

**ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES  
VACCINES FOR CHILDREN PROGRAM**

**HEPATITIS B**

**VACCINES TO PREVENT HEPATITIS B**

The purpose of this resolution is to correct unintentional inconsistencies between VFC Resolution (02/03-1) and current ACIP recommendations for the use of hepatitis B vaccines.

VFC resolution 02/03-1 is repealed and replaced by the following:

***Eligible Groups***

All previously unvaccinated children and adolescents from birth through 18 years.\*

*\*PEDIARIX™ is indicated for children  $\geq 6$  weeks of age and  $< 7$  years of age; COMVAX® is indicated for children  $\geq 6$  weeks of age; Twinrix® is only indicated for persons 18 years and older, and only children 18 years of age are eligible for Twinrix® through the VFC program.*

**Eligible Groups for Post-Exposure Immunoprophylaxis**

1. Infants of hepatitis B surface antigen (HBsAg) positive mothers:  
Infants born to mothers who are HBsAg-positive should receive appropriate doses of hepatitis B vaccine and hepatitis B immune globulin (HBIG) (0.5 ml) within 12 hours of birth and should complete the hepatitis B vaccine series according to the recommended schedule.
2. Persons whose sexual partners have acute hepatitis B:  
All previously unvaccinated sexual partners of persons with acute hepatitis B virus infection should receive the hepatitis B vaccine series and single dose of HBIG (0.06 ml/kg) if HBIG can be started within 14 days of the last sexual contact. The recommended schedule for hepatitis B vaccination of these persons is: 0, 1, 6 months; 0, 1, 4 months; or 0, 2, 4 months.
3. Persons with percutaneous or mucosal exposure to blood that contains (or might contain) HBsAg:  
For unvaccinated persons who have percutaneous or mucosal exposure to blood, the hepatitis B vaccine series should be initiated. If the source of exposure is HBsAg-positive, HBIG (0.06 ml/kg) should also be administered within 7 days of exposure.
4. Unvaccinated infants whose primary caregiver has acute hepatitis B:  
Infants whose primary caregiver has acute hepatitis B should receive a single dose of HBIG (0.5 ml) and complete the 3-dose hepatitis B vaccine series according to the recommended schedule.

**Recommended schedule for hepatitis B vaccination for  
infants born to hepatitis B surface antigen (HBsAg) negative mothers:**

**Vaccination Schedule Options**

| Dose | Option 1 (Preferred)        |   |                                       | Option 2                    |           |              |
|------|-----------------------------|---|---------------------------------------|-----------------------------|-----------|--------------|
|      | Single antigen <sup>†</sup> | Single antigen <sup>†</sup> / PEDIARIX™ | Single antigen <sup>†</sup> / COMVAX® | Single antigen <sup>†</sup> | PEDIARIX™ | COMVAX®      |
| 1    | Birth                       | Birth (single antigen) <sup>‡</sup>     | Birth (single antigen) <sup>‡</sup>   | 1-2 months                  | 2 months  | 2 months     |
| 2    | 1-2 months                  | 2 months                                | 2 months                              | 4 months                    | 4 months  | 4 months     |
| 3    | 6 months                    | 4 months                                | 4 months                              | 6-18 months                 | 6 months  | 12-15 months |
| 4    |                             | 6 months                                | 12-15 months                          | NA                          | NA        | NA           |

<sup>†</sup>Single antigen vaccine: ENGERIX-B® or RECOMBIVAX HB®

<sup>‡</sup> Only a single antigen hepatitis B vaccine can be given at birth

### COMBINATION VACCINES

After single antigen hepatitis B vaccine is given at birth, an additional 3 doses of a hepatitis B containing combination vaccine can be given to complete the series starting at  $\geq 6$  weeks of age if the infant is also scheduled to receive the other components of the combination vaccine, and there are no contraindications to any of the components.

COMVAX®: The combination hepatitis B and *Haemophilus influenzae* type b (Hib) vaccine (COMVAX®) is licensed for use as a 3-dose series beginning at  $\geq 6$  weeks- of age. COMVAX® is not approved for the hepatitis B vaccine dose at birth, and cannot be given to infants  $< 6$  weeks of age. This vaccine may be used when administration of any component of this combination vaccine is indicated and if no components are contraindicated.

PEDIARIX™: The DTaP-hepatitis B-inactivated poliovirus vaccine combination (PEDIARIX™) is licensed for use as a 3-dose series beginning at  $\geq 6$  weeks of age. PEDIARIX™ is not approved for the hepatitis B vaccine dose at birth and cannot be given to infants  $< 6$  weeks of age or individuals  $\geq 7$  years of age. This vaccine may be used when administration of any component of this combination vaccine is indicated and if no components are contraindicated.

**PRETERM INFANTS:** Preterm infants of HBsAg negative mothers who weigh less than 2kg at birth should receive the first dose of hepatitis B vaccine series when the infant is  $\geq 1$  month of age, including infants who remain hospitalized. Preterm infants discharged from the hospital before chronological age 1 month can also be administered hepatitis B vaccine at discharge, if they are medically stable and have gained weight consistently.

♦ Use of brand names is not meant to preclude the use of other comparable licensed hepatitis B-Hib or DTaP-hepatitis B-IPV combination vaccines.

**Recommended schedule for hepatitis B immunoprophylaxis to prevent perinatal transmission of hepatitis B virus infection:**

**Infant born to an HBsAg-positive woman**

**Vaccination Schedule Options**

| <b>Dose</b> | <b>Single antigen vaccine*</b> | <b>PEDIARIX™</b>        | <b>COMVAX®</b>          |
|-------------|--------------------------------|-------------------------|-------------------------|
| 1           | Birth‡                         | Birth (single antigen)‡ | Birth (single antigen)‡ |
| 2           | 1-2 months                     | 2 months                | 2 months                |
| 3           | 6 months                       | 4 months                | 4 months                |
| 4           | NA                             | 6 months                | 12-15 months            |

\* Single antigen vaccine: ENGERIX-B® or RECOMBIVAX HB®

‡ Both single antigen hepatitis B vaccine (0.5mL) and hepatitis B immune globulin (HBIG) (0.5mL) should be given within 12 hours of birth. HBIG should be administered intramuscularly at a site different from that used for vaccine.

**COMBINATION VACCINES**

After single antigen hepatitis B vaccine is given at birth, an additional 3 doses of a hepatitis B containing combination vaccine can be given to complete the series starting at  $\geq 6$  weeks of age if the infant is also scheduled to receive the other components of the combination vaccine, and there are no contraindications to any of the components.

COMVAX®: The combination hepatitis B and *Haemophilus influenzae* type b (Hib) vaccine (COMVAX®)□ is licensed for use as a 3-dose series beginning at  $\geq 6$  weeks . COMVAX® is not approved for the hepatitis B vaccine dose at birth, and cannot be given to infants  $< 6$  weeks of age. This vaccine may be used when administration of any component of this combination vaccine is indicated and if no components are contraindicated.

PEDIARIX™: The DTaP-hepatitis B-inactivated poliovirus vaccine combination (PEDIARIX™)□ is licensed for use as a 3-dose series beginning at  $\geq 6$  weeks . PEDIARIX™ is not approved for the hepatitis B vaccine dose at birth and cannot be given to infants  $< 6$  weeks of age or individuals  $\geq 7$  years of age. This vaccine may be used when administration of any component of this combination vaccine is indicated and if no components are contraindicated.

**PRETERM INFANTS:** For preterm infants who weigh  $< 2$  kg at birth, the initial vaccine dose should not be counted as part of the vaccine series, and three additional doses of vaccine should be administered beginning when the infant is  $\geq 1$  month of age.

♦ Use of brand names is not meant to preclude the use of other comparable licensed hepatitis B-Hib or DTaP-hepatitis B-IPV combination vaccines.

**Recommended schedule for hepatitis B immunoprophylaxis to prevent perinatal transmission of hepatitis B virus infection:**

**Infant born to woman whose HBsAg status is unknown**

**Vaccination Schedule Options**

| <b>Dose</b> | <b>Single antigen vaccine*</b> | <b>PEDIARIX™</b>        | <b>COMVAX®</b>          |
|-------------|--------------------------------|-------------------------|-------------------------|
| 1           | Birth‡                         | Birth (single antigen)‡ | Birth (single antigen)‡ |
| 2           | 1-2 months                     | 2 months                | 2 months                |
| 3           | 6 months                       | 4 months                | 4 months                |
| 4           | NA                             | 6 months                | 12-15 months            |

\* Single antigen vaccine: ENGERIX-B® or RECOMBIVAX HB®

‡ Single antigen hepatitis B vaccine should be given within 12 hours of birth. Maternal blood should be drawn as soon as possible to determine the mother's HBsAg status. HBIG (0.5 mL) should be given as soon as possible (no later than 7 days) if the mother tests HBsAg-positive.

**COMBINATION VACCINES**

After single antigen hepatitis B vaccine is given at birth, an additional 3 doses of a hepatitis B containing combination vaccine can be given to complete the series starting at  $\geq 6$  weeks of age if the infant is also scheduled to receive the other components of the combination vaccine, and there are no contraindications to any of the components.

**COMVAX®:** The combination hepatitis B and *Haemophilus influenzae* type b (Hib) vaccine (COMVAX®)□ is licensed for use as a 3-dose series beginning at  $\geq 6$  weeks of age. COMVAX® is not approved for the hepatitis B vaccine dose at birth, and cannot be given to infants  $< 6$  weeks of age. This vaccine may be used when administration of any component of this combination vaccine is indicated and if no components are contraindicated.

**PEDIARIX™:** The DTaP-Hepatitis B-Inactivated Poliovirus Vaccine combination (PEDIARIX™)□ is licensed for use as a 3-dose series beginning at  $\geq 6$  weeks of age. PEDIARIX™ is not approved for the hepatitis B vaccine dose at birth and cannot be given to infants  $< 6$  weeks of age or individuals  $\geq 7$  years of age. This vaccine may be used when administration of any component of this combination vaccine is indicated and if no components are contraindicated.

**PRETERM INFANTS:** For preterm infants who weigh  $< 2$  kg at birth, the initial vaccine dose should not be counted as part of the vaccine series, and three doses of vaccine should be administered beginning when the infant is  $\geq 1$  month of age.

♦Use of brand names is not meant to preclude the use of other comparable licensed hepatitis B-Hib or DTaP-Hepatitis B-IPV combination vaccines.

### Catch-Up Vaccination

The ACIP recommends catch-up vaccination of previously unvaccinated children and adolescents less than 19 years of age. The recommended dosing schedules for unvaccinated children and adolescents are:

Option 1: 3 dose pediatric/adolescent formulation for children < 19 years of age:

| <u>Dose</u> | <u>Usual Interval</u>  |
|-------------|--|
| Hep B-1     | -----  |
| Hep B-2     | 1 month after dose 1   |
| Hep B-3     | 4-6 months after dose 1 (as long as there is an 8 week minimum interval between dose 2 and dose 3) |

Option 2: 2 dose adult formulation (RECOMBIVAX HB<sup>®</sup>, Merck & Co.) for children 11-15 years of age:

| <u>Dose</u> | <u>Usual Interval</u>   |
|-------------|-------------------------|
| Hep B-1     | -----                   |
| Hep B-2     | 4-6 months after dose 1 |

Option 3: 3 dose adult formulation (Twinrix<sup>®</sup>, GlaxoSmithKline) for persons 18 years of age:

| <u>Dose</u> | <u>Usual Interval</u> |
|-------------|-----------------------|
| Hep B-1     | -----                 |
| Hep B-2     | 1 month after dose 1  |
| Hep B-3     | 6 months after dose 1 |

**Minimum Age and Dosage Intervals**

| Vaccine  | Minimum age at first dose | Minimum interval from dose 1 to 2 | Minimum interval from dose 2 to 3 (when applicable) | Minimum interval from dose 1 to 3 (when applicable) |
|--|---------------------------|-----------------------------------|---|---|
| <b>Infants</b>   |                           |                                   |   |   |
| Hepatitis B (3 dose schedule with pediatric single antigen formulation)                          | Birth                     | 4 weeks                           | 8 weeks   | 16 weeks ♦  |
| COMVAX <sup>®</sup> *  | 6 weeks                   | 4 weeks                           | 8 weeks ‡   | N/A ‡   |
| PEDIARIX <sup>™</sup> *  | 6 weeks                   | 4 weeks                           | 8 weeks   | 16 weeks ♦  |
| <b>Adolescents (11-18 years)</b>   |                           |                                   |   |   |
| Hepatitis B (3 dose schedule with pediatric single antigen formulation)                          | N/A                       | 4 weeks                           | 8 weeks   | 16 weeks  |
| Hepatitis B (2 dose schedule with adult formulation for children 11-15 years of age)             | 11 years                  | 16 weeks                          | N/A   | N/A   |
| Hepatitis B (3 dose schedule as combined hepatitis A/hepatitis B vaccine, Twinrix <sup>®</sup> ) | 18 years                  | 4 weeks                           | 5 months  | 6 months  |

♦ The last dose of hepatitis B vaccine dose should not be given to infants before 24 weeks of age.

\*Three doses of combination vaccines may be given to complete the hepatitis B vaccine series after the preferred dose at birth. Combination vaccines cannot be given before 6 weeks of age. When used following a birth dose, dose number refers to the dose of combination vaccine.

‡ If Comvax is<sup>®</sup> given for the first two doses of Hib vaccine, the third dose (booster should be given at 12 –15 months of age.

## Contraindications and Precautions

A contraindication is a condition in a recipient that increases the risk for a serious adverse reaction. A vaccine will not be administered when a contraindication is present.

A precaution is a condition in a recipient that might increase the risk for a serious adverse reaction or that might compromise the ability of the vaccine to produce immunity. Benefits and risk of administering a specific vaccine to a person under these circumstances should be considered. If the risk from the vaccine is believed to outweigh the benefit, the vaccine should not be administered. If the benefit of vaccination is believed to outweigh the risk, the vaccine should be administered.

Contraindications and precautions for monovalent hepatitis B vaccine, for combination vaccines that contain hepatitis B vaccine, and for hepatitis B immune globulin are listed below.

### **Monovalent hepatitis B vaccine:**

#### **Contraindications:**

- Severe allergic reaction after a previous dose or to a vaccine component.

#### **Precautions:**

- Infant weighing <2000 grams.  
(Hepatitis B vaccination should be deferred for infants weighing <2000 grams if the mother is documented to be hepatitis B surface antigen (HBsAg)-negative. For infants born to HBsAg-positive women, hepatitis B immune globulin and hepatitis B vaccine should be administered at or soon after birth regardless of birthweight -see Vaccination of Preterm Infants).
- Moderate or severe acute illness with or without fever.

### **COMVAX® (HepB-Hib combination vaccine):**

#### **Contraindications:**

- Severe allergic reaction after a previous dose or to a vaccine component.
- Age <6 weeks.

#### **Precautions:**

- Moderate or severe acute illness with or without fever.

### **PEDIARIX™ (DtaP-HepB-IPV combination vaccine):**

#### **Contraindications:**

- Severe allergic reaction after a previous dose or to a vaccine component.
- Age <6 weeks or ≥7 years.
- Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of administration of previous dose of DTP or DtaP.
- Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy: defer DTaP until neurologic status is clarified and stabilized.

**Precautions:**

- Fever of  $>40.5^{\circ}\text{C}$   $\leq 48$  hours after vaccination with a previous dose of DTP or DtaP, or a combination vaccine that contains DTP or DtaP.
- Collapse or shock-like state (i.e., hypotonic hyporesponsive episode)  $\leq 48$  hours after receiving a previous dose of DTP or DTaP, or a combination vaccine that contains DTP or DtaP.
- Seizure occurring  $\leq 3$  days after receiving a previous dose of DTP or DTaP, or a combination vaccine that contains DTP or DtaP.
- Persistent, inconsolable crying lasting  $\geq 3$  hours and occurring  $\leq 48$  hours after receiving a previous dose of DTP or DTaP, or a combination vaccine that contains DTP or DtaP.
- Moderate or severe acute illness with or without fever.

**TWINRIX® (HepA-HepB combination vaccine):**

**Contraindications**

- Severe allergic reaction after a previous dose or to a vaccine component.
- Age  $< 18$  years.

**Precautions:**

- Moderate or severe acute illnesses with or without fever.
- Pregnancy.

**Hepatitis B Immune Globulin (HBIG):**

**Contraindications**

- Severe allergic reaction to a previous dose of any immune globulin preparation.
- Serum immunoglobulin A deficiency.

**Adopted and Effective: October 16, 2003**