

LEAD TOXICITY SCREENING

GENERAL INFORMATION

Children from 6 to 72 months may be at risk for lead poisoning (lead poisoning can affect any child regardless of race, economic status, or living conditions)

Children under the age of 6, living in older homes, and living in poverty have the highest risk for lead poisoning

Sources of lead exposure include:

Housing built prior to 1978 with old chipping paint, lead water pipes, or lead soldered pipes
 Recently renovated home or frequently visited house/building built before 1978
 Close proximity (80 ft) to a heavily traveled highway (leaded gasoline) or near industrial site
 Work or hobbies involving paint, chemicals, battery, mining, lead smelting, leaded glass, lead sinkers, and lead glazed pottery
 Pewter or leaded crystal containers for storing, cooking, or eating food/drink
 Plastic or vinyl mini blinds, (purchased prior to 1996)
 Folk medicine such as Mexican, Asian, and Middle Eastern
 Sibling, housemate, frequent visitor, playmates of children with known lead toxicity

Effects of lead toxicity include:

Very severe lead exposure in children can cause coma, convulsions, and even death
 Lower levels can affect the central nervous system and kidneys
 Very low levels are associated with decreased intelligence, behavior problems, decreased growth, and hearing difficulties

SUBJECTIVE

Have parent/guardian complete the **Blood Lead Risk Assessment Questionnaire** (see Table 1). Document all positive risk factors in the medical record. If the parent/guardian answers “yes” or “don’t know” to any of the questions, the child is considered to be at **high risk** and should be **screened with a finger stick BLL at that time.**

OBJECTIVE

Obtain a finger stick blood lead level at well child visit on all children **12 months and 24 months of age**

Obtain a finger stick blood lead level at well child visit on **children 36 to 72 months of age** **Who do not have a previously documented blood test**

Confirm all elevated blood lead levels (5 µg/dL or greater) using venous blood sampling in accordance with the **Recommended Schedule for a Confirmatory Venous Sample** (see Table 2)

Obtain a finger stick blood lead level for siblings (6-72 months of age) of children with a confirmed elevated blood lead level, and consult with parents regarding the need to test other frequent playmates, pregnant household members, and others

Consult parent(s) or caretaker regarding results and need for follow-up (document any parent/guardian refusal)

Comprehensive follow-up services must be based on the child's confirmed Blood Lead Level (BLL) and managed according to **Schedule for Follow-up Blood Lead Testing** (see Table 3)

ASSESSMENT

All children with a confirmed **BLL ≥ 5 $\mu\text{g}/\text{dL}$** should receive comprehensive follow-up services based on the confirmed Blood Lead Level (BLL) and managed according to **Schedule for Follow-up Blood Lead Testing** (see Table 3)

PLAN

Provide comprehensive follow-up services for confirmed **BLL ≥ 5 $\mu\text{g}/\text{dL}$** according to **Schedule for Follow-up Blood Lead Testing** (see Table 3)

Stress need for appropriate follow-up, testing, treatment, and intervention

Repeat blood lead level (BLL) according to guidelines

If developmentally delayed, refer to appropriate programs

Health Teaching (for confirmed cases of lead exposure of 5 $\mu\text{g}/\text{dL}$ or greater)

Provide anticipatory guidance during pregnancy, when children are 3-6 months of age, and again when they are 12 months of age (parental guidance during this time frame might prevent some lead exposure)

Provide lead poisoning prevention counseling to all children receiving child health exams

Educate about the effects/problems of lead poisoning, important sources of lead (be alert to parental occupations/hobbies), and discuss ways to prevent access to causative agents

Stress hand washing (especially before eating), showering, proper handling of soiled clothes, and frequent washing of toys and pacifiers

Educate about soil contaminated with lead (if soil near house is contaminated because of lead-based paint or near major highway, advise to plant shrubs near house to decrease play activity in that area)

Educate about miniblinds and possible lead contamination

Provide nutritional counseling regarding the need for 3 small meals and 3 snacks a day with adequate iron and calcium (iron deficiency can enhance lead absorption and empty stomach increases lead absorption)

Stress need to clean floors, window frames, windowsills, and other surfaces at least weekly with warm water and a general all-purpose cleaner or a cleaner made specifically for lead

Discuss the ineffectiveness of dry methods of cleaning, such as sweeping or vacuuming (unless a Hepavac is used) for lead removal

If drinking water has increased lead, use only fully flushed water (let water run one to two minutes) from cold-water tap for cooking, drinking, and making formula (encourage breast-feeding)

For cooking preparation and storage, use pottery that is labeled safe for cooking and/or storing food, and do not store food in open cans

Table 1: BLOOD LEAD RISK ASSESSMENT QUESTIONNAIRE

<p>Mandatory Questions:</p> <p>Does your child live in or regularly visit a house built before 1950? (This could include a day care center, home of a baby sitter, or a relative.)</p> <p>Does your child live in or regularly visit a house built before 1978 with recent, ongoing, or planned renovations or remodeling (within the past 6 months)?</p> <p>Does your child have a sibling or a playmate that has, or did have, lead poisoning?</p>
<p>Optional Questions (may be asked at the provider's discretion):</p> <p>Does your child frequently come in contact with an adult who works with lead? (Examples include construction, welding, pottery, etc.)</p> <p>Does your home contain any plastic or vinyl mini blinds made before July 1996?</p> <p>Have you ever been told that your child has low iron?</p> <p>Have you seen your child eating paint chips, crayons, soil, or dirt?</p> <p>Does your child live near or visit with someone who lives near a lead smelter, battery recycling plant or other industry that could release lead?</p> <p>Do you give your child any home or folk remedies that may contain lead? (such as moonshine, Azarcon, Greta, Paylooah)</p> <p>Does your child live within 80 feet (or one block) of areas with a constant flow of traffic, such as busy intersections and streets, highways and interstates? (The soil near heavily used streets and roads may contain lead as a result of past use of lead in gasoline; automobile exhaust from past leaded gasoline contributes to both air and soil lead pollution)</p> <p>Does your home's plumbing have lead pipes or copper pipes with lead solder joints?</p> <p>Does your family use pottery ware or leaded crystal for cooking, eating, or drinking?</p>

Table 2: RECOMMENDED SCHEDULE FOR A CONFIRMATORY VENOUS SAMPLE

Screening test result ($\mu\text{g}/\text{dL}$)	Time to confirmation testing:
5-9	1-3 months
10-44	1 week - 1 month*
45-59	48 hours
60-69	24 hours
≥ 70	Urgently as emergency test

* The higher the BLL on the screening test, the more urgent the need for confirmatory testing

Table 3: SCHEDULE FOR FOLLOW-UP BLOOD LEAD TESTING^a

Medical management includes follow-up blood lead testing. The following table (Table 3) presents the suggested frequency of follow-up tests and should be used as guidance. Case managers and PCPs should consider individual patient characteristics and caregiver capabilities and adjust the frequency of follow-up tests accordingly.

Venous Blood Lead Level ($\mu\text{g}/\text{dL}$)	Early Follow-Up (first 2-4 tests after identification)	Late Follow-Up (after BLL begins to decline)
5-9	3 months ^b	6-9 months
10-19	1-3 months ^b	3-6 months
20-24	1-3 months ^b	1-3 months
25-44	2 weeks-1 month	1 month
≥ 45	As soon as possible	As soon as possible

^a Seasonal variation of BLLs exists and may be more apparent in colder climate areas. Greater exposure in the summer months may necessitate more frequent follow-ups.

^b Some case managers or PCPs may choose to repeat blood lead tests on all new patients within a month to ensure that their BLL is not rising more quickly than anticipated.

Table 4: SUMMARY OF RECOMMENDED ACTIONS FOR CHILDREN BASED ON BLOOD LEAD LEVEL($\mu\text{g}/\text{dL}$) VALUES

<5	5 - 44	45 – 69	≥ 70
Lead education* -Dietary -Environmental	Lead education* -Dietary -Environmental	Lead education* -Dietary -Environmental	Hospitalize and commence chelation therapy (following confirmatory venous blood lead test) in conjunction with consultation from a medical toxicologist or a pediatric environmental health specialty unit.
Environmental assessment for pre-1978 housing	Follow-up blood lead monitoring (see guidelines)	Follow-up blood lead monitoring (see guidelines)	
Follow-up blood lead monitoring	Complete history and physical exam Lab work: -Iron status -Consider hemoglobin or hematocrit Environmental investigation** Lead hazard reduction Neurodevelopmental monitoring Abdominal X-ray (if particulate lead ingestion is suspected) with bowel decontamination if indicated	Complete history and physical exam Lab work: - Iron Status -Hemoglobin or hematocrit -Free erythrocyte protoporphyrin (FEP) Environmental investigation** Lead hazard reduction Neurodevelopmental monitoring Abdominal X-ray (if particulate lead ingestion is suspected) with bowel decontamination if indicated Oral Chelation therapy Consider hospitalization if lead-safe environment cannot be assured	Proceed according to actions for 45-69 $\mu\text{g}/\text{dL}$

*<http://pediatrics.aappublications.org/content/116/4/1036.full.pdf>

**Environmental investigations are requested by a Childhood Lead Prevention Nurse at the Central office .

If the child lives in Section 8 housing and has an elevated blood lead level, the Tennessee Housing Development Agency will be notified for environmental investigation, assessment, and correction of the problem. For certified inspection, assessment, and abatement firms in the area, call the Lead Line at 1-888-771-5323.

The following actions are **NOT** recommended at any blood lead level:

- Searching for gingival lead lines
- Testing of neurophysiologic function
- Evaluation of renal function
(except during chelation with EDTA)
- Testing of hair, teeth, or fingernails for lead
- Radiographic imaging of long bones
- X-ray fluorescence of long bones

REFERENCES

“Recommendations for Blood Lead Screening of Young Children Enrolled in Medicaid: Targeting a Group at High Risk”, MMR, December 8, 2000
Centers for Disease Control and Prevention. Managing Elevated Blood Lead Levels Among Young Children: Recommendations from the Advisory Committee on Childhood Lead Poisoning Prevention. Atlanta: CDC; 2002
http://www.cdc.gov/nceh/lead/ACCLPP/Final_Document_030712.pdf

HAEMOPHILUS INFLUENZA type b CONJUGATE VACCINE (Hib)

GENERAL INFORMATION

Contraindications and Precautions include the following:

- Anaphylactic reaction to a vaccine component or following a prior dose of that vaccine
- Moderate or severe acute illness
- Children younger than 6 weeks of age

Adverse events include the following:

- Swelling, redness and/or pain
- Systemic reactions infrequent, serious adverse reactions rare

ACIP Recommended Population

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

The number of doses in the primary series depends on the type of vaccine used.

A primary series of PRP-OMP (PedvaxHIB) vaccine is two doses; PRP-T (ActHIB) requires a three-dose primary series (see table). A booster is recommended at 12-15 months regardless of which vaccine is used for the primary series.

For persons older than age 5 years (including adults) who have a medical indication for the vaccine (e.g., bone marrow transplant or spleen removed), a single dose of Hib vaccine may be given. These indications are rare. Administer with MD or APN order.

[To determine if a patient in an ACIP-recommended group is eligible for free, Federal vaccine, please see the current Tennessee Immunization Program Policy on the use of Federal vaccine.](#)

Administration of Vaccine:

Appropriate age for Hib: at least 2 months old, but less than 5 years

Appropriate time interval since last Hib

Children who have started the 3 dose primary series of vaccinations with ActHib vaccine may complete the primary series with Pedvax HIB but will still need a total of 3 doses in the primary series. The dose administered routinely after age 12 months is a booster dose.

PLAN

Ask patient/guardian about contraindications

Have patient/guardian read Vaccine Information Statement

Counsel regarding benefits, side effects, and management

NOTE: This vaccine is lyophilized and must be reconstituted with the diluent that is provided with the vaccine; NO OTHER DILUENT CAN BE USED; reconstitute with entire content of diluent vial and inject the entire amount of the reconstituted vial; this is a single unit dose and must be administered within 24 hours of reconstitution

Advise to wait in clinic for 20 minutes after injection

Document vaccine administration on the immunization clinic record

Instruct patient/guardian to contact Health Department if adverse reaction occurs

HAEMOPHILUS INFLUENZAE type b CONJUGATE VACCINE (Hib)

VACCINE	AGE BEGINNING PRIMARY SERIES	PRIMARY SERIES	BOOSTER
PRP-T (ActHIB) 0.5 cc IM	2-6 months	3 doses, 2 months apart	12-15 months**
	7-11 months	2 doses, 2 months apart	12-15 months**
	12-14 months	1 dose	2 months later
	15-59 months	1 dose	---
PRP-OMP (PedvaxHIB) 0.5 cc IM	2-6 months	2 doses, 2 months apart	12-15 months**
	7-11 months	2 doses, 2 months apart	12-15 months**
	12-14 months	1 dose	2 months later
	15-59 months	1 dose	---

**At least 2 months after previous dose

NOTE:

- If child is greater than 59 months of age, HIB vaccine is not routinely indicated
- Ideally, the same brand of vaccine should be used throughout the entire vaccination series; however, where it is necessary to change the types of vaccine, a child 2-6 months of age seen for the primary series should receive three doses of Hib vaccine (i.e., child receives 1 dose ActHIB should then receive 2 doses of Pedvax HIB or if child receives 2 doses of ActHIB should then receive 1 dose of Pedvax HIB for primary series; child would then get booster at 12-15 months)
- Hib vaccines may be given simultaneously at different injection sites with all other vaccines.

Referral Indicators:

Allergic hypersensitivity to any component of the vaccine

Follow-up:

If severe reaction is reported as occurring within 30 days following vaccine administered by health department personnel, VAERS Report form must be completed
Return at appropriate interval according to schedule

REFERENCES

“Epidemiology and Prevention of Vaccine - Preventable Diseases”, 10th Edition, Centers for Disease Control and Prevention, Department of Health and Human Services, February 2008
ACIP Adult Immunization Schedule footnote, 2009

HEPATITIS A VACCINE

GENERAL INFORMATION

Hepatitis A disease is a serious liver infection caused by the Hepatitis A virus (HAV). HAV is found in the stool of persons with Hepatitis A. It is not often fatal, but is highly contagious with transmission occurring primarily by the fecal-oral route.

Hepatitis A vaccine is inactivated and contains no live organisms; it is a 2-dose series (0 and 6-12 months); 3 doses are given (at 0, 1, and 6 months) if the patient is receiving a combination hepatitis A and hepatitis B vaccine (Twinrix™ by GSK). Monovalent hepatitis A vaccines are licensed for use in persons \geq 12 months of age. Hepatitis A vaccine may be administered simultaneously with other vaccines.

In 2005, hepatitis A vaccine was added to the US routine childhood immunization schedule, beginning at 1 year of age (i.e., age 12-23 months).

ACIP Recommended Populations for pre-exposure vaccination include the following:

All children 12-23 months

Previously unvaccinated children 23 months through 18 years of age (with emphasis on children coming for school-entry immunizations)

International travelers

Users of illegal drugs

Persons who have blood clotting-factor disorders or chronic liver disease (with MD or NP order)

Persons working with hepatitis A-infected non-human primates (refer)

Persons working with hepatitis A in a laboratory setting (refer)

Military personnel (refer to military facility)

Men who have sex with men

To determine if a patient in an ACIP-recommended group is eligible for free, Federal vaccine, please see the current Tennessee Immunization Program Policy on the use of Federal vaccine.

Contraindications to giving the vaccine include the following:

Persons with a history of severe reaction to a prior dose of hepatitis A vaccine or to any hepatitis A vaccine component

Precautions (risks and benefits of vaccination should be carefully evaluated for individuals under the following circumstances):

Moderate to severe acute illness (defer until illness resolves)

Pregnancy¹, MD or NP order required (**breastfeeding is NOT a precaution**)

Adverse Reactions:

Severe allergic reaction to vaccine (rare)

Injection site soreness, tenderness, redness, swelling (common)

Fatigue, fever, malaise, anorexia, nausea, headache (systemic)

¹ The safety of hepatitis A vaccination during pregnancy has not been determined; however, there is no evidence that the vaccine is harmful to pregnant women or their unborn babies; the theoretical risk associated with vaccination should be weighed against the risk of hepatitis A disease in women who might be at high risk for exposure to HAV (e.g., while traveling or during a community outbreak)

PLAN

Ask patient/guardian about contraindications
 Have patient/guardian read Vaccine Information Statement
 Administer the appropriate pediatric or adult formulation of the vaccine according to manufacturer instructions
 Counsel regarding side effects of vaccine
 Advise patient or parent/guardian to return for the second dose in 6-12 months
 Advise to wait in clinic for 20 minutes after injection
 Document vaccine administration on the immunization clinic record
 Instruct patient/guardian to contact Health Department if adverse reaction occurs

Dosage:

VAQTA (Merck) **or** HAVRIX (GlaxoSmithKline) hepatitis A vaccines:
Pediatric Formulation (ages 12 mos. to 19 years) Administer 0.5 cc IM,
 2 doses required. Administer second dose 6-12 months later.
Adult Formulation (≥ 19 years) Administer 1.0 cc IM, 2 doses required.
 Administer second dose 6-12 months later.

TWINRIX Combination Hepatitis A and B vaccine (GlaxoSmithKline) (If available):
Adult Formulation Only (Licensed for persons ≥ 18 years)
 Administer 1.0 cc IM, 3 doses required. Administer second dose 1 month
 after the first dose. Administer third dose 6 months after the first dose.

Referral Indicators:

If patient is pregnant, written order from MD or NP is needed

If vaccine is indicated for liver disease or blood clotting factor disorder², written order from MD or NP
 is needed

Severe reaction to previous vaccine (consult MD)

REFERENCES

CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases. 12th edition, May 2012:pp 101-114.

² Per Advisory Committee on Immunization Practices (ACIP) guidelines, hemophilia is not a contraindication for any vaccination, but administration should be done in consultation with a physician to minimize the risk of hematoma formation

HEPATITIS B RECOMBINANT VACCINE, Adult (age 19 years and up) Pre-Exposure

GENERAL INFORMATION

Please consult current state or local health department policy concerning adults eligible to receive hepatitis B vaccine at the health department. Refer to the **current** Tennessee Immunization Program Policy on the use of Federal vaccine and any current guidance on the use of any special supplies of hepatitis B vaccine.

Immunization is recommended by CDC for the following unvaccinated persons:

ALL at risk adult patients (with ANY one of the following risk factors):

All sexually-active persons not in long term, mutually-monogamous relationships

History of more than one sex partner in the past 6 months

Persons seeking evaluation or treatment of sexually transmitted infection

History of injecting drug use or sexual partner(s) who use injecting drugs

Men who have sex with men

At risk (generally, household, sexual or needle-sharing) contacts of persons with hepatitis B

ALL persons served in HIV risk reduction, outreach activities

Residents and staff of facilities for developmentally delayed persons

Persons with end-stage renal disease, dialysis, HIV or chronic non-hepatitis B liver disease

ALL adults with diabetes younger than age 60 years, generally as soon as possible after diagnosis

Adults with diabetes aged 60 and over, with MD or NP order.

ALL adults requesting vaccination against hepatitis B (no reported risk factor required)

To determine if a patient in an ACIP-recommended group is eligible for free, Federal vaccine, please see the current Tennessee Immunization Program Policy on the use of Federal vaccine.

Contraindications and precautions include the following:

Anaphylactic reaction to a previous dose of hepatitis B vaccine or vaccine component

Moderate to severe febrile illness (defer until recovered)

Pregnancy or breast feeding are NOT contraindications if immunization is indicated

Administration of vaccine (see dosing schedule charts below):

HBV may be administered simultaneously with any other vaccines; if not administered simultaneously, schedule next visit for deferred vaccine(s) at any time interval (does not have to be 30 days)

If any dose in the series is delayed, it should be administered when possible and the schedule resumed;
DO NOT RE-START SERIES

Immunocompetent persons are not recommended for booster doses. Immunocompetent persons who require serologic evidence of immunity with a documented remote history of hepatitis B immunization and a negative serology may receive a dose to stimulate an immune response and be retested for serologic evidence of immunity in 4 weeks.

HEPATITIS B RECOMBINANT VACCINE

Adult (age 19 years and up) Pre-Exposure

PLAN

If patient being evaluated for potential sexual or blood exposure to a person with hepatitis B infection, evaluate possible need for HBIG according to section on hepatitis.

Read Vaccine Information Statement (VIS)

Educate about post-immunization serologic testing if in a group for whom testing is recommended (health care providers, sexual or neonatal contacts of persons with hepatitis B)

Draw up vaccine in accordance with package insert instructions

Administer vaccine IM using deltoid according to dosage schedule for age

Document vaccine administration on the immunization clinic record

Recommended Schedule/Dosage for Adults 19 Years of Age

VACCINE Brand	DOSE	ROUTINE SCHEDULE	MINIMUM INTERVAL (accelerated schedule)*
Recombivax HB (Merck) 0.5 ml (5mcg) Pediatric or Adult Formula, or	Dose 1	1st visit	4 weeks after 1 st dose
	Dose 2	4 weeks after 1 st dose	
Engerix-B (GSK) 0.5ml (10 mcg) of Pediatric Formula, or Engerix-B Adult formulation 1.0 ml (20 mcg) ³	Dose 3	4-6 months after 2 nd dose	8 weeks after Dose 2 <i>and</i> 16 weeks after Dose 1

*doses administered more than 4 days earlier than any minimum interval are considered invalid

Recommended Schedule/Dosage for Adults 20 Years of Age and Older

VACCINE	DOSE	SCHEDULE	MINIMUM INTERVAL (accelerated schedule)*
Recombivax HB (Merck) 1.0ml (10 mcg) of Adult Formula, or	Dose 1	1st visit	4 weeks after 1 st dose
	Dose 2	4 weeks after 1 st dose	
Engerix-B (GSK) 1.0 ml (20mcg)	Dose 3	4-6 months after 2 nd dose	8 weeks after Dose 2 <i>and</i> 16 weeks after Dose 1

*doses administered more than 4 days earlier than any minimum interval are considered invalid

³ The adult formulation of Engerix-B may be used in adolescents, but the approved dose is 1.0 ml (20 mcg).

HEPATITIS B RECOMBINANT VACCINE
Adult (age 19 years and up) Pre-Exposure

Recommended Schedule/Dosage for Hemodialysis and Immunocompromised Patients Aged 20 Years or Older (<20 years, recommendations same as general population)

VACCINE	DOSE	SCHEDULE	MINIMUM INTERVAL (accelerated schedule)*
Recombivax HB (Merck): 1.0ml (40 mcg) of <u>Dialysis Formulation</u> , or	Dose 1	1st visit	None given
	Dose 2	4 weeks after 1 st dose	
	Dose 3	6 months after 1 st dose	
	Booster	If annual serologic testing <10 mIU/mL	
Engerix-B (GSK): each dose requires 40 mcg. Use two doses of the 1.0 ml (20 mcg) Adult Formulation	Dose 1	1st visit	None given
	Dose 2	1 month after 1 st dose	
	Dose 3	2 months after 1 st dose	
	Dose 4	6 months after 1 st dose	
	Booster	If annual serologic testing <10 mIU/mL	

*doses administered more than 4 days earlier than any minimum interval are considered invalid

Referral Indicators:

Contraindications as noted under "General Information"

REFERENCES

- CDC. "Epidemiology and Prevention of Vaccine-Preventable Diseases, 10th Edition", DHHS, January 2007
- CDC. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP). Part II: Immunization of Adults. MMWR 2006;55(No. RR-16).
- "Federally Funded Vaccines for Adults" memo from Dr. Kelly Moore and Dr. Tom Jaselskis, July 8, 2009

HERPES ZOSTER (SHINGLES) VACCINE – LIVE VACCINE (Zostavax)

GENERAL INFORMATION

Herpes Zoster vaccine is recommended by the Advisory Committee on Immunization Practices of the CDC as a single dose for adults 60 years of age and older.¹ It is not licensed for use under age 50. Vaccination is recommended by CDC irrespective of a patient's history of shingles in order to reduce the risk of recurrence.

To determine if a patient in an ACIP-recommended group is eligible for free, Federal vaccine, please see the current Tennessee Immunization Program Policy on the use of Federal vaccine.

Contraindications

History of severe allergic reaction (anaphylaxis) to any component of the vaccine, including neomycin or gelatin

Cancer: persons with leukemia, lymphoma or other malignancy affecting the bone marrow or lymphatic system. It may be given to persons with leukemia in remission who have not had chemotherapy or radiation in at least 3 months.

Persons with AIDS or other clinical manifestations of HIV infection

Persons on immunosuppressive therapy, including ≥ 20 mg/day of prednisone or equivalent for 2 or more weeks. Defer vaccination for at least 1 month after discontinuation.

Persons with cellular immunodeficiency

Persons undergoing stem cell transplants (may be considered at least 2 years after transplant)

Persons receiving recombinant human immune mediators and immune modulators (such as adalimumab, infliximab, etanercept). Defer vaccination for at least 1 month after discontinuation.

Precautions include the following:

Moderate to severe acute illness: postpone until recovery

Adverse events include the following:

Local reactions (erythema, pain or tenderness, and swelling)

Administration of Vaccine:

Give a single dose of Herpes Zoster vaccine for adults 60 years of age and older whether or not they report a prior episode of shingles.

This may be given simultaneously with any other vaccines indicated for the recipient. If not given simultaneously, live virus vaccines (e.g., MMR, yellow fever) must be administered at least 1 month apart.

PLAN

Have patient/guardian read Vaccine Information Statement/Vaccine Information Material
Counsel regarding benefits, side effects, and management
Administer unit dose of Herpes Zoster vaccine subcutaneously
Advise to wait in clinic 20 minutes after injection
Document vaccine administration on the immunization clinic record
Instruct patient to contact Health Department if severe reaction occurs

Referral Indicators:

Person with contraindications as noted under “General Information”

Follow-Up:

All serious adverse events that occur after receipt of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS).

REFERENCE

CDC. Prevention of Herpes Zoster: Recommendations of the Advisory Committee on Immunization Practices. May 15, 2008

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e0515a1.htm>

Package insert 06/2011

MEASLES, MUMPS, RUBELLA VACCINE (MMR)

GENERAL INFORMATION – MMR is a live virus vaccine that is administered subcutaneously. MMR vaccine may be stored in the refrigerator or freezer and should be used within 8 hours of reconstitution.

Contraindications and Precautions, include the following:

Severe allergic (e.g., anaphylaxis) reaction to vaccine component, such as gelatin or neomycin, or to a previous dose of MMR vaccine (Refer)

Moderate to severe acute illness (wait until resolving)

Pregnancy (if known, testing is not required before vaccinating)

Known severe immunodeficiency (e.g., from hematologic or solid tumors; receiving chemotherapy; congenital immunodeficiency; or, patients with HIV and severe immunocompromise) (Refer)

Patients currently on long term immune suppression therapy: has had ≥ 14 days of ≥ 2 mg/kg/day (or, ≥ 20 mg/day) of prednisone, or equivalent. (Defer vaccination until high dose therapy has been stopped for 1 month).

Recent (within 11 months) antibody-containing blood product (specific interval depends upon the blood product – see CDC’s General Recommendations on Immunization for details)

MMR vaccine may be given on the same day as other live virus vaccines (e.g. varicella) however, if not given on the same day, they must be separated by 4 weeks (28 days).

If not given on the same day, wait 4 weeks from date of MMR vaccine to administer TST.

History of thrombocytopenic purpura or thrombocytopenia (low platelet count) (Refer)

Note: The following are NOT contraindications or precautions to MMR vaccination: egg allergy; breast feeding or pregnant household contact; oral low dose, short course or inhaled steroid use.

Adverse events

Common: Susceptible recipients may develop the following mild symptoms caused by measles vaccine virus replication 5 to 12 days after immunization:

1-2 days of fever of 103°F or higher (5-15%)

rash (5%)

Joint symptoms (pain or inflammation) with onset 1-3 weeks after vaccination and lasting up to 3 weeks (up to 25% of adult females, uncommon in children and males)

Rare:

severe allergic reaction (e.g., anaphylaxis)

pain in arms and legs 1-3 weeks after vaccination

thrombocytopenia

parotitis

deafness

encephalopathy

ACIP Recommended Populations

NOTE: *See current policy from the Tennessee Immunization Program for guidance concerning which recommended persons are eligible for federally funded vaccine*

All children (2 doses)

Adults born in 1957 or later (at least 1 dose if no acceptable history of disease), with emphasis on certain groups at higher risk of infection or complication:

Women of childbearing age (who have never had MMR or who lack serologic evidence of immunity)

Unvaccinated HIV patients without evidence of severe immunocompromise

College students (2 doses required by state law for full time students in TN)

International travelers (total of 2 doses, §federal vaccine only for ages 6 months through 18 years)

Healthcare workers (2 doses or evidence of immunity)

Vaccinate susceptible persons age 6 months and up within ≤72 hours of exposure to measles

Administration of Vaccine:

Give first dose at 12-15 months of age

Give second dose at 4-6 years* (recommended if born after 1957)

MMR vaccine may be given simultaneously with all other vaccines; if MMR and varicella (or another live virus vaccine) are not administered at the same visit, they should be separated by at least 28 days

For children traveling outside the United States:

6-11 months: 1 MMR before travel (because it gives less than ideal protection, this extra dose does not count toward the 2 dose routine MMR series).

12 months or up: should get 2 doses of MMR before travel (28 days apart, minimum interval). Two doses after 12 months of age completes the MMR series.*

Vaccine is not needed if patient has laboratory evidence of immunity to all three (measles, mumps and rubella). However, if any is negative, documentation of 2 MMR doses is needed.

*The 2nd dose of MMR is recommended routinely at 4-6 yrs of age but may be administered during any visit, provided at least 1 month has elapsed since receipt of the 1st dose and that both doses are administered beginning at or after 12 months of age.

PLAN

Have patient or accompanying adult read Vaccine Information Statement
Counsel regarding benefits, side effects, and management
Counsel females of childbearing age to avoid pregnancy for 28 days post vaccination (document LMP)
Administer unit dose of MMR subcutaneously
Advise to wait in clinic 20 minutes after injection
Record manufacturer and lot number of the vaccine administered, date, name, address, and title of person administering vaccine (National Childhood Vaccine Injury Act)
Instruct patient to contact Health Department if adverse reaction occurs

NOTE: Any dose of MMR vaccine given earlier than 4 days before the 1st birthday will not count as one of the routine two-dose series; persons who have not received 2 doses of measles mumps and rubella-containing vaccines, such as those who received only a monovalent measles vaccine or combined Measles/Rubella (MR) vaccine should complete a 2 dose series of MMR.

Referral indicators (in addition to contraindications or precautions listed above):

Uncontrolled neurological conditions, such as uncontrolled seizures
Active untreated tuberculosis

Follow-Up:

If severe reaction is reported as occurring within 30 days following vaccine administered by health department personnel, VAERS Report form must be completed.
Return at appropriate interval according to schedule

REFERENCES

Manufacturer Packet Inserts.
National Childhood Vaccine Injury Act, 1986.
Epidemiology and Prevention of Vaccine-Preventable Diseases. Department of Health and Human Services, Centers for Disease Control and Prevention, 12th Ed., May 2011.

MENINGOCOCCAL VACCINE MENINGOCOCCAL CONJUGATE VACCINE (MCV4) (MENACTRA™, MENVEO™)

GENERAL INFORMATION

Meningococcal disease is caused by bacteria (*Neisseria meningitidis*) that infect the bloodstream and the linings of the brain and spinal cord, causing serious illness. Meningococcal disease is rare in the United States, but is now the leading cause of bacterial meningitis in children. Of people with meningococcal disease, 10% die and 11-19% of survivors have permanent disabilities (such as mental retardation, hearing loss, and loss of limbs). Meningococcal disease is most likely to occur in infants and toddlers, although the type (serogroup B) that causes most disease in this age group is not preventable by vaccine. After infancy, the next period of increased risk is from 16-21 years. Infection is spread by direct contact with infected individuals (e.g., sharing a glass or cigarette, or kissing), or via droplets of respiratory secretions (e.g., coughing or sneezing). Symptoms include the sudden onset of fever, chills, severe headache, stiff neck, rash, nausea, vomiting and lethargy.

Meningococcal vaccine is inactivated and contains no live organisms. The vaccine is designed to prevent infections from serogroups A, C, Y and W-135. Protective antibody levels may be achieved within 7-10 days after vaccination. Meningococcal vaccine may be given at the same time as other immunizations, if needed.

Meningococcal Conjugate Vaccine (MCV4)

There are 2 MCV4 vaccines: Menactra™ by Sanofi Pasteur (licensed age 9 months through 55 years) and Menveo™ by Novartis (licensed age 24 months through 55 years)

Immunity is expected to last 3-5 years following a single dose.

MCV4 is recommended for routine use in preteens and certain individuals who are at elevated risk for meningococcal disease and are between 2 and 55 years of age

Where MCV4 is not available, Meningococcal Polysaccharide Vaccine (MPSV4, Menomune™) is an acceptable substitute for some, not all, persons for whom MCV4 is recommended; refer to Meningococcal Polysaccharide vaccine (MPSV4, Menomune) protocol as needed for additional information. MCV4 is always preferred to MPSV4.

ACIP Recommended Populations include the following:

Adolescents (First dose routinely for children 11 through 12 years and as catch up for any children 13 through 18 years not previously vaccinated with MCV4)

College freshmen in dormitories, including those through age 21 who enroll in college and present for vaccine before moving on campus, if not previously vaccinated or booster indicated

Persons age 2 through 55 years who have anatomic or functional asplenia or terminal complement component deficiencies, including such persons who had received one dose of MPSV4 three (3) or more years earlier (with physician order)

Persons age 2 through 55 years who travel to, or reside in, countries in which *N. meningitidis* is hyperendemic or epidemic, particularly if contact with local populations is prolonged

Military recruits (Health departments should refer)

Microbiologists routinely exposed to isolates to *N. meningitidis* (Health departments refer)

To determine if a patient in an ACIP-recommended group is eligible for free, Federal vaccine, please see the current Tennessee Immunization Program Policy on the use of Federal vaccine.

Contraindications to giving the vaccine include the following:

- Persons under 2 years or over 55 years of age
- If known to be pregnant, consult with health officer or refer to medical provider
- Hypersensitivity to any component of the vaccine, including diphtheria toxoid
- Menactra only: hypersensitivity to dry natural latex (contained in vaccine vial stopper)
- Note: Menveo packaging does not contain latex.

Precautions include the following:

- Immunization should be deferred during the course of any moderate to severe illness
- Anyone who has ever had Guillain-Barre Syndrome

Adverse Reactions include the following:**COMMON**

- Mild injection site pain and redness (within 1 -2 days of vaccination)
- Mild systemic reactions such as headache and malaise (within 7 days of vaccination)

RARE

- Fever (within 7 days of vaccination) or severe systemic reaction

PLAN

Vaccinate according to the following table [Use federally-funded vaccine, in accordance with current guidance for its use (see cover letter). If state or locally-purchased vaccine is available, persons ineligible for federally-funded vaccine may be vaccinated in accordance with local policy]:

Risk group	First dose (age in years)	Booster dose (age in years)§
Persons aged 11 through 18 years	11 through 12	16 (catch up dose through age 18)*
	13 through 15	16 through 18*
	16 or older	-none-
HIV-infected persons age 11 through 18 years	11 through 12 (primary 2-dose series, at least 8 weeks apart*)	16 (catch up dose through age 18)* ‡
	13 through 15 (primary 2-dose series, at least 8 weeks apart*)	16 through 18*‡
	≥16 (primary 2-dose series, at least 8 weeks apart*)	-none-
Persons aged 2 through 55 years with persistent complement component deficiency (such as C5-C9, properdin or factor D) or asplenia (functional or anatomic)	At earliest opportunity (primary 2-dose series, at least 8 weeks apart)	Every 5 years following the second primary series dose.
Persons age 2-55 years with prolonged increased risk for exposure to N. meningitidis**	1 dose	If aged 2 through 6 years, after 3 years, <i>if still at increased risk</i> If aged 7 years or older, after 5 years <i>if still at increased risk</i>
§ Minimum interval between primary and booster doses of vaccine is 8 weeks		
* To determine if a patient in an ACIP-recommended group is eligible for free, Federal vaccine, please see the current Tennessee Immunization Program Policy on the use of Federal vaccine..		
‡ Calculate need for booster dose based upon age at receipt of the second dose in the primary 2-dose series.		
**Microbiologists routinely working with <i>Neisseria meningitidis</i> and travelers or residents of countries where meningococcal disease is hyperendemic or epidemic.		

If using Menveo, reconstitute product according to manufacturer package insert prior to administration.
Administer a single dose of vaccine, 0.5 ml **INTRAMUSCULARLY**

Ask patient/guardian about contraindications
Have patient/guardian read Vaccine Information Statement
Document vaccine administration on the immunization clinic record
Advise to wait in clinic for 20 minutes after injection
Instruct patient/guardian to contact Health Department if adverse reaction occurs

Health Teaching:

Provide current Vaccine Information Sheet (VIS) about meningococcal disease and the benefits of vaccination
If the vaccine is used in persons receiving immunosuppressive therapy, the expected immune response may not be obtained
Educate recipients for whom a booster dose is recommended about the timing and importance of the booster dose

Referral:

Pregnancy
Military recruits
Microbiologists occupationally exposed to isolates of *N. meningitidis*
Travelers (to a travel clinic)

REFERENCES

Menactra® [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine] package insert, Sanofi Pasteur (Aventis Pasteur), April 2008
MENVEO® [Meningococcal (Groups A, C, Y and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine] package insert, Novartis, January 2011
MMWR, Prevention and Control of Meningococcal Disease, Recommendations of the Advisory Committee on Immunization Practices (ACIP), U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Atlanta, GA 30333, May 27, 2005/Vol.54/No. RR-7
MMWR, Notice to Readers: Recommendation from the Advisory Committee on Immunization Practices (ACIP) for Use of Quadrivalent Meningococcal Conjugate Vaccine (MCV4) in Children Aged 2--10 Years at Increased Risk for Invasive Meningococcal Disease. December 7, 2007 / 56(48);1265-1266
MMWR, Updated Recommendations for the Use of Meningococcal Conjugate Vaccines – Advisory Committee on Immunization Practices (ACIP) 2010, January 28, 2011. <http://www.cdc.gov/mmwr/pdf/wk/mm6003.pdf>

MENINGOCOCCAL VACCINE MENINGOCOCCAL POLYSACCHARIDE VACCINE (MPSV4) (MENOMUNE)

GENERAL INFORMATION

Meningococcal disease is caused by bacteria (*Neisseria meningitidis*) that infect the bloodstream and the linings of the brain and spinal cord, causing serious illness. Every year in the United States, 1,400 to 2,800 people get meningococcal disease. Ten to 14 percent of people with meningococcal disease die, and 11-19 percent of survivors have permanent disabilities (such as mental retardation, hearing loss, and loss of limbs). Infection is spread by direct contact with infected individuals (e.g., sharing a glass or cigarette, or kissing), or through the air via droplets of respiratory secretions (e.g., coughing or sneezing). Symptoms include the sudden onset of fever, chills, severe headache, stiff neck, rash, nausea, vomiting and lethargy.

Meningococcal vaccine is inactivated and contains no live organisms. Different strains of the meningococcus are more likely to produce disease and the vaccine is designed to prevent infections from groups A, C, Y and W-135. Serogroup B is the most common cause of meningococcal disease in children < 1 year of age; no vaccine is yet available to offer protection against serogroup B. Protective antibody levels may be achieved within 7-10 days after vaccination. Meningococcal vaccine may be given at the same time as other immunizations, if needed.

Meningococcal Polysaccharide Vaccine (MPSV4, Menomune)

Licensed in 1981

It is manufactured by Sanofi Pasteur and is marketed as **MENOMUNE™**

Immunity expected to last 3-5 years following a single dose

It may be administered to persons 2 years of age and older

MPSV4 (Menomune) should only be administered to persons aged 11-55 years when Meningococcal Conjugate Vaccine (MCV4) is not available

MPSV4 (Menomune) is an acceptable alternative for college freshmen living in dormitories when Meningococcal Conjugate Vaccine (MCV4) is not available

MPSV4 (Menomune) is not recommended as a substitute for MCV4 in healthy adolescents ages 11-12 or for adolescents entering high school; healthy adolescents in these age groups, without medical or travel risk factors for disease, are recommended only to receive MCV4

ACIP Recommended Populations include the following:

College freshmen living in dormitories, including those enrolled in college who present for immunization before moving on campus who have not previously received MCV4

Persons who have anatomic or functional asplenia or terminal complement component deficiencies (with physician order)

(recommended population cont.)

Persons who travel to, or reside in, countries in which *N. meningitidis* is hyperendemic or epidemic, particularly if contact with the local population will be prolonged

Military recruits (Health departments should refer)

Microbiologists who are routinely exposed to isolates to *N. meningitidis* (Health departments should refer)

To determine if a patient in an ACIP-recommended group is eligible for free, Federal vaccine, please see the current Tennessee Immunization Program Policy on the use of Federal vaccine.

Contraindications to giving the vaccine include the following:

Children under 2 years of age (effectiveness questionable in this age group)

Hypersensitivity to any component of the vaccine, including Thimerosal

Anaphylactic hypersensitivity to dry natural rubber latex (contained in vial stopper)

If pregnant, consult with health officer or refer to medical provider

Precautions include the following:

Immunization should be deferred during the course of any moderate to severe illness

If the vaccine is used in persons receiving immunosuppressive therapy, the expected immune response may not be obtained

Adverse Reactions include the following:

MOST COMMON

Mild injection site pain and redness

Transient fever

RARE

Headache, malaise, chills

PLAN

Ask patient/guardian about contraindications

Have patient/guardian read Vaccine Information Statement

Vaccine Administration:

¹Reconstitute the vaccine using only the diluent supplied for this purpose May be administered to persons 2 years of age and older as outlined in program policy

May be given to any college student requesting vaccine

Administer to individuals 2 years through 10 years of age that have medical or travel risk factors for meningococcal disease (see Recommended Population)

¹ **Single dose vial - should be used within 30 minutes after reconstitution**

Multidose vial - discard remainder of vaccine within 35 days after reconstitution

Administer a single dose of vaccine, 0.5 ml, **SUBCUTANEOUSLY**

Advise to wait in clinic for 20 minutes after injection

Document vaccine administration on the immunization clinic record

Instruct patient/guardian to contact Health Department if adverse reaction occurs

Health Teaching:

Provide current Vaccine Information Sheet (VIS) about meningococcal disease and the benefits of vaccination

Counsel regarding side effects of vaccine

Referrals:

Pregnancy

Military recruits

Microbiologists occupationally exposed to isolates of *N. meningitidis*

REFERENCES

Meningococcal Disease and Meningococcal Vaccines Fact Sheet, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Atlanta, GA 30333, April 2005

Meningococcal Polysaccharide Vaccine Groups A, C, Y & W-135 Combined package insert, Sanofi Pasteur (Aventis Pasteur), February 2001

MMWR, Prevention and Control of Meningococcal Disease and Meningococcal Disease, Recommendations of the Advisory Committee on Immunization Practices (ACIP), U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Atlanta, GA 30333, May 27, 2005/Vol.54/No. RR-7

PNEUMOCOCCAL POLYSACCHARIDE VACCINE (PPV23)

GENERAL INFORMATION

More than 40,000 cases of invasive pneumococcal disease (4,400 deaths) occurred in the US in 2005. Overall, this vaccine reduces the risk of invasive pneumococcal disease by 60-70%. It may be less effective persons with significant underlying illness, but is still recommended because they are at high risk of severe disease. It has not been shown to prevent pneumococcal pneumonia.

Refer to the Pneumococcal Conjugate Vaccine (PCV) protocol for information about vaccination of certain high risk adults with PCV in addition to PPV23.

Contraindications and Precautions include the following:

- Moderate to severe acute illness
- Severe allergic reaction to vaccine component or following prior dose of vaccine (e.g., phenol)
- Pregnancy
- Children less than 2 years of age

ACIP recommended groups (single dose – see note for second dose recipients):

All adults 65 years of age and older

Adults aged 19 through 64 in the following categories:

- Current smokers
- Persons with chronic illness: diabetes, liver disease (include cirrhosis and alcoholism), chronic lung disease (include asthma), chronic renal failure, nephrotic syndrome, chronic cardiovascular disease (not essential hypertension)
- Asplenia (functional or anatomic)
- Immunocompromising conditions: ASAP after HIV diagnosis; leukemia, lymphoma, Hodgkin disease, multiple myeloma, generalized malignancy, organ or bone marrow transplantation, immunosuppressive chemotherapy and high dose corticosteroids for >14 days
- residents of nursing homes or other long-term care facilities
- Cochlear implant recipients
- Persons with CSF leaks

Children aged 2-18 in the following categories:

- Same as adults 19-64, except not indicated for asthma, smokers in this age group, administer at least 2 months after last dose of pneumococcal conjugate vaccine.

To determine if a patient in an ACIP-recommended group is eligible for free, Federal vaccine, please see the **current Tennessee Immunization Program Policy on the use of Federal vaccine.**

Additional notes: (1) Persons with unknown or uncertain immunization history may be vaccinated. (2) Give vaccine at least 2 weeks before planned splenectomy or initiation of immunocompromising treatments that will cause a person to become high risk. (3) Give PPV23 at least 2 months after the last dose of PCV.

PLAN

Have patient or accompanying adult read Vaccine Information Statement
Administer one dose of 0.5 cc pneumococcal vaccine intramuscularly or subcutaneously
(preferably in the deltoid muscle or lateral mid thigh)
Counsel regarding benefits, side effects, and management
Advise to wait in clinic for 20 minutes after injection
Document vaccine administration on the immunization clinic record
Instruct patient to contact Health Department if adverse reaction occurs (complete VAERS form)

NOTE: REVACCINATION RECIPIENTS

Because of the lack of evidence of improved protection with multiple doses of this vaccine, **a second dose (revaccination) is not recommended for most recipients.** PPV23 **revaccination** is recommended only for certain persons at the highest risk of severe disease.

A second dose ≥ 5 years after the first is recommended for the following:

- Persons ≥ 2 years of age with ongoing high risk:
 - functional or anatomic asplenia (ex. sickle cell disease, splenectomy)
 - immunosuppression (HIV, leukemia, lymphoma, Hodgkin disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome, organ or bone marrow transplantation, immunosuppressive chemotherapy and long term corticosteroids.)
- Persons aged 65 and older who received one *or two* doses before age 65 and 5 or more years have passed since the most recent dose (such persons may receive up to 3 total doses).

Referral Indicators:

Persons with contraindications as noted under “General Information”

REFERENCES

Epidemiology and Prevention of Vaccine Preventable Diseases, Centers for Disease Control and Prevention, February 2008