

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

VACCINES FOR CHILDREN PROGRAM

VACCINES TO PREVENT DIPHTHERIA, TETANUS AND PERTUSSIS

The purpose of this resolution is to revise the previous resolution to incorporate the use of a pentavalent vaccine: diphtheria and tetanus toxoids, acellular pertussis, haemophilus influenza type b, and polio vaccines and a quadravalent vaccine: diphtheria and tetanus toxoids, acellular pertussis, and polio vaccines.

VFC resolution 6/05-1 is repealed and replaced by the following:

Eligible Groups

Children and adolescents aged 6 weeks through 18 years.

Recommended Schedule for Diphtheria, Tetanus, and Pertussis Vaccines

| <u>Dose</u> | <u>Age</u> |
|---------------------|---------------|
| Primary 1 | 2 months |
| Primary 2 | 4 months |
| Primary 3 | 6 months |
| First Booster* | 15-18 months |
| Second Booster† | Age 4-6 years |
| Tdap or Td Booster‡ | 11-12 years |

* The first booster dose may be administered as early as age 12 months, provided 6 months have elapsed since the third dose.

† The second booster is not necessary before entering kindergarten or elementary school if fourth dose is administered on or after the fourth birthday.

‡ Tdap is preferred over Td as adolescents are susceptible to pertussis due to waning immunity. A Tdap or Td booster is recommended at any age from 11 through 18 years if they have completed the recommended childhood DTP/DTaP vaccination series and have not received a Td dose. In some special situations, Td, rather than Tdap may be indicated (please see ACIP recommendations).

DTaP, DT, Tdap, and Td vaccine formulations

There are currently two licensed formulations of Tdap for adolescents, BOOSTRIX[®] and ADACEL[®]. BOOSTRIX (Tdap) vaccine is indicated for active immunization of persons 10-18 years of age. ADACEL (Tdap) is indicated for active immunization of persons aged 11 years and older. Td vaccine is indicated for active immunization of persons 7 years of age or older for prevention of tetanus and diphtheria. For immunization of infants and children younger than 7 years of age against pertussis, tetanus and diphtheria, refer to the manufacturers' package inserts for Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP) or combination vaccines containing DTaP and for Diphtheria and Tetanus Toxoids Adsorbed (For Pediatric Use) (DT). Use diphtheria and tetanus toxoids, adsorbed (DT or Td) if encephalopathy has occurred after administration of a previous dose of pertussis-containing vaccine. The use of brand names is not meant to preclude the use of other comparable licensed vaccines.

Dosage Intervals for Vaccination for Diphtheria, Tetanus, and Pertussis Containing Vaccines

| Vaccine | Minimum Age | Minimum interval between doses | | | |
|--------------------------------|----------------|--------------------------------|-------------|-------------|-------------|
| | | Dose 1 to 2 | Dose 2 to 3 | Dose 3 to 4 | Dose 4 to 5 |
| DTaP | 6 weeks | 4 weeks | 4 weeks | 6 months | 6 months* |
| DTaP-HepB-IPV† | 6 weeks | 4 weeks | 8 weeks | | |
| DTaP-Hib-IPVΔ | 6 weeks | 4 weeks | 4 weeks | 6 months | |
| DT | 6 weeks | 4 weeks | 4 weeks | 6 months | 6 months* |
| DTaP-Hib‡ | 15-18 months | | | 6 months | |
| DTaP-IPVθ | 4 years | | | | 6 months* |
| Tdap§ | 10 or 11 years | | | | |
| Td (catch-up schedule)¶ | 7 years | 4 weeks | 6 months | 5 years | ----- |

Note: DT containing vaccines are not indicated for children > 6 years of age.

* The fifth dose is not necessary if the fourth dose was given after the fourth birthday.

† The combined DTaP-HepB-IPV vaccine may be used when any component of the combination is indicated, and if the other components are not contraindicated. The combined DTaP-HepB-IPV vaccine is approved for the primary series only (Doses 1-3). For adequate immune response, the last dose of hepatitis B vaccine should be given at ≥ 24 weeks of age and therefore this combination vaccine should not be administered as a complete primary series on an accelerated schedule at 4 week intervals for prevention of pertussis.

Δ The combined DTaP-Hib-IPV vaccine may be used when any component of the combination is indicated, and if the other components are not contraindicated. The combined DTaP-Hib-IPV vaccine is approved for the primary series and first booster dose (Doses 1-4). The combined DTaP-Hib-IPV vaccine is not indicated for children 5 years of age and older.

‡ The combined DTaP/Haemophilus influenzae type b (Hib) vaccine is only indicated for the fourth dose at age 15-18 months.

θ The combined DTaP-IPV vaccine may be used when any component of the combination is indicated, and if the other components are not contraindicated. The combined DTaP-IPV vaccine is approved for the booster dose at age 4-6 years.

§ Recommended at age 11 years or older as a booster dose. Tdap is preferred over Td as adolescents are susceptible to pertussis due to waning immunity. Tdap is indicated for a single booster dose if the childhood DTP/DTaP vaccination series has been completed. A five year interval is encouraged if Tdap is administered after Td. Please see ACIP recommendations for further information.

¶ Recommendation at age 11 years or older as a booster rather than Tdap may be indicated in some special situations (please see ACIP recommendations). May be used as early as age 7 years if needed for catch-up including for a primary series if indicated. The interval from the 3rd to 4th dose may vary for catch-up schedules depending on the timing of previous doses – please see the ACIP recommendations for further information.

Recommended Dosages

Refer to product package inserts for age indications and dosages for vaccine formulation used.

Contraindications and Precautions

A. DTaP vaccines

The following conditions are contraindications to the administration of DTaP vaccine:

1. An immediate anaphylactic reaction.

Further vaccination with any of the three components of DTaP or with any component of a combination vaccine with DTaP should be deferred because of uncertainty as to which component of the vaccine might be responsible. However, because of the importance of tetanus vaccination, persons who experience anaphylactic reactions may be referred to an allergist for evaluation and (if specific allergy can be demonstrated) desensitized to tetanus toxoid.

2. Encephalopathy not attributed to another identifiable cause.

An acute, severe central nervous system disorder occurring within 7 days after vaccination and generally consisting of major alterations in consciousness, unresponsiveness, or generalized or focal seizures that persist more than a few hours, without recovery within 24 hours. In such cases, DT vaccine should be administered for the remaining doses in the vaccination schedule to ensure protection against diphtheria and tetanus.

The following conditions are precautions to receipt of DTaP vaccine:

If any of the following events occurs within the specified period after administration of DTaP, vaccine providers and parents should evaluate the risks and benefits of administering subsequent doses of a pertussis-containing vaccine:

- 1. Temperature $\geq 105^{\circ}$ F ($\geq 40.5^{\circ}$ C) within 48 hours, not attributable to another identifiable cause.**
- 2. Collapse or shock-like state (hypotonic hyporesponsive episode) within 48 hours.**
- 3. Persistent crying lasting ≥ 3 hours, occurring within 48 hours.**
- 4. Convulsions with or without fever, occurring within 3 days.**
- 5. Acute, moderate or severe illnesses with or without fever.**
- 6. Latex Allergy.**

Some presentations of DTaP contain latex. These presentations should not be administered to children with a history of a severe (anaphylactic) allergy to latex; this product may be administered to persons with less severe allergies (e.g. contact allergy to latex gloves). See the package insert for further information.

B. DT vaccines

The following conditions are contraindications to the administration of DT vaccine:

1. An immediate anaphylactic reaction.

Further vaccination with any of the components of DT or with any component of a combination vaccine with DT should be deferred because of uncertainty as to which component of the vaccine might be responsible. However, because of the importance of tetanus vaccination, persons who

experience anaphylactic reactions may be referred to an allergist for evaluation and (if specific allergy can be demonstrated) desensitized to tetanus toxoid.

The following conditions are a precaution to receipt of DT vaccine:

1. Arthus-type hypersensitivity reactions.

Persons who experienced Arthus-type hypersensitivity reactions following a prior dose of tetanus toxoid usually have high serum tetanus antitoxin levels and should not be given DT or even emergency doses of Td more frequently than every 10 years, even if they have a wound that is neither clean nor minor.

2. Acute, moderate or severe illnesses with or without fever.

3. Latex Allergy.

Some presentations of DT contain latex. These presentations should not be administered to children with a history of a severe (anaphylactic) allergy to latex; this product may be administered to persons with less severe allergies (e.g. contact allergy to latex gloves). See the package insert for further information.

C. Tdap vaccines

The following conditions are contraindications to the administration of Tdap vaccine:

1. An immediate anaphylactic reaction.

Further vaccination with any of the three components of Tdap or with any component of a combination vaccine with Tdap should be deferred because of uncertainty as to which component of the vaccine might be responsible. However, because of the importance of tetanus vaccination, persons who experience anaphylactic reactions may be referred to an allergist for evaluation and (if specific allergy can be demonstrated) desensitized to tetanus toxoid.

2. Encephalopathy not attributed to another identifiable cause.

Encephalopathy (e.g. coma, prolonged seizures) within 7 days of administration of a pertussis vaccine that is not attributable to another identifiable cause. In such cases, Td vaccine should be administered for the remaining doses in the vaccination schedule to ensure protection against diphtheria and tetanus.

The following conditions are precautions to receipt of Tdap vaccine:

1. Arthus-type hypersensitivity reactions:

Persons who experienced Arthus-type hypersensitivity reactions following a prior dose of tetanus toxoid usually have high serum tetanus antitoxin levels and should not be given even emergency doses of Td or Tdap more frequently than every 10 years, even if they have a wound that is neither clean nor minor.

2. Progressive neurological disorder, uncontrolled epilepsy, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized.

If a decision is made to withhold pertussis vaccination, then Td may be used instead of Tdap.

3. Latex Allergy.

The tip and rubber plunger of the BOOSTRIX[®] (Tdap) syringe presentation contains latex. This BOOSTRIX[®] product should not be administered to adolescents with a history of a severe (anaphylactic) allergy to latex; this product may be administered to persons with less severe allergies (e.g. contact allergy to latex gloves). The BOOSTRIX[®] (Tdap) single dose vial presentation and ADACEL[®] (Tdap) contain no latex.

4. Guillain-Barre syndrome (GBS) within 6 weeks after a previous dose of tetanus toxoid containing vaccines.

5. Acute, moderate or severe illnesses with or without fever.

D. Td vaccines

The following conditions are contraindications to the administration of Td vaccine:

1. An immediate anaphylactic reaction.

Further vaccination with any of the three components of DTaP or with any component of a combination vaccine with DTaP should be deferred because of uncertainty as to which component of the vaccine might be responsible. However, because of the importance of tetanus vaccination, persons who experience anaphylactic reactions may be referred to an allergist for evaluation and (if specific allergy can be demonstrated) desensitized to tetanus toxoid.

2. Moderate or severe illnesses with or without fever.

The following conditions are precautions to receipt of Td vaccine:

1. Arthus-type hypersensitivity reactions:

Persons who experienced Arthus-type hypersensitivity reactions following a prior dose of tetanus toxoid usually have high serum tetanus antitoxin levels and should not be given even emergency doses of Td more frequently than every 10 years, even if they have a wound that is neither clean nor minor.

2. Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus toxoid containing vaccines.

3. Acute, moderate or severe illnesses with or without fever.

4. Latex Allergy.

Some presentations of Td contain latex. These presentations should not be administered to adolescents with a history of a severe (anaphylactic) allergy to latex; this product may be administered to persons with less severe allergies (e.g. contact allergy to latex gloves). See the package insert for further information.

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