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



Polio and Haemophilus influenzae type b Vaccines

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Learning Objectives

- Describe the Advisory Committee on Immunization Practices General Best Practice Guidelines on Immunization.
- Describe an emerging immunization issue.
- For each vaccine-preventable disease, identify those for whom routine immunization is recommended.
- For each vaccine-preventable disease, describe characteristics of the vaccine used to prevent the disease.
- Locate current immunization resources to increase knowledge of team's role in program implementation for improved team performance.
- Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.

Continuing Education Information

- CE credit, go to: <u>https://tceols.cdc.gov/</u>
- Search course number: WD4564-090622
- CE credit expires: July 1, 2024
- CE instructions are available on the Pink Book Web-on-Demand Series web page
- Questions and additional help with the online CE system, e-mail <u>CE@cdc.gov</u>



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Polio Disease

Poliomyelitis Disease

Epidemics starting in the late 19th century

Polio epidemics were reported each summer and fall

More than 21,000 paralytic cases reported in the U.S. in 1952

Vaccine introduction in 1955; polio incidence declined rapidly

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 mouth

Replicates in pharynx and GI tract

 Invades local lymphoid tissue, may enter bloodstream then infect cells of the central nervous system

Viral spread along nerve fibers

Destruction of motor neurons

Poliomyelitis Clinical Features

Incubation period

- 3 to 6 days for nonparalytic poliomyelitis
- 7 to 21 days for onset of paralysis in paralytic poliomyelitis

Risk of severe disease increases with age

Outcomes of Poliovirus Infection

Asymptomatic 75% Minor non-specific illness 24% Aseptic meningitis 1% Flaccid paralysis < 0.5% 0% 20% 40% 60% 80% 100%

Types of Paralytic Polio

- Spinal polio: Asymmetric paralysis that most often involves the legs.
- Bulbar polio: Weakness of facial, oropharyngeal, and respiratory muscles innervated by cranial nerves
- Bulbospinal polio: Combination of bulbar and spinal paralysis



Asymmetric paralysis

Poliovirus Epidemiology

Epidemiology	
Reservoir	Human
Transmission	Fecal-oral Oral-oral possible
Communicability	Most infectious: 7–10 days before onset Virus present in stool 3–6 weeks

Cases of Polio Paralysis in the US Before and After Vaccine Introduction



Poliomyelitis in the US

1980-1999: 162 confirmed cases of paralytic polio reported

- -6 cases wild poliovirus acquired outside the US
- -2 cases imported and classified as indeterminate
- -154 cases vaccine-associated paralytic polio
- 2005: Asymptomatic infections with a circulating vaccinederived poliovirus
- 2009: Vaccine-derived poliovirus reported in an immunocompromised person likely infected years ago

Polio -- 2022

July 21, 2022: CDC is aware of a case of polio in an unvaccinated individual from Rockland County, New York, and is consulting with the New York State Department of Health on their investigation. Public health experts are working to understand how and where the individual was infected and provide protective measures, such as vaccination services to the community to prevent the spread of polio to under- and unvaccinated individuals. There is no cure for polio, but it is preventable through safe and effective vaccination.



Polio Vaccine

Poliovirus Vaccines

1955–Inactivated vaccine

 Early 1960s–Live, attenuated vaccine (OPV)

1987–Enhanced-potency, inactivated vaccine (IPV)



Polio-Containing Vaccine Products

Vaccine name	Vaccine components	Age indication	Dose in polio series	Injection route
Ipol (SP)	IPV	6 weeks and older	Any	IM or SC
Pentacel (SP)	DTaP-IPV/Hib	6 wks–4 yrs	1, 2, 3, 4	IM
Kinrix (GSK)	DTaP-IPV	4–6 yrs	4	IM
Quadracel (SP)	DTaP-IPV	4–6 yrs	4, 5	IM
Vaxelis (Merck)	DTap-IPV-Hib- HepB	6 wks–4 yrs	1, 2, 3	IM
Pediarix (GSK)	DTaP-HepB- IPV	6 wks–6 yrs	1, 2, 3	IM

IM = Intramuscular; SC = Subcutaneous; All vaccines in the table above are non-live

Enhanced Inactivated Polio Vaccine

IPV highly effective in producing immunity to poliovirus

- 90% of recipients are immune after 2 doses
- 99% of recipients are immune after 3 doses

Duration of immunity not known with certainty

Preparation and Administration for IPV-Containing Vaccines

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*

*IPV may be administered by subcutaneous injection using a 5/8-inch needle given in the fatty tissue over the upper, outer triceps or anterolateral thigh

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Clinical Considerations

ACIP Polio Vaccine Recommendations

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16 yrs	17–18 yrs
Inactivated poliovirus (IPV <18 yrs)			1ª dose	2 nd dose	•		– 3 rd dose –					4 th dose					

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

Polio Schedule and Combination Vaccines

A dose of IPV on or after age 4 years (i.e., minimum age) is recommended regardless of the number of previous doses.

When DTaP-IPV/Hib (Pentacel) is used, following the schedule for DTaP, 4 doses are given by age 18 months.

A final IPV-containing dose should be administered at 4-6 years; resulting in a 5-dose series.

ACIP Polio Immunization Recommendations Catch-Up Schedule

- Infants ages 6 months and younger, follow the recommended schedule
- If accelerated protection is needed (e.g., travel to polio-endemic area), minimum age and intervals may be followed

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				

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

Children turning 4 in less than 4 weeks who have only had 2 doses should receive a final dose in 6 months

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 1, 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.

Routine vaccination of U.S. residents 18 years of age or older was not previously recommended; however, all adults who are unvaccinated or have incomplete vaccination for poliovirus should catch up.

Adults who have never been vaccinated against polio should receive three doses of IPV:

- The first dose at any time
- The second dose 1 to 2 months later
- The third dose 6 to 12 months after the second
- Adults who have had one or two doses of polio vaccine in the past should receive the remaining one or two doses.

Adults at increased risk of exposure

- Laboratory workers handling specimens that may contain polioviruses
- Healthcare personnel treating patients who could have polio or have close contact with a person who could be infected with poliovirus
- Travelers to areas where poliomyelitis is endemic or epidemic.

Use routine IPV schedule if possible

- 0, 1 through 2 months, 6 through 12 months intervals
- If accelerated protection is needed (e.g., travel to polioendemic area), use the minimum intervals.

Dose	Minimum Intervals to the Next Dose
Dose 1	4 weeks
Dose 2	6 months
Dose 3	

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

Polio

Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component


Polio

Pregnancy

Moderate or severe acute illness with or without fever

IPV Adverse Reactions

Polio	
Local reactions (pain, redness, swelling)	3.2-18%
Severe reactions	rare

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 1–3

 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

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Storage and Handling

Polio Vaccine Storage and Handling

- Store in the refrigerator between 2°C and 8°C (36°F and 46°F)
 - Should not be frozen
 - Refrigerate on arrival

IPV					
Ages:	6 weeks and older				
Use for:	Any dose in the series				
Route:	Intramuscular (IM) injection OR Subcutaneous (subcut) injection				

Knowledge Check

- When DTaP-IPV/Hib (Pentacel) is used, 4 doses of IPV are given at ages 2, 4, 6, and 15-18 months.
 This results in 4 doses of IPV by the age of 18 months. The series is complete at 18 months.
- A. True
- B. False



Answer

When DTaP-IPV/Hib (Pentacel) is used, 4 doses of IPV are given at ages 2, 4, 6, and 15-18 months. This results in 4 doses of IPV by the age of 18 months. The series is complete at 18 months.

B. False



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Hib Disease

Haemophilus influenzae type b

Severe bacterial infection, particularly among infants

First described in 1892 during an influenza outbreak

Established H. influenzae did not cause influenza in 1933

Impact of *Haemophilus influenzae* type b Disease: Prevaccine

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

Aerobic gram-negative bacteria

Polysaccharide capsule

6 different serotypes (a through f) of polysaccharide capsule

95% of invasive disease caused by type b (prevaccine era)

Hib Pathogenesis

Enters body through nasopharynx

Invasive infection: Bacteria spread in bloodstream to distant sites in the body

Haemophilus influenzae type b Clinical Manifestations

Can affect many organ systems; most common types of disease:

- -Meningitis
- Bacteremia
- Epiglottitis
- Pneumonia
- -Arthritis
- -Cellulitis

Meningitis most common clinical manifestation



Facial cellulitis or infection of the soft tissues of the face, caused by Hib

Haemophilus influenzae type b Epidemiology

Epidemiology	
Reservoir	Human asymptomatic carriers
Transmission	Airborne respiratory droplets or direct contact with respiratory secretions
Temporal pattern	Prevaccine peak in Sept. through Dec. and March through May
Communicability	Generally limited but higher in some circumstances (e.g., household, childcare)

Hib Disease Burden

• 1980s: ~20,000 cases, or 40 to 50 cases per 100,000 (age <5 years)</p>

Incidence declined more than 99% since prevaccine era

2019: Rate of Hib infections 0.04 per 100,000 (all ages)

MMWR 2014;63(RR1):1–14; https://www.cdc.gov/abcs/downloads/HFLU_Surveillance_Report_2019.pdf

Incidence of invasive Hib disease, United States, 1999-2019





Hib Vaccine

Haemophilus influenzae type b Polysaccharide Vaccine

- Available 1985 until 1988
- Not effective in children younger than 18 months of age
- Efficacy in older children varied
- Age-dependent immune response
- No booster response

Haemophilus influenzae Type b Conjugate Vaccines

- First conjugate vaccine licensed in 1987
- Conjugation improves immunogenicity
 - Immune response with booster doses
- 3 single-component conjugate Hib vaccine products
- 2 combination vaccine products available that contain Hib conjugate vaccine

Hib-Containing Vaccine Products

Vaccine Product	Age Indications	Dose in series
PRP-T (polysaccharide, te		
ActHIB	2, 4, and 6 months	1, 2, 3, booster
Pentacel (SP)	6 weeks-4 years	1, 2, 3, booster
Hiberix (GSK)	2, 4, and 6 months	1, 2, 3, booster
PRP-OMP (polysaccharide protein)		
PedvaxHIB	2 and 4 months	1, 2, booster
Vaxelis (Merck)	6 weeks-4 years	1, 2, 3

Preparation and Administration of Hib-Containing Vaccine

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

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	НіБ	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 ^g 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 Rotaria¹), select a syringe and needle of proper length to be used for both reconstitution and administration of the vaccine. For Rotarix, see the package insert.¹ 2 Before reconstituting, check labels on both the lycphilized 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:

· removing the protective caps and wiping each stop-

per with an alcohol swab, inserting needle of syrings into diluent vial and withdrawing entire contents, and · injecting diluent into hophilized vaccine viel 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

vaccine cannot be thoroughly mixed, mark the vial as "DO NOT USE," return it to proper storage conditions, and contact your state or local health department immunization program or the vaccine manufacturer. 5 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 not freeze, and use only within the time indicated on chart abo

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If 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
 r to popular to the governey, let ominer. Internet any a termine of instance of edu.
Rotaria vaccine is administered by mooth using the applicator that contains the dilawet. It is not administered as an injectio
IASDI<sub>a</sub> is composed of 3-O-detacyl+f-monophosphoryl lipid A (MPL) from Salmonala minetata and QS-21, a taponin
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purified from plant extract Oulliais sationaria Molina, combined in a liposomal formulation. The liposomes are composed of diolecyl phosphatidylcholine (DOPC) and cholesterol in phosphate-buffered saline solution containing disodium phosphate anlydrous, 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)



Clinical Considerations

HIB Vaccine Recommendations

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16 yrs	17–18 yrs
Haemophilus influenzae type b (Hib)			1 st dose	2 nd dose	See Notes		3 rd or 4 th See №	th dose, Notes									

Vaccine	19–26 years	27-49 years	50–64 years	≥65 years					
Haemophilus influenzae type b (Hib)		1 or 3 doses depending on indication							

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, Vaxelis: follow the 4-dose schedule at 2, 4, 6, and 12–15 months of age (3-dose primary series, 1 booster dose)
 - PedvaxHIB: follow the 3-dose schedule at 2, 4, and 12–15 months of age (2-dose primary series, 1 booster dose)
- 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:

- Catch-up guidance for healthy children
- Detailed schedule p. 128 of Pink Book



https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/hib-actHib.pdf

- Vaccination recommendations for children with conditions that increase the risk of invasive Hib are based on age, vaccination history, and condition.
 - Functional or anatomic asplenia
 - Immunoglobulin deficiency or early complement component deficiency
 - HIV infection
 - Receipt of chemotherapy or radiation therapy

Children age 12–59 months at increased risk of invasive Hib*

- 0 or 1 dose before age 12 months: 2 doses, 8 weeks apart
- 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

- Unvaccinated* persons ages 15 months or older undergoing elective splenectomy: 1 dose (preferably at least 14 days before procedure)
- Unvaccinated* persons ages 5 years or older with anatomic or functional asplenia: 1 dose
- Unvaccinated persons ages 5–18 years with HIV infection: 1 dose
- Hematopoetic stem cell transplant recipients (any age): 3 doses ≥4 weeks apart (beginning 6–12 months post-transplant)

- Children younger 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 preferentially 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 primary series.

Knowledge Check

- Vaxelis can be used for all 4 recommended doses in the Hib series
- A. True
- B. False



Answer

 Vaxelis can be used for all 4 recommended doses in the Hib series

B. False





Contraindications

Hib

Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component

Age younger than 6 weeks



Hib

Moderate or severe acute illness with or without fever
Hib Vaccine Adverse Reactions

Hib	
Swelling, redness, or pain	5 to 30% of recipients
Fever	31%
Crying	11%
Injection site erythema	11%
Irritability	10%
Rash	9%

Hib: Vaccine Administration Errors

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



ActHIB vaccine



Storage and Handling

Vaccine Storage and Handling

- Store all Hib-containing vaccine refrigerated between 2°C and 8°C (36°F and 46°F)
- Do not freeze vaccine or diluents, or expose to freezing temperatures
- Store Hib vaccine in the original packaging
 - For Hib vaccines that require reconstitution (Pentacel[®], ActHIB[®], Hiberix[®]), they should be stored together in the refrigerator

Ages
Lieo form
Route:
rer-
urs.

 Ages:
 6 weeks through 4 years

 Use for:
 Any dose in the series

 Route:
 Intramuscular (IM) injection

 Reconstitute Hib powder ONLY with manufacturersupplied 0.9% sodium chloride diluent

Beyond Use Time: If not used immediately after reconstitution, store at 2°C to 8°C (36°F to 46°F) and discard if not used within 24 hours. Shake well prior to administration.

Hib (PedvaxHIB)

ages:6 weeks through 4 yearsUse for:Any dose in the seriesRoute:Intramuscular (IM) injection



Resources

Additional Resource

- 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





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E-mail Your Immunization Questions to Us

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Thank You From Atlanta!

