



# Pentacel™

## DTaP-IPV/Hib Combination Vaccine



**Los Angeles County  
Immunization Program**



# Objectives

- After attending this course, participants will be able to:
  - List the major categories of persons who should be vaccinated with DTaP-IPV/Hib vaccine (Pentacel™)
  - Identify the contraindications to Pentacel™ vaccination
  - Describe the most common adverse reactions associated with Pentacel™ vaccination
  - State the dose and route of vaccine administration
  - Discuss the use of Pentacel™ during the Hib shortage
  - Discuss the use of Pentacel™ vs. Pediarix™
  - Discuss recent updates from the CDC





# Pentacel™

- Combination vaccine – DTaP, IPV, and Hib
- Contains:
  - diphtheria and tetanus toxoids (DT)
  - acellular pertussis adsorbed (aP)
  - inactivated poliovirus (IPV)
  - *Haemophilus influenzae* type b conjugate (Hib)





# Indications and Usage

- Indicated for active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to *Haemophilus influenzae* type b
- Approved for use in children 6 weeks through 4 years of age (prior to 5<sup>th</sup> birthday)
- Pentacel™ may be used whenever any component(s) of the combination is indicated and there are no contraindications





# Contraindications

- Anaphylaxis
- Encephalopathy
- Progressive neurologic disorder





# Precautions

- Temperature  $\geq 105^{\circ}$  F within 48 hours that is not attributable to another identifiable cause
- Collapse or shock-like state within 48 hours
- Persistent, inconsolable crying lasting  $\geq 3$  hours within 48 hours
- Seizure with or without fever within 3 days
- Moderate or severe acute illness





# Adverse Reactions

## Injection Site

- redness
- swelling
- tenderness
- increase in arm circumference

## Systemic

- fever
- decreased activity/lethargy
- inconsolable crying
- fussiness/irritability





# Dosage and Administration

- Dose - 0.5 ml
- Given intramuscularly (IM)
- 4 dose series
- Given at 2, 4, 6, and 15-18 months\*

**\* Defer the booster dose of Hib for healthy children 15-18 months.**





# Children with Previous Vaccine Administration

Pentacel™ may be used to complete the series if a child was:

- Previously vaccinated with 1 or more doses of **IPV**
- Previously vaccinated with 1 or more doses of **Hib conjugate**
- Previously vaccinated with 1 or more doses of **DTaP**



# How Pentacel™ is Supplied

- 5 single dose vials of DTaP-IPV component per package
- 5 single dose vials of lyophilized (freeze-dried) ActHIB vaccine component per package

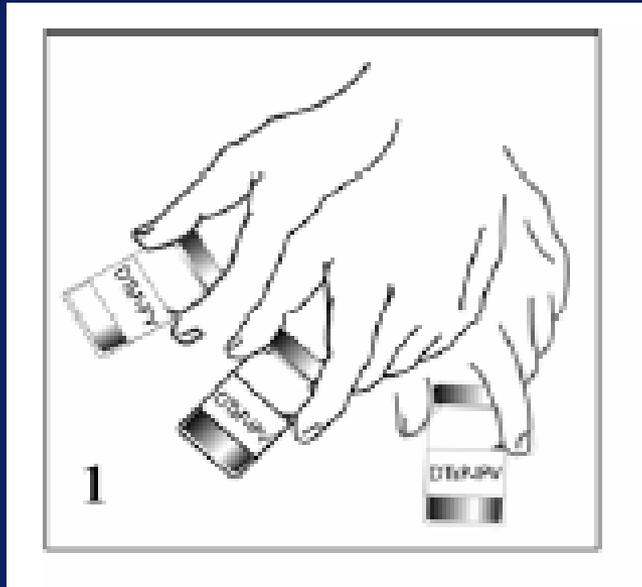


**PLEASE STORE BOTH  
COMPONENTS  
TOGETHER TO AVOID  
MISUSE OF  
PRODUCTS**

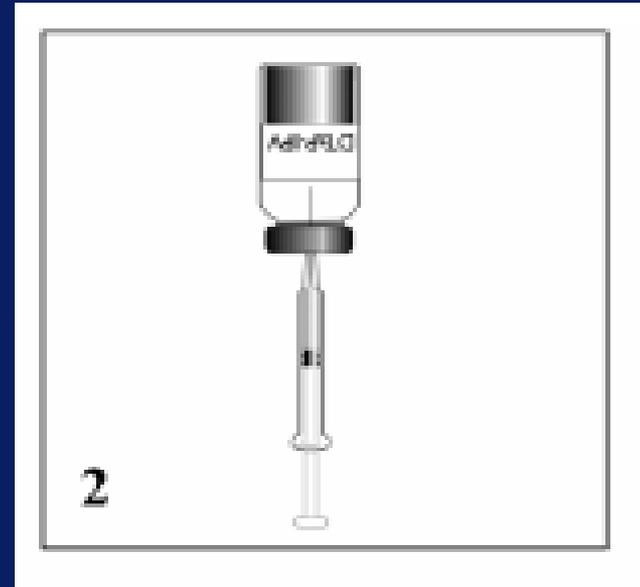




# Reconstitution



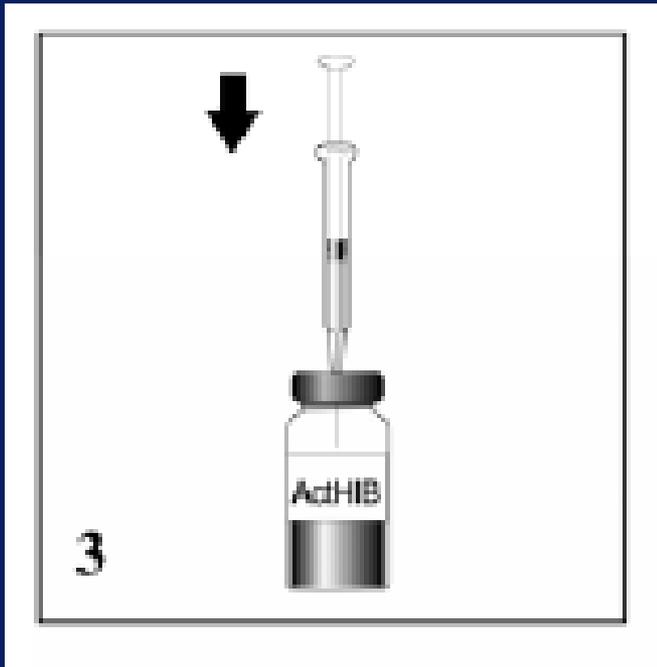
**Step 1 – gently shake  
the vial containing the  
DTaP-IPV component**



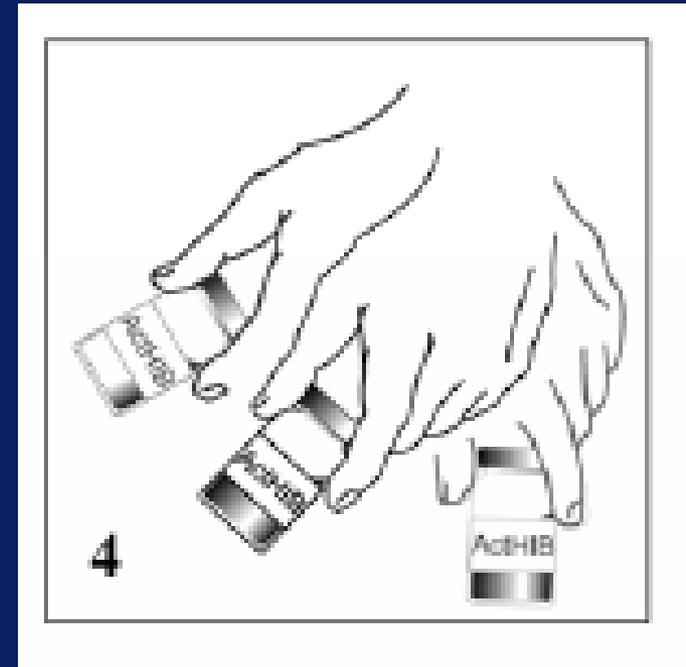
**Step 2 – withdraw the  
entire liquid content**



# Reconstitution



Step 3 – insert the syringe needle **straight** through the center of the stopper of the vial of lyophilized ActHIB vaccine component and inject the liquid into the vial

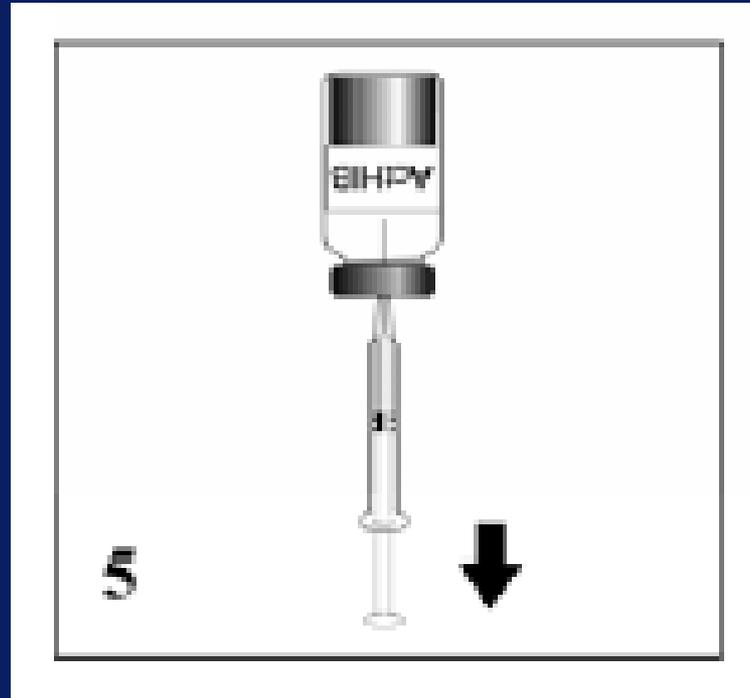


Step 4 – shake the vial thoroughly





# Reconstitution



**Step 5 – after reconstitution, inspect vial for particulate matter and/or discoloration; withdraw 0.5 ml and administer immediately**



# Storage and Handling

- Store *both* DTaP-IPV *and* ActHIB components at 35° to 46° F
- Do not freeze
- Use *immediately* after reconstitution



# Hib Vaccine Shortage

## Vaccine Use Guidelines



# Hib Vaccine Shortage Guidelines

- During the Hib vaccine shortage, the booster dose should be deferred for children who have completed the primary series. The primary series is complete if the child has received:
  - ✓ **2 or more Hib doses before 12 months of age**
    - **2 doses of Comvax or PedvaxHib**
    - **3 doses of ActHib**
  - ✓ **1 dose at 12 months of age or later**
- **Healthy children 12-59 months of age who have not completed the primary series should receive 1 dose of Hib vaccine to complete the primary series**



# Hib Vaccine Shortage Guidelines

- California school law special immunization schedule :
  - one dose of Hib vaccine at any age is required for children 15 months to four years, six months.
- Continue to give all Hib booster doses to high risk children with asplenia, sickle cell disease, immunodeficiency (HIV), malignant neoplasms, or Alaskan/Native American children



# Schedule for Hep B, Hib, DTaP and IPV Without Pentacel™ or Pediarix™ During Hib Shortage

Birth	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
Hep B	Hep B		Hep B		
	Hib	Hib	Hib		
	DTaP	DTaP	DTaP	DTaP	DTaP
	IPV	IPV	IPV		IPV





# Hib Shortage and Pentacel™ Use

- Until the Hib shortage improves, Pentacel™ should be used **ONLY** for the first 3 doses of the primary series of DTaP, IPV, and Hib
- Give the fourth dose of single antigen DTaP at 15 months (do not defer)



# Use of Pentacel™ During Hib Shortage

Schedule for Hep B, Hib, IPV, and DTaP *using Pentacel for all Doses*

Birth	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 yrs.
Hep B	Hep B		Hep B		
				DTaP	DTaP
					IPV
	Pentacel*	Pentacel*	Pentacel*	Defer Hib dose	

**\*Pentacel = DTaP+IPV+Hib**



# Scenario #1

Skye is a 15 month old healthy child. She received Pentacel at 2 months, 4 months and 6 months of age. Can she receive Hib at this time?

**Answer:** No, she is healthy. She is only eligible to receive dose #4 of a single antigen DTaP as well as other vaccines that are recommended at this age. As a reminder, the booster dose of Hib should be deferred for healthy children 15-18 months until Hib supplies improve.



# Use of Pediarix™ During Hib Shortage

Schedule for Hep B, Hib, IPV, and DTaP *using Pediarix only*  
(no Pentacel)

Birth	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 yrs.
Hep B					
	Hib	Hib	Hib	Defer booster Hib dose	
				DTaP	DTaP
					IPV
	Pediarix*	Pediarix*	Pediarix*		



\* Pediarix = DTaP + Hep B + IPV

# Scenario #2

Leilani is a 3 year old healthy child. She received Pediarix at 2 months, 4 months, and 6 months. She received Hib at 2 months, 4 months, and 6 months. Can she receive Hib vaccine today?

**Answer:** No, she is healthy and not eligible for the Hib booster dose. She should receive a single antigen dose of DTaP today.



# An Example of Mixed Use of Pentacel™ and Pediarix™ During Hib Shortage

Schedule for Hep B, Hib, IPV, and DTaP *using Pentacel for first dose only and Pediarix for remainder of doses*

Birth	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 yrs.
Hep B	Hep B				
		Hib	Hib		
				DTaP	DTaP
					IPV
	Pentacel**				
		Pediarix*	Pediarix*		

\*Pediarix = DTaP + Hep B + IPV

\*\*Pentacel = DtaP + Hib + IPV



# Scenario #3

Jayden is a 15 month old with sickle cell disease. He received Pentacel at 2 months and Pediarix and single-antigen Hib vaccine at 4 months and 6 months. Can he receive Hib today?

**Answer:** Yes, he is in a high risk category and is eligible to receive the booster dose of Hib given at 15-18 months. He can receive Pentacel because two components of the combination vaccine are indicated (DTaP and Hib).



# Questions



# 2008 Immunization Update





# Recommended Immunization Schedule for Persons Aged 0-18 Years

## Correction for HPV vaccine:

- Interval between dose 2 to dose 3 is 12 weeks
- Dose 3 must be given at least 24 weeks after the first dose
- Corrected immunization schedules can be found on CDC's website at:

[www.cdc.gov/vaccines/recs/schedules/child-schedule.htm](http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm)



# Syncope After Immunization

- May occur after immunization
- Most commonly seen among adolescents
- Rates have increased primarily among females aged 11-18
- Associated with Tdap, MCV4, and HPV vaccination
- Patients should be observed for 15 minutes after vaccine is given





# Pneumococcal Conjugate Vaccine (PCV7) for Children 24-59 months

- All healthy children who have not completed any recommended schedule for PCV 7 – administer 1 dose
- Children with underlying medical conditions who have received 3 doses – administer 1 dose
- Children with underlying medical conditions who have received <3 doses – administer 2 doses at least 8 weeks apart



# Previously Published PCV7 Recommendations

Age at first dose	Total of doses	Schedule
2-6 months	4	2, 4, 6, 12-15m
7-11 months	3	2 doses 4-8 wks apart: plus booster
12-23 months	2	8 wks apart
24-59 months	1	If healthy child
	2	If high-risk child





# New Influenza Vaccine Recommendations

- In addition to children 6-59 months, annual vaccination for *all* children aged 5-18 years is recommended
- Annual vaccination for children 5-18 years should begin in 2008-2009, no later than 2009-2010 influenza season
- Recommendations for annual vaccination of persons in other age or risk groups remain unchanged



# Rotavirus Vaccines

- Rotarix® (GSK) (RV1) – new rotavirus vaccine licensed in April 2008
- June 2008 – ACIP made provisional recommendations for the use of the 2 licensed rotavirus vaccines
- “Window” to give 1<sup>st</sup> dose for rotavirus vaccine extended from 12 weeks to 14 weeks/6 days
- *No* rotavirus vaccine should be started for infants 15 weeks/0 days or older
- All doses should be given by age 8 months/0 days



# DTaP-IPV Combination Vaccine

- Kinrix™
- Manufactured by GlaxoSmithKline
- Approved in June 2008 by FDA
- Licensed for children 4-6 years of age as a booster vaccination
- Approved for one (IM) dose
- CHDP approved



# Tdap Vaccines

GlaxoSmithKline's  
**BOOSTRIX®** for persons  
aged 10 – 18 years

*Do not give to anyone 19  
years or older.*



Sanofi pasteur's **ADACEL™**  
for persons aged  
11 – 64 years

*Do not give to anyone less  
than 11 years or 65  
years and older*



# Tdap Recommendations

- Adolescents 11-18 years – should receive a single dose of Tdap *instead* of Td
- Adults/adolescents who have never received tetanus-diphtheria-pertussis vaccination – should receive a series of 3 vaccinations
  - single dose of Tdap
  - Td at least 4 weeks after the Tdap dose
  - 2<sup>nd</sup> dose of Td at least 6 months after the Td dose



# Tdap and Pregnancy

- Pregnancy is not considered a contraindication to Tdap or Td
- 2008 recommendations from ACIP on use of Tdap during pregnancy include:
  - Pregnant women who received the last tetanus toxoid-containing vaccine <10 years previously should receive Tdap in the postpartum period; interval as short as two years is okay
  - Pregnant women who received the last tetanus toxoid-containing vaccine  $\geq 10$  years previously should generally receive Td
    - Tdap can be used in the postpartum period instead of Td during pregnancy, if sufficient tetanus and diphtheria protection is likely until delivery



# Current Editions of VISs

- **Diphtheria, Tetanus, Pertussis (DTaP, DT, DTP):** 5/17/07
- ***Haemophilus influenzae* type b (Hib):** 12/16/98
- **Hepatitis A:** 3/21/06
- **Hepatitis B:** 7/18/07
- **Human Papillomavirus (HPV)** 2/02/07
- **Influenza (LAIV & TIV)** 7/24/08
- **Measles, Mumps, Rubella (MMR):** 3/13/08
- **Meningococcal Conjugate (MCV):** 1/28/08
- **Multiple Vaccines (DTaP, PCV, Hib, Hep B, Rotavirus)\*** 9/18/08
- **Pneumococcal conjugate (PCV):** 9/30/02
- **Polio:** 1/01/00
- **Rotavirus** 8/28/08
- **Tetanus Diphtheria (Td)/Tdap (interim):** 11/18/08
- **Varicella (chickenpox):** 3/13/08

\* For Infants age 0-6 months



# Post-Test

1. Pentacel vaccine contains which of the following:
  - a) DTaP
  - b) IPV
  - c) Hib
  - d) all of the above

Answer: d – all of the above



# Post-Test

2. What is the minimum age that the first dose of Pentacel can be given?
- a) 2 months
  - b) 4 months
  - c) 6 weeks
  - d) no minimum age

Answer: c – 6 weeks



# Post-Test

- 3) Pentacel is licensed for how many doses?
- a) 2
  - b) 3
  - c) 4
  - d) 6

Answer: c - 4



# Post-Test

4. What are some contraindications for the use of Pentacel?
- a) anaphylaxis
  - b) encephalopathy
  - c) progressive neurologic disorder
  - d) all of the above

Answer: d – all of the above



# Post-Test

5. What are some adverse reactions to Pentacel?
- a) redness, swelling, tenderness, rash, crying
  - b) swelling, tenderness, increase in arm circumference, redness, fever, crying
  - c) both a and b
  - d) neither a or b

Answer: b



# Post-Test

6. The dosage for Pentacel is 0.5 ml and it is given intramuscularly.
- a) true
  - b) false

Answer: a - true



# Post-Test

7. Until the Hib shortage improves, how many doses of Pentacel should be used for healthy children?
- a) 2
  - b) 3
  - c) 4
  - d) 5

Answer: b - 3



# Post-Test

8. Pentacel requires reconstitution. Each package contains 5 single dose vials of DTaP-IPV liquid component and 5 single dose vials of a powder component. What is the powder component?

- a) IPV
- b) DTaP
- c) Hib
- d) Hep B

Answer: Hib



# Post-Test

9. Both DTaP-IPV and ActHib components require refrigeration.

a) true

b) false

Answer: a - true



# Post-Test

10. Syncope (fainting) that may occur after vaccine administration requires the provider to observe the patient for how long after vaccine administration?
- a) 5 minutes
  - b) 10 minutes
  - c) 15 minutes
  - d) no observation necessary

Answer: c – 15 minutes



# Thank You

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