIV-infected adults</td>
<td>Hib vaccination is not recommended</td>
</tr>
</tbody>
</table>
Special Populations

- **Children less than 24 months of age with invasive Hib disease**
  - Administer complete series as recommended for child’s age
  - Vaccinate during the convalescent phase of the illness

- **American Indian/Alaska natives**
  - Hib disease peaks earlier in infancy
  - PedVaxHIB vaccine produces protective antibody after first dose/early protection
  - PedVaxHIB vaccine is specifically recommended for primary series doses
Hib Vaccine Interchangeability

- All single-component conjugate Hib vaccines are interchangeable for primary series and booster dose.

- 3-dose primary series (4 doses total) if more than one brand of vaccine used at 2 or 4 months of age.

- Whenever feasible, use same combination vaccine for subsequent doses.

- If vaccine used for earlier doses is not known or not available, any brand may be used to complete the series.
Contraindications and Precautions

- Severe allergic reaction to vaccine component or following previous dose
- Moderate to severe acute illness
- Age younger than 6 weeks
Hib Vaccine Adverse Reactions

- Swelling, redness, or pain in 5–30% of recipients
- Systemic reactions infrequent
- Serious adverse reactions rare
Clinical Considerations for Hib-Containing Vaccine

- **Storage:** Refrigerate between 2°C and 8°C (36°F and 46°F)
- **Preparation:** Prepare vaccine just prior to administration
  - ActHIB, Pentacel, and Hiberix require reconstitution
  - Reconstitute the lyophilized vaccine with the diluent supplied by the manufacturer
- **Route:** IM injection
- **Site:**
  - 11 months and younger: Anterolateral thigh muscle
  - 12 months and older: Anterolateral thigh muscle or deltoid muscle of arm
- **Needle:** 22–25 gauge, 1-inch needle
Hib: Vaccine Administration Errors

- Preparation errors: Using the wrong diluent to reconstitute the lyophilized component

CDC vaccine storage label examples [https://www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf](https://www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf)
Additional Clinical Considerations

- Provide the polio and Hib vaccine information statement (VIS) when a combination vaccine is administered
  - There are no VISs specific for Kinrix, Pediarix, Pentacel, or Quadracel
- Other option: multiple vaccines VIS
  - May be used in place of the individual VISs for DTaP, Hib, hepatitis B, polio, and PCV13 when two or more of these vaccines are administered during the same visit
  - It may be used for infants through children receiving their routine 4- to 6-year vaccines

CDC vaccine information statements www.cdc.gov/vaccines/hcp/vis/vis-statements/multi.html
Resources and references are available on the webinar webpage.