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SECTION 8 Vaccines

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SUBJECT: DTAP

DTaP Vaccine

(Diphtheria Toxoid, Tetanus Toxoid, and Acellular Pertussis)

Schedule

DTaP (diphtheria and tetanus toxoids and acellular pertussis vaccine) is the vaccine of choice for children 6 weeks through 6 years of age (up to the 7th birthday).

- Use pediatric DT if pertussis vaccine is contraindicated. •
- Td (or Tdap; see note below*) is the vaccine of choice for children 7 years old through 9 years. • DTaP is NOT licensed for children ≥7 years. ACIP recommends that children 7–10 years not fully vaccinated* against pertussis—and without a contraindication to pertussis vaccine receive a single dose of Tdap. Those never vaccinated against tetanus, diphtheria, or pertussis—or who have unknown vaccination status—should receive a series of 3 vaccinations containing tetanus and diphtheria toxoids. ACIP recommends that Tdap be the 1st of these 3 doses. This ACIP recommendation is currently an off-label use of both Boostrix® and Adacel® Tdap** vaccines. Refer to pages 8-8 through 8-12 for additional Td and Tdap information.
- Tdap is the vaccine of choice for adolescents and adults age 10 through 64 years**. A single dose of Tdap is recommended by the ACIP for the individual who is unvaccinated or undervaccinated against pertussis.

*Fully vaccinated is defined as 5 doses of DTaP or 4 doses of DTaP if the 4th dose was administered on or after the 4th birthday.

**Boostrix[®] is approved for ages 10–64 years. Adacel[®] is approved for ages 11–64 years.

Dose	Customary Age	Age/Interval	Product
Primary 1	2 months	6 weeks old or older	DTaP§
Primary 2	4 months	4–8 weeks after 1 st dose†	DTaP§
Primary 3	6 months	4–8 weeks after 2 nd dose†	DTaP§
Primary 4	12–18 months 6–12 months after 3 rd dose†		DTaP§
Booster (or dose 5)	4–6 years old, before entering kindergarten or elementary school (not necessary if fourth primary immunizing dose administered after 4 th birthday)		DTaP§

Routine Diphtheria, Tetanus, and Acellular Pertussis Immunization Schedule Summary for Children <7 years old

§ Use DT if pertussis vaccine is contraindicated. If the child is 1 year of age or older at the time that dose three is due, a third dose 6-12 months after the second completes primary immunization with DT.

† Prolonging the interval does not require restarting series.

Interrupting the recommended schedule or delaying subsequent doses does not reduce the ultimate immunity. There is no need to restart a series regardless of the time elapsed between doses.

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Dosage Administration

0.5cc Intramuscular (IM) Infants—Anterolateral thigh muscle Toddlers and Children—Deltoid muscle

- Reducing the dose of DTaP vaccine, or giving the full dose in multiple smaller doses may result in an altered immune response and inadequate protection.
- ✓ Any vaccination using less than the standard dose or a nonstandard route or site of administration should not be counted, and the person should be revaccinated according to age as if the non-standard injection had not been administered.

Contraindications

• 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. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.

• 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.

Precautions (Warnings)

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:

- ★ Temperature ≥105° F (≥40.5°C) within 48 hours, not attributable to another identifiable cause
- ***** Collapse or shock-like state (hypotonic hyporesponsive episode) within 48 hours
- ★ Persistent crying lasting ≥3 hours, occurring within 48 hours
- ★ Convulsions with or without fever, occurring within 3 days
- ***** Acute, moderate or severe illnesses with or without fever
- ✗ Latex allergy

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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.

Adverse Events

- Local reactions (erythema, induration)
- Nodule at injection site
- Low grade fever
- More severe adverse events are uncommon with DTaP
- Swelling involving the entire thigh or upper arm has been reported after booster doses of different acellular pertussis vaccines (see Special Considerations)

ACIP recommends that a history of extensive swelling after the 4th dose should NOT be considered a contraindication to receipt of a 5th dose at school entry.

General Storage and Handling

- Refrigerate immediately upon arrival
- Store continuously at a temperature of 2° to 8°C (35° to 46°F)
- Should not be frozen—this reduces potency, and it should not be stored in direct contact with ice packs

Product	Manufacturer(s)	Licensed
Infanrix® (DTaP)	Glaxo Smith Kline	Licensed for all 5 doses of series
Daptacel® (DTaP)	Sanofi Pasteur, Inc.	Licensed for all 5 doses of series

Special Considerations

Interchangeability of DTaP Vaccines

- DTaP when not contraindicated, is recommended for all doses of the series
- Whenever possible, use the same brand of DTaP vaccine for all doses in the series
- Vaccination should NOT be deferred when the type of DTaP used for earlier doses is not available or known

Limb swelling after booster doses of DTaP

- Increases in frequency and magnitude of substantial reactions at the injection site with increasing dose number have been reported for all currently licensed DTaP vaccines.
- Data are insufficient to establish if adverse event rates are different (either higher or lower) for children receiving mixed sequences of DTaP vaccines.

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While available data demonstrate that these reactions are self-limited and resolve without sequelae, children who develop pain, erythema, and swelling after DTaP vaccine may have another condition requiring treatment (e.g., cellulitis) and should be evaluated on a caseby-case basis.

Underlying Neurologic Disorders and Use of Pertussis Vaccine

A family history of seizures or other neurologic diseases, or stable or resolved neurologic con-1 ditions (e.g., controlled idiopathic epilepsy, cerebral palsy, developmental delay) are not contraindications to pertussis vaccination.

Underlying Condition	Recommendation
Prior seizure†	Do not administer until condition stabilized*
Suspected neurologic disorder†	Do not administer until condition stabilized*
Neurologic event between doses†	Do not administer until condition stabilized*
Stable/resolved neurologic condition	Vaccinate

†These conditions include the presence of an evolving neurologic disorder (e.g., uncontrolled epilepsy, infantile spasms, and progressive encephalopathy), a history of seizures which has not been evaluated, or a neurologic event which occurs between doses of pertussis vaccine.

*Vaccinate after treatment initiated and condition stabilized

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DT Vaccine

(Diphtheria Toxoid and Tetanus Toxoid)

Schedule

If a child <7 years of age (up to the 7th birthday) has a valid contraindication to pertussis vaccine, DT should be used to complete the series.

DT Immunization Schedule Summary for Children <7 years old

Dose	Customary Age Age/Interval		Product
Primary 1	2 months	6 weeks old or older	DT
Primary 2	4 months	4–8 weeks after 1st dose*	DT
Primary 3**	6 months	4–8 weeks after 2 nd dose*	DT
Primary 4	12–18 months	6–12 months after 3 rd dose*	DT
Booster	4–6 years old, before entering kindergarten or elementary school (not necessary if fourth primary immunizing dose administered on or after 4 th birthday)		DT
Additional Boosters	Every 10 years after last dose		Td/Tdap

*Prolonging the interval does not require restarting series.

**If the child was younger than 12 months old when the first dose of DT was administered (as DTP, DTaP, or DT), the child should receive a total of four primary DT doses. If the child was 12 months of age or older at the time the first dose of DT was administered, three doses (third dose 6–12 months after the second) completes the primary DT series. The child would then still need the booster at 4–6 years of age.

• Interrupting the recommended schedule or delaying subsequent doses does not reduce the ultimate immunity. There is no need to restart a series regardless of the time elapsed between doses.

Dosage	Administration
0.5cc	Intramuscular (IM)
	Infants—Anterolateral Thigh Muscle Toddlers and Children—Deltoid Muscle

Contraindications

• 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. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering

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vaccines, providers should consult product package inserts for precautions, warnings, and contraindications. 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.

Precautions

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

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.

Adverse Events

- Local reactions (erythema, induration)
- Nodule at injection site
- Hypersensitivity reactions (Arthus-type: Unusual reactions which present as extensive painful swelling, often from elbow to shoulder and generally begin from 2–8 hours after injections. Reported most often in adults, particularly those who have received frequent doses of tetanus toxoid.)
- Fever and systemic symptoms uncommon
- Severe systemic reactions rare

General Storage and Handling

- Refrigerate immediately upon arrival
- Store continuously at a temperature of 2° to 8°C (35° to 46°F) ۲
- Should not be frozen—this reduces potency, and it should not be stored in direct contact • with ice packs

Product	Manufacturer(s)
Tetanus, Diphtheria Toxoids (DT)	Sanofi Pasteur, Inc.

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SUBJECT: TD/TDAP

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Td and Tdap Vaccine

(Tetanus Toxoid, Diphtheria Toxoid and acellular Pertussis)

Schedule

- There is virtually no reason to use tetanus toxoid as a single antigen for protection. Instead, it should be given in combination with diphtheria toxoid, since periodic boosting is needed to prevent both diseases.
- *Persons 7 through 9 years of age.* Td is the vaccine of choice for children 7 years through 9 years of age. ACIP recommends that children 7–10 years not fully vaccinated* against pertussis—and without a contraindication to pertussis vaccine—receive a single dose of Tdap. Those never vaccinated against tetanus, diphtheria, or pertussis—or who have unknown vaccination status—should receive a series of 3 vaccinations containing tetanus and diphtheria toxoids. ACIP recommends that Tdap be the 1st of these 3 doses. This ACIP recommendation is currently an off-label use of both Boostrix® and Adacel® Tdap** vaccines.
- *Persons 11 through 18 years of age*. Adolescents aged 11 through 18 years who have completed the recommended DTP/DTaP vaccination series should receive a single dose of Tdap. Ideally, adolescents should receive Tdap at the 11–12 year old preventive health care visit.
- *Persons 19 through 64 years of age*. Adults aged 19 through 64 years who have not received a previous dose of Tdap should receive a single dose.
- The ACIP recommends that all healthcare personnel (HCP), regardless of age, receive a single dose of Tdap as soon as feasible if they have not previously received Tdap and regardless of the time since their last Td dose.
- *Persons 65 years and older*. ACIP recommends that those who have, or anticipate having, close contact with an infant <12 months of age receive a single dose of Tdap. Adults ≥65 years may be given a single dose of Tdap. This ACIP recommendation is currently an off-label use of both Boostrix[®] and Adacel[®] Tdap** vaccines.
- Tdap should be considered for all adults who come into close contact with infants (e.g., childcare and health personnel, and parents).
- *Timing of Tdap*. Tdap can be administered regardless of the interval since the last tetanusor diphtheria-toxoid containing vaccine. Tdap is approved only for a single booster dose.
- Td and Tdap contain only $\frac{1}{3}$ as much diphtheria toxoid as DT.
- The first booster dose should be given as a Tdap.
- If a booster dose is given sooner than 10 years as part of wound management, the next booster is not needed for 10 years thereafter (see "Tetanus Wound Management" page 8-12 for additional information).
- More frequent boosters are not indicated and have been reported to result in an increased incidence and severity of adverse reactions.
- Tdap is approved only for a single booster dose.

*Fully vaccinated is defined as 5 doses of DTaP or 4 doses of DTaP if the 4th dose was administered on or after the 4th birthday. **Boostrix® is approved for ages 10–64 years. Adacel® is approved for ages 11–64 years.

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SUBJECT: TD/TDAP

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Routine Tetanus and Diphtheria Vaccination Schedule Summary for Persons Beginning Immunization >7 years of age

Dose	Age/Interval	Product*
Primary 1	First dose	Tdap
Primary 2	4–8 weeks after first dose	Td
Primary 3	6–12 months after 2 nd dose	Td
Booster	Every 10 years after last dose	Td

*Boostrix® is approved for ages 10-64 years. Adacel® is approved for ages 11-64 years.

Dosage	Administration
0.5cc	Intramuscular (IM), Adults and Children—Deltoid Muscle

Contraindications to Tdap Vaccine

• 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. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.

• 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.

Precautions to Tdap Vaccine

• 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.

• **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.

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(Precautions to Tdap Vaccine Continued)

• Latex allergy

Some presentations of Tdap contain latex. These presentations should not be administered to persons 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.

- Guillain-Barre syndrome (GBS) within 6 weeks after a previous dose of tetanus toxoid containing vaccines
- Acute, moderate or severe illnesses with or without fever
- Providers should take appropriate measures to prevent injuries if a patient becomes weak or dizzy or loses consciousness after vaccination. Adolescents and adults should be seated or lying down during vaccination. Vaccine providers, particularly when vaccinating adolescents, should consider observing patients (with patients seated or lying down) for 15 minutes after vaccination to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve.

Contraindications to Td Vaccine

• An immediate anaphylactic reaction

Further vaccination with any of the components of the Td vaccine or with any component of a combination vaccine with Td 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. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.

• Moderate or severe illnesses with or without fever

Precautions to Td Vaccine

• 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.

- Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus toxoid containing vaccines
- Acute, moderate or severe illnesses with or without fever

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(Precautions to Td Vaccine Continued)

• 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.

• Providers should take appropriate measures to prevent injuries if a patient becomes weak or dizzy or loses consciousness after vaccination. Adolescents and adults should be seated or lying down during vaccination. Vaccine providers, particularly when vaccinating adolescents, should consider observing patients (with patients seated or lying down) for 15 minutes after vaccination to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve.

Use of Tdap During Pregnancy

Until additional information is available, CDC's Advisory Committee on Immunization Practices recommends that pregnant women who were not vaccinated previously with Tdap:

- 1) receive Tdap in the immediate postpartum period before discharge from hospital or birthing center,
- 2) receive Td during pregnancy for tetanus and diphtheria protection when indicated, or
- 3) defer the Td vaccine indicated during pregnancy to substitute Tdap vaccine in the immediate postpartum period if the woman is likely to have sufficient protection against tetanus and diphtheria.

Although pregnancy is not a contraindication for receiving Tdap vaccine, health-care providers should weigh the theoretical risks and benefits before choosing to administer Tdap vaccine to a pregnant woman.

Adverse Events

- Local reactions (erythema, induration, pain at injection site)
- Nodule at injection site (felt for several weeks)
- Abscess at injection site has been reported
- Hypersensitivity reactions (Arthus-type: Unusual reactions which present as extensive painful swelling, often from elbow to shoulder and generally begin from 2–8 hours after injections. Reported most often in adults, particularly those who have received frequent doses of tetanus toxoid.)
- Fever and systemic symptoms uncommon
- Severe systemic reactions rare

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SUBJECT: TD/TDAP

General Storage and Handling

- Refrigerate immediately upon arrival
- Store continuously at a temperature of 2° to 8°C (35° to 46°F)
- Should not be frozen—this reduces potency, and it should not be stored in direct contact with ice packs

Product	Manufacturer(s)	Licensed	
DECAVAC™ (Td)	Sanofi Pasteur, Inc.	Persons ≥ 7 years of age	_
Boostrix® (Tdap)	Glaxo Smith Kline	Persons 10 through 64 years of age	_
Adacel™ (Tdap)	Sanofi Pasteur, Inc.	Persons 11 through 64 years of age	_

Special Considerations

Wound Management

- The need for active immunization, with or without passive immunization, depends on the condition of the wound and the patient's immunization history.
- Adolescents and adults ages 10–64 years years who require a tetanus toxoid-containing vaccine as part of wound management should receive a single dose of Tdap instead of Td, if they have not previously received Tdap. If Tdap is not available, or was previously administered, these persons should receive Td.

Tetanus Wound Management

	Clean, mino	r wounds	All other wounds	
Vaccination History	Td*	TIG	Td* TIG	
Unknown or <3 doses	Yes	No	Yes Yes	
3+ doses	No**	No	No*** No	

*Tdap may be substituted for Td if the person has not previously received Tdap and is ≥10 years

Yes, if >10 years since last dose *Yes, if >5 years since last dose

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SUBJECT: DTAP/HIB

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Combined DTaP/Hib Vaccine*

(Diphtheria, Tetanus Toxoid, and Acellular Pertussis–Haemophilus influenzae type b)

Schedule

As a general rule, combination vaccines may be used when all the components are indicated.

- Only one combination DTaP and Hib (TriHIBitTM) has been licensed. *TriHIBitTM has been discontinued. Supplies are expected to last through the second quarter of 2011.
- This vaccine is currently licensed only for the following indications:
 - ✓ Approved ONLY for the fourth dose of the DTaP/Hib series (in children ≥12 months of age), after the child has been immunologically primed with Hib antigen. (Data suggest that initial priming with DTaP/Hib combined vaccine can lead to a significantly reduced response to the Hib component.)
 - ✓ This vaccine should NOT be used for any of the first three doses of the Hib series.
 - ✓ The Sanofi Pasteur, Inc. DTaP and Sanofi Pasteur, Inc. Hib are the approved vaccines to combine.

Dosage	Administration
0.5cc	Intramuscular (IM) Infants—Anterolateral Thigh Muscle Toddlars and Children—Deltaid Muscle

Contraindications & Precautions

- The same as those for its individual component vaccines (i.e., DTaP, pg. 8-3 or Hib, pg. 8-20)
- A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.

Adverse Events

The same are expected as when its individual component vaccines (i.e., DTaP, pg. 8-4 or Hib, pg. 8-21) are given.

General Storage and Handling

- Should be shipped in insulated container to help prevent freezing
- Refrigerate immediately upon arrival
- Store continuously at a temperature of 2° to 8°C (35° to 46°F). •
- Do not freeze—this reduces potency, and it should not be stored in direct contact with ice packs

Product	Manufacturer(s)	Licensed
TriHlBit™	Sanofi Pasteur, Inc.	September 1997; only for the fourth dose of the DTaP/Hib series

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SUBJECT: DTAP/HEP B/IPV

Combined DTaP-Hep B-IPV Vaccine (PEDIARIX™)

(Diphtheria, Tetanus Toxoid, and acellular Pertussis–Hepatitis B and Inactivated Poliovirus Vaccine)

Schedule

As a general rule, combination vaccines may be used when all the components are indicated.

- Only one combination DTaP–HepB–IPV vaccine (PEDIARIX[™]) has been licensed.
- This vaccine is currently licensed for the following indications: •
 - ✓ Approved ONLY for the 3 dose primary series, normally given at 2,4 and 6 months. Can be given for dose 1,2 or 3 to any child ages 6 weeks through 6 years.

Dosage	Administration
0.5cc	Intramuscularly (IM)

Contraindications

- Infants less than 6 weeks of age.
- The same as those for its individual component vaccines (i.e., DTaP, pg. 8-3, Hep B pg. 8-37, IPV pg. 8-24).

Precautions (Warning)

- The same as those for its individual component vaccines (i.e., DTaP, pg. 8-3, Hep B pg. 8-37, IPV pg. 8-24).
- A list of components (including any latex, thimerosal, or antibiotic content) for each vac-• cine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.

Adverse Events

The same as those for its individual component vaccines (i.e., DTaP, pg. 8-4, Hep B pg. 8-37, IPV pg. 8-25).

General Storage and Handling

- Refrigerate immediately upon arrival
- Store continuously at a temperature of 2°–8°C (35°–46°F).

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SUBJECT: DTAP/HEP B/IPV

Special Considerations

PEDIARIXTM is licensed only for the primary series. It should be followed with the 4th and 5th doses of DTaP and a 4th dose of IPV at the appropriate ages.

The minimum interval between doses 1 and 2 is 4 weeks and the minimum interval between doses 2 and 3 is 8 weeks. The 3rd dose should not be administered before age 24 weeks. This is due to the hepatitis B component.

A child who receives a birth dose of monovalent hepatitis B (Hep B) can receive PEDI-ARIXTM for subsequent doses. The child can still receive a 3-dose series of PEDIARIXTM, even though this would mean getting an extra dose of hepatitis B (Hep B).

PEDIARIXTM has been approved by ACIP for use to complete the hepatitis B (Hep B) vaccination series regardless of the mother's HBsAg status.

DTaP-HepB-IPV combination (PEDIARIXTM) and HepB from a different manufacturer are interchangeable for HepB vaccination. DTaP-HepB-IPV (PEDIARIXTM) and IPV from a different manufacturer are interchangeable for poliovirus vaccination.

DTaP-HepB-IPV (PEDIARIXTM) combination can be administered with Hib and PCV vaccines at separate injection sites.

DTaP-HepB-IPV (PEDIARIXTM) combination can be used to complete the primary series in infants and children who have received INFANRIX[®] (DTaP) and are scheduled to receive the other components of the combination. Data are limited on the safety and immunogenicity of interchanging currently used DTaP vaccines from different manufacturers. ACIP recommends that, whenever feasible, the same brand of DTaP should be used for the primary series but that vaccination should not be deferred because the type of DTaP previously administered is unavailable or unknown.

Product		Licensed
PEDIARIX™	Glaxo Smith Kline	December, 2002; only for the 3-dose primary series at ages 2, 4 and 6 months. Pediarix® can be given for dose 1, 2 or 3 to any child ages 6 weeks through 6 years.

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SUBJECT: DTAP/IPV

Combined DTaP-IPV Vaccine (Kinrix®)

(Diphtheria, Tetanus Toxoid, and acellular Pertussis and Inactivated Poliovirus Vaccine)

Schedule

• Approved for use as the fifth dose of the DTaP vaccine series and the fourth dose of the IPV series in children aged 4–6 years whose previous DTaP vaccine doses were DTaP (Infanrix) and/or DTaP-Hep B-IPV (Pediarix) for the first 3 doses and DTaP (Infanrix) for the fourth dose. It is approved for children aged 4 through 6 years of age.

Dosage	Administration	Site
0.5cc	Intramuscularly (IM)	Preferably Deltoid

Contraindications

- Children <4 years or ≥7 years (however, if Kinrix is inadvertently administered for an earlier dose of the DTaP and/or IPV series, the dose should be counted as valid and does not need to be repeated provided minimum interval requirements have been met.)
- The same as those for its individual component vaccines (i.e., DTaP pg. 8-3 and IPV pg. 8-24).

Precautions (Warning)

- The same as those for its individual component vaccines (i.e., DTaP pg. 8-3 and IPV pg. 8-24).
- A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.

Adverse Events

■ The same as those for its individual component vaccines (i.e., DTaP pg. 8-4 and IPV pg. 8-25).

General Storage and Handling

- Refrigerate immediately upon arrival
- Store at a temperature of 35°–46°F (2°–8°C). Kinrix must never be frozen.

Special Considerations

ACIP recommends that, whenever feasible, the same manufacturer's DTaP vaccines should be used for each dose in the series; however, vaccination should not be deferred because the type of DTaP previously administered is unavailable or unknown.

Revised: 5/1/11

SECTION-PAGE: 8-17

SUBJECT: DTAP/HIB/IPV

Issued: 9/1/98

Combined DTaP-Hib/IPV Vaccine (Pentacel®)

Diphtheria, Tetanus Toxoid, and acellular Pertussis—Inactivated Poliovirus Vaccine and *Haemophilus influenzae* type b)

Schedule

- May be used whenever any component(s) of the combination is indicated and no other component of the vaccine is contraindicated. This means that Pentacel can be used when a child needs one or two components, but does not need the others.
- Approved for the first four doses in children aged 6 weeks through 4 years of age (Recom-• mended schedule 2, 4, 6 and 15–18 months of age)

Parameter	Age/interval
Minimum age for any dose	6 weeks
Minimum interval for doses 1 and 2	4 weeks
Minimum age for dose 2	10 weeks
Minimum interval for doses 2 and 3	4 weeks
Minimum age for dose 3	14 weeks
Minimum interval for dose 3 and 4	6 months (determined by DTaP component; minimum interval for dose 3–4 is two months for Hib)
Minimum age for dose 4	12 months (determined by DTaP and Hib components). Note that both the minimum interval AND age must be met for the fourth dose of DTaP or Hib (as Pentacel or any other formulation) to be counted as valid
Maximum age for any dose	4 years, 364 days (i.e., do not administer at age 5 years or older)

Administration Dosage

1 individual dose vial Intramuscularly (IM)

Contraindications

- Infants less than 6 weeks of age.
- The same as those for its individual component vaccines (i.e., DTaP pg. 8-3, Hib pg. 8-20 • and IPV pg. 8-24).
- A list of components (including any latex, thimerosal, or antibiotic content) for each vac-• cine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.

Precautions (Warning)

The same as those for its individual component vaccines (i.e., DTaP pg. 8-3, Hib pg. 8-20 and IPV pg. 8-24).

Colorado Immunization Manual Issued: 9/1/98 Revised: 5/1/11 Section-Page: 8-18

SUBJECT: DTAP/HIB/IPV

Adverse Events

■ The same as those for its individual component vaccines (i.e., DTaP pg. 8-4, Hib pg. 8-21 and IPV pg. 8-25).

General Storage and Handling

- Refrigerate immediately upon arrival
- Store at a temperature of 35°–46°F (2°–8°C). Pentacel must never be frozen.

Special Considerations

In general ACIP recommends the same brand of DTaP be used for all doses of the series. However, different brands can be used if the provider does not know or have available the brand of DTaP used for prior doses.

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Issued: 9/1/98

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SUBJECT: HIB

Hib Vaccine

(Haemophilus influenzae type b)

Schedule

All infants, including those born prematurely, should receive a primary series of conjugate Hib vaccine (separate or in combination), beginning at 2 months of age.

- Children >59 months (5 years) of age do not require Hib vaccination (except under special • circumstances—see special considerations on page 8-21).
- The number of doses in the primary series depends on the type of vaccine used.
- Previously unvaccinated children or those with a lapsed schedule may not require a series of 3 or 4 doses. For a child behind schedule, the number of doses needed depends on the child's current age and vaccination history. An unvaccinated child's current age determines the number of Hib doses needed.
- On April 19, 2009, the FDA licensed Hiberix[™](PRP-T; GlaxoSmithKline). Hiberix[™] is • approved for use as the booster (final) dose for Hib vaccination in children 12 months through 4 years of age (before the 5th birthday) who have received a primary Hib vaccination series of 2 or 3 doses (depending on the formulation). **Hiberix[™] is not licensed for** the primary vaccination series.
- ACIP recommends Hib booster vaccination at 12 through 15 months of age. To facilitate • timely booster vaccination, HiberixTM and other Hib conjugate vaccines can be administered as early as age 12 months, in accordance with Hib vaccination schedules for routine and catch-up immunization.
- Children aged 12 months through 4 years who did not receive a booster because of the recent shortage of Hib vaccines should receive a booster with any of the available Hib-containing vaccines at the earliest opportunity. Vaccination providers should review patient immunization records to identify and recall children in need of a booster dose.

ACIP-Recommended Haemophilus influenzae type b (Hib) Routine Vaccination Schedule

Vaccine	2 months	4 months	6 months	12–15 months
PRP-T (ActHIB™)	Dose 1	Dose 2	Dose 3	Booster
PRP-OMP (PedvaxHIB®)	Dose 1	Dose 2		Booster

Minimal Intervals

- The optimal interval between doses is 2 months, with an acceptable minimum interval of 1 month.
- At least 2 months should separate the booster dose from the previous (2nd or 3rd) dose.

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SECTION-PAGE: 8-20

SUBJECT: НІВ

• Hib vaccines, including combination vaccines that contain Hib conjugate, should never be given to a child younger than 6 weeks of age. Recent data suggest that when given before 6 weeks of age, the child may induce immunologic tolerance to additional doses of Hib vaccine.

Vaccine Age at 1st dose (months) Primary Series Booster PRP-T 2-6 3 doses, 2 months apart 12-15 months* (ActHIB TM) 7-11 2 doses, 2 months apart 12-15 months* 12-14 1 dose 2 months later 15-59 1 dose PRP-OMP 2-6 2 doses, 2 months apart 12-15 months* (PedvaxHIB®) 7-11 2 doses, 2 months apart 12-15 months* 12-14 1 dose 2 doses, 2 months apart 12-15 months* (PedvaxHIB®) 7-11 2 doses, 2 months apart 12-15 months* 12-14 1 dose 2 months later 12-15 months* 12-15 1 dose 2 months later 12-15 months*			71	
PRP-T 2-6 3 doses, 2 months apart 12-15 months* (ActHIB™) 7-11 2 doses, 2 months apart 12-15 months* 12-14 1 dose 2 months later 15-59 1 dose PRP-OMP 2-6 2 doses, 2 months apart 12-15 months* (PedvaxHIB®) 7-11 2 doses, 2 months apart 12-15 months* 12-14 1 dose 2 months later 12-15 months* 12-15 12-15 12-15 months 12-15 months* (PedvaxHIB®) 7-11 2 doses, 2 months apart 12-15 months* 12-14 1 dose 2 months later 12-15 months 12-15 12-14 1 dose 2 months later	Vaccine	Age at 1 st dose (months)	Primary Series	Booster
(ActHIB™) 7-11 2 doses, 2 months apart 12-15 months* 12-14 1 dose 2 months later 15-59 1 dose PRP-OMP 2-6 2 doses, 2 months apart 12-15 months* (PedvaxHIB®) 7-11 2 doses, 2 months apart 12-15 months* 12-14 1 dose 2 months later 12-15 12-15 12-15 months* 12-14 1 dose 2 months later 15-59 1 dose	PRP-T	2–6	3 doses, 2 months apart	12–15 months*
12–14 1 dose 2 months later 15–59 1 dose — PRP-OMP 2–6 2 doses, 2 months apart 12–15 months* (PedvaxHIB®) 7–11 2 doses, 2 months apart 12–15 months* 12–14 1 dose 2 months later 15–59 1 dose 2 months later	(ActHIB™)	7-11	2 doses, 2 months apart	12–15 months*
15-59 1 dose — PRP-OMP 2-6 2 doses, 2 months apart 12-15 months* (PedvaxHIB®) 7-11 2 doses, 2 months apart 12-15 months* 12-14 1 dose 2 months later 15-59 1 dose —		12-14	1 dose	2 months later
PRP-OMP 2-6 2 doses, 2 months apart 12-15 months* (PedvaxHIB®) 7-11 2 doses, 2 months apart 12-15 months* 12-14 1 dose 2 months later 15-59 1 dose		15–59	1 dose	_
(PedvaxHIB®) 7-11 2 doses, 2 months apart 12-15 months* 12-14 1 dose 2 months later 15-59 1 dose —	PRP-OMP	2–6	2 doses, 2 months apart	12–15 months*
12-14 1 dose 2 months later 15-59 1 dose —	(PedvaxHIB®)	7-11	2 doses, 2 months apart	12–15 months*
15-59 1 dose -		12-14	1 dose	2 months later
		15-59	1 dose	—

Detailed Vaccination Schedule for Haemophilus influenzae type b Conjugate Vaccines

*at least 2 months after previous dose.

Detailed Vaccination Schedule for Interrupted Haemophilus influenzae Vaccine Series*

Present Age (mos)	Prior Doses of Hib	Recommended
7 to 11	1 dose	1 dose at 7 to 12 months plus booster (must be after 12 months)
7 to 11	2 doses of PRP-T	Same as above
12 to 14	2 doses before 12 months	1 dose (any licensed conjugate)
12 to 14	1 dose before 12 months	2 doses (any licensed conjugate, 2 months apart
15 to 59	Any incomplete doses, including zero doses	1 dose (any licensed conjugate)
>59	None	No doses

*Reference: AAP 1997 Redbook, p.230, Table 3.11 and CDC's, Communicating with Parents CME Teleconference Series, 10/21/99.

Dosage Administration

0.5cc

Intramuscular (IM), Infants—Anterolateral Thigh Muscle, Toddlers and Children—Deltoid Muscle

Contraindications

- Severe allergic reaction to vaccine component or following prior dose. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.
- Moderate to severe acute illness
- Contraindications and precautions for the use of TriHIBitTM, ComvaxTM, and PentacelTM are the same as those for their individual component vaccines.

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SUBJECT: НІВ

Adverse Events

- Uncommon
- Swelling, redness, and/or pain in 5–30% of recipients
- Systemic reactions infrequent
- Serious adverse reactions rare

General Storage and Handling

- Should be shipped in insulated container to help prevent freezing
- Refrigerate immediately upon arrival
- Store continuously at a temperature of 2° to 8°C (35° to 46°F)
- **Do not freeze**—this reduces potency, and it should not be stored in direct contact with ice packs

Product	Manufacturer(s)	Licensed
PRP-T (ActHIB™)	Sanofi Pasteur, Inc.	Licensed for infants >6 weeks of age
PRP-T (Hiberix™)	GlaxoSmithKline	For booster dose only in children ≥12 months through 4 years
PRP-OMP (PedvaxHIB®)	Merck & Co., Inc.	Licensed for infants >6 weeks of age

Special Considerations

Interchangeability of Hib Vaccines

- If possible, use same conjugate vaccine for the primary series, although:
 - ✓ Any combination of 3 doses of conjugate vaccine (except Hiberix[™]) constitute primary series
 - ✔ Children who have previously been ill with HIB disease would be vaccinated as usual as infection does not guarantee full immunity

Vaccination of older children and adults

Some older children and adults are at increased risk for invasive Hib disease and may be vaccinated. These high risk persons include those with:

- Functional or anatomic asplenia (e.g., sickle cell disease, postsplenectomy)
- Immunodeficiency (in particular, persons with IgG2 subclass deficiency)
- Immunosuppression from cancer chemotherapy, and infection with human immunodeficiency virus
- Stem cell transplant

Previously unvaccinated persons with one of these high risk conditions should be given at least one dose of any licensed Hib conjugate vaccine.

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REVISED: 5/1/11 **S**ECTION-**P**AGE: 8-22

SUBJECT: HEP B/HIB

Issued: 9/1/98

Combined Hepatitis B-Hib Vaccine (COMVAX™)

(Hepatitis B-Haemophilus influenzae type b)

Schedule

As a general rule, combination vaccines may be used when all the components are indicated.

COMVAXTM is licensed for use when both antigens are indicated.

- COMVAX contains a standard dose of PRP-OMP (PedvaxHIB®), and 5 micrograms of Merck's hepatitis B vaccine.
- As Hib vaccine should not be used in infants <6 weeks of age because of the potential of immune tolerance to the Hib antigen, **COMVAX[™] also should not be used in infants <6** weeks of age (i.e., for the hepatitis B birth dose, or the hepatitis B dose at one month of age).
- May be administered at the same time as other childhood vaccines given at >6 weeks of age.
- Not licensed for infants born to mothers known to be hepatitis B surface antigen positive (i.e., acute or chronic infection with hepatitis B virus).
- As stated in the manufacturer insert, "children who receive dose one of hepatitis B at birth or shortly after, may be administered COMVAXTM on the schedule of 2, 4, and 12–15 months of age. There are no data to support the use of a three-dose series of COMVAXTM in infants who have previously received more than one dose of hepatitis B vaccine. How-ever, COMVAXTM may be administered to children otherwise scheduled to receive concurrent RECOMBIVAX HB and PedvaxHib."

•	0			
Birth	2 Months	4 Months	6 Months	12-15 Mont
Hepatitis B	COMVAX	Hib	COMVAX	Hib
Hepatitis B	COMVAX	COMVAX		COMVAX

Sample schedules using COMVAX™

Dosage Administration

0.5cc Intramuscular (IM) Infants—Anterolateral Thigh Muscle Toddlers and Children—Deltoid Muscle

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R e v i s e d: 5/1/11

SUBJECT: HEP B/HIB

Issued: 9/1/98

Contraindications & Precautions

- The same as those for its individual component vaccines (i.e., hepatitis B or Hib)
 - Severe allergic reaction to vaccine component or following prior dose. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.
 - **X** Moderate to severe acute illness

Adverse Events

- The same are expected as when its individual component vaccines (i.e., Hep B or Hib) are given.
 - ★ pain at injection site
 - systemic reactions infrequent with Hib and mild (e.g., fatigue, headache, and irritability) with Hep B
 - ★ serious adverse reactions to Hib or Hep B are rare

General Storage and Handling

- Should be shipped in insulated container to help prevent freezing
- Refrigerate immediately upon arrival
- Store continuously at a temperature of 2° to 8°C (35° to 46°F)
- **Do not freeze**—this reduces potency, and it should not be stored in direct contact with refrigerant

Product	Manufacturer(s)	Licensed
COMVAX TM	Merck	October 1996; Only for infants >6 weeks of age; not licensed for use if mother is HBsAg+

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SECTION-PAGE: 8-24

SUBJECT: IPV

IPV Vaccine

Inactivated Poliovirus Vaccine

Schedule

- To eliminate the risk for vaccine-associated paralytic polio (VAPP), the ACIP has recommended an all-IPV schedule for routine childhood polio vaccination in the United States.
- OPV is no longer available for use in the United States. If OPV doses have already been given they do not need to be repeated. Any combination of 4 doses of IPV and OPV by 4–6 years of age constitutes a complete series.
- All children should receive four doses of IPV at ages 2 months, 4 months, 6–18 months, and 4–6 years.
- 4 doses of IPV that meet minimum age and interval levels is a complete series. The minimum interval from dose 1 to dose 2 and dose 2 to dose 3 is 4 weeks. The minimum interval from dose 3 to dose 4 is 6 months.
- The 4th dose must be given on or after the 4th birthday. If it is given prior to the 4th birthday, an additional dose must be administered after age 4. (This recommendation is not retroactive—an adolescent who received the fourth dose of IPV before age 4, according to the schedule used prior to August 7, 2009, does not require an extra dose, unless they will be traveling to an area where polio is endemic.)
- Use of the minimum age and minimum intervals for vaccine administration in the first 6 months of life are recommended only if the vaccine recipient is at risk for imminent exposure to circulating poliovirus (e.g., during an outbreak or because of travel to a polio-endemic region). Shorter intervals and earlier start dates lead to lower seroconversion rates.

Schedule	Usual Age†				
	2mos* 4mos 6–18mos 4–6 years§				
All IPV	IPV	IPV	IPV	IPV	

Routine Inactivated Polio Vaccination Schedule

- * Series may be started as early as 6 weeks of age.
- t The minimum interval from dose 1 to dose 2 and dose 2 to dose 3 is 4 weeks. The minimum interval from dose 3 to dose 4 is 6 months.
- S The 4th dose is not needed if the third dose is given on or after the 4th birthday, as long as there is an interval of 6 months between the 2nd and 3rd dose providing the series was all IPV. If the series contains both IPV and OPV there must be a total of 4 doses to complete the series.

Dose	Administration	Product
0.5cc	Subcutaneous (SC) or Intramuscular (IM), Infants—Anterolateral aspect of thigh Toddlers, Children and Adults—Outer aspect of upper arm (SC) or Deltoid muscle (IM)	IPV

Contraindications/Precautions

• Serious allergic reaction to a vaccine component or following a prior dose of vaccine; IPV contains trace amounts of streptomycin, neomycin, and polymixin B. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.

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SECTION-PAGE: 8-25

SUBJECT: IPV

- Moderate or severe acute illness
- In general, IPV should not be given to pregnant women, unless immediate protection is needed.

Adverse Events

- Rare local reactions (IPV)
- No serious reactions to IPV have been documented

Storage and Handling

IPV

- Should be maintained at 2° to 8° C (35° to 46° F)
- Should be perfectly clear and colorless

Product	Manufacturer	Licensed
e-IPV (IPOL)	Sanofi Pasteur, Inc.	1987

Special Considerations

Polio Vaccination of Adults

- In general, routine vaccination of U.S. residents >18 years of age is not necessary; most are already immune and have a very low risk of exposure to wild poliovirus in the U.S.
 - However, the following groups of adults are at increased risk of poliovirus infection and may need to be vaccinated, depending on their vaccination status:
 - ✔ Travelers to endemic areas
 - ✓ Lab workers handling specimens which may contain polioviruses
 - ✓ Health care workers in close contact with patients who may be excreting polioviruses

Unvaccinated Adults

- IPV recommended if at increased risk for exposure
- Use standard IPV schedule if possible (0, 1–2 months, 6–12 months)
 - The following alternatives are recommended when time will not allow completion of the schedule (e.g., impending travel):
 - ✓ 8 weeks or more available before protection needed: 3 doses of IPV given at least 4 weeks apart
 - ✓ 4-8 weeks available before protection needed: 2 doses of IPV given at least 4 weeks apart
 - ✓ Less than 4 weeks available: A single dose of IPV is recommended NOTE: In all instances, the remaining doses of the vaccine should be given later, at the recommended intervals, if the person remains at increased risk.

Adults Previously Given a Complete Primary Course of OPV or IPV

• Adults at increased risk of poliomyelitis exposure and who have previously completed a primary course of OPV should be given one dose of IPV

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R e **v** i s e **d**: 4 / 1 / 10

SECTION-PAGE: 8-26

SUBJECT: MMR

MMR Vaccine

Measles, Mumps, Rubella

Schedule

• For protection against measles, mumps and/or rubella, combination MMR vaccine is recommended. Single antigen measles, mumps and rubella vaccines are no longer manufactured or available in the U.S. When immunity to a single antigen is desired, it is appropriate and recommended to use the combination MMR vaccine.

MMR (Measles, Mumps, Rubella) Immunization Schedule

Dose	Customary Age	Age/Interval	**Product
Primary 1	12–15 months	Not younger than 1st birthday	MMR
Primary 2	4–6 years or *11–12 years	†Must be at least 28 days since dose # 1	MMR

*Age 11–12 years, can serve as a catch-up opportunity to verify vaccination status and administer MMR vaccine to those children who have not yet received two doses of MMR (with the first dose administered no earlier than the first birthday).

† The second dose of MMR may be administered as soon as one month (i.e., minimum of 28 days) after the first dose.

** Single antigen measles, mumps and rubella vaccines are no longer manufactured or available in the U.S.

Dosage	Administration
0.5cc	Subcutaneously (SC) Toddlers, Children and Adults—Outer aspect of upper arm

Recommendations for Health Care Workers

- For healthcare personnel born in 1957 or later without serologic evidence of immunity or prior vaccination, give 2 doses of MMR, 4 weeks apart.
- For unvaccinated personnel born before 1957 who lack laboratory evidence of measles, mumps and/or rubella immunity or laboratory confirmation of disease, healthcare facilities should consider vaccinating personnel with two doses of MMR vaccine at the appropriate interval (for measles and mumps) and one dose of MMR vaccine (for rubella), respectively.
- For unvaccinated personnel born before 1957 who lack laboratory evidence of measles, mumps and/or rubella immunity or laboratory confirmation of disease, healthcare facilities should recommend two doses of MMR vaccine during an outbreak of measles or mumps and one dose during an outbreak of rubella.

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SECTION-PAGE: 8-27

SUBJECT: MMR

Contraindications and Precautions

- Severe allergic reaction to prior dose or vaccine component (gelatin or neomycin). Egg allergy is no longer considered a contraindication to MMR. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.
- Persons with moderate to severe illness should not be vaccinated until the illness has resolved
- Pregnancy
- Immunosuppression
- Recent blood product

Adverse Events

- Fever (5%–15%)
- Rash—(5%) transient, appearing 7–10 days after MMR vaccination, non-infectious
- Joint symptoms (25%—susceptible women)
- Thrombocytopenia (<1/30,000 doses)
- Parotitis (rare)
- Deafness (rare)
- Encephalopathy (<1/1,000,000 doses)

Storage and Handling

- Use insulated container
- Ship with refrigerant
- Maintain at 10°C (50°F) or less
- If shipped with dry ice, diluent must be shipped separately
- Diluent may be shipped with vaccine but do not freeze
- On arrival, vaccine should be below 10°C (50°F)—if above this temperature, call CDPHE
- Refrigerate immediately on arrival
- Vaccine may be stored separately from diluent
- Store vaccine at 2° to 8°C (35° to 46°F) but may be frozen
- MMR vaccine may be stored frozen between -58°F and +5°F (-50°C to -15°C).
- Protect vaccine from light at all times, since any light exposure may inactivate the virus store in the original box with the box lid intact
- Diluent may be stored at 20° to 25°C (68° to 77°F)—room temperature—do not freeze
- Freeze dried (lyophilized) vaccines may be maintained at freezer temperatures

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SUBJECT: MMR

- Use only the diluent supplied to reconstitute the vaccine
- After reconstitution, use immediately or store in a dark place at 2° to 8°C (35° to 46°F)— discard if not used within 8 hours

Special Considerations

Rubella Vaccination of Childbearing-Age Women

- ✓ Ask if pregnant or likely to become so in the next month
- ✓ Exclude those who say "yes"
- ✔ For others
 - Explain the theoretical risks of being pregnant or becoming pregnant in the next month
 - Vaccinate
- ✓ Pregnant, non-vaccinated women should return for MMR vaccination in the immediate post-partum period.

Measles Vaccine

- ✓ Women known to be pregnant should not receive measles vaccine.
- ✓ Pregnancy should be avoided for 1 month following receipt of measles vaccine or MMR vaccine.
- ✓ Close contact with pregnant women is NOT a contraindication to MMR vaccination of the contact.
- Breast-feeding is not a contraindication to vaccination of either the woman or the breast-feeding child.

MMR and Varicella

✓ If MMR and Varicella vaccine are not given at the same visit, they should be separated by at least 28 days.

MMR and Tuberculin testing (PPD)

✓ Apply PPD at the same time as MMR. Delay PPD 4–6 weeks if not given on same day.

MMR and HIV infection

- ✓ MMR recommended for persons with asymptomatic HIV infection
- ✓ Persons with severe immunosuppression due to HIV infection should not receive measles vaccine or MMR (see immunosuppression for further information)
- ✓ Prevaccination HIV testing not recommended

Product	Manufacturer(s)	
MMR	Merck & Co., Inc.	

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SUBJECT: VARICELLA

Revised: 5/1/11

Varicella Vaccine

Schedule

- Children who have not been immunized previously and who do not have a healthcareprovider-certified history of chickenpox are considered susceptible. (Note: The definition of healthcare providers includes school or occupational clinic nurses, nurse practitioners, physician assistants, physicians.)
- Adolescents and adults without a health-care-provider-certified history of chickenpox can • be considered to be susceptible, or may be tested to determine varicella immunity. Serologic testing is likely to be more cost effective prior to vaccination because most adolescents and adults (including those without a reliable history of chickenpox) are actually immune.

Varicella Immunization Schedule Summary for Children, Adolescents and Adults

Age	Dose	Age/Interval	Product
Children 12 months	Primary 1	Not younger than 1 st birthday	Varicella vaccine
through 12 years	Primary 2	4–6 years/at least 3 months after 1 st dose*	Varicella vaccine
Adolescents & adults	Primary 1	≥13 years of age	Varicella vaccine
≥13 years	Primary 2	at least 4–8 weeks since dose 1**	Varicella vaccine

*If 2nd dose administered at least 28 days after 1st dose, 2nd dose does not need to be repeated **Prolonging the interval doesn't require restarting the series.

Administration Dosage 0.5cc Subcutaneous (SC) Toddlers, Children and Adults-Outer aspect of upper arm

Contraindications/Precautions

- Severe allergy to vaccine component or prior dose of vaccine; contains trace amounts of neomycin and gelatin. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.
- Pregnancy; in addition, pregnancy should be avoided for 1 month after vaccination •
- Cellular immunodeficiencies
- Moderate or severe acute illness
- Recent receipt of blood product

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SUBJECT: VARICELLA

Adverse Events

- Injection site complaints (i.e., pain, redness, swelling)—20%
- Rash—4–6%—most commonly maculopapular rather than vesicular; usually occurs within 2–3 weeks after vaccination; may be at injection site only or generalized; average 5 lesions
- Systemic reactions uncommon
- Temperature of 102°F or higher—10–15%

Storage and Handling

- Store frozen $\leq +5^{\circ}F(-15^{\circ}C)$
- May be stored at refrigerator temperature (35–46°F) for up to 72 hours but then must be discarded if not used
- Reconstitute only with diluent supplied by manufacturer
- Discard if not used within 30 minutes of reconstitution
- CDC strongly discourages transport of varicella-containing vaccines to off-site clinics. If these vaccines must be transported to an off-site clinic, the vaccine manufacturer recommends they be transported and stored at refrigerator temperatures, between 35°F and 46°F (2°C to 8°C), for no more than 72 continuous hours prior to reconstitution. Vaccine stored between 35°F and 46°F (2°C to 8°C) that is not used within 72 hours of removal from the freezer should be discarded. Varicella-containing vaccines cannot be refrozen.
- Mishandled vaccine should never be destroyed until the manufacturer (Merck) has been consulted at 1-800-9VARIVAX (1-800-982-7482).

Product	Manufacturer(s)	Licensed
Varivax	Merck & Co., Inc.	1995

Special Considerations

- Approximately 1% of vaccinees per year develop breakthrough infection (i.e., develop varicella disease even though they have responded to the vaccine); breakthrough disease is much milder than wild virus disease
- If varicella vaccine and MMR or LAIV vaccines are not given at the same visit, they should be separated by at least 30 days
- Persons vaccinated following an exposure should have illness managed as if they were susceptible because the protective effects of post-exposure vaccination are unknown
- Recipients should avoid the use of salicylates for 6 weeks after vaccination because of the association between aspirin use and Reye syndrome following chickenpox
- Administration of varicella vaccine within 72 hours and possibly up to 120 hours after varicella exposure may prevent or significantly modify disease.
- Antiviral drugs active against herpesviruses (e.g., acyclovir and valacyclovir) might reduce the efficacy of live, attenuated varicella vaccines. These drugs should be discontinued ≥24 hours before administration of vaccines containing varicella zoster virus, if possible.

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SUBJECT: VARICELLA

Vaccination of Adolescents and Adults (≥13 years) at High Risk for Exposure or Transmission

- Assessment of all adolescents and adults, and vaccination of those who are susceptible, is desirable to protect those individuals from the higher risk of complications from acquired varicella. However, specific assessment should be focused on the following groups who are most likely to transmit varicella to others and who are at highest risk of exposure:
 - 1 Family members of immunocompromised persons
 - Adolescents and adults living in 1 households with children
 - ~ Teachers of young children
 - / Day care employees
 - Military personnel ~

- International travelers ~
- Nonpregnant women of childbearing age
- Residents and staff in institutional settings
- Health care workers
- College students

Seroconversion after vaccination does not always result in full protection against disease.

- If a vaccinated health care worker is exposed to varicella, s/he should be tested for varicella antibody to see if antibody appears quickly after exposure. If antibody is present less than 7 days after exposure, it is unlikely that the exposed person will develop the disease. Persons who remain susceptible (i.e., antibody negative) 7 days after exposure, should be furloughed, or monitored very closely and then furloughed at the onset of symptoms suggestive of varicella.
- The risk of transmission of vaccine virus from a vaccinated person to a susceptible contact appears to be very low but may occur if the vaccinee develops a vaccine-associated rash. As a safeguard, institutions may want to consider precautions for personnel who develop a rash following vaccination (e.g., avoidance of contact with persons at high risk of serious complications, such as immunocompromised persons).

Vaccination of HIV-Infected Children and Other Persons With Altered Immunity (See Section 12)

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ISSUED: 8/1/07 SUBJECT: MMRV **Revised:** 5/1/11

MMRV Vaccine (ProQuad®)

Measles, Mumps, Rubella and Varicella

Schedule

As a general rule, combination vaccines may be used when all the components are indicated. Minimum ages and intervals for both vaccine components should be considered.

- Combination MMRV vaccine is approved for use among healthy children aged 12 months–12 years. MMRV vaccine is indicated for simultaneous vaccination against measles, mumps, rubella, and varicella. MMRV is not indicated for persons outside of this age group.
- MMRV vaccine may be used whenever any components of the combination vaccine are indicated and the other components are not contraindicated. Using combination vaccines containing some antigens not indicated at the time of administration might be justified when 1) products that contain only the needed antigen(s) are not readily available or would result in extra injections and 2) potential benefits to the child outweigh the risk of adverse events associated with the extra antigen(s).
- For the first dose of measles, mumps, rubella, and varicella vaccines given at 12–47 months of age, either MMRV vaccine or separate MMR and varicella vaccines may be used. Providers who are considering administering MMRV vaccine should discuss the benefits and risks of both vaccination options with the parents or caregivers. Unless the parent or caregiver expresses a preference for MMRV vaccine, CDC recommends that MMR vaccine and varicella vaccine be administered for the 1st dose in this age group. Compared with use of MMR vaccine and varicella vaccine at the same visit, use of MMRV vaccine results in one fewer injection but is associated with a higher risk for fever and febrile seizures 5–12 days after the 1st dose among children aged 12–23 months (approximately one extra febrile seizure for every 2,300–2,600 MMRV vaccine doses.) Use of separate MMR vaccine and separate varicella vaccine avoids this increased risk for fever and febrile seizures following MMRV vaccine. For the 2nd dose of measles, mumps, rubella, and varicella vaccines at any age (15 months–12 years) and for the 1st dose at age ≥48 months, use of MMRV vaccines (i.e., MMR vaccine and varicella vaccine).
- At least one month should elapse between a dose of measles containing vaccine, such as MMR vaccine, and a dose of MMRV vaccine. For a second dose of varicella vaccine in children aged 12 months through 12 years, at least 3 months should elapse between administration of any 2 doses of varicella vaccine, including single antigen varicella vaccine or MMRV vaccine.
- MMRV vaccine may be administered simultaneously with other vaccines.

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SUBJECT: MMRV

Dose	Customary Age	Age/Interval	Product
Primary 1	12–15 months	Not younger than 1st birthday	Proquad®*
Primary 2	4–6 years	At least 3 mo after 1 st dose**	Proquad®*

*refer to 3rd bullet on previous page

**not to be administered over the age of 12 years

Dose	Administration	
.5 ml	Subcutaneous	

Contraindications

- History of anaphylactic reaction to neomycin
- Allergic reaction to gelatin, other component of the vaccine, or after previous vaccination with MMRV vaccine, varicella vaccine or MMR vaccine. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.
- Altered immunity (i.e., blood dyscrasias, leukemia, lymphomas of any type, or other • malignant neoplasms affecting the bone marrow or lymphatic system)
- Primary or acquired immunodeficiency including AIDS or other clinical manifestation of • HIV infection, cellular immune deficiencies, hypogammaglobulinemia, and dysgammaglobulinemia
- Family history of congenital or hereditary immunodeficiencies, unless the immune compe-• tence of the potential vaccine recipient has been demonstrated
- Systemic immunosuppressive therapy, including oral steroids $\geq 2 \text{ mg/kg}$ of body weight or \geq 20 mg/day of prednisone or equivalent for persons who weigh \geq 10kg, when administered for ≥2 weeks
- Pregnancy ۲

Precautions

- Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on dose administered)
- History of thrombocytopenia or thrombocytopenic purpura
- . Moderate or severe acute illness with or without fever
- A personal or family (i.e., sibling or parent) history of seizures of any etiology. Children with a personal or family history of seizures of any etiology generally should be vaccinated with separate MMR vaccine and separate varicella vaccine.

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• Antiviral drugs active against herpesviruses (e.g., acyclovir and valacyclovir) might reduce the efficacy of live, attenuated varicella vaccines. These drugs should be discontinued ≥24 hours before administration of vaccines containing varicella zoster virus, if possible.

Adverse Events

See adverse events for MMR and varicella components in section 8 of this manual

Storage and Handling

- MMRV vaccine must be stored frozen between -58°F and +5°F (-50°C to -15°C). MMRV vaccine cannot be stored in the refrigerator.
- CDC strongly discourages transport of varicella-containing vaccines to off-site clinics. If these vaccines must be transported to an off-site clinic, the vaccine manufacturer recommends they be transported and stored at refrigerator temperatures, between 35°F and 46°F (2°C to 8°C), for no more than 72 continuous hours prior to reconstitution. Vaccine stored between 35°F and 46°F (2°C to 8°C) that is not used within 72 hours of removal from the freezer should be discarded. Varicella-containing vaccines cannot be refrozen.
- The diluent should be stored separately at room temperature or in the refrigerator.
- Discard if reconstituted vaccine is not used within 30 minutes.

Recommendations and side effects for MMR (page 8-26) and varicella (page 8-29) vaccines are applicable for the respective components of MMRV vaccine.

For further recommendations, refer to the 12/2/05 MMWR Vol. 54, No. MM47; 1212 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5447a4.htm and to the 05/07/10 MMWR Recommendations and Reports Vol. 59, RR03; 1–12 http://www.cdc.gov/mmwr/preview/ mmwrhtml/rr5903a1.htm?s_cid=rr5903a1_e

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SUBJECT: HEP B

Hepatitis B Vaccine

Schedule

Hepatitis B Vaccine—Routine Infant Schedule

Dose	Usual Age	Minimum Interval
Primary 1	Birth	
Primary 2	1–2 months	4 weeks after 1 st dose
Primary 3*	6–18 months	8 weeks after 2 nd dose & 16 weeks after 1 st dose
		—OR—
Primary 1	1–2 months	
Primary 2	4 months	4 weeks after 1 st dose
Primary 3*	6–18 months	8 weeks after 2 nd dose & 16 weeks after 1 st dose

*Third dose in infants:

- MINIMUM of 8 weeks after second dose, AND
- At least 16 weeks after first dose, AND •
- At least 24 weeks of age (third dose should not be given prior to this age)
- Please see combination vaccines for alternative schedules. •

It is not necessary to add doses or restart the series if the interval between doses is longer than that which is recommended.

Hepatitis B Vaccine Routine Adolescent and Adult Schedule

Dose	Usual Interval Minimum Interval	
Primary 1		
Primary 2	1 month	4 weeks
Primary 3	5 months	*8 weeks

* Minimum schedule—The series should not be given in less than 4 months.

- The second dose should be administered at least 4 weeks after the first dose, and the third 1 dose should be administered at least 16 weeks after the first dose and at least 8 weeks after the second dose. (MMWR. Nov 22, 1996, Vol.45/No. RR-13)
- For adults and children with normal immune status, booster doses of vaccine are not rou-~ tinely recommended, nor is routine serologic testing to assess immune status of vaccinees indicated. The need for booster doses after longer intervals will continue to be assessed as additional information becomes available.

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SUBJECT: HEP B

Merck's 2-dose Hepatitis B (Recombivax) Schedule

- The 2-dose Recombivax (10µg/1.0cc/dose) schedule is approved **only for adolescents 11 through 15 years** of age. It must **NOT** be started prior to age 11 years and must be completed before the child's 16th birthday. If an adolescent has already begun the routine 3dose schedule, he or she should not be changed to the new 2-dose schedule.
- For the purposes of rules pertaining to immunization requirements of students attending school, documentation issues become critical and more complex with the 2-dose schedule.*
- * The provider must document that the adolescent, when aged 11–15 years, has received two doses of Recombivax HB using the adult dose (1.0cc containing 10µg of Hepatitis B surface antigen), with the second dose given 4–6 months after the first dose. The specific name of the vaccine, the exact dose of antigen per injection, and the dates of administration must be included as part of the documentation.

Dosage	Administration	
See chart below	Intramuscular (IM) Infants and neonates—Anterolateral thigh Adults and children—deltoid muscle	

Note: **Never select dose based on volume (cc) alone:** instead, select dose based on micrograms you wish to administer. The same 0.5cc dose may contain 5 or 10µg of hepatitis B surface antigen.

	Single-Antigen Vaccine			Combination Vaccine						
	Recomb	ivax HB	Enge	erix-B	Comvax Pediarix			arix	Twinrix	
Age Group	Dose (µg)*	Volume (mL)	Dose (µg)*	Volume (mL)	Dose (µg)*	Volume (mL)	Dose (µg)*	Volume (mL)	Dose (µg)*	Volume (mL)
Infants (<1 yr)	5	0.5	10	0.5	5	0.5	10	0.5	N/A**	N/A
Children (1-10 yrs)	5	0.5	10	0.5	5	0.5	10	0.5	N/A	N/A
Adolescents										
11-15 yrs	10 [†]	1.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
11-19 yrs	5	0.5	10	0.5	N/A	N/A	N/A	N/A	N/A	N/A
Adults (<u>></u> 20 yrs)	10	1.0	20	1.0	N/A	N/A	N/A	N/A	20	1.0
Hemodialysis patients and other immunocompromised persons										
<20 yrs [§]	5	0.5	10	0.5	N/A	N/A	N/A	N/A	N/A	N/A
<u>≥</u> 20 yrs	40 [¶]	1.0	40 [‡]	2.0	N/A	N/A	N/A	N/A	N/A	N/A

Decommonded decose of ourrently	licenced formulations of	f hanatitia D vasaina	hu aga graun and	lucacina tura
Recommended doses of currently	/ licensed formulations of	of nepatitis B vaccine,	by age group and	і vaccine type

* Recombinant hepatitis B surface antigen protein dose.

† Adult formulation administered on a 2-dose schedule.

§ Higher doses might be more immunogenic, but no specific recommendations have been made.

Pialysis formulation administered on a 3-dose schedule at age 0, 1, and 6 months.

Two 1.0 mL doses administered at one site, on a 4-dose schedule at age 0, 1, 2, and 6 months.

** Not applicable.

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SUBJECT: НЕР В

Contraindications and Precautions

- Severe allergic reaction to a vaccine component (yeast) or following a previous dose. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.
- Persons with moderate to severe illness should not be vaccinated until their conditions improve

Adverse Events

- Pain at the site of injection—Adults 13%–29%; Infants and Children 3%–9%
- Mild systemic complaints—fatigue, headache and irritability—Adults 11%–17%; Infants and Children 0%–20%
- Low grade fever—Adults 1%; Infants and Children 0.4%–6.0%
- Serious systemic adverse events and allergic reactions are rarely reported

Storage and Handling

- Use insulated container
- Must be shipped with ice packs
- Should not have been frozen
- Refrigerate on arrival
- Store at 2° to 8°C (35° to 46°)
- Do not freeze

Special Considerations

Prevention of Perinatal Hepatitis B Virus Infections (Also see Labor & Delivery Unit and Nursery Unit Guidelines to Prevent HBV Transmission, under Section 12.)

- Begin treatment within 12 hours of birth
- Hepatitis B vaccine (first dose) and hepatitis B immune globulin (HBIG) at different sites
- Give 2nd dose at 1 month of age. Complete vaccination schedule at 6 months of age.
- Test for antibody response after third dose, when child is at least 9 months of age

Product	Manufacturer(s)
Recombivax HB	Merck & Co., Inc.
Engerix-B	Glaxo Smith Kline

Thimerosal-Free Vaccine and Birth Dose

- Thimerosal-free hepatitis B vaccines are widely available
- Hospitals should have hepatitis B vaccination birth dose policies for all newborn infants

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SECTION-PAGE: 8-38

SUBJECT: HEP A

Hepatitis A Vaccine

Schedule

Candidates for Vaccination

- Routine vaccination in Colorado should be considered in persons ≥12 months of age •
- The following groups are at increased risk and should be identified and vaccinated:
 - Travelers to countries with high or intermediate risk of hepatitis A infection (all areas 1 of the world except Canada, Western Europe, Scandinavia, Japan, New Zealand, Australia)
 - 1 Men who have sex with other men
 - 1 Users of illegal injectable drugs
 - 1 Persons with clotting factor disorders
 - ~ Persons with chronic liver disease
 - Persons with occupational risk of infection. Includes those who work with hepatitis ~ A-infected primates or with hepatitis A virus in a laboratory setting. No other groups (e.g., health care workers, sewer workers, day care workers, restaurant workers) have been shown to be at increased risk of infection due to occupational exposure
 - 1 Previously unvaccinated household members and other close personal contacts (e.g., regular babysitters) of adopted children newly arriving from countries with high or intermediate hepatitis A endemicity.

Recommended Doses of Havrix® Hepatitis A Vaccine					
Group	Age	Dose (EL.U.)	Volume	No. Doses	Schedule*
Children and Adolescents	1–18 years	720	0.5mL	2	0, 6–12
Adults	≥19 years	1,440	1.0 mL	2	0, 6–12

Recommended Doses of VAQTA® Hepatitis A Vaccine					
Group	Age	Dose (U)	Volume	No. Doses	Schedule*
Children and Adolescents	1–18 years	25	0.5mL	2	0, 6–18
Adults	≥19 years	50	1.0 mL	2	0, 6–18

*Months: 0 represents timing of the initial dose; subsequent number(s) represent months after the initial dose.

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SUBJECT: HEP A

Use of Hep A Vaccine for Post-Exposure Prophylaxis

Persons who recently have been exposed to HAV and who previously have not received hepatitis A vaccine should be administered a single dose of vaccine or IG (0.02 mL/kg) as soon as possible. Information about the relative efficacy of vaccine compared to IG postexposure is limited, and no data are available in persons >40 years of age or those with underlying medical conditions. Therefore, decisions to use vaccine or IG should take into account patient characteristics associated with more severe manifestations of hepatitis A, including older age and chronic liver disease. Additionally, the magnitude of the risk of HAV transmission from the exposure should be considered.

- For healthy persons age \geq 12 months–40 years, hepatitis A vaccine at the age appropriate dose is preferred to IG because of vaccine's advantages, including long term protection and ease of administration.
- For persons >40 years of age, IG is preferred because of the absence of information regarding vaccine performance and the more severe manifestations of hepatitis A in this age group. Vaccine can be used if IG cannot be obtained.
- IG should be used for children age <12 months, immunocompromised persons, persons • who have been diagnosed with chronic liver disease, and persons for whom vaccine is contraindicated.

Persons administered IG for whom hepatitis A vaccine is also recommended should receive a dose of vaccine simultaneously with IG. For persons who receive vaccine, the second dose should be administered according to the licensed schedule to complete the series. The efficacy of IG or vaccine when administered >2 weeks after exposure has not been established.

Contraindications

- Severe allergy to vaccine component or following prior dose. Both vaccines contain aluminum. Havrix contains the preservative 2-phenoxyethanol. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.
- Moderate or severe acute illness

Adverse Events

- Injection site complaints (i.e., pain, redness, swelling)-20%-50% of recipients
- Systemic reactions uncommon— <10% of recipients

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SUBJECT: HEP A

Storage and Handling

- Should not be frozen
- Should be stored and shipped at temperatures ranging from 35.0°F (2°C) to 46.0°F (8°C)

Product	Manufacturer	Licensed
Havrix	Glaxo Smith Kline	For persons ≥12 months of age
Vaqta	Merck & Co., Inc.	For persons ≥12 months of age

Special Considerations

- No efficacy or safety data available for interchangeability of brands
- If originally-used product is not available or known, vaccination with either product is acceptable
- Children whose first dose was Havrix 360 EL.U. or unknown should receive 2 additional doses of any pediatric or hepatitis A vaccine formulation
- Prevaccination serologic testing of children not indicated because of their expected low prevalence of infection
- Prevaccination serologic testing will probably be most cost effective for:
 - ✓ Adults born in or who have lived for extensive periods in geographic areas that have a high endemicity of HAV infection (e.g., Central and South America, Africa, Asia)
 - ✓ Older adolescents and adults in certain populations (i.e., Native Americans, Alaskan Natives, Hispanics)
 - ✔ Adults >40 years old
- Post vaccination testing not indicated because of high rate of vaccine response among adults and children

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SECTION-PAGE: 8-41

SUBJECT: HEP A/HEP B

Combined Hep A-Hep B Vaccine (TWINRIX™)

(Hepatitis A and Hepatitis B Vaccine)

Schedule

As a general rule, combination vaccines may be used when all the components are indicated.

- Only one combination Hep A–Hep B vaccine (TWINRIX[™]) has been licensed.
- This vaccine is currently licensed for the following indications: •
 - ✓ For adults \geq ages 18 years.
 - ✓ Adults with indications for both Hep A and Hep B vaccines

Routine Schedule	0 (dose #1)	1 month (dose #2)	6–12 months (dose #3)
Minimum Age	18 years		
Minimum Intervals	N/A	4 weeks between dose #1 and dose #2	5 months between dose #2 and dose #3 AND 6 months between dose #1 and dose #3
Accelerated Dosing Schedule*	7 days between dose #1 and dose #2	21–30 days between dose #1 and dose #3	Booster dose 12 months after 1st dose

*per FDA approval 4/2/07—for more information refer to www.gsk.com

Administration Dosage

1.0cc Intramuscularly (IM)

Contraindications

- Children (less than age 18 years).
- The same as those for its individual component vaccines (i.e., Hep B pg. 8-37, Hep A pg. • 8-39).
- A list of components (including any latex, thimerosal, or antibiotic content) for each vac-• cine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.

Precautions (Warning)

The same as those for its individual component vaccines (i.e., Hep B pg. 8-37, Hep A pg. 8-39).

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SUBJECT: HEP A/HEP B

Adverse Events

The same as those for its individual component vaccines (i.e., Hep B pg. 8-37, Hep A pg. 8-39).

General Storage and Handling

- Refrigerate immediately upon arrival
- Store continuously at a temperature of 2°–8°C (35°–46°F).

Special Considerations

TWINRIX[™] is licensed only for adults.

The recommended interval between dose #1 and #2 is one month and between dose #2 and dose #3 is 6–12 months. The minimum interval between doses #1 and #2 is 4 weeks and between doses #2 and #3 is 5 months AND 6 months between doses #1 and #3.

Following one dose of TWINRIXTM, the Hep A schedule may be completed with two doses of adult formulation Hep A vaccine administered at least 5 months apart.

Following two doses of TWINRIXTM the Hep A schedule may be completed with one adult formulation Hep A vaccine administered > 5 months later.

Following one dose of adult formulation Hep A vaccine, the Hep A schedule may be completed with two doses of TWINRIXTM.

Because the Hep B component of TWINRIXTM is equivalent to a standard dose of Hep B vaccine, the schedule is the same whether TWINRIXTM or single-antigen Hep B vaccine is used.

Product	Manufacturer(s)	Licensed
TWINRIX™	Glaxo Smith Kline	May, 2001; only for Adults

For further information, refer to page 109 of the 12th edition of pink book, http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hepa.pdf

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Revised: 5/1/11

SUBJECT: PCV13

PCV13

(13-Valent Pneumococcal Conjugate Vaccine)

PCV13 is recommended for all children 2 through 59 months of age, and for children 60 through 71 months of age who have underlying medical conditions that increase their risk of pneumococcal disease or complications (table 3). See recommendations below for transition from PCV7 to PCV13 for children who have already started a schedule with PCV7 (table 2).

Schedule

Table 1. Recommended routine vaccination schedule for 13-valent pneumococcal conjugate vaccine (PCV13) among infants and children who have not received previous doses of 7-valent vaccine (PCV7) or PCV13, by age at first dose— Advisory Committee on Immunization Practices (ACIP), United States, 2010

Age at first dose (mos)	Primary PCV13 series*	PCV13 booster dose†
2-6	3 doses	1 dose at age 12–15 mos
7-11	2 doses	1 dose at age 12–15 mos
12–23	2 doses	—
24–59 (Healthy children)	1 dose	—
24–71 (Children with certain chronic diseases or immunocompromising conditions§)	2 doses	_

* Minimum interval between doses is 8 weeks except for children vaccinated at age <12 months for whom minimum interval between doses is 4 weeks. Minimum age for administration of first dose is 6 weeks.

† Given at least 8 weeks after the previous dose.

§ For complete list of conditions, see Table 3.

Table 2. Recommended transition schedule from 7-valent pneumococcal conjugate vaccine (PCV7) to 13-valent vaccine
(PCV13) vaccination among infants and children, according to number of previous PCV7 doses received—Advisory
Committee on Immunization Practices (ACIP), United States, 2010

Infant series			Booster dose	Supplemental PCV13 dose
2 mos	4 mos	6 mos	≥12 mos*	14-59 mos†
PCV7	PCV13	PCV13	PCV13	—
PCV7	PCV7	PCV13	PCV13	—
PCV7	PCV7	PCV7	PCV13	—
PCV7	PCV7	PCV7	PCV7	PCV13

* No additional PCV13 doses are indicated for children age 12–23 months who have received 2 or 3 doses of PCV before age 12 months and at least 1 dose of PCV13 at age ≥12 months.

† For children with underlying medical conditions (see Table 1), a single supplemental PCV13 dose is recommended through age 71 months

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SUBJECT: PCV13

Table 3. Underlying medical conditions that are indications for pneumococcal vaccination among children, by risk group—Advisory Committee on Immunization Practices (ACIP), United States, 2010

Risk group	Condition
	Chronic heart disease*
	Chronic lung diseaset
Immunocompetent children	Diabetes mellitus
	Cerebrospinal fluid leaks
	Cochlear implant
Children with functional or anatomic asplenia	Sickle cell disease and other hemoglobinopathies Congenital or acquired asplenia, or splenic dysfunction
	HIV infection
	Chronic renal failure and nephrotic syndrome
Children with immunocompromising conditions	Diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; or solid organ transplantation
	Congenital immunodeficiency§

* Particularly cyanotic congenital heart disease and cardiac failure

† Including asthma if treated with prolonged high-dose oral corticosteroids

§ Includes B- (humoral) or T-lymphocyte deficiency; complement deficiencies, particularly C1, C2, C3, and C4 deficiency; and phagocytic disorders (excluding chronic granulomatous disease)

Contraindications

• Severe allergic reaction (e.g., anaphylaxis) to any component of Prevnar 13, Prevnar or any diphtheria toxoid-containing vaccine. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.

Adverse Reactions

- Pain, redness and swelling at the injection site
- Fever, decreased appetite, irritability, and decreased/increased sleep
- Reactions similar to what has been observed with PCV7, which has a good safety record in the United States

Precautions

• Safety of PCV13 during pregnancy has not been evaluated.

How Supplied

Pre-filled Syringe, 1 Dose (10 per package). The vial stopper, the tip cap and rubber plunger of the pre-filled syringe do not contain latex.

Storage

Store refrigerated at $+2^{\circ}$ C to $+8^{\circ}$ C (36° F to 46° F). Do not freeze.

For further information, refer to the March 12, 2010 issue of the *MMWR* 59(09);258–261 http://www.cdc.gov/vaccines/recs/provisional/downloads/pcv13-mar-2010-508.pdf and the December 10, 2010 MMWR available at http://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf

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Revised: 5/1/11

SUBJECT: INFLUENZA

Influenza Vaccine

- Both the inactivated influenza vaccine and live, attenuated influenza vaccine (LAIV) can be used to reduce the risk of influenza. LAIV is only approved for use among healthy persons aged 2–49 years. Inactivated influenza vaccine is approved for persons aged ≥6 months, including those with high-risk conditions (see following sections on inactivated influenza vaccine and live, attenuated influenza vaccine).
- Influenza activity peaks between late December and early March. Optimal time for vaccination programs is October through mid-November. May start earlier if necessary.
- A newly approved inactivated trivalent vaccine containing 60 mcg of hemagglutinin antigen per influenza vaccine virus strain (Fluzone High-Dose [sanofi pasteur]) is an alternative inactivated vaccine for persons aged ≥65 years. Persons aged ≥65 years can be administered any of the standard-dose TIV preparations or Fluzone High-Dose. Persons aged <65 years who receive inactivated influenza vaccine should be administered a standard-dose (depending on age) TIV preparation.
- Previously approved inactivated influenza vaccines that were approved for expanded age indications in 2009 include Fluarix (GlaxoSmithKline), which is now approved for use in persons aged ≥3 years, and Afluria (CSL Biotherapies), which is now approved for use in persons aged ≥6 months. A new inactivated influenza vaccine, Agriflu (Novartis), has been approved for persons aged ≥18 years.
- With the exception of influenza vaccine and PPSV23 given to adults, providers should only accept written, dated records as evidence of vaccination; self-reported doses of influenza vaccine and PPSV23 are acceptable.

Annual Vaccination against Influenza is Recommended for:

• All persons 6 months of age and older

Eligible Groups for INACTIVATED Influenza Vaccine

• Persons aged ≥6 months, including those with high-risk conditions

Contraindications to Inactivated Influenza Vaccine

The following populations should not be vaccinated:

- Persons with a severe allergic reaction to a previous dose of influenza vaccine, or to a vaccine component (e.g. eggs, thimerosal) should not receive influenza vaccine. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.
- Persons with moderate to severe acute illness normally should not be vaccinated until their symptoms have decreased.

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SUBJECT: INFLUENZA

Precautions to Inactivated Influenza Vaccine

History of Guillain-Barré Syndrome following influenza vaccination

Schedule

Age Group	Dosage	Number of doses	Route
6–35 months	0.25cc	1 or 2*	IM
3–8 years	0.50cc	1 or 2*	IM
≥9 years	0.50 сс	1	IM

*Children ≥6 months-8 years who have never received a seasonal influenza vaccine before or who did not receive ≥1 dose of a 2009 H1N1 monovalent vaccine should receive 2 doses, spaced ≥4 weeks apart. Those children aged 6 months-8 years who were vaccinated for the 1st time during the 2009–2010 season with the seasonal 2009–10 vaccine but who received only 1 dose of seasonal influenza vaccine should receive 2 doses in the following year, spaced ≥4 weeks apart.

Adverse Events to Inactivated Influenza Vaccine

- Local reactions (soreness, erythema, induration)—15%–20%
- Non-specific systemic symptoms (fever, chills, malaise, and myalgias)-uncommon
- Rarely, immediate hypersensitivity, presumably allergic, reactions (such as hives, angioedema, allergic asthma, or systemic anaphylaxis)
- Neurologic reactions—very rare (specifically Guillain-Barré Syndrome)

Storage and Handling of Inactivated Influenza Vaccine

- Should be delivered in the shortest possible time
- Should not be exposed to excessive temperatures
- Should not have been frozen-do not freeze •
- Refrigerate immediately on arrival—store at 2° to 8°C (35° to 46°F). .

Eligible Groups for LIVE ATTENUATED Influenza Vaccine

All healthy children and adults aged 2 years through 49 years who are not pregnant

Contraindications to LAIV

The effectiveness or safety of LAIV is not known for the following groups, and these persons should not be vaccinated with LAIV:

- persons with a history of hypersensitivity, including anaphylaxis, to any of the components of LAIV or to eggs. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.
- persons aged <2 years or those aged \geq 50 years

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SUBJECT: INFLUENZA

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- persons with any of the underlying medical conditions that serve as an indication for routine influenza vaccination, including asthma, reactive airways disease, or other chronic disorders of the pulmonary or cardiovascular systems; other underlying medical conditions, including such metabolic diseases as diabetes, renal dysfunction, and hemoglobinopathies; or known or suspected immunodeficiency diseases or immunosuppressed states
- children aged 2–4 years whose parents or caregivers report that a health-care provider has told them during the preceding 12 months that their child had wheezing or asthma, or whose medical record indicates a wheezing episode has occurred during the preceding 12 months
- children or adolescents receiving aspirin or other salicylates (because of the association of Reye syndrome with wild-type influenza virus infection)
- persons with a history of GBS after influenza vaccination
- pregnant women

Severely immunocompromised persons should not administer LAIV.

The vaccine does not need to be repeated even if the patient coughs or sneezes immediately after receiving the dose.

LAIV can be administered to persons with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infection with or without fever). However, if nasal congestion is present that might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration should be considered until resolution of the illness. LAIV should not be administered until 48 hours after cessation of therapy with antiviral influenza drugs. If feasible, to avoid possible reduction in vaccine effectiveness, antiviral medication should not be administered for 14 days after LAIV administration.

Schedule

Age Group	Dosage	Number of doses	Route
2–8 years	0.2cc (0.1cc per nostril)	1 or 2*	Intranasal
≥9 years	0.2cc (0.1cc per nostril)	1	Intranasal

*Children \geq 6 months-8 years who have never received a seasonal influenza vaccine before or who did not receive \geq 1 dose of a 2009 H1N1 monovalent vaccine should receive 2 doses, spaced \geq 4 weeks apart. Those children aged 6 months-8 years who were vaccinated for the 1st time during the 2009–2010 season with the seasonal 2009–10 vaccine but who received only 1 dose of seasonal influenza vaccine should receive 2 doses in the following year, spaced \geq 4 weeks apart.

Adverse Events to LAIV

• Nasal congestion, sore throat, headache, vomiting, myalgia

Storage and Handling of LAIV

- Refrigerate immediately upon arrival.
- Store at 35° to 46° F (2° to 8°C).
- Do not freeze or expose to freezing temperatures.

Refer to the August 6, 2010 available at http://www.cdc.gov/mmwr/pdf/rr/rr5908.pdf for additional information.

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SUBJECT: PNEUMOCOCCAL POLYSACCHARIDE (PPSV23)

Pneumococcal Polysaccharide Vaccine—23 Valent

Schedule

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- PSV23 should be administered to adults aged 19–64 years with chronic or immunosuppressing medical conditions, including those who have asthma.
- Adults aged 19–64 years who smoke cigarettes should receive PPSV23 and smoking cessation guidance.
- Routine PPSV23 use is no longer recommended for Alaska Natives or American Indians aged <65 years unless they have medical indications for PPSV23. However, in certain situations, public health authorities may recommend PPSV23 for Alaska Natives and American Indians aged 50–64 years who are living in areas where the risk for invasive pneumococcal disease is increased.
- All persons should be vaccinated with PPSV23 at age 65 years. Those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years or later if at least 5 years have passed since their previous dose. Those who receive PPSV23 at or after age 65 years should receive only a single dose.
- ACIP does not recommend routine revaccination for most persons for whom PPSV23 is indicated. A second dose of PPSV23 is recommended 5 years after the first dose for persons aged 19–64 years with functional or anatomic asplenia and for persons with immuno-compromising conditions. ACIP does not recommend multiple revaccinations because of uncertainty regarding clinical benefit and safety.
- With the exception of influenza vaccine and PPSV23 given to adults, providers should only accept written, dated records as evidence of vaccination; self-reported doses of influenza vaccine and PPSV23 are acceptable.

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SUBJECT: PNEUMOCOCCAL POLYSACCHARIDE (PPSV23)

TABLE 1. Underlying medical conditions or other indications for administration of 23-valent pneumococcal polysaccharide vaccine (PPSV23) among adults aged 19-64 years, by risk group—Advisory Committee on Immunization Practices, (ACIP) 2010

Risk group	Underlying medical condition or other indication
	Chronic heart disease (excluding hypertension)*
	Chronic lung disease [†]
	Diabetes mellitus
	Cerebrospinal fluid leaks
Immonocompetent persons	Cochlear implant
	Alcoholism
	Chronic liver disease, including cirrhosis
	Cigarette smoking
Persons with functional or anotomic asplanias	Sickle cell disease and other hemoglobinopathies
reisons with functional of analomic aspientas	Congenital or acquired asplenia, splenic dysfunction, or splenectomy
	Congenital or acquired immunodeficiencies [¶]
	HIV infection
	Chronic renal failure
	Nephrotic syndrome
	Leukemias
Immunocompromised persons§	Lymphomas
	Hodgkin disease
	Generalized malignancy
	Diseases requiring treatment with immunosuppressive drugs, including
	long-term systemic corticosteroids or radiation therapy
	Solid organ transplantation
	Multiple myeloma

* Including congestive heart failure and cardiomyopathies.

[†] Including chronic obstructive pulmonary disease, emphysema, and asthma.

§ A second dose of PPSV23 is recommended 5 years after the first dose for persons with functional or anatomic asplenia and for immunocompromised persons.

Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease).

Child and Adolescent Recommendations—Polysaccharide Vaccine (PPSV23) to Prevent Pneumococcal Disease

ELIGIBLE GROUPS

Administration of PPSV23 After PCV7 Or PCV13 Among Children Aged 2-18 Years Who Are at Increased Risk for Pneumococcal Disease

Children aged ≥ 2 years with underlying medical conditions (Table 2) should receive PPSV23 after completing all recommended doses of PCV13. These children should be given 1 dose of PPSV23 at age \geq 2 years and at least 8 weeks after the most recent dose of PCV13.

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SUBJECT: PNEUMOCOCCAL POLYSACCHARIDE (PPSV23)

- Children who have received PPSV23 previously also should receive recommended PCV13 doses.
- Children aged 24–71 months with underlying medical conditions who received <3 doses of PCV7 before age 24 months should receive a series of 2 doses of PCV13 followed by 1 dose of PPSV23 administered ≥8 weeks later.
- Children aged 24-71 months with underlying medical conditions who received any incomplete schedule of 3 doses of PCV7 before age 24 months should receive 1 dose of PCV13 followed by 1 dose of PPSV23 administered ≥ 8 weeks later.

Revaccination With PPSV23 Among Children at Highest Risk

A second dose of PPSV23 is recommended 5 years after the first dose of PPSV23 for children who have anatomic or functional asplenia, including SCD, HIV infection, or other immunocompromising conditions (Table 3). No more than 2 PPSV23 doses are recommended.

American Indian/Alaska Native Children

Routine use of PPSV23 after PCV7 or PCV13 is not recommended for American Indian/Alaska Native children aged ≥ 24 months without underlying medical conditions. However, in special situations, public health authorities might recommend use of PPSV23 after PCV7 or PCV13 for American Indian/Alaska Native children who are living in areas/communities in which risk for invasive pneumococcal disease is increased.

Risk group	Condition
	Chronic heart disease*
	Chronic lung disease [†]
Immunocompetent children	Diabetes mellitus
	Cerebrospinal fluid leaks
	Cochlear implant
Children with functional or	Sickle cell disease and other hemoglobinopathies
anatomic asplenia	Congenital or acquired asplenia, or splenic dysfunction
	HIV infection
	Chronic renal failure and nephrotic syndrome
Children with immunocom- promising conditions	Diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas and Hodgkin disease; or solid organ transplantation
	Congenital immunodeficiency§

TABLE 2. Underlying medical conditions that are indications for	pneumococcal vaccination among	g children, b	y risk group
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Source: Advisory Committee on Immunization Practices, 2010.

* Particularly cyanotic congenital heart disease and cardiac failure.

[†] Including asthma if treated with high-dose oral corticosteroid therapy.

§ Includes B- (humoral) or T-lymphocyte deficiency; complement deficiencies, particularly C1, C2, C3, and C4 deficiency; and phagocytic disorders (excluding chronic granulomatous disease).

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SUBJECT: PNEUMOCOCCAL POLYSACCHARIDE (PPSV23)

TABLE 3. Schedule for vaccination using 23-valent polysaccharide vaccine (PPSV23) after 13-valent pneumococcal conjugate vaccine (PCV13) for children aged ≥2 years with underlying medical conditions

Group	Schedule for PPSV23	Revaccination with PPSV23
Children who are immunocompromised, have sickle cell disease, or functional or anatomic asplenia	1 dose of PPSV23 administered at age ≥2 yrs and ≥8 weeks after last indicated dose of PCV13	1 dose 5 years after the first dose of PPSV23
Immunocompetent children with chronic illness*	1 dose of PPSV23 administered at age ≥2 yrs and ≥8 weeks after last indicated dose of PCV13	Not recommended

* Chronic heart disease, chronic lung disease, diabetes mellitus, cerebrospinal fluid leaks, or cochlear implant.

Administration Dosage

0.5cc Intramuscular (IM) or Subcutaneously (SC)

Contraindications

- Severe allergic reaction to vaccine component or following prior dose. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.
- Moderate or severe acute illness

Adverse Events

- 30% to 50% report pain, swelling, or erythema at the site of injection
- Fever and myalgias—uncommon
- Severe systemic adverse events are rare

Storage and Handling

- Should be shipped in insulated container with ice packs. Do not freeze •
- Refrigerate immediately on arrival—should not have been frozen •
- Store at 2° to 8° C (35° to 46° F) •

Product	Manufacture(s)
Pneumovax 23	Merck & Co., Inc.

Special Considerations

Timing of vaccination

- If elective splenectomy or cochlear implant is being considered, vaccinate at least 2 weeks before surgery.
- There should be a 2 week interval between vaccination and initiation of cancer chemotherapy or other immunosuppressive therapy

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SUBJECT: MENINGOCOCCAL VACCINE

Meningococcal Vaccine

(Neisseria meningitides serogroups A, C, Y, and W-135)

Both the polysaccharide (MPSV4) and conjugated (MCV4) vaccines can be used to reduce the risk of meningococcal disease. MPSV4 is licensed for use in persons aged 2 yrs and older and is the only meningococcal vaccine licensed for persons over age 55. MCV4 is the vaccine of choice for persons aged 2–55 years. There are 2 MCV4 vaccines currently available: Menactra[®] (sanofi pasteur) and Menveo[®] (Novartis Vaccines and Diagnostics). Both Menactra[®] and Menveo[®] are licensed for use in persons 2–55 years.

Schedule

Recommendation for Routine Vaccination of Persons 11–18 Years

- ACIP recommends routine vaccination of persons with MCV4 at age 11–12 years, with a booster dose at age 16 years.
- For adolescents who received the 1st dose at age 13–15 years, a one-time booster dose should be administered, preferably at age 16–18 years.
- Persons who receive their first dose of MCV4 at ≥ 16 years do not need a booster dose.

Recommendation for Persons Aged 2–54 Years with Reduced Immune Response

- Persons with persistent complement component deficiencies (e.g., C5–C9, properidin, Factor H, or Factor D) or asplenia should receive a 2-dose primary series administered 2 months apart and then receive a booster dose every 5 years.
- Adolescents aged 11–18 years with HIV infection should be routinely vaccinated with a 2dose primary series. Other persons with HIV who are vaccinated should receive a 2-dose primary series administered 2 months apart.

Additional Considerations:

- All other persons at increased risk for meningococcal disease (e.g., microbiologists or travelers to an epidemic or highly endemic country) should receive a single dose.
- Routine vaccination of healthy persons who are not at increased risk for exposure to *N*. *meningitidis* is not recommended after age 21 years.
- Some colleges and universities have policies requiring vaccination against meningococcal disease as a condition of enrollment. For ease of program implementation, persons aged ≤21 years should have documentation of receipt of a dose of MCV4 ≤5 years before enrollment. If the primary dose was administered ≤15 years, a booster dose should be administered before enrollment in college. The booster dose can be administered anytime after the 16th birthday.
- The minimum interval between doses of MCV4 is 8 weeks.

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SUBJECT: MENINGOCOCCAL VACCINE

Precautions

- Persons with moderate to severe acute illness normally should not be vaccinated until their symptoms have decreased.
- Any person who has ever had Guillain-Barré Syndrome.
- Providers should take appropriate measures to prevent injuries if a patient becomes weak or dizzy or loses consciousness after vaccination. Adolescents and adults should be seated or lying down during vaccination. Vaccine providers, particularly when vaccinating adolescents, should consider observing patients (with patients seated or lying down) for 15 minutes after vaccination to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve.

Contraindications

• Persons with a severe allergic reaction to a previous vaccine dose, or to a vaccine component. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.

Schedule

TABLE 1. Summary of meningococcal conjugate vaccine recommendations, by risk group—Advisory Committee on Immunization Practices (ACIP), 2010

Risk group	Primary series	Booster dose
	1 1 1	At age 16 years if primary dose at age 11 or 12 years
Persons aged 11 through 18 years	ably at age 11	At age 16 through 18 years if primary dose at age 13 through 15 years
	or 12 years	No booster needed if primary dose on or after age 16 years
		At age 16 years if primary dose at age 11 or 12 years
HIV-infected persons in this age group	2 doses, 2 months apart	At age 16 through 18 years if primary dose at age 13 through 15 years
		No booster needed if primary dose on or after age 16 years
Persons aged 2 through 55 years with per-	2 daga 2	Every 5 years
sistent complement component deficiency* or functional or anatomical asplenia	months apart	At the earliest opportunity if a 1-dose primary series administered, then every 5 years
Persons aged 2 through 55 years with pro-	1 daga	Persons aged 2 through 6 years: after 3 years
longed increased risk for exposure [†]		Persons aged 7 years or older: after 5 years§

Abbreviation: HIV = human immunodeficiency virus.

* Such as C5–C9, properidin, or factor D.

[†] Microbiologists routinely working with *Neisseria meningitidis* and travelers to or residents of countries where meningococcal disease is hyperendemic or epidemic.

§ If the person remains at increased risk.

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SUBJECT: MENINGOCOCCAL VACCINE

Adverse Events

- Local reactions (soreness, erythema, induration, tenderness at injection site)
- Occasional low-grade fever and mild systemic reactions such as headache and malaise
- Severe systemic reactions rare
- A few cases of Guillain-Barré Syndrome have been reported among people who received MCV4 vaccine. Currently health officials are investigating evidence to determine causality.

Storage and Handling

- Refrigerate immediately on arrival
- Store continuously at a temperature of 2° to 8°C (35° to 46°F)
- Discard remainder of multi-dose vials of vaccine within 10 days after reconstitution
- Single dose vial should be used within 30 minutes after reconstitution

Products	Manufacturer
Menomune®	Sanofi Pasteur, Inc.
Menactra®	Sanofi Pasteur, Inc.
Menveo®	Novartis Vaccines and Diagnostics

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ЅИВЈЕСТ: НРV

HPV Vaccine

Human Papillomavirus Vaccine

Schedule

Routine vaccination with three doses of HPV vaccine is recommended for females 11-12 years of age. The series can be started in females as young as 9 years of age. HPV vaccine is also recommended for females aged 13 through 26 years who have not been previously vaccinated or who have not completed the full vaccination series. There are two HPV vaccines currently licensed in the United States. The quadrivalent vaccine, Gardasil[®], is manufactured by Merck; the bivalent vaccine, Cervarix[®], is manufactured by GSK. Both are licensed for use in females. The quadrivalent vaccine, Gardasil[®], is also approved for use in males, aged 9 through 26 years, to reduce their likelihood of acquiring genital warts. The bivalent vaccine, Cervarix[®], is not approved for use in males.

Dose	Customary Age	Age/Minimum Intervals	Product Females	Product Males**
Primary 1	11–12 years*	9–26 years	Gardasil®, Cervarix®	Gardasil®
Primary 2	2 months after 1 st dose	at least 4 weeks after 1 st dose	Gardasil®, Cervarix®	Gardasil®
Primary 3	6 months after 1 st dose	at least 12 weeks after 2 nd dose and at least 24 weeks after 1 st dose	Gardasil®, Cervarix®	Gardasil®

*Can be given as early as 9 years of age; Catch up vaccination is recommended for females 13–26 years of age who have not been vaccinated previously or who have not completed the full vaccine series.

** The 3 dose series of quadrivalent HPV (Gardasil®) may be given to males, aged 9 through 26 years, to reduce their likelihood of acquiring genital warts.

Dose	Administration

0.5 ml Intramuscular (IM) (deltoid)

- Ideally, quadrivalent HPV vaccine should be administered before potential exposure to HPV through sexual contact. However, sexually active persons will still benefit from getting the vaccine. Sexually active persons who have not been infected with any of the four HPV strains will receive full benefit from the vaccine; sexually active persons infected with one strain of HPV would still be protected against the other strains included in the vaccine.
- ACIP recommends vaccination with either the bivalent (Cervarix®) or the quadrivalent (Gardasil®) vaccine for the prevention of cervical cancers and precancers, and vaccination with the quadrivalent vaccine for prevention of cervical cancers and precancers, genital warts, and anal cancer.
- HPV vaccine can be administered at the same visit when other age appropriate vaccines are provided, such as Tdap, Td and/or MCV4.
- At present, cervical cancer screening (pap test) recommendations have not changed for females who receive HPV vaccine.

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SUBJECT: HPV

- Whenever possible, the same HPV vaccine product should be used for all doses in the series.
- ACIP states that if a female reaches age 26 years before the vaccination series is complete, the remaining doses can be administered after 26 years.
- Because of lack of efficacy data for HPV vaccine administration using minimum intervals, providers are encouraged, when possible, to use routine dosing intervals for females 11–26 years who have not yet received 3 HPV vaccine doses as recommended.

Contraindications

- HPV vaccines are contraindicated for persons with a history of immediate hypersensitivity to any vaccine component. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.
- Quadrivalent HPV vaccine is contraindicated for persons with a history of immediate hypersensitivity to yeast.
- Bivalent HPV vaccine in prefilled syringes is contraindicated for persons with anaphylactic latex allergy.

Adverse Events

- Injection site pain (83.9%)
- Swelling (25.4%)
- Erythema (24.7%)
- Temperature \geq 100 degrees (4.0–4.9%)

Storage and Handling

- Should not be frozen
- Should be stored and shipped at temperatures of 35–46°F (2–8°C)
- Protect from light at all times

Special Considerations:

HPV vaccine can be given to persons with:

- Equivocal or abnormal pap test
- Positive HPV test
- Genital warts
- Immunosuppression
- Lactating women

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S U B J E C T: **H P V**

Pregnancy

 HPV vaccines are not recommended for use in pregnant women. However, pregnancy testing is not needed before vaccination. Any exposure to vaccine during pregnancy should be reported to the appropriate vaccine pregnancy registry: 1-800-986-8999 (Merck and Co., Inc. for quadrivalent HPV vaccine) 1-888-452-9622 (GlaxoSmithKline for bivalent HPV vaccine)

Precautions

- HPV vaccine can be administered to persons with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infections, with or without fever). Vaccination of people with moderate or severe acute illnesses should be deferred until after the illness improves.
- Syncope (i.e., vasovagal or vasodepressor reaction) can occur after vaccination, most commonly among adolescents and young adults. Healthcare providers are reminded that HPV vaccine recipients should be observed closely for 15 minutes after vaccination. Vaccine recipients should be encouraged to remain seated or lying down and be alert for signs and symptoms that can occur before fainting (syncope), such as paleness, sweating, nausea, dizziness, ringing in the ears, or vision changes. Individuals who faint sometimes have tonic-clonic (jerking) movements and seizure-like activity. Fainting and its associated signs and symptoms usually last only a short time (seconds to minutes) and resolve when the patient is placed in a position, such as lying down, to restore adequate blood flow to the brain. Fainting has been reported after administration of other adolescent and adult vaccines and is not unique to HPV vaccine.

For further information, refer to 05/28/2010 **MMWR** available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5920a4.htm?s_cid=mm5920a4_e

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ZOSTER Vaccine (Zostavax®)

Schedule

- Recommended for adults 60 years of age and older for the prevention of herpes zoster (shingles) and post-herpetic neuralgia (PHN)
- No booster dose licensed for zoster vaccine
- Not indicated for the treatment of zoster or PHN
- Should be administered regardless of whether or not the vaccine recipient reports a prior episode of herpes zoster

Dosage and Administration

- Single, 0.65 ml dose
- Administer subcutaneously in upper arm

Contraindications

Allergy to Vaccine Components

Zoster vaccine is contraindicated for persons who have a history of anaphylactic reaction to any component of the vaccine, including gelatin and neomycin. Neomycin allergy is usually manifested as a contact dermatitis, which represents a delayed-type immune response. A history of contact dermatitis to neomycin is not a contraindication for receiving zoster vaccine. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications.

Zoster vaccine is contraindicated for immunocompromised persons—see section 12 for full details.

Pregnancy

Zoster vaccine is not recommended for use in pregnant women, although these women are unlikely to be in the vaccine target age group. The effects of the live, attenuated VZV-based zoster vaccine on the fetus are unknown. Women should avoid becoming pregnant for 4 weeks following zoster vaccination. Having a pregnant household member is not a contraindication to zoster vaccination. If a pregnant woman is vaccinated or becomes pregnant within 1 month of vaccination, she should be counseled about potential effects on the fetus.

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<u>Colorado Immunization Manual</u>

SUBJECT: ZOSTER

ISSUED: 8/1/07

R E **v** i **s** E **d**: 5/1/11

Precautions

Moderate to Severe Illness

Zoster vaccination of persons who have severe acute illness should be postponed until recovery. The decision to delay vaccination depends on the severity of symptoms and the etiology of the disease. Zoster vaccine can be administered to persons who have mild acute illnesses with or without fever.

Special Groups and Circumstances

Persons with a Reported History of Zoster

Persons with a reported history of zoster can be vaccinated.

Persons Anticipating Immunosuppression

The risk for zoster and its severe morbidity and mortality is much greater among persons who are immunosuppressed. Such patients without a history of zoster vaccination should receive 1 dose of zoster vaccine at the first possible clinical encounter while their immunity is intact. Zoster vaccine should be administered at least 14 days before initiation of immunosuppressive therapy, although some experts advise waiting 1 month after zoster vaccination to begin immunosuppressive therapy if delay is possible.

Persons Receiving Antiviral Medications

Persons taking acyclovir, famciclovir, or valacyclovir should discontinue these medications at least 24 hours before administration of zoster vaccine, if possible. These medications should not be used for at least 14 days after vaccination, by which time the immunologic effect should be established.

Persons Receiving Blood Products

Zoster vaccine can be administered to persons at any time before, concurrent with, or after receiving blood or other antibody-containing blood product

Nursing Mothers

Breast feeding is not a contraindication for zoster vaccination. However, this situation will be extremely rare in the target age group for this vaccine.

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Adverse Events

- Injection site symptoms such as erythema, pain, swelling, warmth, and pruritis
- Headaches

Groups for Which Vaccine is Licensed

Vaccination of Persons Aged <60 Years

On March 24, 2011, the FDA expanded licensing for $Zostavax^{TM}$ to include those 50 through 59 years of age. $Zostavax^{TM}$ is not licensed for use in persons \leq 49 years. $Zostavax^{TM}$ was already approved for use in individuals 60 years of age and older. As of May 1, 2011, ACIP had not expanded its recommendations to include persons aged 50 through 59 years. These recommendations will be included in the *CIM* once they become available. Full prescribing information for ZostavaxTM is available at **www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM132831.pdf**.

Vaccination of Persons Who Have Received Varicella Vaccine

Zoster vaccination is not recommended for persons of any age who have received varicella vaccine. However, health-care providers do not need to inquire about varicella vaccination history before administering zoster vaccine because virtually all persons currently or soon to be in the recommended age group have not received varicella vaccine.

Storage and Handling

- Store zoster vaccine between -58°F and 5°F (-50°C and -15°C) before reconstitution.
- The diluent should be stored separately at room temperature or in the refrigerator
- Discard reconstituted vaccine if not used within 30 minutes
- Before reconstitution, protect from light
- CDC strongly discourages transport of Zostavax to off-site clinics.

Complete ACIP recommendations can be accessed at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5705a1.htm?s_cid=rr5705a1_e

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SECTION-PAGE: 8-61

SUBJECT: ROTAVIRUS

Rotavirus Vaccine

Schedule

There are two vaccines for Rotavirus licensed in the United States. RotaTeq® (RV5) was licensed February 3, 2006 and Rotarix[®] (RV1) was licensed April 3, 2008. The products differ in composition and schedule of administration. ACIP recommends routine vaccination of U.S. infants according to the following schedules (dependent upon which brand of vaccine is used) and does not express a preference for one brand over the other.

RotaTeq® (RV5)

Dose	Customary Age	Age/Interval	Product
Primary 1	2 months	age 6 wks through 14 wks 6 days	RotaTeq®
Primary 2	4 months	4 wks minimum between doses	RotaTeq®
Primary 3	6 months	4 wks minimum between doses	RotaTeq®

Vaccination should not be initiated for infants on or after 15 weeks, 0 days of age or older and last dose should not be administered after 8 months, 0 days of age.

Administration Dose

2 ml (single dose vial) Oral

Rotarix[®] (RV1)

Dose	Customary Age	Age/Interval	Product
Primary 1	2 months	age 6 wks through 14 wks 6 days	Rotarix®
Primary 2	4 months	4 wks minimum between doses	Rotarix®

Vaccination should not be initiated for infants on or after 15 weeks, 0 days of age or older and last dose should not be administered after 8 months, 0 days of age.

Oral

Administration Dose

1 ml (must be reconstituted with accompanying diluent according to manufacturer instructions)

- Can administer to breastfeeding infants •
- Can administer simultaneously with other routinely recommended childhood vaccines • (i.e. DTaP, Hib, IPV, Hep B and Pneumococcal conjugate vaccines)
- May administer to infants with mild illness

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Interchangeability of Rotavirus Vaccines

- ACIP recommends that the rotavirus vaccine series be completed with the same product whenever possible. However, vaccination should not be deferred if the product used for previous doses is not available or is unknown. In this situation, the provider should continue or complete the series with the product available.
- If any dose in the series was RotaTeq[®] (RV5) or the product is unknown for any dose in the series, a total of three doses of rotavirus vaccine should be given (unless the child has reached 8 months of age at which time you would no longer administer additional doses).

Contraindications

- History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of rotavirus vaccine or to a vaccine component. A list of components (including any latex, thimerosal, or antibiotic content) for each vaccine can be found in Section 13. Before administering vaccines, providers should consult product package inserts for precautions, warnings, and contraindications. Latex rubber is contained in the Rotarix[®] (RV1) oral applicator, so infants with a severe (anaphylactic) allergy to latex should not receive RV1. The RotaTeq[®] (RV5) dosing tube is latex-free.
- History of uncorrected congenital malformation of the gastrointestinal tract that would predispose the infant to intussusception.
- Rotavirus vaccine (both RotaTeq[®] and Rotarix[®]) is contraindicated in infants diagnosed with severe combined immunodeficiency (SCID). Consultation with an immunologist or infectious disease specialist is advised for infants with known or suspected altered immunocompetence before rotavirus vaccine is administered.
- If a child ≥6 weeks has been in the hospital since birth, deferral of rotavirus vaccine is recommended until the time of discharge.

Precautions

- Moderate to severe illness, including acute gastroenteritis
- Chronic gastrointestinal disease
- History of intussusception

Adverse Events

- Fussiness, irritability, nasopharyngitis, bronchospasm, otitis media, fever, vomiting, and loss of appetite were all noted at a less than 5% rate above those in the studies who received placebo doses.
- On October 28, 2010, summaries of post-licensure evaluations on rotavirus vaccines and intussusception were presented to ACIP. Some studies performed outside the U.S. have detected a low-level increased risk of intussusception following rotavirus vaccination, particularly shortly after the 1st dose. Considering that the data currently available suggest a

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small risk of intussusception caused by rotavirus vaccine is possible and considering that the benefits of rotavirus vaccination are great, CDC continues to recommend both Rotarix[®] and RotaTeq[®] to prevent severe rotavirus disease in U.S. infants and children. CDC will continue to monitor additional data on intussusception as they become available.

Storage and Handling

- Should not be frozen
- Should be stored and shipped at temperatures of 35–46°F (2–8°C)
- Protect from light at all times

Special Considerations

- ACIP supports vaccination of premature infants (less than 37 weeks gestation) if they are at least chronologically aged 6 weeks, are being or have been discharged from the hospital nursery, and are clinically stable.
- Infants living in households with immunocompromised persons can be vaccinated.
- Infants living in households with pregnant women can be vaccinated.
- ACIP recommends that providers not repeat the dose if the infant spits out or regurgitates the vaccine. Any remaining doses should be administered on schedule. Doses of rotavirus vaccine should be separated by at least 4 weeks.
- If a recently vaccinated child is hospitalized for any reason, no precautions other than routine universal precautions need be taken to prevent the spread of vaccine virus in the hospital setting.

The February 6, 2009 recommendations can be accessed at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5802a1.htm

The 2006 ACIP recommendations for the prevention of rotavirus gastroenteritis among infants and children are available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5512a1.htm

Addition of Severe Combined Immunodeficiency as a Contraindication for Administration of Rotavirus Vaccine" is in the 06/11/2010 **MMWR** available at **http://www.cdc.gov/mmwr/ preview/mmwrhtml/mm5922a3.htm**

Statement Regarding Rotarix[®] and RotaTeq[®] Rotavirus Vaccines and Intussusception" is available on the CDC website at http://www.cdc.gov/vaccines/vpd-vac/rotavirus/intussusception-studies-acip.htm

The Rotarix® package insert is available at http://www.fda.gov/downloads/BiologicsBlood Vaccines/Vaccines/ApprovedProducts/UCM133539.pdf

The RotaTeq® package insert is available at http://www.merck.com/product/usa/pi_circulars/r/rotateq/rotateq_pi.pdf