Centers for Disease Control and Prevention





Polio and Haemophilus influenzae type b

Pink Book Webinar Series

Andrew Kroger MD, MPH
Medical Officer
Communications and Education Branch

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

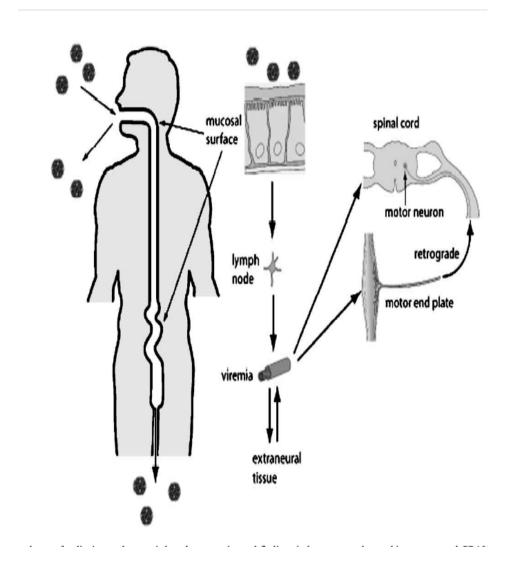


Poliovirus

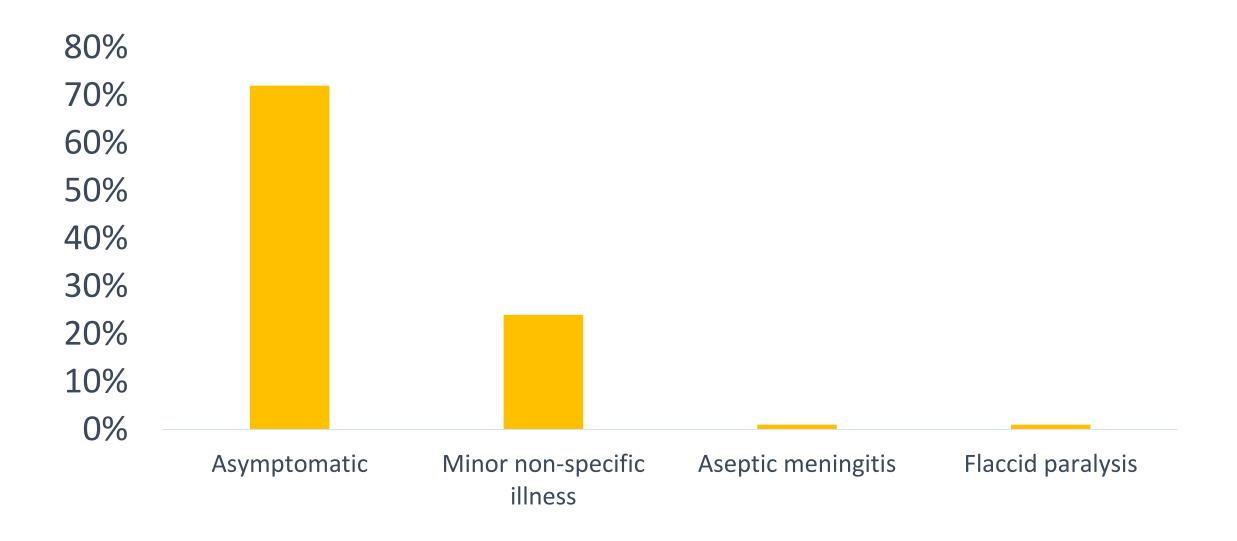
- Three serotypes of wild poliovirus:
 - -WPV1
 - -WPV2
 - -WPV3
- Minimal heterotypic immunity between serotypes
- Rapidly inactivated by heat, chlorine, formaldehyde, and ultraviolet light

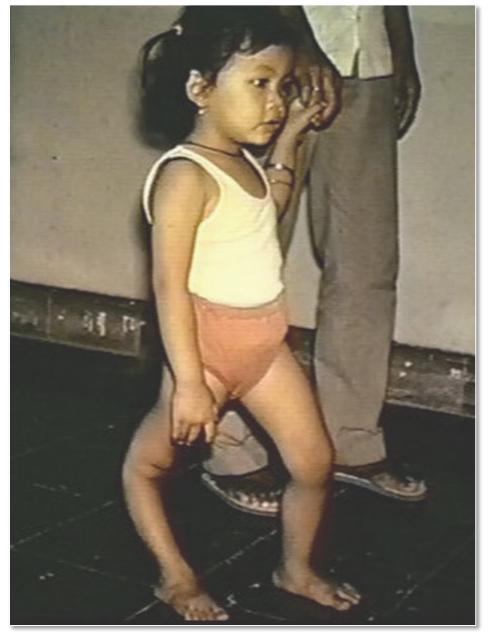
Poliomyelitis Pathogenesis

- 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



Outcomes of Poliovirus Infection





Asymmetric paralysis

Poliovirus Epidemiology

Reservoir

Human

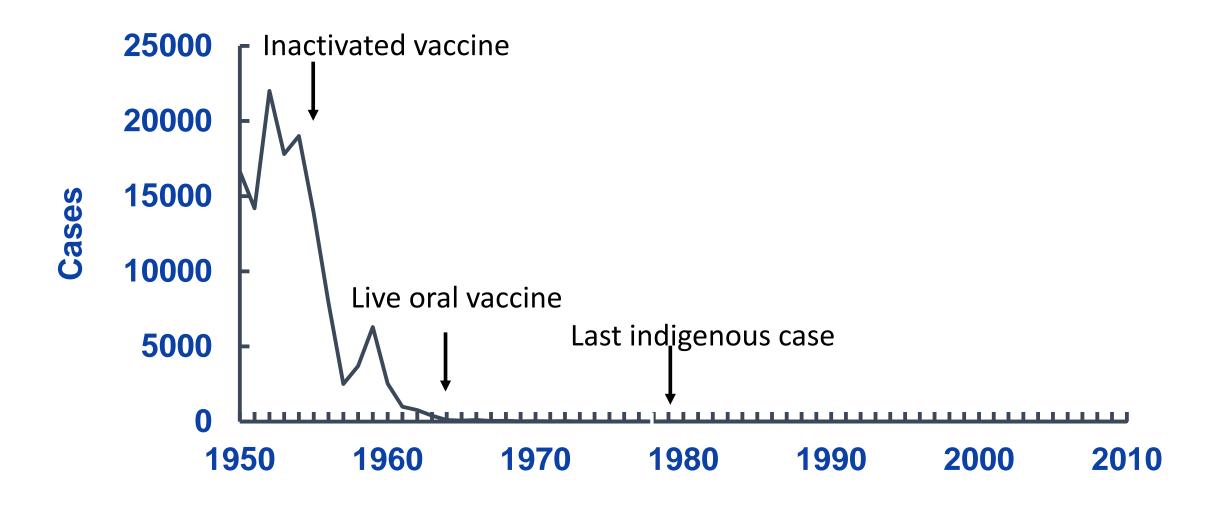
Transmission

Fecal-oral Oral-oral possible

Communicability

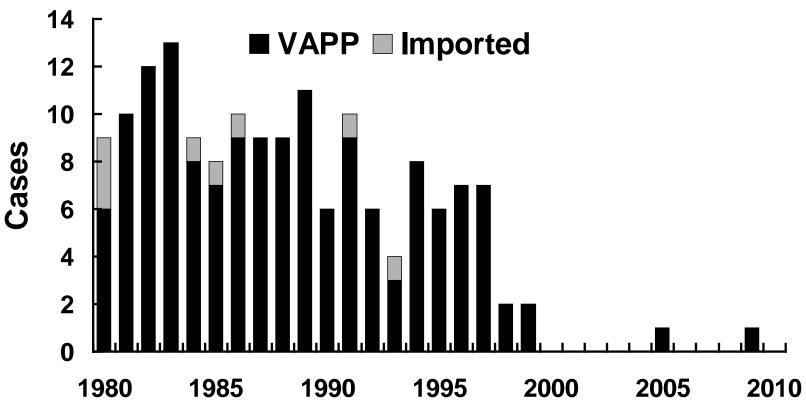
Most infectious: 7–10 days before onset Virus present in stool 3–6 weeks

Poliomyelitis—United States, 1950–2011



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

Polio-Containing Vaccine Products

Product ACIP Abbreviation	Age Indications	IPV Series
IPOL IPV	6 weeks and older	Any dose in the series
Pediarix DTaP-IPV-HepB	6 weeks through 6 years	Doses 1 through 3
Pentacel DTaP-IPV/Hib	6 weeks through 4 years	Doses 1 through 4
Kinrix DTaP-IPV	4 through 6 years	Dose 4
Quadracel DTaP-IPV	4 through 6 years	Dose 4 or 5

ACIP Polio Immunization Recommendations Routine Childhood Schedule

IPV Dose	Routinely Recommended Age	
1	2 months	
2	4 months	
3	6–18 months	
4	4–6 years	

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 polioendemic area), minimum age and intervals may be followed

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Dose Minimum Age Minimum Interval to the Next Dose

Dose 1 6 weeks 4 weeks

Dose 2 10 weeks 4 weeks

Dose 3 14 weeks 6 months

Dose 4 4 years --------
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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 polioendemic area), use the minimum intervals

Minimum Intervals to the Next Dose

Dose 1 4 weeks

Dose 2 6 months

Dose 3 ------

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

Contraindication

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

Precaution

Moderate to severe acute illness

IPV Adverse Reactions

Local reactions

2.8% (pain, redness, swelling)

Severe reactions

rare

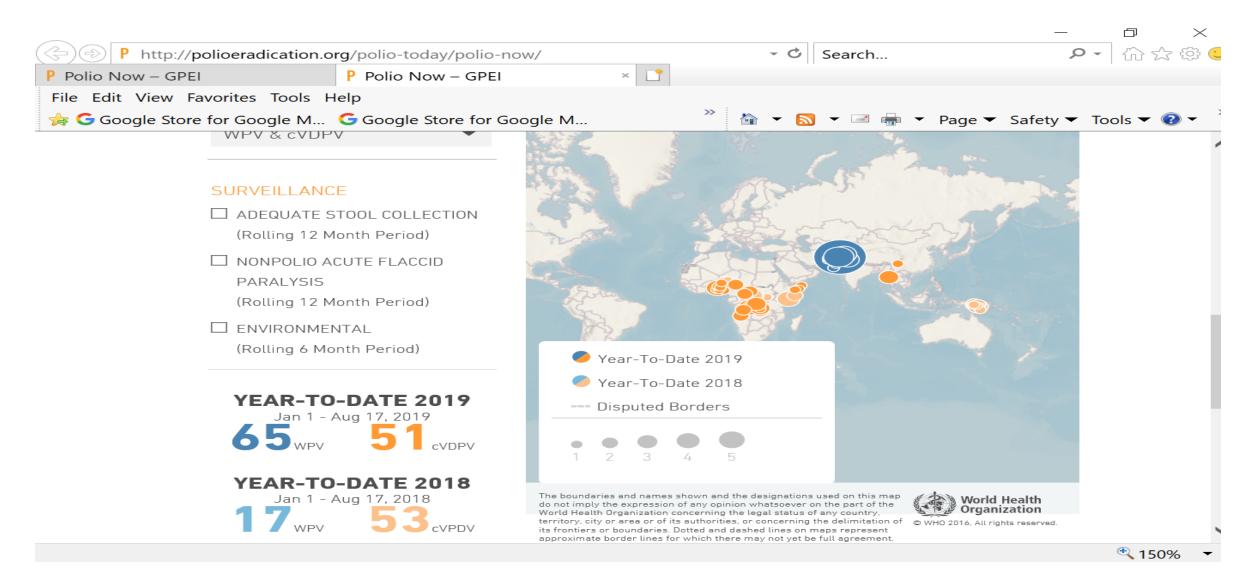
Polio Eradication

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 Initiative



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

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)

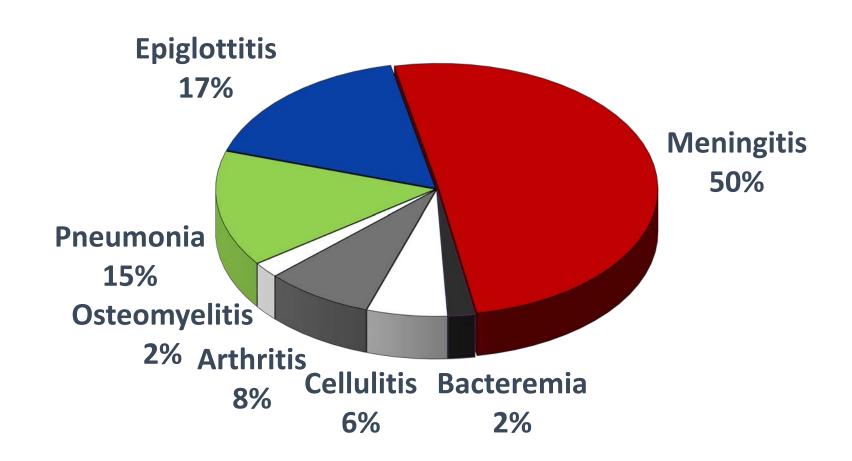
Impact of Haemophilus influenzae type b Disease

 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*





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

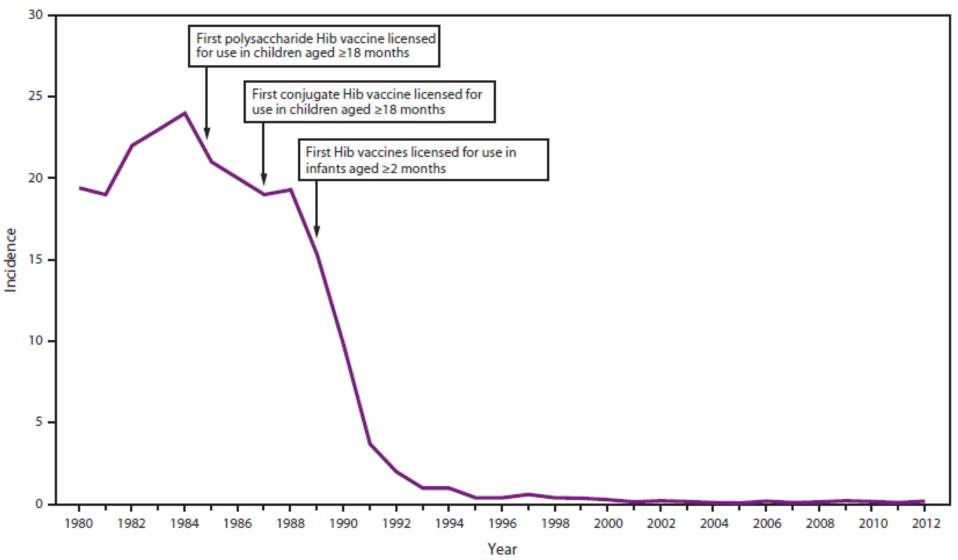
Temporal pattern

Peaks in Sept. through Dec. and March
through May

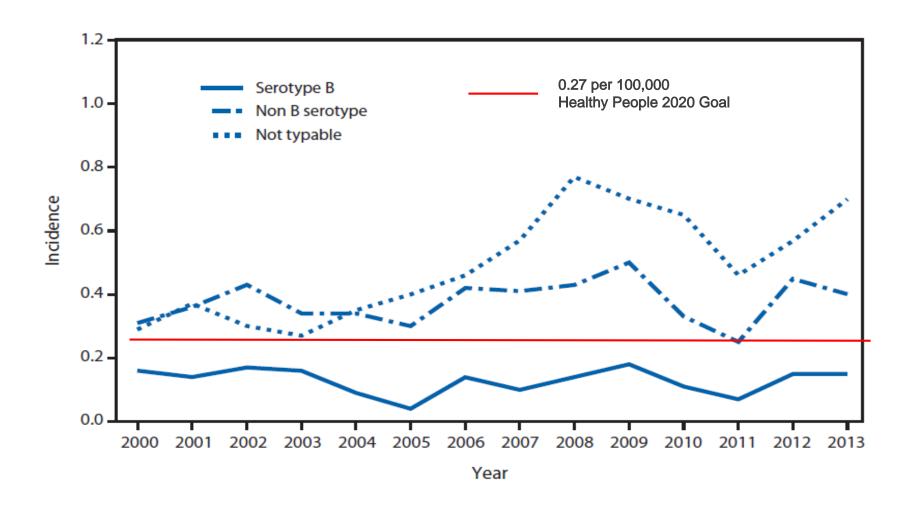
Communicability

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



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

- 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 single-component conjugate Hib vaccine products
- 1 combination vaccine products available that contain Hib conjugate vaccine

Hib-Containing Vaccine Products

Vaccine product	Age indications			
PRP-T (polysaccharide, tetanus toxoid)				
ActHIB	All doses of primary schedule and booster dose 2 months through 5 years			
Hiberix	All doses of primary schedule and booster dose 6 weeks through 4 years			
Pentacel (DTaP, IPV, Hib)	For doses 1 through 4 6 weeks through 4 years of age			
PRP-OMP (polysaccharide, outer membrane protein)				
PedvaxHIB	All doses of primary schedule and booster dose 2 to 71 months of age			
Vaxelis (DTaP, IPV, Hib, HepB)	All doses of primary schedule (2) and booster dose 6 weeks-4 years			

ACIP Hib Immunization Recommendations Routine Schedule

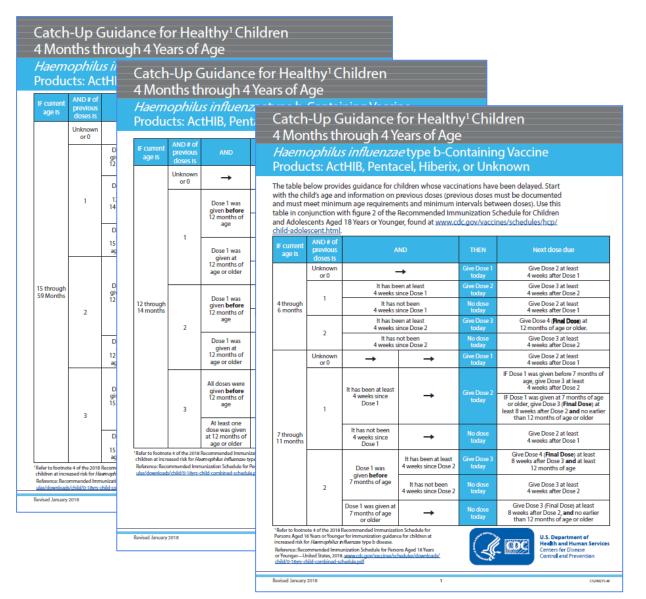
- Routinely recommended for all infants beginning at 2 months of age*
- Schedule varies based on the product used
 - ActHib, Pentacel, Hiberix: Follow the 4-dose schedule at 2, 4, 6, and 12–15 months of age
 - PedvaxHIB: Follow the 3-dose schedule at 2, 4, and 12–15 months of age
- If any dose in the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

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



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

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

"Unvaccinated" and High-Risk Catch-Up

"Unvaccinated" means someone who meets both criteria:

Less than the routine series through 14 months;

AND

No doses after 14 months of age

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

Vaccines with Diluents: How to Use Them

administering them! Reconstitution means that the Ivophilized (freeze-dried) vaccine powder or wafer in one vial must . ALWAYS check the expiration date on the diluent and vaccine. be reconstituted (mixed) with the diluent (liquid) in another.

- vaccine as indicated on the chart.
- NEVER use expired diluent or vaccine

Vaccine product name	Manufacturer	Lyophilized vaccine (powder)	Liquid diluent (may contain vaccine)	Time allowed between reconstitution and use, as stated in package insert*	Diluent storage environment
ActHIB (Hib)	Sanofi Pasteur	Hib	0.4% sodium chloride	24 hrs	Refrigerator
Hiberix (Hib)	GlaxoSmithKline	Hib	0.9% sodium chloride	24 hrs	Refrigerator or room temp
Imovax (RAB _{HDCV})	Sanofi Pasteur	Rabies virus	Sterile water	Immediately [†]	Refrigerator
M-M-R II (MMR)	Merck	MMR	Sterile water	8 hrs	Refrigerator or room temp
Menveo (MenACWY)	GlaxoSmithKline	MenA	MenCWY	8 hrs	Refrigerator
Pentacel (DTaP-IPV/Hib)	Sanofi Pasteur	Hib	DTaP-IPV	Immediately [†]	Refrigerator
ProQuad (MMRV)	Merck	MMRV	Sterile water	30 min	Refrigerator or room temp
RabAvert (RAB _{PCECV})	GlaxoSmithKline	Rabies virus	Sterile water	Immediately†	Refrigerator
Rotarix (RV1)‡	GlaxoSmithKline	RV1	Sterile water, calcium carbonate, and xanthan	24 hrs	Refrigerator or room temp
Shingrix (RZV)	GlaxoSmithKline	RZV	AS01 _B s adjuvant suspension	6 hrs	Refrigerator
Varivax (VAR)	Merck	VAR	Sterile water	30 min	Refrigerator or room temp
YF-VAX (YF)	Sanofi Pasteur	YF	0.9% sodium chloride	60 min	Refrigerator or room temp
Zostavax (ZVL)	Merck	LZV	Sterile water	30 min	Refrigerator or room temp

Always refer to package inserts for detailed instructions on reconstituting specific vaccines. In general, follow the steps below.

- Rotaria¹), select a syringe and needle of proper length of the vaccine. For Rotarix, see the package insert.
- 2 Before reconstituting, check labels on both the lyophilized vaccine vial and the diluent to verify that they are the correct two products to mix together, the diluent is the correct volume, and neither the vaccine nor the diluent has expired
- 3 Reconstitute (i.e., mix) vaccine just prior to use by:
- per with an alcohol awab, inserting needle of syrings into diluent vial and withdrawing entire contents, and
- injecting diluent into lyophilized vaccine vial and rotating or agitating to thoroughly dissolve the 4 Check the appearance of the reconstituted vaccine.
- Reconstituted vaccine may be used if the color and appearance match the description on the package
- If there is discoloration, extraneous particulate
- socine cannot be thoroughly mixed, mark the vial as "DO NOT USE," return it to proper storage condi-
- or comes in a multidose vial, he sure to · clearly mark the vial with the date and time the
- maintain the product at 2°-8°C (36°-46°F); do no

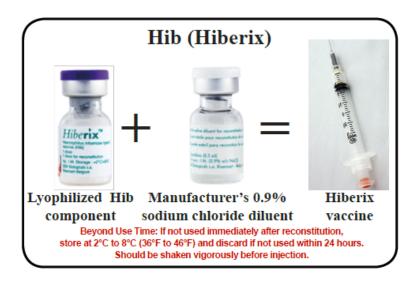
IMMUNIZATION ACTION COALITION Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org www.immunize.org/catg.d/p3040.pdf • Item #P3040 (8/18)

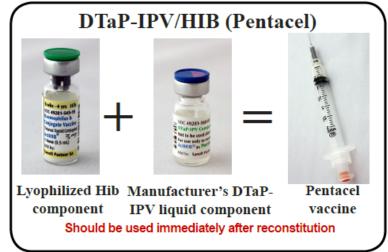
For purposes of this guidance, IAC defines "immediately" as within 30 minutes or less

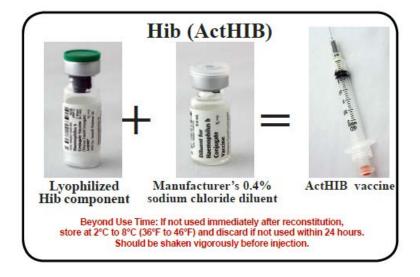
purified from plant extract Cullisis seasonaris Molina, combined in a liposomal formulation. The liposomes are composed

Hib: Vaccine Administration Errors

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







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

VACCINE INFORMATION STATEMENT

Your Child's First Vaccines

Hib Vaccine

What You Need to Know

1 Why get vaccinated?

Haemophilus influenzae type b (Hib) disease is a serious

disease caused by bacteria. It usually affects children

under 5 years old. It can also affect adults with certain

Your child can get Hib disease by being around other

children or adults who may have the bacteria and not

know it. The germs spread from person to person. If

the germs stay in the child's nose and throat, the child

probably will not get sick. But sometimes the germs

can cause serious problems. This is called invasive

spread into the lungs or the bloodstream, and then Hib

Before Hib vaccine, Hib disease was the leading cause

in the United States. Meningitis is an infection of the

damage and deafness. Hib disease can also cause:

lining of the brain and spinal cord. It can lead to brain

severe swelling in the throat, making it hard to breathe

· infections of the blood, joints, bones, and covering of

Before Hib vaccine, about 20,000 children in the United

States under 5 years old got Hib disease each year, and

Hib vaccine can prevent Hib disease. Since use of

Hib vaccine began, the number of cases of invasive Hib disease has decreased by more than 99%. Many

more children would get Hib disease if we stopped

about 3% - 6% of them died

of bacterial meningitis among children under 5 years old

What You Need to Know

The vaccines covered on this statement are those most likely to during infancy and early childhood. Other vaccines (including m rotavirus; influenza; and hepatitis A) are also routinely recomme

Your child will get these vaccines today:

1 Why get v Vaccine-preventable di

than they used to be, t

have not gone away. O

diseases still occur acr fewer babies get vacc

7 childhood diseases

1. Diphtheria (the 'D

Signs and symptom

back of the throat the

Diphtheria can lead

paralysis and heart fa

About 15,000 peop

from diphtheria be

2. Tetanus (the 'T' i

Signs and sympton

the muscles, usually

Tetanus can lead to

make it difficult to o

- Tetanus kills about

3. Pertussis (the 'P'

spells that can make

or breathe. These spe

Pertussis can lead t

damage, or death. Pe

- Most pertussis dea

as Lockjaw)

vaccines:

medical conditions

VACCINE INFORMATION STATEMENT

Polio Vaccine

What You Need to Know

1 Why get vaccinated?

Influenzae Type b)

VACCINE INFORMATION STATEMENT

Most adults do not need IPV because they were already vaccinated against polio as children. But some adults

e at higher risk and should consider polio vaccination

people traveling to certain parts of the world, aboratory workers who might handle polio virus, and health care workers treating patients who could have

iese higher-risk adults may need 1 to 3 doses of IPV, pending on how many doses they have had in the past. here are no known risks to getting IPV at the same time

2 Hib vaccine

Second Dose:

Final/Booster Dose: 12-15 months of age

Hib vaccine may be given as part of a combination vaccine. Combination vaccines are made when two or more types of vaccine are combined together into a more than one disease.

Children over 5 years old and adults usually do not need Hib vaccine. But it may be recommended for older children or adults with asplenia or sickle cell disease, before surgery to remove the spleen, or following a bone marrow transplant. It may also be recommended for people 5 to 18 years old with HIV. Ask your doctor for

Your doctor or the person giving you the vaccine can give you more information.

Several different brands of Hib vaccine are available. Your child will receive either 3 or 4 doses, depending on which vaccine is used

Doses of Hib vaccine are usually recommended at

 First Dose: 2 months of age

4 months of age 6 months of age (if needed, depending on brand of vaccine)

single shot, so that one vaccination can protect against

Some people should not get this vaccine

Il the person who is giving the vaccine:

If the person getting the vaccine has any severe. life-threatening allergies.

If you ever had a life-threatening allergic reaction after a dose of IPV, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Ask your health care provider if you want information about vaccine components.

If the person getting the vaccine is not feeling well. If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise vou.

Risks of a vaccine reaction

ith any medicine, including vaccines, there is a chance side effects. These are usually mild and go away on eir own, but serious reactions are also possible

me people who get IPV get a sore spot where the shot as given. IPV has not been known to cause serious oblems, and most people do not have any problems





Polio and Vaccine Resources and References

Resources and references are available on the webinar web page

Polio and Haemophilus influenzae type b Vaccines Resources and References

2018 PINK BOOK WEBINAR SERIES

ACIP recommendations

- Current ACIP Hagmonhilus influenzage type b vaccine recommendations www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hib.html
- Current ACIP Polio vaccine recommendations www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/polio.html
- ACIP General Best Practice Guidelines on Immunization www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

Manufacturer's vaccine package inserts (PI)

- DTaP-IPV (Kinrix), GlaxoSmithKline, Biologicals www.fda.gov/downloads/BiologicsBloodVaccines/ApprovedProducts/UCM241453.pdf
- DTaP-IPV (Quadracel) Sanofi Pasteur Limited www.fda.gov/downloads/biologicsbloodyaccines/vaccines/approvedproducts/ucm439903.pdf
- DTaP-IPV-HepB (Pediarix) GlaxoSmithKline, Biologicals www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM241874.pdf
- DTat-IPV/Hib (Pentacel). Sanofi Pasteur Limited www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109810.pdf
- Acthib, Sanofi Pasteur Limited www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109841.pdf
- Hiberix, GlaxoSmithKline, Biologicals, www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm179527.htm
- PedyaxHIB, Merck & Co., Inc. www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094051.htm
- IPOL, Sanofi Pasteur Limited www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm200582.htm

Schedule

- 2018 Recommended immunization schedule for persons aged 18 years and younger www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html
- 2018 Recommended immunization schedule for adults 19 years and older | www.cdc.gov/vaccines/schedules/hcp/adult.html

Disease

- CDC Haemophilus influenzae type b disease webpage www.cdc.gov/hi-disease/clinicians.html
- CDC Polio disease webpage https://www.cdc.gov/polio/us/hcp.html
- Hib disease information you need to know ww.chop.edu/conditions-diseases/haemophilus-influenzae-infections
- · Polio information you need to know
- The Global Polio Eradication Initiative http://polioeradication.org/

Information for health care personnel

- Epidemiology and Prevention of Vaccine-Preventable Diseases: Hagmanhilus influenzag type b chapter www.cdc.gov/vaccines/pubs/pinkbook/hib.html
- Epidemiology and Prevention of Vaccine-Preventable Diseases: Polio chapter www.cdc.gov/vaccines/pubs/pinkbook/downloads/polio.pdf
- Ask the Experts: Combination vaccine questions www.immunize.org/askexperts/experts combo.asp
- Ask the Experts: Hagmaphilus influenzag type b questions www.immunize.org/askexperts/experts hib.asp
- Ask the Experts: Polio questions <u>www.immunize.org/askexperts/experts pol.asp</u>
- CDC Hib vaccination www.cdc.gov/vaccines/vpd/hib/hcp/index.html