Hib Session

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Advisory Committee for Immunization Practices
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National Center for Immunization & Respiratory Diseases
Meningitis and Vaccine Preventable Diseases Branch

Outline

- Objectives of updated Hib statement
- Summary of updated Hib statement
- Vote

- HibMenCY Inclusion in Hib VFC
- Vote

Objectives of Updated Hib statement

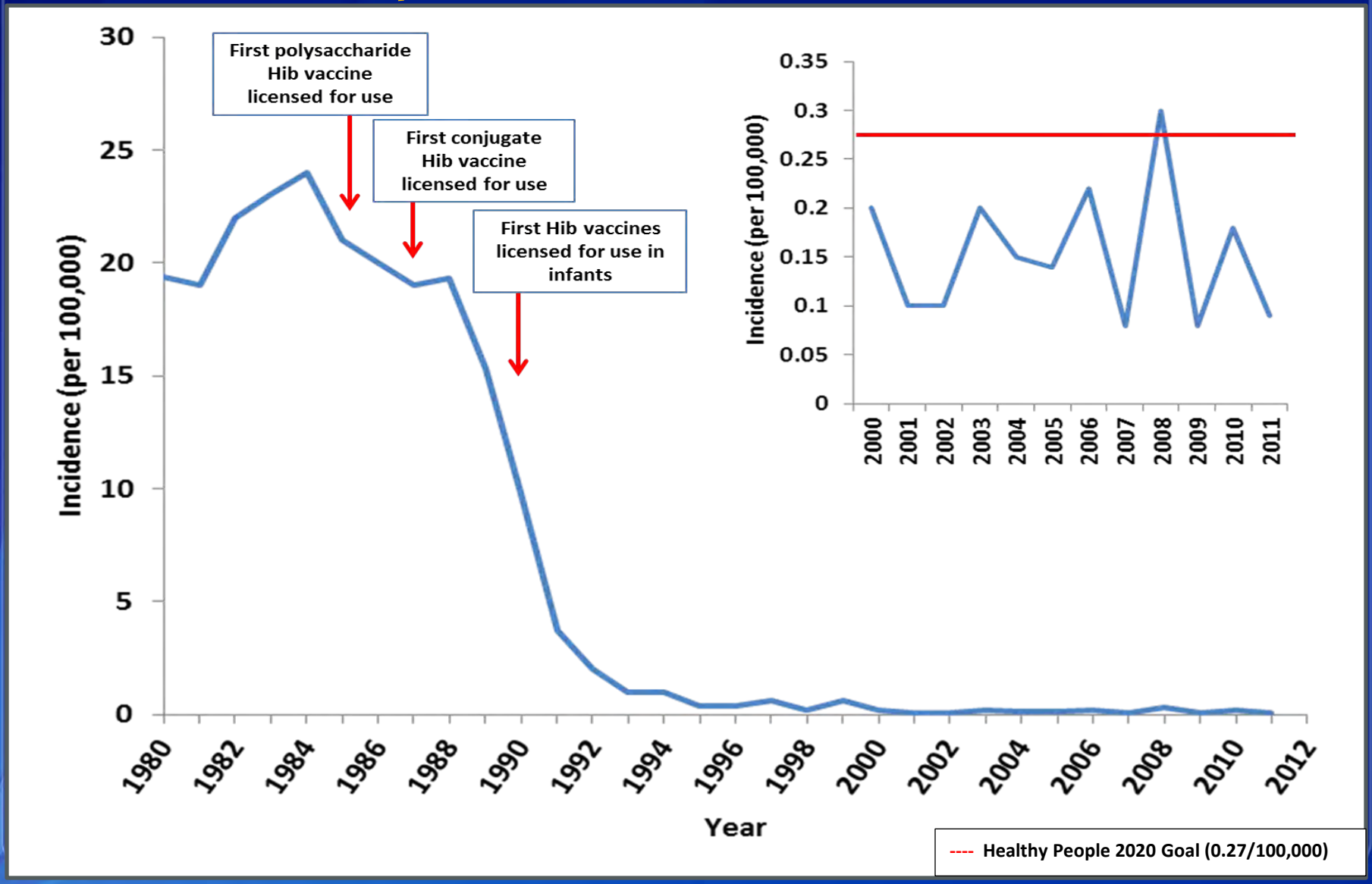
- Provide overview of current Hib epidemiology
- Provide updated list of current Hib vaccines
- Provide recommendations for routine vaccination and guidance for special populations in one document
- Provide guidance for chemoprophylaxis of household and childcare contacts

Statement Revision Activities

- **Reviewed**
  - Published Hib vaccine recommendations, including draft of evidence-based IDSA Clinical Practice Guidelines for Vaccination of the Immunocompromised Host
  - Peer-reviewed literature
  - Surveillance data from ABCs and NNDSS
- **The WG reviewed draft statement and provided comments by teleconference meeting**
- **ACIP voting members reviewed draft statement and provided comments**
  - Revised draft statement provided for voting members prior to February meeting

SUMMARY OF UPDATED HIB STATEMENT

Estimated incidence of invasive Hib infection in <5 year olds, United States 1980-2011*



Sources: *1980-1997: National Bacterial Meningitis Reporting System and National Notifiable Diseases Surveillance (NDSS); 1997-2011: ABCs cases estimated to the U.S. population

Current Licensed and Available Hib Vaccines*

Vaccine Product (Manufacturer)	Trade Name	Components	Primary series	Booster dose
Monovalent vaccines				
PRP-OMP (Merck & Co, Inc)	PedvaxHIB	PRP conjugated to OMP	2, 4 months	12 – 15 months
PRP-T (sanofi pasteur)	ActHIB	PRP conjugated to tetanus toxoid	2, 4, 6 months	12 – 15 months
PRP-T (GlaxoSmithKline)	Hiberix	PRP conjugated to tetanus toxoid	Not licensed	12 – 15 months
Combination vaccines				
PRP-OMP-HepB (Merck & Co, Inc)	Comvax	PRP-OMP + hepatitis B vaccine	2, 4 months	12 – 15 months
DTaP-IPV/PRP-T (sanofi pasteur)	Pentacel	DTaP-IPV + PRP-T	2, 4, 6 months	12 – 15 months
MenCY/PRP-T (GlaxoSmithKline)	MenHibRix	MenCY + PRP-T	2, 4, 6 months	12 – 15 months

*Adapted from Red Book: 2012 Report of the Committee on Infectious Diseases

Hib Vaccine Recommendations and Guidance

- **Routine Hib Recommendations**
  - Last statement published in 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 (not yet published)
    - 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

Special Populations

- **Alaskan Natives/American Indians**
  - Brief history of experience with Hib vaccines; rationale for OMP recommendation
- **Children <24 months of age with invasive Hib**
  - Consider unvaccinated and revaccinate
- **Preterm infants**
- **High-risk groups**
  - Functional or anatomic asplenia, HIV, IgG deficiency, early component complement deficiency, HSCT and chemotherapy recipients

Guidance for High-Risk Groups

High-risk group*	Hib Vaccine Guidance
Patient <12 months of age	Follow routine Hib vaccination recommendations
Patients 12 through 59 months of age	If unimmunized or received 0 or 1 dose before age 12 months: 2 doses 2 months apart If received 2 or more doses before age 12 months: 1 dose If completed a primary series and received a booster dose at age 12 months or older: no additional doses

Guidance for High-Risk Groups

High-risk group*	Hib Vaccine Guidance
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
HIV-infected children>59 months of age	If unimmunized: 1 dose
HIV-infected adults	Hib vaccination is not recommended
Recipients of hematopoietic stem cell transplant, all ages	Regardless of Hib vaccination history: 3 doses (at least 1 month apart) beginning 6-12 months after transplant

Guidance for Chemoprophylaxis

- **Limited guidance included in last statement**
- **Guidance consistent with guidance in**
  - 2012 Red Book
- **Rifampin recommended chemoprophylaxis for Hib cases only**
  - ***Hib cases:*** if treated with antibiotic other than cefotaxime or ceftriaxone and <2 yrs
  - ***Household contacts:*** entire household if with members <4 yrs who are not fully vaccinated or members who are immunocompromised
  - ***Childcare contacts:*** 2 or more cases within 60 days and unimmunized or under immunized attend facility

Today's vote

- **Affirm updated Hib statement**
  - No new vaccine recommendations

VOTE

HIBMENCY INCLUSION IN HIB VFC

Background

- **HibMenCY is a combination vaccine with protection against Hib and meningococcal serogroups C/Y**
  - Licensed June 2012 as 4-dose primary series (2,4,6, 12-15 months)
  - Expected to be available late summer 2013
- **October 2012 ACIP meeting**
  - Recommended for routine use only in infants at high-risk for meningococcal disease
  - Included HibMenCY in meningococcal VFC resolution for high-risk infants
  - HibMenCY may be used in any infant for routine Hib vaccination

Background

- **All new combination vaccines require ACIP vote for VFC inclusion**
  - Need vote to include HibMenCY in Hib VFC resolution
- **First combination vaccine with one component routinely recommended for all infants; second component only for high-risk groups**

Hib portion of HibMenCY is non-inferior to other monovalent Hib vaccines*

- **Hib portion immunogenic for infant/toddler doses** and 1, 3, and 5 years post 4th dose**
- **Based on anti-PRP levels (≥0.15 µg/ml), HibMenCY provides excellent duration of protection 5 years post 4th dose**
  - Anti-PRP concentrations ≥0.15 µg/ml in >98% of HibMenCY recipients post-dose 3, 4 and 1,3, and 5 years post 4th dose
  - Anti-PRP concentrations ≥1 µg/ml in >93% of HibMenCY recipients post-dose 3 and 4 and in > 50% at 1, 3, and 5 years post 4th dose
  - Anti-PRP GMCs significantly higher for HibMenCY than for monovalent Hib

*Bryant KA, Marshall GS, Marchant CD, et al. Pediatrics 2011;127:e1375–85. Marchant CD, Miller JM, Marshall GS, et al. Pediatr Infect Dis J 2010;29:48–52. Marshall, GS, Marchant CD, Blatter M, et al.. Pediatr Infect Dis J 2010; 29:469-471.

**PRP-TT for doses 1-3 and PRP-OMP for dose 4

HibMenCY is safe compared to other monovalent Hib vaccines

- **Frequency of serious adverse events (SAE) similar to monovalent Hib vaccine***
  - 3-14% of study participants who received HibMenCY alone or with concomitant vaccines reported at least one SAE
  - 2-10% of controls who received monovalent Hib with concomitant vaccines reported at least one SAE
  - Difference between intervention and control groups not statistically significant
- **Mild local and systemic reactions to HibMenCY were similar to monovalent Hib vaccine**

*PRP-TT for doses 1-3 and PRP-OMP for dose 4

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HIB VFC RESOLUTION WORDING AND VOTE