Polio and Polio Vaccine

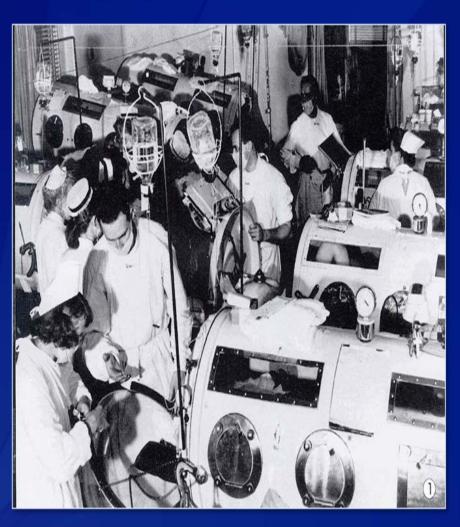
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Pink Book Webinar Series August 10, 2016



Poliomyelitis Disease



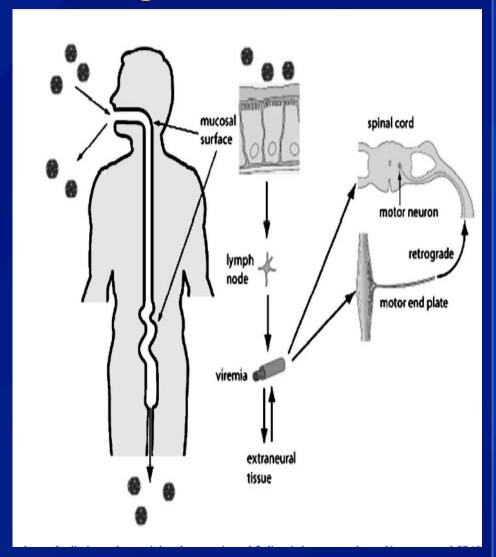
- First outbreak described in the U.S. in 1843
- More than 21,000 paralytic cases reported in the U.S. in 1952
- Global eradication within this decade

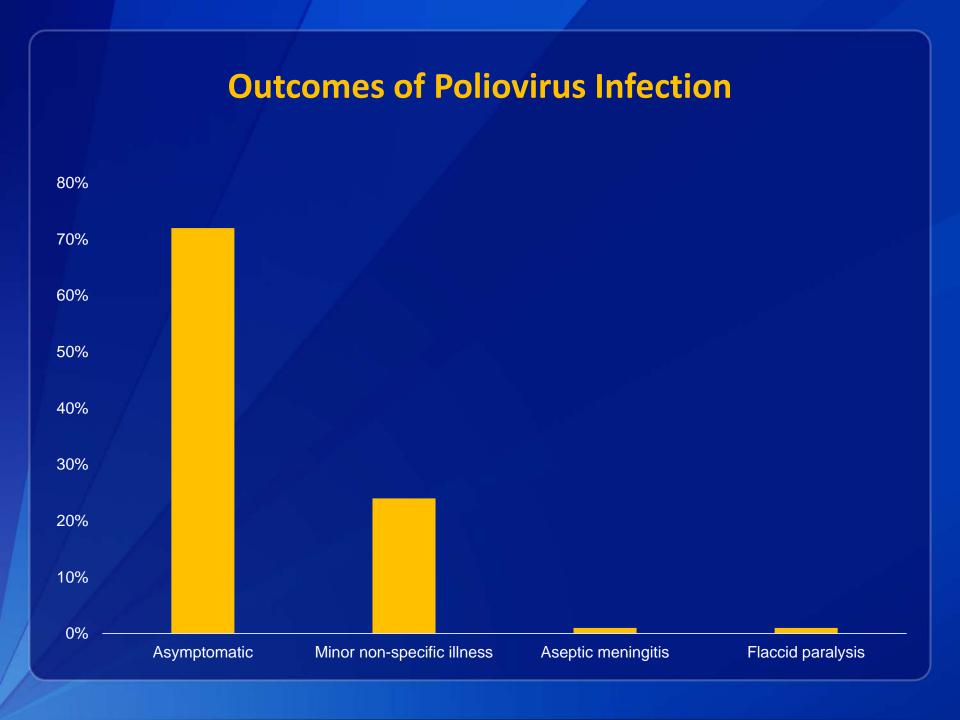
Poliovirus

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

Poliomyelitis Pathogenesis

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







Poliovirus Epidemiology

Reservoir

Human

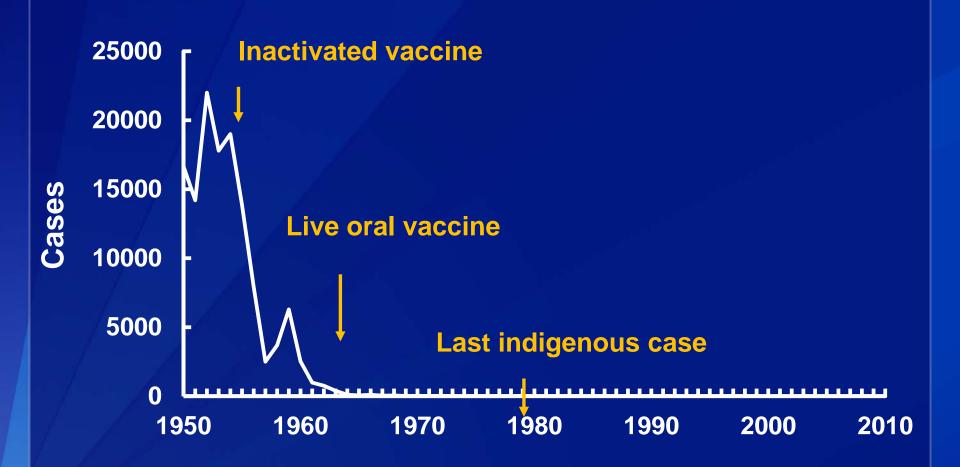
Transmission

Fecal-oral Oral-oral possible

Communicability

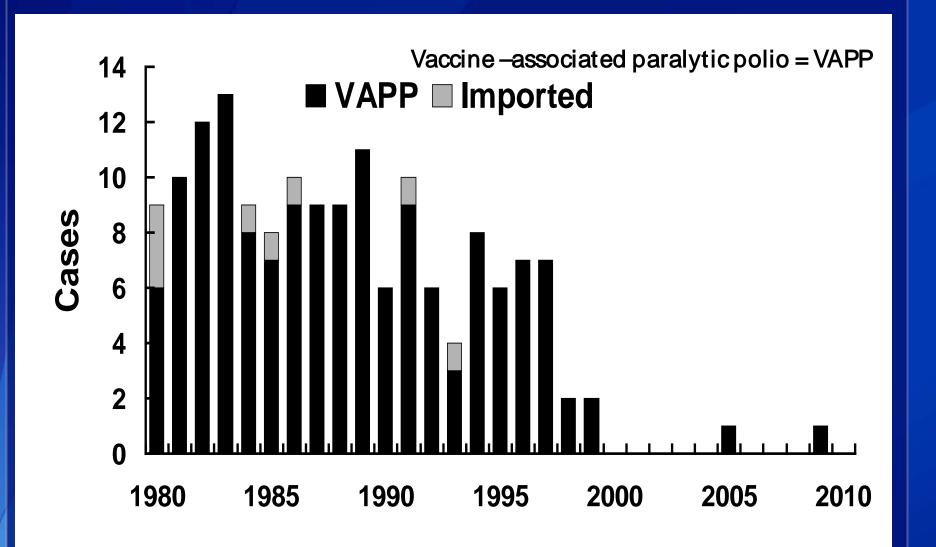
Most infectious: 7-10 days before onset
Virus present in stool
3-6 weeks

Poliomyelitis—United States, 1950-2011



Source: National Notifiable Disease Surveillance System, CDC

Poliomyelitis—United States, 1980-2010



Poliovirus Vaccines

- 1955 Inactivated vaccine
- 1963 Trivalent OPV
- 1987 Enhanced-potency (IPV)



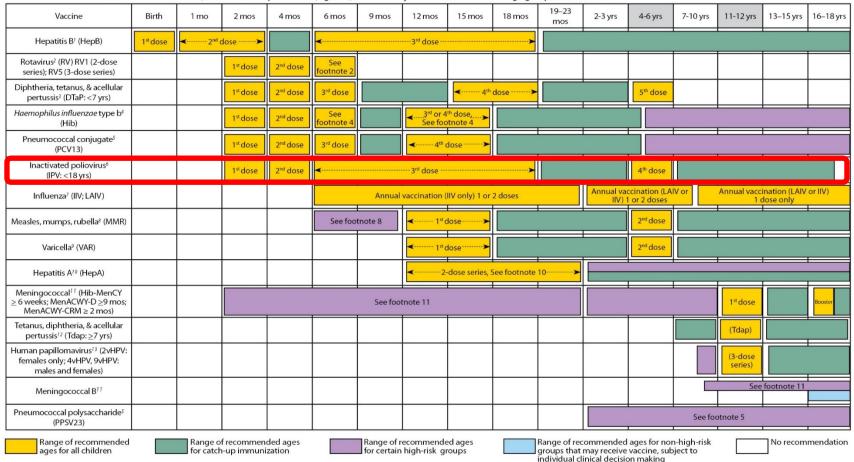
Inactivated Polio Vaccine

- 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

Figure 1. Recommended immunization schedule for persons aged 0 through 18 years - United States, 2016.

(FOR THOSE WHO FALL BEHIND OR START LATE, SEE THE CATCH-UP SCHEDULE [FIGURE 2]).

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are shaded.



This schedule includes recommendations in effect as of January 1, 2016. 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/hcp/acip-recs/index.html. 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/recs/vac-admin/contraindications.htm) or by telephone (800-CDC-INFO [800-232-4636]).

This schedule is approved by the Advisory Committee on Immunization Practices (http://www.cdc.gov/vaccines/acip), the American Academy of Pediatrics (http://www.aap.org), the American Academy of Family Physicians (http://www.aafp.org), and the American College of Obstetricians and Gynecologists (http://www.acog.org).

NOTE: The above recommendations must be read along with the footnotes of this schedule.

Childhood Polio Vaccination Schedule

Vaccine	Birth	1mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18mos	19-23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13-15 yrs	16-18 yrs
Inactivated poliovirus ⁶ (IPV: <18 yrs)			1 st dose	2 nd dose	4		3 rd dose		······			4 th dose				

IPV Dose	Routinely Recommended at	Minimum Interval
1/	2 months of age	
2	4 months of age	4 weeks
3	6- 18 months of age	4 weeks
4	4-6 years of age	6 months

Catch-up IPV Vaccination

- In the first 6 months of life, minimum age and minimum intervals are only recommended if the person is at risk of imminent exposure to circulating poliovirus
- If 4 or more doses are administered before age 4 years, an additional dose should be administered at age 4 through 6 years and at least 6 months after 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

Schedules that Include Both IPV and OPV

- Only IPV is available in the United States
- If both OPV and IPV were administered as part of a series, the series should be completed with IPV. Any combination of 4 doses of OPV and IPV by 4 to 6 years of age constitutes a complete series
- If only OPV doses were administered, and all doses were given prior to 4 years of age, one dose of IPV should be given at 4 years or older, at least 4 weeks after the last OPV dose

Poliovirus-containing Vaccine Products

- Single component vaccine IPV (IPOL)
- FOUR polio-containing combination vaccine products:
 - DTaP-IPV/Hib (Pentacel)
 - DTaP-HepB-IPV (Pediarix)
 - DTaP-IPV (Kinrix)
 - DTaP-IPV (Quadracel)

DTaP-IPV/Hib (Pentacel)

- FDA-approved for:
 - IPV doses 1 through 4
 - Children 6 weeks through 4 years of age
- Use DTaP-IPV diluent to reconstitute the Hib component





Reminder: Only use the manufacturer's supplied diluent

www.cdc.gov/vaccines/hcp/clinical-resources/downloads/pentacel-delay.pdf

DTaP-HepB-IPV (Pediarix)

- FDA-approved for:
 - IPV doses 1 through 3
 - Children 6 weeks through 6 years of age



DTaP-IPV (Kinrix & Quadracel)

Kinrix

- IPV dose 4
- Children 4 through 6 years of age

Quadracel

- IPV dose 4 or 5
- 4 through 6 years of age





VA error: Do NOT use to reconstitute the Hib component of Pentacel vaccine

Polio Vaccination of Adolescents and Adults

- <u>Routine</u> 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

Polio Vaccination of Unvaccinated Adults

- Use standard IPV schedule if possible
 - 0, 1-2 months, 6-12 months intervals
- May separate first and second doses by 4 weeks if accelerated schedule needed
- The minimum interval between the second and third doses is 6 months

Polio Vaccination of 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 Efforts





- The number of worldwide reported cases has decreased from an estimated 350,000 in 1988 to 19 as of June 29, 2016
- Afghanistan 6 cases of WPV1
- Pakistan 13 cases of WPV1
- Nigeria Polio-free

http://www.polioeradication.org

http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/oral_polio_vaccine/en/

Haemophilus influenzae Type b and Hib Vaccine



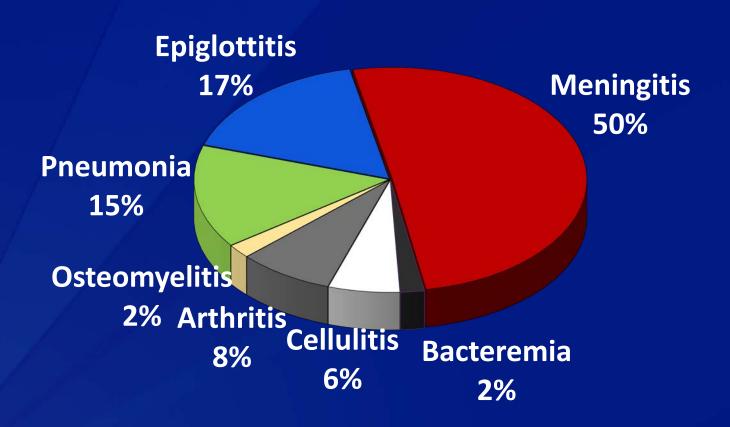
Haemophilus influenzae

- 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*





Haemophilus influenzae Type b Epidemiology

Reservoir

Human asymptomatic carriers

Transmission

Respiratory droplets presumed

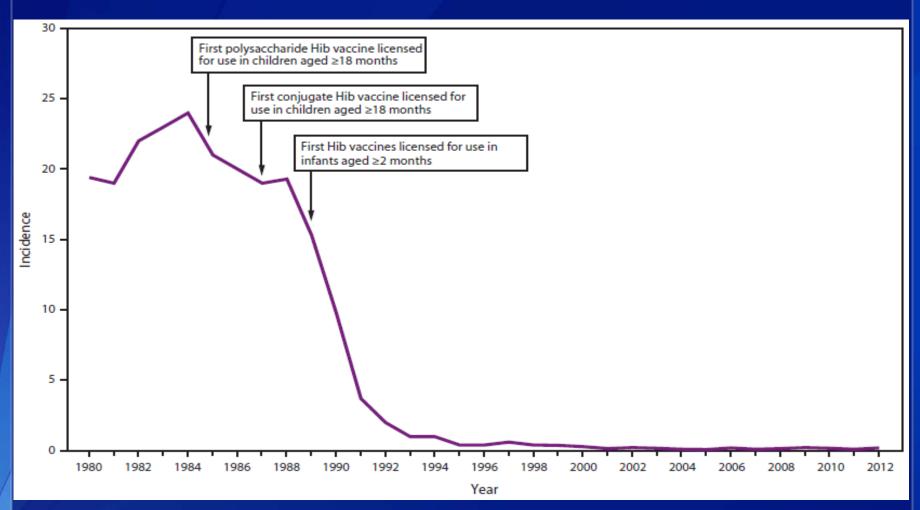
Temporal pattern

Peaks in Sept-Dec and March-May

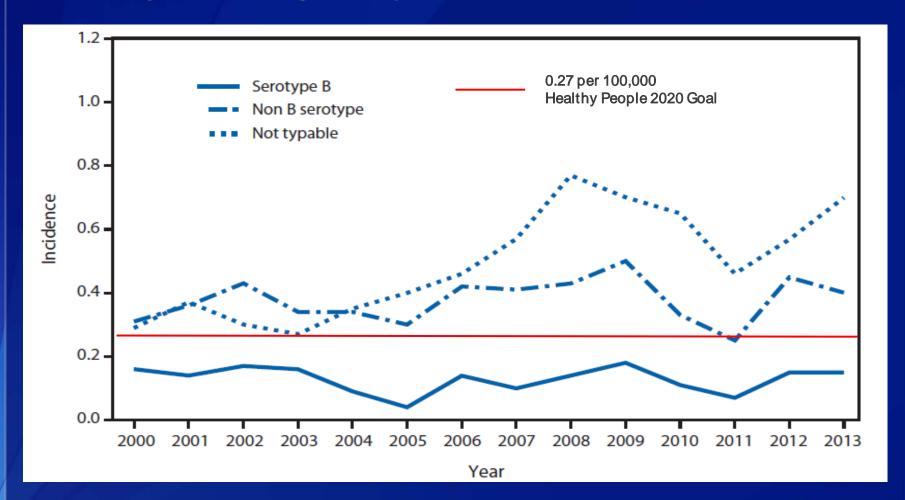
Communicability

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 — United States, 1980–2012



Haemophilus influenzae, Invasive Disease Incidence of reported cases (per 100,000), by serotype among children aged <5 years — United States, 2000–2013



Haemophilus influenzae Type b Polysaccharide Vaccine

- Available 1985-1988
- 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 monovalent conjugate vaccines
- 2 combination vaccines available that contain Hib vaccine

Conjugate Hib Vaccines

PRP-T

ActHIB

Hiberix

Pentacel

MenHibrix

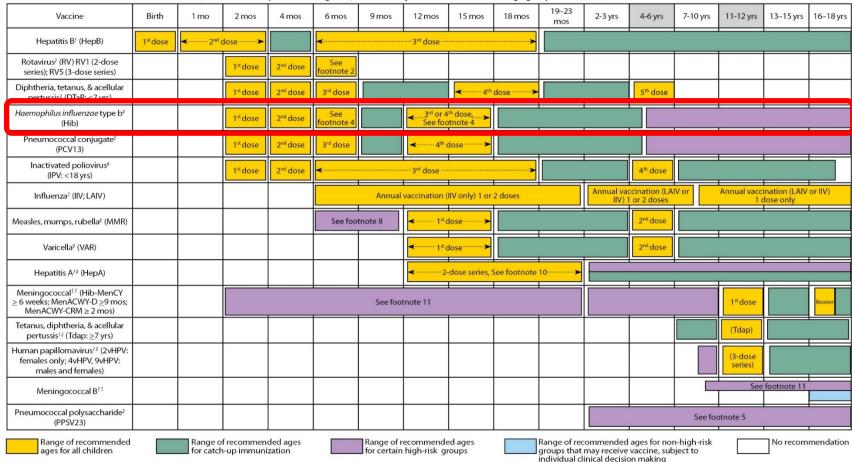
PRP-OMP

PedvaxHIB

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NOTE: The above recommendations must be read along with the footnotes of this schedule.

Hib Vaccine



- Recommended interval 8 weeks for primary series
- Minimum interval 4 weeks for primary series
- Minimum age 6 weeks
- Booster dose at 12-15 months

Hib Vaccine Routine Schedule

Vaccine	2 months	4 months	6 months	12-18 months
PRP-T	X	X	Χ	X
PRP-OMP	X	X	NA	X

Unvaccinated 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
- See detailed schedule p. 128 of Pink Book, and 2016 catch-up schedule

Hib Vaccine Use in Older Children and Adults

- Generally not recommended for persons older than 59 months of age
- High-risk older children and adolescents may be vaccinated if not vaccinated in childhood
 - Asplenia
 - Immunodeficiency
 - HIV infection
 - Receipt of chemotherapy or radiation therapy
- Special populations

Guidance for Hib Vaccination in High-risk Groups

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Hib vaccine guidance

Elective splenectomy If unimmunized:

1 dose, prior to procedure

Asplenic patient If unimmunized: 1 dose

HIV-infected children If unimmunized: 1 dose

HIV-infected adults

Hib vaccination not recommended

Hematopoietic cell transplant 3 doses (at least 4 weeks apart) beginning 6-12 months after transplant

Special Populations

- Children aged <24 months 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
 - PRP-OMP vaccines specifically recommended for primary series doses
 - Hib disease peaks earlier in infancy
 - PRP-OMP vaccines produce protective antibody after first dose/early protection

Monovalent Hib Vaccines

ActHIB (PRP-T)

Hiberix (PRP-T)

PedvaxHIB (PRP-OMP)

ActHIB (PRP-T)

- Approved for all doses of primary schedule and booster dose
- Can be used for previously unvaccinated children per the catch-up schedule
- Must be reconstituted only with 0.4% sodium chloride (NaCl)
 ActHIB diluent

Hiberix (PRP-T)

Approved for all doses of primary schedule and booster dose

Can be used for previously unvaccinated children per the catch-up schedule

PedvaxHIB (PRP-OMP)

- Approved for all doses of primary schedule and booster dose
 - Remember primary series for PRP-OMP vaccines is 2 doses
- Can be used for previously unvaccinated children per the catch-up schedule

Hib-containing Combination Vaccines

- DTaP- IPV/Hib (Pentacel)
- Hib-MenCY (MenHIBrix)

Pentacel

- Contains DTaP, Hib (PRP-T), and IPV
- Approved for doses 1 through 4 among children 6 weeks through 4 years of age
- Do NOT use for children 5 years or older
- Package contains lyophilized Hib (ActHIB) that is reconstituted with a liquid DTaP-IPV solution

MenHibrix

- Contains Hib (PRP-T) and Neisseria meningitidis serogroups C and Y
- Approved for 4 doses between 6 weeks and 18 months of age
- Only recommended for routine meningococcal vaccination of infants who are at increased risk for meningococcal disease
 - Persistent complement pathway deficiencies
 - Anatomic or functional asplenia, including sickle cell disease

Hib Vaccine Interchangeability

- All monovalent 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

Comvax

- Hepatitis B-Hib (PRP-OMP) combination
- Removed from existing contracts and pricing programs
- Listed as "Discontinued" on FDA website
- Last supplies expected to expire August 19, 2016

Contraindications and Precautions

- Severe allergic reactions 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