**Centers for Disease Control and Prevention** National Center for Immunization and Respiratory Diseases



## Polio and Haemophilus influenzae type b

**Pink Book Webinar Series** 

JoEllen Wolicki BSN, RN

**Nurse Educator** 

**Communications and Education Branch** 

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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**





## 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





#### **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	<b>IPV Series</b>	
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 Schedule

<b>IPV Dose</b>	<b>Routinely Recommended Age</b>	
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
  - Dose Minimum Age Minimum Interval to the Next Dose

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- Dose 1 6 weeks 4 weeks
- Dose 2 10 weeks 4 weeks
- Dose 3 14 weeks 6 months
- Dose 4 4 years

#### ACIP Polio Immunization Recommendations 4<sup>th</sup> 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**

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**



YEAR-TO-DATE 2018 Jan 1 - Aug 21, 2018 13<sub>WPV</sub> 24<sub>cVDPV</sub>

2017 TOTAL Jan 1 - Dec 31, 2017 22<sub>WPV</sub> 96<sub>cVPDV</sub>

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.

World Health Organization

## **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

National Center for Immunization & Respiratory Diseases Immunization Services Division

## 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–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

Year

# *Haemophilus influenzae,* Invasive Disease Incidence of Reported Cases (per 100,000), by serotype Among Children aged <5 years—U.S., 2000–2013



Year

#### 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
- I combination vaccine products available that contain Hib conjugate vaccine

### **Hib-Containing Vaccine Products**

Product ACIP Abbreviation	Age Indications	Approved for	
ActHIB Hib	6 weeks and older	Primary series (3 doses) Booster dose (1)	
Hiberix Hib	6 weeks and older	Primary series (3 doses) Booster dose (1)	
PedvaxHIB Hib	6 weeks and older	Primary series (2 doses) Booster dose (1)	
Pentacel DTaP-IPV/Hib	6 weeks through 4 years	Primary series (3 doses) Booster dose (1)	

## 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



Catch-Up Guidance for Healthy Children 4 Months through 4 Years of Age www.cdc.gov/vaccines/schedules/downloads/child/job-aids/hib-actHib.pdf

### 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	<b>Hib Vaccine Guidance</b>
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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

## **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

Be sure to reconstitute the following vaccines correctly before • Only use the diluent provided by the manufacturer for that administering them! Reconstitution means that the lyophilized (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 <sub>HDCV</sub> )	Sanofi Pasteur	Rabies virus	Sterile water	Immediately <sup>†</sup>	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 <sup>†</sup>	Refrigerator
ProQuad (MMRV)	Merck	MMRV	Sterile water	30 min	Refrigerator or room temp
RabAvert (RAB <sub>PCECV</sub> )	GlaxoSmithKline	Rabies virus	Sterile water	Immediately <sup>†</sup>	Refrigerator
Rotarix (RV1)*	GlaxoSmithKline	RV1	Sterile water, calcium carbonate, and xanthan	24 hrs	Refrigerator or room temp
Shingrix (RZV)	GlaxoSmithKline	RZV	AS01 <sub>B</sub> <sup>g</sup> 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.

1 For single-dose vaccine products (exception is Rotarix<sup>1</sup>), select a syringe and needle of proper length to be used for both reconstitution and administratio of the vaccine. For Rotarix, see the package insert.<sup>1</sup> 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 swab, inserting needle of syrings into diluent vial and withdrawing entire contents, and injecting diluent into lyophilized vaccine visit and rotating or agitating to thoroughly dissolve the lyophilized powder 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

matter, obvious lack of resuspension, or the

accine cannot be thoroughly mixed, mark the vial as "DO NOT USE," return it to proper storage conditions, and contact your state or local health departmen immunization program or the vaccine manufacturer. If reconstituted vaccine is not used immediately or comes in a multidoas vial, he sure to clearly mark the vial with the date and time the vaccine was reconstitu maintain the product at 2°-8°C (36°-46°F); do no freeze, and use only within the time indicated on chart abo

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f the reconstituted vaccine is not used within this time period, it must be discarded
For purposes of this guidance, IAC defines "immediately" as within 30 minutes or less
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removing the protective cape and wiping each stop.

The populate of the generation, but contrast, internationary as which to minute the main terms of the Postaria vacation is administered by mouth using the applicator that contains the diluent. It is not administered as an in IASDI<sub>10</sub> is composed of 3-O-desacyI-(F-monophosphory) lipid A (MPL) from Salmonalia minuteate and QS-21, a saponir

purified from plant extract Quillais assonants Molina, combined in a liposonial formulation. The liposonies are composed ophatidylcholine (DOPC) and cholesterol in phosphate-buffered saline solution containing disodium hydrous, potassium dihydrogen phosphate, sodium chloride, and water for injection.

Technical content reviewed by the Centers for Disease Control and Prevention

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)

## **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





### **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 Haemonhilus influenzas type b vaccine recommendations www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hib.html
- Current ACIP Polio vaccine recommendations <u>www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/polio.html</u>
- ACIP General Best Practice Guidelines on Immunization <u>www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html</u>

#### Manufacturer's vaccine package inserts (PI)

- DTaP-IPV (Kinrix), GlaxoSmithKline, Biologicals www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM241453.pdf
- DTaP-IPV (Quadracel) Sanofi Pasteur Limited www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm439903.pdf
- DTaP-IPV-HepB. (Pediarix) GlaxoSmithKline, Biologicals www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM241874.pdf
- DTaP-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
- PedvaxHIB, Merck & Co., Inc www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094051.htm
- IPOL, Sanofi Pasteur Limited <u>www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm200582.htm</u>

#### 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: Harmonhilus influenzar, 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 <u>www.immunize.org/askexperts/experts combo.asp</u>
- Ask the Experts: Haemophilus influenzae 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 <u>www.cdc.gov/vaccines/vpd/hib/hcp/index.html</u>