2014 ACIP Hib Vaccination Statement

Elizabeth Briere, MD, MPH
Current Issues in Immunization NetConference
April 2, 2014
2014 Hib Vaccine Recommendations and Guidance

- **Routine Hib Recommendations**
  - Last statement published in 1993
  - Additional Hib vaccines licensed since 1993
  - No changes to previously published routine recommendations

- **Guidance for special populations**
  - Not included in 1993 statement
  - Updated statement includes guidance for all special populations
  - Guidance consistent with guidance in:
    - 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised
    - 2012 Red Book
    - 2011 ACIP General Recommendations on Immunizations
    - 2009 ACIP Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents
Estimated incidence of invasive Hib infection in <5 year olds, United States 1980-2012

Sources: *1980 1997: National Bacterial Meningitis Reporting System and National Notifiable Diseases Surveillance (NDSS); 1997 2012: ABCs cases estimated to the U.S. population
Risk of Hib disease continues among unimmunized and underimmunized infants and children.

FIGURE 3. Percentage of children aged <5 years with cases of invasive *Haemophilus influenzae* type b (Hib) disease,* by vaccine status — United States 2002–2012

![Bar chart showing percentage of children with Hib disease by vaccination status.](chart.png)

- **Too young for immunization**
- **Age-appropriate**
- **Incomplete primary series**
- **Missing booster**
- **Unimmunized (≥2 months)**

**Sources:** Active Bacterial Core surveillance system and National Notifiable Diseases Surveillance System.

* N = 265. An additional 57 children aged <5 years with Hib had unknown vaccine status and were excluded.

† Among those with age-appropriate vaccine status, 41% were too young to complete the primary series, 16% completed the primary series, and 43% completed the full series.
# Current Licensed and Available Hib Vaccines

## Table 1. *Haemophilus influenzae* type b (Hib) conjugate vaccines licensed and available in the United States as of January 2014

<table>
<thead>
<tr>
<th>Vaccine product</th>
<th>Manufacturer</th>
<th>Trade Name</th>
<th>Components</th>
<th>Primary series</th>
<th>Booster dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monovalent vaccine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRP-OMP*†</td>
<td>Merck &amp; Co, Inc</td>
<td>PedvaxHIB</td>
<td>PRP conjugated to OMP</td>
<td>2, 4 mos</td>
<td>12–15 mos</td>
</tr>
<tr>
<td>PRP-T</td>
<td>sanofi pasteur</td>
<td>ActHIB</td>
<td>PRP conjugated to tetanus toxoid</td>
<td>2, 4, 6 mos</td>
<td>12–15 mos</td>
</tr>
<tr>
<td>PRP-T</td>
<td>GlaxoSmithKline</td>
<td></td>
<td>PRP conjugated to tetanus toxoid</td>
<td>Not licensed for primary series</td>
<td></td>
</tr>
<tr>
<td>Combination vaccine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRP-OMP-HepB*†</td>
<td>Merck &amp; Co, Inc</td>
<td>Comvax</td>
<td>PRP-OMP + hepatitis B vaccine</td>
<td>2, 4 mos</td>
<td>12–15 mos</td>
</tr>
<tr>
<td>DTaP-IPV/PRP-T</td>
<td>sanofi pasteur</td>
<td>Pentacel</td>
<td>DTaP-IPV + PRP-T</td>
<td>2, 4, 6 mos</td>
<td>15–18 mos</td>
</tr>
<tr>
<td>MenCY/PRP-T**</td>
<td>GlaxoSmithKline</td>
<td>MenHibRix</td>
<td>MenCY + PRP-T</td>
<td>2, 4, 6 mos</td>
<td>12–15 mos</td>
</tr>
</tbody>
</table>


* If a PRP-OMP vaccine is not administered as both doses in the primary series, or if there is uncertainty about which products were administered previously, a third dose of Hib conjugate vaccine is needed to complete the primary series.

† Preferred vaccine for American Indian/Alaska Native children.

§ To facilitate timely booster vaccination, Hiberix can be administered as early as age 12 months, in accordance with Hib vaccination schedules for routine and catch-up immunization (CDC. Licensure of a *Haemophilus influenzae* type b (Hib) vaccine [Hiberix] and updated recommendations for use of Hib vaccine. MMWR 2009;58:1008–9).

‖ The booster dose may be administered as early as age 12 months, provided that at least 6 months have elapsed since the third dose.

** Recommendations for the MenCY component of MenCY/PRP-T have been published previously (CDC. Infant meningococcal vaccination: Advisory Committee on Immunization Practices (ACIP) recommendations and rationale. MMWR 2013;62:52–4).
## Current Licensed and Available Hib Vaccines

<table>
<thead>
<tr>
<th>Vaccine product</th>
<th>Manufacturer</th>
<th>Trade Name</th>
<th>Components</th>
<th>Primary series</th>
<th>Booster dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monovalent vaccine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRP-OMP* †</td>
<td>Merck &amp; Co, Inc</td>
<td>PedvaxHIB</td>
<td>PRP conjugated to OMP</td>
<td>2, 4 mos</td>
<td>12–15 mos</td>
</tr>
<tr>
<td>PRP-T</td>
<td>sanofi pasteur</td>
<td>ActHIB</td>
<td>PRP conjugated to tetanus toxoid</td>
<td>2, 4, 6 mos</td>
<td>12–15 mos</td>
</tr>
<tr>
<td>PRP-T</td>
<td>GlaxoSmithKline</td>
<td>Hiberix</td>
<td>PRP conjugated to tetanus toxoid</td>
<td></td>
<td>Not licensed for primary series</td>
</tr>
<tr>
<td>Combination vaccine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRP-OMP-HepB* †</td>
<td>Merck &amp; Co, Inc</td>
<td>Convax</td>
<td>PRP-OMP + hepatitis B vaccine</td>
<td>2, 4 mos</td>
<td>12–15 mos</td>
</tr>
<tr>
<td>DTaP-IPV/PRP-T</td>
<td>sanofi pasteur</td>
<td>Pentacel</td>
<td>DTaP-IPV + PRP-T</td>
<td>2, 4, 6 mos</td>
<td>15–18 mos†</td>
</tr>
<tr>
<td>MenCY/PRP-T**</td>
<td>GlaxoSmithKline</td>
<td>MenHibRix</td>
<td>MenCY + PRP-T</td>
<td>2, 4, 6 mos</td>
<td>12–15 mos</td>
</tr>
</tbody>
</table>


* If a PRP-OMP vaccine is not administered as both doses in the primary series, or if there is uncertainty about which products were administered previously, a third dose of Hib conjugate vaccine is needed to complete the primary series.
† Preferred vaccine for American Indian/Alaska Native children.
‡ To facilitate timely booster vaccination, Hiberix can be administered as early as age 12 months, in accordance with Hib vaccination schedules for routine and catch-up immunization (CDC). Licensure of a Haemophilus influenzae type b [Hib] vaccine [Hiberix] and updated recommendations for use of Hib vaccine. MMWR 2009;58:1008–9.
§ The booster dose may be administered as early as age 12 months, provided that at least 6 months have elapsed since the third dose. **Recommendations for the MenCY component of MenCY/PRP-T have been published previously (CDC. Infant meningococcal vaccination: Advisory Committee on Immunization Practices (ACIP) recommendations and rationale. MMWR 2013;62:52–4).**
## Current Licensed and Available Hib Vaccines

### TABLE 1. *Haemophilus influenzae* type b (Hib) conjugate vaccines licensed and available in the United States as of January 2014

<table>
<thead>
<tr>
<th>Vaccine product</th>
<th>Manufacturer</th>
<th>Trade Name</th>
<th>Components</th>
<th>Primary series</th>
<th>Booster dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monovalent vaccine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRP-OMP*†</td>
<td>Merck &amp; Co, Inc</td>
<td>PedvaxHIB</td>
<td>PRP conjugated to OMP</td>
<td>2, 4 mos</td>
<td>12–15 mos</td>
</tr>
<tr>
<td>PRP-T</td>
<td>sanofi pasteur</td>
<td>ActHIB</td>
<td>PRP conjugated to tetanus toxoid</td>
<td>2, 4, 6 mos</td>
<td>12–15 mos</td>
</tr>
<tr>
<td>PRP-P</td>
<td>GlaxoSmithKline</td>
<td>Hiberix</td>
<td>PRP conjugated to tetanus toxoid</td>
<td>Not licensed for primary series</td>
<td>12–15 mos§</td>
</tr>
<tr>
<td>Combination vaccine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRP-OMP-HepB*†</td>
<td>Merck &amp; Co, Inc</td>
<td>Comvax</td>
<td>PRP-OMP + hepatitis B vaccine</td>
<td>2, 4 mos</td>
<td>12–15 mos</td>
</tr>
<tr>
<td>DTaP-IPV/PRP-P</td>
<td>sanofi pasteur</td>
<td>Pentacel</td>
<td>DTaP-IPV + PRP-T</td>
<td>2, 4, 6 mos</td>
<td>15–18 mos¶</td>
</tr>
<tr>
<td>MenCY/PRP-P**</td>
<td>GlaxoSmithKline</td>
<td>MenHibRix</td>
<td>MenCY + PRP-T</td>
<td>2, 4, 6 mos</td>
<td>12–15 mos</td>
</tr>
</tbody>
</table>


* If a PRP-OMP vaccine is not administered as both doses in the primary series, or if there is uncertainty about which products were administered previously, a third dose of Hib conjugate vaccine is needed to complete the primary series.

† Preferred vaccine for American Indian/Alaska Native children.

§ To facilitate timely booster vaccination, Hiberix can be administered as early as age 12 months, in accordance with Hib vaccination schedules for routine and catch-up immunization (CDC. Licensure of a *Haemophilus influenzae* type b [Hib] vaccine [Hiberix] and updated recommendations for use of Hib vaccine. MMWR 2009;58:1008–9).

¶ The booster dose may be administered as early as age 12 months, provided that at least 6 months have elapsed since the third dose.

** Recommendations for the MenCY component of MenCY/PRP-P have been published previously (CDC. Infant meningococcal vaccination: Advisory Committee on Immunization Practices (ACIP) recommendations and rationale. MMWR 2013;62:52–4).
Recommendations for Hib Vaccine Use in 2014 Statement

- Recommendations for routine vaccine use remain unchanged
- Guidance for catch-up vaccination remains unchanged
- Guidance for special populations (children and adults)
  - Included in 2014 statement
  - Consistent with previously published guidance
Special Populations

- Alaskan Natives/American Indians
- Children <24 months of age with invasive Hib
- Preterm infants
- High-risk groups
  - Functional or anatomic asplenia
  - HIV
  - Immunoglobulin deficiency (including IgG2 deficiency or early component complement deficiency)
  - Hematopoietic stem cell transplant (HSCT) recipient
  - Chemotherapy/radiation recipients
Special Populations

- **American Indians/Alaskan Natives (AI/AN)**
  - Hib meningitis peaks at younger age (4-7 months)
  - Comvax and PedvaxHib (PRP-OMP) produce an early protective antibody response (after first dose)
    - Preferred for AI/AN infants to provide early protection
  - **Alaskan experience**
    - 1991-1996 – PRP-OMP vaccine used; >90% decrease in Hib
    - 1996-1997 – switch to non-PRP-OMP vaccine; significant increases in Hib among native children
    - 1998-present – PRP-OMP vaccine used; Hib disease decreased
Special Populations

- **Children <24 months of age with invasive Hib**
  - Consider unvaccinated and revaccinate
- **Preterm infants**
  - Start at 2 months of age, based on chronological age
Special Populations

- **High-risk groups**
  - Functional or anatomic asplenia
  - HIV
  - Immunoglobulin deficiency (including IgG2 deficiency or early component complement deficiency)
  - Hematopoietic stem cell transplant (HSCT) recipient
  - Chemotherapy/radiation recipients
# Guidance for High-Risk Groups

<table>
<thead>
<tr>
<th>High-risk group*</th>
<th>Hib Vaccine Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient &lt;12 months of age</td>
<td>Follow routine Hib vaccination recommendations</td>
</tr>
<tr>
<td>Patients 12 through 59 months of age</td>
<td>If unimmunized or received 0 or 1 dose before age 12 months: 2 doses, 8 weeks apart</td>
</tr>
<tr>
<td></td>
<td>If received 2 or more doses before age 12 months: 1 dose, 8 weeks after last dose</td>
</tr>
<tr>
<td></td>
<td>If completed a primary series and received a booster dose at age 12 months or older: no additional doses</td>
</tr>
</tbody>
</table>

*Persons with functional or anatomic asplenia, HIV infection, immunoglobulin deficiency including immunoglobulin G2 subclass deficiency, or early component complement deficiency, recipients of a hematopoietic stem cell transplant, and those receiving chemotherapy or radiation therapy for malignant neoplasms.
# Guidance for High-Risk Groups

<table>
<thead>
<tr>
<th>High-risk group*</th>
<th>Hib Vaccine Guidance</th>
</tr>
</thead>
</table>
| **Patients undergoing chemotherapy or radiation therapy, age <59 months** | If routine Hib doses given 14 or more days before starting therapy: revaccination not required  
If dose given within 14 days of starting therapy or given during therapy: repeat doses starting at least 3 months following therapy completion |
| **Patients undergoing elective splenectomy, age ≥ 15 months** | If unimmunized: 1 dose prior to procedure |
| **Asplenic patients >59 months of age and adults** | If unimmunized: 1 dose |

*Persons with functional or anatomic asplenia, HIV infection, immunoglobulin deficiency including immunoglobulin G2 subclass deficiency, or early component complement deficiency, recipients of a hematopoietic stem cell transplant, and those receiving chemotherapy or radiation therapy for malignant neoplasms.*
# Guidance for High-Risk Groups

*Persons with functional or anatomic asplenia, HIV infection, immunoglobulin deficiency including immunoglobulin G2 subclass deficiency, or early component complement deficiency, recipients of a hematopoietic stem cell transplant, and those receiving chemotherapy or radiation therapy for malignant neoplasms.*

<table>
<thead>
<tr>
<th>High-risk group*</th>
<th>Hib Vaccine Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-infected children ( \geq 60 ) months of age</td>
<td>If unimmunized: 1 dose</td>
</tr>
<tr>
<td>HIV-infected adults</td>
<td>Hib vaccination is not recommended</td>
</tr>
<tr>
<td>Recipients of hematopoietic stem cell transplant, all ages</td>
<td>Regardless of Hib vaccination history: 3 doses (at least 4 weeks apart) beginning 6-12 months after transplant</td>
</tr>
</tbody>
</table>
Summary

- Last Hib statement published in 1993
- 2014 Hib statement:
  - Meant to be one-stop resource that includes guidance for immunocompetent and immunocompromised/special populations
  - Recommendations for routine vaccine use remain unchanged
  - Guidance for catch-up vaccination remains unchanged
  - Guidance for special populations (children and adults) included
    - Consistent with previously published guidance
Thank you!

For more information please contact Centers for Disease Control and Prevention
1600 Clifton Road NE, Atlanta, GA 30333
Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov  Web: www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.