

PUBLIC HEALTH

NURSING PROTOCOL

Tennessee Department of Health
Bureau of Health Services
Patient Care Services
Revised 12/08

PREFACE

A protocol represents delegated medical management. The Public Health Nursing (PHN) Protocols, establish standard of care for the general Public Health Nurse practicing at the local level in rural and Metro Public Health Departments. The PHN Protocol was developed, and is maintained, by the Public Health Nursing Practice Committee. These Protocols represent an enormous amount of work from a variety of nurses, physicians and other staff throughout the State. They have been reviewed by the State Medical Director, State Nursing Director, Medical Services Evaluation Committee, and specific individuals that are involved in developing Program guidelines that impact nursing practice.

The manual is divided into seven distinct sections. **Section I.** includes those protocols related to **Emergency Management.** **Section II.** includes those protocols related to **Family Planning.** **Section III.** is the **General section.** It covers treatments for various conditions that are not included in the other distinct sections. This section also includes recommended periodicity schedules for maintenance of health for both adults and children. **Section IV.** includes the **Immunization** protocols. **Section V.** includes those protocols related to **Sexually Transmitted Diseases.** **Section VI.** includes protocols related to **Disaster Preparedness and Bioterrorism.** Finally, an **Appendix** section (**section VII.**), includes additional program specific information and the **List of Standard Abbreviations.**

As always, we welcome your comments and suggestions with regards to additions, revisions, format changes etc. It is our goal to maintain an accurate, viable, and user friendly document.

Deborah Hardin, BS, RN
Public Health Nursing Director

Carol Williams, RN, BA
Assistant Public Health Nursing Director

Staff Support
PHN Practice Committee

PUBLIC HEALTH NURSING PROTOCOL AGREEMENT

Region _____

County/Site _____

This protocol has been jointly prepared by public health nurses and physicians and is approved for use by all licensed nurses. The health providers whose names are signed below agree that this protocol establishes the standard for public health nursing practice for those conditions included in the protocol. This protocol expires one year from the date of signatures. It shall be renewed, or revised, and signed annually and more frequently as deemed necessary.

Name	Date		
_____	_____	Regional Medical Director	Date
_____	_____		
_____	_____	Regional Nursing Director	Date
_____	_____		
_____	_____	County Health Officer	Date
_____	_____		
_____	_____	County Nursing Supervisor	Date
_____	_____		
_____	_____		
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TABLE OF CONTENTS

	<u>Page No.</u>
Preface.....	i
Public Health Nursing Protocol Ageement.....	ii
Table of Contents.....	iii

SECTION I: EMERGENCY MANAGEMENT

ACUTE ASTHMA ATTACK	1.010
ACUTE POISONING	1.020
ANAPHYLAXIS	1.030
Emergency Drug Chart	
ANIMAL BITES	1.040
BURN - FIRST DEGREE	1.050
CARDIAC EMERGENCIES.....	1.060
EMERGENCY CHILDBIRTH	1.070
Apgar Scoring System	
HEMORRHAGE/HEMORRHAGIC SHOCK.....	1.080
INSECT (NON SPIDER) BITES	1.090
LACERATION.....	1.100
PUNCTURE WOUND	1.110
RESPIRATORY EMERGENCY	1.120
SEIZURES.....	1.130
SHOCK.....	1.140
SYNCOPE/VASOVAGAL REACTION/COMMON FAINT.....	1.150
TICK BITE.....	1.160

SECTION II: FAMILY PLANNING

ALL METHODS, INITIAL AND/OR ANNUAL FAMILY PLANNING VISIT	2.010
CERVICAL CANCER SCREENING.....	2.020
COMBINED ORAL CONTRACEPTIVE PILLS.....	2.030
CONDOMS, SPONGE, AND SPERMICIDAL AGENTS	2.040
CONTRACEPTIVE PATCH.....	2.050
DIAPHRAGM	2.060
DYSMENORRHEA	2.070
EMERGENCY CONTRACEPTIVE PILLS (ECPS).....	2.080
FERTILITY AWARENESS-BASED METHODS (FAM).....	2.090
INTRAUTERINE DEVICE (IUD).....	2.100
PREGNANCY TEST	2.110
PROGESTIN-ONLY IMPLANT(S)	2.120

PROGESTIN-ONLY INJECTABLE CONTRACEPTION.....	2.130
PROGESTIN-ONLY PILLS (MINIPILL).....	2.140
STERILIZATION.....	2.150
VAGINAL CONTRACEPTIVE RING.....	2.160

SECTION III: GENERAL

ACNE.....	3.010
ACUTE UPPER RESIRATORY INFECTION (COMMON COLD).....	3.020
ASCARIASIS (ROUNDWORMS).....	3.030
BLOOD PRESSURE, ELEVATED, ADULT.....	3.040
BLOOD PRESSURE, ELEVATED, CHILD.....	3.050
CERUMEN, IMPACTED (EAR WAX).....	3.060
CHIGGERS, (DEMATOPHILIS PENTRANS).....	3.070
CHILDHOOD ANEMIA.....	3.080
CHOLESTEROL RISK ASSESSMENT.....	3.090
CONSTIPATION, ACUTE, CHILD.....	3.100
CONSTIPATION, ADULT.....	3.110
DIAPER DERMATITIS (DIAPER RASH).....	3.120
DIARRHEA.....	3.130
ENTEROBIUS VERMICULARIS (PINWORMS).....	3.140
FEVER, VACCINE ASSOCIATED.....	3.150
FLUORIDE DEFICIENCY.....	3.160
FLUORIDE VARNISH.....	3.170
FOLIC ACID PROPHYLACTIC THERAPY FOR WOMEN AGED 10-44.....	3.180
FOODBORNE OUTBREAK INVESTIGATION.....	3.190
HAEMOPHILUS MENINGITIS, CONTACT.....	3.200
HEPATITIS A, CASE OR PRESUMPTIVE.....	3.210
HEPATITIS A, POST EXPOSURE.....	3.220
HERPES SIMPLEX TYPE I (FEVER BLISTER).....	3.230
HERPETIC STOMATITIS (GINGIVOSTOMATITIS).....	3.240
HORDEOLUM (STY).....	3.250
IMPETIGO/BULLOUS IMPETIGO.....	3.260
IRON DEFICIENCY ANEMIA, 18 YEARS AND OLDER.....	3.270
LEAD TOXICITY SCREENING.....	3.280
MENINGOCOCCAL MENINGITISS, CASE.....	3.290
MENINGOCOCCAL MENINGITIS, CONTACT.....	3.300
MILIARIA (PRICKLY HEAT, HEAT RASH).....	3.310
OBSTRUCTED NASOLACRIMAL DUCT.....	3.320
ORAL CANDIDIASIS/MONILIASIS (THRUSH).....	3.330
PEDICULOSIS CAPITIS (HEAD LICE).....	3.340
PERIODICITY SCHEDULE - INFANCY-ADOLESCENCE.....	3.350
PERIODICITY SCHEDULE - 22 YEARS & OVER.....	3.360

PITYRIASIS ROSEA.....	3.370
POISON IVY DERMATITIS.....	3.380
PREVENTION OF VITAMIN DEFICIENCY - PRENATAL.....	3.390
SARCOPTES SCABIEI (SCABIES).....	3.400
SEBORRHEIC DERMATITIS (CRADLE CAP).....	3.410
SMOKING CESSATION.....	3.420
Smoking Cessation Counseling & Treatment	
Patient Willing to Make Quit Attempt	
Patient Not Willing to Make Quit Attempt	
Pharmacotherapies for Smoking Cessation	
Patient Tobacco Survey	
Tobacco Cessation Clinical Form -Initial Clinical Visit	
Tobacco Cessation Clinical Form - Resupply Visit	
TINEA CORPORIS (RINGWORM).....	3.430
TINEA CRURIS (JOCK ITCH, GYM ITCH).....	3.440
TINEA VERSICOLOR.....	3.450
TUBERCULIN SKIN TESTING (TST).....	3.460
TUBERCULIN SKIN TESTING, TWO STEP PROCEDURE.....	3.470
TUBERCULOSIS, CASE OR SUSPECT (INITIAL VISIT).....	3.480
TUBERCULOSIS, TREATMENT OF LATENT TUBERCULOSIS INFECTION (LTBI).....	3.490
URINE, ABNORMAL, ADULT.....	3.500
URINE, ABNORMAL, CHILD.....	3.510
URTICARIA (HIVES).....	3.520
VARICELLA (CHICKENPOX).....	3.530

SECTION IV: IMMUNIZATIONS

COMVAX (Combined HIB/Hep B).....	4.010
DIPHThERIA, TETANUS TOXOID & ACELLULAR PERTUSSIS VACCINE (DTaP).....	4.020
DIPHThERIA and TETANUS TOXOID, PEDIATRIC (DT Pediatric).....	4.030
DIPHThERIA, TETANUS TOXOID, ACELLULAR PERTUSSIS, INACTIVATED POLIO VACCINE (DTaP-IPV).....	4.040
DIPHThERIA, TETANUS TOXOID and ACELLULAR PERTUSSIS, INACTIVATED POLIO, HAEMOPHILUS INFLUENZAE TYPE B COMBINATION VACCINE (DTaP-IPV-Hib).....	4.050
GENERIC INJECTIONS.....	4.060
HAEMOPHILUS b CONJUGATE VACCINE (Hib).....	4.070
HEPATITIS A VACCINE.....	4.080
HEPATITIS A INACTIVATED, HEPATITIS B RECOMBINANT VACCINE ADULT (age 18 years and up).....	4.090
HEPATITIS B RECOMBINANT VACCINE, Pre-Exposure (Birth - 18 years).....	4.100

HEPATITIS B RECOMBINANT VACCINE, Pre-Exposure Adult (19 years & Up)	4.110
HERPES ZOSTER (SHINGLES) VACCINE.....	4.115
HUMAN PAPILOMAVIRUS VACCINE (HPV).....	4.120
2009 H1N1 INFLUENZA (For Information and Guidance).....	4.125
INFLUENZA VACCINE, LIVE ATTENUATED (LAIV)	4.130
INFLUENZA VACCINE, TRIVALENT INACTIVATED (TIV)	4.140
MEASLES, MUMPS, RUBELLA VACCINE (MMR)	4.150
MENINGOCOCCAL VACCINE (MENACTRA).....	4.160
MENINGOCOCCAL VACCINE (MENOMUNE)	4.170
PEDIARIX (DTaP/HEP B/IPV).....	4.180
PNEUMOCOCCAL CONJUGATE VACCINE	4.190
PNEUMOCOCCAL POLYSACCHARIDE VACCINE.....	4.200
POLIO VACCINE, INACTIVATED.....	4.210
RABIES VACCINE, POST-EXPOSURE.....	4.220
RABIES VACCINE, PRE-EXPOSURE	4.230
ROTAVIRUS VACCINE.....	4.240
TETANUS, DIPHTHERIA, AND ACELLULAR PERTUSSIS VACCINE, (Tdap) (11 through 18 years)	4.250
TETANUS, DIPHTHERIA, AND ACELLULAR PERTUSSIS VACCINE, (Tdap) (19 through 64 YEARS)	4.260
TETANUS AND DIPHTHERIA TOXOID, ADULT TYPE (Td).....	4.270
TETANUS PROPHYLAXIS IN WOUND MANAGEMENT	4.280
VARICELLA VACCINE.....	4.290

SECTION V: SEXUALLY TRANSMITTED DISEASES

CHLAMYDIA TRACHOMATIS, CASE OR CONTACT.....	5.010
CHLAMYDIA TRACHOMATIS, CASE OR CONTACT, OPT-OUT HIV TESTING (METRO AREAS ONLY).....	5.020
CHLAMYDIA TRACHOMATIS, CONTACT PARTNER DELIVERED THERAPY.....	5.030
GONORRHEA, CASE OR CONTACT.....	5.040
GONORRHEA, CASE OR CONTACT OPT-OUT HIV TESTING (METRO AREAS ONLY).....	5.050
HEPATITIS B, CASE OR PRESUMPTIVE	5.060
HEPATITIS B, INFANT CONTACTS.....	5.070
HEPATITIS B, OTHER NON-OCCUPATIONAL CONTACTS, POST- EXPOSURE.....	5.080
HEPATITIS C, (NON - A, NON - B), CASE	5.090
HERPES SIMPLEX - TYPE II.....	5.100
HIV TESTING AND COUNSELING.....	5.110
HIV OPT-OUT HIV TESTING (METRO AREAS ONLY).....	5.120

PEDICULOSIS PUBIS (PUBIC LICE)	5.130
SYPHILIS, CASE OR CONTACT	5.140
SYPHILIS, CASE OR CONTACT OPT-OUT HIV TESTING (METRO AREAS ONLY)	5.150
TRICHOMONIASIS, CASE OR CONTACT.....	5.160
 SECTION VI: DISASTER PREPAREDNESS AND BIOTERRORISM	
ANTHRAX VACCINE	6.010
POTASSIUM IODIDE ADMINISTRATION	6.020
SMALLPOX VACCINE	6.030
 APPENDICES	
A. ADDITIONAL IMMUNIZATION INFORMATION	7.010
ADMINISTERING VACCINES: DOSE, ROUTE, SITE, AND NEEDLE SIZE	
HOW TO ADMINISTER INTRAMUSCULAR (IM) INJECTIONS	
HOW TO ADMINISTER SUBCUTANEOUS (SC) INJECTIONS	
MEDICATION ADMINISTRATION (How To Avoid Medication Errors)	
Follow The Five Rights of Medication Administration	
TIPS ON SAFEGUARDING YOUR VACCINE SUPPLY	
(Refer to Vaccine Storage and Handling Toolkit)	
VACCINES AND ROUTE OF ADMINISTRATION	
VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)	
B. LIST OF STANDARD ABBREVIATIONS	7.020
 REFERENCES	 7.030
 INDEX	 7.040

INTRAUTERINE DEVICE (IUD)

GENERAL INFORMATION

All PHNs must be able to discuss the intrauterine device (IUD) option with clients, provide the client with written information on the safety and effectiveness of IUDs, and answer any questions the client may have. All PHNs must know how to make IUD referrals. IUDs cannot be provided by deferred exam. See Family Planning Clinical Guidelines and the most current edition of Contraceptive Technology for method counseling details.

Before making an IUD referral, review the patient package insert (available on line at www.paragard.com listed on homepage top right or www.mirena.com under professional information, then educational materials) with the client and give it to her to read. Tell her to take the patient package insert with her to the IUD referral visit. Document in the chart that the patient package insert was reviewed with and given to the client.

Candidates for either IUD (levonorgestrel-releasing or copper-bearing) may have (but are not limited to) the following characteristics:

- Parous (Mirena only)
- Interested in long-term, reversible, low-cost method
- Stable, monogamous relationship
- No recent history of STDs or PID (see package insert for both products as recommendation varies)
- No current evidence of active purulent cervicitis, gonorrhea, chlamydia, or other genital tract infection.
- No current risk factors for PID
- No known anatomic uterine anomalies
- No unexplained abnormal vaginal bleeding

SUBJECTIVE FINDINGS

Collect medical history for the NP or physician to review with the client.

OBJECTIVE FINDINGS (Laboratory tests for FP clients are chosen as indicated by the method, or by client need. However, laboratory tests cannot exceed any established department or program screening or testing limits. Limitations on laboratory testing may be established to meet funding or other needs).

- Blood pressure
- Physical examination¹ performed annually by examiner

¹ If a TennCare child (under the age of 21) receives the major components of a Child Health/EPSTD exam through the health department's women's health clinic, she should also receive developmental, vision, and hearing screening in order to complete the recommended AAP standards for preventive health care.

- Height and weight for BMI
- Hemoglobin or Hematocrit initially and then as indicated
- Pap smear in accordance with current Pap smear guidelines
- Sickle cell screening
- Syphilis serology
- Mantoux tuberculin test
- Pregnancy test
- Rubella titer
- Wet prep (examiner)
- HIV testing
- Urinalysis
- Gonorrhea and chlamydia screening –new guidance 2008.
 - Screen all family planning clients less than age 25 annually (at the routine initial/annual exam). This is the only age group that will receive annual screening in all locations.
 - For family planning clients ages 25-29, routine screening should only be provided in those counties with a chlamydia positivity rate of 3 percent or higher. (Healthy People 2010 target for chlamydia prevalence is no more than 3%).
 - As of 2007, these counties included: Anderson, Benton, Claiborne, Coffee, Fayette, Fentress, Gibson, Giles, Hamblen, Hardeman, Hardin, Haywood, Henry, Jefferson, Maury, McNairy, Meigs, Monroe, Montgomery, Overton, Pickett, Roane, Shelby County including Memphis Planned Parenthood, Stewart, and White.
 - In all other counties, for family planning clients ages 25 and over, screen only as follows:
 - a client who is being prepared for IUD insertion
 - a client who has documented signs or symptoms
 - a client who is named as a contact
 - a client who is using drugs
 - a client who is exchanging sex for money or drugs.
 - A client who has been treated for a positive chlamydia test in the last 3 to 12 months and has returned to clinic for another reason WILL NOT BE SCREENED again for chlamydia, during this second visit, though recommended by the CDC 2006 STD Guidelines. (This is due to 2008 funding limits).
 - According to CDC 2006 STD treatment guidelines, test of cure (3 weeks to 3 months post-treatment of the infection) is not recommended unless the client is pregnant. Test of cure during pregnancy will occur only in those counties that provide full service comprehensive prenatal care. Clients with positive urine pregnancy tests and positive urine chlamydia tests will receive test of cure with their prenatal care provider. With client consent, forward records.

ASSESSMENT

Possible candidate for IUD insertion/Candidate for IUD referral

PLAN

A **plan of care** will be developed and signed by either the PHN with gyn skills, the RN who graduated from a certificate program, the APN, or Physician (all referred to as “examiner”). The plan of care is developed in accordance with the protocol for the particular examiner. The plan of care written by the examiner must be reviewed and followed by the PHN at each visit. The suggested components of the examiner’s plan of care can be found in The Family Planning Clinical Guidelines. The most current edition of Contraceptive Technology is also a good resource for the examiner’s plan of care.

PHN with gyn skills will not insert either type of IUD. PHNs with gyn skills could perform the pre-insertion examination and collect the pre-insertion labs if requested to do so by the inserter.

INSTRUCTIONS

IUD insertion day instructions

- Provide written and oral instructions on the use of the IUD including name of the IUD, date of insertion, number of years the device is effective.
- Prior to insertion, assure informed consent using the patient package insert found packaged with the device (or online as noted above) and the teaching tool found on the back of the method specific consent form.
- With the inserter’s approval, advise client to take either aspirin 650 mg or acetaminophen 1000 mg by mouth., one hour prior to insertion.
- With the inserter’s approval, a prostaglandin inhibitor such as ibuprofen 400 mg. by mouth, repeat q 4-6 hrs prn can be used for post-insertion cramping.
- Advise client to bring someone with her to the clinic to provide a ride home in case she experiences pain or nausea immediately after insertion
- IUD users will need to check for the IUD string at the end of each period. After insertion, give the client the trimmed IUD strings to help her learn how they feel. She should report the absence of or any changes in the length of the strings. She should report the presence of the plastic portion of the IUD if it is palpable at the cervical os.
- Schedule IUD follow-up appointment in 4-12 weeks or as recommended by the inserter.
- Encourage the client to call or come in for any questions or problems.

IUD insertion charting and tracking

- Document in chart that the patient package insert was reviewed with and given to the client.
- Record name of IUD, lot number, date of insertion, date for removal, and expiration date in the chart.
- If region uses a problem list, record “IUD surveillance” on problem list with insertion date as the date of onset.

IUD Warning Signs

All IUD clients must be counseled in and report the signs of pelvic infection. These include:

- Malodor
- Fever (101°F or more without obvious cause)
- Sudden severe abdominal or suprapubic pain
- Dyspareunia

Other **WARNING SIGNS** that IUD clients must report immediately include:

- Abdominal or pelvic pain (ectopic pregnancy)
- Prolonged or heavy bleeding/discharge/odor (infection)
- Painful sexual intercourse
- Fever or chills (infection)
- Any signs of pregnancy
- Exposure to gonorrhea/chlamydia/any STD
- Cannot feel string or can feel plastic
- Missed period or abnormal spotting or bleeding (infection or ectopic pregnancy)
- Flu-like illness (infection)

The following is a useful acronym for remember the IUD warning signs:

- P** Period late (pregnancy), abnormal spotting or bleeding
- A** Abdominal pain, pain with intercourse
- I** Infection exposure (any STD), abnormal discharge
- N** Not feeling well, fever, chills
- S** String missing, shorter or longer

IUDs do not protect against STDs and HIV. Advise clients to use latex condoms to decrease the risks of STDs. Also, counsel the client to avoid high risk sexual behaviors including multiple partners and having a sexual partner with multiple partners.

HEALTH TEACHING

Through the Title X Program Guidelines, the federal Office of Population Affairs requires that counseling about certain topics occur with family planning clients. These required topics should be discussed with the client at least once during the time the client is under the care of the family planning program. Ideally, the client will receive instruction on 3-4 of the required topics at each visit until all topics, required are covered. Review past client counseling at each visit and base current counseling/education on client needs and program requirements.

There is a detailed list of the REQUIRED counseling/education topics in the Family Planning Program Clinical Guidelines, under Visit Guidelines. Other counseling topics are detailed there also. Or, you may review a brief list of counseling/education topics in the All Methods, Initial and/or Annual Family Planning Visit section of the PHN Protocol.

REFERENCES:

- American College of Obstetricians and Gynecologists, "Intrauterine Devices", Number 59, Jan 2005
Contraceptive Technology, Nineteenth-Revised Edition, 2007, Robert A. Hatcher, MD et. al.
Family Planning Clinical Guidelines, Tennessee Department of Health, 2007.
ParaGard T 380A, Intrauterine Copper Contraceptive, Prescribing Information, Duramed Pharmaceuticals, Inc., May 2006.
Mirena Intrauterine System, Prescribing Information, Bayer HealthCare Pharmaceuticals, July 2008.
A Pocket Guide to Managing Contraception, Hatcher, R. A., Nelson, A. L., Ziemann, A., et al., . Tiger, Georgia: Bridging the Gap Foundation, 2007-2009.
World Health Organization, "Medial Eligibility Criteria for Contraceptive Use, Third Edition, Geneva, 2004
www.paragard.com
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<http://www.healthypeople.gov/Document/HTML/Volume2/25STDs.htm>

HEPATITIS A, POSTEXPOSURE

GENERAL INFORMATION

Hepatitis A virus (HAV) symptoms may appear two to seven weeks after exposure to the infected source, but usually occur about four weeks after exposure. However, people who have been infected are contagious from about two weeks before the symptoms appear and continue to be contagious for about one week after the onset of jaundice. After they recover from HAV they are immune to it for life and do not continue to carry the virus.

The recommendations for the use of hepatitis A vaccine after exposure to HAV have changed. People who recently have been exposed to HAV and who previously have not had hepatitis A vaccine should be given a single dose of hepatitis A vaccine (not the combination vaccine) **or** immune globulin (IG) as soon as possible and within 14 days of the last exposure. The effectiveness of postexposure prophylaxis declines over time. Decisions to use vaccine or IG should take into account which of them is readily available and patient characteristics associated with more severe manifestations of hepatitis A, including older age and chronic liver disease.

Federally funded vaccine and IG may be used for PEP. Federally funded vaccine is not available for second doses of vaccine unless the recipient would otherwise be provided the second dose as part of the routine hepatitis A immunization protocol.

Hepatitis A vaccine is preferred for:

- Most people age 12 months through 40 years of age (exceptions below)

IG is preferred for:

- People over 40 years of age (hepatitis A vaccine can be used if IG is unavailable)
- Children younger than 12 months of age
- Immunocompromised persons
- Persons who have diagnosed chronic liver disease
- Persons for whom vaccine is contraindicated

Contact to a known or suspected hepatitis A case is defined as follows:

Close personal contact (with not more than 14 days since last exposure to infectious case):

- Household and sexual contacts
- Persons who have shared illicit drugs
- Close family and playmates
- Ongoing personal contact (e.g., regular babysitting)

HEPATITIS A, POSTEXPOSURE (continued)

Daycare contact (with not more than 14 days since exposure)

Hepatitis A vaccine or IG should be administered to all previously unvaccinated staff members and attendees of child care centers or homes if:

- 1) one or more cases of hepatitis A are recognized in children or employees
or
- 2) cases are recognized in two or more households of center attendees

In centers that do not provide care to children who wear diapers, hepatitis A vaccine or IG need be administered only to classroom contacts of the index patient. When an outbreak occurs (i.e., hepatitis A cases in three or more families), hepatitis A vaccine or IG also should be considered for members of households that have children (center attendees) in diapers.

Common-source exposure

If case is a **food handler**, hepatitis A vaccine or IG should be given to other food handlers in the same establishment (if not more than 14 days since exposure) - consult with communicable disease director and regional health officer before acting.

Recommended for patrons if

- 1) during the time when the food handler was likely to be infectious, the food handler both directly handled uncooked or cooked foods and had diarrhea or poor hygienic practices, AND
- 2) patrons can be identified and treated ≤ 2 weeks after the exposure
In settings in which repeated exposures to HAV might have occurred (e.g., institutional cafeterias), stronger consideration of hepatitis A vaccine or IG use could be warranted.

Schools, hospitals, and work settings

Hepatitis A postexposure prophylaxis is not routinely indicated when a single case occurs in an elementary or secondary school or an office or other work setting, and the source of infection is outside the school or work setting. Also, when a person who has hepatitis A is admitted to a hospital, staff members should not routinely be administered hepatitis A postexposure prophylaxis; instead, careful hygienic practices should be emphasized. Hepatitis A vaccine or IG should be administered to persons who have close contact with index patients if an epidemiologic investigation indicates HAV transmission has occurred among students in a school or among patients or between patients and staff members in a hospital.

HEPATITIS A, POSTEXPOSURE (continued)

Plan

Report all know cases and suspects to the Communicable Disease Representative
For persons exposed to HAV within the past 14 days and who previously have not received hepatitis A vaccine administer appropriate postexposure prophylaxis, according to guidelines above: either a single dose of single-antigen vaccine (refer to the Hepatitis A Vaccine protocol for dosage and administration) or IG (0.02mL/kg) as soon as possible (and **only** within 14 days of exposure); see Dosage for IG Prophylaxis Chart

The Tennessee Department of Health provides post-exposure prophylaxis with vaccine or immune globulin for contacts to hepatitis A cases who meet listed criteria
If using immune globulin, obtain order from public health or private physician to administer immune globulin

Delay administration of live virus vaccine(s) for at least 3 months after IG administration

If immune globulin is given within 14 days after a live virus vaccine has been given, the live virus vaccine should be repeated in 3 months

If immune globulin has been given in the previous 3 months, consult communicable disease director or public health physician prior to repeating

If the preferred postexposure prophylaxis (immune globulin or vaccine) for a particular patient is not readily available, but the alternative product is, consult with a public health physician or communicable disease director to determine acceptability of administering the alternative product.

Health Teaching:

Household and close contacts

Fecal/oral precautions

Wash hands after elimination, and before preparing food and eating; keep nails short

Daycare Facilities

Prompt and proper diaper changing

Proper disposal of diapers and disinfection of changing area

Hand washing after elimination, diaper changing, before eating, before food preparation

Disinfection of toys and play equipment in areas with diagnosed children

Educate that all children 12 months and up are now recommended to be vaccinated routinely against hepatitis A

Food Service Facilities

Environmental inspection and emphasis on personal hygiene, hand washing and sanitation

Remove food handler with diarrhea from direct food handling duties

HEPATITIS A, POSTEXPOSURE (continued)

Management to notify health department if secondary cases indicated in food handlers (fever, malaise, anorexia, abdominal pain, or nausea)
Contact health provider immediately if symptoms develop in coinfecting cases (similar time frame) or in secondary cases (within six weeks)

Follow-up

If hepatitis A vaccine is initiated for postexposure, instruct patient that they may obtain a second dose after 6 months or longer to complete the series for lifelong immunity. The second dose of vaccine is not necessary for post-exposure prophylaxis and is not provided by the health department to persons for whom the health department would not otherwise provide hepatitis A vaccine.

Referral Indicators:

Symptomatic for hepatitis A

REFERENCES

MMWR, Update: Prevention of Hepatitis A After Exposure to Hepatitis A...., October 19, 2007 /56 (41); 1080-1084
Red Book, 27th Edition 2006
“Federally Funded Vaccines for Adults” memo from Dr. Kelly Moore and Dr. Tom Jaselskis, July 8, 2009

DOSAGE OF IMMUNE GLOBULIN (IG) FOR PROPHYLAXIS OF HEPATITIS A

Dosage is 0.02 ml of IG/kg

1 kg = 2.2 lbs

<u>Weight</u>	<u>Immune Globulin</u>
11 lbs.....	.1 ml
22 lbs.....	.2 ml
33 lbs.....	.3 ml
44 lbs.....	.4 ml
55 lbs.....	.5 ml
66 lbs.....	.6 ml
77 lbs.....	.7 ml
88 lbs.....	.8 ml
99 lbs.....	.9 ml
110 lbs.....	1.0 ml
121 lbs.....	1.1 ml
132 lbs.....	1.2 ml
143 lbs.....	1.3 ml
154 lbs.....	1.4 ml
165 lbs.....	1.5 ml
176 lbs.....	1.6 ml
187 lbs.....	1.7 ml
198 lbs.....	1.8 ml
209 lbs.....	1.9 ml
220 lbs.....	2.0 ml
231 lbs.....	2.1 ml
242 lbs.....	2.2 ml
253 lbs.....	2.3 ml
264 lbs.....	2.4 ml
275 lbs.....	2.5 ml

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 ≥ 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). This vaccine is covered for eligible children in the Vaccines for Children Program.

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 (refer to a travel clinic)
- Users of illegal drugs (refer)
- *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 (refer)

***Federally funded vaccine may be used for these groups; federally funded vaccine may also be used as a single dose for post-exposure prophylaxis of appropriate recipients (see Hepatitis A Post-Exposure Prophylaxis protocol)**

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)

(Continued on next page)

HEPATITIS A VACCINE (continued)

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)

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
Record manufacturer and lot number of the vaccine administered, date vaccine and VIS given, address of facility, and name and title of person administering vaccine
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:

Adults requesting hepatitis A vaccine, except where specifically permitted by health department policy (e.g., in a travel clinic or during certain outbreaks)
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

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)

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 A VACCINE (continued)

Severe reaction to previous vaccine (consult MD)

REFERENCES

“Federally Funded Vaccines for Adults” memo from Dr. Kelly Moore and Dr. Tom Jaselskis, July 8, 2009

COMVAX

(Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant Vaccine))

GENERAL INFORMATION:

Hepatitis B vaccine is available in combination with *Haemophilus influenzae* type b (Hib) vaccine as Comvax® (by Merck). It is licensed for use when either or both antigens are indicated and the other antigen is not contraindicated. Because premature Hib vaccination can cause non-response to subsequent doses (“immunotolerance”) of Hib vaccine, instead of immunity, no Hib-containing vaccine should ever be administered before 6 weeks of age. Comvax may be used to complete the hepatitis B vaccine series in all infants, including those whose mothers are or may be infected with hepatitis B virus (HBsAg positive or HBsAg status unknown). (For additional information, see HIB and Hepatitis protocols)

Contraindications and precautions

Severe allergic reaction to vaccine component or following a prior dose
Moderate or severe acute illness
Age younger than 6 weeks

Adverse events may include:

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

PLAN

Have accompanying adult read “Vaccine Information Statement”/“Vaccine Information Materials”

Counsel regarding benefits, side effects, and management

Administration of Vaccine:

RECOMMENDED SCHEDULE

Age		Volume and Route	Minimum Age	Minimum interval
2 months	Primary dose	0.5ml IM	6 weeks	
4 months	Primary dose	0.5ml IM		4 weeks after dose 1
12-15 months	Booster dose	0.5ml IM	12 months	8 weeks after dose 2

OFF SCHEDULE AND MIXING WITH OTHER HIB AND HEPATITIS B VACCINE

Children who have started the vaccine with Comvax or PedvaxHIB may complete the series with PedvaxHIB and/or Comvax following the 2 –dose primary series with a third dose as a booster after the first birthday (remember to administer Hepatitis B with PedvaxHIB)

If it is necessary to change vaccine type (by switching to a different type of Hib vaccine, such as ActHIB® or Pentacel® by Sanofi Pasteur), then three (3) doses of any combination constitute the primary series. In such cases, either vaccine may be used for the booster (4th dose), regardless of what was administered in the primary series (remember to administer a hepatitis B vaccine, if necessary, when using a Hib vaccine other than Comvax)

DELAYED VACCINE SCHEDULES

VACCINE	AGE STARTING HIB AND HEP B SERIES	RECOMMENDED CATCH-UP FOR OLDER CHILDREN
Hepatitis B	Birth (no Hib given)	Follow routine Comvax schedule above. Final valid Hep B dose is the booster dose (a 4-month dose is too early to be a valid 3 rd Hep B).
Comvax	Starting at 12-14 months	Give 2 doses of Comvax two (2) months apart and the third hepatitis B vaccine six (6) months after first Comvax
Comvax	Starting at 15-59 months	Give one dose of Comvax; give second hepatitis B at least 4 weeks later, and 3 rd (final) dose at least 8 weeks after the second dose and at least 16 weeks after the Comvax dose;* only one dose of Hib vaccine is required at this age

*The accelerated catch up schedule is recommended whenever children are behind on their shots.

NOTE

If a child is **greater than 59 months of age**, Hib-containing vaccine is not normally indicated

Older children, if at **high risk** (e.g., sickle cell, post splenectomy, immunodeficient), may receive Hib-containing vaccine with a physician or nurse practitioner's order

Comvax may be given **simultaneously with all other vaccines**

Comvax may be **interchangeable** with other Hib and Hepatitis B vaccine, but the total number of doses changes if switching brands of Hib vaccines (see schedule above)

COMVAX (Continued)

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

Instruct parent to contact Health Department if adverse reaction occurs (complete VAERS form)

Referral Indicators:

Severe allergic (anaphylactic) hypersensitivity to any component of the vaccine

Follow-up:

Return for next Comvax at appropriate intervals

REFERENCES:

"Epidemiology and Prevention of Vaccine-Preventable Diseases, Department of Health and Human Services, Centers for Disease Control and Prevention, 10th Edition, February 2008

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 is indicated. These indications are rare. Administer with MD or APN order.

***Federally funded vaccine may be used for these groups.**

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

Have accompanying adult read “Vaccine Information Statement”/ “Vaccine Information Materials”

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

HAEMOPHILUS INFLUENZAE type b CONJUGATE VACCINE (Hib)

Administer IM 0.5 cc of vaccine as follows:

VACCINE	AGE BEGINNING PRIMARY SERIES	PRIMARY SERIES	BOOSTER
PRP-T (ActHIB)	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)	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.

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

Referral Indicators:

Allergic hypersensitivity to any component of the vaccine

HAEMOPHILUS *INFLUENZAE* type b CONJUGATE VACCINE (Hib)

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
“Federally Funded Vaccines for Adults” memo from Dr. Kelly Moore and Dr. Tom Jaselskis
July 8, 2009

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 with or without a physician or nurse practitioner order.

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

***Federally funded vaccine may be used in all health departments for these groups.**

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

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

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.

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

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	Dose 3	4-6 months after 2 nd dose	8 weeks after Dose 2 <i>and</i> 16 weeks after Dose 1
		Engerix-B Adult formulation 1.0 ml (20 mcg) ³	

*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

HEPATITIS B RECOMBINANT VACCINE (Continued)
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

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

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

GENERAL INFORMATION

Herpes Zoster vaccine is recommended by the Advisory Committee on Immunization Practices of the CDC for adults 60 years of age and older.¹ It is not licensed for use < age 60.

Contraindications and Precautions include the following:

- History of shingles is **NOT** a contraindication. Vaccination is recommended by CDC irrespective of a patient's history of shingles in order to reduce the risk of recurrence.
- History of severe allergic reaction (anaphylaxis) to neomycin or gelatin
- Immunosuppression
- Current blood dyscrasias, leukemia, lymphomas or other malignant neoplasms affecting the one marrow or lymphatic system
- Currently receiving immunosuppressive therapy or immunosuppressive therapy in the last 3 months
- Diagnosis of primary or acquired immunodeficiency state
- Moderate to severe acute illness

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.¹

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

Record manufacturer and lot number of the vaccine administered, date, name, address, and title of person administering vaccine.

Instruct patient to contact Health Department if severe reaction occurs

¹Herpes Zoster vaccine may be used for established primary care clinic patients only at this time, ages 60 through 64 or Medicare ineligible if over 64.

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

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

Prevention of Varicella, MMWR, ACIP Recommendations, 2006
Package Insert
Epidemiology and Prevention of Vaccine-Preventable Diseases, 10th Edition, February 2008
“Federally Funded Vaccines for Adults” memo from Dr. Kelly Moore and Dr. Tom Jaselskis,
July 8, 2009

2009 H1N1 INFLUENZA (For Information and Guidance)

In the primary care setting, established patients or the uninsured, may receive evaluation for 2009 H1N1 influenza.

The following protocol covers the use of oseltamivir (Tamiflu), and zanamivir (Relenza) in the primary care setting under the guidance of the Regional Health Officer and the prescribing provider in that clinic.

GENERAL INFORMATION

Influenza antiviral medications are prescription drugs that decrease the ability of influenza viruses to reproduce and reduce the impact of influenza.

Influenza antiviral medications have long been used to limit the spread and impact of influenza outbreaks, especially in individuals at high risk for morbidity and mortality. They are also used for treatment and chemoprophylaxis of persons in other settings. Four antiviral medications (amantadine, rimantadine, oseltamivir and zanamivir) are approved for treatment of influenza and chemoprophylaxis. The choice of antiviral treatment will be dependent on the susceptibility of the influenza strain.

This protocol addresses the use of oseltamivir and zanamivir only. **When used for treatment within the first two days of illness, oseltamivir and zanamivir are similarly effective in reducing the duration and intensity of illness by one or two days.**

MODE OF SPREAD		Person-to-person, Respiratory secretions
INCUBATION PERIOD		1 –7-days (Average 1-4 days)
INFECTIVITY	Adults	1 day before symptoms through 5 days post illness onset
	Children	> 10 days
	Young Children	< 6 days before illness onset
	Severely immunocompromised	Weeks to months*

* This information could change as we learn more about 2009 H1N1.

SUBJECTIVE:

Patient states signs and symptoms of influenza-like illness.

- fever, chills
- cough, sneezing
- sore throat
- body aches

- fatigue
- headache
- may have nausea, vomiting or diarrhea

Clinical Signs and symptoms of Influenza

Uncomplicated influenza:

- Abrupt onset of fever, myalgia, headache, malaise, nonproductive cough, sore, throat, and rhinitis
- Children - otitis media, nausea, and vomiting
- For the majority of persons, symptoms typically resolve after 7 – 10 days, although cough and malaise can persist for >2 weeks

Respiratory illness caused by influenza is difficult to distinguish from illness caused by other respiratory pathogens on the basis of symptoms alone.

Comparing the Symptoms of Influenza and the Common Cold

	INFLUENZA	COMMON COLD
Onset	Abrupt	More gradual
Fever	Common 37.7-40° C (100-104°F)	Uncommon or increase of only about 0.5°C (1°F)
Myalgia	Severe, common	Uncommon
Arthralgia	Severe, common	Uncommon
Anorexia	Common	Uncommon
Headache	Severe, common	Mild, uncommon
Cough (dry)	Common, severe	Mild to moderate
Malaise	Severe	Mild
Fatigue, weakness	More common, lasting 2-3 weeks	Very mild, short lasting
Chest discomfort	Common, severe	Mild to moderate
Stuffy nose	Occasional	Common
Sneezing	Occasional	Common
Sore throat	Occasional	Common

Note: Patients with 2009 H1N1 may have more nausea, vomiting and diarrhea than patients with seasonal influenza.

Complications of Influenza

- Influenza can exacerbate underlying medical conditions
 - Pulmonary or Cardiac Disease:
 - Secondary bacterial pneumonia
 - Primary influenza viral pneumonia
 - Co infection with other viral or bacterial pathogens
 - Young Children:
 - $\leq 20\%$ of children hospitalized with influenza have febrile seizures
 - Also Associated with:
 - Encephalopathy
 - Transverse myelitis
 - Reye syndrome
 - Myositis
 - Myocarditis
 - Pericarditis

OBJECTIVE:

- Weight
- Blood Pressure
- Temperature

ASSESSMENT:

Indications for Treatment

Patient presents to the primary care clinic with influenza-like symptoms. Refer patient to the APN, MD, or DO in primary care clinic.

PLAN:

Primary Care patients in a health department primary care setting will be evaluated and provided appropriate care which may include antiviral medication as ordered by the APN, MD, or DO.

For additional guidance refer to the following:

- CDC: Oseltamivir and Zanamivir Fact Sheets
- <http://www.cdc.gov/swineflu/recommendations.htm>
- TDH: Interim Guidance/Algorithm for Clinicians: May 5, 2009

Assure patient has a copy of the appropriate FDA/EUA (Emergency Use Authorizations) medication fact sheet.

Assure patient has health department telephone number for questions.

Health Teaching:

Discuss the following respiratory precautions:

- Take medication as prescribed.
- Cover nose and mouth with tissue when coughing or sneezing.
- Throw the tissue in the trash after use.
- Wash hands often with soap and water, especially after coughing or sneezing.
- Alcohol-based hands cleaners are also effective.
- Avoid touching eyes, nose or mouth.
- Remain home and avoid close contact with others until illness subsides.
- Try to avoid close contact with high risk individuals (closer than 6 feet).

Follow-up:

As instructed by your health care provider.

REFERENCE:

Resources: For more information, visit www.cdc.gov/flu
<http://www.cdc.gov/swineflu/recommendations.htm>
Indications for Treatment 2009 H1N1

LIVE ATTENUATED SEASONAL INFLUENZA VACCINE (LAIV) (FluMist® by MedImmune)

GENERAL INFORMATION

Seasonal influenza vaccine comes in two forms: trivalent inactivated vaccine (TIV) administered by injection and live attenuated, intranasally-administered vaccine (LAIV).

Decisions about eligibility for influenza vaccination in health departments are made each fall. In the absence of an influenza vaccine shortage, the Tennessee Immunization Program recommends vaccination of persons in all CDC-recommended groups.

Any changes in eligibility for vaccination during influenza season will be announced through Tennessee Immunization Program policy updates.

LAIV provided with federal funds is only for use in children <19 years.

No preference between TIV and LAIV is expressed for persons who are eligible to receive either. See the TIV protocol for influenza vaccination of persons who are not eligible for LAIV

A separate protocol will cover 2009 pandemic influenza vaccine

Seasonal LAIV indication:

LAIV is approved by the Food and Drug Administration (FDA) for use in healthy persons aged 24 months through 49 years who are not pregnant.

Special situations:

LAIV may be co-administered with any other vaccine at the same visit. Live vaccines that are not given on the same day (e.g., varicella, MMR) should be administered at least 4 weeks apart.

Patients <9 years of age who require 2 doses of vaccine this season do not have to use the same type of vaccine (TIV or LAIV) for both doses

Breastfeeding is not a contraindication to vaccination

Contraindications and precautions:

People less than 2 years of age or age 50 years or older

People with a medical condition that places them at high risk for complications from influenza [e.g., chronic heart or lung disease, asthma, diabetes, kidney disease, hemoglobinopathies, any condition that compromises the ability to handle respiratory secretions, pregnant women, or persons with a weakened immune system]

Children less than 5 years old with a history of recurrent (more than 1 episode) wheezing

Children or adolescents receiving aspirin therapy

People with a history of Guillain-Barré syndrome

Common Adverse Reactions (≥10% of patients)

Nasal congestion

Sore throat in adults

Fever >100°F in children ages 2-6 years

PLAN

Have recipient, parent, or guardian read Vaccine Information Statement (VIS)

Counsel regarding benefits, side effects, and management

Administer vaccine intranasal spray (0.1ml in each nostril) according to manufacturer's recommendation

Remind about the need for pandemic influenza vaccine and that seasonal influenza vaccine is recommended annually (advise parent or guardian of recipients less than 9 years of age to return for a second dose in 1 month if the child is receiving seasonal influenza vaccine for the first time *or* if they were vaccinated for the first time during the previous influenza season but only received one dose in that season)

Advise to wait in clinic 20 minutes after intranasal administration

Record manufacturer and lot number of the vaccine administered, date, name, address, and title of person administering vaccine

Instruct patient to contact Health Department if adverse reaction occurs (complete appropriate VAERS form: <http://vaers.hhs.gov>)

Recommended Schedule and Dosage of LAIV (FluMist®):

Age Group	Influenza Vaccination Status	Dosage Schedule
Children 24 months through 8 years	Not previously vaccinated (or vaccinated for the first time in the previous influenza season but received only one dose during that season)	2 doses (each dose 0.1ml per nostril) given at least 1 month apart
Children 24 months through 8 years	Previously vaccinated	1 dose (0.1 ml per nostril)
Other persons aged 9-49 years	n/a	1 dose (0.1 ml per nostril)

Referral Indicators:

Persons with severe allergy to eggs or other components of vaccine (gelatin, gentamicin, arginine)

Persons with history of Guillain-Barré syndrome

Persons having moderate to severe acute febrile illness or illnesses with significant nasal congestion (until illness resolves)

REFERENCES

Prevention and Control of Seasonal Influenza with Vaccines, Recommendations of the Advisory Committee on Immunization Practices (ACIP), U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, July 31, 2009. Available at <http://www.cdc.gov/mmwr/PDF/rr/rr5707.pdf>. Last accessed August 13, 2009.

FluMist® Influenza Vaccine, Live Intranasal Vaccine Package Insert (MedImmune). Revised June 2009.

TRIVALENT INACTIVATED SEASONAL INFLUENZA VACCINE (TIV)

GENERAL INFORMATION

General Recommendations for Influenza Vaccination:

Seasonal influenza vaccine comes in two forms: trivalent inactivated vaccine (TIV) administered by injection and live-attenuated, intranasally-administered vaccine (LAIV). See LAIV protocol for healthy persons 24 months and up who choose LAIV, where available.

Decisions about eligibility for influenza vaccination in health departments are made each fall. In the absence of influenza vaccine shortages, the Tennessee Immunization Program recommends persons in all CDC-recommended groups be vaccinated.

Any changes in eligibility for vaccination during influenza season will be announced through Tennessee Immunization Program policy updates.

A separate, specific protocol will cover 2009 pandemic influenza vaccine

Licensed TIV formulations by Manufacturer (not all are available in health departments):

Manufacturer	Product Formulation	FDA-licensed ages
Sanofi Pasteur TIV (Fluzone®)	0.25 ml preservative-free, pre-filled syringe (PFS)	6-35 months only
	0.5 ml PFS or single dose vial	≥36 months
	5 ml multidose vial	≥ 6 months
Novartis TIV (Fluvirin®)	5 ml multidose vial	≥4 years
CSL Biotherapies (Afluria®)	0.5 ml PFS or 5 ml multidose vial	≥18 years
GSK TIV (Fluarix®)	0.5 ml PFS	≥18 years
GSK TIV (Flulaval®)	5 ml multidose vial	≥18 years

Centers for Disease Control and Prevention (CDC) recommendations:

The CDC has recommended influenza vaccine for the following categories of people:

Persons at high risk for influenza-related complications and severe disease

ALL children aged 6 months through 18 years (especially <5 years, chronically ill)

Pregnant women in any trimester (or those planning pregnancy during flu season)

Persons aged ≥50 years

Persons of any age with certain chronic medical conditions¹

¹ Those with chronic medical conditions at increased risk for complications include: Persons who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematological or metabolic disorders (including diabetes mellitus); persons who have immunosuppression (including immunosuppression caused by medication or HIV); children (aged 6 months--18 years) on long-term aspirin therapy.

INFLUENZA VACCINE (Continued)

Persons who live with or care for persons at high risk, including

Healthcare workers

Household contacts or out-of-home caregivers of all children <5 years and adults aged ≥ 50 years and other (above-listed) persons at high risk (*this does not include household contacts of healthy children ages 5 through 18*)

Others:

All other persons who request vaccination to reduce the risk of influenza disease

Persons who should not receive the influenza vaccine include the following:

(See Referral Indicators)

Persons with a severe allergy (i.e., anaphylactic allergic reaction) to a previous dose of influenza vaccine or its components

Children less than 6 months of age

PLAN

Have recipient, parent, or guardian read Vaccine Information Statement (VIS)

Counsel regarding benefits, side effects, and management

Administer vaccine injection/intranasal spray according to manufacturer's recommendation

Remind about the need for pandemic influenza vaccine and that seasonal influenza vaccine is recommended annually (advise parent or guardian of recipients less than 9 years of age to return for a second dose in 1 month if the child is receiving influenza vaccine for the first time **or** if this is the second season they are being vaccinated and they received only one dose in their first season)

Advise to wait in clinic 20 minutes after injection/intranasal administration

Record manufacturer and lot number of the vaccine administered, date, name, address, and title of person administering vaccine

Instruct patient to contact Health Department if adverse reaction occurs (complete appropriate VAERS form)

Recommended Schedule and Dosage of Seasonal Trivalent Inactivated Vaccine (TIV):

Age Group	Dosage	No. Doses	Route
6-35 months	0.25 ml	1 or 2*	Intramuscular
3-8 years	0.50 ml	1 or 2*	Intramuscular
Age 9 and older	0.50 ml	1	Intramuscular

* Two doses administered at least 1 month apart are recommended for children <9 years of age who are receiving influenza vaccine for the first time AND for those receiving the vaccine for the second season, who received only one dose in their first season; the first dose in these children does not provide protective immunity. TIV or LAIV may be used interchangeably for either dose, if appropriate.

Referral Indicators:

Persons allergic to eggs or components of vaccine (see package insert)

Persons with history of Guillain-Barré syndrome

Persons having moderate to severe acute febrile illness (until illness resolves)

INFLUENZA VACCINE (Continued)

REFERENCES

Prevention and Control of Seasonal Influenza with Vaccines, Recommendations of the Advisory Committee on Immunization Practices (ACIP), U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, July 31, 2009. Available at <http://www.cdc.gov/mmwr/PDF/rr/rr5808.pdf>. Last accessed August 11, 2009.

MEASLES, MUMPS, RUBELLA VACCINE (MMR)

GENERAL INFORMATION

Contraindications and Precautions include the following:

- Anaphylactic reaction to gelatin or neomycin
- Moderate to severe acute illness
- Pregnancy
- Immunosuppression (except HIV)
- Received blood product within the previous 6 months (inactivates live virus)

Adverse events include the following:

- Low grade fever
- Parotitis (rare)
- Rash, pruritus (mild)
- Deafness (rare)
- Joint symptoms (rare)
- Thrombocytopenia (rare)
- Encephalopathy (rare)

ACIP Recommended Populations

*All children (2 doses)

Adults born after 1957 (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 (including infants 6-11 months)

Healthcare workers (2 doses or evidence of immunity)

*Vaccination of susceptible persons within 72 hours of exposure to measles (post-exposure prophylaxis)

***Federally funded vaccine may be used for these groups**

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 30 days

Laboratory evidence of immunity to all three diseases (Measles, Mumps and Rubella)

*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.

would substitute for the need for vaccine (ex. college students needing MMR).
However, if any one of the labs is negative, they would still need 2 doses.

PLAN

Have patient or accompanying adult read Vaccine Information Statement/Vaccine Information Material

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 currently recommended two-dose series; persons who have received monovalent (Measles, Mumps, or Rubella) or combined Measles/Rubella should complete a 2 dose series of MMR.

Referral indicators:

Uncontrolled neurological conditions

Known pregnancy (breast feeding or pregnant household contact NOT contraindication)

Leukemia

Lymphoma or other generalized malignancy

Immunodeficiency (Hematologic and solid tumors, congenital immunodeficiency, long-term immunosuppressive therapy) and current immune suppression therapy

Active untreated tuberculosis

Persons with known anaphylactic reactions to gelatin and neomycin, (i.e., hives, swelling of mouth/throat, difficult breathing, hypotension, shock)

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

Packet Inserts

National Childhood Vaccine Injury Act

“Epidemiology and Prevention of Vaccine-Preventable Diseases” Centers for Disease Control and Prevention, DHH’s, February 2008

“Federally Funded Vaccines for Adults” memo from Dr. Kelly Moore and Dr. Tom Jaselskis, July 8, 2009

MENINGOCOCCAL VACCINE

MENINGOCOCCAL CONJUGATE VACCINE (MCV4)

(MENACTRA)

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 Conjugate Vaccine (MCV4, Menactra)

This meningococcal vaccine (originally licensed by the U.S. Food and Drug Administration (FDA) on January 14, 2005), is currently licensed **for use in persons aged 2 through 55 years.**

It is manufactured by Sanofi Pasteur and is marketed as **MENACTRA™**.

Immunity is expected to last 8 or more years following a single dose.

Meningococcal Conjugate Vaccine (MCV4, Menactra) is recommended for routine use in adolescents and other groups that are at elevated risk for meningococcal disease and are between 2 and 55 years of age.

Where MCV4 (Menactra) 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 (Routinely for all children 11 through 12 years and as catch up for any children 13 through 18 years not previously vaccinated with MCV4/Menactra)
- College freshmen living in dormitories, including those enrolled in college who present for immunization before moving on campus, if not previously vaccinated with MCV4
- 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 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)

Contraindications to giving the vaccine include the following:

- Persons under 2 years or over 55 years of age
- Hypersensitivity to any component of the vaccine, including diphtheria toxoid
- Hypersensitivity to dry natural rubber latex (contained in vaccine 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
- Anyone who has ever had Guillain-Barre Syndrome

Adverse Reactions include the following:

- COMMON
 - Mild injection site pain and redness
 - Transient fever
- RARE
 - Headache, malaise, chills

PLAN

Administration of Vaccine:

- May be administered for ages 2 through 55 years of age as outlined in program policy
- Targeted populations are:
 - All individuals 11 through 12 years of age
 - All adolescents age 13 through 18 years not previously vaccinated
 - College freshmen regardless of age that are, or will be, living in dorms, if not previously vaccinated
- Administer a single dose of vaccine, 0.5 ml **INTRAMUSCULARLY**

(continued on next page)

Health Teaching:

- Provide current Vaccine Information Sheet (VIS) about meningococcal disease and the benefits of vaccination
- Counsel regarding side effects of vaccine

Referral:

- 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 (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine package insert, Sanofi Pasteur (Aventis Pasteur), April 2008
- 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

(STREP) PNEUMOCOCCAL CONJUGATE VACCINE (PCV7)

GENERAL INFORMATION

Pneumococcal conjugate vaccine helps to prevent diseases caused by *S. pneumoniae* (including meningitis and ear infections).

The vaccine can be given to infants and children at least six (6) weeks of age through 59 months old.

Immunosuppressed children may not respond optimally to immunization.

Pneumococcal conjugate vaccine may be administered simultaneously with other vaccines.

Pneumococcal vaccine is recommended for:

All children who have not reached their 5th birthday.

Contraindications to giving the vaccine include the following:

An immediate anaphylactic reaction to the vaccine or a constituent of the vaccine, such as diphtheria toxoid

Acute, moderate, or severe illnesses with or without fever (defer until resolution)

Note: Mild illness with or without fever is NOT a contraindication.

The following precaution, although not considered a contraindication, should be carefully evaluated concerning the risks and benefits of vaccination for individuals under this circumstance:

Patients with history of anaphylactic allergy to latex (vial stopper contains dry natural rubber)

Adverse events:

Swelling, redness and/or pain at site of administration

Low-grade fever

Systemic reactions infrequent, serious adverse reactions rare

PLAN

Have accompanying adult read "Vaccine Information Statement" (VIS)

Counsel regarding benefits, side effects, and management

Administration of vaccine:

The recommended immunization schedule consists of three (3) doses at approximately two (2) month intervals (ages 2, 4, and 6 months), followed by a fourth dose at 12-15 months of age.

The usual age for the first dose is 2 months, but it can be given as young as six (6) weeks of age.

The recommended dosing interval is 4-8 weeks.

(STREP) PNEUMOCOCCAL CONJUGATE VACCINE (CONTINUED)

The fourth dose should be administered at age 12-15 months, and at least 8 weeks after the third dose.

Healthy children age 24-59 months with *any* incomplete schedule should receive one dose of PCV7.

Children age 24-59 months who are incompletely immunized and have underlying medical conditions predisposing them to severe pneumococcal disease (sickle cell disease, asplenia, HIV infection, immunocompromise or chronic illness) should follow the catch-up recommendations in Table 2 below.

The dose is 0.5 ml to be given intramuscularly.

Shake vigorously immediately prior to administration of vaccine in order to obtain a uniform suspension

Table 1. Recommended Schedule (and catch-up schedule for older infants):

VACCINE	AGE AT FIRST DOSE	PRIMARY SERIES	BOOSTER
Pneumococcal Conjugate (PCV7)	2-6 months of age (recommended)	3 doses, 8 weeks apart	12-15 months*
	7-11 months of age	2 doses, 8 weeks apart	15 months (at least 8 weeks after dose 2)
	12-23 months of age	2 doses, 8 weeks apart	---
	24-59 months of age (at first dose or for any incomplete schedule)	1 dose	

* A 4th dose is only necessary for children aged 12 months -5 years who received 3 doses before age 12 months.

Table 2. Recommendations for Children 24-59 Months of Age with Underlying Medical Conditions Who Are Not Completely Vaccinated*

Pneumococcal Conjugate (PCV7)	Those who have received 3 doses of PCV7	Administer 1 dose PCV7
	Those who have received fewer than 3 doses	Administer 2 doses of PCV7 at least 8 weeks apart

***Note:** The use of PCV7 does not replace the use of 23-valent pneumococcal polysaccharide vaccine (PPV23) in children ≥ 24 months of age with sickle cell disease, asplenia, HIV infection, chronic illness or who are immunocompromised.

Post Immunization Administrative Issues:

Advise to wait in clinic 20 minutes after injection

(continued on next page)

(STREP) PNEUMOCOCCAL CONJUGATE VACCINE (CONTINUED)

Record manufacturer and lot number of the vaccine administered, date, name, address and title of person administering vaccine

Instruct parent to contact Health Department if adverse reaction occurs (complete appropriate Vaccine Adverse Event Report [VAERS] Form)

Referral Indicators:

A history of anaphylactic hypersensitivity to any component of the vaccine
Patients with a history of anaphylactic latex allergy

Follow-up:

Return for next pneumococcal vaccine at appropriate interval

REFERENCES

Advisory Committee on Immunization Practices Guidelines, March 2000

Advisory Committee on Immunization Practices Vaccines for Children Program, Resolution No. 6/00-1, September 2000

Recommendations off the Advisory Committee on Immunization Practices, October 6, 2000

Packet Insert

MMWR, Updated Recommendation from the Advisory Committee on Immunization Practices for Use of 7-Valent Pneumococcal Conjugate Vaccine in Children Aged 24-59 Months Who Are Not Completely Vaccinated, April 4, 2008, Vol 57 #13

CDC 2009 Schedule's Catch-up Chart

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.

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.

****Federally funded vaccine may be used for these groups, and for those >64, if not Medicare eligible.***

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 PCV7.

PNEUMOCOCCAL POLYSACCHARIDE VACCINE (Continued)

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
Record manufacturer and lot number of the vaccine administered, date, name, address,
and title of person administering vaccine
Instruct patient to contact Health Department if adverse reaction occurs (complete
VAERS form)

NOTE: SECOND DOSE (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. Only one PPV23 revaccination** dose is recommended for certain persons at the highest risk of severe disease.

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

- Persons \geq 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 whose first dose was given younger than age 65 and 5 or more years have passed since that dose

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
“Federally Funded Vaccines for Adults” memo from Dr. Kelly Moore and Dr. Tom Jaselskis, July 8, 2009

**TETANUS, DIPHTHERIA, AND PERTUSSIS VACCINE
TETANUS, DIPHTHERIA, AND ACELLULAR PERTUSSIS
(Tdap) VACCINE FOR ADULTS (19 through 64 years)
(ADACEL™ OR BOOSTRIX™)**

GENERAL INFORMATION

Tdap vaccine is inactivated and contains no live organisms. The vaccine protects from tetanus (“lockjaw”), diphtheria, and pertussis (“whooping cough”). Like tetanus and diphtheria, immunity to pertussis wanes following childhood immunization or natural infection, leaving adults susceptible. With pertussis, adults may suffer prolonged coughing illness and may infect others, including infants at risk for severe complications. ADACEL™ (Sanofi Pasteur) was licensed in 2005 by the U.S. Food and Drug Administration (FDA) for use in persons aged **11 through 64 years** as a **ONE-TIME DOSE**. BOOSTRIX™ (GlaxoSmithKline) is licensed for **ages 10 through 64** as a **ONE –TIME DOSE**.

Tdap is currently recommended by the Advisory Committee on Immunization Practices (ACIP) for routine use in persons 11 through 64 years¹. (See the Tdap protocol for adolescents for recommendations ages 11 through 18 years) **Subsequent routine Td BOOSTERS are recommended every 10 years** (see Td protocol).

Tdap vaccine may be given at the same time as other immunizations, including meningococcal vaccine. It may be given before or after meningococcal vaccine if both vaccines cannot be given simultaneously.

Tdap SHOULD NOT BE GIVEN TO PERSONS WHO HAVE ALREADY RECEIVED Tdap.

ACIP Recommendations for Use:

Tdap may be used **ONE TIME** (11 through 64 years) either as a routine **BOOSTER** dose, **OR** as one of a **PRIMARY** vaccine series, **OR** for tetanus **PROPHYLAXIS** in accordance with standard guidelines for wound management.

Adults (19 through 64 years) DUE FOR A ROUTINE TETANUS BOOSTER - A single dose of Tdap is routinely recommended to replace a single dose of Td for booster immunization if they received the last dose of tetanus toxoid-containing vaccine ≥ 10 years earlier. Certain individuals should be given Tdap < 10 years after their last Td; see below

Adults (19 through 64 years) WITHOUT A COMPLETE PRIMARY SERIES of Td-containing vaccine - A single dose of Tdap should be **substituted for one Td** in the primary series; it is preferred as the first dose

Adults (19 through 64 years), REQUIRING TETANUS PROPHYLAXIS FOR WOUND MANAGEMENT - A **single dose** of Tdap is preferred to Td if the patient has not had Tdap before (See Protocol for Wound Management)

SHORTER DOSING INTERVALS: Certain adults (19 through 64) should receive a single dose of Tdap if it has been at least 2 years since they received their last tetanus-containing vaccine*:

- (a) Adults who have contact or anticipate having close contact with infants <12 months of age (e.g., parents, grandparents <65, childcare providers, healthcare workers, post-partum mothers, women planning to become pregnant). Administration at least one month before exposure to the infant is ideal, if possible
- (b) Health-care personnel with direct patient contact in hospitals and outpatient facilities (highest priority to those who have contact with children <12 months)

*Intervals <2 years may be used, but require a physician or nurse practitioner order

PREGNANCY: Pregnancy is not a contraindication to Td or Tdap; if tetanus vaccination during pregnancy is indicated, Td is preferred. Td should be given to pregnant women if they have had an incomplete primary series of tetanus vaccine, require tetanus immunization for wound management, or if it has been ≥ 10 years since their last tetanus shot. Otherwise, advise pregnant women to receive Tdap as soon as possible post-partum. If a pregnant woman may need Tdap (e.g., during an outbreak of pertussis in the community), Tdap may be given with an MD or NP order.

REFERRAL INDICATORS (PER ACIP)

Contraindications to giving the vaccine include the following:

History of an immediate severe allergic reaction (anaphylaxis) to any of the three components of Tdap (i.e., tetanus, diphtheria, or pertussis vaccines) or to any combination vaccine containing Tdap components

History of encephalopathy (e.g., coma, prolonged seizures) within 7 days of administration of a pertussis-containing vaccine that is not attributable to another identifiable cause; tetanus/diphtheria vaccine (Td) should be used instead of Tdap in such patients

Precautions which may require referral include the following:

History of Arthus-type hypersensitivity reactions (extensive painful limb swelling within hours of injection) following tetanus vaccination administered <10 years previously; such patients should not be given any tetanus-containing vaccine more frequently than every 10 years

A current unstable neurologic disorder, uncontrolled epilepsy, or progressive encephalopathy; defer vaccination with pertussis-containing vaccine until treatment regimen is established and condition is stabilized; Td may be used

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

Defer immunization if the patient has an acute moderate-to-severe illness, with or without fever, until illness has resolved

PLAN

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

Counsel regarding benefits, side effects, and management

Shake the vial well, administer 0.5 ml of vaccine INTRAMUSCULARLY

Remind that tetanus/diphtheria vaccine boosters are recommended every 10 years

Advise to wait in clinic 20 minutes after injection

Record manufacturer and lot number of the vaccine administered, date, name, address and title of the person administering vaccine

Instruct patient to contact Health Department if adverse reaction occurs (complete appropriate form)

Referral Indicators:

History of an immediate severe allergic reaction (anaphylaxis) to prior tetanus, diphtheria, or pertussis vaccines

History of encephalopathy (e.g., coma, prolonged seizures) within 7 days of administration of a pertussis-containing vaccine

Refer or defer immunization for precautions as indicated

Immunization considered <2 years since last tetanus booster (MD or NP order only)

Pregnancy (MD or NP order only)

Follow-up:

Return for Td booster in 10 years

Return for wound management as required

REFERENCES

Advisory Committee on Immunization Practice (ACIP) Votes to Recommend Use of Combined Tetanus, Diphtheria and Pertussis (Tdap) Vaccines for Adults, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Atlanta, GA 30333, March 2, 2006. http://www.cdc.gov/nip/vaccine/tdap/tdap_adult_recs.pdf Last accessed May 12, 2006

Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (ADACEL™) Vaccine package insert, Sanofi Pasteur (Aventis Pasteur), June 2005

Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (BOOSTRIX™) Prescribing information, GlaxoSmithKline, May 2005, revised January 2009. http://us.gsk.com/products/assets/us_boostrix.pdf

Centers for Disease Control and Prevention. Vaccine Information Statement – Interim Tdap vaccine 9/22/05. <http://www.cdc.gov/nip/publications/VIS/vis-tdap.pdf>. Last accessed May 12, 2006

VARICELLA VACCINE (VARIVAX® by Merck)

GENERAL INFORMATION

Varicella virus causes chickenpox and lies dormant in nerve roots following the primary infection. The virus can cause recurrent infection, resulting in herpes zoster (“shingles”). The virus is highly contagious and enters the body through the respiratory tract or mucus membranes. Up to 90% of susceptible household contacts of persons with chickenpox will become infected. In the U.S. each year, before routine vaccination, there were about 4 million cases of chickenpox, resulting in 11,000 hospitalizations and 100 deaths, with the highest risk of death among susceptible adults.

Varicella vaccine is a live attenuated (weakened) virus vaccine derived from the Oka strain of varicella and administered subcutaneously; it is licensed by the Food and Drug Administration (FDA) for administration to persons 12 months of age and older. Two doses of the vaccine are recommended for all recipients, including a second dose for those who may have had a single dose earlier in childhood. A single dose confers approximately 70-90% protection from disease; the seroconversion rate of 2-dose recipients is approximately 99%. The vaccine is not recommended for persons with evidence of immunity to varicella (see below).

The vaccine may be simultaneously administered with other vaccines, including other live virus vaccines. It is stored frozen at an average temperature of $\leq -15^{\circ}\text{C}$ (5°F). It must be discarded if not administered to the recipient within 30 minutes of reconstitution.

Evidence of immunity to varicella:

Persons with evidence of immunity to varicella should not be vaccinated. Acceptable evidence includes the following (Advisory Committee on Immunization Practices, ACIP, 2006):

1. Documentation of age-appropriate vaccination:
 - a. Children 12 months up to school entry: one dose
 - b. School-aged children: 2 doses
2. Laboratory evidence of immunity or laboratory confirmation of disease
3. Born in the US before 1980 (this is insufficient evidence for healthcare workers or pregnant women)
4. Healthcare provider diagnosis of varicella or provider verification of history of varicella disease (for “atypical” or “mild” disease, this verification should include an epidemiologic link to a person with typical disease or laboratory confirmation, because other diseases may mimic atypical varicella)
5. Healthcare provider diagnosis of herpes zoster

(continued)

ACIP Recommendations for Use:

- *Routine immunization schedule: first dose at age 12-15 months, second dose at age 4-6 years (before starting school) (See below)
- *A second, catch-up dose is recommended for all children and adults who previously had received only one dose (unless they have appropriate evidence of immunity due to breakthrough disease)
- *Adults without insurance coverage for the vaccine (2-dose series) for whom it is medically indicated (in other words, they do not meet criteria for immunity listed above)
Not federally funded: Varicella vaccine for adult travelers, adults with Insurance coverage for the vaccine, vaccine required by an employee for occupational health

* Federally funded vaccine may be used for these groups

Routine Immunization Schedule

Dose Number	Recommended age at administration	Minimum interval to next dose
Dose 1	12-15 months	3 months (age 1-12 years)** 28 days (age ≥13 years) **At any age, a second dose administered at least 28 days after the first dose does not need to be repeated
Dose 2	4-6 years	

Contraindications to giving the vaccine include the following:

- Evidence of immunity (per above criteria)
- Pregnancy
- Moderate to severe acute illness (defer until recovery) [Note: Low grade fever <100.5°F or mild illnesses are not reasons for deferring immunization]
- Anaphylactic reaction to a previous dose of the vaccine or any component (including neomycin and gelatin)
- Blood dyscrasias, leukemia, lymphoma of any type, other malignant neoplasm affecting the bone marrow or lymphatic system
- Primary or acquired cellular immunodeficiencies (e.g., AIDS or clinical manifestations of HIV)
- Untreated, active tuberculosis (not latent tuberculosis infection)

Family history of congenital or hereditary immunodeficiency in a first-degree relative (e.g., parent or sibling), unless the immunocompetence of the recipient has been clinically confirmed by a physician or verified by a laboratory
Ongoing immunosuppressive therapy (does not apply to corticosteroid replacement therapy)

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

Persons on steroid therapy not otherwise immunocompromised (refer)
Impaired humoral immunity or asymptomatic HIV infection (refer)

Receipt of a blood or plasma transfusion or immune globulin within the past 5 months (defer vaccination until at least 5 months after receipt of blood products)

Receipt of another live virus vaccine within 28 days (defer until 28 days after previous live virus vaccine)

Special Situations (per ACIP):

Breastfeeding is not a contraindication to immunization

Vaccinees who are healthcare workers or household contacts of susceptible, high-risk persons in whom a vaccine-related vesicular rash develops should avoid contact with such persons while they have the rash

Women should be advised to avoid becoming pregnant for at least 1 month (per ACIP) following vaccination, though having a pregnant household contact is not a contraindication to vaccination

Aspirin use during natural varicella disease is associated with Reye's Syndrome and recipients should be advised to avoid salicylates for 6 weeks following vaccination

Adverse Reactions:

Soreness, swelling or redness around the injection site within 48 hours of immunization

An injection site or full body rash up to 1 month following vaccination in $\leq 5\%$ of recipients

PLAN

Ask parent/guardian or recipient about contraindications, precautions

Have parent/guardian or recipient read Vaccine Information Statement

Reconstitute vaccine and administer the vaccine subcutaneously according to the manufacturer instructions

Counsel regarding side effects of vaccine, e.g., rash

Advise women of child-bearing age to avoid becoming pregnant for at least 1 month

Advise that recipients should avoid use of salicylates (e.g., aspirin) for 6 weeks

Advise parent/guardian or recipient to return for the next dose at the appropriate interval
Advise to wait in clinic for 20 minutes after administration of vaccine
Record manufacturer and lot number of the vaccine administered, date vaccine and VIS given, address of facility, and name and title of person administering vaccine
Instruct patient/guardian to contact Health Department if adverse reaction occurs

Referral Indicators

Persons with impaired immune systems (acquired or primary)
Persons on steroid therapy (other than corticosteroid replacement)

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CHLAMYDIA TRACHOMATIS, CONTACT PARTNER DELIVERED THERAPY

NOTE: *In 2002 the Board of Medical Examiners and the Board of Osteopaths adopted an amendment to the medical practice act allowing providers and those who provide medical services under their responsibility and control to use partner delivered therapy.*

The following protocol should be implemented as an important DISEASE CONTROL STRATEGY and in accordance with CDC recommendations.

SUBJECTIVE

Consider partner delivered therapy for those contacts to index cases of chlamydia when it is unlikely that the contact will seek medical care.

OBJECTIVE

A laboratory confirmed Chlamydia infection without evidence of co-infection with gonorrhea or other complications suggestive of a relationship to Chlamydia infection
Provision of treatment of the (index) patient for Chlamydia
An attempt to persuade the infected patient to have all partners evaluated and treated and indication from the patient that partner(s) would not comply

PLAN

Document objective findings in index patient's record.
Provide a Chlamydia fact sheet to the patient with copies for all partners.
<http://www.cdc.gov/std/chlamydia/chlamydia-fact-sheet.pdf>
<http://www.nlm.nih.gov/medlineplus/druginfo/meds/a697037.html>
Counsel the patient on sexual abstinence for seven days after treatment and until seven days after partners have been treated.
Provide to the treated patient a non-named signed (MD or NP) prescription(s) or a signed, name-specific prescription(s) **OR**
Dispense to the treated patient 1 gram of azithromycin for each of the unnamed sex partners or for each of the total number of known sex partners named by the patient.
Contacts who present to the health department requesting treatment for Chlamydia will be given the following:
 1 gram azithromycin
 Opportunity for a full STD examination
 Opportunity for questioning about other STD symptoms and encouragement to have HIV testing

HEPATITIS B, Infant Contacts

GENERAL INFORMATION

Infant born to a woman infected with hepatitis B, either chronically or acutely, which includes all women who test positive for hepatitis B surface antigen (HBsAg) (see Tennessee Department of Health, Perinatal Hepatitis B Prevention Program Guidelines for further information)

PLAN

Notify CEDS Regional Director or designated Regional Perinatal Hepatitis B Coordinator of the infant that needs follow-up by the Perinatal Hepatitis B Prevention Program and care.

Assure that infant has received Hepatitis B Immune Globulin (HBIG) and the first dose of hepatitis B vaccine (HBV) (0.5 ml) I.M. within 12 hours of birth. If infant was not given HBIG and HBV at birth and more than 7 days have elapsed since birth - **do not give HBIG**. If infant was not given HBIG and **fewer than 7 days** have elapsed since birth, **give HBIG**, if available, or notify those listed above to arrange for HBIG to be given as soon as possible.

Administer the second and third dose of HBV according to Hepatitis B Vaccine protocol. Combination vaccines containing hepatitis B also may be used to complete the vaccine series using their recommended schedules.

Test infant for HBsAg and anti-HBs no earlier than one month after completion of HBV series at 9 to 18 months of age.

If infant is positive for HBsAg, refer for medical evaluation.

If infant is negative for anti-HBs and HBsAg, repeat the complete HBV series according to HBV single antigen vaccine protocol; retest for anti-HBs and HBsAg one month after last dose of HBV and follow Perinatal Hepatitis B Prevention Program guidelines.

Assure that the designated Regional Perinatal Hepatitis B Prevention Coordinator is aware of immunization visits and test results to facilitate case management.

Health Teaching:

Although many hepatitis B viral infections cause no symptoms, discuss the following symptoms of hepatitis which would need medical evaluation if present:

- serum sickness-like prodrome
- skin eruptions, urticaria
- arthralgias, arthritis
- lassitude
- anorexia
- nausea, vomiting
- headaches, fever
- dark urine, jaundice, moderate liver enlargement with tenderness

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HEPATITIS B, Other Non-Occupational Contacts POST-EXPOSURE

GENERAL INFORMATION

Client may have:

History of sexual contact, needle sharing, or household exposure to blood or body fluids.
 Most will need testing for markers of hepatitis B infection and vaccination, if susceptible.

PLAN

Notify Regional Communicable and Environmental Disease Services (CEDS) Director or Regional Perinatal Hepatitis B Coordinator if patient is pregnant.
 Evaluate need for Hepatitis B Immune Globulin (HBIG) and Hepatitis B Vaccine (HBV) (percutaneous or mucosal exposure) based on the HBsAg status of the source and the HBV immunization and vaccine-response status of the person exposed.
 Evaluate need for pre- and post-vaccination serologic testing.

Table 1. Guidelines for **Pre-Vaccination** Testing and Interpretation of Results for Non-Occupational Contacts of HBsAg Positive Persons

Exposure	Testing	Timing of test	
All household, needle-sharing, sexual contacts	HBsAg and anti-HBs	Before administering PEP (at same visit)	
Test Results	HBsAg positive	HBsAg negative, anti-HBs positive	HBsAg negative, anti-HBs negative
Next steps	Patient is infected. Discontinue vaccination, refer for medical follow-up, refer to Regional CEDS Director for case investigation, contact management	Patient immune, discontinue vaccination	Patient is susceptible, complete vaccine series

HEPATITIS B, Other Non-Occupational Contacts POST-EXPOSURE (Continued)

Table 2. Guidelines for **Postexposure Prophylaxis (PEP)** of susceptible persons with non-occupational discrete exposures to blood or body fluids that contain blood from a known HBsAg positive source, by exposure type and vaccination status**:

Exposure	Unvaccinated (or incompletely vaccinated)	Previously vaccinated (without prior serologic confirmation of immunity)*
Percutaneous (e.g., bite or needle stick) or mucosal exposure (within 7 days)	Administer HBIG and initiate HBV series	Administer one HBV booster dose
Sexual contact (within 14 days of last contact)	Administer HBIG and initiate HBV series	Administer one HBV booster dose
Victim of sexual assault (within 14 days)	Administer HBIG and initiate HBV series	Administer one HBV booster dose

*Persons who have ever had laboratory confirmation of immunity (e.g., positive for anti-HBs) do not require a booster dose or HBIG.

**Administer PEP as soon as possible, preferably within 24 hours. PEP should not be given after the maximum number of days specified in the exposure category, because it is not expected to be protective. Vaccine may still be appropriate to protect from future exposure.

Federally funded vaccine may be used for all HBV vaccine used as PEP and to complete immunization series of all at risk contacts, regardless of age.

Table 3. Guidelines for PEP of susceptible persons with non-occupational discrete exposures to blood or body fluids that contain blood from a person of **unknown HBsAg status**, by exposure type and vaccination status**:

Exposure	Unvaccinated (or incompletely vaccinated)	Previously vaccinated (with <i>or</i> without previous serologic testing)
Percutaneous (e.g., bite or needle stick) or mucosal exposure (within 7 days)	Initiate HBV series	No treatment
Sexual contact (within 14 days of last contact)	Initiate HBV series	No treatment
Victim of sexual assault (within 14 days)	Initiate HBV series	No treatment

** Administer PEP as soon as possible, preferably within 24 hours. PEP should not be given after the maximum number of days specified in the exposure category, because it is not expected to be protective. Vaccine may still be appropriate to protect from future exposure.

HEPATITIS B, Other Non-Occupational Contacts POST-EXPOSURE (Continued)

Certain contacts should receive post-vaccination testing to document immunity.

Table 4. Guidelines for **Post-Vaccination Testing of Certain Contacts** of HBsAg positive persons.

Type of exposure	Test needed	Test timing (never earlier than 1 month after vaccination)
Ongoing sexual partner of infected person	Anti-HBs	At least 1 month after vaccination
Ongoing needle-sharing partner of infected person	Anti-HBs	At least 1 month after vaccination
Children <5 years in household of an infected person (not offspring of case)*	Anti-HBs	At least 1 month after vaccination
Fully immunized children of woman with chronic hepatitis B: considered perinatal contacts	Anti-HBs and HBsAg (if not previously tested)	At least 1 month after vaccination: see detailed information below

* Children under 5 years are at high risk of chronic infection if they remain susceptible following vaccination and are exposed to the virus. This risk declines with age.

If HBIG has been given in past 4 months, consult with Health Officer.

For fully immunized children of a woman who is HBsAg+, where there is any possibility that she was HBsAg+ during her pregnancy with them: these children are not simply household contacts, but should be considered incompletely evaluated perinatal contacts that are overdue for post-vaccination testing. Like younger perinatal contact infants, these children are still due to have serology done for both **HBsAg and anti-HBs**.

Testing should **not** be done if there is documentation that the child has ever had serology proving they were immune or proving they were already infected. **If they are fully immunized, HBsAg negative and anti-HBs negative, a single challenge dose of vaccine** should be given and the patient should have an anti- HBs drawn 1 month later. This will stimulate a positive antibody response in the vast majority of children who are immune but whose antibody levels had dropped.

For patients that test negative for anti-HBs following three doses of vaccine, **repeat the vaccine series of 3 doses** in accordance with the routine vaccination schedule and re-test for anti-HBs at least 1 month after the second series. If the patient remains non-immune, they are a vaccine **non-responder** and no further vaccination will be of benefit. Educate about risk

HEPATITIS B, Other Non-Occupational Contacts POST-EXPOSURE (Continued)

behaviors and their ongoing risk of HBV infection if exposed. HBIG will be needed for protection if an exposure occurs in the future.

Health Teaching:

Although many hepatitis B viral infections cause no symptoms, discuss symptoms of hepatitis B: serum sickness-like prodrome (skin eruptions, urticaria, arthralgias, arthritis), lassitude, anorexia, nausea, vomiting, headache, fever, dark urine, jaundice, and moderate liver enlargement with tenderness.

Encourage HBV vaccine and the importance of testing, where relevant.

Avoid sharing needles with others.

Abstain from sexual contact with infected partners.

Use condoms for each sexual encounter to prevent exchange of body fluids or skin contact.

Discuss the use of lubricants (such as K-Y) during sexual encounter (do not use oil-based products).

Avoid donating blood or organs if test positive for hepatitis B.

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“Federally Funded Vaccines for Adults” memo from Dr. Kelly Moore and Dr. Tom Jaselskis
July 8, 2009

HEPATITIS C, (Non - A, Non - B), Case

NOTE: Only applicable for patients with physician diagnosed, active acute or chronic hepatitis C

General Information:

Hepatitis C may be chronic or acute.

If patient has positive hepatitis C antibody test, refer to physician for evaluation.

Client may have history of blood transfusion, IV drug use, tattooing, or percutaneous exposure to blood or be referred by physician, health care provider or blood donation agency because of hepatitis C or positive serology.

Acute disease tends to be mild and insidious, in onset, and most infections are asymptomatic; however symptoms may include jaundice, anorexia, nausea, vomiting, malaise, abdominal discomfort, flu-like syndrome and fever.

Hepatomegaly, splenomegaly, elevated ALT and AST enzyme levels may be seen in acute cases; positive anti- HCV (antibody to HCV) serology in chronic cases.

Hepatitis C virus infection becomes chronic in approximately 75-85% of cases.

Plan:

Inform patient of false positives in early serologic testing, unclear risk of perinatal transmission, possible development of chronic active hepatitis, cirrhosis and need to refrain from donating blood.

Teach patient about transmission and prevention measures for percutaneous and sexual exposures (although not necessarily the method of transmission).

Immune Globulin is not recommended for contacts at this time.

Health Teaching:

Avoid IV drug use or sharing of needles with others.

Use condoms with each sexual encounter to prevent exchange of body fluids or skin-to-skin contact.

Use of lubricant (such as KY) during sexual encounters can lower risk of tissue damage (do not use oil-based products).

Refrain from donating blood, organs, tissue or semen and from sharing toothbrushes and razors if test positive for hepatitis C.

Avoid alcohol/OTC medications that affect the liver.

Inform of need for immunization against hepatitis A and hepatitis B.

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INDEX

-A-

Abbreviations, 7.020
Acne, 3.010
Acute Asthma Attack, 1.010
Acute Poisoning, 1.020
Acute Upper Respiratory Infection
(Common Cold), 3.020
Administering Vaccines: Dose, Route, Site,
and Needle Size, 7.010
All Methods, Initial and/or Annual Family
Planning Visit, 2.010
Anaphylaxis, 1.030
Animal Bites, 1.040
Anthrax Vaccine, 6.010
Apgar Scoring System, 1.070
Ascariasis (Roundworms), 3.030

-B-

Blood Pressure, Elevated, Adult, 3.040
Blood Pressure, Elevated, Child, 3.050
Burn, First Degree, 1.050

-C-

Cardiac Emergencies, 1.060
Cerumen Impacted (Ear Wax), 3.060
Cervical Cancer Screening, 2.020
Chickenpox, 3.530
Chiggers (Dematophilis Pentrans), 3.070
Childhood Anemia, 3.080
Chlamydia Trachomatis, Case or
Contact, 5.010
Chlamydia Trachomatis, Case or Contact,
Opt-out HIV Testing (Metro Areas Only),
5.020
Chlamydia Trachomatis, Contact Partner
Delivered Therapy, 5.030
Cholesterol Risk Assessment, 3.090
Combined Oral Contraceptive Pills, 2.030
Common Cold, 3.020
Common Faint, 1.150
Comvax Vaccine (Hib/Hep B), 4.010

Condoms, Sponge and Spermicidal Agents,
2.040
Constipation, Acute, Child, 3.100
Constipation, Adult, 3.110
Contraceptive Patch, 2.050
Cradle Cap in Infants, 3.410

-D-

Dematophilis Pentrans, 3.070
Diaper Dermatitis (Diaper Rash), 3.120
Diaphragm, 2.060
Diarrhea, 3.130
Diphtheria, Tetanus Toxoid and Acellular
Pertussis Vaccine (DTaP), 4.020
Diphtheria and Tetanus Toxoid, Pediatric
Vaccine (DT), 4.030
Diphtheria, Tetanus Toxoid, Acellular
Pertussis, Inactivated Polio Vaccine
(DTaP-IPV) (Kinrix), 4.040
Diphtheria, Tetanus Toxoid, Acellular
Pertussis, Inactivated Polio, Haemophilus
Influenzae Type B Combination Vaccine
(DTaP-IPV-Hib) (Pentacel), 4.050
Dysmenorrhea, 2.070

-E-

Emergency Childbirth, 1.070
Emergency Contraceptive Pills (ECPs),
2.080
Emergency Drug Chart, 1.030
Enterobius Vermicularis (Pinworms), 3.140

-F-

Fertility Awareness-Based Methods (FAM),
2.090
Fever Blister, 3.230
Fever, Vaccine Associated, 3.150
Five Rights of Medication Administration,
7.010
Fluoride Deficiency, 3.160

INDEX

Fluoride Varnish, 3.170
Folic Acid Prophylactic Therapy for Women
Aged 10-44, 3.180
Foodborne Outbreak Investigation, 3.190

-G-

Generic Injections, 4.060
Genital Herpes, 5.090
Gingivostomatitis, 3.240
Gonorrhea, Case or Contact, 5.040
Gonorrhea, Case or Contact, Opt-out HIV
Testing (Metro Areas Only), 5.050

-H-

Haemophilus b Conjugate Vaccine (Hib),
4.070
Haemophilus Meningitis, Contact, 3.200
Head Lice, 3.340
Hemorrhage/Hemorrhagic Shock, 1.080
Hepatitis A, Case or Presumptive, 3.210
Hepatitis A, Post Exposure, 3.220
Hepatitis A Vaccine, 4.080
Hepatitis A Inactivated , Hepatitis B
Recombinant Vaccine (Twinrix)), 4.090
Hepatitis B, Case or Presumptive, 5.060
Hepatitis B, Infant Contact, 5.070
Hepatitis B, Other Non-Occupational
Contacts, Post-Exposure, 5.080
Hepatitis B Recombinant Vaccine, Pre-
exposure (Birth through 18 years), 4.100
Hepatitis B Recombinant Vaccine, Pre-
exposure Adult (19 years and up), 4.110
Hepatitis C (Non-A, Non-B), Case, 5.090
Herpes Simplex - Type I (Fever Blister),
3.230
Herpes Simplex - Type II (Genital Herpes),
5.100
Herpes Zoster Vaccine, 4.115
Herpetic Stomatitis, 3.240
Hives, 3.520
HIV Testing and Counseling, 5.110

HIV Testing and Counseling, Opt-out HIV
Testing for STD Program (Metro Areas
Only), 5.120
H1N1 Influenza, 2009 (Information and
Guidance), 4.125
Hordeolum (Sty), 3.250
How to Administer Intramuscular (IM)
Injections, 7.010
How to Administer Subcutaneous (SC)
Injections, 7.010
Human Papillomavirus (HPV) Vaccine,
4.120

-I-

Immune Globulin Hepatitis A Prophylaxis
Dosage Chart, 3.220
Impetigo/Bullous Impetigo, 3.260
Influenza Vaccine, Live Attenuated (LAIV),
4.130
Influenza Vaccine, Trivalent Inactivated
(TIV), 4.140
Insect Bites, 1.090
Intrauterine Device (IUD), 2.100
Iron Deficiency Anemia, Adult (18 years
and older), 3.270

-J-

Jock Itch, Gym Itch, 3.440

-K-

Kinrix®, 4.040

-L-

Laceration, 1.100
Lead Toxicity Screening, 3.280
List of Standard Abbreviations, 7.020

INDEX

-M-

Measles, Mumps, Rubella Vaccine (MMR),
4.150
Medication Administration, 7.010
Meningococcal Meningitis, Case, 3.290
Meningococcal Meningitis, Contact, 3.300
Meningococcal Vaccine (Menactra), 4.160
Meningococcal Vaccine (Menomune), 4.170
Miliaria, 3.310

-N-

Nasolacrimal Duct, Obstructed, 3.320

-O-

Obstructed Nasolacrimal Duct, 3.320
Oral Candidiasis/Moniliasis, 3.330

-P-

Pediarix (DTaP/Hep B/IPV), 4.180
Pediculosis Capitis, 3.340
Pediculosis Pubis, 5.130
Periodicity Schedule (Infancy-
Adolescence), 3.350
Periodicity Schedule (22 years and over),
3.360
Pinworms, 3.140
Pityriasis Rosea, 3.370
Pneumococcal Conjugate Vaccine (PCV7),
4.190
Pneumococcal Vaccine, 4.200
Poison Ivy Dermatitis, 3.380
Poisoning, Acute, 1.020
Poison Oak, 3.380
Poison Sumac, 3.380
Polio Vaccine, Inactivated (IPV), 4.210

Potassium Iodide (KI) Administration, 6.020
Pregnancy Test, 2.110
Prevention of Vitamin Deficiency - Prenatal,
3.390
Preventive Health Care, Children, 3.350
Preventive Health Care, Adults, 3.360
Prickly Heat, 3.310
Progestin-only Implants, 2.120
Progestin-only Injectable Contraception,
2.130
Progestin Only Pills (Minipill), 2.140
Pubic Lice, 5.130
Puncture Wound, 1.110

-Q-

-R-

Rabies Vaccine, Post-Exposure, 4.220
Rabies Vaccine, Pre-Exposure, 4.230
Respiratory Emergency, 1.120
Ringworm, 3.430
Rotavirus Vaccine, 4.240
Roundworms, 3.030

-S-

Sarcoptes Scabiei, 3.400
Scabies, 3.400
Seborrheic Dermatitis, 3.410
Seizures, 1.130
Shingles Vaccine, 4.115
Shock, 1.140
Smallpox Vaccine (Vaccinia), 6.030
Smoking Cessation, 3.420
Sterilization, 2.150
Sty, 3.250
Supplemental Iron (Chart), 3.080
Syncope/Vasovagal Reaction/Common
Faint, 1.150
Syphilis, Case or Contact, 5.140
Syphilis, Case or Contact Opt-out HIV
Testing (Metro Areas only), 5.150

INDEX

-T-

Tetanus, Diphtheria and Acellular Pertussis Vaccine (Tdap) (11 through 18 years), 4.250
Tetanus, Diphtheria and Acellular Pertussis Vaccine (Tdap) (19 through 64 years), 4.260
Tetanus and Diphtheria Toxoid, Adult Type (Td), 4.270
Tetanus Prophylaxis in Wound Management, 4.280
Thrush, 3.330
Tick Bite, 1.160
Tinea Corporis, 3.430
Tinea Cruris, 3.440
Tinea Versicolor, 3.450
Tips on Safeguarding Your Vaccine Supply, 7.010
Tobacco Cessation, 3.420
Trichomoniasis, Case or Contact, 5.160
Tuberculin Skin Testing, 3.460
Two Step Tuberculin Skin Test Procedure, 3.470
Tuberculosis, Case or Suspect, 3.480
Tuberculosis, Initial Visit, 3.480
Tuberculosis, Treatment of Latent Tuberculosis Infection, 3.490
Tuberculin Skin Testing, Two Step Procedure, 3.470

-U-

Upper Respiratory Infection, Acute, 3.020
Urine, Abnormal, Adult, 3.500
Urine, Abnormal, Child, 3.510
Urticaria, 3.520

-V-

Vaccine Adverse Event Reporting System (VAERS), 7.010

Vaccines and Route of Administration, 7.010
Varicella, 3.530
Varicella Vaccine, 4.290
Vasovagal Reaction, 1.150
Vaginal Contraceptive Ring, 2.160

-W-

Wound, Puncture, 1.110

-X-

-Y-

-Z-