SECTION 8
Vaccines

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Colorado Immunization Manual
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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 is the vaccine of choice for children 7 years old through 9 years.
- Tdap is the vaccine of choice for adolescents and adults age 10 through 64 years*.

* Boostrix® is approved for ages 10–64 years, Adacel® is approved for ages 11–64 years

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

Dose	Customary Age	Age/Interval	Product
Primary 1	2 months	6 weeks old or older	DTaP§
Primary 2	4 months	4–8 weeks after 1st dose†	DTaP§
Primary 3	6 months	4–8 weeks after 2nd dose†	DTaP§
Primary 4	12–18 months	6–12 months after 3rd 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 4th birthday)		DTaP§

§ 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.**

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.
- **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**

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

- May be shipped without ice packs if deliverable in 4 days and the temperature is below 100°F. (ice packs may be used)
- 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
Tripedia® (DTaP)	Sanofi Pasteur, Inc.	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
- Series begun with whole cell vaccine may be completed with DTaP
- 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.

- 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 case-by-case basis.

Underlying Neurologic Disorders and Use of Pertussis Vaccine

✓ A family history of seizures or other neurologic diseases, or stable or resolved neurologic conditions (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

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 2nd dose*	DT
Primary 4	12–18 months	6–12 months after 3rd dose*	DT
Booster	4–6 years old, before entering kindergarten or elementary school (not necessary if fourth primary immunizing dose administered on or after 4th 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. 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

- May be shipped without ice packs if deliverable in 4 days and the temperature is below 100°F (ice packs may be used)
- 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)
Tetanus, Diphtheria Toxoids (DT)	Sanofi Pasteur, Inc.

Td and Tdap Vaccine

(Tetanus Toxoid, Diphtheria Toxoid and acellular Pertussis)

Schedule

Td is the vaccine of choice for children 7 years old through 9 years old. Tdap is the vaccine of choice for adolescents 10 years old through 18 years old. Use of Tdap is also now approved by ACIP for vaccination of adults 19–64 years of age.

- 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 7–9 years of age or older should receive Td (adult type); children younger than 7 years of age should receive DTaP, or DT.
- Td contains only one-third as much diphtheria toxoid as DT and is the vaccine of choice for >7 years of age because local adverse events from higher doses of diphtheria toxoid and pertussis vaccine are more common in older children and adults.

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

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

*One dose of the series should be Tdap if vaccine recipient ≥10 years old.

**Boostrix® approved for ages 10–64, Adacel® approved for ages 11–64

- The first booster dose should be given as a Tdap. ACIP guidelines place no absolute minimum on length between Td and Tdap doses—the clinician must decide whether risk of pertussis outweighs risk of local reactions.
- 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.
- **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.
- Tdap should be considered for all adults who come into close contact with infants (e.g., childcare and health personnel, and parents).

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

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
- **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**
- **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.

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) may receive Tdap at an interval as short as 2 years since the most recent Td vaccine,
3) receive Td during pregnancy for tetanus and diphtheria protection when indicated, or
4) 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

General Storage and Handling

- May be shipped without ice packs if deliverable in 4 days and temperature is below 100°F (ice packs may be used)
- 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, minor wounds		All other wounds	
Vaccination History	**Td**	**TIG**	**Td**	**TIG**
Unknown or <3 doses	Yes	No	Yes	Yes
3+ doses	No*	No	No**	No

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

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 (TriHIBit™) has been licensed.
- 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 until it has been approved and licensed for this use by the Food and Drug Administration.**
  - ✔ 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 Toddlers and Children—Deltoid Muscle

Contraindications & Precautions

- The same as those for its individual component vaccines (i.e., DTaP, pg. 8-3 or Hib, pg. 8-19)

Adverse Events

- The same are expected as when its individual component vaccines (i.e., DTaP, pg. 8-4 or Hib, pg. 8-20) 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
TriHIBit™	Sanofi Pasteur, Inc.	September 1997; only for the fourth dose of the DTaP-Hib series

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. 8-35, IPV pg. 8-23).

Precautions (Warning)

- The same as those for its individual component vaccines (i.e., DTaP, pg. 8-3, Hep B pg. 8-35, IPV pg. 8-23).

Adverse Events

- The same as those for its individual component vaccines (i.e., DTaP, pg. 8-4, Hep B pg. 8-35, IPV pg. 8-23).

General Storage and Handling

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

Special Considerations

PEDIARIX™ 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 recommended interval between doses is 6–8 weeks (preferably 8 weeks). The minimum interval between doses 1 and 2 is 4 weeks and the third dose should not be administered before age 24 weeks.

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

PEDIARIX™ 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 (PEDIARIX™) and HepB from a different manufacturer are interchangeable for HepB vaccination. DTaP–HepB–IPV (PEDIARIX™) and IPV from a different manufacturer are interchangeable for poliovirus vaccination.

DTaP–HepB–IPV (PEDIARIX™) combination can be administered with Hib and PCV vaccines at separate injection sites.

DTaP–HepB–IPV (PEDIARIX™) 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	Manufacturer(s)	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.**

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
1 individual dose vial	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. 8-23).

Precautions (Warning)

- The same as those for its individual component vaccines (i.e., DTaP pg. 8-3 and IPV pg. 8-23).

Adverse Events

- The same as those for its individual component vaccines (i.e., DTaP pg. 8-4 and IPV pg. 8-23).

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.

Combined DTaP-Hib-IPV Vaccine (Pentacel®)

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

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 (Recommended 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 and four weeks for IPV)
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)

Dosage	Administration
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. 8-19 and IPV pg. 8-23).

Precautions (Warning)

- The same as those for its individual component vaccines (i.e., DTaP pg. 8-3, Hib pg. 8-19 and IPV pg. 8-23).

Adverse Events

- The same as those for its individual component vaccines (i.e., DTaP pg. 8-4, Hib pg. 8-20 and IPV pg. 8-23).

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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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 8-20).
- The number of doses in the primary series depends on the type of vaccine used.
- Children behind schedule for Hib vaccine may not require a full primary series of 3 or 4 doses.
  - ✔ When behind schedule, the number of doses a child needs to complete the series depends on the child's current age, and does not depend on the number of prior doses of Hib vaccine the child has received. Please refer to the catch-up schedule in section 7-3.

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

Vaccine	2 months	4 months	6 months	12–15 months
HbOC (HibTITER™)	Dose 1	Dose 2	Dose 3	Booster
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.
- **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.

Detailed Vaccination Schedule for *Haemophilus influenzae* type b Conjugate Vaccines

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

*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 or HbOC	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
- Moderate to severe acute illness
- Contraindications and precautions for the use of TriHIBit™ are the same as those for its individual component vaccines (i.e., DTaP, and Hib)

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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
HbOC (HibTITER™)	Wyeth/Lederle	Licensed for infants >6 weeks of age
PRP-T (ActHIB™ or Omni HIB™)	Sanofi Pasteur, Inc.	Licensed for infants >6 weeks of age
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:
  - ✔ Vaccines are interchangeable
  - ✔ Any combination of 3 doses of conjugate vaccine 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.

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.

COMVAX™ 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 COMVAX™ 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 COMVAX™ in infants who have previously received more than one dose of hepatitis B vaccine. However, COMVAX™ may be administered to children otherwise scheduled to receive concurrent RECOMBIVAX HB and PedvaxHib."

Sample schedules using COMVAX™

Birth	2 Months	4 Months	6 Months	12–15 Months
Hepatitis B	COMVAX	Hib	COMVAX	Hib
Hepatitis B	COMVAX	COMVAX	————	COMVAX

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

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
  - ✖ 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™	Merck	October 1996; Only for infants >6 weeks of age; not licensed for use if mother is HBsAg+

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 OPV/IPV to complete the series is considered valid.
- **As of January 1, 2000, 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.

Routine Inactivated Polio Vaccination Schedule

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

* Series may be started as early as 6 weeks of age

† 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 is not needed if the third dose is given on or after the 4th birthday

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, and neomycin
- 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

- May be shipped without refrigeration if delivered within 4 days
- 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
- 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 IPV

MMR Vaccine

Measles, Mumps, Rubella

Schedule

- For pre-school aged children, school aged children and adolescents, the combined vaccine of measles, mumps and rubella should be administered.

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.

Rubella Vaccine—Recommendations for Increasing Coverage

- Continued routine vaccination of children at >12 months of age with vaccination required for school entry.
- Screen and vaccinate susceptibles
  - ✔ Health care workers
  - ✔ College entry
  - ✔ Premarital
  - ✔ Prenatal with postpartum vaccination
  - ✔ Other health care visits

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

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.
- 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
- 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 15° to 30°C (59° to 86°F)—room temperature—do not freeze
- Freeze dried (lyophilized) vaccines may be maintained at freezer temperatures
- 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

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
- ✔ Apply PPD first—give MMR when skin test is read
- ✔ Delay PPD 4–6 weeks if MMR is given first

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.

Varicella Vaccine

Schedule

- Children who have not been immunized previously and who do not have a health-care-provider–certified history of chickenpox are considered susceptible.
- 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 through 12 years	Primary 1	Not younger than 1st birthday	Varicella vaccine
	Primary 2	4–6 years/at least 3 months after 1st dose*	Varicella vaccine
Adolescents & adults ≥13 years	Primary 1	≥13 years of age	Varicella vaccine
	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.

Dosage	Administration
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.
- Pregnancy; in addition, pregnancy should be avoided for 1 month after vaccination
- Cellular immunodeficiencies
- Moderate or severe acute illness
- Recent receipt of blood product

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 ≤ +5°F (-15°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
- Transport of the vaccine from a central clinic to an off-site clinic is very difficult and is discouraged. However, if off-site transport is attempted, a high quality container should be used, the vaccine should be transported on dry ice, and the temperature should be monitored continuously
- 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.

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:
  - ✔ Family members of immunocompromised persons
  - ✔ Adolescents and adults living in 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

- Persons with impaired humoral immunity may now be vaccinated with Varicella
- Varicella vaccine **should not** be administered to persons who have cellular immunodeficiencies.
- Varicella vaccine **should be considered** for asymptomatic or mildly symptomatic HIV-infected children in CDC class N1 or A1* with age-specific CD4+ T-lymphocyte percentages of greater than or equal to 15%. A 2-dose schedule separated by 3 months should be used.
- MMRV vaccine not approved by FDA for HIV-infected persons.

*In CDC's pediatric HIV Classification system, Class 1 is an immunologic category defined as "no evidence of suppression." For this ACIP recommendation, two clinical categories under Class 1 are used—N1, defined as "no signs or symptoms," and AI, defined as "mild signs or symptoms."

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. ACIP does not express a preference for use of MMRV vaccine over separate injections of equivalent component vaccines (i.e., MMR vaccine and varicella vaccine.) 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 can be used. For the first dose of measles, mumps, rubella, and varicella vaccines given at 4 years of age or older, and for the second dose given at any age, the use of a combination vaccine is generally preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events. Provider assessment should include the number of injections, vaccine availability, likelihood of improved coverage, likelihood of patient return, and storage and cost consideration.
- 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.

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 1st dose**	Proquad®*

*or separate MMR or varicella vaccine as indicated by vaccines needed at time of visit
**not to be administered over the age of 12 years

Dose	Administration
.5 ml	Subcutaneous

Contraindications

See contraindications for MMR and varicella components in section 8 of this manual.

In addition, a personal or family history of seizures is a precaution for MMRV vaccine use.

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 at a temperature ≤5°F or ≤ neg15°C. MMRV vaccine cannot be stored in the refrigerator.
- The diluent should be stored separately at room temperature or in the refrigerator.
- Discard if reconstituted vaccine is not used within 30 minutes.

Special Considerations

- MMRV vaccine should not be administered as a substitute for the component vaccines when vaccinating children with HIV until revised recommendations can be considered for the use of MMRV in this population.

Recommendations, contraindications and side effects for MMR and varicella 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

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 1st dose
Primary 3*	6–18 months	8 weeks after 2nd dose & 16 weeks after 1st dose
	—OR—	
Primary 1	1–2 months	———
Primary 2	4 months	4 weeks after 1st dose
Primary 3*	6–18 months	8 weeks after 2nd dose & 16 weeks after 1st 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 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 routinely 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.

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 3-dose 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.

Recommended doses of currently licensed formulations of hepatitis B vaccine, by age group and vaccine type

	Single-Antigen Vaccine				Combination Vaccine					
	Recombivax HB		Engerix-B		Comvax		Pediarix		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	0	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 (≥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
≥20 yrs	40¶	1.0	40‡	2.0	N/A	N/A	N/A	N/A	N/A	N/A

* 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.
¶ Dialysis 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.

Contraindications and Precautions

- Severe allergic reaction to a vaccine component (yeast or thimerosal) or following a previous dose
- 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%–6.4%
- 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
- Complete vaccination schedule at 1–2 and 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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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 of the world except Canada, Western Europe, Scandinavia, Japan, New Zealand, Australia)
  - ✔ Men who have sex with other men
  - ✔ Users of illegal injectable drugs
  - ✔ 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

Recommended Doses of Havrix® Hepatitis A Vaccine

Group	Age	Dose (U)	Volume	No. Doses	Schedule*
Children and Adolescents	1-18 years	720	0.5 mL	2	0, 6-12
Adults	>18 years	1,440	1.0 mL	2	0, 6-12

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

Recommended Doses of VAQTA® Hepatitis A Vaccine

Group	Age	Dose (U)	Volume	No. Doses	Schedule*
Children and Adolescents	1-18 years	25	0.5 mL	2	0, 6-18
Adults	>18 years	50	1.0 mL	2	0, 6-18

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

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 ≥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.
- 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

Storage and Handling

- Should not be frozen
- Should be stored and shipped at temperatures ranging from 35.6°F (2°C) to 46.4°F (8°C)
- Reactogenicity and immunogenicity are not altered by storage for 1 week at 98.6°F (30°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

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 ≥ 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**

Dosage	**Administration**
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. 8-35, Hep A pg. 8-37).

Precautions (Warning)

- The same as those for its individual component vaccines (i.e., Hep B pg. 8-35, Hep A pg. 8-37).

Adverse Events

- The same as those for its individual component vaccines (i.e., Hep B pg. 8-35, Hep A pg. 8-37).

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 TWINRIX™, 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 TWINRIX™ the Hep A schedule may be completed with one adult formulation Hep A vaccine administered > 5 months apart.

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

Because the Hep B component of TWINRIX™ is equivalent to a standard dose of Hep B vaccine, the schedule is the same whether TWINRIX™ 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 93 of 11th edition of pink book,
http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hepa-508.pdf

PCV7

(7-Valent Pneumococcal Conjugate Vaccine)

PCV7 is recommended for all children aged 6 weeks through 59 months of age according to the following schedules:

Schedules

ACIP recommended schedule for use of PCV7 among previously unvaccinated infants and children, by age at time of first vaccination.

Age at first dose	Primary series	Additional dose
2–6 months	3 doses, 2 months apart*	1 dose at 12–15 months†
7–11 months	2 doses, 2 months apart*	1 dose at 12–15 months†
12–23 months	2 doses, 2 months apart¶	————
24–59 months Healthy children Children with sickle cell disease, asplenia, HIV infection, chronic illness, or immunocompromising condition§	 1 dose 2 doses, 2 months apart	 ———— ————

* For children vaccinated at age < 1 year, minimum interval between doses is 4 weeks.

† The additional dose should be administered ≥8 weeks after the primary series has been completed.

¶Minimum interval between doses is 8 weeks.

§ Recommendations do not include children who have undergone a bone marrow transplantation. See footnote * under chart on page 8-42 for expanded list of underlying medical conditions.

ACIP recommendations for use of PCV7 among children with a lapse in vaccine administration.

Age at examination	Previous PCV7 vaccine history	Recommended regimen
7–11 months	1 dose 2 doses	1 dose PCV7 at 7–11 months, with a second dose ≥2 months later, at 12–15 months Same Regimen
12–23 months	1 dose before age 12 months 2 doses before age 12 months	2 doses PCV7 ≥2 months apart 1 dose PCV7 ≥2 months after the most recent dose
24–59 months	Any incomplete schedule	Healthy children—1 dose of PCV7 For children with underlying medical condition see footnote*

*For all children with underlying medical conditions aged 24–59 months who have received 3 doses, administer 1 dose of PCV7 and all children with underlying medical conditions age 24–59 months who have received <3 doses, administer 2 doses of PCV7 at least 8 weeks apart.

Underlying medical conditions include:

- Sickle cell disease, congenital or acquired asplenia, or splenic dysfunction
- Infection with human immunodeficiency virus
- Cochlear implant (Immunize at least 2 weeks before the procedure or as soon as possible after surgery)
- Immunocompromising conditions, including
  - ✔ Congenital immunodeficiencies: b-(humoral) or T-lymphocyte deficiency; complement deficiencies, particularly c1, c2, c3, and c4 deficiency; and phagocytic disorders, excluding chronic granulomatous disease
  - ✔ Renal failure and nephrotic syndrome
  - ✔ Diseases associated with immunosuppressive therapy or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin's disease; or solid organ transplantation
- Chronic Illness, including
  - ✔ Chronic cardiac disease, particularly cyanotic congenital heart disease and cardiac failure
  - ✔ Chronic pulmonary disease, excluding asthma unless on high dose corticosteroid therapy
  - ✔ Cerebrospinal fluid leaks
  - ✔ Diabetes mellitus

Recommendations for use of PCV7 among children previously vaccinated with 23-valent polysaccharide vaccine (PPV23)

- Children 24–59 months who are at increased risk for pneumococcal disease and who have already received PPV23 could benefit from the immune response induced by PCV7.
- Health-care providers should vaccinate children aged 24–59 months at high risk who have not previously received PCV7 but who have already received PPV23 with 2 doses of PCV7 administered ≥2 months apart.
- Vaccination with PCV7 should be initiated ≥2 months after vaccination with PPV23.
- Providers should be aware that minimal safety data are available regarding this vaccine sequence.

Special Considerations

For recommendations on use of Pneumococcal Polysaccharide vaccine-23 valent among children previously vaccinated with PCV7, see section on PPV23.

Dosage Intervals

- For children vaccinated at younger than 12 months of age, the minimum interval between doses is 4 weeks
- Doses given at 12 months of age and older should be separated by at least 8 weeks
- Vaccination should not begin prior to 6 weeks of age
- Booster dose should be administered between 12 and 15 months of age
  - For children who receive their primary series between 6 and 11 months of age, the recommended interval before the booster dose is 2 months and the minimal interval is 4 weeks after the second dose of the primary series.
  - When PPV23 is recommended following the conjugate vaccination, the minimal interval between the conjugate and polysaccharide is 2 months.

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

Contraindications

- Allergy to vaccine components (anaphylactic reaction to the vaccine or a constituent of the vaccine).
- Acute, moderate or severe illnesses with or without fever.

Precautions (Warnings)

- Safety of PCV7 during pregnancy has not been evaluated

Adverse Events

- Injection site reactions (pain, redness)—30%–50%
- Fever (>38°C/100.4°F)—11%–40%
- Severe reactions—rare

General Storage and Handling

- Refrigerate immediately upon arrival
- Store in refrigerator, away from the freezer compartment
- Store at 35°F to 46°F (2°C to 8°C)
- **Do not freeze**

Product	Manufacturer
7-valent Pneumococcal Conjugate	Wyeth Lederle

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.

Annual Vaccination against Influenza is Recommended for:

- all children aged 6 months through 18 years;
- all persons who want to reduce the risk of becoming ill with influenza or of transmitting influenza to others;
- all persons aged 50 years and older;
- women who will be pregnant during the influenza season;
- persons who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological or metabolic disorders (including diabetes mellitus);
- persons who have immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus);
- persons who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration;
- residents of nursing homes and other chronic-care facilities;
- health-care personnel;
- healthy household contacts and caregivers of children aged <5 years and adults aged 50 years and older, with particular emphasis on vaccinating contacts of children aged <6 months; and
- healthy household contacts and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza

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.
- Persons with moderate to severe acute illness normally should not be vaccinated until their symptoms have decreased.

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 cc	1	IM

*Children <9 years of age receiving influenza vaccine for the first time should receive two doses administered at least 1 month apart. Children <9 years of age who receive only one dose in the first year of vaccination should receive two doses in their second year of vaccination. Children < 9 years of age who receive one dose in the first year of vaccination and one dose in the second year of vaccination should receive only one dose in the third year of vaccination.

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.
- persons aged <2 years or those aged ≥50 years;
- 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; or
- pregnant women.

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.

Schedule

Age Group	Dosage	Number of doses	Route
2–8 years	0.50cc (0.25ml per nostril)	1 or 2*	Intranasal
≥9 years	0.50 cc (0.25ml per nostril)	1	Intranasal

*Children less than 9 years of age receiving influenza vaccine for the first time should receive two doses at least 6–10 weeks apart. Children under 9 who receive only one dose in the first year of vaccination should receive two doses in their second year of vaccination. Children less than 9 years of age who receive one dose in the first year of vaccination and one dose in the second year of vaccination should receive only one dose in the third year of vaccination.

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.

Pneumococcal Polysaccharide Vaccine—23 Valent

Schedule

One dose of PPV23 should be administered routinely to:

- ✔ All adults > 65 years of age
  - Including those who have not received the vaccine within 5 years and were <65 years of age at the time of vaccination
- ✔ Adults with normal immune systems who have chronic illness
  - Chronic cardiovascular disease (CHF, cardiomyopathies)
  - Pulmonary disease (COPD or emphysema, but not asthma)
  - Diabetes mellitus
  - Alcoholism, cirrhosis
  - CSF leaks
  - Cochlear implant
  - Asthma
- ✔ Cigarette smokers (Cigarette smokers should also be offered smoking cessation counseling)
- ✔ Immunocompromised persons
  - Sickle cell disease
  - Multiple myeloma
  - Generalized malignancy
  - Recipients of organ or bone marrow transplant
  - Recipients of immunosuppressive chemotherapy
  - Hodgkin's disease
  - Lymphoma
  - Chronic renal failure
  - Nephritic syndrome
  - Functional or anatomic asplenia
    - ✔ With elective splenectomy, vaccine should be administered at least 2 weeks prior to surgery
  - Persons with HIV infection (symptomatic or asymptomatic)
- ✔ Persons living in special environmental or social settings
  - Alaska Natives and American Indians aged 50 through 64 years who are living in areas in which the risk of invasive pneumococcal disease is increased
- ✔ Persons with uncertain or unknown vaccination status

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

Eligible groups

Children and adolescents aged 2 through 18 years who have functional or anatomical asplenia, immunocompromising illness or medications, chronic illness (as specified above), who are Alaska Native or American Indian, or who have received a bone marrow transplant.

Recommended Pneumococcal Polysaccharide Vaccine Schedule

One dose of pneumococcal polysaccharide vaccine is recommended for children and adolescents who are at least 2 years of age and at high risk, as listed under Eligible Groups.

For children who are immunocompromised or who have functional or anatomical asplenia: a single revaccination is recommended if 5 or more years have elapsed since the previous dose.

Dosage Intervals for Pneumococcal Polysaccharide Vaccine

For a child who has received the pneumococcal conjugate vaccine and is >2 years old, the recommended and minimal interval between the conjugate and polysaccharide is 2 months.

For children in specified high risk groups, recommended interval between a first and second dose of polysaccharide vaccine is 5 years (see Recommended Pneumococcal Polysaccharide Vaccine Schedule, above).

Revaccination of Adults

- Routine revaccination of immunocompetent persons is not recommended.
- Persons 65 years and older should be administered a second dose of pneumococcal vaccine if they received the vaccine more than 5 years previously and were less than 65 years of age at the time of the first dose.
- Revaccinate once, those at highest risk of serious pneumococcal infection, including those with:
  - ✔ asplenia
  - ✔ immunosuppression
  - ✔ chronic renal failure
  - ✔ nephrotic syndrome
  - ✔ sickle cell disease

Dosage	Administration
0.5cc	Intramuscular (IM) or Subcutaneously (SC)

Contraindications

- Severe allergic reaction to vaccine component or following prior dose
- 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.
Pnu-Immune 23	Wyeth/Lederle

Special Considerations

Timing of vaccination

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

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. MCV4 is licensed for (and is the vaccine of choice) for persons aged 2–55 years. MPSV4 is licensed for use in persons aged 2 yrs and older and is the only meningococcal vaccine licensed for persons over age 55.

Schedule

Candidates for Vaccination

- Adolescents (11–12 years of age) routinely at their preadolescent visit.
- All persons aged 11–18 years of age who have not previously been vaccinated with MCV4.
- Students entering college who will be living in dormitories.
- Immunodeficient persons ≥2 years of age
  - Late complement components C3, C5–C9
  - Functional or actual asplenia
- Persons with laboratory or industrial exposure to *N. meningitides* aerosols
- Travelers ≥2 years of age to epidemic or hyperendemic areas such as sub-Saharan Africa.
- U.S. military recruits.
- Other adolescents or college students who want to decrease their risk of meningococcal disease can also get the 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.

Contraindications

- Persons with a severe allergic reaction to a previous dose vaccine, or to a vaccine component.

Schedule

Age	Indications	Vaccine	Route/Dosage
2–10 years	Immunodeficiency Travel risk	MCV4—Menactra®	IM (0.5cc)
11–55 years	Adolescent routine vaccination Pre-college entry Immunodeficiency Travel risk Occupational risk Military	MCV4—Menactra®	IM (0.5cc)
>55 years	Immunodeficiency Travel risk Occupational risk Military	MPSV4—Menomune®	SC (0.5cc)

Revaccination may be indicated for persons at high risk for infection if it has been more than 3–5 years since they last received MPSV4 vaccine.

Children who last received MPSV4 more than 3 years ago and remain at risk for meningococcal disease should be vaccinated with MCV4 as soon as possible. For children at lifelong increased risk for meningococcal disease, subsequent doses of MCV4 likely will be needed. ACIP will make recommendations for revaccination with MCV4 as more data on duration of protection become available.

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.

HPV Vaccine (Gardasil®)

Human Papillomavirus Vaccine

Schedule

Routine vaccination with three doses of quadrivalent 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. The only HPV vaccine currently licensed is Gardasil® manufactured by Merck and Co. Inc.

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

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 females will still benefit from getting the vaccine. Sexually active females who have not been infected with any of the four HPV strains will receive full benefit from the vaccine; sexually active females infected with one strain of HPV would still be protected against the other strains included in the vaccine.
- Quadrivalent 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 quadrivalent HPV vaccine.

Contraindications

- Quadrivalent HPV vaccine is contraindicated for people with a history of immediate hypersensitivity to yeast or to any vaccine component.

Adverse Events

- Injection site pain (83.9%)
- Swelling (25.4%)
- Erythema (24.7%)
- Temperature ≥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 women with:

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

Pregnancy

- Quadrivalent HPV vaccine is not recommended for use in pregnancy.

The vaccine has not been associated causally with adverse outcomes of pregnancy or adverse events to the developing fetus. However, data on vaccination during pregnancy are limited. Any exposure to vaccine during pregnancy should be reported to the vaccine pregnancy registry (1-800-986-8999).

Precautions

- Quadrivalent HPV vaccine can be administered to females 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 Gardasil™ 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 Gardasil™.

For further information, refer to the March 12, 2007 issue of the MMWR 56(RR02);1–24
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm#tab7

Colorado Immunization Manual
ISSUED: 8/1/07 REVISED: 7/1/09 SECTION-PAGE: 8-54
SUBJECT: ZOSTER

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 deltoid region of 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.

Immunocompromised Persons

Zoster vaccine should not be administered to persons with primary or acquired immunodeficiency including:

- Persons with leukemia, lymphomas, or other malignant neoplasms affecting the bone marrow or lymphatic system. However, patients whose leukemia is in remission and who have not received chemotherapy (e.g., alkylating drugs or antimetabolites) or radiation for at least 3 months can receive zoster vaccine.
- Persons with AIDS or other clinical manifestations of HIV, including persons with CD4+ T-lymphocyte values ≤200 per mm3 or ≤15% of total lymphocytes.
- Persons on immunosuppressive therapy, including high-dose corticosteroids (≥20 mg/day of prednisone or equivalent) lasting two or more weeks. Zoster vaccination should be deferred for at least 1 month after discontinuation of such therapy. Short-term corticosteroid therapy (<14 days); low-to-moderate dose (<20 mg/day of prednisone or equivalent); topical (e.g., nasal, skin, inhaled); intra-articular, bursal, or tendon injections; or long-term alternate-day treatment with low to moderate doses of short-acting systemic

corticosteroids are not considered to be sufficiently immunosuppressive to cause concerns for vaccine safety. Persons receiving this dose or schedule can receive zoster vaccine. Therapy with low-doses of methotrexate (≤0.4 mg/Kg/week), azathioprine (≤3.0 mg/Kg/day), or 6-mercaptopurine (≤1.5 mg/Kg/day) for treatment of rheumatoid arthritis, psoriasis, polymyositis, sarcoidosis, inflammatory bowel disease, and other conditions are also not considered sufficiently immunosuppressive to create vaccine safety concerns and are not contraindications for administration of zoster vaccine.

- Persons with clinical or laboratory evidence of other unspecified cellular immunodeficiency. However, persons with impaired humoral immunity (e.g., hypogammaglobulinemia or dysgammaglobulinemia) can receive zoster vaccine.
- Persons undergoing hematopoietic stem cell transplantation (HSCT). The experience of HSCT recipients with VZV-containing vaccines (e.g., zoster vaccine) is limited. Physicians should assess the immune status of the recipient on a case-by-case basis to determine the relevant risks. If a decision is made to vaccinate with zoster vaccine, the vaccine should be administered at least 24 months after transplantation.
- Persons receiving recombinant human immune mediators and immune modulators, especially the antitumor necrosis factor agents adalimumab, infliximab, and etanercept. The safety and efficacy of zoster vaccine administered concurrently with these agents is unknown. If it is not possible to administer zoster vaccine to patients before initiation of therapy, physicians should assess the immune status of the recipient on a case-by-case basis to determine the relevant risks and benefits. Otherwise, vaccination with zoster vaccine should be deferred for at least 1 month after discontinuation of such therapy.

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.

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 chronic 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.

Adverse Events

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

Groups for Which Vaccine is Not Licensed

Vaccination of Persons Aged <60 Years

The vaccine is not licensed for persons aged <60 years, and no recommendation exists for routine vaccination of persons aged <60 years.

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

- Zoster vaccine must be stored frozen at a temperature of ≤5°F or ≤ neg 15°C.
- 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

Complete ACIP recommendations can be accessed at **http://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e0515a1.htm**

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.

Dose	Administration
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.

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

- 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

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. 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.

Precautions

- Known or suspected altered immunocompetence—consider the potential risks and benefits
- 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.
- Intussusception has not been shown to be greater in rotavirus vaccine recipients than in the general population, but studies continue to assure vaccine safety. Any case of intussusception following a dose of rotavirus vaccine should be reported to VAERs.

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.
- When using Rotateq® vaccine, do not re-administer a dose to an infant who regurgitates, spits out, or vomits during or after a dose of vaccine. The infant can receive the remaining doses of vaccine at appropriate intervals. When using Rotarix® vaccine, if the infant spits out or regurgitates most of the vaccine dose, a second dose of the vaccine may be considered at the same vaccine visit.
- 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**

The Rotarix® package insert is available at **http://www.us-gsk.com/products/assets/us_rotarix.pdf**

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