

VACCINATE ADULTS!

A bulletin for adult medicine specialists from the Immunization Action Coalition

Highlighting the latest developments in routine adult immunization and chronic hepatitis B virus infection.

Ask the Experts

Editor's note: The Immunization Action Coalition thanks William L. Atkinson, MD, MPH; Linda A. Moyer, RN; and Eric E. Mast, MD, of the Centers for Disease Control and Prevention (CDC) for answering the following questions for our readers. Dr. Atkinson, medical epidemiologist at the National Immunization Program, serves as a CDC liaison to the Coalition. Ms. Moyer is an epidemiologist, and Dr. Mast is a medical epidemiologist, both at CDC's Division of Viral Hepatitis.

Immunization questions

by William L. Atkinson, MD, MPH

I've noted that more adults are being diagnosed with pertussis. When will we see a pertussis vaccine licensed for adults?

It's likely there will be a product licensed for older children and adults in the future. This vaccine is already available in Canada and is being studied in the U.S. If the Food and Drug Administration approves the vaccine, ACIP will then make recommendations regarding the use of the vaccine, including who should receive it, and how often.

I'm confused about who needs to be revaccinated with PPV. Should I revaccinate a healthy 75-year-old patient who was given PPV at 65 years of age?

No. He would only need revaccination if he has developed a high-risk condition after receiving the first dose of PPV. An excellent fact sheet on pneumococcal polysaccharide vaccination and revaccination is available on the IAC website at www.immunize.org/catg.d/2015pne.pdf

Stay informed about influenza!
Visit CDC's influenza website at:
www.cdc.gov/flu

Immunization questions?

- Email nipinfo@cdc.gov
- Call CDC's Immunization Information Hotline at (800) 232-2522
- Call your state health dept. (phone numbers at www.immunize.org/coordinators)

I have a patient who received single-antigen tetanus (TT) in the emergency room rather than Td. Should he be revaccinated?

ACIP recommends that patients always receive Td rather than TT, as long as there is no contraindication to the diphtheria component. However, since it's already been given, you can wait until his next scheduled booster dose is due and administer Td at that time. The exception is if he plans to travel internationally, in which case you should give him Td before he travels.

Should providers who have a contraindication to live attenuated influenza vaccine (LAIV; FluMist) administer it? For instance, should a nurse who has asthma or is immunosuppressed administer the vaccine?

Environmental contamination with live attenuated influenza vaccine virus is probably unavoidable. There are no data on the risk of infection with vaccine virus for the person administering the vaccine. Until such data are available, it seems prudent that providers who have a contraindication to LAIV avoid administering the vaccine.

Where can I refer my patients who have concerns about vaccine safety?

There are many excellent websites that have abundant information about vaccine safety, including www.immunize.org/safety, www.cdc.gov/nip/menus/vacc_safety.htm, www.vaccineinformation.org, www.vaccine.chop.edu, and www.immunizationinfo.org

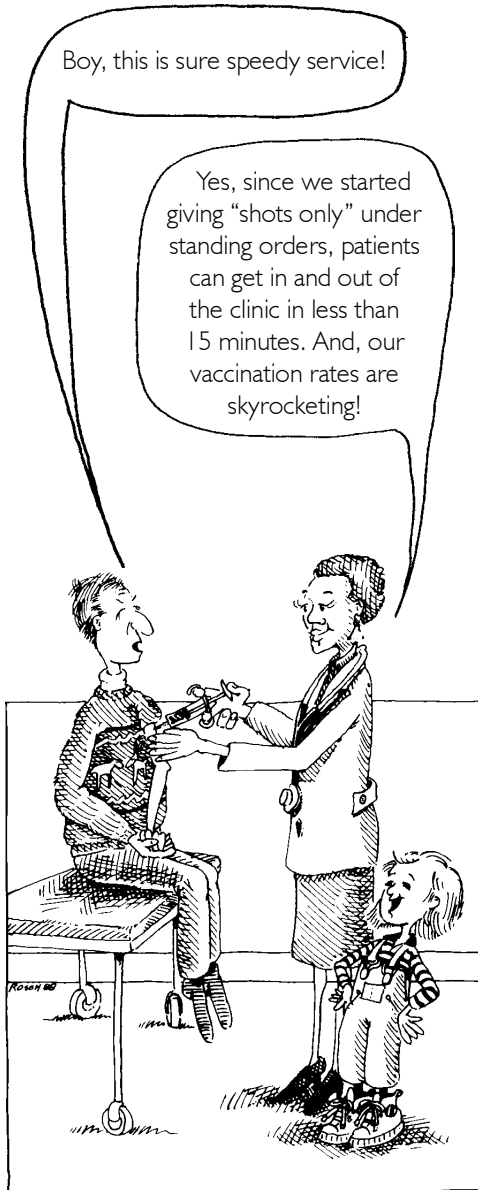
How important is it to vaccinate adolescents and adults against varicella?

It is critical to vaccinate susceptible adolescents and adults against varicella whenever the opportunity arises. With young children being routinely vaccinated, the chance of being exposed to cases of chickenpox is decreasing. Adolescents and adults who have not had chickenpox now have a greater chance of remaining susceptible. These older individuals, when they contract chickenpox, are more likely to become seriously ill and have disease complications than younger children.

(continued on page 4)

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VACCINATE ADULTS!

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The **Immunization Action Coalition (IAC)**, a 501(c)3 nonprofit organization, publishes practical immunization information for health professionals to help increase immunization rates and prevent disease.

The **Hepatitis B Coalition**, a program of IAC, promotes hepatitis B vaccination for all children 0–18 years; HBsAg screening for all pregnant women; testing and vaccination for high-risk groups; and education and treatment for people chronically infected with hepatitis B.

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Prevent Viral Hepatitis: Vaccinate!

Since the licensure of the first vaccine against hepatitis B virus (HBV) in 1981, much progress has been made toward eliminating HBV transmission in children and reducing the risk for HBV infection in adults. Substantial declines in the incidence of acute hepatitis B have occurred among highly vaccinated populations, such as young children and health care workers.

However, nearly 80,000 persons become infected with HBV each year in the United States. Vaccinating adults at high risk of HBV infection has been recommended since June 1982, but the rate of vaccine utilization among these individuals remains low.

High-risk adults—those with multiple sex partners, those with a history of recent sexually transmitted disease (STD), men who have sex with men, and injection drug users—still account for more than 75% of new cases of HBV infection each year. Studies have shown that 70% of persons newly infected with HBV have had a missed opportunity for vaccination.

Recommendations for certain individuals at high risk

1. Give hepatitis B vaccine to persons with multiple sex partners or a recent STD.

- Heterosexual activity is now the predominant source of HBV infection among U.S. adults.
- Fewer than 1% of persons at risk for sexually transmitted HBV seeking care in the private sector are vaccinated against hepatitis B.

2. Give hepatitis B and hepatitis A vaccine to men who have sex with men.

- A high prevalence (5%–20%) of HBV infection has been documented among men who have sex with men (MSM), a group with low rates of hepatitis B immunization (3%–28%).
- In a study of MSM ages 15–22 years recruited at public venues in seven U.S. metropolitan areas during 1994–98, only 9% had serologic evidence of hepatitis B vaccination.

3. Give hepatitis B and hepatitis A vaccine to injecting drug users.

- Within 5 years of beginning injection drug use, 50%–70% of injection drug users become infected with HBV.
- In one study, only 13%–25% of injection drug users in the United States reported being offered hepatitis B vaccination.
- During outbreak years, up to 10% of nationally reported cases of hepatitis A occur among users

of injecting and noninjecting drugs and among men who have sex with men.

4. Vaccinate prison inmates against hepatitis B.

- Approximately 0.7% of the U.S. population (2 million people) is incarcerated in a correctional system.
- Up to 47% of prison inmates have evidence of current or past HBV infection.
- It is estimated that 12%–39% of all Americans with chronic HBV or hepatitis C virus (HCV) infection were released from a correctional facility during the previous year.

5. Give hepatitis B and hepatitis A vaccine to persons with chronic liver disease from HCV.

- HCV infection is the most common chronic blood-borne viral infection in the United States. Approximately 2.7 million people in the U.S. are infected with HCV.

We can do better!

Our success in vaccinating health care workers proves that the goal of protecting high-risk adults against hepatitis B can be accomplished. What is stopping us from vaccinating others at risk of HBV infection?

Targeting high-risk U.S. adults for hepatitis B vaccination has been found to be cost effective even assuming a less-than-50% completion rate of the three-dose series. While providing three doses of hepatitis B vaccine is desirable, protective levels of antibodies develop in 32%–56% of adults after one dose and in more than 70% of adults after two doses. For this reason, certainty of completion of the vaccine series should not be a prerequisite for starting to vaccinate high-risk adults.

The national health objectives for 2010 call for a reduction of 75%–90% of acute hepatitis B cases among high-risk adults. Unless we begin to identify and vaccinate adults with behavioral risk factors for HBV infection, significant reduction will not be possible.

Sources

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Vaccine Highlights

Latest recommendations and schedules

Editor's note: The information on these pages is current as of January 2, 2004.

ACIP statements

All clinicians should have a set of ACIP statements, the public health recommendations on vaccines, published in the *Morbidity and Mortality Weekly Report (MMWR)*. Free continuing education credits are available for reading many of the statements and completing the brief test at the end of the statement. To obtain ACIP statements:

- Download individual statements from links on IAC's website: www.immunize.org/acip
- Download individual statements from links on CDC's website: www.cdc.gov/mmwr
- Call CDC's Immunization Hotline: (800) 232-2522.

New (revised) standards

In August 2003, the revised document "Standards for Adult Immunization Practices" was published in the *American Journal of Preventive Medicine (AJPM)*. The National Vaccine Advisory Committee led the revision effort, in collaboration with more than 60 organizations. The standards also provide links to tools and websites accessible in provider offices. To obtain the standards, including the article in *AJPM*, visit www.cdc.gov/nip/recs/rev-immz-stds.htm

Influenza news

In December 2003, CDC issued multiple updates on the current year's influenza activity. Surveillance data indicated that the 2003–04 influenza season began unusually early, with community activity first reported in early October. Reports of severe pediatric illnesses and deaths due to influenza created an unusually high demand for vaccine. The majority of the viruses identified have been type A (H3N2) viruses of the A/Fujian strain, although different influenza viruses might predominate later in the season. Influenza seasons dominated by type A (H3N2) viruses typically are associated with higher levels of severe illness and death than seasons when other types of viruses predominate. Although this year's vaccine contains the Panama strain of influenza A (H3N2), it is expected to provide some cross-protection against the Fujian-like viruses that are currently

circulating. The other two virus strains in the vaccine (influenza A [H1N1] and influenza B) closely match their circulating counterparts. For more information about influenza, visit www.cdc.gov/flu

On Sept. 26, 2003, CDC published "Using Live, Attenuated Influenza Vaccine for Prevention and Control of Influenza: Supplemental Recommendations of the ACIP" in *MMWR*. LAIV is currently approved for use among healthy persons (e.g., those not at high risk for complications from influenza infection) age 5–49 years. To obtain a copy of the recommendations, visit www.immunize.org/acip

Hepatitis B & A news

On Jan. 2, 2004, *MMWR* published an article titled "Incidence of Acute Hepatitis B—U.S., 1990–2002." It reported that the incidence of acute hepatitis B cases in the U.S. decreased 67% during 1990–2002. The decline was greatest among children and adolescents (89% decrease in cases among persons 0–19 years of age), reflecting the effect of routine childhood vaccination. Since 1999, however, after more than a decade of decline, hepatitis B incidence among men age >19 years and women age ≥40 years has increased. The most common risk factors reported among adults continue to be multiple sex partners, men who have sex with men, and injection-drug use. To read the full article, go to www.cdc.gov/mmwr/preview/mmwrhtml/mm5251a3.htm

On Nov. 15, 2003, CDC issued an official Health Advisory concerning hepatitis A outbreaks associated with green onions. At that time, the outbreaks were confined to restaurants in Tennessee, North Carolina, and Georgia in September. On Nov. 28, CDC reported green onions as the source of another outbreak of hepatitis A among patrons of a single restaurant in Pennsylvania. Three deaths have been associated with this outbreak. To read the *MMWR* article about the hepatitis A outbreak in PA, visit www.cdc.gov/mmwr/preview/mmwrhtml/mm5247a5.htm

Visit IAC's newest website at
www.vaccineinformation.org

IAC developed this site to be a one-stop source of comprehensive, clear, reliable immunization information for patients, parents, and the media. The website features more than 200 photographs of vaccine-preventable diseases from around the world.

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Free CDC video coming soon!

An updated "How to Protect Your Vaccine Supply!" will be available in spring 2004.

Watch IAC EXPRESS for an announcement.
(See page 1 for IAC EXPRESS subscription information.)

Hepatitis A and B

by Linda A. Moyer, RN, and Eric E. Mast, MD

Which STD patients need vaccination against hepatitis A and B?

All people seeking or needing treatment for an STD are candidates for hepatitis B vaccination, and certain persons with risk factors (e.g., men who have sex with men and injection-drug users) should be vaccinated against hepatitis A as well. Evaluation for vaccination is most effectively done through a risk assessment that inquires about risk factors for infection (e.g., sex partners, sexual preference, use of illegal drugs), educates patients about the importance of vaccination, and excludes persons who are not candidates for vaccination (e.g., those previously vaccinated).

**Looking for a brief sex history
questionnaire to use with patients?
Visit www.immunize.org/sxhx**

Who should have an anti-HBs test after receiving hepatitis B vaccination?

It is only necessary to confirm the immune response for persons in the following risk groups:

- health care workers who are at risk of exposure to blood or body fluids in the workplace
- infants born to HBsAg-positive mothers
- immunocompromised persons, e.g., dialysis patients, AIDS patients
- sex partners of persons with chronic HBV infection

If postvaccination testing is indicated for persons other than infants, perform the testing 1–2 months after the last dose of vaccine. Testing is not recommended after routine vaccination of infants, children, or adolescents.

Do you have HBsAg+ patients?

They need medical monitoring, including liver cancer screening; many can benefit from treatment. Consult a liver specialist experienced in the treatment of viral hepatitis for appropriate monitoring guidelines and for help in determining which of your patients might benefit from treatment.

Is HBsAg detectable in the serum after vaccination with the hepatitis B vaccine?

Because hepatitis B vaccine contains noninfectious HBsAg particles, it is possible that a person might have detectable HBsAg in their serum for as long as 3 weeks after vaccination. This in no way indicates (or causes) infection. Because of this, people who receive hepatitis B vaccine should not donate blood for 30 days following vaccination. Otherwise, they might not be allowed to be blood donors in the future.

How do I interpret some of the common hepatitis B panel results?

Tests	Results	Interpretation
HBsAg anti-HBc anti-HBs	negative negative negative	susceptible
HBsAg anti-HBc anti-HBs	negative negative positive with ≥10mIU/mL*	immune due to vaccination
HBsAg anti-HBc anti-HBs	negative positive positive	immune due to natural infection
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive positive negative	acutely infected
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive negative negative	chronically infected
HBsAg anti-HBc anti-HBs	negative positive negative	four interpretations possible†

*Postvaccination testing, when it is recommended, should be performed 1–2 months following dose #3.

- †
1. May be recovering from acute HBV infection.
 2. May be distantly immune and the test is not sensitive enough to detect a very low level of anti-HBs in serum.
 3. May be susceptible with a false positive anti-HBc.
 4. May be chronically infected and have an undetectable level of HBsAg present in the serum.

Is there any reason not to give hepatitis A vaccine to a person who requests it, especially in light of recent deaths from hepatitis A from eating contaminated green onions?

Hepatitis A vaccine is safe and effective and is licensed for anyone 2 years of age or older. If someone requests hepatitis A vaccine for themselves or their children who are 2 years of age or older, there is no medical reason that it cannot be given. The cost of the vaccine might not be covered by insurance. Patients should be informed that they might have to pay out of pocket.

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Hepatitis A and B lab tests

Hepatitis A lab nomenclature

anti-HAV: *Antibody to hepatitis A virus.* This diagnostic test detects total antibody of both IgG and IgM subclasses of HAV. Its presence indicates either acute or resolved infection.

IgM anti-HAV: *IgM antibody subclass of anti-HAV.* Its presence indicates a recent infection with HAV (≤6 mos). It is used to diagnose acute hepatitis A.

Hepatitis B lab nomenclature

HBsAg: *Hepatitis B surface antigen* is a marker of infectivity. Its presence indicates either acute or chronic HBV infection.

anti-HBs: *Antibody to hepatitis B surface antigen* is a marker of immunity. Its presence indicates an immune response to HBV infection, an immune response to vaccination, or the presence of passively acquired antibody. (It is also known as **HBsAb**, but this abbreviation is best avoided since it is often confused with abbreviations such as HBsAg.)

anti-HBc: *Antibody to hepatitis B core antigen* is a marker of acute, chronic, or resolved HBV infection. It is *not* a marker of vaccine-induced immunity. It may be used in prevaccination testing to determine previous exposure to HBV infection. (It is also known as **HBcAb**, but this abbreviation is best avoided since it is often confused with other abbreviations.)

IgM anti-HBc: *IgM antibody subclass of anti-HBc.* Positivity indicates recent infection with HBV (≤6 mos). Its presence indicates acute infection.

IgG anti-HBc: *IgG antibody subclass of anti-HBc* is a marker of past or current infection with HBV. If it and HBsAg are both positive (in the absence of IgM anti-HBc), this indicates chronic HBV infection.

HBsAg: *Hepatitis B “e” antigen* is a marker of a high degree of HBV infectivity, and it correlates with a high level of HBV replication. It is primarily used to help determine the clinical management of patients with chronic HBV infection.

Anti-HBe: *Antibody to hepatitis B “e” antigen* may be present in an infected or immune person. In persons with chronic HBV infection, its presence suggests a low viral titer and a low degree of infectivity.

HBV-DNA: *HBV Deoxyribonucleic acid* is a marker of viral replication. It correlates well with infectivity. It is used to assess and monitor the treatment of patients with chronic HBV infection.

How do I know if I've already been infected?

The only way to know if you've been infected is to have your blood tested.

Should I have a blood test before I start the hepatitis B vaccine series?

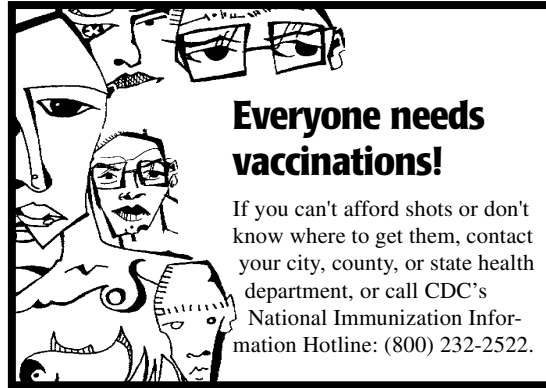
Talk to your health professional about whether you need this testing. Most people do not need a blood test. If you and your doctor decide you need testing, start the vaccine series at the same visit. That way, you will be closer to being protected from HBV.

Will hepatitis B vaccine protect me from hepatitis A or hepatitis C?

No. Hepatitis A and hepatitis C are different diseases caused by different viruses. There is a vaccine for hepatitis A, but there is no vaccine for hepatitis C at this time. For information on hepatitis A and hepatitis C, talk to your health professional or call your local health department.

How can I pay for these shots?

If you have insurance, the cost of hepatitis B vaccination may be covered. If not, sometimes these shots are available free or at low cost through special clinics or health departments. Call your local health department for details. And, while you're at it, find out what other vaccinations you need, too!



Every week hundreds of sexually active people get hepatitis B



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Get protected! Get vaccinated!

What is hepatitis B?

Hepatitis B is a sexually transmitted disease. It is a liver infection caused by the hepatitis B virus (HBV). HBV is spread much like HIV, the virus that causes AIDS. HBV is found in the blood, semen, and vaginal secretions of an infected person. HBV is easier to catch than HIV because it is more than 100 times more concentrated in an infected person's blood.

How serious is hepatitis B?

Hepatitis B can cause long-term (chronic) infection that can lead to liver scarring (cirrhosis) and liver cancer. More than 5,000 people in the United States die every year from hepatitis B-related liver disease. Fortunately, there is a vaccine to prevent this disease.

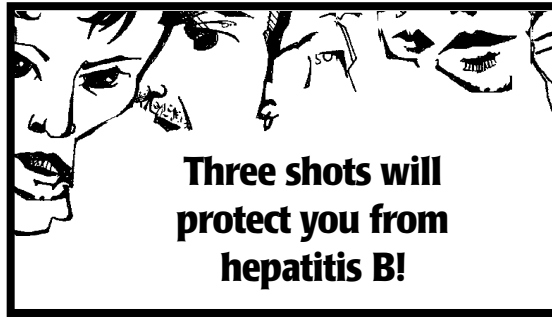
How great is my risk of getting HBV infection from sex?

If you answer "yes" to any of the following questions, you are at risk for HBV infection and need to be vaccinated!

Do you have more than one sex partner? yes no

During any six-month period, have you, or your partner, had sex with more than one person? yes no

Do you or your sex partner have a sexually transmitted disease at this time or have you had one recently? yes no



Is sex the only way I can get hepatitis B?

No. Hepatitis B is a sexually transmitted disease, but it is spread in other ways, too. HBV is a hardy virus that can exist on almost any surface for up to one month. You can get hepatitis B by

- unprotected vaginal or anal sex
- sharing needles or paraphernalia (works) for illegal drug use
- contact with an infected person's blood or body fluids
- living in a household with a person with long-term HBV infection
- tattooing with unsterile equipment
- sharing toothbrushes, razors, nail clippers, or washcloths
- human bites
- mother-to-infant transmission during birth

You do not get hepatitis B from sneezing, coughing, dry lip kissing, or holding hands.

How do I protect myself from hepatitis B?

Get vaccinated against hepatitis B! Three shots are usually given over a period of six months.

Tell your sex partner(s) to get vaccinated too, and always follow "safer sex" practices.

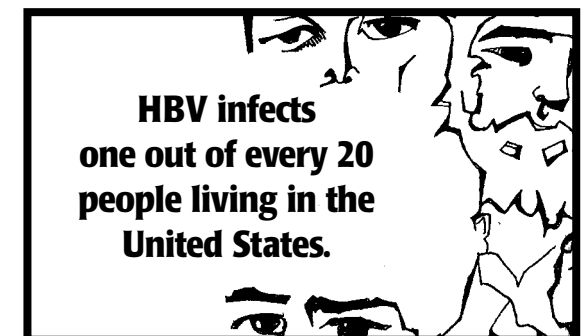
What are the symptoms of hepatitis B?

Only about half of the people who are infected with HBV get symptoms. Symptoms might include

- loss of appetite
- nausea
- fever
- dark-colored urine
- yellowing of skin and whites of eyes
- extreme tiredness
- pain in joints
- bloated and tender belly

Do people fully recover from hepatitis B?

Most people who get hepatitis B as adults will fully recover. However, 6–10% will remain infectious and carry HBV in their bodies for life. Chronically infected people do not necessarily look or feel ill, but they are at increased risk for liver failure and liver cancer and need ongoing medical care. They can also spread the virus to others.



Standing Orders for Administering Hepatitis B Vaccine to Adolescents and Adults

Purpose: To reduce morbidity and mortality from hepatitis B virus (HBV) infection by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses may vaccinate patients who meet the criteria below.

Procedure:

1. Identify adolescents and adults in need of hepatitis B vaccination based on the following criteria:
 - a. Persons less than 19 years of age who have not received the vaccine
 - b. Age 19 years or older meeting any of the following criteria:
 - having had more than one sex partner in the previous 6 months, a recently acquired sexually transmitted disease, or recent treatment for a sexually transmitted disease
 - male who has had sex with males
 - injection drug user
 - sex partner or household member of a person who is chronically infected with HBV
 - at occupational risk of infection through exposure to blood or serous fluid (e.g., health care worker, public safety worker, trainee in a health professional or allied health school)
 - client or staff of an institution for the developmentally disabled
 - hemodialysis patient or patient with early renal failure (who will become a dialysis patient)
 - receiving clotting-factor concentrate
 - planning to travel to or live in a high endemic area of the world for more than 6 months and will have close contact with the local population; also short-term travelers who are likely to have contact with blood (e.g., in a medical setting) or sexual contact with residents of areas with high or intermediate levels of endemic disease
 - housed in a long-term correctional facility
2. Screen all patients for contraindications and precautions to hepatitis B vaccine:
 - a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of hepatitis B vaccine or to a hepatitis B vaccine component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/excipient.pdf
 - b. **Precautions:** a moderate or severe acute illness with or without fever
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient’s medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speakers with the VIS in their native language if available; these can be found at www.immunize.org/vis
4. For persons 20 years of age or older, administer 1.0 mL hepatitis B vaccine IM (22–25g, 1–1½" needle) in the deltoid muscle. For persons 19 years of age or younger, administer 0.5 mL hepatitis B vaccine IM (22–25g, 1–1½" needle) in the deltoid muscle. (For persons 11–15 years of age, a 2-dose schedule, spaced 4–6 months apart, using 1.0 mL Recombivax [adult] can be used.)
5. Provide subsequent doses of hepatitis B vaccine to complete each patient’s 3-dose schedule by observing a minimum interval of 4 weeks between the first and second doses, 8 weeks between the second and third doses, and at least 4 months between the first and third doses.
6. Document each patient’s vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to hepatitis B vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or by calling (800) 822-7967. VAERS report forms are available at www.vaers.org

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date). (name of practice or clinic)

Medical Director’s signature: _____ Effective date: _____

CDC's Guidelines for Maintaining and Managing the Vaccine Cold Chain

Editor's note: The following article is reprinted from the Centers for Disease Control and Prevention's Morbidity and Mortality Weekly Report, October 24, 2003, Vol. 52(42):1023–25.

For more information on vaccine handling and storage, visit:
www.immunize.org/izpractices
www.cdc.gov/nip/menus/vaccines.htm#Storage
 or call (800) 232-2522

In February 2002, the Advisory Committee on Immunization Practices (ACIP) and American Academy of Family Physicians (AAFP) released their revised General Recommendations on Immunization (1), which included recommendations on the storage and handling of immunobiologics. Because of increased concern over the potential for errors with the vaccine cold chain (i.e., maintaining proper vaccine temperatures during storage and handling to preserve potency), this notice advises vaccine providers of the importance of proper cold chain management practices. This report describes proper storage units and storage temperatures, outlines appropriate temperature-monitoring practices, and recommends steps for evaluating a temperature-monitoring program. The success of efforts against vaccine-preventable diseases is attributable in part to proper storage and handling of vaccines. Exposure of vaccines to temperatures outside the recommended ranges can affect potency adversely, thereby reducing protection from vaccine-preventable diseases (1). Good practices to maintain proper vaccine storage and handling can ensure that the full benefit of immunization is realized.

Recommended Storage Temperatures

The majority of commonly recommended vaccines require storage temperatures of 35°F–46°F (2°C–8°C) and must not be exposed to freezing temperatures. Introduction of varicella vaccine in 1995 and of live attenuated influenza vaccine (LAIV) more recently increased the complexity of vaccine storage. Both varicella vaccine and LAIV must be stored in a continuously frozen state ≤5°F (-15°C) with no freeze-thaw cycles (Table 1). In recent years, instances of improper vaccine storage have been reported. An estimated 17%–37% of providers expose vaccines to improper storage temperatures, and refrigerator temperatures are more commonly kept too cold than too warm (2,3).

Freezing temperatures can irreversibly reduce the potency of vaccines required to be stored at 35°F–46°F (2°C–8°C). Certain freeze-sensitive vaccines contain an aluminum adjuvant that precipitates when exposed to freezing temperatures. This results in loss of the adjuvant effect and vaccine potency (4). Physical changes are not always apparent after exposure to freezing temperatures and

visible signs of freezing are not necessary to result in a decrease in vaccine potency.

Although the potency of the majority of vaccines can be affected adversely by storage temperatures that are too warm, these effects are usually more gradual, predictable, and smaller in magnitude than losses from temperatures that are too cold. In contrast, varicella vaccine and LAIV are required to be stored in continuously frozen states and lose potency when stored above the recommended temperature range.

Vaccine Storage Requirements

Vaccine storage units must be selected carefully and used properly. A combination refrigerator/freezer unit sold for home use is acceptable for vaccine storage if the refrigerator and freezer compartments each have a separate door. However, vaccines should not be stored near the cold air outlet from the freezer to the refrigerator. Many combination units cool the refrigerator compartment by using air from the freezer compartment. In these units, the freezer thermostat controls freezer temperature while the refrigerator thermostat con-

TABLE 1. Vaccine storage temperature requirements

35°F–46°F (2°C–8°C)		≤5°F (-15°C)	
Instructions	Vaccine	Instructions	Vaccine
Do not freeze or expose to freezing temperatures.	Diphtheria-, tetanus-, or pertussis-containing vaccines (DT, DTaP, Td)	Maintain in continuously frozen state with no freeze-thaw cycles.	Live attenuated influenza vaccine (LAIV)
Contact state or local health department or manufacturer for guidance on vaccines exposed to temperatures above or below the recommended range.	Haemophilus conjugate vaccine (Hib)* Hepatitis A (HepA) and hepatitis B (HepB) vaccines Inactivated polio vaccine (IPV) Measles, mumps, and rubella vaccine (MMR) in the lyophilized (freeze-dried) state† Meningococcal polysaccharide vaccine Pneumococcal conjugate vaccine (PCV) Pneumococcal polysaccharide vaccine (PPV) Trivalent inactivated influenza vaccine (TIV)	Contact state or local health department or manufacturer for guidance on vaccines exposed to temperatures above the recommended range.	Varicella vaccine

*ActHIB® (Aventis Pasteur, Lyon, France) in the lyophilized state is not expected to be affected detrimentally by freezing temperatures, although no data are available.

†MMR in the lyophilized state is not affected detrimentally by freezing temperatures.

trols the volume of freezer temperature air entering the refrigerator. This can result in different temperature zones within the refrigerator.

Refrigerators without freezers and stand-alone freezers usually perform better at maintaining the precise temperatures required for vaccine storage, and such single-purpose units sold for home use are less expensive alternatives to medical specialty equipment. Any refrigerator or freezer used for vaccine storage must maintain the required temperature range year-round, be large enough to hold the year's largest inventory, and be dedicated to storage of biologics (i.e., food or beverages should not be stored in vaccine storage units). In addition, vaccines should be stored centrally in the refrigerator or freezer, not in the door or on the bottom of the storage unit, and sufficiently away from walls to allow air to circulate.

Temperature Monitoring

Proper temperature monitoring is key to proper cold chain management. Thermometers should be placed in a central location in the storage unit, adjacent to the vaccine. Temperatures should be read and documented twice each day, once when the office or clinic opens and once at the end of the day. Temperature logs should be kept on file for ≥ 3 years, unless state statutes or rules require a longer period. Immediate action must be taken to correct storage temperatures that are outside the recommended ranges. Mishandled vaccines should not be administered.

One person should be assigned primary responsibility for maintaining temperature logs, along with one backup person. Temperature logs should be reviewed by the backup person at least weekly. All staff members working with vaccines should be familiar with proper temperature monitoring.

Different types of thermometers can be used, including standard fluid-filled, min-max, and continuous chart recorder thermometers (Table 2).

Standard fluid-filled thermometers are the simplest and least expensive products, but some models might perform poorly. Product temperature thermometers (i.e., those encased in biosafe liquids) might reflect vaccine temperature more accurately. Min-max thermometers monitor the temperature range. Continuous chart recorder thermometers monitor temperature range and duration and can be recalibrated at specified intervals. All thermometers used for monitoring vaccine storage temperatures should be calibrated and certified by an appropriate agency (e.g., National Institute of Standards and Technology). In addition, temperature indicators (e.g., Freeze Watch™ [3M, St. Paul, Minnesota] or ColdMark™ [Cold Ice, Inc., Oakland, California]) can be considered as a backup monitoring system (5); however, such indicators should not be used as a substitute for twice daily temperature readings and documentation.

All medical care providers who administer vaccines should evaluate their cold chain maintenance and management to ensure that 1) designated personnel and backup personnel have written duties and are trained in vaccine storage and handling; 2) accurate thermometers are placed properly in all vaccine storage units and any limitations of the storage system are fully known; 3) vaccines are placed properly within the refrigerator or freezer in which proper temperatures are maintained; 4) temperature logs are reviewed for completeness and any deviations from recommended temperature ranges; 5) any out-of-range temperatures prompt immediate action to fix the problem, with results of these actions documented; 6) any vaccines exposed to out-of-range temperatures are marked "do not use" and isolated physically; 7) when a problem is discovered, the exposed vaccine is maintained at proper temperatures while state or local health departments, or the vaccine manufacturers, are contacted for guidance; and 8) written emergency retrieval and storage procedures are in place in case of equipment failures or power outages.

Around-the-clock monitoring systems might be considered to alert staff to after-hours emergencies, particularly if large vaccine inventories are maintained.

Additional information on vaccine storage and handling is available from the Immunization Action Coalition at <http://www.immunize.org/izpractices/index.htm> Links to state and local health departments are available at <http://www.cdc.gov/other.htm> Especially detailed guidelines from the Commonwealth of Australia on vaccine storage and handling, vaccine storage units, temperature monitoring, and stability of vaccines at different temperatures (6) are available at <http://immunise.health.gov.au/cool.pdf>

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- (Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.)

TABLE 2. Comparison of thermometers used to monitor vaccine temperatures

Thermometer type	Advantages	Disadvantages
Standard fluid-filled	<ul style="list-style-type: none"> • Inexpensive and simple to use. • Thermometers encased in biosafe liquids can reflect vaccine temperatures more accurately. 	<ul style="list-style-type: none"> • Less accurate (+/-1°C). • No information on duration of out of specification exposure. • No information on mini-max temperatures. • Cannot be recalibrated. • Inexpensive models might perform poorly.
Min-max	<ul style="list-style-type: none"> • Inexpensive. • Monitors temperature range. 	<ul style="list-style-type: none"> • Less accurate (+/-1°C). • No information on duration of out of specification exposure. • Cannot be recalibrated.
Continuous chart recorder	<ul style="list-style-type: none"> • Most accurate. • Continuous 24-hour readings of temperature range and duration. • Can be recalibrated at regular intervals. 	<ul style="list-style-type: none"> • Most expensive. • Requires most training and maintenance.

Temperature Logs (F° and C°) for Vaccines

Fahrenheit Temperature Log: To obtain a ready-to-copy, full-size (8½" x 11") version of this 2-page document, visit www.immunize.org/catg.d/p3039.pdf

Temperature Log for Vaccines (Fahrenheit)

Month/Year: _____ Days 1-15

Instructions: Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. Store the vaccine under proper conditions as quickly as possible; 2. Call the vaccine manufacturer(s) to determine whether the potency of the vaccine(s) has been affected; 3. Call the immunization program at your local health department for further assistance: (_____) _____ and 4. Document the action taken on the reverse side of this log.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Exact Time															
F Temp															
C Temp															
Refrigerator temperature															
Freezer temp															
Room temp															
Start/Finish															

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Temperature Log for Vaccines (Fahrenheit)

Month/Year: _____ Days 16-31

Instructions: Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. Store the vaccine under proper conditions as quickly as possible; 2. Call the vaccine manufacturer(s) to determine whether the potency of the vaccine(s) has been affected; 3. Call the immunization program at your local health department for further assistance: (_____) _____ and 4. Document the action taken on the reverse side of this log.

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Exact Time																
F Temp																
C Temp																
Refrigerator temperature																
Freezer temp																
Room temp																
Start/Finish																

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Celsius Temperature Log: To obtain a ready-to-copy, full-size (8½" x 11") version of this 2-page document, visit www.immunize.org/news.d/celsius.pdf

Temperature Log for Vaccines (Celsius)

Month/Year: _____ Days 1-15

Instructions: Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. Store the vaccine under proper conditions as quickly as possible; 2. Call the vaccine manufacturer(s) to determine whether the potency of the vaccine(s) has been affected; 3. Call the immunization program at your local health department for further assistance: (_____) _____ and 4. Document the action taken on the reverse side of this log.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Exact Time															
C Temp															
F Temp															
Refrigerator temperature															
Freezer temp															
Room temp															
Start/Finish															

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Temperature Log For Vaccines (Celsius)

Month/Year: _____ Days 16-31

Instructions: Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. Store the vaccine under proper conditions as quickly as possible; 2. Call the vaccine manufacturer(s) to determine whether the potency of the vaccine(s) has been affected; 3. Call the immunization program at your local health department for further assistance: (_____) _____ and 4. Document the action taken on the reverse side of this log.

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
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IAC Executive Director

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