



OSHA INSTRUCTION

U.S. DEPARTMENT OF LABOR

Occupational Safety and Health Administration

DIRECTIVES NUMBER: CPL 2-2.44D

EFFECTIVE DATE: November 5, 1999

SUBJECT: Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens

ABSTRACT

- Purpose:** This instruction establishes policies and provides clarification to ensure uniform inspection procedures are followed when conducting inspections to enforce the Occupational Exposure to Bloodborne Pathogens Standard..
- Scope:** This instruction applies OSHA-wide..
- References:** 29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens
OSHA Instruction CPL 2.103, Field Inspection Reference Manual.
- Cancellations:** This instruction cancels OSHA Instruction CPL 2-2.44C
- State Impact:** This instruction describes a Federal Program Change for which State adoption is not required (See Paragraph VI)..
- Action Offices:** National, Regional and Area Offices.
- Originating Office:** Directorates of Compliance Programs.
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- I. **Purpose.** This instruction establishes policies and provides clarifications to ensure uniform inspection procedures are followed when conducting inspections to enforce the Occupational Exposure to Bloodborne Pathogens Standard.
- II. **Scope.** This instruction applies OSHA-wide.
- III. **Cancellation.** This instruction cancels OSHA Instruction CPL 2-2.44C, Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens Standard, 29 CFR 1910.1030, February 13, 1992.
- IV. **References**
 - A. OSHA Instruction, CPL 2.103, Field Inspection Reference Manual (FIRM), September 26, 1994.
 - B. OSHA Instruction CPL 2.111, Citation Policy for Paperwork and Written Program Violations., November 27, 1995.
 - C. OSHA Instruction, CPL 2-2.30, Authorization of Review of Medical Opinions, November 14, 1980.
 - D. OSHA Instruction, CPL 2-2.32, January 19, 1981, Authorization of Review of Specific Medical Information.
 - E. OSHA Instruction, CPL 2-2.33, February 8, 1982, Rules of Agency Practice and Procedure Concerning OSHA Access to Employee Medical Records-Procedures Governing Enforcement Activities.
 - F. OSHA Instruction, CPL 2-2.46, January 5, 1989, Authorization and Procedures for Reviewing Medical Records.
 - G. OSHA Instruction, PER 8-2.4, March 31, 1989, CSHO Pre-Employment Medical Examinations.
 - H. Centers for Disease Control *Morbidity and Mortality Weekly Report*: "Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis." May 15, 1998; Vol. 47, No. RR-7.

- I. Centers for Disease Control *Morbidity and Mortality Weekly Report*: “Recommendations for Follow-Up of Health-Care Workers After Occupational Exposure to Hepatitis C Virus”. July 4, 1997; Vol. 46, No. 26.
- J. Record Summary of the Request for Information (RFI) on Occupational Exposure to Bloodborne Pathogens due to Percutaneous Injury. May 20, 1999.
- K. Safer Needle Devices: Protecting Health Care Workers , Directorate of Technical Support, Office of Occupational Health Nursing, October 1997.
- L. Needlestick Injuries Among Health Care Workers: A Literature Review, Directorate of Technical Support, Office of Occupational Health Nursing, July, 1998.
- M. International HealthCare Worker Safety Center, #407, Health Sciences Center, University of Virginia, Charlottesville, VA 22908, EPINet, Exposure Prevention Information Network, E-mail: *epinet@virginia.edu*.
- N. DHHS, Public Health Service, “FDA Safety Alert: Needlestick and Other Risks from Hypodermic Needles on Secondary IV Administration Sets - Piggyback and Intermittent IV”, April 16, 1992.
- O. Glass Capillary Tubes: Joint Safety Advisory About Potential Risks, OSHA/NIOSH/FDA, February, 1999 and Memorandum dated February 18, 1999, from Steve Witt to the Regional Administrators.
- P. NIOSH, “Selecting, Evaluating, and Using Sharps Disposal Containers”, DHHS (NIOSH) Publication No. 97-111, January 1998.
- Q. Centers for Disease Control, *MMWR*, October 16, 1998/Vol.47/No. RR-19 “Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease.”
- R. Centers for Disease Control, *American Journal of Infection Control*, June 1998, Vol. 26, “Guideline for Infection Control in Health Care Personnel, 1998.”
< <http://www.cdc.gov/ncidod/hip/Guide/guide.htm> >
- S. Centers for Disease Control, *MMWR*, December 26, 1997, Vol.46, No.RR-18, Immunization of Health-Care Workers: Recommendations

- T. 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens; Final Rule, Federal Register/Vol.56, No.235/ December 6, 1991.
 - U. Training for Development of Innovative Control Technology Project, “Safety Feature Evaluation Forms”.
- V. **Action.** OSHA Regional Administrators and Area Directors should use the guidelines in this instruction to ensure uniform enforcement of the Bloodborne Pathogens Standard. The Directorate of Compliance Programs will provide support necessary to assist the Regional Administrators and Area Directors in enforcing the Bloodborne Pathogens Standard.
- VI. **Federal Program Change:** This instruction describes a Federal Program Change for which State adoption is not required. NOTE: In order to effectively enforce safety and health standards, guidance to compliance staff is necessary. Therefore, although adoption of this instruction is not required, States are expected to have standards, enforcement policies and procedures which are at least as effective as those of Federal OSHA.
- VII. **Background.** In September 1986, OSHA was petitioned by various unions representing healthcare employees to develop an emergency temporary standard to protect employees from occupational exposure to bloodborne diseases. The agency decided to pursue the development of a Section 6(b) standard and published a proposed rule on May 30, 1989.
- A. The agency also concluded that the risk of contracting the hepatitis B virus (HBV) and human immunodeficiency virus (HIV) among members of various occupations within the healthcare sector required an immediate response and therefore issued OSHA Instruction CPL 2-2.44, January 19, 1988. That instruction was superseded by CPL 2-2.44A, August 15, 1988; subsequently, CPL 2-2.44B was issued February 27, 1990.
 - B. On December 6, 1991, the agency issued its final regulation on occupational exposure to bloodborne pathogens (29 CFR 1910.1030). Based on a review of the information in the rulemaking record, OSHA has determined that employees face a significant health risk as the result of occupational exposure to blood and other potentially infectious materials (OPIM) because they may contain bloodborne pathogens. **These pathogens include but are not limited to HBV, which causes hepatitis B; HIV, which causes acquired immunodeficiency syndrome (AIDS); hepatitis C virus; human T-lymphotrophic virus Type 1; and pathogens causing malaria, syphilis, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeldt-Jakob disease, and viral hemorrhagic fever.** The agency further concludes that these hazards can be

minimized or eliminated by using a combination of engineering and work practice controls, personal protective clothing and equipment, training, medical surveillance, hepatitis B vaccination, signs and labels, and other provisions. Both the standard and CPL 2-2.44C became effective on March 6, 1992.

VIII. Inspection Scheduling, and Scope.

- A. Inspection scheduling should be conducted in accordance with the procedures outlined in the FIRM (CPL 2.103), Chapter II, Inspection Procedures.
- B. All inspections, programmed or unprogrammed, should include, if appropriate, a review of the employer's exposure control plan and employee interviews to assess compliance with the standard.
- C. Expansion of an inspection to areas involving the hazard of occupational exposure to blood or other potentially infectious materials (including on site healthcare units and emergency response or first aid personnel) should be performed when:
 - 1. The exposure control plan or employee interviews indicate deficiencies in complying with OSHA requirements, as set forth in 29 CFR 1910.1030 or this instruction.
 - 2. Relevant formal employee complaints are received which are specifically related to occupational exposure to blood or OPIM.
 - 3. A fatality/catastrophe inspection is conducted as the result of occupational exposure to blood or OPIM.

IX. General Inspection Procedures. The procedures given in the FIRM, Chapter II, should be followed except as modified in the following sections:

- A. Where appropriate, the facility administrator, as well as the directors of infection control, employee (occupational) health, training and education, and environmental services (housekeeping) will be included in the opening conference or interviewed early in the inspection.
- B. The facility's file of "incident reports" that document the circumstances of exposure incidents in accordance with the provisions in the exposure control plan, or a first aid log of injuries (e.g., needlesticks), should be reviewed. The compliance officer should ask for any other additional records that track

bloodborne incidents. The compliance officer should review the most recent Part 1904 - Recording and Reporting Occupational Injuries and Illnesses regulations prior to citing recordkeeping violations. Compliance Officers are reminded that the publication of the final recordkeeping standard may affect certain recording requirements that will impact their bloodborne inspections.

- C. Compliance officers should take necessary precautions to avoid direct contact with blood or OPIM and should not participate in activities that will require them to come into contact with blood or OPIM. The CSHO should avoid direct contact with needles or other sharp instruments potentially contaminated with blood or OPIM. To evaluate such activities, compliance officers normally should establish the existence of hazards and adequacy of work practices through employee interviews and should observe them at a safe distance.
- D. On occasions when entry into potentially hazardous areas is judged necessary, the compliance officer should be properly equipped as required by the facility as well as by his/her own professional judgment, after consultation with the supervisor, who should refer to OSHA's exposure control plan for further guidance.
- E. Compliance officers should use appropriate caution when entering patient care areas of the facility. When such visits are judged necessary for determining actual conditions in the facility, the privacy of patients must be respected. Photos or videos are normally not necessary and in no event should identifiable photos be taken without the patient's consent.

X. Recording of Exposure Incidents. For recordkeeping purposes, an occupational bloodborne pathogens exposure incident (e.g., needlestick, laceration, or splash) should be classified as an injury since it is usually the result of an instantaneous event or exposure. The compliance officer should review the most current Part 1904, to determine when injuries must be recorded.

XI. Multi-Employer and Related Worksites. There are a number of different types of multi-employer worksites. This paragraph addresses a few typical situations but does not address all the circumstances that occur. In addition, this paragraph deals with situations in which employees are sent out to sites that are not multi-employer worksites. Where these guidelines do not address a particular question, see Chapter III C6. of the FIRM, dealing with multi-employer worksites.

- A. Employment Agencies.** An employment agency refers job applicants to potential employers but does not put these workers on the payroll or otherwise establish an

employment relationship with them; thus, the employment agency is not the employer of these workers. These agencies shall not be cited for violations affecting the workers they refer. The company that uses these workers, *e.g.*, a hospital, is the employer of these workers and shall be cited for all violations affecting them.

- B. Personnel Services.** Personnel services firms employ medical care staff and service employees who are assigned to work at hospitals and other healthcare facilities that contract with the firm. Typically, the employees are on the payroll of the personnel services firm, but the healthcare facility exercises day-to-day supervision over them. In these circumstances, due to the concerns expressed by the court in **American Dental Association v. Martin**, 984 F.2d 823, 829-30 (7th Cir. 1993) (dictum about medical personnel services) the personnel services firm should be cited for violations of the bloodborne pathogens standard only in the following categories: (1) hepatitis B vaccinations; (2) post-exposure evaluation and follow-up; (3) recordkeeping under paragraph (h) of the standard; (4) generic training; (5) violations occurring at the healthcare facility about which the personnel services firm actually knew and where the firm failed to take reasonable steps to have the host employer (the employer using the workers, *e.g.*, a hospital) correct the violation (see FIRM multi-employer worksite guidelines); and (6) pervasive serious violations occurring at the healthcare facility about which the personnel service firm could have known with the exercise of reasonable diligence.

When the host employer exercises day-to-day supervision over the personnel service workers, they are the employees of the host employer, as well as of the personnel service, and thus the host employer must comply with all provisions of the standard with respect to these workers. With respect to Hepatitis B vaccination, post-exposure evaluation and follow-up, recordkeeping, and generic training, the host employer's obligation is to take reasonable measures to assure that the personnel service firm has complied with these provisions.

- C. Home Health Services.** The **American Dental Association v. Martin** decision upheld the bloodborne pathogens standard but restricted its application in the home health services industry. These are companies whose employees provide home health services in private homes. The court held that OSHA had not adequately considered feasibility problems for such employers, where employees work at sites that the employer does not control. As a result, OSHA may not cite those employers for site-dependent provisions of the standard when the hazard is site-specific.

In implementing this decision, OSHA determined that the employer will not be held responsible for the following site-specific violations: housekeeping requirements, such as the maintenance of a clean and sanitary worksite and the handling and disposal of regulated waste; ensuring the use of personal protective equipment; and ensuring that specific work practices are followed (e.g., handwashing with running water) and ensuring the use of engineering controls.

The employer will be held responsible for all non-site-specific requirements of the standard, including the non-site specific requirements of the exposure control plan, hepatitis B vaccinations, post exposure evaluation and follow-up, recordkeeping, and the generic training requirements. OSHA will also cite employers for failure to supply appropriate personal protective equipment to employees.

- D. Physicians and Healthcare professionals who have established an independent practice.** In applying the provisions of the standard in situations involving physicians, the status of the physician is important. Physicians may be employers or employees. Physicians who are unincorporated sole proprietors or partners in a bona fide partnership are employers for purposes of the OSH Act and may be cited if they employ at least one employee (such as a technician or secretary). Such physician-employers may be cited if they create or control bloodborne pathogens hazards that expose employees at hospitals or other sites where they have staff privileges may be cited in accordance with the multi-employer worksite guidelines of the FIRM. Because the physicians in these situations are not themselves employees, citations may not be based on the exposure of such physicians to the hazards of bloodborne diseases.

Physicians may be employed by a hospital or other healthcare facility or may be members of a professional corporation and conduct some of their activities at host employer sites where they have staff privileges. In general, professional corporations are the employers of their physician-members and must comply with the hepatitis B vaccination, post-exposure-evaluation and follow up, recordkeeping, and generic training provisions with respect to these physicians when they work at host employer sites. The host employer is not responsible for these provisions with respect to physicians with staff privileges, but in appropriate circumstances, may be cited under other provisions of the standard in accordance with the multi-employer worksite guidelines of the FIRM. The professional corporation may also be cited under other provisions of the standard for the exposure of its physicians and other workers at a host employer site in accordance with the multi-employer worksite guidelines of the FIRM.

E. Independent Contractors. These are companies that provide a service, such as radiology or housekeeping, to host employers. They provide supervisory personnel, as well as rank-and-file workers, to carry out the service. These companies and the host employers are responsible for complying with all provisions of the standard in accordance with the multi-employer worksite guidelines of the FIRM.

XII. Federal Agency Facilities. Agencies of the Federal Government are covered by this instruction.

XIII. Clarification of the Standard on Occupational Exposure to Bloodborne Pathogens, 29 CFR 1910.1030. The guidance that follows relates to specific provisions of **29 CFR 1910.1030** and is provided to assist compliance officers in conducting inspections where the standard may be applicable:

A. Scope and Application - 29 CFR 1910.1030(a). This paragraph defines the range of employees covered by the standard.

1. Since there is no population that is risk free for HIV, HBV or other bloodborne disease infection, any employee who has occupational exposure to blood or other potentially infectious material will be included within the scope of this standard.
2. Although a list is included below of a number of job classifications that may be associated with tasks that have occupational exposure to blood and other potentially infectious materials, **the scope of this standard is not limited to employees in these jobs**. The hazard of exposure to infectious materials affects employees in many types of employment and is not restricted to the healthcare industry. At the same time, **employees in the following jobs are not automatically covered unless they have the potential for occupational exposure:**

Physicians, physician's assistants, nurses, nurse practitioners, and other healthcare employees in clinics and physicians' offices; employees of clinical and diagnostic laboratories; housekeepers in healthcare and other facilities; personnel in hospital laundries or commercial laundries that service healthcare or public safety institutions; tissue bank personnel; employees in blood banks and plasma centers who collect, transport, and test blood; freestanding clinic employees (e.g., hemodialysis clinics, urgent

care clinics, health maintenance organization (HMO) clinics, and family planning clinics); employees in clinics in industrial, educational, and correctional facilities (e.g., those who collect blood, and clean and dress wounds); employees designated to provide emergency first aid; dentists, dental hygienists, dental assistants and dental laboratory technicians; staff of institutions for the developmentally disabled; hospice employees; home healthcare workers; staff of nursing homes and long-term care facilities; employees of funeral homes and mortuaries; HIV and HBV research laboratory and production facility workers; employees handling regulated waste; custodial workers required to clean up contaminated sharps or spills of blood or OPIM; medical equipment service and repair personnel; emergency medical technicians, paramedics, and other emergency medical service providers; fire fighters, law enforcement personnel, and correctional officers (employees in the private sector, the Federal Government, or a State or local government in a State that has an OSHA-approved State plan); maintenance workers, such as plumbers, in healthcare facilities and employees of substance abuse clinics.

3. **INSPECTION GUIDELINES.** The scope paragraph of this standard states that it "applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b)." The compliance officer must take careful note of the definition of "occupational exposure" in paragraph (b) in determining if an employee is covered by this standard.
 - a. **Part-time, temporary, and healthcare workers known as "per diem" employees are covered by this standard.**
 - b. OSHA jurisdiction extends only to employees in the workplace. It does not extend to students if they are not considered employees, to state, county, or municipal employees, to health care professionals who are sole practitioners or partners, and to the self-employed.
 - c. If an employee is trained in first aid and identified by the employer as responsible for rendering medical assistance **as part of his/her job duties**, that employee is covered by the standard. See the citation policy for **paragraph (f)(2)** of the standard below regarding designated first aid providers, who administer first aid as a **collateral duty** to their routine work assignments. An employee who routinely provides first aid to fellow

employees with the knowledge of the employer may also fall, *de facto*, under this designation even if the employer has not officially designated this employee as a first aid provider.

- d. Exposure to bloodborne pathogens in **shipyard operations** is covered under 29 CFR 1915.1030, which states that its requirements are identical to those in 29 CFR 1910.1030.
- e. **Other Industries:** The bloodborne pathogens standard **does not** apply to the construction, agriculture, marine terminal and longshoring industries. OSHA has not, however, stated that these industries are free from the hazards of bloodborne pathogens. For industries not covered by the bloodborne pathogens standard, Section 5(a)(1) of the OSH Act provides that "each employer shall furnish to each of his employees employment and a place of employment which is free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees." The General Duty Clause should not be used to cite for violations of the bloodborne pathogens rule, but may be used to cite for failure to provide a workplace free from exposure to bloodborne pathogens. Section 5(a)(1) citations must meet the requirements outlined in the FIRM, OSHA Instruction CPL 2.103, Chapter III. Failure to implement all or any part of **29 CFR 1910.1030** should not be, in itself, the basis for a citation. Accordingly, **29 CFR 1910.1030** should not be specifically referenced in a citation.

B. Definitions - 29 CFR 1910.1030(b). The following provides further clarifications of some definitions found in this paragraph:

1. **"Blood"**: The term "human blood components" includes plasma, platelets, and serosanguinous fluids (e.g., exudates from wounds). Also included are medications derived from blood, such as immune globulins, albumin, and factors 8 and 9. (See letter of interpretation, 5/5/98)
2. **"Bloodborne Pathogens"**: While HBV and HIV are specifically identified in the standard, **the term includes any pathogenic microorganism** that is present in human blood or OPIM and can infect and cause disease in persons who are exposed to blood containing the pathogen. **Pathogenic microorganisms can also cause diseases such as hepatitis C, malaria, syphilis, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeldt-Jakob disease, adult**

T-cell leukemia/lymphoma (caused by HTLV-I), HTLV-I associated myelopathy, diseases associated with HTLV-II, and viral hemorrhagic fever.

NOTE: According to the Centers for Disease Control and Prevention (CDC), hepatitis C virus (HCV) infection is the most common chronic bloodborne infection in the United States. (*MMWR: Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease, October 16, 1998/Vol.47/No. RR-19.*)

HCV is a viral infection of the liver that is transmitted primarily by exposure to blood. Currently there is no vaccine effective against HCV. See discussion of paragraph (f)(3) below.

3. **"Exposure Incident"**: "Non-intact skin" includes skin with dermatitis, hangnails, cuts, abrasions, chafing, acne, etc
4. **"Engineering controls"** means controls that isolate or remove the bloodborne pathogens hazard from the workplace. Examples include needleless devices, shielded needle devices, blunt needles, plastic capillary tubes.
5. **"Occupational Exposure"**: The term "reasonably anticipated contact" includes the potential for contact as well as actual contact with blood or OPIM. Lack of history of blood exposures among designated first aid personnel of a particular manufacturing site, for instance, does not preclude coverage. "Reasonably anticipated contact" includes, among others, contact with blood or OPIM (including regulated waste) as well as incidents of needlesticks. For example, a compliance officer may document incidents in which an employee observes uncapped needles or contacts other regulated waste in order to substantiate "occupational exposure."

NOTE: This definition does not cover "Good Samaritan" acts which result in exposure to blood or other potentially infectious materials from voluntarily assisting a fellow employee, although OSHA encourages employers to offer follow-up procedures to these employees in such cases.

6. **"Other Potentially Infectious Materials" (OPIM):** Coverage under this definition also extends to blood and tissues of experimental animals who are infected with HIV or HBV.
7. **"Parenteral":** This definition includes human bites that break the skin, which are most likely to occur in violent situations such as may be encountered by prison personnel and police and in emergency rooms or psychiatric wards.

C. Exposure Control Plan - 29 CFR 1910.1030(c). This paragraph requires the employer to identify those tasks and procedures in which occupational exposure may occur and to identify the positions whose duties include those tasks and procedures identified as having occupational exposure. The exposure control plan required by paragraph (c)(1) is a key provision of the standard because it requires the employer to identify the individuals who will receive the training, protective equipment, vaccination, and other protections of the standard.

1. **INSPECTION AND CITATION GUIDELINES.** The Compliance Officer should review the facility's written exposure control plan. While the plan may be part of a larger document, such as one addressing all health and safety hazards in the workplace, in order for the plan to be accessible to employees, it must be a cohesive entity by itself or there must be a guiding document which states the overall policy goals and references the elements of existing separate policies that comprise the plan.

The Compliance Officer should determine whether the plan is reviewed annually and updated to reflect significant modifications in tasks or procedures which may result in occupational exposure as required in paragraph (c)(1)(iv).

The location of the plan may be adapted to the circumstances of a particular workplace, provided that the employee can access a copy at the workplace, during the workshift (e.g., if the plan is maintained solely on computer, employees must be trained to operate the computer). In accordance with 29 CFR 1910.1020, a hard copy of the exposure control plan must be made available to the employee within 15 working days of the employee's request.

If a facility is lacking an exposure control plan and the other requirements of the standard have not been implemented, the other relevant paragraphs

of the standard should be cited in addition to **paragraph (c)**. These should normally be classified as serious violations.

2. **Paragraphs (c)(1)(ii)(A) and (c)(2)(i)**. The exposure determination requires employers to identify and document:
 - a. Those job classifications in which all employees have occupational exposure, and/or
 - b. Those job classifications in which **some** employees have occupational exposure.
 - 1) In the latter case, the specific tasks and procedures, or groups of closely related tasks and procedures, which are associated with occupational exposure must be delineated. For example, only **some** of the employees in a hospital laundry room might be assigned the task of handling contaminated laundry.
 - 2) The tasks and procedures that are grouped must be related; i.e., they must share a common activity such as "vascular access procedures," "handling of contaminated sharps," or "handling of deceased persons," etc.
NOTE: If a job classification, task, or procedure involving occupational exposure is omitted from the list, but all employees in the job or performing the task or procedure have been included in all other aspects of the plan (e.g., vaccinations, training, etc.), it is to be considered an other-than-serious violation.
 - 3) The exposure determination must have been made without taking into consideration the use of personal protective clothing or equipment.
3. **Paragraph (c)(1)(ii)(B)**. While the primary purpose of the exposure control plan is to identify those employees who have occupational exposure and to commit the employer to a timetable for implementation of the standard's requirements, paragraphs **(d)-(h)** of the standard must also be addressed in a manner appropriate to the circumstances of the particular workplace. An annotated copy of the final standard may be adequate for

small facilities. Larger facilities could develop a broad facility-wide program incorporating provisions from the standard that apply to their establishments.

4. **Paragraph (c)(1)(ii)(C).** The exposure control plan must include the procedure for evaluating the circumstances surrounding exposure incidents, in accordance with **paragraph (f)(3)(i)**.

CITATION GUIDELINES: If the employer failed to include procedures for the documentation of exposure incidents in the exposure control plan, a citation for paragraph (c)(1)(ii)(C), should be issued. If procedures are included in the plan but not implemented, then **paragraph (f)(3)(i)** should be cited.

5. **Paragraph (c)(1)(iv)** requires the exposure control plan to be reviewed and updated at least annually (every 12 months) and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. According to the preamble to the standard, the requirement to review and update the plan means that the plan must reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens. [56 Fed. Reg. 64109-10 (1991).] A periodic review ensures that the exposure control plan remains current with the latest information and scientific knowledge pertaining to bloodborne pathogens. The exposure control plan must document consideration and implementation of appropriate commercially available and effective engineering controls designed to eliminate or minimize exposure.

NOTE: While the exact number of injuries sustained annually in the United States is unknown, current estimates vary between 590,000 and 800,000 injuries annually. This compliance instruction clarifies the agency's position regarding the implementation of effective engineering controls to reduce needlesticks and other sharps injuries. Effective engineering controls include the safer medical devices used to prevent percutaneous injuries before, during, or after use through safer design features. When the Final Rule was published in December 1991, the variety of engineering controls was limited although some were available. At that time adequate data and information on effective engineering controls and their effectiveness were not available. The preamble to the Final Rule in 1991 stated that "with regard to percutaneous incidents, such

as needlestick injuries, evidence indicated that most injuries were preventable 75 percent of all exposure incidents are caused by disposable syringes . . . and could be prevented by using syringes which incorporate resheathing or retracting designs.” [56 Fed. Reg./64057(1991)] Since publication of the standard, there has been a substantial increase in the number and assortment of effective engineering controls available to employers. There is now a large body of research and data available to OSHA and to the public concerning the effectiveness of these engineering controls.

According to OSHA’s “Record Summary of the Request for Information on Occupational Exposure to Bloodborne Pathogens Due to Percutaneous Injury (“Record Summary”)” issued on May 20, 1999, < <http://www.osha-slc.gov/html/ndlreport052099.html> >, use of effective engineering controls such as safer medical devices appear to be steadily increasing in some applications. Nearly every healthcare facility responding to the RFI noted a reduction in injuries after use of effective engineering controls. Most IV line access is now accomplished using safer devices. Engineering controls are an effective and feasible method of hazard control in many instances.

NOTE: The Exposure Control Plan must include the procedure for evaluation of circumstances surrounding exposure incidents. See discussion of paragraph **(f)(3)(i)**.

CITATION GUIDELINES: The employer must review and update the plan, as necessary, to reflect changes in technology, such as the use of effective engineering controls, that can eliminate or minimize exposures. If the employer did not review and update its exposure control plan at least annually, paragraph **(c)(1)(iv)** should be cited. See Appendix D for a Sample Exposure Control Program.

D. Methods of Compliance - 29 CFR 1910.1030(d). Paragraph **(d)** sets forth the method by which employers must protect their employees from the hazards of bloodborne pathogens and comply with this standard through the use of universal precautions, engineering controls, work practice controls, personal protective equipment, proper housekeeping and handling of regulated waste.

1. **Universal Precautions - Paragraph (d)(1).** Universal precautions are OSHA's required methods of control to protect employees from exposure

to all human blood and OPIM. The term "universal precautions" refers to a concept of bloodborne disease control which requires that all human blood and OPIM be treated as if known to be infectious for HIV, HBV, HCV or other bloodborne pathogens, regardless of the perceived "low risk" status of a patient or patient population.

Alternative concepts in infection control are called Body Substance Isolation (BSI) and Standard Precautions. These methods define **all** body fluids and substances as infectious. These methods incorporate not only the fluids and materials covered by this standard but expands coverage to include all body fluids and substances.

These concepts are acceptable alternatives to universal precautions, provided that facilities utilizing them adhere to all other provisions of this standard.

CITATION GUIDELINES. If the employer has a policy of treating the blood or OPIM of some patients as potentially infectious and the blood or OPIM of others (e.g., the elderly or children) as not infectious, a violation of this provision exists.

2. **Engineering Controls and Work Practices - Paragraph (d)(2)(i).** This paragraph requires the employer to institute engineering and work practice controls as the primary means of eliminating or minimizing employee exposure. It conforms to OSHA's traditional adherence to a hierarchy of controls [See 56 Fed. Reg. 64114-15 (1991)]. OSHA has always required employers to use engineering and work practice controls. Thus the employer must use engineering and work practice controls that eliminate occupational exposure or reduce it to the lowest feasible extent. It is OSHA's view that preventing exposures requires a comprehensive program, including engineering controls (e.g., needleless devices, shielded needle devices, and plastic capillary tubes) and proper work practices (e.g., no-hands procedures in handling contaminated sharps, eliminating hand-to-hand instrument passing in the operating room). If engineering and work practice controls do not eliminate exposure, the use of personal protective equipment (e.g., eye protection) is required.

The employer must also make changes to its Exposure Control Plan to include these engineering controls. [See **discussion of paragraph (c)(1)(iv)** above.] Safer medical devices are generally of two types:

needleless systems (e.g., needleless IV connectors) and sharps with engineered sharps injury protection (e.g., self-sheathing needles on syringes). Substitution methods such as the use of plastic (instead of glass) capillary tubes are also available. Appendix B (Safety Evaluation Forms) and Appendix C (Web Site Resource List) have been provided to assist in the evaluation of these devices. OSHA encourages employers to involve employees in the selection of effective engineering controls to improve employee acceptance of the newer devices and to improve the quality of the selection process.

NOTE: Where engineering controls will reduce employee exposure either by removing, eliminating or isolating the hazard, they must be used. Significant improvements in technology are most evident in the growing market of safer medical devices that minimize, control or prevent exposure incidents. OSHA does not advocate the use of one particular device over another.

The FDA is responsible for clearing medical devices for marketing, although this “clearance” alone is not enough to guarantee the device will be effective in the workplace. The employer must rely on further evidence to ensure its effectiveness in the situations it will be used. There are specific design features for recessed needle systems that the Food and Drug Administration (FDA Safety Alert, April 16, 1992 and Draft Supplementary Guidance on the Content of Premarket Notification 510(K) Submissions for Medical Devices with Sharps Injury Prevention Features, March 1995) has published and agrees are important in preventing percutaneous injury. These design features have the following characteristics:

- a. A fixed safety feature provides a barrier between the hands and the needle after use; the safety feature should allow or require the worker’s hands to remain behind the needle at all times;
- b. The safety feature is an integral part of the device and not an accessory;
- c. The safety feature is in effect before disassembly and remains in effect after disposal to protect users and trash handlers, and for environmental safety;
- d. The safety feature is as simple as possible, and requiring little or no training to use effectively.

OSHA has changed the language of the compliance instruction to clarify the agency's position regarding the use of engineering and work practice controls in light of the increased use and acknowledged feasibility of effective engineering controls, as discussed in the Record Summary. See the discussion of paragraph (c)(1)(iv). Furthermore, the preamble to the standard supports this change in the instruction. It states that the exposure control plan is to be updated to reflect new technology to control occupational exposure to bloodborne pathogens [56 Fed. Reg. 64109-10 (1991)].

INSPECTION GUIDELINES. The Compliance Officer should determine through interviews or observation of work involving exposure to blood or OPIM whether sufficient engineering controls and work practices are used. While it is generally accepted that an exposure incident can occur at any time or place, a review of the facility records can better direct the Compliance Officer to areas that are more likely to be sites of exposure incidents. Data from The Uniform Needlestick and Sharp Object Injury Report, 77 Hospitals, 1993-1995 (Exposure Prevention Information Network EPINet at < <http://www.med.virginia.edu/~epinet/soio.html> >) show that injuries occurred, in order of frequency, in patient rooms, operating rooms, emergency departments, and intensive/critical care units. The report indicates that nurses (RN's and LPN's) were injured more often than any other type of healthcare worker. Furthermore, the report finds that an overwhelming majority (93%) of the injuries were caused by items that were not a "safe design with a shielded, recessed, or retractable needle." The Compliance Officer should determine if there were occasions where injuries were incurred during the same procedure, using the same equipment, in the same location or among similar employees (e.g., housekeepers) and determine whether engineering or work practices have been implemented to prevent or minimize future injuries. The Compliance Officer should investigate whether the employer has instituted alternative engineering controls and work practices to eliminate or minimize employee exposure in areas where exposure incidents have been documented.

CITATION GUIDELINES. Paragraph (d)(2)(i) should be cited for failure to use engineering/work practice controls as discussed above. The Compliance Officer should carefully evaluate the exposure control measures, such as effective engineering controls, that are in use at the facility. Part of this evaluation should include whether other devices that

are commercially available were reviewed or considered by the employer and whether there is evidence that other engineering controls would reduce exposures. Such evidence might include CDC studies of efficacy, pilot tests by the employer, or data available in published studies. The Record Summary indicates that employers are using safer equipment and devices, e.g., over 87% of the respondents who provided information on device usage now use needleless or shielded needle IV line access. Other popular devices include blunt suture needles, safer syringes, and safer phlebotomy devices. This is not an exhaustive list of effective engineering controls that are available. Appendix B provides some examples of forms an employer might use for evaluation of engineering controls.

Compliance with this paragraph should take into consideration that the availability or use of an engineering control is not enough to guarantee that an employee cannot be injured. Employee acceptance and employee training are required for the engineering control to be effective. The Compliance Officer should evaluate the training in accordance with paragraph **(g)(2)(vii)**. A citation for the appropriate paragraph of **(g)(2)(vii)** should be grouped with paragraph **(d)(2)(i)**, if the Compliance Officer determines that inadequate training caused the failure to use such controls. Examples of effective engineering controls can be found in several resources linked on OSHA's Needlestick Injuries page, < <http://www.osha-slc.gov/SLTC/needlestick/index.html> >.

Citations for paragraph (d)(2)(i) should be issued when these criteria are met:

If a combination of engineering and work practice controls used by the employer does not eliminate or minimize exposure, the employer shall be cited for failing to use engineering and work practice controls.

When the compliance officer finds that an employer is using an engineering control, but believes another device would be clearly more effective than the one in use, the compliance officer should document how the device was being used and how it was selected by the employer and/or employee. The compliance officer should consult with the Regional Bloodborne Pathogens Coordinator to determine if a violation of (d)(2)(i) exists.

The citation should describe that the employer failed to use engineering controls or work practices that would “eliminate or minimize exposures.” [e.g., failed to identify opportunities for change based upon their evaluation of circumstances surrounding exposure incidents (f)(3)(i); failed to evaluate feasible alternatives; failed to incorporate the changes based on an annual review of the exposure control plan]

Paragraph **(d)(2)(i)** should not be cited where another provision of the standard mandates a specific engineering or work practice control (e.g., paragraph **(d)(4)(iii)(A)** for sharps containers and paragraph **(d)(2)(vii)** for the prohibition of recapping).

3. **Paragraph (d)(2)(ii).** This paragraph requires that engineering controls be examined and maintained or replaced on a regular schedule to ensure their effectiveness. Regularly scheduled inspections are required to confirm, for instance, that engineering controls such as safer devices continue to function effectively, that protective shields have not been removed or broken, and that physical, mechanical or replacement-dependent controls are functioning as intended.

CITATION GUIDELINES. It is the employer's responsibility to regularly examine and repair and/or replace engineering controls as often as necessary to ensure that each control is maintained and that it provides the protection intended. If the Compliance Officer finds that there is no system for regular checking of the engineering controls or that regular checking is not done, paragraph **(d)(2)(ii)** should be cited.

4. **Paragraphs (d)(2)(iii) through (d)(2)(vi).** These paragraphs require employers to provide handwashing facilities which are readily accessible to employees. Handwashing with soap and at least tepid running water must be performed as soon as feasible, particularly in cases of gross contamination, to adequately flush contaminated material from the skin.
 - a. **Paragraph (d)(2)(iv).** This paragraph allows the use of alternative handwashing methods as an interim measure when soap and water are not a feasible means of washing the hands or other parts of the body. In such cases, the employer must provide either antiseptic hand cleaner and clean cloth/paper towels, or antiseptic towelettes.

When these types of alternatives are used, employees must wash their hands (or other affected area) with soap and running water as soon as feasible thereafter.

The Compliance Officer may see these types of alternative washing methods used by ambulance-based paramedics and emergency medical technicians (EMT's), fire fighters, police, and mobile blood collection personnel who are exposed to blood or OPIM but have no means of washing up with running water at the site of the exposure (e.g., a crime scene, traffic accident, fire).

- b. **Paragraph (d)(2)(v).** This paragraph requires employers to ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other PPE. There is no requirement for handwashing upon leaving the work area unless contact with blood or OPIM has occurred or gloves/PPE have been removed.

CITATION GUIDELINES. If the compliance officer finds that required handwashing facilities are not being provided, paragraph **(d)(2)(iii)** should be cited unless the employer demonstrates that handwashing facilities are not feasible. If infeasibility is demonstrated, paragraph **(d)(2)(iv)** should be cited when the required alternatives are not used. If handwashing is not performed by the employees after exposures or removal of gloves, paragraphs **(d)(2)(iv), (v), or (vi)** should be cited. A citation for one or more of these paragraphs may be grouped with the pertinent training paragraphs of **(g)(2)** if employees have not been adequately trained in handwashing procedures.

At a fixed establishment, if employees need to perform handwashing, they must have a location for washing available at a reasonable distance from their normal work area.

If an employee must thread his/her way through doorways and/or stairs to wash with appropriate frequency so that there is a reasonable chance of resultant environmental surface contamination, a violation of paragraph **(d)(2)(iii)** exists.

- 5. **Paragraph (d)(2)(vii).** Shearing or breaking of contaminated sharps is completely prohibited by this paragraph. Bending, recapping, or removing contaminated needles is prohibited as a general practice. Needles are

expected to be used and immediately discarded, un-recapped, into accessible sharps containers. Certain circumstances may exist, however, in which recapping, bending, or removing needles is necessary (e.g., administering incremental doses of a medication such as an anesthetic to the same patient).

- a. In these procedures, if the employer can demonstrate that such action is required by a specific medical procedure, recapping must be performed by some method other than the traditional two-handed procedure, e.g., by means of a mechanical device or forceps.
 - b. Similarly, if the employer can demonstrate that no alternative, such as immediately discarding used needles into an accessible and appropriate sharps container, is feasible, recapping is also allowed.
 - c. The use of the properly performed one-hand scoop method (in which the hand holding the sharp is used to scoop up the cap from a flat surface) for recapping is a recognized and acceptable method; however, the scoop method must be performed in a safe manner and must also be limited to situations in which recapping is necessary.
 - d. An acceptable means of demonstrating that no alternative to bending, recapping, or removing contaminated needles is feasible or that such action is required by a specific medical procedure would be a written justification (supported by reliable evidence) included as part of the exposure control plan. This justification must state the basis for the employer's determination that no alternative is feasible or must specify that a particular medical procedure requires, for example, the bending of the needle and the use of forceps to accomplish this.
6. **Paragraph (d)(2)(viii).** Since reusable sharps, such as large bore needles, scalpels, and saws, pose the same percutaneous exposure hazard as disposable sharps, they must be contained in a manner that eliminates or minimizes the hazard until they are reprocessed. Therefore, the containers for reusable sharps must meet the same requirements as containers for disposable sharps, with the exception that they are not required to be

closable since it is anticipated that containers used for collecting and holding reusable sharps will, themselves, be reused.

7. **Paragraphs (d)(2)(ix) and (x).** These paragraphs are intended primarily to eliminate or minimize indirect transmission of bloodborne pathogens from contaminated environmental surfaces.

Hand cream is not considered a "cosmetic" and is permitted. It should be noted that some petroleum-based hand creams can adversely affect glove integrity, and the hand washing requirements of paragraph (d)(2)(v) and (d)(2)(vi) must be followed.

NOTE: The term "work area" means the area where work involving exposure or potential exposure to blood or OPIM exists, along with the potential contamination of surfaces. Employees are permitted to eat and drink in an ambulance cab, for example, as long as the employer has implemented procedures to permit employees to wash up and change contaminated clothing prior to entering the ambulance cab, and to ensure that patients and contaminated material remain behind the separating partition.

INSPECTION GUIDELINES. In addition to direct contamination of food or drink by blood or OPIM, the Compliance Officer must keep in mind that containers of food and beverage may also become contaminated, resulting in unsuspected contamination of the hands. The purpose of this paragraph is to prevent food and drink from being contaminated by the leakage/spilling of specimen containers, contact with contaminated items, or the performance of activities (e.g., laboratory analysis) that could generate splashes, sprays, or droplets of blood or OPIM, for example.

CITATION GUIDELINES. Deficiencies of paragraphs (d)(2)(iv) through (x) should be cited in conjunction with the appropriate paragraph of (g)(2) if inadequate training exists.

8. **Paragraph (d)(2)(xi).** The intent of this paragraph is not only to decrease the chances of direct employee exposure through spraying or splashing of infectious materials onto employees, but also to reduce contamination of surfaces in the general work area.

Surgical power tools, lasers, and electrocautery devices may generate aerosols as well as be a source for splashing and spattering. Some of these devices include labeling recommendations such as local exhaust ventilation. The employer is responsible for appropriate operation of these devices, including controls recommended by the manufacturer.

Typically, reasonably anticipated spattering or generation of droplets would necessitate use of eye protection and mask or a face shield to prevent contamination of the mucous membranes of the eyes, nose, and mouth.

CITATION GUIDELINES. The use of sprays, brushes, and high pressure in equipment lines is particularly hazardous. A citation should normally be issued for paragraph **(d)(2)(xi)** if cleaning procedures cause unnecessary splashing, spraying, spattering, or generation of droplets of blood or OPIM.

9. **Paragraph (d)(2)(xii).** While this paragraph prohibits mouth pipetting/suctioning, the agency allows a recognized emergency care method of clearing an infant's airways called "DeLee suctioning" in the following situation: in an emergency; when no other method is available, and a trap which prevents suctioned fluid from reaching the employee's mouth is inserted in-line between the infant and the employee.
10. **Paragraphs (d)(2)(xiii)-(d)(2)(xiii)(C).** These paragraphs deal with the containerization and labeling of specimens with the intent to eliminate or minimize the possibility of inadvertent employee contact with blood or OPIM which have leaked out of the container, contaminated exterior surfaces of the container, and/or surrounding surfaces. The labeling requirement warns employees that these substances are present so that proper handling precautions can be taken.

The labeling exemption listed in paragraph **(d)(2)(xiii)(A)** applies to facilities which handle **all** specimens (not just those specimens which contain blood or OPIM) with universal precautions. This exemption applies only while these specimens remain within the facility. All employees who will have contact with the specimens must be trained to handle all specimens with universal precautions. If the specimens leave the facility (e.g., during transport, shipment, or disposal) a label or red color-coding is required.

Extracted teeth which are being discarded or used as specimens are subject to the containerization and labeling provisions of the standard. However, OSHA does not issue citations to dentists and doctors for non-employee exposures. Extracted teeth, gall stones and kidney stones may be given to the patients. In these situations, the teeth and stones are not subject to the containerization and labeling provisions of the standard.

The use of **pneumatic tube** systems for transport of small materials in hospitals now includes transmittal of laboratory specimens and other more fragile items. The primary concern in the transportation of clinical specimens in a pneumatic tube system is leakage of the specimen into the carrier and potentially into the system tubing. Some systems have virtually eliminated breakage as a cause of leakage by means of padded inserts for carriers and soft delivery of the carrier. Leakage generally results from improper packaging and/or the use of primary containers that do not prevent leakage during transport.

All employees who might potentially open a carrier must be trained to regard the contents as biohazardous in nature. Employees who open biohazard carriers must wear gloves in accordance with paragraph **(d)(3)** when removing specimens from the tube system carrier, because it may be contaminated with leakage. They must be trained in decontamination of the carrier and, if need be, the tube system in accordance with paragraph **(g)(2)**.

All precautions and standards for manual transport of specimens also apply to the automated transport of specimens (e.g., containerization and tagging/labeling).

INSPECTION GUIDELINES. The Compliance Officer must observe or document work practices to determine whether a secondary container is being used when necessary. If a bloody glove contaminates the outside of a primary container while the employee is placing a specimen, the employee would need to use a secondary container. Also, primary containers which may be punctured by their contents, including such items as pointed bone slivers, must be placed in a puncture-resistant secondary container.

11. **Paragraph (d)(2)(xiv).** When it is not possible to decontaminate equipment prior to servicing or shipping (e.g., highly technical or sensitive equipment and/or limited access to contaminated parts), at least partial

decontamination, such as flushing lines and wiping the exterior, must be accomplished.

INSPECTION AND CITATION GUIDELINES. The Compliance Officer should ensure that the employer's program makes provision for the required equipment labels. A label must be attached to equipment stating which portions of the equipment remain contaminated in order to inform downstream servicing/repair employees of the hazard and precautions they need to take.

Before citing paragraph **(d)(2)(xiv)**, the Compliance Officer should document that equipment is being shipped and/or serviced. Compliance Officers should observe or document work practices used when employees are decontaminating equipment. When decontaminating reusable equipment that is heavily soiled, the employee will have to perform some prewashing before proceeding with decontamination because most disinfectants/sterilants cannot sufficiently penetrate the organic material that may remain on such heavily soiled equipment.

12. **Personal Protective Equipment - Paragraph (d)(3).** When there is occupational exposure, PPE must be provided at no cost to the employee to prevent blood or OPIM from passing through to, or contacting, the employees' work or street clothes, undergarments, skin, eyes, mouth, or other mucous membranes.
13. **Paragraph (d)(3)(i).** The type and amount of PPE must be chosen to protect against contact with blood or OPIM based upon the type of exposure and quantity of these substances reasonably anticipated to be encountered during the performance of a task or procedure.

INSPECTION AND CITATION GUIDELINES. The financial responsibility for purchasing and providing PPE rests with the employer. The employer is not obligated under this standard to provide general work clothes to employees, but is responsible for providing PPE. If laboratory coats or uniforms are intended to protect the employee's body from contamination, they are to be provided by the employer at no cost to the employee.

Laboratory coats, uniforms and the like that are used as PPE must be laundered by the employer and not sent home with the employee for cleaning.

Scrubs are usually worn in a manner similar to street clothing, and normally should be covered by appropriate gowns, aprons or laboratory coats when splashes to skin or clothes are reasonably anticipated.

If a pullover scrub (as opposed to scrubs with snap closures) becomes minimally contaminated, employees should be trained in accordance with paragraph **(g)(2)(vii)(G)** to remove the pullover scrub in such a way as to avoid contact with the outer surface, e.g., rolling up the garment as it is pulled toward the head for removal.

However, if the amount of blood exposure is such that the blood penetrates the scrub and contaminates the inner surface, not only is it impossible to remove the scrub without exposure to blood, but the penetration itself would constitute skin exposure. Even though wearing scrubs for protection against exposures of this magnitude is inappropriate, it may also be prudent to train employees on the proper methods to remove grossly contaminated scrubs and prevent exposure to the face.

A gown which is frequently ripped or falls apart under normal use would not be considered "appropriate PPE."

Resuscitator devices are to be readily available and accessible to employees who can reasonably be expected to perform resuscitation procedures. Emergency ventilation devices also fall under the scope of PPE and hence must be provided by the employer for use in resuscitation (e.g., masks, mouthpieces, resuscitation bags, shields/overlay barriers). Improper use of these devices should be cited as a violation of paragraph **(d)(3)(ii)**. In addition, paragraph **(g)(2)(vii)(G)**, which requires employees to be trained in the types, proper use, location, etc., of the PPE should be cited if inadequate training exists. Improper use includes failure to follow the manufacturer's instructions and/or accepted medical practice.

NOTE: The American Society for Testing and Materials (ASTM) has several complete testing and evaluation methods which can be used for assessing the resistance of materials used for PPE for medical use. (ASTM-F1819-98, ASTM-F-1671-97b, and ASTM-F1670-97)

14. **Paragraph (d)(3)(ii).** This paragraph requires the use of PPE. It also provides for a limited exemption from the use of PPE, based on situations in which use of PPE would prevent the proper delivery of healthcare or public safety services, or would pose an increased hazard to the personal safety of the worker or coworker. The following represent examples of when such a situation could occur:

- a. A sudden change in patient status occurs such as when an apparently stable patient unexpectedly begins to hemorrhage profusely, putting the patient's life in immediate jeopardy;
- b. A fire fighter rescues an individual who is not breathing from a burning building and discovers that his/her resuscitation equipment is lost/damaged and he/she must administer CPR;
- c. A bleeding suspect unexpectedly attacks a police officer with a knife, threatening the safety of the officer and/or coworkers.

NOTE: An employee's decision not to use PPE is to be made on a case-by-case basis and must have been prompted by legitimate and truly extenuating circumstances. In such cases, no citation should be issued when the employee temporarily and briefly abandons use of PPE. This does not relieve the employer of the responsibility to ensure that PPE is readily accessible at all times. The employer must investigate and document why PPE was not used in each case and evaluate the circumstances surrounding the incident to reduce the likelihood of a future (unprotected) incident.

CITATION GUIDELINES. Paragraph **(d)(3)(ii)** should be cited if PPE is not being used properly. Improper use would include wearing the wrong PPE (e.g., wearing a laboratory coat when a rubber apron is needed) or wearing the wrong size glove.

In addition, paragraph **(g)(2)(vii)(G)** should also be cited if the employees have not been adequately trained.

Unless all elements of the exemption, including the documentation requirement, are met, the employer should not receive the benefit of this exemption and paragraph **(d)(3) (ii)** should be cited.

15. **Paragraph (d)(3)(iii).** This paragraph requires that the employer provide PPE in appropriate sizes and accessible locations. In addition, “hypoallergenic” gloves (see Note below), glove liners, powderless gloves, or other similar alternatives must be readily available and accessible at no cost to those employees who are allergic to the gloves normally provided. Similar alternatives must supply appropriate barrier protection and must be approved by the FDA for use as a medical glove. The compliance officer should review the employer’s program and, through employee interviews and inspection of places where PPE is kept, ensure that these provisions have been met.

NOTE: In accordance with a notice published in the Federal Register, Volume 62, No. 189, effective September 30, 1998, the FDA now requires labeling statements for medical devices which contain natural rubber and prohibits the use of the word “hypoallergenic” to describe such products. Additional information on the incidence of hypersensitivity reactions to natural rubber latex can be found in the following documents: NIOSH Alert, Preventing Allergic Reactions to Natural Rubber Latex in the Workplace (Publication No. 97-135) published in June 1997; Directorate of Technical Support, Technical Information Bulletin: Potential for Allergy to Natural Rubber Latex Gloves and other Natural Rubber Products,
< <http://www.osha-slc.gov/html/hotfoias/tib/TIB19990412.html> >.

CITATION GUIDELINES. If PPE is not provided at no cost to the employee, the Compliance Officer should cite paragraph **(d)(3)(i)**. If PPE is not being used properly or the wrong PPE is used (e.g., wearing a laboratory coat when a rubber apron is needed) or wearing the wrong size PPE, paragraph **(d)(3)(ii)** should be cited. If PPE is not available in appropriate sizes or readily accessible, the Compliance Officer should cite paragraph **(d)(3)(iii)**. For example, the clothing of paramedics out on an emergency call may become blood soaked. If they are unable to change before the next emergency call because a second set of clothing is located at the ambulance's home base, and the ambulance does not return to base for prolonged periods, a violation of paragraph **(d)(3)(iii)** would exist.

If it is common practice that PPE is not utilized during certain situations or procedures where exposure to blood or OPIM is anticipated, then a violation of paragraph **(d)(3)(ii)** would exist. If inaccessibility of PPE exists, paragraph **(d)(3)(iii)** should also be cited.

16. **Paragraph (d)(3)(iv).** It is the employer's responsibility not only to provide PPE, but to clean, maintain, and/or dispose of it. Home laundering is not permitted since the employer cannot guarantee that proper handling or laundering procedures are being followed.

While many employees have traditionally provided and laundered their own uniforms or laboratory coats or the like, if the item's intended function is to act as PPE, then it is the employer's responsibility to provide, clean, repair, replace, and/or dispose of it.

Home laundering by employees is not permitted since the standard requires that the laundering be performed by the employer at no cost to the employee. Home laundering is unacceptable because the employer cannot ensure that proper handling or laundering procedures are being followed and because contamination could migrate to the homes of employees.

If the employee wishes to choose, wear, and maintain his/her own uniform or laboratory coat, then he/she would need to don additional employer-handled and employer-controlled PPE when performing tasks where it is reasonable to anticipate exposure to blood or OPIM.

CITATION GUIDELINES. If PPE is not cleaned, laundered, and disposed of by the employer, or if the employer cleans the PPE but there is a charge to the employee, then paragraph **(d)(3)(iv)** should be cited. If PPE is not repaired and/or replaced by the employer at no cost to the employee, then paragraph **(d)(3)(v)** should be cited.

If a garment is not removed as soon as possible when penetrated by blood or OPIM, the Compliance Officer should cite paragraph **(d)(3)(vi)**.

If the PPE is not changed, and additional PPE was available, paragraph **(g)(2)(vii)(G)** may also be cited if employees have not been adequately trained.

17. **Paragraph (d)(3)(vii).** To minimize migration of contamination beyond the work area, employees must wash up and change any contaminated clothing before leaving a work area. Then, for example, they may enter designated lunchrooms or break rooms.

INSPECTION AND CITATION GUIDELINES. While "work areas" must be determined on a case-by-case basis, a work area is generally considered to be an area where work involving occupational exposure occurs or where the contamination of surfaces may occur. The standard would not require employees to change PPE when traveling, for example, from one hospital laboratory area to another, provided the connecting hallway is also considered to be a work area. The Compliance Officer should evaluate on a case-by-case basis whether the employee received adequate training in accordance with paragraph **(g)(2)(vii)(F)** to ensure that no surface contamination occurs during the employee's movement. A violation would exist for the following:

An employee wearing contaminated gloves exits from a pathology laboratory to use a public telephone located in a public hallway of the hospital. Under such circumstances, it can be reasonably anticipated that another employee, without benefit of gloves or knowledge of the potential surface contamination, could use the phone and unwittingly become contaminated.

18. **Paragraph (d)(3)(ix)(A)-(C).** These paragraphs discuss the use of gloves. Gloves of appropriate sizes must be made available in accordance with paragraph **(d)(3)(iii)**. Studies have shown that gloves provide a barrier, but that neither vinyl nor latex procedure gloves are completely impermeable. Thus, hand washing after glove removal is required. Disposable gloves must be replaced as soon as practical or as soon as feasible when contaminated.

While disposable gloves must be replaced as soon as practical when contaminated, obviously some critical procedures (i.e., surgery, delivery) cannot be interrupted to change gloves. The key words to evaluate are "practical" and "feasible."

Disinfecting agents may cause deterioration of the glove material; washing with surfactants could result in "wicking" or enhanced penetration of liquids into the glove via undetected pores, thereby transporting blood or other potentially infectious materials into contact with the hand. For this reason, disposable (single use) gloves may not be washed and reused.

The Compliance Officer should note that certain solutions, such as iodine, may cause discoloration of gloves without affecting their integrity and function.

At a minimum, gloves must be used where there is reasonable anticipation of employee hand contact with blood, OPIM, mucous membranes, or non-intact skin; when performing vascular access procedures; or when handling or touching contaminated surfaces or items.

Gloves are usually not necessary when administering intramuscular or subcutaneous injections as long as bleeding that could result in hand contact with blood or OPIM is not anticipated.

Plastic film food handling gloves ("cafeteria" or "baggie" gloves) are not considered to be appropriate for use in exposure-related tasks. They would not fit the employee as required by paragraph **(d)(3)(iii)** of the standard.

19. **Paragraph (d)(3)(ix)(D).** The exemption regarding the use of gloves during phlebotomy procedures applies only to employees of volunteer donor blood collection centers, and does not apply to phlebotomy conducted in other settings such as plasmapheresis centers or hospitals.

INSPECTION GUIDELINES. Where an employer in a volunteer donor blood collection center does not require routine gloving for all phlebotomies, the Compliance Officer should document that the employer has fulfilled the requirements of paragraphs **(d)(3)(ix)(D)(1)** through **(d)(3)(ix)(D)(4)(iii)**, and that employees have received the training necessary to make an informed decision on the wearing of gloves.

CITATION GUIDELINES. Paragraph **(d)(3)(ix)(D)** should not be cited. Rather, the other paragraphs of **(d)(3)** should be cited if such an employer violates them and if the employer has not demonstrated fulfillment of all the requirements of the exemptions.

20. **Paragraph (d)(3)(x).** This paragraph requires protection for the mucous membranes of the face and upper respiratory tract from exposure. Depending on the degree and type of anticipated exposure, protection for

the face would consist of a surgical mask in conjunction with goggles or eye glasses with solid side shields or, alternatively, a chin length face shield.

The employer would not necessarily have to provide prescription eyewear for employees. He/she could provide and mandate the use of side shields, goggles, and/or protective face shields, and provide proper training in decontamination procedures.

During microsurgery, when it is not reasonably anticipated that there would be any splattering, a surgeon would not be required to wear eye protection while observing surgery through the microscope.

21. **Paragraphs (d)(3)(xi)-(xii).** Requirements for the use of protective body clothing, such as gowns, aprons, laboratory coats, clinic jackets, surgical caps, or shoe covers, and the degree to which such PPE must resist penetration, are performance based. The employer must evaluate the task and the type of exposure expected and, based on the determination, select the "appropriate" personal protective clothing in accordance with paragraph **(d)(3)(i)**. For example, laboratory coats or gowns with long sleeves must be used for procedures in which exposure of the forearm to blood or OPIM is reasonably anticipated to occur.

INSPECTION GUIDELINES. The Compliance Officer will need to evaluate the task being performed and the degree of anticipated exposure by direct observation, employee interview, or review of written standard operating procedures.

22. **Housekeeping (d)(4).** The term "worksites" in this paragraph refers not only to permanent fixed facilities such as hospitals, dental/medical offices, clinics, etc., but also covers temporary non-fixed workplaces. Examples of such facilities include but are not limited to ambulances, bloodmobiles, temporary blood collection centers, and any other non-fixed worksites which have a reasonable possibility of becoming contaminated with blood or OPIM.

Paragraph (d)(4)(i). Cleaning schedules and methods will vary according to the factors outlined in this paragraph. While extraordinary attempts to disinfect or sterilize environmental surfaces such as walls or floors are rarely indicated, routine cleaning and removal of soil are required.

The employer must determine and implement an appropriate written schedule of cleaning and decontamination based upon the location within the facility (e.g., surgical operatory versus patient room), type of surface to be cleaned (e.g., hard-surfaced flooring versus carpeting), type of soil present (e.g., gross contamination versus minor splattering), and tasks and procedures being performed (e.g., laboratory analyses versus routine patient care).

The particular disinfectant used, as well as the frequency with which it is used, will depend upon the circumstances in which the housekeeping task occurs.

23. **Paragraph (d)(4)(ii).** Since environmental contamination is an effective method of disease transmission for HBV (the CDC states that HBV can survive for at least one week in dried blood on environmental surfaces or contaminated needles and instruments), paragraph (d)(4)(ii) provides the minimum requirements for the cleaning and decontamination of equipment and environmental and working surfaces that come into contact with blood or OPIM.

Under paragraph (d)(4)(ii)(A), cleaning of contaminated work surfaces after completion of procedures is required to ensure that employees are not unwittingly exposed to blood or OPIM remaining on a surface from previous procedures. This paragraph requires contaminated work surfaces to be cleaned with an **“appropriate disinfectant.”** Appropriate disinfectants include a diluted bleach solution and EPA-registered tuberculocides (List B), sterilants (List A), or products registered against HIV/HBV (List D). The lists of these EPA Registered Products are available from the National Antimicrobial Information Network at (800) 447-6349 or its web site at < <http://ace.orst.edu/info/nain/lists.htm> >. List D includes primarily quaternary ammonia products that EPA has approved as effective against HIV and HBV. OSHA allows the use of these products provided the surfaces have not become contaminated with agents or volumes of or concentrations of agents for which higher level disinfection is recommended.

NOTE: The lists contain the primary registrants' products only. The same formulation is repackaged and renamed and distributed by other companies. These renamed products will not appear on the list, but their EPA Registration number must appear on the label.

INSPECTION GUIDELINES. Compliance Officers should check the product label for EPA registration and/or consult the Environmental Protection Agency (EPA) lists of registered sterilants (representing the highest level of antimicrobial activity that destroys all viruses), tuberculocidal disinfectants (effective against tuberculosis bacteria and the specific viruses named on the product label as well as the hepatitis B virus), and antimicrobials with HIV/HBV efficacy claims for verification that the disinfectant used is appropriate. The employer must follow the label instructions regarding the amount of disinfectant and the length of time it must remain wet on the surface. Since the effectiveness of a disinfectant is governed by strict adherence to the instructions on the label, Compliance Officers should also interview employees to ensure that the disinfectants are being used according to the manufacturer's instructions. If employees have not been trained in the proper use of the disinfectant, a violation of the appropriate paragraph in **(g)(2)(vii)** should be cited.

NOTE: Fresh solutions of diluted household bleach made up daily (every 24 hours) are also considered appropriate for disinfection of environmental surfaces and for decontamination of sites following initial cleanup (i.e., wiping up) of spills of blood or other potentially infectious materials. Contact time for bleach is generally considered to be the time it takes the product to air dry. Solutions of bleach should not be stored in glass containers, but in material such as the plastic in which the bleach, the consumer product, is packaged in. Household bleach (5.25 sodium hypochlorite) diluted to the appropriate strength for the clean up job at hand is also an effective disinfectant, although bleach may cause damage to some medical instruments and therefore cannot be used in all cases. In addition, gross contamination must be cleaned up first with a soap and water solution, to ensure the disinfectant is completely effective.

Where procedures are performed on a continual basis throughout a shift or a day, as may be the case with a clinical laboratory technician performing blood analyses, it is not the agency's intent for the work surface to be decontaminated before the technician can proceed to the next analysis; rather the intention is for contaminated work surfaces to be decontaminated after the procedures are completed which, in the above example, would include a set of analyses. The completion of procedures might also occur when the employee is going to leave the work area for a period of time.

Decontamination is not automatically required after each patient care procedure, but is required only after procedures resulting in surface contamination.

There may be some instances in which "immediate" decontamination of overt contamination and spills may not be practical as in, for example, an operating table during surgery.

The work surface decontamination is to be performed at the end of the work shift **if** the work surface may have become contaminated since the last cleaning by, for example, setting down contaminated instruments or specimens on the work surface. This requirement is based upon the existence of a contaminated work surface rather than a particular worksite location. It does not, for example, encompass desks, countertops, and so forth that remain uncontaminated.

The use of protective coverings described in paragraph **(d)(4)(ii)(B)** is an acceptable alternative for protecting items and surfaces against contamination and is particularly useful in situations in which a piece of equipment would be difficult to decontaminate but could be protected by a cover.

If this option is chosen, the covering must be removed and replaced at the stated minimum intervals, i.e., as soon as feasible following overt contamination or at the end of a workshift if it may have become contaminated during the shift.

More stringent decontamination rules, such as cleaning equipment or changing coverings between patients, may be prudent infection control policy but do not fall under OSHA's mandate to safeguard employee (not patient) health.

24. Paragraph **(d)(4)(ii)(C)** requires both the inspection and decontamination, on a regularly scheduled basis, of cans, bins, pails, and so forth which are intended for reuse.

Since these containers may be used in a manner which presents the potential for their becoming contaminated with blood or OPIM, they must be cleaned immediately or as soon as feasible upon visible contamination. For example, a reusable metal trash can could have been lined with a

disposable plastic regulated waste bag which leaks and contaminates the can. In addition, regular decontamination will prevent the can from leaking, spilling, or contaminating the outside of successive bags. Disinfection of these containers is not necessary to ensure their safety for their intended use; it may be possible to achieve their proper decontamination by means of a soap and water wash.

Since contaminated broken glass (e.g., glass capillary tubes, lab specimen dishes, phlebotomy tubes) is capable of inflicting percutaneous injury and direct inoculation of bloodborne pathogens into the bloodstream, paragraph **(d)(4)(ii)(D)** stipulates that broken glassware which may be contaminated must not be picked up directly with the hands. The tools which are used in cleanup (e.g., forceps) must be properly decontaminated or discarded after use and the broken glass placed in a sharps container, and employees must be given specific information and training with respect to this task in accordance with the requirements of paragraph **(g)(2)**. Vacuum cleaners are not appropriate for cleanup of contaminated broken glass.

25. Paragraph **(d)(4)(ii)(E)** prohibits employers from allowing employees to place their hands into containers whose contents include reusable sharps contaminated with blood or OPIM. The intent is to prevent conditions of use in which the contents cannot be seen and safely handled. For example, employees must not reach into sinks filled with soapy water into which sharp instruments have been placed; appropriate controls in such a circumstance would include the use of strainer type baskets to hold the instruments and forceps to remove the items.

The final standard recognizes that proper decontamination of reusable equipment, such as glassware or hand instruments, cannot be achieved in the presence of organic debris (e.g., blood) because it interferes with the efficacy of the disinfecting/sterilizing process, and the number of products which can successfully penetrate a heavy bioburden is limited.

Violations of paragraphs **(d)(4)(ii)** and **(d)(4)(ii)(A)-(E)** may result from a failure to adequately train employees in proper housekeeping procedures. If the Compliance Officer determines this is the case, violations should be grouped with the appropriate paragraph(s) of paragraph **(g)(2)**.

26. **Regulated Waste (d)(4)(iii).** This paragraph requires regulated waste to be properly contained and disposed of, so as not to become a source of transmission of disease to employees.

To eliminate the implication that OSHA has determined the "infectivity" of certain medical wastes, the bloodborne pathogens standard uses the term "regulated waste" to refer to the following categories of waste which require special handling, at a minimum: liquid or semi-liquid blood or OPIM; items contaminated with blood or OPIM and which would release these substances in a liquid or semi-liquid state if compressed; items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; contaminated sharps; pathological and microbiological wastes containing blood or OPIM.

INSPECTION AND CITATION GUIDELINES. The compliance officer should not use the actual volume of blood to determine whether or not a particular material is to be considered regulated waste, since 10 ml of blood on a disposable bed sheet would appear as a spot (not regulated waste) while the same amount of blood on a cotton ball would likely cause saturation and dripping (regulated waste). Similarly, an item may adequately contain these materials when in a static state yet liberate them when compacted in the waste container. Instead, the compliance officer should the potential for the generation of bulk blood should be considered (e.g., through dripping or flaking off of material that may contain either blood or OPIM). Under no circumstances should a bag of waste be squeezed or shaken to determine this. The compliance officer should exercise professional judgment to make a determination based on visual factors such as a pool of liquid in the bottom of the container or dried blood flaking or falling off during handling, or based on employee interviews.

NOTES: The Compliance Officer should keep in mind that, while OSHA specifies certain features of the regulated waste containers, including appropriate tagging, the ultimate disposal method (landfilling, incinerating, and so forth) for medical waste falls under the purview of the EPA and possibly State and local regulations.

Lacking information to the contrary, the Compliance Officer should consider a used needle to be contaminated.

27. **Paragraph (d)(4)(iii)(A)(1).** The construction of the sharps containers must meet at least four criteria, two of which will be easily discernible. The Compliance Officer should examine a container, preferably empty, to check that it is closable and color-coded or labeled. Sharps containers are made from a variety of products, from cardboard to plastic. As long as they meet the criteria for a sharps container, the Compliance Officer should consider them to be acceptable no matter what the composition. If questions arise, the Compliance Officer should consult the manufacturer's literature or contact the manufacturer directly to determine if the container is leakproof on the sides and bottom, as well as puncture resistant. The NIOSH publication, "Selecting, Evaluating and Using Sharps Disposal Containers" is also a good resource.

If the container is considered puncture resistant by the manufacturer, but there is evidence, through observation or employee statements, that sharps have been protruding through a container, paragraph **(d)(4)(iii)(A)(1)(ii)** should be cited.

The sharps container should not create additional hazards. Some sharps containers have unwinders that are used to separate needles from reusable syringes or from reusable vacutainer holders. The design of the sharps container and the location of the unwinder must allow the needle removal to be accomplished in a safe, one-handed manner. If this situation is encountered, the Compliance Officer should determine if the circumstances warrant needle removal. If they do not, paragraph **(d)(2)(vii)(A)**, which prohibits needle removal unless no alternative is feasible or it is required by a specific medical procedure, should be cited. If needle removal must be accomplished, the employee must be trained in the correct procedure as required by paragraph **(g)(2)(vii)(F)**.

The needle sheath is **not** to be considered a "waste container" because it is viewed as a temporary measure. Self-sheathing needle products must be disposed of in a sharps container which conforms to the requirements of paragraph **(d)(4)(iii)(A)(1)**.

Duct tape may be used to secure a sharps container lid, but tape is not acceptable if it serves as the lid itself.

28. **Paragraph (d)(4)(iii)(A)(2)(i).** The Compliance Officer should ensure that the sharps container is as close as feasible to where sharps are used or can be reasonably anticipated to be found.

If an employee must travel to a remote location to discard a sharp, it will increase the possibility of an accidental needlestick and increase the chances that needles and sharps will be improperly discarded and create potential hazards for other staff members.

Areas such as correctional facilities, psychiatric units, pediatric units, or residential homes may have difficulty placing containers in the immediate use area. Alternatives include using containers which are lockable or which are designed to prevent removal of syringes while maintaining easy accessibility for discarding. Containers may also be locked onto a mobile cart if one is used by healthcare workers in these units, or they may be brought to the site and removed by the employee upon leaving.

The determination of whether or not the container is as close as feasible should be made on a case-by-case basis. After interviewing employees, if the Compliance Officer believes there is a better location for the container, management should be given the opportunity to explain the reasons for the present location of the container. The acceptability of the new site should also be discussed. The Compliance Officer should then decide if a violation of this paragraph exists.

Laundries must also have sharps containers easily accessible because of the high incidence of needles being mixed with laundry. Facilities that handle shipments of waste which may contain contaminated sharps must also have sharps containers available in the event a package accidentally opens and releases sharps.

29. **Paragraph (d)(4)(iii)(A)(2)(iii).** The Compliance Officer should ensure that sharps containers are being replaced routinely to prevent overfilling. The Record Summary states that overfilling of sharps containers is an often reported problem. Overfilling is often associated with containers that were too small to accommodate the volume of sharps, limited ability to see the contents in order to determine the remaining capacity, and lax procedures for container maintenance. Examples of methods by which sharps containers can be examined to determine a need for replacement, are the use of sharps containers which have a transparent window or are

placed at a height which allows employees to see if the container needs to be replaced. Overfilling of sharps containers should be cited under paragraph **(d)(4)(iii)(A)(2)(iii)**. A citation for inadequate training on work practices, paragraph **(g)(2)(vii)(F)**, should be grouped with the citation for this paragraph if the overfilled containers are present because of lack of training.

NOTE: The Exposure Prevention Information Network (EPINet) study Uniform Needlestick and Sharp Object Injury Report (77 Hospitals, 1993-1995) reports that 717 injuries occurred in this time period when an employee was putting an item into a disposal container. The Compliance Officer should closely inspect sharps disposal containers at the site to ensure containers are not overfilled. Additional information on sharps disposal containers is available in the NIOSH publication, "Selecting, Evaluating and Using Sharps Disposal Containers," January 1998, DHHS (NIOSH) Publication No. 97-111.

30. **Paragraphs (d)(4)(iii)(A)(3)(i) and (ii).** If work practice violations of these paragraphs exist (e.g., not closing the container prior to movement or not placing the container in a secondary container if leakage is possible), the citations should be grouped with paragraph **(g)(2)(vii)(F)** if employees have not received adequate training.
31. **Paragraph (d)(4)(iii)(A)(3)(ii)(B).** It is reasonable to presume that some sharps containers will contain residual liquids. If the container cannot be sealed to prevent leakage, it must be placed in a secondary container.
32. **Paragraph (d)(4)(iii)(A)(4).** A reusable sharps container system for disposable sharps will be acceptable if it does not expose employees to the risk of percutaneous injury. No system involving the manual opening, emptying, or cleaning of the containers will be allowed. The only acceptable system is a fully automated container cleaning system that eliminates employee exposure to sharps.
33. **Paragraph (d)(4)(iii)(B).** While this paragraph requires that regulated waste containers be closable, simply being closed does not ensure that waste will be contained. Waste-containing bags may break and spill their contents, including liquid blood, while, for example, being loaded onto incinerator hoppers, thus contaminating both the employees and the work area. Also, small medical offices which generate only a small volume of

regulated waste may place that waste in a large holding container until the container is filled. In such a case, the design of the container must be such that it is able to retain the waste over an extended period of time between pickups by a specialized waste service. The Compliance Officer should, therefore, check for visual signs of leakage of fluids during handling, storage, transport, or shipping.

Any failures to comply with the container construction requirements would be cited under this paragraph. If the compliance officer determines that the employee was not properly trained to recognize the problem or use the containers correctly, a citation for the appropriate paragraph of paragraph **(g)(2)** should be grouped with violations of paragraph **(d)**.

34. **Paragraphs (d)(4)(iii)(B)(1)(iii) and (2)(iii).** Regulated waste containers are required to be labeled with the biohazard symbol or color-coded to warn employees who may have contact with the containers of the potential hazard posed by their contents.

Even if a facility considers all of its waste to be regulated waste, the waste containers must still bear the required label or color-coding in order to protect new employees, employees who would not normally come into contact with wastes, and employees from outside the facility. This requirement is in contrast to the labeling alternative allowed when laundries use universal precautions for the handling of all soiled laundry.

Regulated waste that has been decontaminated need not be labeled or color-coded. The compliance officer in such a case should verify that the employer's exposure control plan states the decontamination procedures to be followed. In order to ensure that the decontamination process is successful, the employer must monitor factors such as the content, volume, density, configuration, and organic content of the load of waste. The temperature needed for incineration is sufficient to decontaminate regulated waste. Autoclave efficiency can be verified by means of biological or chemical indicators. While most disposal bags used will contain an indicative color strip, if this is not the case a review may be made of the documentation kept for the sterilizer. Such documentation should include (1) date, time, and operator of each run, (2) type and approximate amount of waste tracked, (3) post-treatment reading of temperature-sensitive tape, (4) dates and results of calibration of the

sterilizer, and (5) results of routine spore testing. Although these paragraphs contain label requirements, failure to label can also be cited under paragraph **(g)(1)(i)**.

35. **Paragraph (d)(4)(iii)(B)(2)**. A second container is required to be used when outside contamination of the first waste container occurs. This provision does not require routine double-bagging but rather requires double-bagging in such circumstances as a waste container being splashed with blood during surgery or autopsy, when a container has been handled by an employee with bloody gloves, or when a waste bag leaks blood or OPIM onto an adjacent bag.
36. **Laundry - Paragraph (d)(4)(iv)**. This paragraph reduces employee exposure to bloodborne pathogens by reducing the amount of manual handling of contaminated laundry. Restricting the sorting to the laundry area will also reduce contamination of additional surfaces.

INSPECTION AND CITATION GUIDELINES. Paragraphs

(d)(4)(iv)(A) and (A)(1) limit the handling of laundry to removal and bagging or containerization. The compliance officer should check the laundry collection program as well as the training of the employees assigned to these tasks.

37. **Paragraph (d)(4)(iv)(A)(2)**. The employer has been given the choice, by this paragraph, to either: label or color-code according to paragraph **(g)(1)(i)**, or to utilize universal precautions in the handling of all soiled (i.e., used) laundry.

If universal precautions are used for handling all soiled laundry, the employer may use an alternative color or label for the bags/containers, as long as all employees are trained to recognize them as containing soiled laundry which requires the use of universal precautions.

Training violations would be cited under the appropriate paragraph of **(g)(2)(vii)**.

38. **Paragraph (d)(4)(iv)(A)(3)**. The material for the bags or containers used in laundry collection must prevent soak-through or leakage of fluids to the exterior, if the contaminated laundry is wet and presents a reasonable

likelihood of soak-through or leakage. Not all contaminated laundry must be placed in such bags or containers; only laundry wet enough to leak or soak through and expose workers handling the bags/containers to blood or OPIM, or contaminate other surfaces should be considered contaminated laundry.

39. **Paragraph (d)(4)(iv)(B).** Employees having direct contact with contaminated laundry must wear protective gloves (e.g., utility gloves) and any other appropriate personal protective equipment, in order to prevent or reduce contact exposure to blood or OPIM. Any other personal protective equipment required must be determined on a case-by-case basis. Gowns, aprons, eyewear, and masks may be necessary to prevent employee exposure.
40. **Paragraph (d)(4)(iv)(C).** The employer generating the laundry must have determined if the facility to which it is shipped utilizes universal precautions in the handling of all laundry. If not, all bags or containers of contaminated laundry must be labeled or color-coded in accordance with paragraph (g)(1)(i). In this instance, if the employer generating the laundry chooses to color-code rather than label, the color of the bag must be red.

INSPECTION AND CITATION GUIDELINES. The compliance officer should check the employer's program to determine if laundry is shipped to another facility for cleaning and should evaluate the methods used to ship contaminated laundry (CL) to a facility that does not utilize universal precautions in the handling of all soiled laundry.

The following are unacceptable shipment methods and constitute violations of this paragraph:

The CL is not shipped labeled or in a red bag, paragraph (d)(4)(iv)(C) would be cited and grouped with the applicable subparagraph of paragraph (g)(1)(i);

The CL is shipped with an improper label, paragraph (d)(4)(iv)(C) would be cited and grouped with the applicable subparagraphs of paragraphs (g)(1)(i) (B), (C) and/or (D);

The CL is shipped in a bag color-coded for in-house use (in a color other than red), paragraph (d)(4)(iv)(C) would be cited and grouped with citations for paragraph (g)(1)(i)(E).

CDC has published "Guidelines for Laundry in Health Care Facilities" Current recommendations for the laundering of contaminated linen stipulate only that normal laundering methods be used according to the manufacturer's recommendations.

- E. HIV and HBV Research Laboratories and Production Facilities** 29 CFR 1910.1030(e). This paragraph includes additional requirements that must be met by research laboratories and production facilities engaged in the culture, production, concentration, and manipulation of HIV and HBV.

"Research laboratory" means a laboratory which produces or uses research laboratory scale amounts of HIV or HBV. Although research laboratories may not have the volume found in production facilities, they deal with solutions containing higher viral titers than those normally found in patients' blood. Academic research laboratories are included in this definition. Laboratories that conduct research on blood and other body fluids unrelated to HIV or HBV, or that use unconcentrated blood or blood components as the source of HIV or HBV, are not considered research laboratories for the purpose of this paragraph.

"Production facilities" are those engaged in industrial scale, large volume, or high concentration production of HIV or HBV.

NOTE: Employers in such facilities remain responsible for complying with the entire standard. Requirements stated elsewhere in the standard are not repeated here. These requirements are based largely on information from published guidelines of the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). (Resource: "Biosafety in Microbiological and Biomedical Laboratories.")

INSPECTION AND CITATION GUIDELINES. The compliance officer should review the covered facility's plan, interview a sufficient number of employees, and observe work practices as necessary to determine if the requirements of this paragraph are met. Care should be taken to ensure the compliance officer understands the special practices and precautions in place at the facility so that the compliance officer is not placed at risk. Specific requirements include:

1. **Paragraph (e)(2)(i).** The term "regulated waste" refers to the OSHA definition as found in paragraph (b) of this standard. The purpose of decontaminating regulated waste is to prevent the accidental exposure of other employees to the concentrated virus.
2. **Paragraphs (e)(2)(ii)(A) through (M).** Paragraphs (A), (C), and (D) require employers to limit access to the laboratory and warn of the hazards associated with bloodborne pathogens. The must review the written policies and procedures to determine if they are adequate to ensure that access to the work areas and animal rooms is limited to authorized persons. Interviews with employees should be used to determine if the policies are followed.
3. **Paragraph (e)(2)(ii)(E).** The "other physical containment device" must be sufficient to ensure that virus containing material will be kept away from the worker's mucous membranes, unprotected skin, and breathing zone.
4. **Paragraphs (e)(2)(ii)(H) and (I).** These paragraphs are designed to prevent the spread of contamination to other work areas. Paragraph (I) allows for an alternative to a HEPA filter as long as it is of equivalent or superior efficiency. HEPA filters may be ineffective in humid atmospheres.

The employer must also have made provisions for routine maintenance and/or replacement of all filters and traps.

If the compliance officer suspects that the engineering controls are failing to prevent the spread of the virus, the manufacturer should be contacted to establish the limits and required maintenance of the filters and traps.

5. **Paragraph (e)(2)(ii)(J).** The compliance officer should determine if the use of needles and syringes is kept to a minimum and that they are properly handled as required, paying particular attention to establishing if the puncture-resistant containers are properly autoclaved or decontaminated before being discarded, reused, or incinerated.
6. **Paragraph (e)(2)(ii)(M).** This paragraph ensures that any necessary additional procedures are developed to protect employees in situations unique to a research/production facility. The biosafety manual required by

this paragraph must be reviewed and updated annually or more often if necessary. The facility will thus be required to review its procedures and determine if they are adequate to protect workers.

7. **Paragraph (e)(2)(iii).** Specific containment equipment is required by this paragraph to minimize or eliminate exposure to the viruses.

If the compliance officer determines that biological safety cabinets (BSC) have been chosen as the means of containment, they must be certified (Class I, Class II, or Class III, as appropriate) when installed or moved, and at least annually.

The compliance officer should check that a dated tag is affixed to the BSC indicating who performed the certification. Alternatively, a certification report attesting to a minimum inward face velocity of at least 75 linear feet per minute and the integrity of the HEPA filters should be reviewed by the compliance officer. The report must be dated and signed by the trained technician performing the measurements and integrity tests.

In the alternative, appropriate combinations of PPE or physical containment devices (examples listed in the standard) will be accepted.

8. **Paragraphs (e)(3)(i) and (e)(4)(iii).** The hand washing facility must be supplied with at least tepid water, soap, and hand towels. The eyewash must supply a sufficient quantity of water to completely flush the eyes. A 15-minute supply of continuous free-flowing water is acceptable. The hands must be free to hold the eyelids open to aid in the complete flushing of the eyes. Portable facilities are acceptable only if they meet these requirements.
9. **Paragraph (e)(4)** covers additional requirements for production facilities only. The requirement in paragraph **(e)(4)(v)** minimizes the potential for accidental exposure of other employees from the transport of culture fluids, plastic ware, and other contaminated equipment.
10. **Training Requirements (e)(5).** The additional training requirements are specified in paragraph **(g)(2)(ix)**. Any violations found would be cited under that paragraph of the standard.

F. Hepatitis B Vaccination and Post Exposure Evaluation and Follow-up 29 CFR 1910.1030(f). This paragraph provides a means to protect employees from infection caused by the hepatitis B virus by requiring employers to make the hepatitis B vaccination available to employees with occupational exposure to blood or OPIM. It also ensures that employees receive appropriate medical follow-up after each specific exposure incident.

1. **General - Paragraph (f)(1).** This paragraph refers to the hepatitis B vaccination as both the hepatitis B vaccine and vaccination series. These are to be made available to all occupationally exposed employees. In addition, a post-exposure evaluation and follow-up procedures are to be made available to all employees who experience an exposure incident. While it is OSHA's intent to have the employer remove, as much as possible, obstacles to the employee's acceptance of the vaccine, the term "made available" emphasizes that the employee has the option to decline participation in the vaccination and follow-up programs.

INSPECTION GUIDELINES. The compliance officer should examine the employer's program to determine if the vaccination series and post-exposure follow-up procedures meet the requirements of paragraph **(f)(1)(ii)**.

2. **Paragraph (f)(1)(ii)(A).** The term "no cost to the employee" means, among other things, no "out of pocket" expense to the employee.

The employer may not permit the employee to use his/her healthcare insurance to pay for the series unless the employer pays all of the cost of the health insurance and unless there is no cost to the employee in the form of deductibles, copayments, or other expenses. Even partial employee contribution to the insurance premium means the employee could be affected by a rise in the total premium caused by insurance company reaction to widespread hepatitis B vaccinations and is therefore unacceptable. Likewise, any use of a spouse or other family member's insurance plan to provide vaccination would not be considered "at no cost" to the employee.

The employer may not institute a program in which the employee pays the original cost of the vaccine and is reimbursed by the employer if she/he remains employed for a specified period of time.

An "amortization contract" which requires employees to reimburse the employer for the cost of the vaccination should they leave his/her employ prior to a specified period of time is similarly prohibited. A waiver of liability with respect to acceptance of the vaccine is also prohibited.

3. **Paragraph (f)(1)(ii)(B).** The term "reasonable time and place" requires the medical procedures and evaluations to be convenient to the employee. They must normally be offered during employees' scheduled work hours. If participation requires travel away from the worksite, the employer must bear the cost.
4. **Paragraph (f)(1)(ii)(C).** The Compliance Officer can contact the National Council of State Boards of Nursing, Inc. at the Board of Nursing Contact Information web site at < <http://www.ncsbn.org> > to obtain the most current lists of addresses and phone numbers for each State Board of Nursing, to determine if the State Board of Nursing allows licensed healthcare professionals other than physicians to carry out the procedures and evaluations required by paragraph (f). The National Commission on Certification of Physicians' Assistants can clarify the role of physician assistants in these procedures. They can be reached at (770) 399-9971.
5. **Paragraph (f)(1)(ii)(D).** This paragraph takes into consideration the changing nature of medical treatment relating to Hepatitis B. The CDC is the U.S. Public Health Service (USPHS) agency responsible for issuing guidelines and making recommendations regarding infectious agents. OSHA requires use of the CDC guidelines current at the time of the evaluation or procedure. Copies of the current guidelines and other CDC documents can be obtained on CDC's web site, < <http://www.cdc.gov> >. The hepatitis B vaccination must be given in the standard dose and through the standard route of administration as recommended in the USPHS/CDC guidelines. The most current CDC guideline regarding Hepatitis B is "Immunization of Health-Care Workers: Recommendations of ACIP and HICPAC" in Vol. 46, No RR-18, published in the 12/26/1997 MMWR. (See Appendix C for the web site address) It recommends that employees who have ongoing contact with patients or blood and are at on going risk for injuries with sharp instruments or needlesticks be tested for antibody to Hepatitis B surface antigen, one to two months after the completion of the three-dose vaccination series.

Employees who do not respond to the primary vaccination series must be revaccinated with a second three-dose vaccine series and retested. Non-responders must be medically evaluated.

INSPECTION GUIDELINES: It is important that the compliance officer investigate thoroughly whether the employer knows of the contents of the CDC guidelines. Evidence may include an interview with the employer, employer's attendance at conferences or seminars where in service training about the CDC guidelines was provided, knowledge of interactive webpages associated with the CDC, actual copies of the MMWR, and/or employee interviews where knowledge of the MMWR has been made evident.

CITATION GUIDELINES: Paragraph **(f)(1)(ii)(D)** should be cited if the employer failed to provide vaccinations, evaluations, or follow-up procedures for **Hepatitis B** in accordance with the CDC recommendations that were current at the time these procedures took place. Any additional requirements (such as obtaining a written healthcare professional's opinion) specified in paragraph **(f)** must also be met.

6. **Paragraph (f)(1)(iii)** requires that all laboratory tests be conducted by an accredited laboratory. The Compliance Officer must determine by means of employer documentation (e.g., certificate) that the laboratory is accredited by a national accrediting body (e.g., American Association of Blood Labs, College of American Pathologists, Joint Commission on Accreditation of Healthcare Organizations, etc.) or equivalent State agency which participates in a recognized quality assurance program.

7. **Hepatitis B Vaccination - Paragraph (f)(2).** The Compliance Officer should determine whether or not all occupationally exposed employees have had the hepatitis B vaccination series made available to them after the training required by paragraph **(g)(2)(vii)(I)** and within 10 working days of their initial assignment. The term "made available" includes the healthcare professional's evaluation and arranging for the administration of the first dose of the hepatitis B vaccination series to begin within the 10 days. This includes all employees with occupational exposure, regardless of how often the exposure may occur. Part-time and temporary employees are included in this coverage. The vaccine does not have to be made available if the employer documents the exemption(s) set forth in

paragraph **(f)(2)**. It does not have to be administered if the employer can produce the signature of the employee on the mandatory declination form (See **Appendix A of 29 CFR 1910.1030.**)

8. **Paragraph (f)(2)(i)** states the circumstances under which an employer is exempted from making the vaccination available. If, (a) the complete hepatitis B vaccination series was previously received (three vaccines or in the case of a non-responder, six), or (b) antibody testing shows the employee to be immune, or (c) the vaccine cannot be given for medical reasons, the series does not have to be made available. If the employer claims one of these exemptions, it must be documented in the employee's medical record in accordance with paragraph **(h)(1)(ii)(B)**.

Current USPHS guidelines recommend post-vaccination screening for antibody to HBsAg (anti-HBs) for certain healthcare workers. See discussion of **(f)(1)(ii)(D)**. Periodic antibody tests thereafter are not currently recommended.

CITATION POLICY. Citations should not be issued when designated first aid providers who have occupational exposure are not offered the pre-exposure hepatitis B vaccine if the following conditions exist:

- a. The primary job assignment of such a designated first aid provider is not the rendering of first aid or other medical assistance, and
- b. Any first aid rendered by such person is rendered **only as a collateral duty**, responding solely to injuries resulting from workplace incidents, generally at the location where the incident occurred.

NOTE: This provision does **not** apply to designated first aid providers who render assistance on a regular basis, for example, at a first aid station, clinic, dispensary or other location where injured employees routinely go for assistance; nor does it apply to any healthcare, emergency, or public safety personnel who are expected to render first aid in the course of their work.

- c. The employer's exposure control plan must specifically address the provision of the hepatitis B vaccine to all unvaccinated first aid providers who render assistance in any situation involving the presence of blood or OPIM (regardless of whether an actual "exposure incident" as defined by

the standard occurred) and the provision of appropriate post-exposure evaluation, prophylaxis, and follow-up for those employees who experience an "exposure incident." The plan must include:

a. Provision for a reporting procedure that ensures that **all** first aid incidents involving the presence of blood or OPIM will be reported to the employer before the end of the work shift during which the incident occurred. The report must include the names of all first aid providers who rendered assistance, regardless of whether personal protective equipment was used and must describe the first aid incident, including time and date. The description must include a determination of whether or not, in addition to the presence of blood or other potentially infectious materials, an "exposure incident," as defined by the standard, occurred. This determination is necessary in order to ensure that the proper post-exposure evaluation, prophylaxis, and follow-up procedures required by paragraph **(f)(3)** of the standard are made available immediately, whenever there has been an "exposure incident" as defined by the standard.

b. A report that lists all such first aid incidents, that is readily available, upon request, to all employees and to the Assistant Secretary.

c. Provision for the bloodborne pathogens training program for designated first aiders to include the specifics of this reporting procedure.

d. Provision for the full hepatitis B vaccination series to be made available as soon as possible, but in no event later than 24 hours, to all unvaccinated first aid providers who have rendered assistance in any situation involving the presence of blood or OPIM, regardless of whether or not a specific "exposure incident," as defined by the standard, has occurred.

e. Unless all the requirements of this de minimis policy are met, paragraph **(f)(2)(i)** should be cited for failure to provide the hepatitis B vaccine.

NOTE: For industries not covered by 1910.1030 or 1915.1030, failure to provide appropriate evaluation of first aid incidents (including the determination of whether an exposure incident occurred) and adequate

follow-up of exposure incidents (including the provision of the hepatitis B vaccine series free of charge) should be considered for a possible 5(a)(1) citation.

9. **Paragraph (f)(2)(ii).** Pre vaccination screening for antibody status cannot be required of an employee, although if an employer wishes, he/she can make it available at no cost to employees. An employee may decline the prescreening, and the employer must still make the vaccination series available to the employee.
10. **Paragraph (f)(2)(iii).** The signing of the hepatitis B vaccine declination form by the employee, at the time the vaccination is made available, does not relieve the employer from the requirement to provide the vaccine at a later date if the employee so chooses.
11. **Paragraph (f)(2)(iv).** Although the declination form set forth in **29 CFR 1910.1030, Appendix A**, need not be reproduced verbatim, any modifications to that language shall be made for the sole purpose of improving employee comprehension.

The standard does not make reference to consent forms. Medical informed consent forms, when they are a part of the healthcare professional's standard medical practice, are acceptable. However, any waiver of liability violates paragraph **f(1)(ii)(A)**, which requires that the vaccine be provided at no cost. Consent forms which require the employee to release his or her test results to the employer violate the confidentiality requirements in paragraph **(f)(5)(iii)**. Consent forms which are used by the employer for training or documentation purposes would violate paragraph **(g)(2)(vii)(I)** if the hazards of the vaccine are clearly exaggerated.

12. **Paragraph (f)(2)(v).** At the time of this publication, the provision of routine boosters of the hepatitis B vaccine is still being assessed. There is no requirement to provide boosters unless the USPHS recommends it at a later date.
13. **Post-Exposure Evaluation and Follow-up paragraph (f)(3).** This paragraph requires the employer to make immediately available a confidential medical evaluation and follow-up to an employee reporting an exposure incident.

Bloodborne pathogens are defined by the standard (see the Definitions paragraph of this Directive), to include more than just HIV and HBV. The standard applies to any pathogenic microorganism present in human blood that can cause disease in humans. **Paragraph (f)(3)** is not specific to HIV and HBV. This paragraph requires that the employer provide post-exposure evaluation and follow-up to employees for bloodborne pathogens, such as **hepatitis C (HCV)**, as recommended by the CDC. The current CDC recommendation for HCV is found in Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease, October 16, 1998/Vol. 47/No. RR-19 < <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00055154.htm>. >.

In addition, the most current HIV post-exposure follow-up recommendations for an exposure incident made applicable by the bloodborne pathogens standard, at paragraph **(f)(3)(iv)** are found in the CDC Morbidity and Mortality Weekly Report: "Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis," May 15, 1998/Vol. 47/ No. RR-7. < <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00052722.htm> > (See Appendix C for the web site address)

NOTE: Employees who do not fall within the scope of this standard may still experience a specific exposure incident at work that is unrelated to the performance of their job duties. An example is "Good Samaritan" assistance, voluntarily performed, to an injured co-worker or a member of the public. In such a case, OSHA strongly encourages employers of these employees to offer them the follow-up procedures set forth in this paragraph.

INSPECTION GUIDELINES. The compliance officer should determine if the employer's plan ensures immediate and confidential post-exposure and follow-up procedures in accordance with the current CDC guidelines. As advised in paragraph **(f)(1)(ii)(D)**, the compliance officer should document the employer's awareness of CDC guidelines. At sites where an exposure incident has occurred it should be determined if the procedures were properly followed through interviews, incident report reviews, and, if necessary, medical records reviews.

CITATION GUIDELINES: The word "**immediately**" is used in the standard to emphasize the importance of prompt medical evaluation and prophylaxis. An exact time was not given in the standard because the time limit on the effectiveness of post-exposure prophylactic measures can vary depending on the infection of concern. OSHA requires the post-exposure evaluation and follow-up to be given as soon as possible after exposure. Where medical practice is an issue, and the compliance officer believes that access to care was delayed or denied or the employer was not following accepted post-exposure procedures, the Regional Bloodborne Pathogens Coordinator shall be contacted. A health care professional in the Directorate of Technical Support will be consulted if necessary. The employer must have established a system that maintains the confidentiality of the employee's identity and test results. If the employer has contracted with a clinic or other healthcare facility to provide the follow-up programs, the confidentiality requirements must be part of the contract.

The boundary between employer and healthcare professional may be blurred in a medical setting in which, for example, the physician is both the employer and the evaluating healthcare professional or where the employer's certified medical laboratory analyzes the serological samples. In such cases, the compliance officer should ensure that requirements for consent and confidentiality have been followed. The medical information is to be confined to the medical department and not to be discussed with or revealed to others (e.g., the personnel department, supervisors, or other healthcare professionals who do not need the information to comply with the standard).

The employer should be cited for violating paragraph **(f)(3)** provisions (except **(iv)**) for not providing a confidential medical evaluation and follow-up, e.g., testing. Failure to provide post-exposure prophylaxis should be cited under **(f)(3)(iv)**.

- 14. Paragraph (f)(3)(i).** Documentation of the circumstances surrounding an exposure incident will help the employer and the Compliance Officer determine, for example, if PPE is being used or if training is lacking. Percutaneous injuries are primarily associated with the following activities: disposing of needles; administering injections; drawing blood, including use of capillary tubes; recapping needles; and handling trash and dirty linens.

Following an exposure incident, such as a needlestick or other sharps injury, employers are required to document, at a minimum, “the route(s) of exposure, and the circumstances under which the exposure incident occurred,” as per **paragraph (f)(3)(i)**. The documentation of circumstances surrounding an incident by the employer allows identification and correction of hazards. To be useful, the documentation must contain sufficient detail about the incident. There should be information about the following: engineering controls in use at the time, work practices followed, a description of the device in use, protective equipment or clothing that was used at the time of the exposure incident, location, procedure being performed when the incident occurred, and the employee’s training. Additional information might also include a comparison of similar occurrences and recommendations to avoid future incidents, although this information is not mandatory. The Compliance Officer should request copies of the employer’s documentation on exposure incidents to determine if they are in compliance with **paragraphs (c)(1)(ii)(C)** and **(f)(3)(i)**.

INSPECTION AND CITATION GUIDELINES. The goal of the employer should be to implement a method or device that prevents exposure incidents from recurring. Evaluating the circumstances around an exposure incident as required by paragraph **(f)(3)(i)** provides the employer with data necessary to make effective decisions about engineering controls and work practices that will reduce the risk of exposure. The compliance officer should review the documentation of incidents available in the facility. The compliance officer should request the Exposure Control Plan and review the procedures for evaluating the circumstances surrounding exposure incidents.

15. **Paragraph (f)(3)(ii)**. This paragraph requires the employer to identify the source individual in an exposure incident, unless this is infeasible. The employer must document in writing the identity of, or infeasibility of identifying, the source individual. Examples of when it may not be feasible to identify the source individual include incidents of needlesticks caused by unmarked syringes left in laundry or those involving blood samples which are not properly labeled, as well as incidents occurring where State or local laws prohibit such identification.
16. **Paragraph (f)(3)(ii)(A)**. This paragraph requires testing of the source individual’s blood after consent is obtained. The employer must ask for consent from the source individual or anyone legally authorized to give

consent on his/her behalf. If legally-required consent is not obtained, the employer must establish this. This fact should be documented in writing, unless there is other clear evidence that consent could not be obtained. The compliance officer should ensure that the employer's plan includes this provision.

For those jurisdictions that do not require consent of the individual, available blood may be used for testing rather than redrawing a specimen. The term "if available" applies to blood samples that have already been drawn from the source individual. OSHA does not require redrawing of blood specifically for HBV and HIV testing without the consent of the source individual.

17. **Paragraph (f)(3)(ii)(C).** This paragraph does not authorize the employer to be informed of the results of source individual or exposed employee testing. However, the results of the source individual's testing must be made available to the exposed employee in accordance with applicable State and Federal laws and regulations concerning medical privacy and confidentiality.
18. **Paragraph (f)(3)(iii).** The Compliance Officer must determine if the employer's program offers covered employees all of the listed requirements in the event of an exposure incident. Counseling and evaluation of reported illnesses are not dependent on the employee's electing to have baseline HBV and HIV serological testing.
19. **Paragraph (f)(3)(iii)(A).** The consent of the employee must be obtained before the collection and testing of his or her blood.
20. **Paragraph (f)(3)(iii)(B).** This paragraph allows employees the opportunity for future testing without the need for an immediate decision. Employees involved in an exposure incident have at least 90 days following baseline blood collection to decide if they wish to have their blood tested for HIV.

To the employee, HIV testing may present adverse ramifications, e.g., confidentiality, employment, prejudice, or lack of medical information. Therefore, the 90-day time frame allows for the opportunity to obtain knowledge about baseline serologic testing after exposure incidents, and to participate in further discussion, education or counseling. This

opportunity will, instead of placing a demand on the employee to make an immediate decision, encourage employees to consent to blood collection at the time of exposure.

Employers are required to preserve the blood the employee consented to have drawn, if it was not tested for HIV initially, for at least the 90-day period. Compliance officers should check that if the employer contracts for post-exposure follow-up, the contractor has been informed of the 90- day requirement.

21. **Paragraph (f)(3)(iv).** Employers must follow the current guidelines at the time of exposure to determine if post-exposure prophylaxis is medically indicated. See **paragraph (f)(3)** above.

CITATION GUIDELINES: Failure to offer post-exposure HIV prophylaxis under the current CDC guidelines should be cited as a violation of paragraph **(f)(3)(iv)**. The guidelines leave decisions about prophylaxis up to the healthcare professional. However, in unusual circumstances involving gross misapplication of the CDC guidelines by the healthcare professional, the employer may be cited. In such cases consultation with the National office is appropriate.

22. **Information Provided to the Healthcare Professional - Paragraph (f)(4).** This paragraph requires the employer to provide information to the healthcare professional responsible for the employee's hepatitis B vaccination and post-exposure incident follow-up.

INSPECTION GUIDELINES. The Compliance officer must determine if the employer's plan includes providing a copy of this standard to the healthcare professional responsible for the employee's hepatitis B vaccination. In the case of an exposure incident, the plan must provide for the transmission of the information required by paragraphs **(f)(4)(ii)(A)-(C) and (E)** to the healthcare professional. The information required by paragraph **(f)(4)(ii)(D)** must be provided only if available. The employer does not have a specific right to know the actual results of the source individual's blood testing, but must ensure that the information is provided to the evaluating healthcare professional. If the evaluating healthcare professional is also the employer, the information must still be in the

employee's record and be made available at the time of a post-exposure incident. All applicable laws and standards of confidentiality apply in this situation.

23. **Healthcare Professional's Written Opinion - Paragraph (f)(5).** The employer is required to obtain a written opinion and provide it to the employee within 15 working days of completion of the original evaluation. Employer access to the healthcare professional's written opinion is specifically allowed.
24. **Paragraph (f)(5)(i)** limits the healthcare professional's written opinion to very specific information regarding the employee's hepatitis B vaccine status, including indication for vaccine and whether such vaccination was initiated (i.e., the first shot had been given.)
25. **Paragraph (f)(5)(ii)** requires documentation that a post-exposure evaluation was performed and that the exposed employee was informed of the results as well as any medical conditions resulting from exposure which require further evaluation and treatment.

G. Employee Information and Training - Paragraph(g). Paragraph (g) ensures that employees receive sufficient warning through labels, signs, and training to eliminate or minimize their exposure to bloodborne pathogens.

1. **Labels, paragraph (g)(1).** Labels must be provided on containers of regulated waste, on refrigerators and freezers that are used to store blood or OPIM, and on containers used to store, transport, or ship blood or OPIM. This requirement alerts employees to possible exposure since the nature of the material or contents will not always be readily identifiable as blood or OPIM.

NOTE: The labeling requirements do not preempt either the U.S. Postal Service labeling requirements (39 CFR Part III) or the Department of Transportation's Hazardous Materials Regulations (49 CFR Parts 171, 180).

DOT labeling is required on some transport containers (i.e., those containing "known infectious substances"). It is not required on all containers for which 29 CFR 1910.1030 requires the biohazard label. Where there is an overlap between the OSHA-mandated label and the

DOT-required label, the DOT label will be considered acceptable on the outside of the transport container, provided that the OSHA-mandated label appears on any internal containers which may be present. Containers serving as collection receptacles within a facility must bear the OSHA label since these are not covered by the DOT requirements.

INSPECTION AND CITATION GUIDELINES. The Compliance Officer should determine that the warning labels in the facility are used as required by paragraphs **(g)(1)(i)(A) through (D)** and include the term "BIOHAZARD."

2. **Paragraphs (g)(1)(i)(E) through (G).** These paragraphs list exemptions from the labeling requirements which are additional to those exemptions listed for specimens in paragraph **(d)(2)(xiii)(A)** and for laundry in paragraph **(d)(4)(iv)(A)(2)**.

Blood and blood products bearing an identifying label as specified by the Food and Drug Administration, which have been screened for HBV and HIV antibodies and released for transfusion or other clinical uses, are exempted from the labeling requirements.

When blood is being drawn or laboratory procedures are being performed on blood samples, then the individual containers housing the blood or OPIM do not have to be labeled, provided the larger container into which they are placed for storage, transport, shipment, or disposal (e.g., a test tube rack) is labeled.

3. **Paragraph (g)(1)(i)(I).** Regulated waste that has been decontaminated by incineration, autoclaving, or chemical means, prior to disposal is not required to bear the BIOHAZARD warning label. Failure to ensure adequate decontamination procedures prior to removal of the hazard label should be cited under paragraph **(g)(1)(i)(A)**, since the material would still be regulated waste.
4. **Information and Training - Paragraph (g)(2).** All employees with occupational exposure must receive initial and annual training on the hazards associated with blood and OPIM, and the protective measures to be taken to minimize the risk of occupational exposure. Retraining must take place when changes in procedures or tasks occur which affect

occupational exposure. While the provisions for employee training are performance oriented, with flexibility allowed to tailor the program to, for example, the employee's background and responsibilities, the categories of information listed in paragraph **(g)(2)(vii)** must be covered, at a minimum. These requirements include some site-specific information.

INSPECTION GUIDELINES. The Compliance Officer should verify that the training is provided at the time of initial employment and at least annually thereafter as well as whenever a change in an employee's responsibilities, procedures, or work situation is such that an employee's occupational exposure is affected. "At the time of initial assignment to tasks where occupational exposure may take place" means that employees must be trained prior to being placed in positions where occupational exposure may occur. The annual retraining for these employees must be provided within one year of their original training. This refresher training must cover topics listed in the standard to the extent needed and must emphasize new information or procedures. It does need to be an exact repetition of the previous annual training.

Part-time and temporary employees, and healthcare employees, known as "per diem" employees, are covered and are also to be trained on company time.

The Compliance Officer should interview a representative number of employees from different work areas to determine that the training (including written material, oral presentations, films, videos, computer programs, or audiotapes) was presented in a manner that was appropriate to the employee's education, literacy level, and language. If an employee is only proficient in a foreign language, the trainer or an interpreter must convey the information in that foreign language.

5. **Paragraphs (g)(2)(vii)(B) and (C).** These paragraphs require that HIV and HBV and other bloodborne diseases be described. The employer must convey the idea that a number of bloodborne diseases other than HIV and HBV exist, such as **hepatitis C (HCV)** and **syphilis**. At the same time, the employer need not cover such uncommon diseases as Creutzfeldt-Jakob disease unless it is appropriate, for example, for employees working in a research facility with that particular virus.

HCV is the most common chronic bloodborne infection in the United States. Persons who are chronically infected with HCV may not be aware of their infection because they may not be clinically ill. The infection may lead to chronic liver disease that develops slowly, often taking two or more decades before it is recognized. It is important that training include information on the transmission and symptoms of HCV.

6. **Paragraph (g)(2)(vii)(F).** This paragraph requires that training include an explanation of the use and limitations of methods that will prevent or reduce exposure, including appropriate engineering controls, work practices, and personal protective equipment.

This requirement is very important, because the development of safer engineering controls introduces a variety of new techniques and practices to the work environment. Manufacturers market passive safety features, active devices, integrated safety designs, and accessory safety devices. The Record Summary respondents “repeatedly” emphasized the necessity of effective training and education whenever new engineering controls are implemented. Training must include instruction in any new techniques and practices. “Hands-on” training is particularly useful. Employee participation in the selection of new devices, which plays a major part in their acceptance and correct use, is encouraged but not required. (See above discussion in paragraphs (c)(1)(iv) and (d)(2) on engineering and work practice controls.)

7. **Paragraph (g)(2)(vii)(J).** The word "emergency" in this paragraph refers to blood or OPIM exposure outside the normal scope of work. This does not refer to hospital emergency rooms or emergency medical technicians' work.
8. **Paragraph (g)(2)(vii)(N).** This paragraph requires that there be an opportunity for interactive questions and answers with the person conducting the training session. During training, it is critical that trainees have an opportunity to ask and receive answers to questions where material is unfamiliar to them. Frequently, a trainee may be unable to go further with the training or to understand related training content until a response is received.

Training the employees solely by means of a film or video without the opportunity for a discussion period would constitute a violation of this paragraph.

Similarly, a generic computer program, even an interactive one, is not considered appropriate unless the employer supplements such training with the site-specific information required (e.g., the location of the exposure control plan and the procedures to be followed if an exposure incident occurs) and a person is accessible for interaction.

Trainees must have direct access to a qualified trainer during training. OSHA's requirement can be met if trainees have direct access to a trainer by way of a telephone hot line. The use of an electronic mail system to answer employee questions is not considered direct access to a qualified trainer, unless the trainer is available to answer e-mailed questions at the time the questions arise.

9. **Paragraph (g)(2)(viii).** The person conducting the training is required to be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address. In addition to demonstrating expertise in the area of the occupational hazard of bloodborne pathogens, the trainer must be familiar with the manner in which the elements in the training program relate to the particular workplace.

The Compliance Officer should verify the competency of the trainer based on the completion of specialized courses, degree programs, or work experience, if he/she determines that deficiencies in training exist.

Possible trainers include a variety of healthcare professionals such as infection control practitioners, nurse practitioners, registered nurses, occupational health professionals, physician's assistants, and emergency medical technicians.

Non-healthcare professionals, such as but not limited to, industrial hygienists, epidemiologists, or professional trainers, may conduct the training provided they are knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace. One way, but not the only way, knowledge can be demonstrated is the fact that the person received specialized training.

In some workplaces, such as dental or physicians' offices, the individual employer may conduct the training, provided he or she is familiar with bloodborne pathogen exposure control and the subject matter required by paragraphs **(g)(2)(vii)(A) through (N)**.

10. **Paragraphs (g)(2)(ix)(A)-(C)**. "Standard microbiological practices" as used in these paragraphs refer to procedures outlined in "Biosafety in Microbiological and Biomedical Laboratories." The requirement that "proficiency" be demonstrated means that employees who are experienced laboratory workers may not need to be retrained in accordance with these paragraphs. Education such as a graduate degree in the study of viral diseases, or another closely related subject area with a period of related laboratory research experience, would also constitute "proficiency." The employer is responsible for evaluating the employee's proficiency and for documenting the mechanism used to determine proficiency.

H. Recordkeeping 29 CFR 1910.1030(h). Records are required to be kept for each employee covered by this standard for training, as well as for medical records.

1. Medical records required by paragraph **(h)(1)** will be of particular importance to the healthcare professional in determining vaccination status and recommendation for treatment in the event of an exposure incident. Although the employer is required to establish and maintain medical records, he/she may contract for the services of a healthcare professional located offsite and that person or company may retain the records.

The requirements of **29 CFR 1910.1020** apply. In particular, **29 CFR 1910.1020(d)(1)(i)(C)** provides that the medical records of employees who have worked for less than one (1) year need not be retained beyond the term of employment if they are provided to the employee upon termination of employment.

NOTE: While paragraph **(h)(1)(iii)** requires that medical records are to be kept confidential, paragraph **(h)(1)(iii)(B)** stipulates that disclosure is permitted when required by this standard or other Federal, State, or local law.

INSPECTION GUIDELINES. All medical records required to be kept by this standard are also required to be made available to OSHA. The Compliance Officer must protect the confidentiality of these records. If

they are copied for the case file, the provisions of **29 CFR 1913.10** must be followed.

The Compliance Officer should review the employer's recordkeeping program to ensure that the required information is collected, and provision has been made to ensure the confidentiality of the medical records in accordance with 29 CFR 1910.1020. While 29 CFR 1910.1020(a) makes allowances for its provisions being carried out on behalf of the employer, **paragraph 1910.1020(b)(3)** states that "each employer must ensure that the preservation and access requirements are complied with regardless of the manner in which the records are made or maintained." If the employer has contracted with a responsible third party to maintain the required records, the employer should only be cited for deficiencies of which she/he knew or could have known with the exercise of reasonable diligence.

2. **Paragraph (h)(2)** requires accurate recordkeeping of training sessions, including titles of the employees who attend. The records are necessary to assist the employer and OSHA in determining whether the training program adequately addresses the risks involved in each job. Additionally, this information is helpful in tracking the relationship between exposure incidents (e.g., needlesticks) and various jobs and the corresponding level of training.

Training records may be stored onsite where the actual documents will be easily accessible for review. In order to ensure that the employee training is complete, all the components of the program required by **paragraph (g)(2)(vii)** must be covered.

Training records are not considered to be confidential. Training records may be stored onsite where the actual documents are readily accessible. They must be retained for 3 years from the training date.

XIV. Interface With Other Standards.

- A. The hazard communication standard, **29 CFR 1910.1200**, applies only to the hazards of chemicals in the workplace and does not apply to biological hazards such as bloodborne diseases.

- B. Records concerning employee exposure to bloodborne pathogens and records about HIV and/or HBV status are both considered employee medical records within the meaning of **29 CFR 1910.1020**. Under **29 CFR 1913.10 (b)(4)** the Compliance Officer may review these records on site for verification of compliance with the medical surveillance requirements. If requested this review shall be conducted under the observation of the medical record holder (or other employer designated healthcare professional). The compliance officer should not record or take offsite any information from the medical record other than documentation of the fact of compliance or noncompliance. Generally, compliance/noncompliance verification requires no additional action (i.e., in-depth review, copying, and/or removal of confidential medical information from the worksite) on behalf of the compliance officer. If additional or more detailed information is required for clarification or to support a suspected violation, the compliance officer is advised to seek a medical access order (MAO) from the director (Medical Records Officer), Office of Occupational Medicine. Also, when a compliance officer anticipates (or if it is known) that there may be a problem in gaining access to confidential medical information/medical records or the employer denies access during the course of the inspection, the compliance officer is advised to obtain an administrative subpoena (from the regional solicitor) in addition to the MAO before looking at any confidential medical information or medical record.
- C. Generally, the respiratory protection standard, **29 CFR 1910.134**, does not apply. However, placing or storing respirators in areas where they could be contaminated by body fluids constitutes a violation of **29 CFR 1910 .134(h)(2)(i)** (or **29 CFR 1910 .139(b)(6)**, if the respirator is used for protection against tuberculosis.)
- D. The Hazardous Waste Operations and Emergency Response (HAZWOPER) standard, **29 CFR 1910.120**, covers four groups of employees: workers at uncontrolled hazardous waste remediation sites; workers at Resource Conservation and Recovery Act (RCRA) permitted hazardous waste treatment, storage and disposal facilities; workers performing corrective actions involving cleanup operations at RCRA sites; and those workers expected to respond to emergencies caused by the uncontrolled release of a hazardous substance.
1. The definition of hazardous substance includes any biological agent or infectious material which may cause disease or death. There are potential scenarios where the bloodborne and HAZWOPER standards may interface, such as: workers involved in cleanup operations at hazardous

waste sites involving infectious waste; workers at RCRA permitted incinerators that burn infectious waste; workers at RCRA permitted incinerators that burn infectious waste and that are involved in cleanup operations; and workers responding to an emergency caused by the uncontrolled release of infectious material, e.g., a transportation accident.

2. Employers of employees engaged in these types of activities must comply with the requirements in **29 CFR 1910.120** as well as the bloodborne pathogens standard. If there is a conflict or overlap, the provision that is more protective of employee safety and health applies.

This directive provides guidance for enforcement of the Bloodborne Pathogens Standard. The agency's application of this policy in any particular matter will, however, depend upon all relevant circumstances. For purposes of providing information and guidance, this directive also restates, clarifies, or explains the provisions of the standard. OSHA's restatement, clarification or explanation of the requirements of the standard does not amend the standard or create new legal duties, obligations or defenses.

APPENDIX A

TYPICAL COMMITTEES IN HEALTH CARE FACILITIES

The Compliance Safety and Health Officer (CSHO) may find that a health care facility has a variety of committees involved in assuring compliance with the bloodborne pathogens standard. Although committees are rarely mandated by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Health Care Financing Administration (HCFA), there are certain committees which are typically found in health care facilities. Although the minutes or reports from these committees may be “protected” (not available to the general public), discussions about the committees’ functions may be useful in evaluating the facility’s processes. Committee functions may vary and there is no prescribed form for their structure. However, listed below are some general functions and the committees which might be involved in those processes:

ASSURING IMPLEMENTATION OF THE EXPOSURE CONTROL PLAN:

Safety Committee/ Employee Health Committee

Typically composed of representatives from the occupational health unit, safety manager, human resources, and employees from the various departments. The duties of this committee usually include:

- Developing and reviewing policies and procedures for safe and healthy work conditions for employees.
- Developing and evaluating all safety and health programs, including implementation of the Exposure Control Plan for Bloodborne Pathogens.
- Establishing and implementing procedures for workplace safety inspections.
- Establishing procedures for investigating and recording all workplace accidents, illnesses, and fatalities.
- Assuring implementation of OSHA standards, including resource allocation.
- Making recommendations in response to exposure incidents.
- Reviewing screening and surveillance data.

Infection Control Committee

Typically composed of employee and management representatives from various departments, including the infection control practitioner and facility epidemiologist. The duties of this committee usually include:

- Analyzing and identifying infections among patients/residents.
- Developing and evaluating infection control plans to protect the patients/residents, including the use of universal precautions.
- Establishing policies and procedures regarding infection control, focusing on risks to patients/residents and the general public (e.g., visitors, volunteers, etc.).

HAZARD IDENTIFICATION (Including worksite inspections and tracking trends)

Safety Committee (see description above)

Facilities Maintenance /Hazardous Waste Committee

Typically composed of the facilities engineer and representatives from various departments. The duties of this committee usually include:

- Developing and reviewing policies and procedures related to environmental, facility, and hazardous waste issues.
- Coordinating with the Safety and Quality Assurance committees for investigation and recording all workplace accidents, illnesses, and fatalities which relate to environmental and hazardous waste issues
- Assuring compliance with applicable OSHA standards.
- Performing building inspections.

Quality Assurance/Utilization Review/Risk Management Committee

Typically composed of a Board of Directors representative, chief executive officer, director of quality care/assurance/utilization review/risk management, and representatives from various departments. The duties of this committee usually include:

- Ensuring the presence of overall acceptable standards of quality care for patients/residents.
- Complying with laws and regulations related to patient safety, specifically JCAHO and HCFA.
- Evaluating the utilization of health care services by patients/residents.

SELECTION, EVALUATION & RECOMMENDATIONS FOR PPE AND NEW DEVICES

Products Management Committee

Typically composed of the safety director, the purchasing agent and representatives from various departments. The duties of this committee typically include:

- Monitoring equipment currently in use.
- Evaluating new products being considered or already ordered.
- Providing information about equipment and products to involved employees.

Quality Care/Assurance/Utilization Review/Risk Management Committee (see description above)

Safety Committee (See description above)

EDUCATION/TRAINING/ORIENTATION

Education Committee

Typically composed of a Board of Directors representative and representatives from various departments. The duties of this committee usually include:

- Assuring delivery of education programs for both professional and non-professional employees within the health care facility and the community, such as training with new equipment.
- Ensuring that educational presentations meet professional standards.
- Evaluating new employee orientation and on-going continuing educational programs.

Products Management Committee (see description above)

RECORDKEEPING

Safety Committee (see description above)

Quality Assurance/Utilization Review/Risk Management Committee (see description above)

Infection Control Committee (see description above)

ASSURE COMPLIANCE BY PHYSICIAN STAFF

Medical Executive Committee

Typically composed of elected officers of the medical staff, the immediate past president of the medical staff, the chairpersons of the various medical departments, and physicians on the Board of Directors.

The president of the hospital, vice president of medical affairs, director of nursing services and director of quality care/assurance/utilization review/risk management serve as nonvoting members.

The duties of this committee usually include:

- Accounting to the Board of Directors for patient/resident care.
- Acting on reports and recommendations offered by other committees.
- Coordinating the activities of the medical staff.
- Making recommendations on medical issues.
- Recommending appointment, reappointment, and corrective action of medical staff.

OTHER COMMITTEES WHICH THE CSHO MAY ENCOUNTER

Budget/Finance and Audit Committee

Typically composed of representatives from the Board of Directors, chief executive officer, chief financial officer, and various departmental directors. The duties of this committee usually include:

- Monitoring the financial status of the health care facility.
- Advising the Board of Directors concerning financial policies.
- Reporting to the Board of Directors on the effectiveness of resource allocations.

Ethics Committee

Typically composed of facility staff such as nurses, physicians, attorneys, hospital administrators, social workers and clergy. May also include community members. The duties of this committee usually include:

- Clarifying complex ethical issues that affect the care and treatment of patients/residents in the health care facility.

Information Systems Committee

Typically composed of the director of information systems and representatives from the various departments. The duties of this committee usually include:

- Evaluating and recommending clinical computer systems.
- Providing training on clinical computer systems.
- Responding to requests for assistance with computer applications.

Pharmacy and Therapeutics Committee

Typically composed of the director of pharmacy, a nursing representative, the infection control practitioner, a dietician, and a physician. The duties of this committee usually include:

- Developing policies and procedures concerning drugs used in the facility.
- Establishing standards concerning the use of investigational drugs.
- Recommending drugs to be made available at the facility (“formulary”), including vaccines.

APPENDIX B

ENGINEERING CONTROL EVALUATION FORMS

The following pages contain sample forms that may be used in evaluating safer engineering controls. These forms are only applicable to certain groups of devices. Safer engineering controls are not limited to the devices contained in the following pages. None of these forms are specifically required by the bloodborne pathogens standard, but they may be useful as guidance documents. Employers are responsible for setting the evaluation criteria for the devices used in their facilities in accordance with the standard.

Sample Forms:

NIOSH

Questionnaire for Evaluating Sharps Disposal Container Performance

ECRI©

ECRI's Needlestick-Prevention Device Evaluation Form

NPD Cost Calculation Worksheet

Training for Development of Innovative Control Technologies Project (TDICT)© SAFETY FEATURE EVALUATION FORMS

SAFETY SYRINGES

I.V. ACCESS DEVICES

SHARPS DISPOSAL CONTAINERS

I.V. CONNECTORS

VACUUM TUBE BLOOD COLLECTION SYSTEMS

E. R. SHARPS DISPOSAL CONTAINERS

SAFETY DENTAL SYRINGES

HOME USE SHARPS DISPOSAL CONTAINER

QUESTIONNAIRE FOR EVALUATING SHARPS DISPOSAL CONTAINER PERFORMANCE

INSTRUCTIONS: Product evaluators should inspect and operate containers to be evaluated in side-by-side comparisons. Representative sharps (syringes, IV sets, blades, biopsy needles, pipettes, etc.) should be used to test candidate products. Actual use conditions should be simulated, if possible. Prior to inserting test sharps, attempt to reopen sealed containers and attempt to spill or remove contents from unsealed containers if this is a functional requirement. Evaluation facilitators should provide product manufacturer literature and visual instructions and should demonstrate proper operation of each of the containers. Use of this guideline requires knowledge that the ideal product may not exist and that this evaluation tool was based on common product designs available at the time.

PLEASE CIRCLE YOUR RESPONSE

FUNCTIONALITY

agree disagree

Container is stable when placed on horizontal surface and when used as described in the product labeling for use in trays, holders, or enclosures	1	2	3	4	5
Container provides for puncture, leak, and impact resistance	1	2	3	4	5
Container, labels, warning devices, and brackets are durable	1	2	3	4	5
Container is autoclavable, if necessary	1	2	3	4	5
Container is available in various sizes and capacities	1	2	3	4	5
Container is available with auxiliary safety features (e.g., restricted access to sharps in the container), if required	1	2	3	4	5
Closure mechanism will not allow needlestick injury	1	2	3	4	5
Closure mechanism provides secure seal	1	2	3	4	5
Design minimizes needle-tip flipback	1	2	3	4	5
Design promotes clinical performance (e.g., will not compromise sterile field or increase injury or infection control hazards)	1	2	3	4	5
Design resists easy reopening after sealing for final disposal or autoclaving	1	2	3	4	5
Inlet design defeats waste removal when open	1	2	3	4	5
Inlet design prevents spillage of contents (physical or liquid) while sharps disposal container is in use in the intended upright position	1	2	3	4	5
Containers designed to be reopenable have removable lids design with tight closure that facilitates ease of removal with grip safety and comfort	1	2	3	4	5
Mounting brackets are rugged and designed for ease of service and decontamination	1	2	3	4	5

ACCESSIBILITY

agree disagree

Container available in various opening sizes and shapes	1	2	3	4	5
Containers are supplied in sufficient quantity	1	2	3	4	5
Container has an entanglement-free opening/access way	1	2	3	4	5
Container opening/access way and current fill status visible to user prior to placing sharps into container	1	2	3	4	5
Internal design/molding of container does not impede ease of use	1	2	3	4	5
Handles, if present, located above full-fill level	1	2	3	4	5
Handles, if present, facilitate safe vertical transport and are located away from opening/access way and potentially soiled surfaces	1	2	3	4	5
Fixed locations place container within arm's reach of point of waste generation	1	2	3	4	5
Fixed locations allow for installation of the container below horizontal vision level	1	2	3	4	5
If necessary, in high patient or visitor traffic areas, container should provide for security against tampering	1	2	3	4	5

VISIBILITY

	agree	disagree			
Color or warning label implies danger.	1	2	3	4	5
A warning indicator (i.e., color or warning label) is readily visible to the user prior to user placing sharps into container	1	2	3	4	5
Overfill level provided and current fill status is readily visible to the user prior to use placing sharps into container	1	2	3	4	5
Sharps disposal container complies with OSHA requirements	1	2	3	4	5
Disposal opening/access way is visible prior to user placing sharps into container	1	2	3	4	5
Security, mounting, aesthetic, and safety features do not distort visibility of the opening/access way or fill status indicator	1	2	3	4	5

ACCOMMODATION

	agree	disagree			
No sharp edges in construction or materials	1	2	3	4	5
Safety features do not impede free access	1	2	3	4	5
Promotes patient and user satisfaction (i.e., aesthetic to extent possible)	1	2	3	4	5
Is simple to operate	1	2	3	4	5
Any emissions from final disposal comply with pollution regulations	1	2	3	4	5
Easy to assemble, if required	1	2	3	4	5
Components of containers that require assembly are easy to store prior to use	1	2	3	4	5
Use allows onehanded disposal	1	2	3	4	5
Product available in special designs for environments with specific needs (e.g., laboratories, emergency rooms, emergency medical services, pediatrics, correctional facilities)	1	2	3	4	5
Mounting system durable, secure, safe, cleanable, and, where appropriate, lockable	1	2	3	4	5
Mounting systems allow height adjustments	1	2	3	4	5
Design promotes task confidence	1	2	3	4	5
Cost effectiveness	1	2	3	4	5

OTHER COMMENTS

What design or performance requirements are missing from the product you evaluated that are really needed to safely or more comfortably conduct your job or sharps related task?

Additional Evaluator Concerns and Comments:

This product selection questionnaire was developed by the Centers for Disease Control and Prevention’s National Institute for Occupational Safety and Health in conjunction with NIOSH Educational Resource Centers; The Johns Hopkins University, Baltimore; the University of Texas, Houston; the University of California, Berkeley; and the Mount Sinai School of Medicine, New York City.

ECRI's Needlestick-Prevention Device Evaluation Form

Device: _____

Supplies/Trade Name _____

Applications: _____

Reviewer: _____ Date: _____

For each question circle the appropriate response for the needlestick-prevention (NPD) device being evaluated.

Healthcare Worker Safety

1. A. Does the NPD prevent needlesticks during use (i.e., before disposal)? Yes No
 B. Does it do so after use(i.e., does the safety mechanism remain activated through disposal of the NPD)? Yes No
2. A. Does NPD provide protection one of the following ways: Either intrinsically or automatically? (Answer "No" if a specific action by the user is required to activate the safety mechanism.) Yes No
 B. If "No," is the mechanism activated in one of the following ways: either by one-handed technique or by a two-handed technique accomplished as part of the usual procedure? Yes No
3. During the use of NPD do user's hands remain behind the needle until activation of the safety mechanism is complete? Yes No
4. Is the safety mechanism reliable when activated properly? Yes No
5. Does the NPD minimize the risk of user exposure to the patient's blood? Yes No

Patient Safety and Comfort

6. Does the NPD minimize the risk of infection to the patient (e.g., through cross-contamination)? Yes No
7. Can the NPD be used without causing more patient discomfort than a conventional device? Yes No
8. *For IV NPDs* : Does the NPD attach comfortably (i.e., without causing patient discomfort at the catheter port or IV tubing? Yes No

Ease of use and Training

9. Is NPD Operation obvious? That is can the device be used properly without extensive training? Yes No
10. Can the NPD be used by a left-handed person as easily as by a right handed person? Yes No
11. Is the technique required for using the NPD the same as that for using a conventional device? Yes No
12. Is it easy to identify the type and size of the product from the packaging? Yes No
13. *For intravenous (IV) catheters and blood collection needle sets*: Does the NPD provide a visible blood flashback during initial insertion? Yes No
14. Please rate the ease of using this NPD Exc. Good Fair Poor
15. Please rate the quality of the in-service training Exc. Good Fair Poor

Compatibility

16. Is the NPD compatible with devices (e.g., blood collection tubes) from a variety of suppliers? Yes No
17. *For IV NPDs*:
 A. Is the NPD compatible with intralipid solutions? Yes No
 B. Does the NPD attach securely at the catheter port? Yes No
 C. Doe the NPD attach securely or lock at a Y-site (e.g. for piggybacking)? Yes No
18. Is the NPD easy to dispose of in sharps containers of all sizes (if required)? Yes No
19. Does using the NPD instead of a conventional device result in only a modest (if any) increase in sharps container waste volume? (Answer "No" if the NPD will increase waste volume significantly.) Yes No

Overall

20. Would you recommend using this device? Yes No

Comments (e.g., describe problems, list incompatibilities)

NPD Cost Calculation Worksheet*

WORKSHEET	SAMPLE DATA
PROTECTIVE SYSTEM	Protective blood collection tube holder
NPD (supplier/trade name)	XYZ Medical Pro Hold
A. Price per device	A= \$4.00
B. Uses per year	B= 130,000
C. Uses per device	C= 300
D. Quantity used per year (B ÷ C)	D= 433
E. NPD cost per year (A × D)	E= \$ 1,732
Additional component	XYZ Medical ProHold Companion 1 Qt Sharps Container
F. Price per device	F= \$3.50
G. Uses per year	G= Dispose of 130,000 needles
H. Uses per device	H= NA (see next entry)
I. Quantity used per year (G ÷ H)	I= 32**
J. Additional component cost per year (F × I)	J= \$112
K. Annual protective system cost (E ÷ J)	K= \$1,844
CONVENTIONAL SYSTEM	Blood collection tube holder
Conventional device	XYZ Medical Tube Holder
L. Price per device	L= \$0.15
M. Uses per year	M= 130,000
N. Uses per device	N= 300
O. Quantity used per year (M ÷ N)	O= 433
P. Conventional device cost per year (L × O)	P= \$65
Additional component	Conventional 1qt sharps container
Q. Price per device	Q= \$2.13
R. Uses per year	R= Dispose of 130,000 needles
S. Uses per device	S= NA (see next entry)
T. Quantity used per year (R ÷ S)	T= 32**
U. Additional component cost per year (Q × T)	U= \$68.16
V. Annual conventional system cost (P + U)	V= \$133.16
RELATED DISPOSAL COSTS	
Additional sharps containers	
W. Disposal volume of each NPD	W= 14 cm ³ (tube holder only)
X. Disposal volume of each conventional device	X= 12 cm ³ (tube holder only)
Y. Sharps container volume	Y= 1 qt (-943cm ³)
Z. Number of additional sharps containers per year ((W × X) ÷ Y)	Z= 1 (assumes 100% packing efficiency)
AA. Price per sharps container	AA= \$3.50
AB. Annual additional sharps containers cost (Z × AA)	AB= \$3.50
AC. Other additional disposal costs	AC= None
AD. Total annual increase in disposal costs (AB + AC)	AD= \$3.50
NSI COST	
AE. Number of NSIs per year with conventional device	AE= 6
AF. Projected NSIs per year with NPD (50% × AE)	AF= 3
AG. Cost of each NSI	AG= \$540
AH. Annual NSI cost savings (AG × [AE - AF])	AH= \$1,620
AI. MISCELLANEOUS COSTS	AI= None
AJ. NET PROTECTIVE SYSTEM COSTS (K+AD+AI -AH)	AJ= \$227.50
AK. ANNUAL INCREASE IN EXPENDITURES (AJ - V)	Annual increase in expenditures: \$94.34

*The figures obtained by completing this worksheet should be used for comparison purposes only. These figures will not reflect the actual costs and cost savings- associated with implementing the alternative under consideration, and they cannot reflect the true value of using an NPD in terms of staff safety and the economic impact on NSIs that result in seroconversion.

**Calculated by multiplying the estimated volume of one needle (0.23 cm³) by the number of needles per year (130,000) and then dividing by the volume of one sharps container (1 qt = 943 cm³). Note that this analysis assume 100% packing efficiency.



GUIDELINES FOR THE USE OF SAFETY FEATURE EVALUATION SHEETS

Coordinators:

Determine which products are to be evaluated and provide at least four or more test samples for each individual evaluating the product. (Each evaluator should have enough samples to disassemble and examine the design thoroughly.)

Set up a testing station for each type of device which allows testers to evaluate products in a simulated patient procedure. Provide training dummies (injection pads, oranges, etc.) as necessary.

Provide visual instructions and demonstrate proper use of each device.

Review the instructions and rating system with each evaluator.

Encourage each evaluator to comment on the sheets and prioritize the questions at the end of the evaluation. This will provide a useful decision making tool and will help alert you to specific areas of concern which may not have been covered by the questionnaire.

Evaluators:

Re-enact all steps of intended or possible procedures performed with the device being tested.

Attempt to misuse the device and circumvent or disable the safety feature.

Answer each question, including the short answer section at the end. If you do not understand a question, please write comments directly on the sheets.

NOTE: Certain assumptions have been made in the development of these forms based on information about currently available products. We recognize the likelihood that the ideal product may not exist. TDICT welcomes your comments on the use of these tools.

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June Fisher, M.D.

© June 1993, revised August 1998

Trauma Foundation, Bldg #1, Room #300

San Francisco General Hospital

1001 Potrero Avenue

San Francisco, CA 94110

SAFETY FEATURE EVALUATION FORM

SAFETY SYRINGES



Date: _____ Department: _____ Occupation: _____
 Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agree.....disagree

DURING USE:

1. The safety feature can be activated using a one-handed technique 1 2 3 4 5 N/A
2. The safety feature **does not** obstruct vision of the tip of the sharp 1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature 1 2 3 4 5 N/A
4. This product does not require more time to use than a non-safety device 1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes 1 2 3 4 5 N/A
6. The device is easy to handle while wearing gloves 1 2 3 4 5 N/A
7. This device **does not** interfere with uses that do not require a needle 1 2 3 4 5 N/A
8. This device offers a good view of any aspirated fluid 1 2 3 4 5 N/A
9. This device will work with all required syringe and needle sizes 1 2 3 4 5 N/A
10. This device provides a better alternative to traditional recapping 1 2 3 4 5 N/A

AFTER USE:

11. There is a clear and unmistakable change (audible or visible) that occurs
 when the safety feature is activated 1 2 3 4 5 N/A
12. The safety feature operates reliably 1 2 3 4 5 N/A
13. The exposed sharp is permanently blunted or covered after use and prior to disposal 1 2 3 4 5 N/A
14. This device is no more difficult to process after use than non-safety devices 1 2 3 4 5 N/A

TRAINING:

15. The user **does not** need extensive training for correct operation 1 2 3 4 5 N/A
16. The design of the device suggests proper use 1 2 3 4 5 N/A
17. It is **not** easy to skip a crucial step in proper use of the device 1 2 3 4 5 N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

SAFETY FEATURE EVALUATION FORM

I.V. ACCESS DEVICES



Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agree.....disagree

1. The safety feature can be activated using a one-handed technique 1 2 3 4 5 N/A
2. The safety feature **does not** interfere with normal use of this product 1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature 1 2 3 4 5 N/A
4. This product **does not** require more time to use than a non-safety device 1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes 1 2 3 4 5 N/A
6. The device allows for rapid visualization of flashback in the catheter or chamber 1 2 3 4 5 N/A
7. Use of this product **does not** increase the number of sticks to the patient 1 2 3 4 5 N/A
8. The product stops the flow of blood after the needle is removed from the catheter
(or after the butterfly is inserted) and just prior to line connections or hep-lock
capping 1 2 3 4 5 N/A
9. A clear and unmistakable change (either audible or visible) occurs when the
safety feature is activated 1 2 3 4 5 N/A
10. The safety feature operates reliably 1 2 3 4 5 N/A
11. The exposed sharp is blunted or covered after use and prior to disposal 1 2 3 4 5 N/A
12. The product **does not** need extensive training to be operated correctly 1 2 3 4 5 N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?



SAFETY FEATURE EVALUATION FORM

SHARPS DISPOSAL CONTAINERS

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

- | | agree.....disagree |
|---|--------------------|
| 1. The container's shape, its markings, or its color, imply danger | 1 2 3 4 5 N/A |
| 2. The implied warning of danger can be seen from the angle at which people commonly view it (very short people, people in wheel chairs, children, etc) | 1 2 3 4 5 N/A |
| 3. The implied warning can be universally understood by visitors, children, and patients | 1 2 3 4 5 N/A |
| 4. The container's purpose is self-explanatory and easily understood by a worker who may be pressed for time or unfamiliar with the hospital setting | 1 2 3 4 5 N/A |
| 5. The container can accept sharps from any direction desired | 1 2 3 4 5 N/A |
| 6. The container can accept all sizes and shapes of sharps | 1 2 3 4 5 N/A |
| 7. The container allows single handed operation. (Only the hand holding the sharp should be near the container opening) | 1 2 3 4 5 N/A |
| 8. It is difficult to reach in and remove a sharp | 1 2 3 4 5 N/A |
| 9. Sharps can go into the container without getting caught on the opening | 1 2 3 4 5 N/A |
| 10. Sharps can go into the container without getting caught on any molded shapes in the interior | 1 2 3 4 5 N/A |
| 11. The container is puncture resistant | 1 2 3 4 5 N/A |
| 12. When the container is dropped or turned upside down (even before it is permanently closed) sharps stay inside | 1 2 3 4 5 N/A |
| 13. The user can determine easily, from various viewing angles, when the container is full | 1 2 3 4 5 N/A |
| 14. When the container is to be used free-standing (no mounting bracket), it is stable and unlikely to tip over | 1 2 3 4 5 N/A |
| 15. It is safe to close the container. (Sharps should not protrude into the path of hands attempting to close the container) | 1 2 3 4 5 N/A |
| 16. The container closes securely. (e.g. if the closure requires glue, it may not work if the surfaces are soiled or wet.) | 1 2 3 4 5 N/A |
| 17. The product has handles which allow you to safely transport a full container | 1 2 3 4 5 N/A |
| 18. The product does not require extensive training to operate correctly | 1 2 3 4 5 N/A |

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

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SAFETY FEATURE EVALUATION FORM

I.V. CONNECTORS



Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agree.....disagree

1. Use of this connector eliminates the need for exposed needles in connections 1 2 3 4 5 N/A
2. The safety feature **does not** interfere with normal use of this product 1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature 1 2 3 4 5 N/A
4. This product **does not** require more time to use than a non-safety device 1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes 1 2 3 4 5 N/A
6. The safety feature allows you to collect blood directly into a vacuum tube,
 eliminating the need for needles 1 2 3 4 5 N/A
7. The connector can be secured (locked) to Y-sites, hep-locks, and central lines 1 2 3 4 5 N/A
8. A clear and unmistakable change (either audible or visible) occurs when the
 safety feature is activated 1 2 3 4 5 N/A
9. The safety feature operates reliably 1 2 3 4 5 N/A
10. The exposed sharp is blunted or covered after use and prior to disposal 1 2 3 4 5 N/A
11. The product **does not** need extensive training to be operated correctly 1 2 3 4 5 N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

SAFETY FEATURE EVALUATION FORM

VACUUM TUBE BLOOD COLLECTION SYSTEMS



Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agree.....disagree

1. The safety feature can be activated using a one-handed technique 1 2 3 4 5 N/A
2. The safety feature **does not** interfere with normal use of this product 1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature 1 2 3 4 5 N/A
4. This product **does not** require more time to use than a non-safety device 1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes 1 2 3 4 5 N/A
6. The safety feature works with a butterfly 1 2 3 4 5 N/A
7. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated 1 2 3 4 5 N/A
8. The safety feature operates reliably 1 2 3 4 5 N/A
9. The exposed sharp is blunted or covered after use and prior to disposal 1 2 3 4 5 N/A
10. The inner vacuum tube needle (rubber sleeved needle) **does not** present a danger of exposure 1 2 3 4 5 N/A
11. The **product does** not need extensive training to be operated correctly 1 2 3 4 5 N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

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SAFETY FEATURE EVALUATION FORM

E. R. SHARPS DISPOSAL CONTAINERS



Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

- | | agree.....disagree |
|--|--------------------|
| 1. The container's shape, its markings, or its color, imply danger which can be understood by visitors, children, and patients | 1 2 3 4 5 N/A |
| 2. The implied warning of danger can be seen from the angle at which people commonly view it. (very short people, people in wheel chairs, children, etc) | 1 2 3 4 5 N/A |
| 3. The container can be placed in a location that is easily accessible during emergency procedures | 1 2 3 4 5 N/A |
| 4. The container's purpose is self-explanatory and easily understood by a worker who may be pressed for time or unfamiliar with the hospital setting | 1 2 3 4 5 N/A |
| 5. The container can accept sharps from any direction desired | 1 2 3 4 5 N/A |
| 6. The container can accept all sizes and shapes of sharps | 1 2 3 4 5 N/A |
| 7. The container is temporarily closable, and will not spill contents (even after being dropped down a flight of stairs) | 1 2 3 4 5 N/A |
| 8. The container allows single handed operation. (Only the hand holding the sharp should be near the container opening) | 1 2 3 4 5 N/A |
| 9. It is difficult to reach in and remove a sharp | 1 2 3 4 5 N/A |
| 10. Sharps can go into the container without getting caught on the opening or any molded shapes in the interior | 1 2 3 4 5 N/A |
| 11. The container can be placed within arm's reach | 1 2 3 4 5 N/A |
| 12. The container is puncture resistant | 1 2 3 4 5 N/A |
| 13. When the container is dropped or turned upside down (even before it is permanently closed) sharps stay inside | 1 2 3 4 5 N/A |
| 14. The user can determine easily, from various viewing angles, when the container is full . . . | 1 2 3 4 5 N/A |
| 15. When the container is to be used free-standing (no mounting bracket), it is stable and unlikely to tip over | 1 2 3 4 5 N/A |
| 16. The container is large enough to accept all sizes and shapes of sharps, including 50 ml preloaded syringes | 1 2 3 4 5 N/A |
| 17. It is safe to close the container. (Sharps should not protrude into the path of hands attempting to close the container) | 1 2 3 4 5 N/A |
| 18. The container closes securely under all circumstances | 1 2 3 4 5 N/A |
| 19. The product has handles which allow you to safely transport a full container | 1 2 3 4 5 N/A |
| 20. The product does not require extensive training to operate correctly | 1 2 3 4 5 N/A |

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/ utility of this product?

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June Fisher, M.D.
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SAFETY FEATURE EVALUATION FORM

SAFETY DENTAL SYRINGES



Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agree.....disagree

1. The safety feature can be activated using a one-handed technique 1 2 3 4 5 N/A
2. The safety feature **does not** obstruct vision of the tip of the sharp and the
intraoral injection site. 1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature 1 2 3 4 5 N/A
4. This product **does not** require more time to use than a non-safety device 1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes 1 2 3 4 5 N/A
6. The device is easy to handle while wearing gloves 1 2 3 4 5 N/A
7. The device is easy to handle when wet 1 2 3 4 5 N/A
8. This device accepts standard anesthetic carpules and does not hinder carpule
changing 1 2 3 4 5 N/A
9. The safety feature **does not** restrict visibility of carpule contents intraorally 1 2 3 4 5 N/A
10. This device accepts standard dental needles of all common lengths and gauges,
and does not interfere with needle changing 1 2 3 4 5 N/A
11. The device provides a better alternative to traditional recapping 1 2 3 4 5 N/A
12. Sterilization of this device is as easy as a standard dental syringe 1 2 3 4 5 N/A
13. For syringes with integral needles only: The needle on this syringe **will not** break
while bending and repositioning in the tissue 1 2 3 4 5 N/A
14. This device is no more difficult to break down after use for sterilization than a
standard dental syringe 1 2 3 4 5 N/A
15. The safety feature operates reliably 1 2 3 4 5 N/A
16. The exposed sharp is permanently blunted or covered after use and prior to
disposal 1 2 3 4 5 N/A
17. There is a clear and unmistakable change (either visible or audible) that occurs
when the safety feature is activated 1 2 3 4 5 N/A
18. The user **does not** need extensive training to operate the product correctly 1 2 3 4 5 N/A
19. The design of the device allows for easy removal of the needle from the syringe 1 2 3 4 5 N/A
20. The design of the device allows for easy removal of the carpule from the syringe 1 2 3 4 5 N/A

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SAFETY FEATURE EVALUATION FORM

HOME USE SHARPS DISPOSAL CONTAINER



Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

	agree.....disagree
The container is puncture resistant	1 2 3 4 5 N/A
The container is stable	1 2 3 4 5 N/A
There is a handle which is robust, comfortable to carry, and compact	1 2 3 4 5 N/A
The container allows single handed use	1 2 3 4 5 N/A
The user can access the container from any direction	1 2 3 4 5 N/A
It is possible to drop sharps into the container vertically	1 2 3 4 5 N/A
Minimal or no force is required to put sharps into the container	1 2 3 4 5 N/A
The container opens and closes easily	1 2 3 4 5 N/A
Container closure maintains integrity after repeated use	1 2 3 4 5 N/A
The box accommodates a range of sharps, including 12 cc syringe, butterfly, and lancet	1 2 3 4 5 N/A
The size of the container is appropriate to its use	1 2 3 4 5 N/A
No one (including a child) can access the contents of the container to retrieve a sharp	1 2 3 4 5 N/A
Needles/tubing do not get caught on the opening or interior shape	1 2 3 4 5 N/A
There is a temporary lock for transport which is secure but reversible	1 2 3 4 5 N/A
There is a permanent lock for final disposal which is not reversible	1 2 3 4 5 N/A
There is an absorbent lining to collect excess fluid	1 2 3 4 5 N/A
The user can determine the fill level visually	1 2 3 4 5 N/A
There is a signal when the box is 2/3 full	1 2 3 4 5 N/A
The container is appropriately labeled	1 2 3 4 5 N/A
Biohazard of container contents is apparent	1 2 3 4 5 N/A
The box is not threatening to patients	1 2 3 4 5 N/A
Use of this container in no way compromises infection control practices	1 2 3 4 5 N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/ utility of this product?

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APPENDIX C

WEB SITE RESOURCE LIST

Effective Engineering Controls CDC Guidelines and Recommendations Vaccine Safety

NOTE: This appendix contains web sites that can be used for the purposes of information and research. The examples of effective engineering controls in this appendix do not include all those on the market, but are simply representative of the devices available. **OSHA does not approve, endorse, register, or certify any medical devices.** Inclusion in this list does not indicate OSHA approval, endorsement, registration, or certification. The final determination of compliance with OSHA's standards takes into account all factors pertaining to the use of such devices at a particular worksite.

Effective Engineering Controls

ECRI

Available: < <http://healthcare.ecri.org/site/whatsnew/press.releases/980724hdneedle.html> >
ECRI, designated as an Evidence-based Practice Center by the Agency for Health Care Policy and Research, is a nonprofit international health services research organization. This web site discusses the June 1998 issue of ECRI's Health Devices, which evaluated 19 needlestick-prevention devices ,and provides information on how to obtain this document.

Food and Drug Administration (FDA) Safety Alert: Needlestick and Other Risks from Hypodermic Needles on Secondary IV Administration Sets - Piggyback and Intermittent IV

Available: < <http://www.fda.gov/cdrh/safety.html> >.

Warns of the risk of needlestick injuries from the use of hypodermic needles as a connection between two pieces of intravenous (IV) equipment. Describes characteristics of devices which have the potential to decrease the risk of needlestick injuries.

International Health Care Worker Safety Center, University of Virginia

Available: < <http://www.people.virginia.edu/~epinet/products.html> >

Features a list of safety devices with manufacturers and specific product names.

National Institute for Occupational Safety and Health (NIOSH) Sharps Disposal Containers

Available: < <http://www.cdc.gov/niosh/sharps1.html> >

Features information on selecting, evaluating, and using sharps disposal containers.

Occupational Safety and Health Administration (OSHA) Glass Capillary Tubes: Joint Safety Advisory About Potential Risks

Available: < http://www.osha-slc.gov/OshDoc/Interp_data/I19990222.html >

Describes safer alternatives to conventional glass capillary tubes.

Occupational Safety and Health Administration (OSHA) Needlestick Injuries

Available: <http://www.osha-slc.gov/SLTC/needlestick/index.html>

Features recent news, recognition, evaluation, controls, compliance, and links to information on effective engineering controls.

Safety Sharp Device Contracts

Available: <http://www.va.gov/vasafety/osh-issues/needlesafety/safetysharpcontracts.htm>

Features safety sharp devices on contract with the US Department of Veterans Affairs (VA).

SHARPS Injury Control Program

Available: <http://www.ohb.org/sharps.htm>

Established by Senate Bill 2005 to study sharps injuries in hospitals, skilled nursing facilities, and home health agencies in California. Features a Beta version of Safety Enhanced Device Database Listing by Manufacturer.

Training for Development of Innovative Control Technologies (TDICT) Project

Available: <http://www.tdict.org/criteria.html>

Features “Safety Feature Evaluation Forms” for specific devices.

US DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS):CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) GUIDELINES AND RECOMMENDATIONS

CDC Prevention Guidelines Database

Available: < <http://aepo-xdv-www.epo.cdc.gov/wonder/PrevGuid/PrevGuid.htm> >

Provides access to the CDC Prevention Guidelines Database, which is a compilation of all of the official guidelines and recommendations published by the CDC for the prevention of diseases, disabilities, and injuries. Information on how to find a specific CDC Prevention Guideline.

Morbidity and Mortality Weekly Report (MMWR)

Available: < <http://www2.cdc.gov/mmwr/mmwr.html> >

Provides access to the MMWR, a series which is prepared by the CDC. Contains comprehensive information on policy statements for prevention and treatment that are within the CDC's scope of responsibility, for example, recommendations from the Advisory Committee on Immunization Practices (ACIP).

The following are CDC guidelines and recommendations on HIV, Hepatitis B, and Hepatitis C:

Guideline for infection control in health care personnel, 1998.

Available: < <http://www.cdc.gov/ncidod/hip/GUIDE/InfectControl98.pdf> >

Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. Publication date 10/16/1998.

Available: < <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00055154.htm> >

Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis. Publication date 05/15/1998.

Available: < <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00052722.htm> >

Appendix - First-Line Drugs for HIV Postexposure Prophylaxis (PEP). Publication date 05/15/1998.

Available: < <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00052801.htm> >

Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). Publication date 12/26/1997.

(Provides recommendations for Hepatitis B).

Available: < <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00050577.htm> >

VACCINE SAFETY

Centers for Disease Control and Prevention (CDC)

Available: < <http://www.cdc.gov/nip/vacsafe/> >

The National Immunization Program (NIP) of the CDC features information on vaccine safety.

Food and Drug Administration (FDA)

Available: < http://www.fda.gov/fdac/features/095_vacc.html > and
< <http://www.fda.gov/cber/vaers/vaers.htm> >

The first site features information on how the FDA ensures vaccine safety. The second site features information on the Vaccine Adverse Event Reporting System (VAERS), a cooperative program for vaccine safety of the FDA and CDC.

Immunization Action Coalition (IAC)

Available: < <http://www.immunize.org/> >

The IAC is a nonprofit organization working to increase immunization rates and prevent disease. Features Vaccine Information Statements, free print materials, and other hepatitis and immunization sites.

Infectious Diseases Society of America (IDSA)

Available: < <http://www.idsociety.org/vaccine/index.html> >

The Vaccine Initiative is a project of the IDSA and the Pediatric Infectious Diseases Society. Features information on vaccination and vaccination-related issues.

Institute for Vaccine Safety, Johns Hopkins School of Public Health

Available: < <http://www.vaccinesafety.edu/> >

The purpose of the Institute is to obtain and distribute information on the safety of recommended immunizations. This is a new web site, which is not currently fully operational. Its official launch will occur later in 1999.

National Institutes of Health (NIH)

Available: < <http://www.niaid.nih.gov/publications/vaccine/undvacc.htm> >

Features a 40 page brochure "Understanding Vaccines."

World Health Organization (WHO)

Available: < <http://www.who.int/gpv-safety/> >

Features a vaccine safety home page which offers links to vaccine safety-related information.

APPENDIX D

MODEL EXPOSURE CONTROL PLAN

The Model Exposure Control Plan is intended to serve as an employer guide to the OSHA Bloodborne Pathogens standard. A central component of the requirements of the standard is the development of an exposure control plan (ECP).

The intent of this model is to provide small employers with an easy-to-use format for developing a written exposure control plan. Each employer will need to adjust or adapt the model for their specific use.

The information contained in this publication is not considered a substitute for the OSH Act or any provisions of OSHA standards. It provides general guidance on a particular standard-related topic but should not be considered as the legal authority for compliance with OSHA requirements. The reader should consult the OSHA standard in its entirety for specific compliance requirements.

POLICY

The (Facility Name) is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this endeavor, the following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens."

The ECP is a key document to assist our firm in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes:

- * Determination of employee exposure
- * Implementation of various methods of exposure control, including:
 - Universal precautions
 - Engineering and work practice controls
 - Personal protective equipment
 - Housekeeping
- * Hepatitis B vaccination
- * Post-exposure evaluation and follow-up
- * Communication of hazards to employees and training

JOB TITLE

DEPARTMENT/LOCATION

(Example: Phlebotomists)

(Clinical Lab)

The following is a list of job classifications in which **some** employees at our establishment have occupational exposure. Included is a list of tasks and procedures, or groups of closely related tasks and procedures, in which occupational exposure may occur for these individuals:

JOB TITLE

DEPARTMENT/LOCATION TASK/PROCEDURE

(Example: Housekeeper

Environmental Services

Handling Regulated Waste)

Part-time, temporary, contract and per diem employees are covered by the standard. How the provisions of the standard will be met for these employees should be described in the ECP.

METHODS OF IMPLEMENTATION AND CONTROL

Universal Precautions

All employees will utilize universal precautions.

Exposure Control Plan

Employees covered by the bloodborne pathogens standard receive an explanation of this ECP during their initial training session. It will also be reviewed in their annual refresher training. All employees have an opportunity to review this plan at any time during their work shifts by contacting (Name of responsible person or department). If requested, we will provide an employee with a copy of the ECP free of charge and within 15 days of the request.

(Name of responsible person or department) is responsible for reviewing and updating the ECP annually or more frequently if necessary to reflect any new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

Engineering Controls and Work Practices

Engineering controls and work practice controls will be used to prevent or minimize exposure to bloodborne pathogens. The specific engineering controls and work practice controls used are listed below:

* (For example: glass capillary tubes in the clinical laboratory, outpatient clinics, and pediatric units)

* _____

* _____

Sharps disposal containers are inspected and maintained or replaced by ____(Name of responsible person or department) every ____(list frequency) or whenever necessary to prevent overfilling.

This facility identifies the need for changes in engineering control and work practices through (Examples: Review of OSHA records, employee interviews, committee activities, etc.)

We evaluate need procedures or new products by (Describe the process)

The following staff are involved in this process: (Describe how employees will be involved)

(Name of responsible person or department) will ensure effective implementation of these recommendations.

Personal Protective Equipment (PPE)

PPE is provided to our employees at no cost to them. Training is provided by ____(Name of responsible person or department) in the use of the appropriate PPE for the tasks or procedures employees will perform.

The types of PPE available to employees are as follows:

(Ex., gloves, eye protection, etc.)

PPE is located _____ (*List location*) _____ and may be obtained through _____ (*Name of responsible person or department*) _____ (Specify how employees are to obtain PPE, and who is responsible for ensuring that it is available.)

All employees using PPE must observe the following precautions:

- * Wash hands immediately or as soon as feasible after removal of gloves or other PPE.
- * Remove PPE after it becomes contaminated, and before leaving the work area.
- * Used PPE may be disposed of in _____ (List appropriate containers for storage, laundering, decontamination, or disposal.)
- * Wear appropriate gloves when it can be reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminated items or surfaces; replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised.
- * Utility gloves may be decontaminated for reuse if their integrity is not compromised; discard utility gloves if they show signs of cracking, peeling, tearing, puncturing, or deterioration.
- * Never wash or decontaminate disposable gloves for reuse.
- * Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth.
- * Remove immediately or as soon as feasible any garment contaminated by blood or OPIM, in such a way as to avoid contact with the outer surface.

The procedure for handling used PPE is as follows: (*may refer to specific agency procedure by title or number and last date of review*)

(*For example, how and where to decontaminate face shields, eye protection, resuscitation equipment*)

Housekeeping

Regulated waste is placed in containers which are closable, constructed to contain all contents and prevent leakage, appropriately labeled or color-coded (see Labels), and closed prior to removal to prevent spillage or protrusion of contents during handling.

The procedure for handling **sharps disposal containers** is: (may refer to specific agency procedure by title or number and last date of review)

The procedure for handling **other regulated waste** is: (may refer to specific agency procedure by title or number and last date of review)

Contaminated sharps are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leakproof on sides and bottoms, and labeled or color-coded appropriately. Sharps disposal containers are available at _____ (must be easily accessible and as close as feasible to the immediate area where sharps are used).

Bins and pails (e.g., wash or emesis basins) are cleaned and decontaminated as soon as feasible after visible contamination.

Broken glassware which may be contaminated is picked up using mechanical means, such as a brush and dust pan.

Laundry

The following contaminated articles will be laundered by this company:

Laundering will be performed by (Name of responsible person or department)
_____ at (time and/or location).

The following laundering requirements must be met:

- * handle contaminated laundry as little as possible, with minimal agitation
- * place wet contaminated laundry in leak-proof, labeled or color-coded containers before transport. Use (red bags or bags marked with biohazard symbol) for this purpose.
- * wear the following PPE when handling and/or sorting contaminated laundry: (List appropriate PPE)

Labels

The following labeling method(s) is used in this facility:

EQUIPMENT TO BE LABELED LABEL TYPE (size, color, etc.)
(e.g., specimens, contaminated laundry, etc.) (red bag, biohazard label, etc.)

(Name of responsible person or department) will ensure warning labels are affixed or red bags are used as required if regulated waste or contaminated equipment is brought into the facility. Employees are to notify _____ if they discover regulated waste containers, refrigerators containing blood or OPIM, contaminated equipment, etc. without proper labels.

HEPATITIS B VACCINATION

(Name of responsible person or department) will provide training to employees on hepatitis B vaccinations, addressing the safety, benefits, efficacy, methods of administration, and availability.

The hepatitis B vaccination series is available at no cost after training and within 10 days of initial assignment to employees identified in the exposure determination section of this plan. Vaccination is encouraged unless: 1) documentation exists that the employee has previously received the series, 2) antibody testing reveals that the employee is immune, or 3) medical evaluation shows that vaccination is contraindicated.

However, if an employee chooses to decline vaccination, the employee must sign a declination form. Employees who decline may request and obtain the vaccination at a later date at no cost. Documentation of refusal of the vaccination is kept at _____ (List location or person responsible for this recordkeeping).

Vaccination will be provided by _____ (*List Health care Professional who is responsible for this part of the plan*) at _____ (*location*).

Following hepatitis B vaccinations, the health care professional's Written Opinion will be limited to whether the employee requires the hepatitis vaccine, and whether the vaccine was administered.

POST-EXPOSURE EVALUATION AND FOLLOW-UP

Should an exposure incident occur, contact _____ (*Name of responsible person*) at the following number: _____.

An immediately available confidential medical evaluation and follow-up will be conducted by _____ (*Licensed health care professional*). Following the initial first aid (clean the wound, flush eyes or other mucous membrane, etc.), the following activities will be performed:

- * Document the routes of exposure and how the exposure occurred.
- * Identify and document the source individual (unless the employer can establish that identification is infeasible or prohibited by state or local law).
- * Obtain consent and make arrangements to have the source individual tested as soon as possible to determine HIV, HCV, and HBV infectivity; document that the source individual's test results were conveyed to the employee's health care provider.
- * If the source individual is already known to be HIV, HCV and/or HBV positive, new testing need not be performed.
- * Assure that the exposed employee is provided with the source individual's test results and with information about applicable disclosure laws and regulations concerning the identity and infectious status of the source individual (e.g., laws protecting confidentiality).
- * After obtaining consent, collect exposed employee's blood as soon as feasible after exposure incident, and test blood for HBV and HIV serological status
- * If the employee does not give consent for HIV serological testing during collection of blood for baseline testing, preserve the baseline blood sample for at least 90 days; if the exposed employee elects to have the baseline sample tested during this waiting period, perform testing as soon as feasible.

ADMINISTRATION OF POST-EXPOSURE EVALUATION AND FOLLOW-UP

(*Name of responsible person or department*) _____ ensures that health care professional(s) responsible for employee's hepatitis B vaccination and post-exposure evaluation and follow-up are given a copy of OSHA's bloodborne pathogens standard.

- * a copy and explanation of the standard
- * an explanation of our ECP and how to obtain a copy
- * an explanation of methods to recognize tasks and other activities that may involve exposure to blood and OPIM, including what constitutes an exposure incident
- * an explanation of the use and limitations of engineering controls, work practices, and PPE
- * an explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE
- * an explanation of the basis for PPE selection
- * information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine will be offered free of charge
- * information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM
- * an explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available
- * information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident
- * an explanation of the signs and labels and/or color coding required by the standard and used at this facility
- * an opportunity for interactive questions and answers with the person conducting the training session.

Training materials for this facility are available at _____.

RECORDKEEPING

Training Records

Training records are completed for each employee upon completion of training. These documents will be kept for at least **three years** at _____(Name of responsible person or location of records)_____.

The training records include:

- * the dates of the training sessions
- * the contents or a summary of the training sessions
- * the names and qualifications of persons conducting the training
- * the names and job titles of all persons attending the training sessions

Employee training records are provided upon request to the employee or the employee's authorized representative within 15 working days. Such requests should be addressed to _____ *(Name of Responsible person or department)*.

Medical Records

Medical records are maintained for each employee with occupational exposure in accordance with 29 CFR 1910.20, "Access to Employee Exposure and Medical **Records.**"

_____ *(Name of Responsible person or department)* is responsible for maintenance of the required medical records. These **confidential** records are kept at _____ *(List location)* for at least the **duration of employment plus 30 years.**

Employee medical records are provided upon request of the employee or to anyone having written consent of the employee within 15 working days. Such requests should be sent to

_____ *(Name of responsible person or department and address)*

OSHA Recordkeeping

An exposure incident is evaluated to determine if the case meets OSHA's Recordkeeping Requirements (29 CFR 1904). This determination and the recording activities are done by

_____ *(Name of responsible person or department)*.

APPENDIX E

GUIDELINES FOR THE MANAGEMENT OF HEALTH-CARE WORKER EXPOSURES

This appendix lists the URLs for the Centers for Disease Control *Morbidity and Mortality Weekly Report*: "Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis." May 15, 1998; Vol. 47, No. RR-7. The Adobe Acrobat pdf version contains the text of the report. The CDC has the text of this report available on their website. The URLs are:

< <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00052722.htm> >

or

< <ftp://ftp.cdc.gov/pub/Publications/mmwr/rr/rr4707.pdf> >

and the RR-7 Appendix:

< <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00052801.htm> >



May 15, 1998 / Vol. 47 / No. RR-7

MMWRTM

*Recommendations
and
Reports*

MORBIDITY AND MORTALITY WEEKLY REPORT

**Public Health Service Guidelines
for the Management of Health-Care
Worker Exposures to HIV and
Recommendations
for Postexposure Prophylaxis**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)
Atlanta, Georgia 30333



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Single copies of this document are available from the Centers for Disease Control and Prevention, National AIDS Clearinghouse, P.O. Box 6003, Rockville, MD 20850. Telephone: (800) 458-5231.

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Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis

Summary

This report updates and consolidates all previous PHS recommendations for the management of health-care workers (HCWs) who have occupational exposure to blood and other body fluids that may contain human immunodeficiency virus (HIV); it includes recommendations for HIV postexposure prophylaxis (PEP) and discusses the scientific rationale for PEP. The decision to recommend HIV postexposure prophylaxis must take into account the nature of the exposure (e.g., needlestick or potentially infectious fluid that comes in contact with a mucous membrane) and the amount of blood or body fluid involved in the exposure. Other considerations include pregnancy in the HCW and exposure to virus known or suspected to be resistant to antiretroviral drugs. Assessments of the risk for infection resulting from the exposure and of the infectivity of the exposure source are key determinants of offering PEP. Systems should be in place for the timely evaluation and management of exposed HCWs and for consultation with experts in the treatment of HIV when using PEP.

Recommendations for PEP have been modified to include a basic 4-week regimen of two drugs (zidovudine and lamivudine) for most HIV exposures and an expanded regimen that includes the addition of a protease inhibitor (indinavir or nelfinavir) for HIV exposures that pose an increased risk for transmission or where resistance to one or more of the antiretroviral agents recommended for PEP is known or suspected. An algorithm is provided to guide clinicians and exposed health-care workers in deciding when to consider PEP.

Occupational exposures should be considered urgent medical concerns to ensure timely administration of PEP. Health-care organizations should have protocols that promote prompt reporting and facilitate access to postexposure care. Enrollment of HCWs in registries designed to assess side effects in HCWs who take PEP is encouraged.

INTRODUCTION

Although preventing blood exposures is the primary means of preventing occupationally acquired human immunodeficiency virus (HIV) infection, appropriate postexposure management is an important element of workplace safety. In January 1990, CDC issued a statement on the management of HIV exposures that included considerations for zidovudine (ZDV) use for postexposure prophylaxis (PEP) (1). At that time, data were insufficient to assess the efficacy of ZDV as a prophylactic agent in humans or the toxicity of this drug in persons not infected with HIV. Although there are still only limited data to assess safety and efficacy, additional information is now available that is relevant to this issue.

In December 1995, CDC published a brief report of a retrospective case-control study of health-care workers (HCWs) from France, the United Kingdom, and the United States exposed percutaneously to HIV; the study identified risk factors for HIV transmission and documented that the use of ZDV was associated with a decrease in the risk for HIV seroconversion (2). This information, along with data on ZDV efficacy in preventing perinatal transmission (3) and evidence that PEP prevented or ameliorated retroviral infection in some studies in animals (4), prompted a Public Health Service (PHS) interagency working group*, with expert consultation (5), in June 1996 to issue provisional recommendations for PEP for HCWs after occupational HIV exposure (6).

Since the provisional recommendations were released, several new antiretroviral drugs have been approved by the Food and Drug Administration (FDA), and more information is available about the use and safety of antiretroviral agents in exposed HCWs (7-10). In addition, questions have been raised about the use of chemoprophylaxis in situations not fully addressed in the 1996 recommendations, including when not to offer PEP, what to do when the source of exposure or the HIV status of the source person is unknown, how to approach PEP in HCWs who are or may be pregnant, and considerations for PEP regimens when the source person's virus is known or suspected to be resistant to one or more of the antiretroviral agents recommended for PEP.

In May 1997, a meeting of expert consultants, convened by CDC to consider the new information, prompted a PHS interagency working group† decision to issue updated recommendations. This document addresses the management of occupational exposure to HIV, including guidance in assessing and treating exposed HCWs, updates previous recommendations for occupational postexposure chemoprophylaxis, and updates and replaces all previous PHS guidelines and recommendations for occupational HIV exposure management for HCWs. Included in this document is an algorithm to guide decisions regarding the use of PEP for HIV exposures. The algorithm and these recommendations together address most issues that may be encountered during postexposure follow-up. As relevant information becomes available, updates of these recommendations will be published. Recommendations for nonoccupational (e.g., sexual or pediatric) exposures are not addressed in these guidelines.

DEFINITIONS OF HEALTH-CARE WORKERS AND EXPOSURE

In this report, "health-care worker" (HCW) is defined as any person (e.g., an employee, student, contractor, attending clinician, public-safety worker, or volunteer) whose activities involve contact with patients or with blood or other body fluids from patients in a health-care or laboratory setting. An "exposure" that may place an HCW at risk for HIV infection and therefore requires consideration of PEP is defined as a

*This interagency working group comprised representatives of CDC, the Food and Drug Administration, the Health Resources and Services Administration, and the National Institutes of Health.

†This interagency working group comprised representatives of CDC, FDA, and the National Institutes of Health. Information included in these recommendations may not represent FDA approval or approved labeling for the particular product or indications in question. Specifically the terms "safe" and "effective" may not be synonymous with the FDA-defined legal standards for product approval.

percutaneous injury (e.g., a needlestick or cut with a sharp object), contact of mucous membrane or nonintact skin (e.g., when the exposed skin is chapped, abraded, or afflicted with dermatitis), or contact with intact skin when the duration of contact is prolonged (i.e., several minutes or more) or involves an extensive area, with blood, tissue, or other body fluids. Body fluids include a) semen, vaginal secretions, or other body fluids contaminated with visible blood that have been implicated in the transmission of HIV infection (11,12); and b) cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids, which have an undetermined risk for transmitting HIV (11). In addition, any direct contact (i.e., without barrier protection) to concentrated HIV in a research laboratory or production facility is considered an "exposure" that requires clinical evaluation and consideration of the need for PEP.

Although one nonoccupational episode of HIV transmission has been attributed to contact with blood-contaminated saliva (13), this incident involved intimate kissing between sexual partners and is not similar to contact with saliva that may occur during the provision of health-care services. Therefore, in the absence of visible blood in the saliva, exposure to saliva from a person infected with HIV is not considered a risk for HIV transmission; also, exposure to tears, sweat, or nonbloody urine or feces does not require postexposure follow-up.*

Human breast milk has been implicated in perinatal transmission of HIV. However, occupational exposure to human breast milk has not been implicated in HIV transmission to HCWs. Moreover, the contact HCWs may have with human breast milk is quite different from perinatal exposure and does not require postexposure follow-up.

BACKGROUND

The rationale is provided here for the postexposure management and prophylaxis recommendations given at the end of the document. Additional details concerning the risk for occupational HIV transmission to HCWs and management of occupational HIV exposures are available elsewhere (16–18).

Risk for Occupational Transmission of HIV to HCWs

Prospective studies of HCWs have estimated that the average risk for HIV transmission after a percutaneous exposure to HIV-infected blood is approximately 0.3% (95% confidence interval [CI]=0.2%–0.5%) (16) and after a mucous membrane exposure is 0.09% (95% CI=0.006%–0.5%) (19). Although episodes of HIV transmission after skin exposure have been documented (20), the average risk for transmission by this route has not been precisely quantified because no HCWs enrolled in prospective studies have seroconverted after an isolated skin exposure. The risk for transmission is estimated to be less than the risk for mucous membrane exposures (21). The risk for

*Although exposure to these body substances generally is not considered a risk for occupational HIV transmission, this does not negate the importance of handwashing and appropriate glove use when contacting these body substances. Handwashing and appropriate glove use are part of standard precautions for infection control to prevent transmission of nosocomial and community-acquired pathogens and are required for compliance with the Occupational Safety and Health Administration bloodborne pathogen standard (14,15). In addition, postexposure evaluation for hepatitis B (and possibly hepatitis C) should be provided if contact with saliva includes a possible portal of entry (i.e., nonintact skin, mucous membrane, or percutaneous injury).

transmission after exposure to fluids or tissues other than HIV-infected blood also has not been quantified.

As of June 1997, CDC has received reports of 52 U.S. HCWs with documented HIV seroconversion temporally associated with an occupational HIV exposure. An additional 114 episodes in HCWs are considered possible occupational HIV transmissions; these workers reported that their infection was occupationally acquired and no other risk for HIV infection was identified, but transmission of infection after a specific exposure was not documented (22). Of the 52 documented episodes, 47 HCWs were exposed to HIV-infected blood, one to a visibly bloody body fluid, one to an unspecified fluid, and three to concentrated virus in a laboratory. Forty-five exposures were percutaneous, and five were mucocutaneous; one HCW had both a percutaneous and a mucocutaneous exposure. The route of exposure for one person exposed to concentrated virus is uncertain. Of the percutaneous exposures, the objects involved included a hollow-bore needle (41), a broken glass vial (two), a scalpel (one), and an unknown sharp object (one) (CDC, unpublished data, 1998).

Epidemiologic and laboratory studies suggest that several factors may affect the risk for HIV transmission after an occupational exposure. The one retrospective case-control study of HCWs who had percutaneous exposure to HIV found that the risk for HIV transmission was increased with exposure to a larger quantity of blood from the source patient as indicated by a) a device visibly contaminated with the patient's blood, b) a procedure that involved a needle placed directly in a vein or artery, or c) a deep injury (23). (A laboratory study that demonstrated that more blood is transferred by deeper injuries and hollow-bore needles lends further support for the observed variation in risk related to blood quantity [24]). The risk also was increased for exposure to blood from source patients with terminal illness, possibly reflecting either the higher titer of HIV in blood late in the course of AIDS or other factors (e.g., the presence of syncytia-inducing strains of HIV). It was estimated that the risk for HIV transmission from exposures that involve a larger volume of blood, particularly when the source patient's viral load is probably high, exceeds the average risk of 0.3% (23).

The utility of viral load measurements from a source patient as a surrogate for estimating the viral titer for assessing transmission risk is not known. Plasma viral load measurement (e.g., HIV RNA) reflects only the level of cell-free virus in the peripheral blood. This measurement does not reflect the level of cell-associated virus in the peripheral blood or the level of virus in other body compartments (e.g., lymphatic tissue). Although a lower viral load, or results that are below the limits of viral quantification, in the peripheral blood probably indicates a lower titer exposure, it does not rule out the possibility of transmission; HIV transmission from persons with a plasma viral load below the limits of viral quantification (based on the assay used at the time) has been reported in instances of mother-to-infant transmission (25,26) and in one HCW seroconversion (J.L. Gerberding, San Francisco General Hospital, unpublished data, May 1997).

There is some evidence that host defenses also may influence the risk for HIV infection. In one small study, HIV-exposed but uninfected HCWs demonstrated an HIV-specific cytotoxic T-lymphocyte (CTL) response when peripheral blood mononuclear cells were stimulated *in vitro* with HIV mitogens (27). Similar CTL responses have been observed in other populations with repeated HIV exposure without resulting infection (28-33). Among several possible explanations for this observation, one

is that the host immune response sometimes may be able to prevent establishment of HIV infection after a percutaneous exposure; another is that the CTL response simply may be a marker for exposure.

HIV Seroconversion in HCWs

Data on the timing and clinical characteristics of seroconversion in HIV-exposed HCWs are limited by the infrequency of infection following occupational exposure, variations in postexposure testing intervals, and differences over time in the sensitivity of HIV-antibody testing methods. Among the HCWs with documented seroconversions reported to CDC for whom data are available, 81% experienced a syndrome compatible with primary HIV infection a median of 25 days after exposure (CDC, unpublished data, 1998). In a recent analysis of 51 seroconversions in HCWs, the estimated median interval from exposure to seroconversion was 46 days (mean: 65 days); an estimated 95% seroconverted within 6 months after the exposure (34). These data suggest that the time course of HIV seroconversion in HCWs is similar to that in other persons who have acquired HIV through nonoccupational modes of transmission (35).

Three instances of delayed HIV seroconversion occurring in HCWs have been reported; in these instances, the HCWs tested negative for HIV antibodies >6 months postexposure but were seropositive within 12 months after the exposure (36,37; J.L. Gerberding, San Francisco General Hospital, unpublished data, May 1997). DNA sequencing confirmed the source of infection in one instance. Two of the delayed seroconversions were associated with simultaneous exposure to hepatitis C virus (HCV) (37; J.L. Gerberding, San Francisco General Hospital, unpublished data, May 1997). In one case, co-infection was associated with a rapidly fatal HCV disease course (37); however, it is not known whether HCV directly influences the risk for or course of HIV infection or is a marker for other exposure-related factors.

Rationale for PEP

Considerations that influence the rationale and recommendations for PEP include the pathogenesis of HIV infection, particularly the time course of early infection; the biologic plausibility that infection can be prevented or ameliorated by using antiretroviral drugs and direct or indirect evidence of the efficacy of specific agents used for prophylaxis; and the risk/benefit of PEP to exposed HCWs. The following discussion considers each of these issues.

Role of Pathogenesis in Considering Antiretroviral Prophylaxis

Information about primary HIV infection indicates that systemic infection does not occur immediately, leaving a brief "window of opportunity" during which post-exposure antiretroviral intervention may modify viral replication. Data from studies in animal models and in vitro tissue studies suggest that dendritic cells in the mucosa and skin are the initial targets of HIV infection or capture and have an important role in initiating HIV infection of CD4+ T-cells in regional lymph nodes (38). In a primate model of simian immunodeficiency virus (SIV) infection, infection of dendritic-like cells occurred at the site of inoculation during the first 24 hours following mucosal exposure to cell-free virus. During the subsequent 24–48 hours, migration of these

cells to regional lymph nodes occurred, and virus was detectable in the peripheral blood within 5 days (39). HIV replication is rapid (generation time: 2.5 days) and results in bursts of up to 5,000 viral particles from each replicating cell (40; M.S. Saag, University of Alabama, personal communication, September 1997). The exponential increase in viral burden continues unless controlled by the immune system or other mechanisms (e.g., exhaustion of available target CD4+ T-cells). Theoretically, initiation of antiretroviral PEP soon after exposure may prevent or inhibit systemic infection by limiting the proliferation of virus in the initial target cells or lymph nodes.

Efficacy of Antiretrovirals for PEP

Studies in animals and humans provide direct and indirect evidence of the efficacy of antiretroviral drugs as agents for postexposure prophylaxis. In human studies and in most animal studies, ZDV was the antiretroviral agent used for prophylaxis (26,41–54). However, in more recent animal studies, newer agents also have been reported to be effective (55,56).

Data from animal studies have been difficult to interpret, in part because of problems identifying a comparable animal model for humans. Most studies use a higher inoculum for exposure than would be expected in needlestick injuries. Among the animal studies, differences in controlled variables (e.g., choice of viral strain [based on the animal model used], inoculum size, route of inoculation, time of prophylaxis initiation, and drug regimen) make attempts to apply these results to humans difficult. In the animal studies that showed efficacy of pre-exposure and/or postexposure prophylaxis, reported outcomes (4,57) have included a) suppression of viremia or delayed antigenemia (41–47); b) drug-facilitated vaccine-type response (i.e., chemoprophylaxis sufficiently inhibited viral replication to permit formation of a long-lasting, protective cellular immune response) (48–56); and c) definitive prevention of infection (i.e., chemoprophylactic efficacy) (41,52–54). More recent refinements in methodology have enabled studies more relevant to humans; in particular, the viral inocula used in animal studies have been reduced to levels more analogous to human exposures (54,56). The results of these studies provide additional evidence of postexposure chemoprophylactic efficacy.

In studies of HIV-2 or SIV in nonhuman primates in which ZDV or 3'-fluorothymidine was used, suppression or delay of antigenemia was the most common outcome; prevention of infection was infrequent (43,52,58–60). However, two other antiretroviral agents, 2',3'-dideoxy-3'-hydroxymethyl cytidine (BEA-005) and (R)-9-(2-phosphonylmethoxypropyl)adenine (PMPA), used to study PEP in primates have been more effective in preventing infection. When PMPA was administered 48 hours before, 4 hours after, or 24 hours after intravenous SIV inoculation to long-tailed macaques, a 4-week regimen prevented infection in all treated animals (55). A 3-day regimen of BEA-005 prevented SIV infection in 12 of 12 pigtailed macaques when administered 1–8 hours after intravenous inoculation; infection also was prevented in four of four animals that received 3 days of BEA-005 within 10 minutes after HIV-2 inoculation (56).

Animal studies have demonstrated that early initiation of PEP and small inoculum size are correlates of successful PEP. ZDV initiated 1 hour or 24 hours after intravenous exposure to a rapidly lethal variant of SIV in pigtailed macaques prevented infection in one of three animals and modified SIV disease in three of six animals, respectively;

PEP initiated at 72 hours had no effect (54). In macaques administered ZDV or BEA-005 1 to 72 hours after SIV intravenous challenge, earlier initiation of PEP was correlated with delayed onset and peak of antigenemia, decreased duration of antigenemia, and reduction in SIV serum titer; the most potent effect was evident when PEP was initiated within 8 hours of exposure (43,56). Studies in primates and murine and feline animal models have demonstrated that larger inocula decrease prophylactic efficacy (47,48,53,60). In addition, delaying initiation, shortening the duration, or decreasing the antiretroviral dose of PEP, individually or in combination, decreased prophylactic efficacy (42,43,45,47,50,55).

There is little information with which to assess the efficacy of PEP in humans. Seroprevalence is infrequent after an occupational exposure to HIV-infected blood; therefore a prospective trial would need to enroll many thousands of exposed HCWs to achieve the statistical power necessary to directly demonstrate PEP efficacy. During 1987–1989, the Burroughs-Wellcome Company sponsored a prospective placebo-controlled clinical trial among HCWs to evaluate 6 weeks of ZDV prophylaxis; however, this trial was terminated prematurely because of low enrollment (61). Because of current indirect evidence of PEP efficacy, it is unlikely that a placebo-controlled trial in HCWs would ever be feasible.

In the retrospective case-control study of HCWs, after controlling for other risk factors for HIV transmission, the risk for HIV infection among HCWs who used ZDV as PEP was reduced by approximately 81% (95% CI=43%–94%) (23). In addition, in a randomized, controlled, prospective trial (AIDS Clinical Trial Group [ACTG] protocol 076) in which ZDV was administered to HIV-infected pregnant women and their infants, the administration of ZDV during pregnancy, labor, and delivery and to the infant reduced transmission by 67% (3). Only 9%–17% (depending on the assay used) of the protective effect of ZDV was explained by reduction of the HIV titer in the maternal blood, suggesting that ZDV prophylaxis in part involves a mechanism other than the reduction of maternal viral burden (26).

The limitations of all of these studies must be considered when reviewing evidence of PEP efficacy. The extent to which data from animal studies can be extrapolated to humans is largely unknown, and the exposure route for mother-to-infant HIV transmission is not similar to occupational exposures; therefore these findings may not reflect a similar mechanism of ZDV prophylaxis in HCWs. Although the results of the retrospective case-control study of HCWs suggest PEP efficacy, the limitations of that study include the small number of cases studied and the use of cases and controls from different cohorts.

Failure of ZDV PEP to prevent HIV infection in HCWs has been reported in at least 14 instances (62–64; G. Ippolito, AIDS Reference Center, Rome, Italy, and J. Heptonstall, Communicable Disease Surveillance Center, London, United Kingdom, personal communication, 1997). Although eight of the 13 source patients had taken ZDV, laboratory assessment for ZDV resistance of the virus from the source patient was performed in only three instances, two of which demonstrated reduced susceptibility to ZDV. In addition to possible exposure to a ZDV-resistant strain of HIV, other factors that may have contributed to the apparent failures in these instances may include a high titer and/or large inoculum exposure, delayed initiation and/or short duration of PEP, and possible factors related to the host (e.g., cellular immune system responsive-

ness) and/or to the source patient's virus (e.g., presence of syncytia-forming strains) (62).

Antiretroviral Agents for PEP

Several antiretroviral agents from at least three classes of drugs are available for the treatment of HIV disease. These include the nucleoside analogue reverse transcriptase inhibitors (NRTIs), nonnucleoside reverse transcriptase inhibitors (NNRTIs), and protease inhibitors (PIs) (See Appendix). Among these drugs, ZDV (an NRTI) is the only agent shown to prevent HIV transmission in humans (2,3). Although there are theoretical concerns that the increased prevalence of resistance to ZDV may diminish its utility for PEP (65), no data are available to assess whether this is a factor for consideration. Clinical data from the ACTG protocol 076 study documented that despite genotypic evidence of maternal ZDV resistance, ZDV prevented perinatal transmission (66). Thus, based on the available information, it is still reasonable that ZDV should continue to be the first drug of choice for PEP regimens.

There are no data to directly support the addition of other antiretroviral drugs to ZDV to enhance the effectiveness of the PEP regimen. However, in HIV-infected patients, combination regimens have proved superior to monotherapy regimens in reducing HIV viral load (67,68). Thus, theoretically a combination of drugs with activity at different stages in the viral replication cycle (e.g., NRTIs with a PI) could offer an additive preventive effect in PEP, particularly for occupational exposures that pose an increased risk for transmission.

Determining which agents and how many agents to use or when to alter a PEP regimen is largely empiric. Guidelines for the treatment of early HIV infection recommend the use of three drugs (two NRTIs and a PI) (69); however, the applicability of these recommendations to PEP remains unknown. In addition, the routine use of three drugs for all occupational HIV exposures may not be needed. Although the use of a highly potent regimen can be justified for exposures that pose an increased risk for transmission, it is uncertain whether the potential additional toxicity of a third drug is justified for lower-risk exposures. For this reason, the recommendations at the end of this report provide guidance for two- and three-drug PEP regimens that are based on the level of risk for HIV transmission represented by the exposure.

NRTIs that can be considered for use with ZDV for PEP are lamivudine (3TC), didanosine (ddI), and zalcitabine, each of which has been included in recommended regimens that include ZDV (69). In previous CDC recommendations, 3TC was recommended as a second agent for PEP based on greater antiretroviral activity of the ZDV/3TC combination and its activity against many ZDV-resistant HIV strains without substantially increased toxicity (6). Also, data suggest that ZDV-resistant mutations develop more slowly in patients receiving the ZDV/3TC combination than those receiving ZDV alone (70), and in vitro studies indicate that the mutation associated with 3TC resistance may be associated with reversal of ZDV phenotypic resistance (71). No additional information has emerged to warrant altering the original recommendation of 3TC as the second agent for PEP. In addition, because ZDV and 3TC are available in a combination formulation (Combivir™, manufactured by Glaxo Wellcome, Inc., Research Triangle Park, NC), the use of 3TC may be more convenient for HCWs. However, individual clinicians may prefer other NRTIs or combinations of other antiretroviral agents based on local knowledge and experience in treating HIV infection and disease.

The addition of a PI as a third drug for PEP following high-risk exposures is based on the site of activity in the replication cycle (i.e., after viral integration has occurred) and demonstrated effectiveness in reducing viral burden. Previously, indinavir (IDV) was recommended as the PI for PEP because of its increased bioavailability when compared with saquinavir and its more favorable immediate toxicity profile compared with zidovudine (ZDV) (72). In addition, requirements for dose escalation when initiating zidovudine make it less practical for use in PEP. Since the 1996 PEP recommendations were published, nelfinavir (NEL) was approved for use by FDA and is now included in regimens recommended for the treatment of primary HIV infection (69). Also, FDA recently approved a soft-gel formulation of saquinavir (FortovaseTM, manufactured by Hoffmann-LaRoche, Inc., Nutley, New Jersey) that has improved bioavailability relative to its hard-gel formulation (InviraseTM, manufactured by Hoffmann-LaRoche, Inc.). However, the recommended dose of soft-gel saquinavir (1200 mg three times a day) is twice that of the hard-gel formulation (600 mg three times a day) and necessitates taking 18 pills a day, a factor that may influence HCW compliance if used for PEP. Based on these considerations, either IDV or NEL is recommended as first choice for inclusion in an expanded PEP regimen. If saquinavir is preferred by the prescribing physician, the soft-gel formulation (FortovaseTM) should be used. Also, differences in the side effects associated with IDV and NEL, discussed below, may influence which of these agents is selected in a specific situation.

The NNRTIs (i.e., nevirapine and delavirdine) have not been included in these recommended regimens for PEP. As a class of antiretroviral agents, the NNRTIs are fast-acting and very potent, making them appealing in concept for PEP. In addition, there is some evidence of prophylactic efficacy (73). However, concerns about side effects and the availability of alternative agents argue against routinely using this class of drugs for initial PEP, although with expert consultation, an NNRTI might be considered.

Side Effects and Toxicity of Antiretroviral Agents

An important goal of PEP is to encourage and facilitate compliance with a 4-week PEP regimen. Therefore, the toxicity profile of antiretroviral agents, including the frequency, severity, duration, and reversibility of side effects, is a relevant consideration. All of the antiretroviral agents have been associated with side effects (See Appendix). However, studies of adverse events have been reported primarily for persons with advanced disease (and longer treatment courses) and therefore may not reflect the experience of persons with less advanced disease or those who are uninfected (74). Side effects associated with many of the NRTIs (e.g., ZDV or ddI) are chiefly gastrointestinal (e.g., nausea or diarrhea), and in general the incidence of adverse effects has not been greater when these agents are used in combination (72).

All of the approved PIs may have potentially serious drug interactions when used with certain other drugs, requiring careful evaluation of concomitant medications being used by an HCW before prescribing a PI and close monitoring for toxicity when an HCW is receiving one of these drugs (See Appendix). PIs may inhibit the metabolism of non-sedating antihistamines and other hepatically metabolized drugs; NEL and ritonavir may accelerate the clearance of certain drugs, including oral contraceptives (requiring alternative or additional contraceptive measures for women taking these drugs). The use of PIs also has been associated with new onset of diabetes mellitus,

hyperglycemia, diabetic ketoacidosis, and exacerbation of pre-existing diabetes mellitus (75–77). Nephrolithiasis has been associated with IDV use (including in HCWs using the drug for PEP) (8); however, the incidence of this potential complication may be limited by drinking at least 48 oz (1.5 L) of fluid per 24-hour period (e.g., six 8 oz glasses of water throughout the day) (72). Rare cases of hemolytic anemia also have been associated with the use of IDV. NEL, saquinavir, and ritonavir have been associated with the development of diarrhea; however, this side effect usually responds to treatment with antimotility agents that can be prescribed for use, if necessary, at the time any one of these drugs is prescribed for PEP. The manufacturer's package insert should always be consulted for questions about potential drug interactions.

Among HCWs receiving ZDV PEP, usually at doses of 1,000–1,200 mg per day (i.e., higher than the currently recommended dose), 50%–75% reported one or more subjective complaints and approximately 30% discontinued the drug because of symptoms (7,78,79). Common symptoms included nausea, vomiting, malaise or fatigue, headache, or insomnia. Mild decreases in hemoglobin and absolute neutrophil count also were observed. All side effects were reversed when PEP was discontinued.

Preliminary information about HCWs receiving combination drugs for PEP (usually ZDV plus 3TC with or without a PI) suggests that approximately 50%–90% of HCWs report subjective side effects that caused 24%–36% to discontinue PEP (8–10). One study documented that combination regimens that included ZDV at a lower dose (600 mg per day) were better tolerated than high-dose ZDV used alone (1,000–1,200 mg per day) (10). However, serious side effects, including nephrolithiasis, hepatitis, and pancytopenia, have been reported with the use of combination drugs for PEP (9,80; J.L. Gerberding, San Francisco General Hospital, personal communication, May 1997).

Resistance to Antiretroviral Agents

Known or suspected resistance of the source virus to antiretroviral agents, particularly to one or more agents that might be included in a PEP regimen, is a concern for those making decisions about PEP. Resistance of HIV has been reported with all available antiretroviral agents (65). However, the relevance of exposure to a resistant virus is not understood. Although transmission of resistant strains has been reported (81–85), in the perinatal clinical trial that studied vertical HIV transmission (ACTG protocol 076), ZDV prevented perinatal transmission despite genotypic resistance of HIV to ZDV in the mother (66). In addition, patients generally take more than one antiretroviral drug and, unless testing is performed, often it is difficult to know to which drug(s) resistance exists. The complexity of this issue is further compounded by the frequency of cross-resistance within drug classes.

Resistance should be suspected in source patients when there is clinical progression of disease or a persistently increasing viral load and/or a decline in CD4 T-cell count despite therapy, or a lack of virologic response to a change in therapy. Nevertheless, in this situation it is unknown whether a modification in the PEP regimen is necessary or will influence the outcome of an occupational exposure.

Antiretroviral Drugs in Pregnancy

Considerations for the use of antiretroviral drugs in pregnancy include their potential effect on the pregnant woman and on her fetus or neonate. The pharmacokinetics

of antiretroviral drugs has not been completely studied in pregnant women. Some of the antiretroviral drugs are known to cross the placenta, but data for humans are not yet available for others (particularly the PIs). In addition, data are limited on the potential effects of antiretroviral drugs on the developing fetus or neonate (86). Decisions on the use of specific drugs in pregnancy also are influenced by whether a drug has specific adverse effects or might further exacerbate conditions associated with pregnancy, (e.g., drugs that cause nausea may be less tolerated when superimposed on the nausea normally associated with pregnancy).

There are data on both ZDV and 3TC from clinical trials in HIV-infected pregnant women. The most extensive experience has been with the use of ZDV after 14 weeks of gestation in pregnant HIV-infected women in phase I studies and the perinatal ACTG protocol 076 (4,87). The dose of ZDV for pregnant women is the same as that in nonpregnant persons, and ZDV appears safe and well tolerated in both women and their infants who have had a follow-up period of several years (88–90). Data from the Antiretroviral Pregnancy Registry have not documented an increased risk for birth defects in infants with in utero exposure to ZDV (91). There are limited data on use of 3TC alone or in combination with ZDV in late gestation in pregnant HIV-infected women. As with ZDV, the pharmacokinetics and dose of 3TC appear to be similar to those for nonpregnant persons. The drug appears safe during pregnancy for women and infants, although long-term safety is not known (92,93).

Carcinogenicity and/or mutagenicity is evident in several in vitro screening tests for ZDV and all other FDA-licensed nucleoside antiretroviral drugs. In some in vivo rodent studies, high-dose lifetime continuous ZDV exposure (94) or very high dose in utero ZDV exposure has been associated with the development of tumors in adult females or their offspring (95,96). The relevance of these animal data to humans is unknown. However, in 1997 an independent panel reviewed these data and concluded that the known benefits of ZDV in preventing perinatal transmission, where the risk for transmission without ZDV is 25%–30%, outweigh the hypothetical concerns about transplacental carcinogenesis (97).

No data are available regarding pharmacokinetics, safety, or tolerability of any of the PIs in pregnant women. The use of PIs in HIV-infected persons has been associated with hyperglycemia; it is unknown whether the use of these agents during pregnancy will exacerbate the risk for pregnancy-associated hyperglycemia. Therefore, close monitoring of glucose levels and careful instruction regarding symptoms related to hyperglycemia are recommended for pregnant HCWs receiving a PI for PEP. IDV is associated with infrequent side effects in adults (i.e., hyperbilirubinemia and renal stones) that could be problematic for the newborn. As the half-life of IDV in adults is short, these concerns may be relevant only if the drug is administered shortly before delivery.

RECOMMENDATIONS FOR THE MANAGEMENT OF POTENTIALLY EXPOSED HCWs

Health-care organizations should make available to their workers a system that includes written protocols for prompt reporting, evaluation, counseling, treatment, and follow-up of occupational exposures that may place HCWs at risk for acquiring any bloodborne infection, including HIV. Employers also are required to establish

exposure-control plans, including postexposure follow-up for their employees, and to comply with incident reporting requirements mandated by the Occupational Safety and Health Administration (15). Access to clinicians who can provide postexposure care should be available during all working hours, including nights and weekends. Antiretroviral agents for PEP should be available for timely administration (i.e., either by providing access to PEP drugs on site or creating links with other facilities or providers to make them available offsite). Persons responsible for providing post-exposure counseling should be familiar with evaluation and treatment protocols and the facility's procedures for obtaining drugs for PEP.

HCWs should be educated to report occupational exposures immediately after they occur, particularly because PEP is most likely to be effective if implemented as soon after the exposure as possible (41,55,56). HCWs who are at risk for occupational exposure to HIV should be taught the principles of postexposure management, including options for PEP, as part of job orientation and ongoing job training.

Exposure Report

If an occupational exposure occurs, the circumstances and postexposure management should be recorded in the HCW's confidential medical record (usually on a form the facility designates for this purpose). Relevant information includes

- date and time of exposure;
- details of the procedure being performed, including where and how the exposure occurred, and if the exposure was related to a sharp device, the type of device and how and when in the course of handling the device the exposure occurred;
- details of the exposure, including the type and amount of fluid or material and the severity of the exposure (e.g., for a percutaneous exposure, depth of injury and whether fluid was injected; or for a skin or mucous-membrane exposure, the estimated volume of material and duration of contact and the condition of the skin [e.g., chapped, abraded, or intact]);
- details about the exposure source (i.e., whether the source material contained HIV or other bloodborne pathogen[s]), and if the source is an HIV-infected person, the stage of disease, history of antiretroviral therapy, and viral load, if known; and
- details about counseling, postexposure management, and follow-up.

Exposure Management

Treatment of an Exposure Site

Wounds and skin sites that have been in contact with blood or body fluids should be washed with soap and water; mucous membranes should be flushed with water. There is no evidence that the use of antiseptics for wound care or expressing fluid by squeezing the wound further reduces the risk for HIV transmission. However, the use of antiseptics is not contraindicated. The application of caustic agents (e.g., bleach) or the injection of antiseptics or disinfectants into the wound is not recommended.

Assessment of Infection Risk

After an occupational exposure, the source-person and the exposed HCW should be evaluated to determine the need for HIV PEP. Follow-up for hepatitis B virus and hepatitis C virus infections also should be conducted in accordance with previously published CDC recommendations (98,99).

Evaluation of exposure. The exposure should be evaluated for potential to transmit HIV based on the type of body substance involved and the route and severity of the exposure. Exposures to blood, fluid containing visible blood, or other potentially infectious fluid (including semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids) or tissue through a percutaneous injury (i.e., needlestick or other penetrating sharps-related event) or through contact with a mucous membrane are situations that pose a risk for bloodborne transmission and require further evaluation (Figure 1). In addition, any direct contact (i.e., personal protective equipment either was not used or was ineffective in protecting skin or mucous membranes) with concentrated HIV in a research laboratory or production facility is considered an exposure that requires clinical evaluation to assess the need for PEP.

For skin exposures, follow-up is indicated if it involves direct contact with a body fluid listed above and there is evidence of compromised skin integrity (e.g., dermatitis, abrasion, or open wound). However, if the contact is prolonged or involves a large area of intact skin, postexposure follow-up may be considered on a case-by-case basis or if requested by the HCW.

For human bites, the clinical evaluation must consider possible exposure of both the bite recipient and the person who inflicted the bite. HIV transmission only rarely has been reported by this route (100,101; CDC, unpublished data, 1998). If a bite results in blood exposure to either person involved, postexposure follow-up, including consideration of PEP, should be provided.

Evaluation and testing of an exposure source. The person whose blood or body fluids are the source of an occupational exposure should be evaluated for HIV infection. Information available in the medical record at the time of exposure (e.g., laboratory test results, admitting diagnosis, or past medical history) or from the source person may suggest or rule out possible HIV infection. Examples of information to consider when evaluating an exposure source for possible HIV infection include laboratory information (e.g., prior HIV testing results or results of immunologic testing [e.g., CD4+ count]), clinical symptoms (e.g., acute syndrome suggestive of primary HIV infection or undiagnosed immunodeficiency disease), and history of possible HIV exposures (e.g., injecting-drug use, sexual contact with a known HIV-positive partner, unprotected sexual contact with multiple partners [heterosexual and/or homosexual], or receipt of blood or blood products before 1985).

If the source is known to have HIV infection, available information about this person's stage of infection (i.e., asymptomatic or AIDS), CD4+ T-cell count, results of viral load testing, and current and previous antiretroviral therapy, should be gathered for consideration in choosing an appropriate PEP regimen. If this information is not immediately available, initiation of PEP, if indicated, should not be delayed; changes in the PEP regimen can be made after PEP has been started, as appropriate.

FIGURE 1. Determining the need for HIV postexposure prophylaxis (PEP) after an occupational exposure*

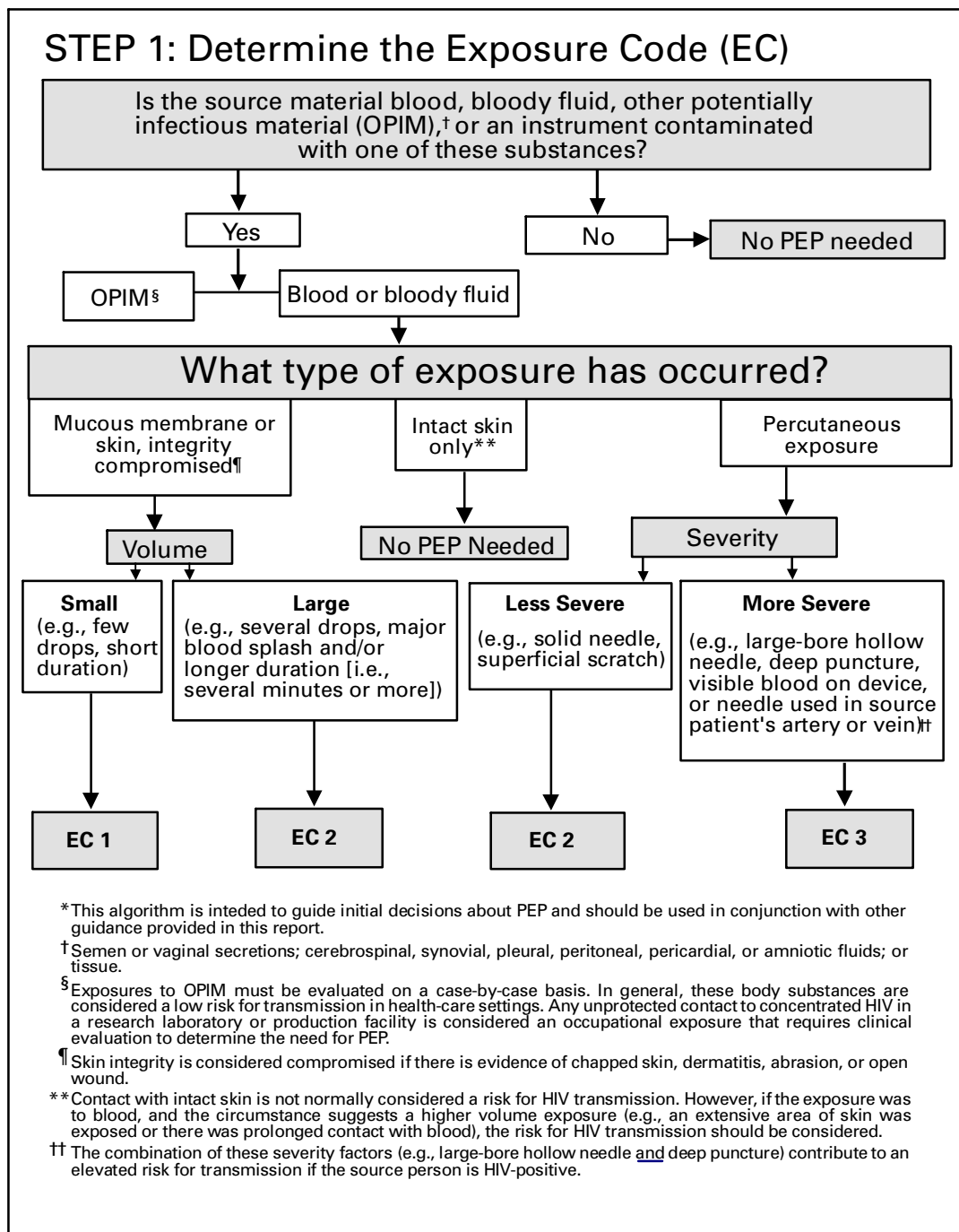
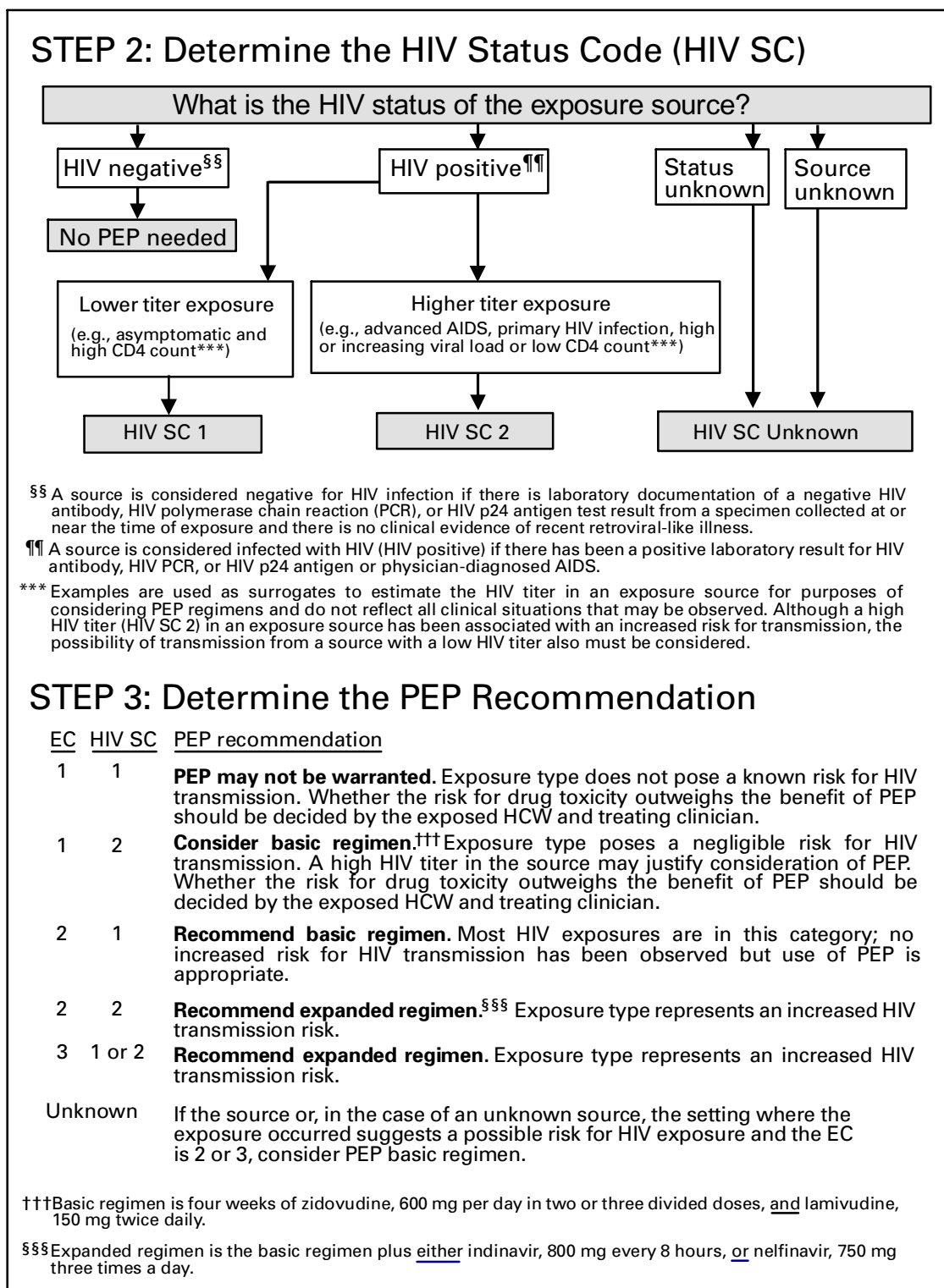


FIGURE 1. Determining the need for HIV postexposure prophylaxis (PEP) after an occupational exposure* — Continued



If the HIV serostatus of the source person is unknown, the source person should be informed of the incident and, if consent is obtained, tested for serologic evidence of HIV infection. If consent cannot be obtained (e.g., patient is unconscious), procedures should be followed for testing source persons according to applicable state and local laws. Confidentiality of the source person should be maintained at all times.

HIV-antibody testing of an exposure source should be performed as soon as possible. Hospitals, clinics, and other sites that manage exposed HCWs should consult their laboratories regarding the most appropriate test to use to expedite these results. An FDA-approved rapid HIV-antibody test kit should be considered for use in this situation, particularly if testing by enzyme immunoassay (EIA) cannot be completed within 24–48 hours. Repeatedly reactive results by EIA or rapid HIV-antibody tests are considered highly suggestive of infection, whereas a negative result is an excellent indicator of the absence of HIV antibody. Confirmation of a reactive result by Western blot or immunofluorescent antibody is not necessary for making initial decisions about postexposure management but should be done to complete the testing process.

If the source is HIV seronegative and has no clinical evidence of acquired immunodeficiency syndrome (AIDS) or symptoms of HIV infection, no further testing of the source is indicated. It is unclear whether follow-up testing of a source who is HIV negative at the time of exposure, but recently (i.e., within the last 3–6 months) engaged in behaviors that pose a risk for HIV transmission, is useful in postexposure management of HCWs; HCWs who become infected generally seroconvert before repeat testing of a source would normally be performed.

If the exposure source is unknown, information about where and under what circumstances the exposure occurred should be assessed epidemiologically for risk for transmission of HIV. Certain situations, as well as the type of exposure, may suggest an increased or decreased risk; an important consideration is the prevalence of HIV in the population group (i.e., institution or community) from which the contaminated source material is derived. For example, an exposure that occurs in a geographic area where injecting-drug use is prevalent or on an AIDS unit in a health-care facility would be considered epidemiologically to have a higher risk for transmission than one that occurs in a nursing home for the elderly where no known HIV-infected residents are present. In addition, exposure to a blood-filled hollow needle or visibly bloody device suggests a higher-risk exposure than exposure to a needle that was most likely used for giving an injection. Decisions regarding appropriate management should be individualized based on the risk assessment.

HIV testing of needles or other sharp instruments associated with an exposure, regardless of whether the source is known or unknown, is not recommended. The reliability and interpretation of findings in such circumstances are unknown.

Clinical Evaluation and Baseline Testing of Exposed HCWs

Exposed HCWs should be evaluated for susceptibility to bloodborne pathogen infections. Baseline testing (i.e., testing to establish serostatus at the time of exposure) for HIV antibody should be performed. If the source person is seronegative for HIV, baseline testing or further follow-up of the HCW normally is not necessary. If the source person has recently engaged in behaviors that are associated with a risk for HIV transmission, baseline and follow-up HIV-antibody testing (e.g., 3 and/or 6 months

postexposure) of the HCW should be considered. Serologic testing should be made available to all HCWs who are concerned that they may have been exposed to HIV.

For purposes of considering HIV PEP, the evaluation also should include information about medications the HCW may be taking and any current or underlying medical conditions or circumstances (i.e., pregnancy, breast feeding, or renal or hepatic disease) that may influence drug selection. Pregnancy testing should be offered to all nonpregnant women of childbearing age whose pregnancy status is unknown.

HIV PEP

The following recommendations apply to situations where an HCW has had an exposure to a source person with HIV or where information suggests that there is a likelihood that the source person is HIV-infected. These recommendations are based on the risk for HIV infection after different types of exposure and limited data regarding efficacy and toxicity of PEP. Because most occupational HIV exposures do not result in the transmission of HIV, potential toxicity must be carefully considered when prescribing PEP. When possible, these recommendations should be implemented in consultation with persons having expertise in antiretroviral therapy and HIV transmission.

Explaining PEP to HCWs

Recommendations for chemoprophylaxis should be explained to HCWs who have sustained occupational HIV exposures (Figure 1). For exposures for which PEP is considered appropriate, HCWs should be informed that a) knowledge about the efficacy and toxicity of drugs used for PEP are limited; b) only ZDV has been shown to prevent HIV transmission in humans; c) there are no data to address whether adding other antiretroviral drugs provides any additional benefit for PEP, but experts recommend combination drug regimens because of increased potency and concerns about drug-resistant virus; d) data regarding toxicity of antiretroviral drugs in persons without HIV infection or in pregnant women are limited for ZDV and not known regarding other antiretroviral drugs; and e) any or all drugs for PEP may be declined by the HCW. HCWs who have HIV occupational exposures for which PEP is not recommended should be informed that the potential side effects and toxicity of taking PEP outweigh the negligible risk of transmission posed by the type of exposure.

Factors in Selection of a PEP Regimen

Selection of the PEP regimen should consider the comparative risk represented by the exposure and information about the exposure source, including history of and response to antiretroviral therapy based on clinical response, CD4+ T-lymphocyte counts, viral load measurements, and current disease stage. Most HIV exposures will warrant only a two-drug regimen, using two NRTIs, usually ZDV and 3TC. The addition of a third drug, usually a PI (i.e., IDV or NEL), should be considered for exposures that pose an increased risk for transmission or where resistance to the other drugs used for PEP is known or suspected.

Timing of PEP Initiation

PEP should be initiated as soon as possible. The interval within which PEP should be started for optimal efficacy is not known. Animal studies have demonstrated the importance of starting PEP within hours after an exposure (43,54,56). To assure timely access to PEP, an occupational exposure should be regarded as an urgent medical concern and PEP started as soon as possible after the exposure (i.e., within a few hours rather than days). If there is a question about which antiretroviral drugs to use, or whether to use two or three drugs, it is probably better to start ZDV and 3TC immediately than to delay PEP administration. Although animal studies suggest that PEP probably is not effective when started later than 24–36 hours postexposure (42,55,56), the interval after which there is no benefit from PEP for humans is undefined. Therefore, if appropriate for the exposure, PEP should be started even when the interval since exposure exceeds 36 hours. Initiating therapy after a longer interval (e.g., 1–2 weeks) may be considered for exposures that represent an increased risk for transmission; even if infection is not prevented, early treatment of acute HIV infection may be beneficial (69). The optimal duration of PEP is unknown. Because 4 weeks of ZDV appeared protective in HCWs (2), PEP probably should be administered for 4 weeks, if tolerated.

PEP if Serostatus of Source Person is Unknown

If the source person's HIV serostatus is unknown at the time of exposure (including when the source is HIV negative but may have had a recent HIV exposure), use of PEP should be decided on a case-by-case basis, after considering the type of exposure and the clinical and/or epidemiologic likelihood of HIV infection in the source (Figure 1). If these considerations suggest a possibility for HIV transmission and HIV testing of the source is pending, it is reasonable to initiate a two-drug PEP regimen until laboratory results have been obtained and later modify or discontinue the regimen accordingly.

PEP if Exposure Source is Unknown

If the exposure source is unknown, use of PEP should be decided on a case-by-case basis. Consideration should include the severity of the exposure and the epidemiologic likelihood that the HCW was exposed to HIV.

PEP for Pregnant HCWs

If the HCW is pregnant, the evaluation of risk and need for PEP should be approached as with any other HCW who has had an HIV exposure. However, the decision to use any antiretroviral drug during pregnancy should involve discussion between the woman and her health-care provider regarding the potential benefits and potential risks to her and her fetus.

Follow-up of HCWs Exposed to HIV

Postexposure Testing

HCWs with occupational exposure to HIV should receive follow-up counseling, postexposure testing, and medical evaluation regardless of whether they receive PEP. HIV-antibody testing should be performed for at least 6 months postexposure (e.g., at

6 weeks, 12 weeks, and 6 months). It is unclear whether an extended follow-up period (e.g., 12 months) is indicated in certain circumstances. Although rare instances of delayed HIV seroconversion have been reported (36,37, J.L. Gerberding, San Francisco General Hospital, unpublished data, May 1997), the infrequency of this occurrence does not warrant adding to HCWs' anxiety by routinely extending the duration of postexposure follow-up. Circumstances for which extending the duration of follow-up have been suggested include the use of highly potent antiretroviral regimens (i.e., more than two drugs) because of theoretical concerns that HIV seroconversion could be delayed, or simultaneous exposure to HCV. Data are insufficient for making a general recommendation in these situations. However, this should not preclude a decision to extend follow-up in an individual situation based on the clinical judgement of the HCW's health-care provider. HIV testing should be performed on any HCW who has an illness that is compatible with an acute retroviral syndrome, regardless of the interval since exposure. HIV-antibody testing using EIA should be used to monitor for seroconversion. The routine use of direct virus assays (e.g., HIV p24 antigen EIA or polymerase chain reaction for HIV RNA) to detect infection in exposed HCWs generally is not recommended (34). Although direct virus assays may detect HIV infection a few days earlier than EIA, the infrequency of HCW seroconversion and increased costs of these tests do not warrant their routine use in this setting. Also, HIV RNA is approved for use in established HIV infection; its reliability in detecting very early infection has not been determined.

Monitoring and Management of PEP Toxicity

If PEP is used, drug-toxicity monitoring should be performed at baseline and again 2 weeks after starting PEP. Clinical judgement, based on medical conditions that may exist in the HCW and any toxicity associated with drugs included in the PEP regimen, should determine the scope of testing. Minimally these should include a complete blood count and renal and hepatic chemical function tests. Monitoring for evidence of hyperglycemia should be included for HCWs whose regimen includes any PI; if the HCW is receiving IDV, monitoring for crystalluria, hematuria, hemolytic anemia, and hepatitis also should be included. If toxicity is noted, modification of the regimen should be considered after expert consultation; further diagnostic studies may be indicated.

HCWs who fail to complete the recommended regimen often do so because of the side effects they experience (e.g., nausea and diarrhea). These symptoms often can be managed without changing the regimen by prescribing antimotility and antiemetic agents or other medications that target the specific symptoms. In other situations, modifying the dose interval (i.e., administering a lower dose of drug more frequently throughout the day, as recommended by the manufacturer), may help promote adherence to the regimen.

Counseling and Education

Although HIV infection following an occupational exposure occurs infrequently, the emotional impact of the exposure often is substantial (102,103). In addition, HCWs are given seemingly conflicting information. Although HCWs are told that there is a low risk for HIV transmission, a 4-week regimen of PEP is recommended and they are asked to commit to behavioral measures (i.e., sexual abstinence or condom use) to

prevent secondary transmission, all of which influence their lives for several weeks to months (102). Therefore, access to persons who are knowledgeable about occupational HIV transmission and who can deal with the many concerns an HIV exposure may raise for the HCW is an important element of postexposure management.

HIV-exposed HCWs should be advised to use the following measures to prevent secondary transmission during the follow-up period, especially during the first 6–12 weeks after the exposure when most HIV-infected persons are expected to seroconvert: use sexual abstinence or condoms to prevent sexual transmission and to avoid pregnancy; and refrain from donating blood, plasma, organs, tissue, or semen. If the exposed HCW is breastfeeding, she should be counseled about the risk for HIV transmission through breast milk, and discontinuation of breastfeeding should be considered, especially following high-risk exposures. If the HCW chooses to receive PEP, temporary discontinuation of breastfeeding while she is taking PEP should be considered to avoid exposing the infant to these agents. NRTIs are known to pass into breast milk; it is not known whether this also is true for PIs.

There is no need to modify an HCW's patient-care responsibilities to prevent transmission to patients based solely on an HIV exposure. If HIV seroconversion is detected, the HCW should be evaluated according to published recommendations for HIV-infected HCWs (104).

Exposed HCWs should be advised to seek medical evaluation for any acute illness that occurs during the follow-up period. Such an illness, particularly if characterized by fever, rash, myalgia, fatigue, malaise, or lymphadenopathy, may be indicative of acute HIV infection but also may be due to a drug reaction or another medical condition.

Exposed HCWs who choose to take PEP should be advised of the importance of completing the prescribed regimen. Information should be provided about potential drug interactions and the drugs that should not be taken with PEP, the side effects of the drugs that have been prescribed (See Appendix), measures to minimize these effects, and the methods of clinical monitoring for toxicity during the follow-up period. They should be advised that the evaluation of certain symptoms should not be delayed (e.g., back or abdominal pain, pain on urination or blood in the urine, or symptoms of hyperglycemia [i.e., increased thirst and/or frequent urination]).

RECOMMENDATIONS FOR THE SELECTION OF DRUGS FOR PEP

The selection of a drug regimen for HIV PEP must strive to balance the risk for infection against the potential toxicity of the agent(s) used. Because PEP is potentially toxic, its use is not justified for exposures that pose a negligible risk for transmission (Figure 1). Also, there is insufficient evidence to recommend a highly active regimen for all HIV exposures. Therefore, two regimens for PEP are provided (Table 1): a "basic" two-drug regimen that should be appropriate for most HIV exposures and an "expanded" three-drug regimen that should be used for exposures that pose an increased risk for transmission (Figure 1) or where resistance to one or more antiretroviral agents is known or suspected. When possible, the regimens should be implemented in consultation with persons having expertise in antiretroviral treatment and HIV transmission.

TABLE 1. Basic and expanded postexposure prophylaxis regimens

Regimen category	Application	Drug regimen
Basic	Occupational HIV exposures for which there is a recognized transmission risk (Figure 1).	4 weeks (28 days) of both zidovudine 600 mg every day in divided doses (i.e., 300 mg twice a day, 200 mg three times a day, or 100 mg every 4 hours) and lamivudine 150 mg twice a day.
Expanded	Occupational HIV exposures that pose an increased risk for transmission (e.g., larger volume of blood and/or higher virus titer in blood) (Figure 1).	Basic regimen plus either indinavir 800 mg every 8 hours or nelfinavir 750 mg three times a day.*

* Indinavir should be taken on an empty stomach (i.e., without food or with a light meal) and with increased fluid consumption (i.e., drinking six 8 oz glasses of water throughout the day); nelfinavir should be taken with meals.

Situations That Require Special Consideration

Resistance of the Source Virus to Antiretroviral Drugs

It is unknown whether drug resistance influences transmission risk; however, transmission of drug-resistant HIV has been reported (81,82) and is therefore a theoretical concern when choosing PEP regimens. If the source-person's virus is known or suspected to be resistant to one or more of the drugs included in the PEP regimen, the selection of drugs to which the source person's virus is unlikely to be resistant is recommended (69). If the resistance is to one class of antiretroviral drugs, the addition to the basic PEP regimen of a drug from another class might be considered (e.g., addition of a PI when a source patient has not been treated with a PI but has virus resistant to one or more NRTIs). It is strongly recommended that PEP be started regardless of the resistance status in the source virus; if resistance is known or suspected, a third or fourth drug may be added to the regimen until consultation with a clinical expert in the treatment of HIV infection or disease can be obtained.

Known or Suspected Pregnancy in the HCW

Pregnancy should not preclude the use of optimal PEP regimens, and PEP should not be denied to an HCW solely on the basis of pregnancy. However, as discussed previously, an occupationally exposed pregnant HCW must be provided with full information about what is known and not known regarding the potential benefits and risks associated with use of the antiretroviral drugs to her and her fetus for her to make an informed decision regarding the use of PEP. The choice of antiretroviral drugs to use for PEP in pregnant HCWs is complicated by the potential need to alter dosing because of physiologic changes associated with pregnancy and the potential for short- or long-term effects on the fetus and newborn. Thus, considerations that should be discussed with a pregnant HCW include the potential risk for HIV transmission based on the type of exposure; the stage of pregnancy (the first trimester being the period of maximal organogenesis and risk for teratogenesis); and what is known about the pharmacokinetics, safety, and tolerability of the drug or combination of drugs in pregnancy.

POSTEXPOSURE REGISTRIES

Health-care providers in the United States are encouraged to enroll HCWs who receive PEP in a confidential registry developed by CDC, Glaxo Wellcome Inc., and Merck & Co., Inc., to assess toxicity; telephone (888) 737-4448 ([888] PEP-4HIV), or write the HIV PEP Registry, 1410 Commonwealth Drive, Suite 215, Wilmington, NC 28405. Unusual or serious and unexpected toxicity from antiretroviral drugs should be reported to the manufacturer and/or FDA, telephone (800) 332-1088.

Health-care providers also should report instances of prenatal exposure to antiretroviral agents to the Antiretroviral Pregnancy Registry. The registry is an epidemiologic project to collect observational, nonexperimental data on antiretroviral drug exposure during pregnancy to assess potential teratogenicity. Referrals should be directed to the Antiretroviral Pregnancy Registry, 1410 Commonwealth Drive, Suite 215, Wilmington, NC 28405; telephone (800) 258-4263 or (800) 722-9292, ext. 39437; fax (800) 800-1052.

A protocol has been developed to evaluate HIV seroconversion in an HCW who received PEP. These events can be reported to CDC, telephone (404) 639-6425.

RESOURCES FOR CONSULTATION

Clinicians who seek consultation on HIV PEP for assistance in managing an occupational exposure should access local experts in HIV treatment as much as possible. In addition, the "National Clinicians' Post-Exposure Prophylaxis Hotline (PEP-Line)" has been created to assist clinicians with these issues; telephone (888) 448-4911. Other resources and registries include the HIV Postexposure Prophylaxis Registry, the Antiretroviral Pregnancy Registry, FDA, and CDC (Table 2).

TABLE 2. HIV postexposure prophylaxis resources and registries

Resource or registry	Contact information
National Clinicians' Postexposure Hotline	Telephone: (888) 448-4911
HIV Postexposure Prophylaxis Registry	Telephone: (888) 737-4448 ([888] PEP4HIV) Write: 1410 Commonwealth Drive Suite 215 Wilmington, NC 28405
Antiretroviral Pregnancy Registry	Telephone: (800) 258-4263 Fax: (800) 800-1052 Write: 1410 Commonwealth Drive Suite 215 Wilmington, NC 28405
Food and Drug Administration (for reporting unusual or severe toxicity to antiretroviral agents)	Telephone: (800) 332-1088
CDC (for reporting HIV seroconversions in health-care workers who received PEP)	Telephone: (404) 639-6425

ADMINISTRATIVE CONSIDERATIONS

Effective implementation of the elements of postexposure management detailed in these recommendations may require various types of expertise. The assessment of the severity of an exposure generally requires clinical training and experience (i.e., medical or nursing). However, the assessment of HIV infection risk and initiation of a basic PEP regimen necessitates knowledge or experience in clinical epidemiology, infection control, occupational health, or the clinical treatment of HIV. Decisions about HIV PEP are particularly complex if PIs are used or there is concern about drug-resistant virus. Thus, expert consultation when prescribing PEP is strongly encouraged. PEP protocols should list the names of readily available resources for consultation and could include policies that require infectious disease evaluation before prescribing an expanded antiretroviral regimen. However, these efforts should not delay initial implementation of PEP where it is appropriate.

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References

1. CDC. Public Health Service statement on management of occupational exposure to human immunodeficiency virus, including considerations regarding zidovudine postexposure use. *MMWR* 1990;39(no. RR-1).
2. CDC. Case-control study of HIV seroconversion in health-care workers after percutaneous exposure to HIV-infected blood—France, United Kingdom, and United States, January 1988–August 1994. *MMWR* 1995;44:929–33.
3. Connor EM, Sperling RS, Gelber R, et al. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. *N Engl J Med* 1994;331:1173–80.
4. Black RJ. Animal studies of prophylaxis. *Am J Med* 1997;102(suppl 5B):39–44.
5. Bell DM, Gerberding JL, eds. Human immunodeficiency virus (HIV) postexposure management of healthcare workers. *Am J Med* 1997;102(suppl 5B).
6. CDC. Update: provisional Public Health Service recommendations for chemoprophylaxis after occupational exposure to HIV. *MMWR* 1996;45:468–72.
7. Ippolito G, Puro V, the Italian Registry of Antiretroviral Prophylaxis. Zidovudine toxicity in uninfected healthcare workers. *Am J Med* 1997;102(suppl 5B):58–62.
8. Wang SA, the HIV PEP Registry Group. Human immunodeficiency virus (HIV) postexposure prophylaxis (PEP) following occupational HIV exposure: findings from the HIV PEP registry [Abstract 482]. In: Program and abstracts of the Infectious Diseases Society of America 35th annual meeting. Alexandria, VA: Infectious Diseases Society of America, 1997:161.
9. Steger KA, Swotinsky R, Snyder S, Craven DE. Recent experience with post-exposure prophylaxis (PEP) with combination antiretrovirals for occupational exposure (OE) to HIV [Abstract 480]. In: Program and abstracts of the Infectious Diseases Society of America 35th annual meeting. Alexandria, VA: Infectious Diseases Society of America, 1997:161.
10. Beekmann R, Fahrner R, Nelson L, Henderson DK, Gerberding JL. Combination post-exposure prophylaxis (PEP): a prospective study of HIV-exposed health care workers (HCW) [Abstract 481]. In: Program and abstracts of the Infectious Diseases Society of America 35th annual meeting. Alexandria, VA: Infectious Diseases Society of America, 1997:161.
11. CDC. Recommendations for prevention of HIV transmission in health-care settings. *MMWR* 1987;36(suppl no. 2S).
12. CDC. Update: universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. *MMWR* 1988;37:377–82,387–8.
13. CDC. Transmission of HIV possibly associated with exposure of mucous membrane to contaminated blood. *MMWR* 1997;46:620–3.

14. Garner JS, Hospital Infection Control Practices Advisory Committee. Guideline for isolation precautions in hospitals. *Infect Control Hosp Epidemiol* 1996;17:53-80.
15. Occupational Safety and Health Administration, Department of Labor. 29 CFR Part 1910.1030, occupational exposure to bloodborne pathogens; final rule. *Federal Register* 1991;56:64004-182.
16. Bell DM. Occupational risk of human immunodeficiency virus infection in healthcare workers: an overview. *Am J Med* 1997;102(suppl 5B):9-15.
17. Marcus R, Bell DM. Occupational risk of human immunodeficiency virus infection in health care workers. In: DeVita VT Jr, Hellman S, Rosenberg SA, eds. *AIDS: biology, diagnosis, treatment and prevention*. 4th ed. Philadelphia, PA: Lippincott-Raven Publishers, 1997:645-54.
18. Cardo DM, Bell DM. Postexposure management. In: DeVita VT Jr, Hellman S, Rosenberg SA, eds. *AIDS: biology, diagnosis, treatment and prevention*. 4th ed. Philadelphia, PA: Lippincott-Raven Publishers, 1997:701-8.
19. Ippolito G, Puro V, De Carli G, the Italian Study Group on Occupational Risk of HIV Infection. The risk of occupational human immunodeficiency virus infection in health care workers. *Arch Intern Med* 1993;153:1451-8.
20. CDC. Update: human immunodeficiency virus infections in health-care workers exposed to blood of infected patients. *MMWR* 1987;36:285-9.
21. Fahey BJ, Koziol DE, Banks SM, Henderson DK. Frequency of nonparenteral occupational exposures to blood and body fluids before and after universal precautions training. *Am J Med* 1991;90:145-53.
22. CDC. HIV/AIDS surveillance report 1997;9:15.
23. Cardo DM, Culver DH, Ciesielski CA, et al. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. *N Engl J Med* 1997;337:1485-90.
24. Mast ST, Woolwine JD, Gerberding JL. Efficacy of gloves in reducing blood volumes transferred during simulated needlestick injury. *J Infect Dis* 1993;168:1589-92.
25. Cao Y, Krogstad P, Korber BT, et al. Maternal HIV-1 viral load and vertical transmission of infection: the Ariel Project for the Prevention of HIV transmission from mother to infant. *Nature Med* 1997;3:549-52.
26. Sperling RS, Shapiro DE, Coombs RW, et al. Maternal viral load, zidovudine treatment, and the risk of transmission of human immunodeficiency virus type 1 from mother to infant. *N Engl J Med* 1996;335:1621-9.
27. Pinto LA, Landay AL, Berzofsky JA, Kessler HA, Shearer GM. Immune response to human immunodeficiency virus (HIV) in healthcare workers occupationally exposed to HIV-contaminated blood. *Am J Med* 1997;102(suppl 5B):21-4.
28. Clerici M, Giorgi JV, Chou C-C, et al. Cell-mediated immune response to human immunodeficiency virus (HIV) type 1 in seronegative homosexual men with recent sexual exposure to HIV-1. *J Infect Dis* 1992;165:1012-9.
29. Ranki A, Mattinen S, Yarchoan R, et al. T-cell response towards HIV in infected individuals with and without zidovudine therapy, and in HIV-exposed sexual partners. *AIDS* 1989;3:63-9.
30. Cheynier R, Langlade-Demoyen P, Marescot M-R, et al. Cytotoxic T lymphocyte responses in the peripheral blood of children born to human immunodeficiency virus-1-infected mothers. *Eur J Immunol* 1992;22:2211-7.
31. Kelker HC, Seidlin M, Vogler M, Valentine FT. Lymphocytes from some long-term seronegative heterosexual partners of HIV-infected individuals proliferate in response to HIV antigens. *AIDS Res Hum Retroviruses* 1992;8:1355-9.
32. Langlade-Demoyen P, Ngo-Giang-Huong N, Ferchal F, Oksenhendler E. Human immunodeficiency virus (HIV) *nef*-specific cytotoxic T lymphocytes in noninfected heterosexual contacts of HIV-infected patients. *J Clin Invest* 1994;93:1293-7.
33. Rowland-Jones S, Sutton J, Ariyoshi K, et al. HIV-specific cytotoxic T-cells in HIV-exposed but uninfected Gambian women. *Nature Medicine* 1995;1:59-64.
34. Busch MP, Satten GA. Time course of viremia and antibody seroconversion following human immunodeficiency virus exposure. *Am J Med* 1997;102(suppl 5B):117-24.
35. Saag MS. Clinical spectrum of human immunodeficiency virus diseases. In: DeVita VT Jr, Hellman S, Rosenberg SA, eds. *AIDS: biology, diagnosis, treatment and prevention*. 4th ed. Philadelphia, PA: Lippincott-Raven Publishers, 1997:203-13.

36. Ciesielski CA, Metler RP. Duration of time between exposure and seroconversion in healthcare workers with occupationally acquired infection with human immunodeficiency virus. *Am J Med* 1997;102(suppl 5B):115-6.
37. Ridzon R, Gallagher K, Ciesielski C, et al. Simultaneous transmission of human immunodeficiency virus and hepatitis C virus from a needle-stick injury. *N Engl J Med* 1997;336:919-22.
38. Blauvelt A. The role of skin dendritic cells in the initiation of human immunodeficiency virus infection. *Am J Med* 1997;102(suppl 5B):16-20.
39. Spira AI, Marx PA, Patterson BK, et al. Cellular targets of infection and route of viral dissemination after an intravaginal inoculation of simian immunodeficiency virus into rhesus macaques. *J Exp Med* 1996;183:215-25.
40. Saag MS. Candidate antiretroviral agents for use in postexposure prophylaxis. *Am J Med* 1997;102(suppl 5B):25-31.
41. Van Rompay KKA, Otsyula MG, Marthas ML, Miller CJ, McChesney MB, Pedersen NC. Immediate zidovudine treatment protects simian immunodeficiency virus-infected newborn macaques against rapid onset of AIDS. *Antimicrob Agents and Chemother* 1995;39:125-31.
42. Shih C-C, Kaneshima H, Rabin L, et al. Postexposure prophylaxis with zidovudine suppresses human immunodeficiency virus type 1 infection in SCID-hu mice in a time-dependent manner. *J Infect Dis* 1991;163:625-7.
43. Martin LN, Murphey-Corb M, Soike KF, Davison-Fairburn B, Baskin GB. Effects of initiation of 3'-azido,3'-deoxythymidine (zidovudine) treatment at different times after infection of rhesus monkeys with simian immunodeficiency virus. *J Infect Dis* 1993;168:825-35.
44. Hayes KA, Lafrado LJ, Erickson JG, Marr JM, Mathes LE. Prophylactic ZDV therapy prevents early viremia and lymphocyte decline but not primary infection in feline immunodeficiency virus-inoculated cats. *J AIDS* 1993;6:127-34.
45. Mathes LE, Polas PJ, Hayes KA, Swenson CL, Johnson S, Kociba GJ. Pre- and postexposure chemoprophylaxis: evidence that 3'-azido-3'-dideoxythymidine inhibits feline leukemia virus disease by a drug-induced vaccine response. *Antimicrob Agents and Chemother* 1992;36:2715-21.
46. Rausch DM, Heyes MP, Murray EA, Eiden LE. Zidovudine treatment prolongs survival and decreases virus load in the central nervous system of rhesus macaques infected perinatally with simian immunodeficiency virus. *J Infect Dis* 1995;172:59-69.
47. Sinet M, Desforges B, Launay O, Colin JN, Pocard JJ. Factors influencing zidovudine efficacy when administered at early stages of Friend virus infection in mice. *Antiviral Res* 1991;16:163-71.
48. Ruprecht RM, Bronson R. Chemoprevention of retroviral infection: success is determined by virus inoculum and strength and cellular immunity. *DNA & Cell Biol* 1994;13:59-66.
49. Ruprecht RM, Mullaney S, Bernard LD, Gama Sosa MA, Hom RC, Finberg RW. Vaccination with a live retrovirus: the nature of the protective immune response. *Proc Natl Acad Sci U S A* 1990;87:5558-62.
50. Tavares L, Roneker C, Johnston K, Nusinoff Lehrman S, de Noronha F. 3'-azido-3'-deoxythymidine in feline leukemia virus-infected cats: a model for therapy and prophylaxis of AIDS. *Cancer Res* 1987;47:3190-4.
51. Ruprecht RM, Chou, T-C, Chipty F, et al. Interferon- and 3'-azido-3'-deoxythymidine are highly synergistic in mice and prevent viremia after acute retrovirus exposure. *J AIDS* 1990;3:591-600.
52. Van Rompay KKA, Marthas ML, Ramos RA, et al. Simian immunodeficiency virus (SIV) infection of infant rhesus macaques as a model to test antiretroviral drug prophylaxis and therapy: oral 3'-azido-3'-deoxythymidine prevents SIV infection. *Antimicrob Agents and Chemother* 1992;36:2381-6.
53. Fazely F, Haseltine WA, Rodger RF, Ruprecht RM. Postexposure chemoprophylaxis with ZDV or ZDV combined with interferon- α : failure after inoculating rhesus monkeys with a high dose of SIV. *J AIDS* 1991;4:1093-7.
54. McClure HM, Anderson DC, Ansari AA, Fultz PN, Klumpp SA, Schinazi RF. Nonhuman primate models for evaluation of AIDS therapy. In: *AIDS: anti-HIV agents, therapies and vaccines*. *Ann N Y Acad Sci* 1990;100:616:287-98.
55. Tsai C-C, Follis KE, Sabo A, et al. Prevention of SIV infection in macaques by (*R*)-9-(2-phosphonylmethoxypropyl)adenine. *Science* 1995;270:1197-9.

56. Böttiger D, Johansson N-G, Samuelsson B, et al. Prevention of simian immunodeficiency virus, SIV_{sm}, or HIV-2 infection in cynomolgus monkeys by pre- and postexposure administration of BEA-005. *AIDS* 1997;11:157-62.
57. Niu MT, Stein DS, Schnittman SM. Primary human immunodeficiency virus type 1 infection: review of pathogenesis and early treatment intervention in humans and animal retrovirus infections. *J Infect Dis* 1993;168:1490-501.
58. Lundgren B, Böttiger D, Ljungdahl-Ståhle E, et al. Antiviral effects of 3'-fluorothymidine and 3'-azidothymidine in cynomolgus monkeys infected with simian immunodeficiency virus. *J AIDS* 1991;4:489-98.
59. Böttiger D, Putkonen P, Oberg B. Prevention of HIV-2 and SIV infections in cynomolgus macaques by prophylactic treatment with 3'-fluorothymidine. *AIDS Res Human Retroviruses* 1992;8:1235-8.
60. Böttiger D, Oberg B. Influence of the infectious dose of SIV on the acute infection in cynomolgus monkeys and on the effect of treatment with 3'-fluorothymidine [Abstract no. 81]. Symposium on Nonhuman Primate Models for AIDS, 1991.
61. LaFon SW, Mooney BD, McMullen JP, et al. A double-blind, placebo-controlled study of the safety and efficacy of Retrovir[®] (zidovudine, ZDV) as a chemoprophylactic agent in health care workers (HCW) exposed to HIV [Abstract 489]. In: Program and abstracts, 30th Interscience Conference on Antimicrobial Agents and Chemotherapy. Washington, DC: American Society for Microbiology, 1990:167.
62. Jochimsen EM. Failures of zidovudine postexposure prophylaxis. *Am J Med* 1997;102(suppl 5B):52-5.
63. Weisburd G, Biglione J, Arbulu MM, Terrazzino JC, Pesiri A. HIV seroconversion after a work place accident and treated with zidovudine [Abstract Pub.C.1141] In: Program and abstracts of the XI International Conference on AIDS. Vancouver, British Columbia, Canada, June 1996:460.
64. Lot F, Abiteboul D. Health-care workers infected with HIV in France: as of June 30, 1995. *Bulletin Epidemiologique Hebdomadaire* 1995;44:193-4.
65. Mayers DL. Prevalence and incidence of resistance to zidovudine and other antiretroviral drugs. *Am J Med* 1997;102(suppl 5B):70-5.
66. Coombs RW, Shapiro DE, Eastman PS, et al. Maternal viral genotypic zidovudine (ZDV) resistance and infrequent failure of ZDV therapy to prevent perinatal transmission [Abstract 17]. In: Program and abstracts of the Infectious Disease Society of America 35th annual meeting. Alexandria, VA: Infectious Disease Society of America, 1997:74.
67. Manion DJ, Hirsch MS. Combination chemotherapy for human immunodeficiency virus-1. *Am J Med* 1997;102(suppl 5B):76-80.
68. Lafeuillade A, Poggi C, Tamalet C, Profizi N, Tourres C, Costes O. Effects of a combination of zidovudine, didanosine, and lamivudine on primary human immunodeficiency virus type 1 infection. *J Infect Dis* 1997;175:1051-5.
69. CDC. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. *MMWR* 1997;46(no. RR-5):43-82.
70. Katlama C, Ingrand D, Loveday C, et al. Safety and efficacy of lamivudine-zidovudine combination therapy in antiretroviral naive patients: a randomized controlled comparison with zidovudine monotherapy. *JAMA* 1996;276:118-25.
71. Larder BA. Viral resistance and the selection of antiretroviral combinations. *J AIDS* 1995;10(suppl 1):S28-S33.
72. Anonymous. New drugs for HIV infection. *The Medical Letter on Drugs and Therapeutics* 1996;38:35-7.
73. Grob PM, Cao Y, Muchmore E, et al. Prophylaxis against HIV-1 infection in chimpanzees by nevirapine, a nonnucleoside inhibitor of reverse transcriptase. *Nature Medicine* 1997;3:665-70.
74. Struble KA, Pratt RD, Gitterman SR. Toxicity of antiretroviral agents. *Am J Med* 1997;102(suppl 5B):65-7.
75. Food and Drug Administration. Protease inhibitors may increase blood glucose in HIV patients. *FDA Medical Bulletin* 1997:27.
76. Dever LL, Oruwari PA, O'Donovan CA, Eng RHK. Hyperglycemia associated with protease inhibitors in HIV-infected patients [Abstract LB-8]. In: Abstracts of the 37th Interscience Con-

- ference on Antimicrobial Agents and Chemotherapy. Washington, DC: American Society for Microbiology, 1997.
77. Dubé MP, Johnson DL, Currier JS, Leedom JM. Protease inhibitor-associated hyperglycaemia [Letter]. *Lancet* 1997;350:713-4.
 78. Tokars JI, Marcus R, Culver DH, et al. Surveillance of HIV infection and zidovudine use among health care workers after occupational exposure to HIV-infected blood. *Ann Intern Med* 1993;118:913-9.
 79. Forseter G, Joline C, Wormser GP. Tolerability, safety, and acceptability of zidovudine prophylaxis in health care workers. *Arch Intern Med* 1994;154:2745-9.
 80. Henry K, Acosta EP, Jochimsen E. Hepatotoxicity and rash associated with zidovudine and zalcitabine chemoprophylaxis [Letter]. *Ann Intern Med* 1996;124:855.
 81. Imrie A, Beveridge A, Genn W, Vizzard J, Cooper DA, the Sydney Primary HIV Infection Study Group. Transmission of human immunodeficiency virus type 1 resistant to nevirapine and zidovudine. *J Infect Dis* 1997;175:1502-6.
 82. Veenstra J, Schuurman R, Cornelissen M, et al. Transmission of zidovudine-resistant human immunodeficiency virus type 1 variants following deliberate injection of blood from a patient with AIDS: characteristics and natural history of the virus. *Clin Infect Dis* 1995;21:556-60.
 83. Erice A, Mayers DL, Strike DG, et al. Brief report: primary infection with zidovudine-resistant human immunodeficiency virus type 1. *N Engl J Med* 1993;328:1163-5.
 84. Fitzgibbon JE, Gaur S, Frenkel LD, et al. Transmission from one child to another of human immunodeficiency virus type 1 with a zidovudine-resistance mutation. *N Engl J Med* 1993;329:1835-41.
 85. Frenkel LM, Wagner LE, Demeter LM, et al. Effects of zidovudine use during pregnancy on resistance and vertical transmission of human immunodeficiency virus type 1. *Clin Infect Dis* 1995;20:1321-6.
 86. CDC. Public Health Service task force recommendations for the use of antiretroviral drugs in pregnant women infected with HIV-1 for maternal health and for reducing perinatal HIV-1 transmission in the United States. *MMWR* 1998;47(no. RR-2).
 87. O'Sullivan MJ, Boyer PJJ, Scott GB, et al. The pharmacokinetics and safety of zidovudine in the third trimester of pregnancy for women infected with human immunodeficiency virus and their infants: Phase I Acquired Immunodeficiency Syndrome Clinical Trials Group Study (protocol 082). *Am J Obstet Gynecol* 1993;168:1510-6.
 88. CDC. Birth outcomes following zidovudine therapy in pregnant women. *MMWR* 1994;43:409,415-6.
 89. White A, Eldridge R, Andrews E, the Antiretroviral Pregnancy Registry Advisory Committee. Birth outcomes following zidovudine exposure in pregnant women: the Antiretroviral Pregnancy Registry. *Acta Paediatr Suppl* 1997;421:86-8.
 90. Culnane M, Fowler MG, Lee S, et al. Evaluation for late effects of in utero (IU) ZDV exposure among uninfected infants born to HIV+ women enrolled in ACTG 076 and 219 [Abstract 485]. *Clin Infect Dis* 1997;25:445.
 91. Anonymous. Antiretroviral Pregnancy Registry for didanosine (VIDEX[®], ddI), lamivudine (EPIVIR[™], 3tc), saquinavir (INVIRASE[®], SAQ), stavudine (ZERIT[®], d4T), zalcitabine (HIVID[®], ddC), zidovudine (RETROVIR[®], ZDV), interim report, 1 January 1989 through 31 December 1996. Research Triangle Park, NC: Bristol Myers Squibb Co., Glaxo Wellcome, Hoffman-LaRoche, and Merck Inc., 1997.
 92. Johnson MA, Goodwin C, Yuen GJ, et al. The pharmacokinetics of 3TC administered to HIV-1 infected women (pre-partum, during labour and post-partum) and their offspring [Abstract Tu.C.445]. In: Proceedings from the XI International Conference on AIDS, Vancouver, British Columbia, Canada; July 7-12, 1996; vol I:249-50.
 93. Moodley J, Moodley D, Pillay K, et al. Antiviral effect of lamivudine alone and in combination with zidovudine in HIV-infected pregnant women [Abstract 607]. In: Abstracts of the 4th Conference on Retroviruses and Opportunistic Infections. Washington D.C.: January 22-26, 1997:176.
 94. Ayers KM, Clive D, Tucker WE Jr., Hajian G, de Miranda P. Nonclinical toxicology studies with zidovudine: genetic toxicity tests and carcinogenicity bioassays in mice and rats. *Fundamental Appl Toxicol* 1996;32:148-58.

95. Ayers KM, Torrey CE, Reynolds DJ. A transplacental carcinogenicity bioassay in CD-1 mice with zidovudine. *Fundamental Appl Toxicol* 1997;38:195-8.
96. Olivero OA, Anderson LM, Diwan BA, et al. AZT is a genomic transplacental carcinogen in animal models. *J AIDS* 1997;14:A29 (Abstract 52).
97. National Institute for Allergy and Infectious Diseases, National Institutes of Health. Summary of the meeting of a panel to review studies of transplacental toxicity of AZT. Washington, DC: National Institutes of Health, 1997.
98. CDC. Immunization of health-care workers—recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). *MMWR* 1997;46(no. RR-18):21-2.
99. CDC. Recommendations for follow-up of health-care workers after occupational exposure to hepatitis C virus. *MMWR* 1997;46:603-6.
100. Richman KM, Rickman LS. The potential for transmission of human immunodeficiency virus through human bites. *J AIDS* 1993;6:402-6.
101. Vidmar L, Poljak M, Tomai J, Seme K, Klavs I. Transmission of HIV-1 by human bite [Letter]. *Lancet* 1996;347:1762.
102. Gerberding JL, Henderson DK. Management of occupational exposures to bloodborne pathogens: hepatitis B virus, hepatitis C virus, and human immunodeficiency virus. *Clin Infect Dis* 1992;14:1179-85.
103. Armstrong K, Gorden R, Santorella G. Occupational exposure of health care workers (HCWs) to human immunodeficiency virus (HIV): stress reactions and counseling interventions. *Social Work in Health Care* 1995;21(3):61-80.
104. CDC. Recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures. *MMWR* 1991;40(no. RR-8).

Appendix

FIRST-LINE DRUGS FOR HIV POSTEXPOSURE PROPHYLAXIS (PEP)*

Nucleoside Reverse Transcriptase Inhibitors

Zidovudine (RETROVIR[®] ; ZDV, AZT)

Dosage

600 mg every day in divided doses (e.g., 300 mg twice a day, 200 mg three times a day, or 100 mg every four hours).

Primary toxicities and/or side effects

Neutropenia, anemia, nausea, fatigue, malaise, headache, insomnia, and asthenia.

Comments

Caution should be used if co-administered with bone marrow suppressive drugs or cytotoxic therapy.

Lamivudine (EPIVIR[™] ; 3TC)

Dosage

150 mg twice a day.

Primary toxicities and/or side effects

Headache, abdominal pain, diarrhea, and in rare cases, pancreatitis. Toxicity of ZDV and 3TC when used in combination is approximately equal to that of ZDV alone.

ZDV plus 3TC (COMBIVIR[™])

Dosage

1 tablet twice a day; each tablet contains 300 mg ZDV and 150 mg 3TC.

Primary toxicities and/or side effects

See above for ZDV and 3TC.

Comments

Caution should be used if co-administered with bone marrow suppressive drugs or cytotoxic therapy.

*Information included in these recommendations may not represent Food and Drug Administration (FDA) approval or approved labeling for the particular products or indications in question. Specifically, the terms "safe" and "effective" may not be synonymous with the FDA-defined legal standards for product approval.

Protease Inhibitors (PIs)*

Indinavir (CRIXIVAN[®]; IDV)

Dosage

800 mg every 8 hours on an empty stomach (i.e., without food or with a light meal).

Primary toxicities and/or side effects

Nephrolithiasis, crystalluria, hematuria, nausea, headache, indirect hyperbilirubinemia, elevated liver function tests (LFTs), and hyperglycemia/diabetes.

Primary drug interactions[†]

No PI should be co-administered with terfenadine (Seldane[®]), astemizole (Hismanal[®]), cisapride (Propulsid[®]), triazolam, and midazolam. Rifampin should not be administered with PIs. Cytochrome P450 metabolism inhibitors like ketoconazole may increase PI plasma concentrations; dose reduction of the PI is only indicated for indinavir. Ergot alkaloid preparations should not be used in combination with PIs. If rifabutin is used concomitantly, rifabutin dose should be reduced because of inhibition of rifabutin metabolism; with concomitant indinavir or nelfinavir use, reduce rifabutin dose by 50%.

Serum levels of PIs may be increased when multiple PIs are used in combination.

Comments

Incidence of nephrolithiasis may be reduced by consuming large quantities of water (i.e., drinking six 8 oz glasses of water [total 48 oz] throughout the day).

Nelfinavir (VIRACEPT[™])

Dosage

750 mg three times a day (with meals or a light snack).

Primary toxicities and/or side effects

Diarrhea and hyperglycemia/diabetes.

Primary drug interactions[†]

See above for indinavir.

Comments

Diarrhea usually can be controlled with over-the-counter antidiarrheal drugs (e.g., loperamide).

If oral contraceptives are being used, alternative or additional contraceptive measures should be used while taking nelfinavir.

*It is recommended that consultation with experts in the treatment of HIV infection and disease be sought when considering the inclusion of PIs or the use of alternative agents in PEP regimens.

[†]See package insert for other contraindications and possible drug interactions.

ANTIRETROVIRAL DRUGS USED FOR TREATMENT OF HIV INFECTION THAT MAY BE CONSIDERED FOR PEP IN SPECIAL CIRCUMSTANCES

Nucleoside Reverse Transcriptase Inhibitors

Zalcitabine (HIVID[®], ddC)

Dosage

0.75 mg every 8 hours.

Primary toxicities and/or side effects

Stomatitis and peripheral neuropathy.

Primary drug interactions*

Do not co-administer ddC with didanosine or stavudine because of the potential for enhanced peripheral neuropathy.

Comments

Peripheral neuropathy from ddC is usually after prolonged exposure.

Didanosine (VIDEX[®], ddl)

Dosage

200 mg twice a day; if body weight is <60 kg, 125 mg twice a day. Should be taken on an empty stomach.

Primary toxicities and/or side effects

Pancreatitis, peripheral neuropathy, nausea, and diarrhea.

Primary drug interactions*

Do not co-administer ddl with ddC because of the potential for enhanced peripheral neuropathy.

Comments

Peripheral neuropathy from ddl is usually after prolonged exposure.

To avoid potential drug interactions, give concomitant medications 2 hours after ddl dosing.

Stavudine (ZERIT[™], d4T)

Dosage

40 mg twice a day; if body weight is <60 kg, 30 mg twice a day.

Primary toxicities and/or side effects

Peripheral neuropathy.

Primary drug interactions*

Do not co-administer d4T with ddC because of the potential for enhanced peripheral neuropathy.

Comments

Peripheral neuropathy from d4T is usually after prolonged exposure.

*See package insert for other contraindications and possible drug interactions.

Protease Inhibitors (PIs)*

Ritonavir (NORVIR™)

Dosage

600 mg twice a day; dose escalation recommended (300 mg twice a day for 1 day, 400 mg twice a day for 2 days, 500 mg twice a day for 1 day, then 600 mg twice a day for duration of regimen).

Primary toxicities and/or side effects

Nausea, emesis, diarrhea, circumoral paresthesia, taste alteration, increased cholesterol and triglycerides, hyperglycemia/diabetes, and increased LFTs.

Primary drug interactions†

No PI should be co-administered with terfenadine (Seldane®), astemizole (Hismanal®), cisapride (Propulsid®), triazolam, or midazolam. Rifampin should not be administered with PIs. Cytochrome P450 metabolism inhibitors such as ketoconazole may increase protease inhibitor plasma concentrations. Ergot alkaloid preparations should not be used in combination with PIs. Rifabutin should not be co-administered with either saquinavir (because of reduction of saquinavir serum concentrations) or ritonavir (because of increased rifabutin concentrations).

Serum levels of PIs may be increased when multiple PIs are used in combination.

Comments

Ritonavir should not be used with various antiarrhythmics and certain sedatives or hypnotics. Ritonavir also has potential interactions with certain analgesics, antibiotics, antidepressants, anti-emetics, antifungals, calcium channel blockers, and other medications.

If oral contraceptives are being used, alternative or additional contraceptive measures should be used while taking ritonavir.

Saquinavir (INVIRASE™, hard-gel formulation) (FORTOVASE™, soft-gel formulation)

Dosage

INVIRASE, 600 mg three times a day with fatty meals; FORTOVASE, 1200 mg three times a day within 2 hours of a meal. (If saquinavir is used for PEP, Fortovase should be used.)

Primary toxicities and/or side effects

Diarrhea, headache, hyperglycemia/diabetes, and increased LFTs and triglycerides.

Primary drug interactions†

See above for ritonavir.

*It is recommended that consultation with experts in the treatment of HIV infection and disease be sought when considering the inclusion of PIs or the use of alternative agents in PEP regimens.

†See package insert for other contraindications and possible drug interactions.

Non-nucleoside Reverse Transcriptase Inhibitors

Nevirapine (VIRAMUNE®)

Dosage

200 mg once a day for the first 2 weeks then 200 mg twice a day.

Primary toxicities and/or side effects

Rash (including rare cases of Stevens-Johnson syndrome), fever, nausea, headache, and increased LFTs.

Primary drug interactions*

Nevirapine induces hepatic cytochrome CYP3A isoforms; however, drug interaction studies with drugs metabolized by this enzyme have not been conducted. Careful monitoring is therefore recommended if nevirapine is co-administered with other drugs metabolized by this route because decreased serum concentrations (and decreased effectiveness) of the other drugs may be observed (e.g., oral contraceptives, rifampin, and rifabutin). Use of nevirapine may decrease levels of indinavir or saquinavir.

This drug should only be used in combination with other antiretroviral drugs.

Comments

Oral contraceptives may be less effective during concomitant use with nevirapine.

Delavirdine (RESCRIPTOR®)

Dosage

400 mg three times a day

Primary toxicities and/or side effects

Rash (including rare cases of Stevens-Johnson syndrome), nausea, and increased LFTs.

Primary drug interactions*

Delavirdine inhibits hepatic cytochrome CYP3A isoforms. Should not be co-administered with terfenadine (Seldane®), astemizole (Hismanal®), cisapride (Propulsid®), triazolam, midazolam, nifedipine, anticonvulsants, amphetamines, rifabutin, or rifampin. Delavirdine may increase PI levels.

This drug should only be used in combination with other antiretroviral drugs.

Comments

Antacids and ddl decrease absorption of delavirdine and should be taken 2 hours apart.

*See package insert for other contraindications and possible drug interactions.

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APPENDIX F

RECOMMENDATIONS FOR PREVENTION AND CONTROL

This appendix lists the URLs for the Centers for Disease Control *Morbidity and Mortality Weekly Report*: “Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease.” October 16, 1998/Vol.47/No. RR-19. The Adobe Acrobat pdf version contains the text of the report. The CDC has the text of this report available on their website.. The URLs are:

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*Recommendations
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Inside: Continuing Medical Education for U.S. Physicians

**Recommendations for Prevention and
Control of Hepatitis C Virus (HCV)
Infection and HCV-Related
Chronic Disease**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)
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Terms and Abbreviations Used in This Publication

Acute hepatitis C	Newly acquired symptomatic hepatitis C virus (HCV) infection.
ALT	Alanine aminotransferase.
Anti-HCV	Antibody to HCV that develops in response to HCV infection; detectable in persons with acute, chronic, and resolved infection.
AST	Aspartate aminotransferase.
Chronic (persistent) HCV infection	Persistent infection with HCV; characterized by detection of HCV RNA ≥ 6 months after newly acquired infection.
Chronic hepatitis C	Liver inflammation in patients with chronic HCV infection; characterized by abnormal levels of liver enzymes.
CSTE	Council of State and Territorial Epidemiologists.
DNA	Deoxyribonucleic acid.
EIA	Enzyme immunoassay.
FDA	U.S. Food and Drug Administration.
HBV	Hepatitis B virus.
HCC	Hepatocellular carcinoma.
HCV	Hepatitis C virus.
HCV-positive	Positive for anti-HCV as verified by supplemental testing or positive for HCV RNA.
HCV RNA	Hepatitis C virus ribonucleic acid.
HIV	Human immunodeficiency virus.
IG	Immune globulin.
IM	Intramuscular.
IV	Intravenous.
MSM	Men who have sex with men.
NHANES III	Third National Health and Nutrition Examination Survey.
NIH	National Institutes of Health.
Positive predictive value	Probability that a positive screening test is truly positive; dependent on prevalence of disease in a population.
Qualitative RT-PCR for HCV RNA	Test to detect HCV RNA by amplification of viral genetic sequences.
Quantitative assays for HCV RNA	Tests to detect HCV RNA concentration (viral load) by amplification of viral genetic sequences or by signal amplification.
Resolved HCV infection	Recovery following hepatitis C virus infection; characterized by sustained disappearance of serum HCV RNA and normalization of liver enzymes.
RIBA™	Recombinant immunoblot assay.
RNA	Ribonucleic acid.
RT-PCR	Reverse transcriptase polymerase chain reaction.
STD	Sexually transmitted disease.
Supplemental anti-HCV test	Additional test (i.e., RIBA™) used to verify a positive anti-HCV result obtained by EIA.

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Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease

Summary

These recommendations are an expansion of previous recommendations for the prevention of hepatitis C virus (HCV) infection that focused on screening and follow-up of blood, plasma, organ, tissue, and semen donors (CDC. Public Health Service inter-agency guidelines for screening donors of blood, plasma, organs, tissues, and semen for evidence of hepatitis B and hepatitis C. MMWR 1991;40[No. RR-4];1-17). The recommendations in this report provide broader guidelines for a) preventing transmission of HCV; b) identifying, counseling, and testing persons at risk for HCV infection; and c) providing appropriate medical evaluation and management of HCV-infected persons. Based on currently available knowledge, these recommendations were developed by CDC staff members after consultation with experts who met in Atlanta during July 15–17, 1998. This report is intended to serve as a resource for health-care professionals, public health officials, and organizations involved in the development, delivery, and evaluation of prevention and clinical services.

INTRODUCTION

Hepatitis C virus (HCV) infection is the most common chronic bloodborne infection in the United States. CDC staff estimate that during the 1980s, an average of 230,000 new infections occurred each year (*CDC, unpublished data*). Although since 1989 the annual number of new infections has declined by >80% to 36,000 by 1996 (1,2), data from the Third National Health and Nutrition Examination Survey (NHANES III), conducted during 1988–1994, have indicated that an estimated 3.9 million (1.8%) Americans have been infected with HCV (3). Most of these persons are chronically infected and might not be aware of their infection because they are not clinically ill. Infected persons serve as a source of transmission to others and are at risk for chronic liver disease or other HCV-related chronic diseases during the first two or more decades following initial infection.

Chronic liver disease is the tenth leading cause of death among adults in the United States, and accounts for approximately 25,000 deaths annually, or approximately 1% of all deaths (4). Population-based studies indicate that 40% of chronic liver disease is HCV-related, resulting in an estimated 8,000–10,000 deaths each year (*CDC, unpublished data*). Current estimates of medical and work-loss costs of HCV-related acute and chronic liver disease are >\$600 million annually (*CDC, unpublished data*), and HCV-associated end-stage liver disease is the most frequent indication for liver transplantation among adults. Because most HCV-infected persons are aged 30–49 years (3), the number of deaths attributable to HCV-related chronic liver disease could increase substantially during the next 10–20 years as this group of infected persons reaches ages at which complications from chronic liver disease typically occur.

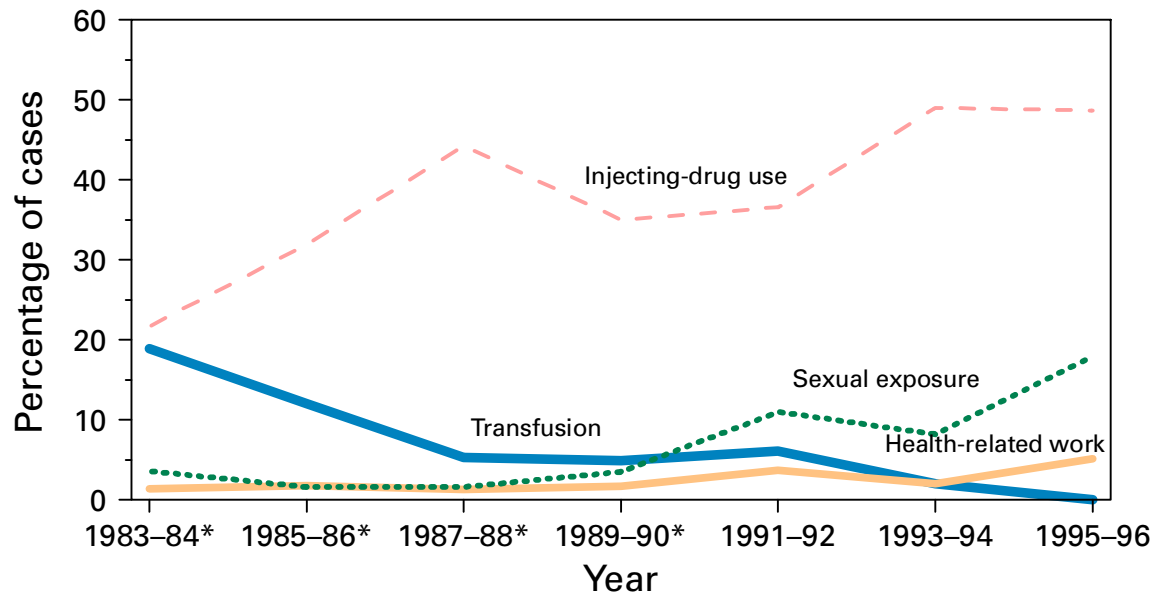
HCV is transmitted primarily through large or repeated direct percutaneous exposures to blood. In the United States, the relative importance of the two most common

exposures associated with transmission of HCV, blood transfusion and injecting-drug use, has changed over time (Figure 1) (2,5). Blood transfusion, which accounted for a substantial proportion of HCV infections acquired >10 years ago, rarely accounts for recently acquired infections. Since 1994, risk for transfusion-transmitted HCV infection has been so low that CDC's sentinel counties viral hepatitis surveillance system* has been unable to detect any transfusion-associated cases of acute hepatitis C, although the risk is not zero. In contrast, injecting-drug use consistently has accounted for a substantial proportion of HCV infections and currently accounts for 60% of HCV transmission in the United States. A high proportion of infections continues to be associated with injecting-drug use, but for reasons that are unclear, the dramatic decline in incidence of acute hepatitis C since 1989 correlates with a decrease in cases among injecting-drug users.

Reducing the burden of HCV infection and HCV-related disease in the United States requires implementation of primary prevention activities to reduce the risk for contracting HCV infection and secondary prevention activities to reduce the risk for liver and other chronic diseases in HCV-infected persons. The recommendations contained in this report were developed by reviewing currently available data and are based on the opinions of experts. These recommendations provide broad guidelines for a) the

*Sentinel counties viral hepatitis surveillance system identifies all persons with symptomatic acute viral hepatitis reported through stimulated passive surveillance to the participating county health departments (four during 1982–1995 and six during 1996–1998). These counties are demographically representative of the U.S. population. Serum samples from reported cases are tested for all viral hepatitis markers, and case-patients are interviewed extensively for risk factors for infection.

FIGURE 1. Reported cases of acute hepatitis C by selected risk factors — United States, 1983–1996



*Data presented for non-A, non-B hepatitis.
Source: Centers for Disease Control and Prevention.

prevention of transmission of HCV; b) the identification, counseling, and testing of persons at risk for HCV infection; and c) the appropriate medical evaluation and management of HCV-infected persons.

BACKGROUND

Prospective studies of transfusion recipients in the United States demonstrated that rates of posttransfusion hepatitis in the 1960s exceeded 20% (6). In the mid-1970s, available diagnostic tests indicated that 90% of posttransfusion hepatitis was not caused by hepatitis A or hepatitis B viruses and that the move to all-volunteer blood donors had reduced risks for posttransfusion hepatitis to 10% (7–9). Although non-A, non-B hepatitis (i.e., neither type A nor type B) was first recognized because of its association with blood transfusion, population-based sentinel surveillance demonstrated that this disease accounted for 15%–20% of community-acquired viral hepatitis in the United States (5). Discovery of HCV by molecular cloning in 1988 indicated that non-A, non-B hepatitis was primarily caused by HCV infection (5,10–14).

Epidemiology

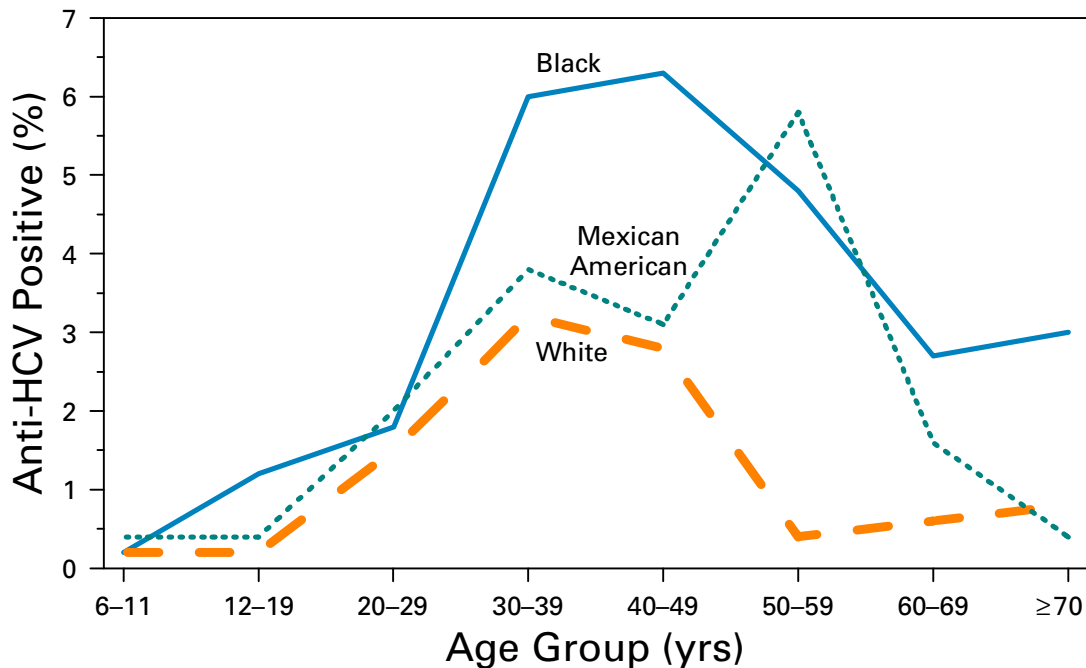
Demographic Characteristics

HCV infection occurs among persons of all ages, but the highest incidence of acute hepatitis C is found among persons aged 20–39 years, and males predominate slightly (5). African Americans and whites have similar incidence of acute disease; persons of Hispanic ethnicity have higher rates. In the general population, the highest prevalence rates of HCV infection are found among persons aged 30–49 years and among males (3). Unlike the racial/ethnic pattern of acute disease, African Americans have a substantially higher prevalence of HCV infection than do whites (Figure 2).

Prevalence of HCV Infection in Selected Populations in the United States

The greatest variation in prevalence of HCV infection occurs among persons with different risk factors for infection (15) (Table 1). Highest prevalence of infection is found among those with large or repeated direct percutaneous exposures to blood (e.g., injecting-drug users, persons with hemophilia who were treated with clotting factor concentrates produced before 1987, and recipients of transfusions from HCV-positive donors) (12,13,16–22). Moderate prevalence is found among those with frequent but smaller direct percutaneous exposures (e.g., long-term hemodialysis patients) (23). Lower prevalence is found among those with inapparent percutaneous or mucosal exposures (e.g., persons with evidence of high-risk sexual practices) (24–28) or among those with small, sporadic percutaneous exposures (e.g., health-care workers) (29–33). Lowest prevalence of HCV infection is found among those with no high-risk characteristics (e.g., volunteer blood donors) (34; *personal communication, RY Dodd, Ph.D., Head, Transmissible Diseases Department, Holland Laboratory, American Red Cross, Rockville, MD, July 1998*). The estimated prevalence of persons with different risk factors and characteristics also varies widely in the U.S. population (Table 1) (3; 35–39; *CDC, unpublished data*).

FIGURE 2. Prevalence of hepatitis C virus (HCV) infection by age and race/ethnicity — United States, 1988–1994



Source: Third National Health and Nutrition Examination Survey, CDC.

Transmission Modes

Most risk factors associated with transmission of HCV in the United States were identified in case-control studies conducted during 1978–1986 (40,41). These risk factors included blood transfusion, injecting-drug use, employment in patient care or clinical laboratory work, exposure to a sex partner or household member who has had a history of hepatitis, exposure to multiple sex partners, and low socioeconomic level. These studies reported no association with military service or exposures resulting from medical, surgical, or dental procedures, tattooing, acupuncture, ear piercing, or foreign travel. If transmission from such exposures does occur, the frequency might be too low to detect.

Transfusions and Transplants. Currently, HCV is rarely transmitted by blood transfusion. During 1985–1990, cases of transfusion-associated non-A, non-B hepatitis declined by >50% because of screening policies that excluded donors with human immunodeficiency virus (HIV) infection and donors with surrogate markers for non-A, non-B hepatitis (5,42). By 1990, risk for transfusion-associated HCV infection was approximately 1.5%/recipient or approximately 0.02%/unit transfused (42). During May 1990, routine testing of donors for evidence of HCV infection was initiated, and during July 1992, more sensitive — multiantigen — testing was implemented, reducing further the risk for infection to 0.001%/unit transfused (43).

Receipt of clotting factor concentrates prepared from plasma pools posed a high risk for HCV infection (44) until effective procedures to inactivate viruses, including HCV, were introduced during 1985 (Factor VIII) and 1987 (Factor IX). Persons with

TABLE 1. Estimated average prevalence of hepatitis C virus (HCV) infection in the United States by various characteristics and estimated prevalence of persons with these characteristics in the population

Characteristic	HCV-infection prevalence		Prevalence of persons with characteristic, %
	%	(range,%)	
Persons with hemophilia treated with products made before 1987	87	(74–90)	<0.01
Injecting-drug users			
current	79	(72–86)	0.5
history of prior use	No Data		5
Persons with abnormal alanine aminotransferase levels	15	(10–18)	5
Chronic hemodialysis patients	10	(0–64)	0.1
Persons with multiple sex partners (lifetime)			
≥50	9	(6–16)	4
10–49	3	(3–4)	22
2–9	2	(1–2)	52
Persons reporting a history of sexually transmitted diseases	6	(1–10)	17
Persons receiving blood transfusions before 1990	6	(5–9)	6
Infants born to infected mothers	5	(0–25)	0.1
Men who have sex with men	4	(2–18)	5
General population	1.8	(1.5–2.3)	NA*
Health-care workers	1	(1–2)	9
Pregnant women	1	—	1.5
Military personnel	0.3	(0.2–0.4)	0.5
Volunteer blood donors	0.16	—	5

*Not applicable.

hemophilia who were treated with products before inactivation of those products have prevalence rates of HCV infection as high as 90% (20–22). Although plasma derivatives (e.g., albumin and immune globulin [IG] for intramuscular [IM] administration) have not been associated with transmission of HCV infection in the United States, intravenous (IV) IG that was not virally inactivated was the source of one outbreak of hepatitis C during 1993–1994 (45,46). Since December 1994, all IG products — IV and IM — commercially available in the United States must undergo an inactivation procedure or be negative for HCV RNA (ribonucleic acid) before release.

Transplantation of organs (e.g., heart, kidney, or liver) from infectious donors to the organ recipient also carried a high risk for transmitting HCV infection before donor screening (47,48). Limited studies of recipients of transplanted tissue have implicated transmission of HCV only from nonirradiated bone tissue of unscreened donors (49,50). As with blood-donor screening, use of anti-HCV-negative organ and tissue donors has virtually eliminated risks for HCV transmission from transplantation.

Injecting and Other Illegal Drug Use. Although the number of cases of acute hepatitis C among injecting-drug users has declined dramatically since 1989, both incidence and prevalence of HCV infection remain high in this group (51,52). Injecting-drug use currently accounts for most HCV transmission in the United States, and has accounted for a substantial proportion of HCV infections during past decades (2,5,53). Many persons with chronic HCV infection might have acquired their infection 20–30 years ago as a result of limited or occasional illegal drug injecting. Injecting-drug

use leads to HCV transmission in a manner similar to that for other bloodborne pathogens (i.e., through transfer of HCV-infected blood by sharing syringes and needles either directly or through contamination of drug preparation equipment) (54,55). However, HCV infection is acquired more rapidly after initiation of injecting than other viral infections (i.e., hepatitis B virus [HBV] and HIV), and rates of HCV infection among young injecting-drug users are four times higher than rates of HIV infection (19). After 5 years of injecting, as many as 90% of users are infected with HCV. More rapid acquisition of HCV infection compared with other viral infections among injecting-drug users is likely caused by high prevalence of chronic HCV infection among injecting-drug users, which results in a greater likelihood of exposure to an HCV-infected person.

A study conducted among volunteer blood donors in the United States documented that HCV infection has been independently associated with a history of intranasal cocaine use (56). (The mode of transmission could be through sharing contaminated straws.) Data from NHANES III indicated that 14% of the general population have used cocaine at least once (CDC, unpublished data). Although NHANES III data also indicated that cocaine use was associated with HCV infection, injecting-drug use histories were not ascertained. Among patients with acute hepatitis C identified in CDC's sentinel counties viral hepatitis surveillance system since 1991, intranasal cocaine use in the absence of injecting-drug use was uncommon (2). Thus, at least in the recent past, intranasal cocaine use rarely appears to have contributed to transmission. Until more data are available, whether persons with a history of noninjecting illegal drug use alone (e.g., intranasal cocaine use) are likely to be infected with HCV remains unknown.

Nosocomial and Occupational Exposures. Nosocomial transmission of HCV is possible if infection-control techniques or disinfection procedures are inadequate and contaminated equipment is shared among patients. Although reports from other countries do document nosocomial HCV transmission (57-59), such transmission rarely has been reported in the United States (60), other than in chronic hemodialysis settings (61). Prevalence of antibody to HCV (anti-HCV) positivity among chronic hemodialysis patients averages 10%, with some centers reporting rates >60% (23). Both incidence and prevalence studies have documented an association between anti-HCV positivity and increasing years on dialysis, independent of blood transfusion (62,63). These studies, as well as investigations of dialysis-associated outbreaks of hepatitis C (64), indicate that HCV transmission might occur among patients in a hemodialysis center because of incorrect implementation of infection-control practices, particularly sharing of medication vials and supplies (65).

Health-care, emergency medical (e.g., emergency medical technicians and paramedics), and public safety workers (e.g., fire-service, law-enforcement, and correctional facility personnel) who have exposure to blood in the workplace are at risk for being infected with bloodborne pathogens. However, prevalence of HCV infection among health-care workers, including orthopedic, general, and oral surgeons, is no greater than the general population, averaging 1%-2%, and is 10 times lower than that for HBV infection (29-33). In a single study that evaluated risk factors for infection, a history of unintentional needle-stick injury was the only occupational risk factor independently associated with HCV infection (66).

The average incidence of anti-HCV seroconversion after unintentional needle sticks or sharps exposures from an HCV-positive source is 1.8% (range: 0%–7%) (67–70), with one study reporting that transmission occurred only from hollow-bore needles compared with other sharps (69). A study from Japan reported an incidence of HCV infection of 10% based on detection of HCV RNA by reverse transcriptase polymerase chain reaction (RT-PCR) (70). Although no incidence studies have documented transmission associated with mucous membrane or nonintact skin exposures, transmission of HCV from blood splashes to the conjunctiva have been described (71,72).

The risk for HCV transmission from an infected health-care worker to patients appears to be very low. One published report exists of such transmission during performance of exposure-prone invasive procedures (73). That report, from Spain, described HCV transmission from a cardiothoracic surgeon to five patients, but did not identify factors that might have contributed to transmission. Although factors (e.g., virus titer) might be related to transmission of HCV, no methods exist currently that can reliably determine infectivity, nor do data exist to determine threshold concentration of virus required for transmission.

Percutaneous Exposures in Other Settings. In other countries, HCV infection has been associated with folk medicine practices, tattooing, body piercing, and commercial barbering (74–81). However, in the United States, case-control studies have reported no association between HCV infection and these types of exposures (40,41). In addition, of patients with acute hepatitis C who were identified in CDC's sentinel counties viral hepatitis surveillance system during the past 15 years and who denied a history of injecting-drug use, only 1% reported a history of tattooing or ear piercing, and none reported a history of acupuncture (41; CDC, unpublished data). Among injecting-drug users, frequency of tattooing and ear piercing also was uncommon (3%).

Although any percutaneous exposure has the potential for transferring infectious blood and potentially transmitting bloodborne pathogens (i.e., HBV, HCV, or HIV), no data exist in the United States indicating that persons with exposures to tattooing and body piercing alone are at increased risk for HCV infection. Further studies are needed to determine if these types of exposures and settings in which they occur (e.g., correctional institutions, unregulated commercial establishments), are risk factors for HCV infection in the United States.

Sexual Activity. Case-control studies have reported an association between exposure to a sex contact with a history of hepatitis or exposure to multiple sex partners and acquiring hepatitis C (40,41). In addition, 15%–20% of patients with acute hepatitis C who have been reported to CDC's sentinel counties surveillance system, have a history of sexual exposure in the absence of other risk factors. Two thirds of these have an anti-HCV-positive sex partner, and one third reported >2 partners in the 6 months before illness (2).

In contrast, a low prevalence of HCV infection has been reported by studies of long-term spouses of patients with chronic HCV infection who had no other risk factors for infection. Five of these studies have been conducted in the United States, involving 30–85 partners each, in which average prevalence of HCV infection was 1.5% (range: 0% to 4.4%) (56,82–85). Among partners of persons with hemophilia coinfecting with HCV and HIV, two studies have reported an average prevalence of HCV infection of

3% (83,86). One additional study evaluated potential transmission of HCV between sexually transmitted disease (STD) clinic patients, who denied percutaneous risk factors, and their steady partners (28). Prevalence of HCV infection among male patients with an anti-HCV-positive female partner (7%) was no different than that among males with a negative female partner (8%). However, female patients with an anti-HCV-positive partner were almost fourfold more likely to have HCV infection than females with a negative male partner (10% versus 3%, respectively). These data indicate that, similar to other bloodborne viruses, sexual transmission of HCV from males to females might be more efficient than from females to males.

Among persons with evidence of high-risk sexual practices (e.g., patients attending STD clinics and female prostitutes) who denied a history of injecting-drug use, prevalence of anti-HCV has been found to average 6% (range: 1%–10%) (24–28,87). Specific factors associated with anti-HCV positivity for both heterosexuals and men who have sex with men (MSM) included greater numbers of sex partners, a history of prior STDs, and failure to use a condom. However, the number of partners associated with infection risk varied among studies, ranging from >1 partner in the previous month to >50 in the previous year. In studies of other populations, the number of partners associated with HCV infection also varied, ranging from >2 partners in the 6 months before illness for persons with acute hepatitis C (41), to ≥ 5 partners/year for HCV-infected volunteer blood donors (56), to ≥ 10 lifetime partners for HCV-infected persons in the general population (3).

Only one study has documented an association between HCV infection and MSM activity (28), and at least in STD clinic settings, the prevalence rate of HCV infection among MSM generally has been similar to that of heterosexuals. Because sexual transmission of bloodborne viruses is recognized to be more efficient among MSM compared with heterosexual men and women, why HCV infection rates are not substantially higher among MSM compared with heterosexuals is unclear. This observation and the low prevalence of HCV infection observed among long-term spouses of persons with chronic HCV infection have raised doubts regarding the importance of sexual activity in transmission of HCV. Unacknowledged percutaneous risk factors (i.e., illegal injecting-drug use) might contribute to increased risk for HCV infection among persons with high-risk sexual practices.

Although considerable inconsistencies exist among studies, data indicate overall that sexual transmission of HCV appears to occur, but that the virus is inefficiently spread through this manner. More data are needed to determine the risk for, and factors related to, transmission of HCV between long-term steady partners as well as among persons with high-risk sexual practices, including whether other STDs promote transmission of HCV by influencing viral load or modifying mucosal barriers.

Household Contact. Case-control studies also have reported an association between nonsexual household contact and acquiring hepatitis C (40,41). The presumed mechanism of transmission is direct or inapparent percutaneous or per mucosal exposure to infectious blood or body fluids containing blood. In a recent investigation in the United States, an HCV-infected mother transmitted HCV to her hemophilic child during performance of home infusion therapy, presumably when she had an unintentional needle stick and subsequently used the contaminated needle in the child (88).

Although prevalence of HCV infection among nonsexual household contacts of persons with chronic HCV infection in the United States is unknown, HCV transmission to such contacts is probably uncommon. In studies from other countries of nonsexual household contacts of patients with chronic hepatitis C, average anti-HCV prevalence was 4% (15). Although infected contacts in these studies reported no other commonly recognized risk factors for hepatitis C, most of these studies were done in countries where exposures commonly experienced in the past from contaminated equipment used in traditional and nontraditional medical procedures might have contributed to clustering of HCV infections in families (75,76,79).

Perinatal. The average rate of HCV infection among infants born to HCV-positive, HIV-negative women is 5%–6% (range: 0%–25%), based on detection of anti-HCV and HCV RNA, respectively (89–101). The average infection rate for infants born to women coinfecting with HCV and HIV is higher — 14% (range: 5%–36%) and 17%, based on detection of anti-HCV and HCV RNA, respectively (90,96,98–104). The only factor consistently found to be associated with transmission has been the presence of HCV RNA in the mother at the time of birth. Although two studies of infants born to HCV-positive, HIV-negative women reported an association with titer of HCV RNA, each study reported a different level of HCV RNA related to transmission (92,93). Studies of HCV/HIV-coinfecting women more consistently have indicated an association between virus titer and transmission of HCV (102).

Data regarding the relationship between delivery mode and HCV transmission are limited and presently indicate no difference in infection rates between infants delivered vaginally compared with cesarean-delivered infants. The transmission of HCV infection through breast milk has not been documented. In the studies that have evaluated breastfeeding in infants born to HCV-infected women, average rate of infection was 4% in both breastfed and bottle-fed infants (95,96,99,100,105,106).

Diagnostic criteria for perinatal HCV infection have not been established. Various anti-HCV patterns have been observed in both infected and uninfected infants of anti-HCV-positive mothers. Passively acquired maternal antibody might persist for months, but probably not for >12 months. HCV RNA can be detected as early as 1 to 2 months.

Persons with No Recognized Source for Their Infection. Recent studies have demonstrated that injecting-drug use currently accounts for 60% of HCV transmission in the United States (2). Although the role of sexual activity in transmission of HCV remains unclear, $\leq 20\%$ of persons with HCV infection report sexual exposures (i.e., exposure to an infected sexual partner or to multiple partners) in the absence of percutaneous risk factors (2). Other known exposures (occupational, hemodialysis, household, perinatal) together account for approximately 10% of infections. Thus, a potential risk factor can be identified for approximately 90% of persons with HCV infection. In the remaining 10%, no recognized source of infection can be identified, although most persons in this category are associated with low socioeconomic level. Although low socioeconomic level has been associated with several infectious diseases and might be a surrogate for high-risk exposures, its nonspecific nature makes targeting prevention measures difficult.

Screening and Diagnostic Tests

Serologic Assays

The only tests currently approved by the U.S. Food and Drug Administration (FDA) for diagnosis of HCV infection are those that measure anti-HCV (Table 2) (107). These tests detect anti-HCV in $\geq 97\%$ of infected patients, but do not distinguish between acute, chronic, or resolved infection. As with any screening test, positive predictive value of enzyme immunoassay (EIA) for anti-HCV varies depending on prevalence of infection in the population and is low in populations with an HCV-infection prevalence of $< 10\%$ (1,34). Supplemental testing with a more specific assay (i.e., recombinant immunoblot assay [RIBA™]) of a specimen with a positive EIA result prevents reporting of false-positive results, particularly in settings where asymptomatic persons are being tested.

Supplemental test results might be reported as positive, negative, or indeterminate. An anti-HCV-positive person is defined as one whose serologic results are EIA-test-positive and supplemental-test-positive. Persons with a negative EIA test result or a positive EIA and a negative supplemental test result are considered uninfected, unless other evidence exists to indicate HCV infection (e.g., abnormal ALT levels in immunocompromised persons or persons with no other etiology for their liver disease). Indeterminate supplemental test results have been observed in recently infected persons who are in the process of seroconversion, as well as in persons chronically infected with HCV. Indeterminate anti-HCV results also might indicate a false-positive result, particularly in those persons at low risk for HCV infection.

Nucleic Acid Detection

The diagnosis of HCV infection also can be made by qualitatively detecting HCV RNA using gene amplification techniques (e.g., RT-PCR) (Table 2) (108). HCV RNA can be detected in serum or plasma within 1–2 weeks after exposure to the virus and weeks before the onset of alanine aminotransferase (ALT) elevations or the appearance of anti-HCV. Rarely, detection of HCV RNA might be the only evidence of HCV infection. Although RT-PCR assay kits for HCV RNA are available for research purposes from various manufacturers of diagnostic reagents, none have been approved by FDA. In addition, numerous laboratories perform RT-PCR using in-house laboratory methods and reagents.

Although not FDA-approved, RT-PCR assays for HCV infection are used commonly in clinical practice. Most RT-PCR assays have a lower limit of detection of 100–1,000 viral genome copies/mL. With adequate optimization of RT-PCR assays, 75%–85% of persons who are anti-HCV-positive and $> 95\%$ of persons with acute or chronic hepatitis C will test positive for HCV RNA. Some HCV-infected persons might be only intermittently HCV RNA-positive, particularly those with acute hepatitis C or with end-stage liver disease caused by hepatitis C. To minimize false-negative results, serum must be separated from cellular components within 2–4 hours after collection, and preferably stored frozen at -20 C or -70 C (109). If shipping is required, frozen samples should be protected from thawing. Because of assay variability, rigorous quality assurance and control should be in place in clinical laboratories performing this assay, and proficiency testing is recommended.

TABLE 2. Tests for hepatitis C virus (HCV) infection

Test/Type	Application	Comments
Hepatitis C virus antibody (anti-HCV)		
<ul style="list-style-type: none"> EIA (enzyme immunoassay) Supplemental assay (i.e., recombinant immunoblot assay [RIBA™]) 	<ul style="list-style-type: none"> Indicates past or present infection, but does not differentiate between acute, chronic, or resolved infection All positive EIA results should be verified with a supplemental assay 	<ul style="list-style-type: none"> Sensitivity ≥97% EIA alone has low-positive predictive value in low-prevalence populations
HCV RNA (hepatitis C virus ribonucleic acid)		
Qualitative tests*†		
<ul style="list-style-type: none"> Reverse transcriptase polymerase chain reaction (RT-PCR) amplification of HCV RNA by in-house or commercial assays (e.g., Amplicor HCV™) 	<ul style="list-style-type: none"> Detect presence of circulating HCV RNA Monitor patients on antiviral therapy 	<ul style="list-style-type: none"> Detect virus as early as 1–2 weeks after exposure Detection of HCV RNA during course of infection might be intermittent; a single negative RT-PCR is not conclusive False-positive and false-negative results might occur
Quantitative tests*†		
<ul style="list-style-type: none"> RT-PCR amplification of HCV RNA by in-house or commercial assays (e.g., Amplicor HCV Monitor™) Branched chain DNA[§] (bDNA) assays (e.g., Quantiplex™ HCV RNA Assay) 	<ul style="list-style-type: none"> Determine concentration of HCV RNA Might be useful for assessing the likelihood of response to antiviral therapy 	<ul style="list-style-type: none"> Less sensitive than qualitative RT-PCR Should not be used to exclude the diagnosis of HCV infection or to determine treatment endpoint
Genotype*†		
<ul style="list-style-type: none"> Several methodologies available (e.g., hybridization, sequencing) 	<ul style="list-style-type: none"> Group isolates of HCV based on genetic differences, into 6 genotypes and >90 subtypes With new therapies, length of treatment might vary based on genotype 	<ul style="list-style-type: none"> Genotype 1 (subtypes 1a and 1b) most common in United States and associated with lower response to antiviral therapy
Serotype*		
<ul style="list-style-type: none"> EIA based on immunoreactivity to synthetic peptides (e.g., Murex HCV Serotyping 1–6 Assay) 	<ul style="list-style-type: none"> No clinical utility 	<ul style="list-style-type: none"> Cannot distinguish between subtypes Dual infections often observed

* Currently not U.S. Food and Drug Administration approved; lack standardization.

† Samples require special handling (e.g., serum must be separated within 2–4 hours of collection and stored frozen [-20 C or -70 C]; frozen samples should be shipped on dry ice).

§ Deoxyribonucleic acid.

Quantitative assays for measuring the concentration (titer) of HCV RNA have been developed and are available from commercial laboratories (110), including a quantitative RT-PCR (Amplicor HCV Monitor™, Roche Molecular Systems, Branchburg, New Jersey) and a branched DNA (deoxyribonucleic acid) signal amplification assay (Quantiplex™ HCV RNA Assay [bDNA], Chiron Corp., Emeryville, California) (Table 2). These assays also are not FDA-approved, and compared with qualitative RT-PCR assays, are less sensitive with lower limits of detection of 500 viral genome copies/mL for the Amplicor HCV Monitor™ to 200,000 genome equivalents/mL for the Quantiplex™ HCV RNA Assay (111). In addition, they each use a different standard, which precludes direct comparisons between the two assays. Quantitative assays should not be used as a primary test to confirm or exclude diagnosis of HCV infection or to monitor the endpoint of treatment. Patients with chronic hepatitis C generally circulate virus at levels of 10^5 – 10^7 genome copies/mL. Testing for level of HCV RNA might help predict likelihood of response to antiviral therapy, although sequential measurement of HCV RNA levels has not proven useful in managing patients with hepatitis C.

At least six different genotypes and >90 subtypes of HCV exist (112). Approximately 70% of HCV-infected persons in the United States are infected with genotype 1, with frequency of subtype 1a predominating over subtype 1b. Different nucleic acid detection methods are available commercially to group isolates of HCV, based on genotypes and subtypes (113). Evidence is limited regarding differences in clinical features, disease outcome, or progression to cirrhosis or hepatocellular carcinoma (HCC) among persons with different genotypes. However, differences do exist in responses to antiviral therapy according to HCV genotype. Rates of response in patients infected with genotype 1 are substantially lower than in patients with other genotypes, and treatment regimens might differ on the basis of genotype. Thus, genotyping might be warranted among persons with chronic hepatitis C who are being considered for antiviral therapy.

Clinical Features and Natural History

Acute HCV Infection

Persons with acute HCV infection typically are either asymptomatic or have a mild clinical illness; 60%–70% have no discernible symptoms; 20%–30% might have jaundice; and 10%–20% might have nonspecific symptoms (e.g., anorexia, malaise, or abdominal pain) (13,114,115). Clinical illness in patients with acute hepatitis C who seek medical care is similar to that of other types of viral hepatitis, and serologic testing is necessary to determine the etiology of hepatitis in an individual patient. In $\leq 20\%$ of these patients, onset of symptoms might precede anti-HCV seroconversion. Average time period from exposure to symptom onset is 6–7 weeks (116–118), whereas average time period from exposure to seroconversion is 8–9 weeks (114; *personal communication, HJ Alter, M.D., Chief, Department of Transfusion Medicine, Clinical Center, National Institutes of Health, Bethesda, MD, September 1998*). Anti-HCV can be detected in 80% of patients within 15 weeks after exposure, in $\geq 90\%$ within 5 months after exposure, and in $\geq 97\%$ by 6 months after exposure (14,114). Rarely, seroconversion might be delayed until 9 months after exposure (14,119).

The course of acute hepatitis C is variable, although elevations in serum ALT levels, often in a fluctuating pattern, are its most characteristic feature. Normalization of ALT levels might occur and suggests full recovery, but this is frequently followed by ALT elevations that indicate progression to chronic disease (14). Fulminant hepatic failure following acute hepatitis C is rare (120,121).

Chronic HCV Infection

After acute infection, 15%–25% of persons appear to resolve their infection without sequelae as defined by sustained absence of HCV RNA in serum and normalization of ALT levels (122; *personal communication, LB Seeff, M.D., Senior Scientist [Hepatitis C], National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Bethesda, MD, July 1998*). Chronic HCV infection develops in most persons (75%–85%) (14,122–124), with persistent or fluctuating ALT elevations indicating active liver disease developing in 60%–70% of chronically infected persons (12–15,116,122–124). In the remaining 30%–40% of chronically infected persons, ALT levels are normal. No clinical or epidemiologic features among patients with acute infection have been found to be predictive of either persistent infection or chronic liver disease. Moreover, various ALT patterns have been observed in these patients during follow-up, and patients might have prolonged periods (≥ 12 months) of normal ALT activity even though they have histologic-confirmed chronic hepatitis (14). Thus, a single ALT determination cannot be used to exclude ongoing hepatic injury, and long-term follow-up of patients with HCV infection is required to determine their clinical outcome or prognosis.

The course of chronic liver disease is usually insidious, progressing at a slow rate without symptoms or physical signs in the majority of patients during the first two or more decades after infection. Frequently, chronic hepatitis C is not recognized until asymptomatic persons are identified as HCV-positive during blood-donor screening, or elevated ALT levels are detected during routine physical examinations. Most studies have reported that cirrhosis develops in 10%–20% of persons with chronic hepatitis C over a period of 20–30 years, and HCC in 1%–5%, with striking geographic variations in rates of this disease (124–128). However, when cirrhosis is established, the rate of development of HCC might be as high as 1%–4%/year. In contrast, a study of >200 women 17 years after they received HCV-contaminated Rh factor IG reported that only 2.4% had evidence of cirrhosis and none had died (129). Thus, longer term follow-up studies are needed to assess lifetime consequences of chronic hepatitis C, particularly among those who acquired their infection at young ages.

Although factors predicting severity of liver disease have not been well-defined, recent data indicate that increased alcohol intake, being aged >40 years at infection, and being male are associated with more severe liver disease (130). In particular, among persons with alcoholic liver disease and HCV infection, liver disease progresses more rapidly; among those with cirrhosis, a higher risk for development of HCC exists (131). Furthermore, even intake of moderate amounts (>10 g/day) of alcohol in patients with chronic hepatitis C might enhance disease progression. More severe liver injury observed in persons with alcoholic liver disease and HCV infection possibly is attributable to alcohol-induced enhancement of viral replication or increased susceptibility of cells to viral injury. In addition, persons who have chronic liver disease are at increased risk for fulminant hepatitis A (132).

Extrahepatic manifestations of chronic HCV infection are considered to be of immunologic origin and include cryoglobulinemia, membranoproliferative glomerulonephritis, and porphyria cutanea tarda (131). Other extrahepatic conditions have been reported, but definitive associations of these conditions with HCV infection have not been established. These include seronegative arthritis, Sjögren syndrome, autoimmune thyroiditis, lichen planus, Mooren corneal ulcers, idiopathic pulmonary fibrosis (Hamman-Rich syndrome), polyarteritis nodosa, aplastic anemia, and B-cell lymphomas.

Clinical Management and Treatment

HCV-positive patients should be evaluated for presence and severity of chronic liver disease (133). Initial evaluation for presence of disease should include multiple measurements of ALT at regular intervals, because ALT activity fluctuates in persons with chronic hepatitis C. Patients with chronic hepatitis C should be evaluated for severity of their liver disease and for possible treatment (133–135).

Antiviral therapy is recommended for patients with chronic hepatitis C who are at greatest risk for progression to cirrhosis (133). These persons include anti-HCV-positive patients with persistently elevated ALT levels, detectable HCV RNA, and a liver biopsy that indicates either portal or bridging fibrosis or at least moderate degrees of inflammation and necrosis.

In patients with less severe histologic changes, indications for treatment are less clear, and careful clinical follow-up might be an acceptable alternative to treatment with antiviral therapy (e.g., interferon) because progression to cirrhosis is likely to be slow, if it occurs at all. Similarly, patients with compensated cirrhosis (without jaundice, ascites, variceal hemorrhage, or encephalopathy) might not benefit from interferon therapy. Careful assessment should be made, and the risks and benefits of therapy should be thoroughly discussed with the patient.

Patients with persistently normal ALT values should not be treated with interferon outside of clinical trials because treatment might actually induce liver enzyme abnormalities (136). Patients with advanced cirrhosis who might be at risk for decompensation with therapy and pregnant women also should not be treated. Interferon treatment is not FDA-approved for patients aged <18 years, and more data are needed regarding treatment of persons aged <18 years or >60 years. Treatment of patients who are drinking excessive amounts of alcohol or who are injecting illegal drugs should be delayed until these behaviors have been discontinued for ≥ 6 months. Contraindications to treatment with interferon include major depressive illness, cytopenias, hyperthyroidism, renal transplantation, and evidence of autoimmune disease.

Most clinical trials of treatment for chronic hepatitis C have been conducted using alpha-interferon (134, 135, 137, 138). When the recommended regimen of 3 million units administered subcutaneously 3 times/week for 12 months is used, approximately 50% of treated patients have normalization of serum ALT activity (biochemical response), and 33% have a loss of detectable HCV RNA in serum (virologic response) at the end of therapy. However, $\geq 50\%$ of these patients relapse when therapy is stopped. Thus, 15%–25% have a sustained response as measured by testing for ALT and HCV RNA ≥ 1 years after therapy is stopped, many of whom also have histologic

improvement. For patients who do not respond by the end of therapy, retreatment with a standard dose of interferon is rarely effective. Patients who have persistently abnormal ALT levels and detectable HCV RNA in serum after 3 months of interferon are unlikely to respond to treatment, and interferon treatment should be discontinued. These persons might be considered for participation in clinical trials of alternative treatments. Decreased interferon response rates (<15%) have been found in patients with higher serum HCV RNA titers and HCV genotype 1 (the most common strain of HCV in the United States); however, treatment should not be withheld based solely on these findings.

Therapy for hepatitis C is a rapidly changing area of clinical practice. Combination therapy with interferon and ribavirin, a nucleoside analogue, is now FDA-approved for treatment of chronic hepatitis C in patients who have relapsed following interferon treatment and might be approved soon for patients who have not been treated previously. Studies of patients treated with a combination of ribavirin and interferon have demonstrated a substantial increase in sustained response rates, reaching 40%–50%, compared with response rates of 15%–25% with interferon alone (139,140). However, as with interferon alone, combination therapy in patients with genotype 1 is not as successful, and sustained response rates among these patients are still <30%.

Most patients receiving interferon experience flu-like symptoms early in treatment, but these symptoms diminish with continued treatment. Later side effects include fatigue, bone marrow suppression, and neuropsychiatric effects (e.g., apathy, cognitive changes, irritability, and depression). Interferon dosage must be reduced in 10%–40% of patients and discontinued in 5%–15% because of severe side effects. Ribavirin can induce hemolytic anemia and can be problematic for patients with preexisting anemia, bone marrow suppression, or renal failure. In these patients, combination therapy should be avoided or attempts should be made to correct the anemia. Hemolytic anemia caused by ribavirin also can be life-threatening for patients with ischemic heart disease or cerebral vascular disease. Ribavirin is teratogenic, and female patients should avoid becoming pregnant during therapy.

Other treatments, including corticosteroids, ursodiol, and thymosin, have not been effective. High iron levels in the liver might reduce the efficacy of interferon. Use of iron-reduction therapy (phlebotomy or chelation) in combination with interferon has been studied, but results have been inconclusive. Because patients are becoming more interested in alternative therapies (e.g., traditional Chinese medicine, antioxidants, naturopathy, and homeopathy), physicians should be prepared to address questions regarding these topics.

Postexposure Prophylaxis and Follow-Up

Available data regarding the prevention of HCV infection with IG indicate that IG is not effective for postexposure prophylaxis of hepatitis C (67,141). No assessments have been made of postexposure use of antiviral agents (e.g., interferon) to prevent HCV infection. Mechanisms of the effect of interferon in treating patients with hepatitis C are poorly understood, and an established infection might need to be present for interferon to be an effective treatment (142). As of the publication of this report, interferon is FDA-approved only for treatment of chronic hepatitis C.

**Continuing Medical Education Activity
Sponsored by the Centers for Disease Control
and Prevention (CDC)**

**Recommendations for Prevention and Control of Hepatitis C Virus (HCV)
Infection and HVC-Related Chronic Disease**

OBJECTIVE

This *MMWR* provides recommendations for preventing transmission of hepatitis C virus (HCV); identifying, counseling, and testing persons at risk for HCV infection; and providing appropriate medical evaluation and management of HCV-infected persons. These recommendations were developed by CDC staff members after consultation with expert consultants. This report is intended to serve as a resource for health-care professionals, public health officials, and organizations involved in the development, delivery, and evaluation of prevention and clinical services. Upon completing this continuing education activity, the reader should possess a clear working knowledge regarding this topic.

ACCREDITATION

Continuing Medical Education (CME) Credit: This activity has been planned and implemented in accordance with the Essentials and Standards of the Accreditation Council for Continuing Medical Education (ACCME) by the CDC. CDC is accredited by the ACCME to provide continuing medical education for U.S. physicians. CDC awards 2.0 hours of category 1 credit toward the AMA Physician's Recognition Award for this activity.

EXPIRATION — October 16, 1999

The response form must be completed and returned electronically, by fax, or by mail, **postmarked no later than one year from the publication date of this report**, for eligibility to receive continuing education credit.

INSTRUCTIONS

1. Read this *MMWR* (Vol. 47, RR-19), which contains the correct answers to the questions beginning on the next page.
2. Complete all registration information on the response form, including your name, mailing address, phone number, and e-mail address, if available.
3. Select your answers to the questions, and mark the corresponding letters on the response form provided. To receive continuing education credit, you must answer *all* of the questions. Questions with more than one answer will instruct you to "indicate all that are true."
4. Return the answer form, or a photocopy of the form, no later than **October 16, 1999**, to CDC by one of the following methods:

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If you answer all of the questions, you will receive an award letter for 2.0 hours of CME credit within 90 days. No fees are charged for participating in this continuing education activity.

To receive continuing education credit, please answer all of the following questions:

- 1. Which of the following statements about hepatitis C virus (HCV) infection and HCV-associated chronic liver disease in the United States are true? (*Indicate all that are true.*)**
 - A. HCV is responsible for 40% of chronic liver disease.
 - B. HCV-associated chronic liver disease often results in death.
 - C. An estimated 8,000–10,000 deaths occur each year as a result of HCV-associated chronic liver disease.
 - D. Persistent HCV infection develops in most persons (85%), including those with no biochemical evidence of active liver disease.
 - E. HCV-associated chronic liver disease is the cause of most liver transplantation in the United States.

- 2. Which of the following is currently the major risk factor for HCV infection in the United States? (*Choose the one correct answer.*)**
 - A. Tattoos
 - B. Injecting-drug use
 - C. Blood transfusion
 - D. Sexual activity
 - E. Working in healthcare occupations

- 3. Which of the following tests could be used to “confirm” the diagnosis of HCV infection in a patient who is anti-HCV positive by enzyme immunoassay (EIA)? (*Indicate all that are true.*)**
 - A. Recombinant Immunoblot Assay (RIBA™)
 - B. Qualitative reverse transcriptase polymerase chain reaction (RT-PCR)
 - C. Quantitative RT-PCR
 - D. Genotyping
 - E. All of the above

- 4. For which of the following persons is routine testing for HCV infection recommended? (*Indicate all that are true.*)**
- A. Persons who have been tattooed
 - B. Persons who have had a history of sexually transmitted disease
 - C. Persons who have ever injected illicit drugs
 - D. Persons who have had a transfusion of blood or blood components before July 1992
 - E. Persons who have received clotting factor concentrates made before 1987
- 5. For which of the following persons is need for routine testing for HCV infection unclear? (*Indicate all that are true.*)**
- A. Injecting-drug users
 - B. Persons who have been tattooed or who have body piercing
 - C. Persons with a history of sexually transmitted disease
 - D. Pregnant women
 - E. All of the above
- 6. For which of the following persons is routine testing for HCV infection not recommended? (*Indicate all that are true.*)**
- A. Persons with a history of blood transfusion
 - B. Pregnant women
 - C. Persons with a history of sexually transmitted disease
 - D. Household contacts of persons with HCV infection
 - E. Health-care and public safety workers

- 7. What is the percentage of persons with HCV infection who develop chronic hepatitis C? (Choose the one correct answer.)**
- A. 10%
 - B. 40%
 - C. 60%–70%
 - D. 100%
 - E. 0%
- 8. What are the licensed therapies for the treatment of chronic hepatitis C? (Indicate all that are true.)**
- A. Milk thistle
 - B. No licensed therapies are available
 - C. Monotherapy with interferon
 - D. Monotherapy with ribavirin
 - E. Combination therapy with interferon and ribavirin
- 9. Indicate the setting where you work.**
- A. State/local health department
 - B. Other public health setting
 - C. Hospital clinic/private practice
 - D. Managed care organization
 - E. Academic institution
 - F. Other, please specify _____

10. Indicate the approximate number of patients with hepatitis C that you treat or counsel on a monthly basis.

- A. None
- B. 1-5
- C. 6-15
- D. 16-25
- E. 25

11. What is your training background?

- A. Internal medicine
- B. Family practice
- C. Gastroenterology
- D. Infectious disease
- E. Other

The following questions will assess your perceptions of the readability of the material.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
12. I understood the rationale for the recommendations.	A	B	C	D	E
13. Overall, the presentation of the article enhanced my ability to read and understand the material	A	B	C	D	E

Answer Guide for questions 1-8
 1.a, c, d, e; 2.b; 3.a, b; 4.c, d, e; 5.b, c; 6.b, d, e; 7.c; 8. c, e

MMWR ANSWER FORM for CME Credit
MMWR Vol. 47/No. RR-19. October 16, 1998

Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection
and HCV-Related Chronic Disease

Fill in the appropriate block(s) to indicate your answer(s).

Detach or photocopy.

- 1. A B C D E F
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The immediate postexposure setting provides opportunity to identify persons early in the course of their HCV infection. Studies indicate that interferon treatment begun early in the course of HCV infection is associated with a higher rate of resolved infection (143). However, no data exist indicating that treatment begun during the acute phase of infection is more effective than treatment begun early during the course of chronic HCV infection. In addition, as stated previously, interferon is not FDA-approved for this indication. Determination of whether treatment of HCV infection is more beneficial in the acute phase than in the early chronic phase will require evaluation with well-designed research protocols.

PREVENTION AND CONTROL RECOMMENDATIONS

Rationale

Reducing the burden of HCV infection and HCV-related disease in the United States requires implementation of *primary* prevention activities that reduce risks for contracting HCV infection and *secondary* prevention activities that reduce risks for liver and other chronic diseases in HCV-infected persons. In addition, surveillance and evaluation activities are required to determine the effectiveness of prevention programs in reducing incidence of disease, identifying persons infected with HCV, providing appropriate medical follow-up, and promoting healthy lifestyles and behaviors.

Primary prevention activities can reduce or eliminate potential risk for HCV transmission from a) blood, blood components, and plasma derivatives; b) such high-risk activities as injecting-drug use and sex with multiple partners; and c) percutaneous exposures to blood in health care and other (i.e., tattooing and body piercing) settings. Immunization against HCV is not available; therefore, identifying persons at risk but not infected with HCV provides opportunity for counseling on how to reduce their risk for becoming infected.

Elements of a comprehensive strategy to prevent and control hepatitis C virus (HCV) infection and HCV-related disease

- Primary prevention activities include
 - screening and testing of blood, plasma, organ, tissue, and semen donors
 - virus inactivation of plasma-derived products;
 - risk-reduction counseling and services; and
 - implementation and maintenance of infection-control practices.
- Secondary prevention activities include
 - identification, counseling, and testing of persons at risk, and
 - medical management of infected persons.
- Professional and public education.
- Surveillance and research to monitor disease trends and the effectiveness of prevention activities and to develop improved prevention methods.

Secondary prevention activities can reduce risks for chronic disease by identifying HCV-infected persons through diagnostic testing and by providing appropriate medical management and antiviral therapy. Because of the number of persons with chronic HCV infection, identification of these persons must be a major focus of current prevention programs. Identification of persons at risk for HCV infection provides opportunity for testing to determine their infection status, medical evaluation to determine their disease status if infected, and antiviral therapy, if appropriate. Identification also provides infected persons opportunity to obtain information concerning how they can prevent further harm to their liver and prevent transmitting HCV to others.

Factors for consideration when making decisions regarding development and implementation of preventive services for a particular disease include the public health importance of the disease, the availability of appropriate diagnostic tests, and the effectiveness of available preventive and therapeutic interventions. However, identification of persons at risk for HCV infection must take into account not only the benefits but also the limitations and drawbacks associated with such efforts. Hepatitis C is a disease of major public health importance, and suitable and accurate diagnostic tests as well as behavioral and therapeutic interventions are available. Counseling and testing can prevent disease transmission and progression through reducing high-risk practices (e.g., injecting-drug use and alcohol intake). However, the degree to which persons will change their high-risk practices based on knowing their test results is not known, and possible adverse consequences of testing exist, including disclosure of test results to others that might result in disrupted personal relationships and possible discriminatory action (e.g., loss of employment, insurance, and educational opportunities). Antiviral treatment is also available, and treatment guidelines have been developed. Such treatment is beneficial for many patients, although sustained response rates and mode of delivery are currently less than ideal.

Persons at risk for HCV infection who receive health-care services in the public and private sectors should have access to counseling and testing. Facilities that provide counseling and testing should include services or referrals for medical evaluation and management of persons identified as infected with HCV. Priorities for implementing new counseling and testing programs should be based on providing access to persons who are most likely to be infected or who practice high-risk behaviors.

PRIMARY PREVENTION RECOMMENDATIONS

Blood, Plasma Derivatives, Organs, Tissues, and Semen

Current practices that exclude blood, plasma, organ, tissue, or semen donors determined to be at increased risk for HCV by history or who have serologic markers for HCV infection must be maintained to prevent HCV transmission from transfusions and transplants (1). Viral inactivation of clotting factor concentrates and other products derived from human plasma, including IG products, also must be continued, and all plasma-derived products that do not undergo viral inactivation should be HCV RNA negative by RT-PCR before release.

High-Risk Drug and Sexual Practices

Health-care professionals in all patient care settings routinely should obtain a history that inquires about use of illegal drugs (injecting and noninjecting) and evidence of high-risk sexual practices (e.g., multiple sex partners or a history of STDs). Primary prevention of illegal drug injecting will eliminate the greatest risk factor for HCV infection in the United States (144). Although consistent data are lacking regarding the extent to which sexual activity contributes to HCV transmission, persons having multiple sex partners are at risk for STDs (e.g., HIV, HBV, syphilis, gonorrhea, and chlamydia). Counseling and education to prevent initiation of drug-injecting or high-risk sexual practices is important, especially for adolescents. Persons who inject drugs or who are at risk for STDs should be counseled regarding what they can do to minimize their risk for becoming infected or of transmitting infectious agents to others, including need for vaccination against hepatitis B (144–148). Injecting and noninjecting illegal drug users and sexually active MSM also should be vaccinated against hepatitis A (149).

Prevention messages for persons with high-risk drug or sexual practices

- Persons who use or inject illegal drugs should be advised
 - to stop using and injecting drugs.
 - to enter and complete substance-abuse treatment, including relapse-prevention programs.
 - if continuing to inject drugs,
 - to never reuse or “share” syringes, needles, water, or drug preparation equipment; if injection equipment has been used by other persons, to first clean the equipment with bleach and water;
 - to use only sterile syringes obtained from a reliable source (e.g., pharmacies);
 - to use a new sterile syringe to prepare and inject drugs;
 - if possible, to use sterile water to prepare drugs; otherwise to use clean water from a reliable source (such as fresh tap water).
 - to use a new or disinfected container (“cooker”) and a new filter (“cotton”) to prepare drugs;
 - to clean the injection site before injection with a new alcohol swab; and
 - to safely dispose of syringes after one use.
 - to get vaccinated against hepatitis B and hepatitis A.
- Persons who are at risk for sexually transmitted diseases should be advised
 - that the surest way to prevent the spread of human immunodeficiency virus infection and other sexually transmitted diseases is to have sex with only one uninfected partner or not to have sex at all.
 - to use latex condoms correctly and every time to protect themselves and their partners from diseases spread through sexual activity.
 - to get vaccinated against hepatitis B, and if appropriate, hepatitis A.

Counseling of persons with potential or existing illegal drug use or high-risk sexual practices should be conducted in the setting in which the patient is identified. If counseling services cannot be provided on-site, patients should be referred to a convenient community resource, or at a minimum, provided easy-to-understand health-education material. STD and drug-treatment clinics, correctional institutions, and HIV counseling and testing sites should routinely provide information concerning prevention of HCV and HBV infection in their counseling messages. Based on the findings of multiple studies, syringe and needle-exchange programs can be an effective part of a comprehensive strategy to reduce the incidence of bloodborne virus transmission and do not encourage the use of illegal drugs (150–153). Therefore, to reduce the risk for HCV infection among injecting-drug users, local communities can consider implementing syringe and needle-exchange programs.

Percutaneous Exposures to Blood in Health Care and Other Settings

Health-Care Settings

Health-care, emergency medical, and public safety workers should be educated regarding risk for and prevention of bloodborne infections, including the need to be vaccinated against hepatitis B (154–156). Standard barrier precautions and engineering controls should be implemented to prevent exposure to blood. Protocols should be in place for reporting and follow-up of percutaneous or permucosal exposures to blood or body fluids that contain blood.

Health-care professionals responsible for overseeing patients receiving home infusion therapy should ensure that patients and their families (or caregivers) are informed of potential risk for infection with bloodborne pathogens, and should assess their ability to use adequate infection-control practices consistently (88). Patients and families should receive training with a standardized curriculum that includes appropriate infection-control procedures, and these procedures should be evaluated regularly through home visits.

Currently, no recommendations exist to restrict professional activities of health-care workers with HCV infection. As recommended for all health-care workers, those who are HCV-positive should follow strict aseptic technique and standard precautions, including appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments (154, 155).

In chronic hemodialysis settings, intensive efforts must be made to educate new staff and reeducate existing staff regarding hemodialysis-specific infection-control practices that prevent transmission of HCV and other bloodborne pathogens (65, 157). Hemodialysis-center precautions are more stringent than standard precautions. Standard precautions require use of gloves only when touching blood, body fluids, secretions, excretions, or contaminated items. In contrast, hemodialysis-center precautions require glove use whenever patients or hemodialysis equipment is touched. Standard precautions do not restrict use of supplies, instruments, and medications to a single patient; hemodialysis-center precautions specify that none of these items be shared among any patients. Thus, appropriate use of hemodialysis-center precautions

Routine precautions for the care of all hemodialysis patients

- Patients should have specific dialysis stations assigned to them, and chairs and beds should be cleaned after each use.
- Sharing among patients of ancillary supplies such as trays, blood pressure cuffs, clamps, scissors, and other nondisposable items should be avoided.
- Nondisposable items should be cleaned or disinfected appropriately between uses.
- Medications and supplies should not be shared among patients, and medication carts should not be used.
- Medications should be prepared and distributed from a centralized area.
- Clean and contaminated areas should be separated (e.g., handling and storage of medications and hand washing should not be done in the same or an adjacent area to that where used equipment or blood samples are handled).

should prevent transmission of HCV among chronic hemodialysis patients, and isolation of HCV-positive patients is not necessary or recommended.

Other Settings

Persons who are considering tattooing or body piercing should be informed of potential risks of acquiring infection with bloodborne and other pathogens through these procedures. These procedures might be a source of infection if equipment is not sterile or if the artist or piercer does not follow other proper infection-control procedures (e.g., washing hands, using latex gloves, and cleaning and disinfecting surfaces).

SECONDARY PREVENTION RECOMMENDATIONS**Persons for Whom Routine HCV Testing Is Recommended**

Testing should be offered routinely to persons most likely to be infected with HCV who might require medical management, and testing should be accompanied by appropriate counseling and medical follow-up. In addition, anyone who wishes to know or is concerned regarding their HCV-infection status should be provided the opportunity for counseling, testing, and appropriate follow-up. The determination of which persons at risk to recommend for routine testing is based on various considerations, including a known epidemiologic relationship between a risk factor and acquiring HCV infection, prevalence of risk behavior or characteristic in the population, prevalence of infection among those with a risk behavior or characteristic, and the need for persons with a recognized exposure to be evaluated for infection.

Persons who should be tested routinely for hepatitis C virus (HCV) infection based on their risk for infection

- Persons who ever injected illegal drugs, including those who injected once or a few times many years ago and do not consider themselves as drug users.
- Persons with selected medical conditions, including
 - persons who received clotting factor concentrates produced before 1987;
 - persons who were ever on chronic (long-term) hemodialysis; and
 - persons with persistently abnormal alanine aminotransferase levels.
- Prior recipients of transfusions or organ transplants, including
 - persons who were notified that they received blood from a donor who later tested positive for HCV infection;
 - persons who received a transfusion of blood or blood components before July 1992; and
 - persons who received an organ transplant before July 1992.

Persons who should be tested routinely for HCV-infection based on a recognized exposure

- Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood.
- Children born to HCV-positive women.

Persons Who Have Ever Injected Illegal Drugs

Health-care professionals in primary-care and other appropriate settings routinely should question patients regarding their history of injecting-drug use, and should counsel, test, and evaluate for HCV infection, persons with such histories. Current injecting-drug users frequently are not seen in the primary health-care setting and might not be reached by traditional media; therefore, community-based organizations serving these populations should determine the most effective means of integrating appropriate HCV information and services into their programs.

Testing persons in settings with potentially high proportions of injecting-drug users (e.g., correctional institutions, HIV counseling and testing sites, or drug and STD treatment programs) might be particularly efficient for identifying HCV-positive persons. HCV testing programs in these settings should include counseling and referral or arrangements for medical management. However, limited experience exists in combining HCV programs with existing HIV, STD, or other established services for populations at high risk for infection with bloodborne pathogens. Persons at risk for HCV infection through limited or occasional drug use, particularly in the remote past, might not be receptive to receiving services in such settings as HIV counseling and testing sites and drug and STD treatment programs. In addition, whether a substantial proportion of this group at risk can be identified in these settings is unknown. Studies are needed to determine the best approaches for reaching persons who might not identify themselves as being at risk for HCV infection.

Persons with Selected Medical Conditions

Persons with hemophilia who received clotting factor concentrates produced before 1987 and long-term hemodialysis patients should be tested for HCV infection. Educational efforts directed to health-care professionals, patient organizations, and agencies who care for these patients should emphasize the need for these patients to know whether they are infected with HCV and encourage testing for those who have not been tested previously. Periodic testing of long-term hemodialysis patients for purposes of infection control is currently not recommended (61). However, issues surrounding prevention of HCV and other bloodborne pathogen transmission in long-term hemodialysis settings are currently undergoing discussion, and updating recommendations for this setting is under development.

Persons with persistently abnormal ALT levels are often identified in medical settings. As part of their medical work-up, health-care professionals should test routinely for HCV infection persons with ALT levels above the upper limit of normal on at least two occasions. Persons with other evidence of liver disease identified by abnormal serum aspartate aminotransferase (AST) levels, which is common among persons with alcohol-related liver disease, should be tested also.

Prior Recipients of Blood Transfusions or Organ Transplants

Persons who might have become infected with HCV through transfusion of blood and blood components should be notified. Two types of approaches should be used — a) a targeted, or directed, approach to identify prior transfusion recipients from donors who tested anti-HCV positive after multiantigen screening tests were widely implemented (July 1992 and later); and b) a general approach to identify all persons who received transfusions before July 1992. A targeted notification approach focuses on a specific group known to be at risk, and will reach persons who might be unaware they were transfused. However, because blood and blood-component donor testing for anti-HCV before July 1992 did not include confirmatory testing, most of these notifications would be based on donors who were not infected with HCV because their test results were falsely positive. A general education campaign to identify persons transfused before July 1992 has the advantage of not being dependent on donor testing status or availability of records, and potentially reaches persons who received HCV-infected blood from donors who tested falsely negative on the less sensitive serologic test, as well as from donors before testing was available.

- **Persons who received blood from a donor who tested positive for HCV infection after multiantigen screening tests were widely implemented.** Persons who received blood or blood components from donors who subsequently tested positive for anti-HCV using a licensed multiantigen assay should be notified as provided for in guidance issued by FDA. For specific details regarding this notification, readers should refer to the FDA document, *Guidance for Industry. Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV.* (This document is available on the Internet at <<http://www.fda.gov/cber/gdlns/gmphcv.txt>>.)

Blood-collection establishments and transfusion services should work with local and state health agencies to coordinate this notification effort. Health-care professionals should have information regarding the notification process and HCV infection so that they are prepared to discuss with their patients why they were notified and to provide appropriate counseling, testing, and medical evaluation. Health-education material sent to recipients should be easy to understand and include information concerning where they can be tested, what hepatitis C means in terms of their day-to-day living, and where they can obtain more information.

- **Persons who received a transfusion of blood or blood components (including platelets, red cells, washed cells, and fresh frozen plasma) or a solid-organ transplant (e.g., heart, lung, kidney, or liver) before July 1992.** Patients with a history of blood transfusion or solid-organ transplantation before July 1992 should be counseled, tested, and evaluated for HCV infection. Health-care professionals in primary-care and other appropriate settings routinely should ascertain their patients' transfusion and transplant histories either through questioning their patients, including such risk factors for transfusion as hematologic disorders, major surgery, trauma, or premature birth, or through review of their medical records. In addition, transfusion services, public health agencies, and professional organizations should provide to the public, information concerning the need for HCV testing in this population. Health-care professionals should be prepared to discuss these issues with their patients and provide appropriate counseling, testing, and medical evaluation.

Health-Care, Emergency Medical, and Public Safety Workers After Needle Sticks, Sharps, or Mucosal Exposures to HCV-Positive Blood

Individual institutions should establish policies and procedures for HCV testing of persons after percutaneous or permucosal exposures to blood and ensure that all personnel are familiar with these policies and procedures (see text box on next page) (141). Health-care professionals who provide care to persons exposed to HCV in the occupational setting should be knowledgeable regarding the risk for HCV infection and appropriate counseling, testing, and medical follow-up.

IG and antiviral agents are not recommended for postexposure prophylaxis of hepatitis C. Limited data indicate that antiviral therapy might be beneficial when started early in the course of HCV infection, but no guidelines exist for administration of therapy during the acute phase of infection. When HCV infection is identified early, the individual should be referred for medical management to a specialist knowledgeable in this area.

Children Born to HCV-Positive Women

Because of their recognized exposure, children born to HCV-positive women should be tested for HCV infection (158). IG and antiviral agents are not recommended for postexposure prophylaxis of infants born to HCV-positive women. Testing of infants for anti-HCV should be performed no sooner than age 12 months, when passively transferred maternal anti-HCV declines below detectable levels. If earlier diagnosis of HCV infection is desired, RT-PCR for HCV RNA may be performed at or after the infant's first well-child visit at age 1–2 months. Umbilical cord blood should not be

Postexposure follow-up of health-care, emergency medical, and public safety workers for hepatitis C virus (HCV) infection

- For the source, baseline testing for anti-HCV.*
- For the person exposed to an HCV-positive source, baseline and follow-up testing including
 - baseline testing for anti-HCV and ALT[†] activity; and
 - follow-up testing for anti-HCV (e.g., at 4–6 months) and ALT activity. (If earlier diagnosis of HCV infection is desired, testing for HCV RNA[§] may be performed at 4–6 weeks.)
- Confirmation by supplemental anti-HCV testing of all anti-HCV results reported as positive by enzyme immunoassay.

* Antibody to HCV.

† Alanine aminotransferase.

§ Ribonucleic acid.

used for diagnosis of perinatal HCV infection because cord blood can be contaminated by maternal blood. If positive for either anti-HCV or HCV RNA, children should be evaluated for the presence or development of liver disease, and those children with persistently elevated ALT levels should be referred to a specialist for medical management.

Persons for Whom Routine HCV Testing Is Not Recommended

For the following persons, routine testing for HCV infection is not recommended unless they have risk factors for infection.

Persons for whom routine hepatitis C virus (HCV) testing is not recommended

- Health-care, emergency medical, and public safety workers.
- Pregnant women.
- Household (nonsexual) contacts of HCV-positive persons.
- The general population.

Health-Care, Emergency Medical, and Public Safety Workers

Routine testing is recommended only for follow-up for a specific exposure.

Pregnant Women

Health-care professionals in settings where pregnant women are evaluated or receive routine care should take risk histories from their patients designed to determine the need for testing and other prevention measures, and those health-care professionals should be knowledgeable regarding HCV counseling, testing, and medical follow-up.

Household (Nonsexual) Contacts of HCV-Positive Persons

Routine testing for nonsexual household contacts of HCV-positive persons is not recommended unless a history exists of a direct (percutaneous or mucosal) exposure to blood.

Persons for Whom Routine HCV Testing Is of Uncertain Need

For persons at potential (or unknown) risk for HCV infection, the need for, or effectiveness of, routine testing has not been determined.

Persons for whom routine hepatitis C virus (HCV) testing is of uncertain need

- Recipients of transplanted tissue (e.g., corneal, musculoskeletal, skin, ova, sperm).
- Intranasal cocaine and other noninjecting illegal drug users.
- Persons with a history of tattooing or body piercing.
- Persons with a history of multiple sex partners or sexually transmitted diseases.
- Long-term steady sex partners of HCV-positive persons.

Recipients of Transplanted Tissue

On the basis of currently available data, risk for HCV transmission from transplanted tissue (e.g., corneal, musculoskeletal, skin, ova, or sperm) appears to be rare.

Intranasal Cocaine and Other Noninjecting Illegal Drug Users

Currently, the strength of the association between intranasal cocaine use and HCV infection does not support routine testing based solely on this risk factor.

Persons with a History of Tattooing or Body Piercing

Because no data exist in the United States documenting that persons with a history of such exposures as tattooing and body piercing are at increased risk for HCV infection, routine testing is not recommended based on these exposures alone. In settings having a high proportion of HCV-infected persons and where tattooing and body piercing might be performed in an unregulated manner (e.g., correctional institutions), these types of exposures might be a risk factor for HCV infection. Data are needed to determine the risk for HCV infection among persons who have been exposed under these conditions.

Persons with a History of Multiple Sex Partners or STDs

Although persons with a history of multiple sex partners or treatment for STDs and who deny injecting-drug use appear to have an increased risk for HCV infection, insufficient data exist to recommend routine testing based on these histories alone. Health-care professionals who provide services to persons with STDs should use that

opportunity to take complete risk histories from their patients to ascertain the need for HCV testing, provide risk-reduction counseling, offer hepatitis B vaccination, and, if appropriate, hepatitis A vaccination.

Long-Term Steady Sex Partners of HCV-Positive Persons

HCV-positive persons with long-term steady partners do not need to change their sexual practices. Persons with HCV infection should discuss with their partner the need for counseling and testing. If the partner chooses to be tested and tests negative, the couple should be informed of available data regarding risk for HCV transmission by sexual activity to assist them in making decisions about precautions (see section regarding counseling messages for HCV-positive persons). If the partner tests positive, appropriate counseling and evaluation for the presence or development of liver disease should be provided.

Testing for HCV Infection

Consent for testing should be obtained in a manner consistent with that for other medical care and services provided in the same setting, and should include measures to prevent unwanted disclosure of test results to others. Persons should be provided with information regarding

- exposures associated with the transmission of HCV, including behaviors or exposures that might have occurred infrequently or many years ago;
- the test procedures and the meaning of test results;
- the nature of hepatitis C and chronic liver disease;
- the benefits of detecting infection early;
- available medical treatment; and
- potential adverse consequences of testing positive, including disrupted personal relationships and possible discriminatory action (e.g., loss of employment, insurance, and educational opportunities).

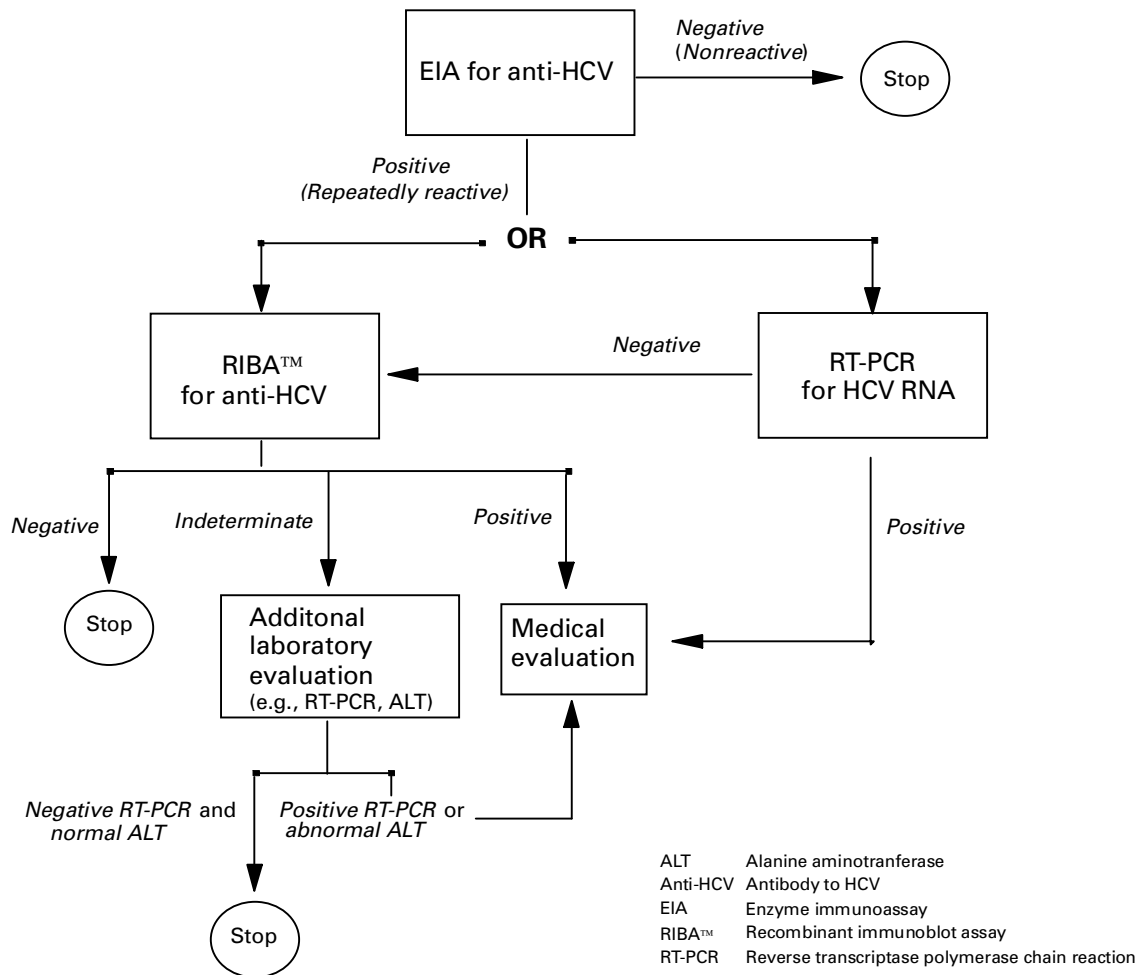
Comprehensive information regarding hepatitis C should be provided before testing; however, this might not be practical when HCV testing is performed as part of a clinical work-up or when testing for anti-HCV is required. In these cases, persons should be informed that a) testing for HCV infection will be performed, b) individual results will be kept confidential, and c) appropriate counseling and referral will be offered if results are positive.

Testing for HCV infection can be performed in various settings, including physicians' offices, other health-care facilities, health department clinics, and HIV or other freestanding counseling and testing sites. Such settings should be prepared to provide appropriate information regarding hepatitis C and provide or offer referral for additional medical care or other needed services (e.g., drug treatment), as warranted. Facilities providing HCV testing should have access to information regarding referral resources, including availability, accessibility, and eligibility criteria of local medical care and mental health professionals, support groups, and drug-treatment centers.

The diagnosis of HCV infection can be made by detecting either anti-HCV or HCV RNA. Anti-HCV is recommended for routine testing of asymptomatic persons, and should include use of both EIA to test for anti-HCV and supplemental or confirmatory testing with an additional, more specific assay (Figure 3). Use of supplemental antibody testing (i.e., RIBA™) for all positive anti-HCV results by EIA is preferred, particularly in settings where clinical services are not provided directly.

Supplemental anti-HCV testing confirms the presence of anti-HCV (i.e., eliminates false-positive antibody results), which indicates past or current infection, and can be performed on the same serum sample collected for the EIA (i.e., routine serology). Confirmation or exclusion of HCV infection in a person with indeterminate anti-HCV supplemental test results should be made on the basis of further laboratory testing, which might include repeating the anti-HCV in two or more months or testing for HCV RNA and ALT level.

FIGURE 3. Hepatitis C virus (HCV)-infection-testing algorithm for asymptomatic persons



In clinical settings, use of RT-PCR to detect HCV RNA might be appropriate to confirm the diagnosis of HCV infection (e.g., in patients with abnormal ALT levels or with indeterminate supplemental anti-HCV test results) although RT-PCR assays are not currently FDA-approved. Detection of HCV RNA by RT-PCR in a person with an anti-HCV-positive result indicates current infection. However, absence of HCV RNA in a person with an anti-HCV-positive result based on EIA testing alone (i.e., without supplemental anti-HCV testing) cannot differentiate between resolved infection and a false-positive anti-HCV test result. In addition, because some persons with HCV infection might experience intermittent viremia, the meaning of a single negative HCV RNA result is difficult to interpret, particularly in the absence of additional clinical information. If HCV RNA is used to confirm anti-HCV results, a separate serum sample will need to be collected and handled in a manner suitable for RT-PCR. If the HCV RNA result is negative, supplemental anti-HCV testing should be performed so that the anti-HCV EIA result can be interpreted before the result is reported to the patient.

Laboratories that perform HCV testing should follow the recommended anti-HCV testing algorithm, which includes use of supplemental testing. Having assurances that the HCV testing is performed in accredited laboratories whose services adhere to recognized standards of good laboratory practice is also necessary. Laboratories that perform HCV RNA testing should review routinely their data regarding internal and external proficiency testing because of great variability in accuracy of HCV RNA testing.

Prevention Messages and Medical Evaluation

HCV-specific information and prevention messages should be provided to infected persons and individuals at risk by trained personnel in public and private health-care settings. Health-education materials should include a) general information about HCV infection; b) risk factors for infection, transmission, disease progression, and treatment; and c) detailed prevention messages appropriate for the population being tested. Written materials might also include information about community resources available for HCV-positive patients for medical evaluation and social support, as appropriate.

Persons with High-Risk Drug and Sexual Practices

Regardless of test results, persons who use illegal drugs or have high-risk sexual practices or occupations should be provided with information regarding how to reduce their risk for acquiring bloodborne and sexually transmitted infections or of potentially transmitting infectious agents to others (see section regarding primary prevention).

Negative Test Results

If their exposure was in the past, persons who test negative for HCV should be reassured.

Indeterminate Test Results

Persons whose HCV test results are indeterminate should be advised that the result is inconclusive, and they should receive appropriate follow-up testing or referral for further testing (see section regarding testing for HCV infection).

Positive Test Results

Persons who test positive should be provided with information regarding the need for a) preventing further harm to their liver; b) reducing risks for transmitting HCV to others; and c) medical evaluation for chronic liver disease and possible treatment.

- To protect their liver from further harm, HCV-positive persons should be advised to
 - not drink alcohol;
 - not start any new medicines, including over-the-counter and herbal medicines, without checking with their doctor; and
 - get vaccinated against hepatitis A if liver disease is found to be present.
- To reduce the risk for transmission to others, HCV-positive persons should be advised to
 - not donate blood, body organs, other tissue, or semen;
 - not share toothbrushes, dental appliances, razors, or other personal-care articles that might have blood on them; and
 - cover cuts and sores on the skin to keep from spreading infectious blood or secretions.
- HCV-positive persons with one long-term steady sex partner do not need to change their sexual practices. They should
 - discuss the risk, which is low but not absent, with their partner (If they want to lower the limited chance of spreading HCV to their partner, they might decide to use barrier precautions [e.g., latex condoms]); and
 - discuss with their partner the need for counseling and testing.
- HCV-positive women do not need to avoid pregnancy or breastfeeding. Potential, expectant, and new parents should be advised that
 - approximately 5 out of every 100 infants born to HCV-infected women become infected (This occurs at the time of birth, and no treatment exists that can prevent this from happening);
 - infants infected with HCV at the time of birth seem to do very well in the first years of life (More studies are needed to determine if these infants will be affected by the infection as they grow older);
 - no evidence exists that mode of delivery is related to transmission; therefore, determining the need for cesarean delivery versus vaginal delivery should not be made on the basis of HCV infection status;
 - limited data regarding breastfeeding indicate that it does not transmit HCV, although HCV-positive mothers should consider abstaining from breastfeeding if their nipples are cracked or bleeding;

- infants born to HCV-positive women should be tested for HCV infection and if positive, evaluated for the presence or development of chronic liver disease (see section regarding routine testing of children born to HCV-positive women); and
- if an HCV-positive woman has given birth to any children after the woman became infected with HCV, she should consider having the children tested.
- Other counseling messages
 - HCV is not spread by sneezing, hugging, coughing, food or water, sharing eating utensils or drinking glasses, or casual contact.
 - Persons should not be excluded from work, school, play, child-care or other settings on the basis of their HCV infection status.
 - Involvement with a support group might help patients cope with hepatitis C.
- HCV-positive persons should be evaluated (by referral or consultation, if appropriate) for presence or development of chronic liver disease including
 - assessment for biochemical evidence of chronic liver disease;
 - assessment for severity of disease and possible treatment according to current practice guidelines in consultation with, or by referral to, a specialist knowledgeable in this area (see excerpts from NIH Consensus Statement in the following section); and
 - determination of need for hepatitis A vaccination.

NIH Consensus Statement Regarding Management of Hepatitis C (Excerpted)

The NIH "Consensus Statement on Management of Hepatitis C" was based on data available in March 1997 (133). Because of advances in the field of antiviral therapy for chronic hepatitis C, standards of practice might change, and readers should consult with specialists knowledgeable in this area.

Persons Recommended for Treatment

Treatment is recommended for patients with chronic hepatitis C who are at greatest risk for progression to cirrhosis, as characterized by

- persistently elevated ALT levels;
- detectable HCV RNA; and
- a liver biopsy indicating either portal or bridging fibrosis or at least moderate degrees of inflammation and necrosis.

Persons for Whom Treatment Is Unclear

Included are

- patients with compensated cirrhosis (without jaundice, ascites, variceal hemorrhage, or encephalopathy);

- patients with persistent ALT elevations, but with less severe histologic changes (i.e., no fibrosis and minimal necroinflammatory changes) (In these patients, progression to cirrhosis is likely to be slow, if at all; therefore, observation and serial measurements of ALT and liver biopsy every 3–5 years is an acceptable alternative to treatment with interferon); and
- patients aged <18 years or >60 years (note that interferon is not approved for patients aged <18 years).

Persons for Whom Treatment Is Not Recommended

Included are

- patients with persistently normal ALT values;
- patients with advanced cirrhosis who might be at risk for decompensation with therapy;
- patients who are currently drinking excessive amounts of alcohol or who are injecting illegal drugs (treatment should be delayed until these behaviors have been discontinued for ≥ 6 months); and
- persons with major depressive illness, cytopenias, hyperthyroidism, renal transplantation, evidence of autoimmune disease, or who are pregnant.

PUBLIC HEALTH SURVEILLANCE

The objectives of conducting surveillance for hepatitis C are to

- identify new cases and determine disease incidence and trends;
- determine risk factors for infection and disease transmission patterns;
- estimate disease burden; and
- identify infected persons who can be counseled and referred for medical follow-up.

Various surveillance approaches are required to achieve these objectives because of limitations of diagnostic tests for HCV infection, the number of asymptomatic patients with acute and chronic disease, and the long latent period between infection and chronic disease outcome.

Surveillance for Acute Hepatitis C

Surveillance for acute hepatitis C — new, symptomatic infections — provides the information necessary for determining incidence trends, changing patterns of transmission and persons at highest risk for infection. In addition, surveillance for new cases provides the best means to evaluate effectiveness of prevention efforts and to identify missed opportunities for prevention. Acute hepatitis C is one of the diseases mandated by the Council of State and Territorial Epidemiologists (CSTE) for reporting to CDC's National Notifiable Diseases Surveillance System. However, hepatitis C

reporting has been unreliable to date because most health departments do not have the resources required for case investigations to determine if a laboratory report represents acute infection, chronic infection, repeated testing of a person previously reported, or a false-positive result. Historically, the most reliable national data regarding acute disease incidence and transmission patterns have come from sentinel surveillance (i.e., sentinel counties study of acute viral hepatitis). As hepatitis C prevention and control programs are implemented, federal, state, and local agencies will need to determine the best methods to effectively monitor new disease acquisition.

Laboratory Reports of Anti-HCV-Positive Tests

Although limitations exist for the use of anti-HCV-positive laboratory reports to identify new cases and to monitor trends in disease incidence, they potentially are an important source from which state and local health departments can identify infected persons who need counseling and medical follow-up. Development of registries of persons with anti-HCV-positive laboratory results might facilitate efforts to provide counseling and medical follow-up and these registries could be used to provide local, state, and national estimates of the proportion of persons with HCV infection who have been identified. If such registries are developed, the confidentiality of individual identifying information should be ensured according to applicable laws and regulations.

Serologic Surveys

Serologic surveys at state and local levels can characterize regional and local variations in prevalence of HCV infection, identify populations at high risk, monitor trends, and evaluate prevention programs. Existing laboratory-based reporting of HCV-positive test results cannot provide this information because persons who are tested will not be representative of the population as a whole, and certain populations at high risk might be underrepresented. Thus, data from newly designed or existing serologic surveys will be needed to monitor trends in HCV infection and evaluate prevention programs at state and local levels.

Surveillance for Chronic Liver Disease

Surveillance for HCV-related chronic liver disease can provide information to measure the burden of disease, determine natural history and risk factors, and evaluate the effect of therapeutic and prevention measures on incidence and severity of disease. Until recently, no such surveillance existed, but a newly established sentinel surveillance pilot program for physician-diagnosed chronic liver disease will provide baseline data and a template for a comprehensive sentinel surveillance system for chronic liver disease. As the primary source of data regarding the incidence and natural history of chronic liver disease, this network will be pivotal for monitoring the effects of education, counseling, other prevention programs, and newly developed therapies on the burden of the disease.

FUTURE DIRECTIONS

To prevent chronic HCV infection and its sequelae, prevention of new HCV infections should be the primary objective of public health activities. Achieving this objective will require the integration of HCV prevention and surveillance activities into current public health infrastructure. In addition, several questions concerning the epidemiology of HCV infection remain, and the answers to those questions could change or modify primary prevention activities. These questions primarily concern the magnitude of the risk attributable to sexual transmission of HCV and to illegal noninjecting-drug use.

Identification of the large numbers of persons in the United States with chronic HCV infection is resource-intensive. The most efficient means to achieve this identification is unknown, because the prevention effectiveness of various implementation strategies has not been evaluated. However, widespread programs to identify, counsel, and treat HCV-infected persons, combined with improvements in the efficacy of treatment, are expected to lower the morbidity and mortality from HCV-related chronic liver disease substantially. Monitoring the progress of these activities to determine their effectiveness in achieving a reduction in HCV-related chronic disease is important.

References

1. CDC. Public Health Service inter-agency guidelines for screening donors of blood, plasma, organs, tissues, and semen for evidence of hepatitis B and hepatitis C. *MMWR* 1991;40(No. RR-4):1-17.
2. Alter MJ. Epidemiology of hepatitis C. *Hepatology* 1997;26:62S-5S.
3. McQuillan GM, Alter MJ, Moyer LA, Lambert SB, Margolis HS. A population based serologic study of hepatitis C virus infection in the United States. In Rizzetto M, Purcell RH, Gerin JL, Verme G, eds. *Viral Hepatitis and Liver Disease*, Edizioni Minerva Medica, Turin, 1997, 267-70.
4. Dufour MC. Chronic liver disease and cirrhosis. In Everhart JE, ed. *Digestive diseases in the United States: epidemiology and impact*. US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. Washington, DC: US Government Printing Office, 1994; NIH publication no. 94-1447, 615-45.
5. Alter MJ, Hadler SC, Judson FN, et al. Risk factors for acute non-A, non-B hepatitis in the United States and association with hepatitis C virus infection. *JAMA* 1990;264:2231-35.
6. Alter HJ, Holland PV, Purcell RH, et al. Posttransfusion hepatitis after exclusion of commercial and hepatitis-B antigen-positive donors. *Ann Intern Med* 1972;77:691-9.
7. Alter HJ, Purcell RH, Holland PV, Feinstone SM, Morrow AG, Moritsugu Y. Clinical and serological analysis of transfusion-associated hepatitis. *Lancet* 1975;2:838-41.
8. Seeff LB, Wright EC, Zimmerman HJ, McCollum RW, VA Cooperative Studies Group. VA cooperative study of post-transfusion hepatitis and responsible risk factors. *Am J Med Sci* 1975;270:355-62.
9. Feinstone SM, Kapikian AZ, Purcell RH, Alter HJ, Holland PV. Transfusion-associated hepatitis not due to viral hepatitis type A or B. *N Engl J Med* 1975;292:767-70.
10. Choo QL, Kuo G, Weiner AJ, Overby LR, Bradley DW. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. *Science* 1989;244:359-62.
11. Kuo G, Choo QL, Alter HJ, et al. An assay for circulating antibodies to a major etiologic virus of human non-A, non-B hepatitis. *Science* 1989;244: 362-4.
12. Alter HJ, Purcell RH, Shih JW, et al. Detection of antibody to hepatitis C virus in prospectively followed transfusion recipients with acute and chronic non-A, non-B hepatitis. *N Engl J Med* 1989;321:1494-1500.
13. Aach RD, Stevens CE, Hollinger FB, et al. Hepatitis C virus infection in post-transfusion hepatitis. An analysis with first- and second-generation assays. *N Engl J Med* 1991;325:1325-9.

14. Alter MJ, Margolis HS, Krawczynski K, Judson, FN, Mares A, Alexander WJ, et al. The natural history of community-acquired hepatitis C in the United States. *N Engl J Med* 1992;327:1899–1905.
15. Alter, MJ. Epidemiology of hepatitis C in the west. *Semin Liver Dis* 1995;15:5–14.
16. Donahue JG, Nelson KE, Muñoz A, et al. Antibody to hepatitis C virus among cardiac surgery patients, homosexual men, and intravenous drug users in Baltimore, Maryland. *Am J Epidemiol* 1991;134:1206–11.
17. Zeldis JB, Jain S, Kuramoto IK, et al. Seroepidemiology of viral infections among intravenous drug users in northern California. *West J Med* 1992; 156:30–5.
18. Fingerhood MI, Jasinski DR, Sullivan JT. Prevalence of hepatitis C in a chemically dependent population. *Arch Intern Med* 1993;153:2025–30.
19. Garfein RS, Vlahov D, Galai N, Doherty, MC, Nelson, KE. Viral infections in short-term injection drug users: the prevalence of the hepatitis C, hepatitis B, human immunodeficiency, and human T-lymphotropic viruses. *Am J Pub Health* 1996;86:655–61.
20. Brettler DB, Alter HJ, Deinstag JL, Forsberg AD, Levine PH. Prevalence of hepatitis C virus antibody in a cohort of hemophilia patients. *Blood* 1990;76:254–6.
21. Troisi CL, Hollinger FB, Hoots WK, et al. A multicenter study of viral hepatitis in a United States hemophilic population. *Blood* 1993;81:412–8.
22. Kumar A, Kulkarni R, Murray DL, et al. Serologic markers of viral hepatitis A, B, C, and D in patients with hemophilia. *J Med Virology* 1993;41:205–9.
23. Tokars JI, Miller ER, Alter MJ, Arduino MJ. National surveillance of dialysis associated diseases in the United States, 1995. *ASAIO Journal* 1998;44:98–107.
24. Osmond DH, Charlebois E, Sheppard HW, et al. Comparison of risk factors for hepatitis C and hepatitis B virus infection in homosexual men. *J Infect Dis* 1993;167:66–71.
25. Weinstock HS, Bolan G, Reingold AL, Polish LB: Hepatitis C virus infection among patients attending a clinic for sexually transmitted diseases. *JAMA* 1993;269:392–4.
26. Thomas DL, Cannon RO, Shapiro CN, Hook EW III, Alter MJ. Hepatitis C, hepatitis B, and human immunodeficiency virus infections among non-intravenous drug-using patients attending clinics for sexually transmitted diseases. *J Infect Dis* 1994;169:990–5.
27. Buchbinder SP, Katz MH, Hessol NA, Liu J, O'Malley PM, Alter, MJ. Hepatitis C virus infection in sexually active homosexual men. *J Infect* 1994;29:263–9.
28. Thomas DL, Zenilman JM, Alter HJ, et al. Sexual transmission of hepatitis C virus among patients attending sexually transmitted diseases clinics in Baltimore—an analysis of 309 sex partnerships. *J Infect Dis* 1995;171:768–75.
29. Thomas DL, Factor SH, Kelen GD, Washington AS, Taylor E Jr, Quinn TC. Viral hepatitis in health care personnel at The Johns Hopkins Hospital. *Arch Intern Med* 1993;153:1705–12.
30. Cooper BW, Krusell A, Tilton RC, Goodwin R, Levitz RE. Seroprevalence of antibodies to hepatitis C virus in high-risk hospital personnel. *Infect Control Hosp Epidemiol* 1992;13:82–5.
31. Panlilio AL, Shapiro CN, Schable CA, et al. Serosurvey of human immunodeficiency virus, hepatitis B virus, and hepatitis C virus infection among hospital-based surgeons. *J Am Coll Surg* 1995;180:16–24.
32. Shapiro CN, Tokars JI, Chamberland ME, and the American Academy of Orthopedic Surgeons Serosurvey Study Committee. Use of hepatitis B vaccine and infection with hepatitis B and C among orthopaedic surgeons. *J Bone Joint Surg* 1996;78-A:1791–1800.
33. Thomas DL, Gruninger SE, Siew C, Joy ED, Quinn TC. Occupational risk of hepatitis C infections among general dentists and oral surgeons in North America. *Am J Med* 1996;100:41–5.
34. Kleinman S, Alter H, Busch M, Holland P, Tegtmeier G, Nelles M, et al. Increased detection of hepatitis C virus (HCV)-infected blood donors by a multiple-antigen HCV enzyme immunoassay. *Transfusion* 1992;32:805–13.
35. Williams AE, Thomson RA, Schreiber GB, et al. Estimates of infectious disease risk factors in US blood donors. *JAMA* 1997;277:967–72.
36. Feinleib JA, Schenpp, Michael RT. Sexually transmitted infections. In Laumann EO, Gagnon JH, Michael RT, Michaels S. *The social organization of sexuality. Sexual practices in the United States.* The University of Chicago Press, Chicago, 1994, 376–441.
37. Zuck TF, Rose GA, Dumaswala UJ, Geer NJ. Experience with a transfusion recipient education program about hepatitis C. *Transfusion* 1990;30:759–61.

38. Murphy EL, Bryzman S, Williams AE, et al. Demographic determinants of hepatitis C virus seroprevalence among blood donors. *JAMA* 1996;275: 995–1000.
39. Li F, Moon D, Michaels S. Homosexuality. In Laumann EO, Gagnon JH, Michael RT, Michaels S. *The social organization of sexuality. Sexual practices in the United States.* The University of Chicago Press, Chicago, 1994,283–320.
40. Alter MJ, Gerety RJ, Smallwood L, et al. Sporadic non-A, non-B hepatitis: frequency and epidemiology in an urban United States population. *J Infect Dis* 1982;145:886–93.
41. Alter MJ, Coleman PJ, Alexander WJ, et al. Importance of heterosexual activity in the transmission of hepatitis B and non-A, non-B hepatitis. *JAMA* 1989;262:1201–5.
42. Donahue JG, Munoz A, Ness PM, et al. The declining risk of post-transfusion hepatitis C virus infection. *N Engl J Med* 1992;327:369–73.
43. Schreiber GB, Busch MP, Kleinman SH, Korelitz JJ. The risk of transfusion-transmitted viral infections. *N Engl J Med* 1996;334:1685–90.
44. Makris M, Garson JA, Ring CJ, Tuke PW, Tedder RS, Preston FE. Hepatitis C viral RNA in clotting factor concentrates and the development of hepatitis in recipients. *Blood* 1993; 81:1898–1902.
45. CDC. Outbreak of hepatitis C associated with intravenous immunoglobulin administration—United States, October 1993–June 1994. *MMWR* 1994;43:505–9.
46. Bresee JS, Mast EE, Coleman PJ, et al. Hepatitis C virus infection associated with administration of intravenous immune globulin. A cohort study. *JAMA* 1996;276:1563–7.
47. Eggen BM, Nordbo SA. Transmission of HCV by organ transplantation. *N Engl J Med* 1992; 326:410–1.
48. Pereira BJ, Milford EL, Kirkman RL, et al. Prevalence of hepatitis C virus RNA in organ donors positive for hepatitis C antibody and in the recipients of their organs. *N Engl J Med* 1992; 327:910–5.
49. Conrad EU, Gretch DR, Obermeyer KR, et al. Transmission of the hepatitis-C virus by tissue transplantation. *J Bone Joint Surgery* 1995;77:214–24.
50. Pereira BJG, Milford EL, Kirkman RL, et al. Low risk of liver disease after tissue transplantation from donors with HCV. *Lancet* 1993;341:903–4.
51. Villano SA, Vlahov D, Nelson KE, Lyles CM, Cohn S, Thomas DL. Incidence and risk factors for hepatitis C among injection drug users in Baltimore, Maryland. *J Clin Microbiol* 1997; 35:3274–7.
52. Garfein RS, Doherty MC, Monterroso ER, Thomas DL, Nelson KE, Vlahov D. Prevalence and incidence of hepatitis C virus infection among young adult injection drug users. *J Acquir Immune Defic Syndr Hum Retrovirol* 1998;18(suppl 1):S11–9.
53. Alter MJ. The epidemiology of acute and chronic hepatitis C. *Clinics in Liver Disease* 1997;1:559–68.
54. Koester SK, Hoffer L. “Indirect sharing”: additional HIV risks associated with drug injection. *AIDS & Pub Policy J* 1994;9:100–5.
55. Heimer R, Khoshnood K, Jariwala-Freeman B, Duncan B, Harima Y. Hepatitis in used syringes: the limits of sensitivity of techniques to detect hepatitis B virus (HBV) DNA, hepatitis C virus (HCV) RNA, and antibodies to HBV core and HCV antigens. *J Infect Dis* 1996;173:997–1000.
56. Conry-Cantilena C, VanRaden M, Gibble J, et al. Routes of infection, viremia, and liver disease in blood donors found to have hepatitis C virus infection. *N Engl J Med* 1996;334:1691–6.
57. Allander T, Gruber A, Naghavi M, et al. Frequent patient-to-patient transmission of hepatitis C virus in a haematology ward. *Lancet* 1995; 345:603–7.
58. Bronowicki JP, Venard V, Botte C, et al. Patient-to-patient transmission of hepatitis C virus during colonoscopy. *N Engl J Med* 1997;337:237–40.
59. Schvarcz R, Johansson B, Nyström B, Sönnernborg A. Nosocomial transmission of hepatitis C virus. *Infection* 1997;25:74–7.
60. Guyer B, Bradley DW, Bryan JA, Maynard JE. Non-A, non-B hepatitis among participants in a plasmapheresis stimulation program. *J Infect Dis* 1979;139:634–40.
61. Moyer LA, Alter MJ. Hepatitis C virus in the hemodialysis setting: a review with recommendations for control. *Seminars in Dialysis* 1994;7:124–7.
62. Niu MT, Coleman PJ, Alter MJ. Multicenter study of hepatitis C virus infection in chronic hemodialysis patients and hemodialysis center staff members. *Am J Kidney Dis* 1993;22: 568–73.

63. Hardy NM, Sandroni S, Danielson S, Wilson WJ. Antibody to hepatitis C virus increases with time on hemodialysis. *Clin Nephrol* 1992;38:44-8.
64. Niu MT, Alter MJ, Kristensen C, Margolis HS. Outbreak of hemodialysis-associated non-A, non-B hepatitis and correlation with antibody to hepatitis C virus. *Am J Kidney Dis* 1992;4:345-52.
65. Favero MS, Alter MJ. The reemergence of hepatitis B virus infection in hemodialysis centers. *Seminars in Dialysis* 1996;9:373-4.
66. Polish LB, Tong MJ, Co RL, Coleman PJ, Alter MJ. Risk factors for hepatitis C virus infection among health care personnel in a community hospital. *Am J Infect Control* 1993;21:196-200.
67. Alter MJ. Occupational exposure to hepatitis C virus: a dilemma. *Infect Control Hosp Epidemiol* 1994;15:742-4.
68. Lanphear BP, Linnemann CC Jr, Cannon CG, DeRonde MM, Pender L, Kerley LM. Hepatitis C virus infection in healthcare workers: risk of exposure and infection. *Infect Control Hosp Epidemiol* 1994;15:745-50.
69. Puro V, Petrosillo N, Ippolito G. Italian Study Group on Occupational Risk of HIV and Other Bloodborne Infections. Risk of hepatitis C seroconversion after occupational exposures in health care workers. *Am J Infect Control* 1995;23:273-7.
70. Mitsui T, Iwano K, Masuko K, et al. Hepatitis C virus infection in medical personnel after needlestick accident. *Hepatology* 1992;16:1109-14.
71. Sartori M, La Terra G, Aglietta M, Manzin A, Navino C, Verzetti G. Transmission of hepatitis C via blood splash into conjunctiva [Letter]. *Scand J Infect Dis* 1993;25:270-1.
72. Ippolito G, Puro V, Petrosillo N, et al. Simultaneous infection with HIV and hepatitis C virus following occupational conjunctival blood exposure [Letter]. *JAMA* 1998; 280:28.
73. Esteban JI, Gomez J, Martell M, et al. Transmission of hepatitis C virus by a cardiac surgeon. *N Engl J Med* 1996;334:555-60.
74. Mansell CJ, Locarnini SA. Epidemiology of hepatitis C in the east. *Semin Liver Dis* 1995;15:15-32.
75. Mele A, Saggiocca L, Manzillo G, et al. Risk factors for acute non-A, non-B hepatitis and their relationship to antibodies for hepatitis C virus: a case-control study. *Am J Public Health* 1994;84:1640-43.
76. Kiyosawa K, Tanaka E, Sodeyama T, et al. Transmission of hepatitis C in an isolated area in Japan: community-acquired infection. *Gastroenterology* 1994;106:1596-1602.
77. Kaldor JM, Archer GT, Buring ML, et al. Risk factors for hepatitis C virus infection in blood donors: a case-control study. *Med J Australia* 1992;157:227-30.
78. Tumminelli F, Marcellin P, Rizzo S, et al. Shaving as a potential source of hepatitis C virus infection. *Lancet* 1995;345:658.
79. Stroffolini T, Menchinelli M, Taliani G, et al. High prevalence of hepatitis C virus infection in a small central Italian town: lack of evidence of parenteral exposure. *Ital J Gastroenterol Hepatol* 1995;27:235-8.
80. Mele A, Corona R, Tosti ME, et al. Beauty treatments and risk of parenterally transmitted hepatitis: results from the hepatitis surveillance system in Italy. *Scand J Infect Dis* 1995;27:441-4.
81. Sun D-X, Zhang F-G, Geng Y-Q, Xi D-S. Hepatitis C transmission by cosmetic tattooing in women [Letter]. *Lancet* 1996;347:541.
82. Everhart JE, Di Bisceglie AM, Murray LM, et al. Risk for non-A, non-B (type C) hepatitis through sexual or household contact with chronic carriers. *Ann Intern Med* 1990;112:544-5.
83. Eyster ME, Alter HJ, Aledort LM, Quan S, Hatzakis A, Goedert JJ. Heterosexual co-transmission of hepatitis C virus (HCV) and human immunodeficiency virus (HIV). *Ann Intern Med* 1991; 115:764-8.
84. Gordon SC, Patel AH, Kulesza GW, Barnes RE, Silverman AL. Lack of evidence for the heterosexual transmission of hepatitis C. *Am J Gastroenterol* 1992;87:1849-51.
85. Tong MJ, Lai PPC, Hwang S-J, et al. Evaluation of sexual transmission in patients with hepatitis C infection. *Clinical and Diagnostic Virology* 1995;3:39-47.
86. Brettler DB, Mannucci PM, Gringeri A, et al. The low risk of hepatitis C virus transmission among sexual partners of hepatitis C-infected males: an international, multicenter study. *Blood* 1992;80:540-3.

87. Mast EE, Darrow WW, Witte J, et al. Hepatitis C virus infection among prostitutes: evidence for sexual transmission and protective efficacy of condoms [Abstract]. Program and abstracts of the Third International Symposium on HCV, Strasbourg, France, September 1991.
88. CDC. Transmission of hepatitis C virus infection associated with home infusion therapy for hemophilia. *MMWR* 1997;46:597-606.
89. Wejstal R, Widell A, Mansson AS, Hernodsson S, Norkrans G. Mother-to-infant transmission of hepatitis C virus. *Ann Intern Med* 1992;117:887-90.
90. Lam JP, McOmish F, Burns SM, Yap PL, Mok JY, Simmonds P. Infrequent vertical transmission of hepatitis C virus. *J Infect Dis* 1993;167:572-6.
91. Roudot-Thoraval F, Pawlotsky J-M, Thiers V, et al. Lack of mother-to-infant transmission of hepatitis C virus in human immunodeficiency virus-seronegative women: a prospective study with hepatitis C virus RNA testing. *Hepatology* 1993; 17:722-77.
92. Ohto H, Terazawa S, Sasaki N, et al. Transmission of hepatitis C virus from mothers to infants. *N Engl J Med* 1994;330:744-50.
93. Lin HH, Kao JH, Hsu HY, et al. Possible role of high-titer maternal viremia in perinatal transmission of hepatitis C virus. *J Infect Dis* 1994;169:638-41.
94. Ni YH, Lin HH, Chen PJ, Hsu HY, Chen DS, Chang MH. Temporal profile of hepatitis C virus antibody and genome in infants born to mothers infected with hepatitis C virus but without human immunodeficiency virus coinfection. *J Hepatology* 1994;20:641-5.
95. Resti M, Azzari C, Lega L, et al. Mother-to-infant transmission of hepatitis C virus. *Acta Paediatr* 1995;84:251-5.
96. Manzini P, Saracco G, Cerchier A, et al. Human immunodeficiency virus infection as risk factor for mother-to-child hepatitis C virus transmission; persistence of anti-hepatitis C virus in children is associated with the mother's anti-hepatitis C virus immunoblotting pattern. *Hepatology* 1995;21:328-32.
97. Giacchino R, Picciotto A, Tasso L, Timitilli A, Sinelli N. Vertical transmission of hepatitis C. *Lancet* 1995;345:1122-3.
98. Zuccotti GV, Ribero ML, Giovannini M, et al. Effect of hepatitis C genotype on mother-to-infant transmission of virus. *J of Pediatrics* 1995;127:278-80.
99. Zanetti AR, Tanzi E, Paccagnini S, et al. Mother-to-infant transmission of hepatitis C virus. *Lancet* 1995;345:289-91.
100. Paccagnini S, Principi N, Massironi E, et al. Perinatal transmission and manifestation of hepatitis C virus infection in a high risk population. *Pediatr Infect Dis J* 1995;14:195-9.
101. Granovsky MO, Minkoff HL, Tess BH, et al. Hepatitis C virus infection in the mothers and infants cohort study. *Pediatrics* 1998;102:355-9.
102. Thomas DL, Villano SA, Riester KA, et al. Perinatal transmission of hepatitis C virus from human immunodeficiency virus type 1-infected mothers. *Women and Infants Transmission Study. J Infect Dis* 1998;177:1480-8.
103. Cilla G, Pérez-Trallero E, Iturriza M, Carcedo A, Echeverita J. Maternal-infant transmission of hepatitis C virus infection [Letter]. *Pediatr Infect Dis* 1992;11:417.
104. Novati R, Thiers V, Monforte AD, et al. Mother-to-child transmission of hepatitis C virus detected by nested polymerase chain reaction. *J Infect Dis* 1992;165:720-3.
105. Lin HH, Kao JH, Hsu HY, et al. Absence of infection in breast-fed infants born to hepatitis C virus-infected mothers. *J Pediatrics* 1995;126:589-91.
106. Ohto H, Okamoto H, Mishiro S. Vertical transmission of hepatitis C virus [Letter]. *N Engl J Med* 1994;331:400.
107. Gretch DR. Diagnostic tests for hepatitis C. *Hepatology* 1997;26:43S-7S.
108. Gretch DR, dela Rosa C, Carithers RL, Wilson RA, Williams B, Corey L. Assessment of hepatitis C viremia using molecular amplification technologies: correlations and clinical implications. *Ann Intern Med* 1995;123:321-9.
109. Davis GL, Lau JY, Urdea MS, et al. Quantitative detection of hepatitis C virus RNA with a solid-phase signal amplification method: definition of optimal conditions for specimen collection and clinical application in interferon-treated patients. *Hepatology* 1994;19:1337-41.
110. Roth WK, Lee JH, Ruster B, Zeuzem S. Comparison of two quantitative hepatitis C virus reverse transcriptase PCR assays. *J Clin Microbiol* 1996;34:261-4.
111. Pawlotsky J-M. Measuring hepatitis C viremia in clinical samples: can we trust the assays? *Hepatology* 1997;26:1-4.

112. Bukh, J, Miller, RH, Purcell RH. Genetic heterogeneity of hepatitis C virus: quasispecies and genotypes [Review]. *Semin Liver Dis* 1995;15:41-63.
113. Lau JY, Mizokami M, Kolberg JA, et al. Application of six hepatitis C virus genotyping systems to sera from chronic hepatitis C patients in the United States. *J Infect Dis* 1995;171:281-9.
114. Alter HJ, Jett BW, Polito AJ, et al. Analysis of the role of hepatitis C virus in transfusion-associated hepatitis. In Hollinger FB, Lemon SM, Margolis HS, eds. *Viral Hepatitis and Liver Disease*, Baltimore, MD: Williams and Wilkins, 1991, 396-402.
115. Koretz RL, Abbey H, Coleman E, Gitnick G. Non-A, non-B post-transfusion hepatitis: looking back in the second decade. *Ann Intern Med* 1993;119:110-5.
116. Koretz RL, Brezina M, Polito AJ, et al. Non-A, non-B posttransfusion hepatitis: comparing C and non-C hepatitis. *Hepatology* 1993;17:361-5.
117. Marranconi F, Mecenero V, Pellizzer GP, et al. HCV infection after accidental needlestick injury in health-care workers [Letter]. *Infection* 1992;20:111.
118. Seeff LB. Hepatitis C from a needlestick injury [Letter]. *Ann Intern Med* 1991;115:411.
119. Ridzon R, Gallagher K, Ciesielski C, et al. Simultaneous transmission of human immunodeficiency virus and hepatitis C virus from a needle-stick injury. *N Engl J Med* 1997;336:919-22.
120. Liang TJ, Jeffers L, Reddy RK, et al. Fulminant or subfulminant non-A, non-B viral hepatitis: the role of hepatitis C and E viruses. *Gastroenterology* 1993;104:556-62.
121. Wright, TL. Etiology of fulminant hepatic failure: is another virus involved? *Gastroenterology* 1993;104:640-3.
122. Shakil, AO, Conry-Cantilena, C, Alter HJ, et al. Volunteer blood donors with antibody to hepatitis C virus: clinical, biochemical, virologic, and histologic features. *Ann Intern Med* 1995; 123:330-7.
123. Esteban JI, Lopez-Talavera JC, Genesca J, et al. High rate of infectivity and liver disease in blood donors with antibodies to hepatitis C virus. *Ann Intern Med* 1991;115:443-9.
124. Seeff LB, Buskell-Bales Z, Wright EC, et al. Long-term mortality after transfusion-associated non-A, non-B hepatitis. *N Engl J Med* 1992;327:1906-11.
125. Kiyosawa K, Sodeyama T, Tanaka E, et al. Interrelationship of blood transfusion, non-A, non-B hepatitis and hepatocellular carcinoma: analysis by detection of antibody to hepatitis C virus. *Hepatology* 1990;12:671-5.
126. Di Bisceglie AM, Order SE, Klein JL, et al. The role of chronic viral hepatitis in hepatocellular carcinoma in the United States. *Amer J Gastroenterol* 1991;86:335-8.
127. Fattovich G, Giustina G, Degos F, et al. Morbidity and mortality in compensated cirrhosis type C: a retrospective follow-up study of 384 patients. *Gastroenterology* 1997;112:463-72.
128. Di Bisceglie AM, Goodman ZD, Ishak KG, Hoofnagle JH, Melpolder JJ, Alter HJ. Long-term clinical and histopathological follow-up of chronic posttransfusion hepatitis. *Hepatology* 1991;14:969-74.
129. Crowe J, Doyle C, Fielding JF, et al. Presentation of hepatitis C in a unique uniform cohort 17 years from inoculation [Abstract]. *Gastroenterology* 1995; 108:A1054.
130. Poynard T, Bedossa P, Opolon P. Natural history of liver fibrosis progression in patients with chronic hepatitis C. *Lancet* 1997;349:825-32.
131. Koff, RS, Dienstag, JL. Extrahepatic manifestations of hepatitis C and the association with alcoholic liver disease. *Semin Liver Dis* 1995;15:101-9.
132. Vento S, Garofano T, Renzini C, et al. Fulminant hepatitis associated with hepatitis A virus superinfection in patients with chronic hepatitis C. *N Engl J Med* 1998;338:286-90.
133. National Institutes of Health Consensus Development Conference Panel Statement: Management of Hepatitis C. *Hepatology* 1997;26:2S-10S.
134. Hoofnagle JH, Di Bisceglie AM. Drug therapy: The treatment of chronic viral hepatitis [Review Article]. *N Engl J Med* 1997;336:347-556.
135. Lindsay KL. Therapy of hepatitis C: overview. *Hepatology* 1997;26:71S-7S.
136. Serfaty L, Chazouilleres O, Pawlotsky JM, Andreani T, Pellet C, Poupon R. Interferon alfa therapy in patients with chronic hepatitis C and persistently normal aminotransferase activity. *Gastroenterology* 1996;110:291-5.
137. Poynard T, Bedossa P, Chevallier M, et al. A comparison of three interferon alfa-2b regimens for the long-term treatment of chronic non-A, non-B hepatitis. Multicenter Study Group. *N Engl J Med* 1995;332:1457-62.

138. Carithers RL Jr, Emerson SS. Therapy of hepatitis C: meta-analysis of interferon alfa-2b trials. *Hepatology* 1997;26:83S–8S.
139. Schvarcz R, Yun ZB, Sonnerborg A, Weiland O. Combined treatment with interferon alpha-2b and ribavirin for chronic hepatitis C in patients with a previous non-response or non-sustained response to interferon alone. *J Med Virol* 1995;46:43–7.
140. Schalm SW, Hansen BE, Chemello L, et al. Ribavirin enhances the efficacy but not the adverse effects of interferon in chronic hepatitis C. Meta-analysis of individual patient data from European centers. *J Hepatology* 1996;26:961–6.
141. CDC. Recommendations for follow-up of health-care workers after occupational exposure to hepatitis C virus [Notice to Readers]. *MMWR* 1997;46:603–6.
142. Peters M, Davis GL, Dooley JS, Hoofnagle JH. The interferon system in acute and chronic viral hepatitis [Review]. *Progress Liver Dis* 1986;8:453–67.
143. Cammà C, Almasio P, Craxi A. Interferon as treatment for acute hepatitis C. A meta-analysis. *Dig Dis Sc* 1996;41:1248–55.
144. U.S. Preventive Services Task Force. *Guide to clinical preventive services*, 2nd ed. Baltimore: Williams & Wilkins, 1996.
145. CDC. Hepatitis B virus: A comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination: Recommendations of the immunization practices advisory committee (ACIP). *MMWR* 1991;40(No. RR-13):1–25.
146. CDC. Update: recommendations to prevent hepatitis B virus transmission — United States. *MMWR* 1995;44:574–5.
147. US Department of Health and Human Services. Medical advice for persons who inject illicit drugs. *HIV Prevention Bulletin*. CDC, Health Resources & Services Administration, National Institute on Drug Abuse of the National Institutes of Health, and the Center for Substance Abuse and Mental Health Services Administration, May 1997.
148. CDC. 1998 Guidelines for treatment of sexually transmitted diseases. *MMWR* 1998;47(No. RR-1):1–118.
149. CDC. Prevention of hepatitis A through active or passive immunization. Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1996;45(No. RR-15):1–30.
150. Hagan H, Des Jarlais DC, Friedman SR, Purchase D, Alter MJ. Reduced risk of hepatitis B and hepatitis C among injection drug users in the Tacoma syringe exchange program. *Am J Pub Health* 1995;85:1531–7.
151. Valleroy LA, Weinstein B, Jones TS, Groseclose SL, Rolfs RT, Kassler WJ. Impact of increased legal access to needles and syringes on community pharmacies' needle and syringe sales—Connecticut, 1992–1993. *J Acquir Immune Defic Syndr Hum Retrovirol* 1995;10:73–81.
152. Groseclose SL, Weinstein B, Jones TS, Valleroy LA, Fehrs LJ, Kassler WJ. Impact of increased legal access to needles and syringes on practices of injecting-drug users and police officers—Connecticut, 1992–1993. *J AIDS*. 1995;10:82–9.
153. Gostin LO, Lazzarini Z, Jones TS, Flaherty K. Prevention of HIV/AIDS and other blood-borne diseases among injection drug users: a national survey on the regulation of syringes and needles. *JAMA* 1997;277:53–62.
154. CDC. Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers. *MMWR* 1989;38(No. S-6).
155. Garner JS, Hospital Infection Control Practices Advisory Committee. Guideline for isolation precautions in hospitals. *Infect Cont Hosp Epidemiol* 1996;17:54–80.
156. CDC. Immunization of health-care workers. Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). *MMWR* 1997;46(No. RR-18).
157. Favero MS, Tokars JI, Arduino MJ, Alter MJ. Nosocomial infections associated with hemodialysis. In Mayhall CG, ed. *Hospital Epidemiology and Infection Control*. Baltimore, MD: Williams & Wilkins, 1998, in press.
158. American Academy of Pediatrics. Hepatitis C. In Peter G, ed. 1997 Red Book: Report of the Committee on Infectious Diseases. 24th ed. Elk Grove Village, IL: American Academy of Pediatrics 1997, 260–5.

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APPENDIX G

IMMUNIZATION OF HEALTH-CARE WORKERS

This appendix lists the URLs for the Centers for Disease Control *Morbidity and Mortality Weekly Report*: “Immunization of Health-Care Workers. Recommendations of the Advisory Committee on Immunization Practices (APIC) and the Hospital Infection Control Practices Advisory Committee (HICPAC).” December 26, 1997, Vol.46, No.RR-18. The Adobe Acrobat pdf version contains the text of the report. The CDC has the text of this report available on their website. The URLs are:

< http://www.cdc.gov/epo/mmwr/preview/ind97_rr.html >

or

< <ftp://ftp.cdc.gov/pub/Publications/mmwr/rr/rr4618.pdf> >

Immunization of Health-Care Workers

Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)
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Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC)

Summary

This report summarizes recommendations of the Advisory Committee on Immunization Practices (ACIP) concerning the use of certain immunizing agents in health-care workers (HCWs) in the United States. It was prepared in consultation with the Hospital Infection Control Practices Advisory Committee (HICPAC) and is consistent with current HICPAC guidelines for infection control in health-care personnel. These recommendations can assist hospital administrators, infection control practitioners, employee health physicians, and HCWs in optimizing infection prevention and control programs. Background information for each vaccine-preventable disease and specific recommendations for use of each vaccine are presented. The diseases are grouped into three categories: a) those for which active immunization is strongly recommended because of special risks for HCWs; b) those for which immunoprophylaxis is or may be indicated in certain circumstances; and c) those for which protection of all adults is recommended. This report reflects current ACIP recommendations at the time of publication. ACIP statements on individual vaccines and disease updates in MMWR should be consulted for more details regarding the epidemiology of the diseases, immunization schedules, vaccine doses, and the safety and efficacy of the vaccines.

INTRODUCTION

Because of their contact with patients or infective material from patients, many health-care workers (HCWs)(e.g., physicians, nurses, emergency medical personnel, dental professionals and students, medical and nursing students, laboratory technicians, hospital volunteers, and administrative staff) are at risk for exposure to and possible transmission of vaccine-preventable diseases. Maintenance of immunity is therefore an essential part of prevention and infection control programs for HCWs. Optimal use of immunizing agents safeguards the health of workers and protects patients from becoming infected through exposure to infected workers (Table 1) (1–15). Consistent immunization programs could substantially reduce both the number of susceptible HCWs in hospitals and health departments and the attendant risks for transmission of vaccine-preventable diseases to other workers and patients (16). In addition to HCWs in hospitals and health departments, these recommendations apply to those in private physicians' offices, nursing homes, schools, and laboratories, and to first responders.

Any medical facility or health department that provides direct patient care is encouraged to formulate a comprehensive immunization policy for all HCWs. The American Hospital Association has endorsed the concept of immunization programs

TABLE 1. Recommendations for immunization practices and use of immunobiologics applicable to disease prevention among health-care workers — Advisory Committee on Immunization Practices (ACIP) statements published as of September 1, 1997

Subject	MMWR Publication
General recommendations on immunization	1994;43(No.RR-1):1-39
Adult immunization	1991;40(No.RR-12):1-94
Altered immunocompetence	1993;42(No.RR-4):1-18
Adverse reactions, contraindications, and precautions	1996;45(No.RR-12):1-35
Bacille Calmette-Guérin vaccine	1996;45(No.RR-4):1-18
Diphtheria, tetanus, and pertussis	1991;40(No.RR-10):1-28 1997;46(No. RR-7)
Hepatitis B	1991;40(No.RR-13):1-25
Hepatitis A	1996;45(No.RR-15):1-30
Influenza*	1997;46(No.RR-9):1-25
Japanese encephalitis	1993;42(No.RR-1):1-15
Measles	1989;38(No.S9):1-18
Measles, mumps, rubella (MMR)	1998;47 (in press)
Meningococcal disease and outbreaks	1997;46(No.RR-5):1-21
Mumps (MMR in press, see Measles above)	1989;38:388-92, 397-400
Pertussis, acellular (see also Diphtheria above) (supplementary statements)	1992;41(No.RR-1):1-10 1992;41(No.RR-15):1-5 1997;46(No.RR-7):1-25
Pneumococcal	1997;46(No.RR-8):1-24
Poliomyelitis	1997;46(No.RR-3):1-25
Rabies	1991;40(No.RR-3):1-19
Rubella (MMR in press, see Measles above)	1990;39(No.RR-15):1-18
Typhoid	1994;43(No.RR-14):1-7
Vaccinia (smallpox)	1991;40(No.RR-14):1-10
Varicella	1996;45(No.RR-11):1-36

*Each year influenza vaccine recommendations are reviewed and amended to reflect updated information concerning influenza activity in the United States for the preceding influenza season and to provide information on the vaccine available for the upcoming influenza season. These recommendations are published annually in the MMWR, usually during May or June.

for both hospital personnel and patients (17). The following recommendations concerning vaccines of importance to HCWs should be considered during policy development (Table 2).

BACKGROUND

Diseases for Which Immunization Is Strongly Recommended

On the basis of documented nosocomial transmission, HCWs are considered to be at significant risk for acquiring or transmitting hepatitis B, influenza, measles, mumps, rubella, and varicella. All of these diseases are vaccine-preventable.

Hepatitis B

Hepatitis B virus (HBV) infection is the major infectious hazard for health-care personnel. During 1993, an estimated 1,450 workers became infected through exposure to blood and serum-derived body fluids, a 90% decrease from the number estimated to have been thus infected during 1985 (18–20). Data indicate that 5%–10% of HBV-infected workers become chronically infected. Persons with chronic HBV infection are at risk for chronic liver disease (i.e., chronic active hepatitis, cirrhosis, and primary hepatocellular carcinoma) and are potentially infectious throughout their lifetimes. An estimated 100–200 health-care personnel have died annually during the past decade because of the chronic consequences of HBV infection (CDC, unpublished data).

The risk for acquiring HBV infection from occupational exposures is dependent on the frequency of percutaneous and permucosal exposures to blood or body fluids containing blood (21–25). Depending on the tasks he or she performs, any health-care or public safety worker may be at high risk for HBV exposure. Workers performing tasks involving exposure to blood or blood-contaminated body fluids should be vaccinated. For public safety workers whose exposure to blood is infrequent, timely postexposure prophylaxis may be considered, rather than routine preexposure vaccination.

In 1987, the Departments of Labor and Health and Human Services issued a Joint Advisory Notice regarding protection of employees against workplace exposure to HBV and human immunodeficiency virus (HIV), and began the process of rulemaking to regulate such exposures (26). The Federal Standard issued in December, 1991 under the Occupational Safety and Health Act mandates that hepatitis B vaccine be made available at the employer's expense to all health-care personnel who are occupationally exposed to blood or other potentially infectious materials (27). Occupational exposure is defined as "...reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties (27)." The Occupational Safety and Health Administration (OSHA) follows current ACIP recommendations for its immunization practices requirements (e.g., preexposure and postexposure antibody testing). These regulations have accelerated and broadened the use of hepatitis B vaccine in HCWs and have ensured maximal efforts to prevent this occupational disease (23).

Prevaccination serologic screening for prior infection is not indicated for persons being vaccinated because of occupational risk. Postvaccination testing for antibody to hepatitis B surface antigen (anti-HBs) response is indicated for HCWs who have blood or patient contact and are at ongoing risk for injuries with sharp instruments or needlesticks (e.g., physicians, nurses, dentists, phlebotomists, medical technicians and students of these professions). Knowledge of antibody response aids in determining appropriate postexposure prophylaxis.

TABLE 2. Immunizing agents and immunization schedules for health-care workers (HCWs)*

Generic name	Primary schedule and booster(s)	Indications	Major precautions and contraindications	Special considerations
IMMUNIZING AGENTS STRONGLY RECOMMENDED FOR HEALTH-CARE WORKERS				
Hepatitis B (HB) recombinant vaccine	Two doses IM 4 weeks apart; third dose 5 months after second; booster doses not necessary.	Preexposure: HCWs at risk for exposure to blood or body fluids. Postexposure: See Table 3.	On the basis of limited data, no risk of adverse effects to developing fetuses is apparent. Pregnancy should <i>not</i> be considered a contraindication to vaccination of women. Previous anaphylactic reaction to common baker's yeast is a contraindication to vaccination.	The vaccine produces neither therapeutic nor adverse effects on HBV-infected persons. Prevaccination serologic screening is not indicated for persons being vaccinated because of occupational risk. HCWs who have contact with patients or blood should be tested 1–2 months after vaccination to determine serologic response.
Hepatitis B immune globulin (HBIG)	0.06 mL/kg IM as soon as possible after exposure. A second dose of HBIG should be administered 1 month later if the HB vaccine series has not been started.	Postexposure prophylaxis (Table 3): For persons exposed to blood or body fluids containing HBsAg and who are not immune to HBV infection — 0.06 mL/kg IM as soon as possible (but no later than 7 days after exposure).		
Influenza vaccine (inactivated whole-virus and split-virus vaccines)	Annual vaccination with current vaccine. Administered IM.	HCWs who have contact with patients at high risk for influenza or its complications; HCWs who work in chronic care facilities; HCWs with high-risk medical conditions or who are aged ≥ 65 years.	History of anaphylactic hypersensitivity to egg ingestion.	No evidence exists of risk to mother or fetus when the vaccine is administered to a pregnant woman with an underlying high-risk condition. Influenza vaccination is recommended during second and third trimesters of pregnancy because of increased risk for hospitalization.

Measles live-virus vaccine	One dose SC; second dose at least 1 month later.	HCWs [†] born during or after 1957 who do not have documentation of having received 2 doses of live vaccine on or after the first birthday or a history of physician-diagnosed measles or serologic evidence of immunity. Vaccination should be considered for all HCWs who lack proof of immunity, including those born before 1957.	Pregnancy; immunocompromised persons [§] , including HIV-infected persons who have evidence of severe immunosuppression; anaphylaxis after gelatin ingestion or administration of neomycin; recent administration of immune globulin.	MMR is the vaccine of choice if recipients are likely to be susceptible to rubella and/or mumps as well as to measles. Persons vaccinated during 1963–1967 with a killed measles vaccine alone, killed vaccine followed by live vaccine, or with a vaccine of unknown type should be revaccinated with 2 doses of live measles virus vaccine.
Mumps live-virus vaccine	One dose SC; no booster.	HCWs [†] believed to be susceptible can be vaccinated. Adults born before 1957 can be considered immune.	Pregnancy; immunocompromised persons [§] ; history of anaphylactic reaction after gelatin ingestion or administration of neomycin.	MMR is the vaccine of choice if recipients are likely to be susceptible to measles and rubella as well as to mumps.

*Persons who provide health care to patients or work in institutions that provide patient care, e.g., physicians, nurses, emergency medical personnel, dental professionals and students, medical and nursing students, laboratory technicians, hospital volunteers, and administrative and support staff in health-care institutions

[†]All HCWs (i.e., medical or nonmedical, paid or volunteer, full time or part time, student or non-student, with or without patient-care responsibilities) who work in health-care institutions (e.g., inpatient and outpatient, public and private) should be immune to measles, rubella, and varicella.

[§]Persons immunocompromised because of immune deficiency diseases, HIV infection, leukemia, lymphoma or generalized malignancy or immunosuppressed as a result of therapy with corticosteroids, alkylating drugs, antimetabolites, or radiation.

Abbreviations: IM = intramuscular; HBV = hepatitis B virus; HBsAg = hepatitis B surface antigen; SC = subcutaneous; HIV = human immunodeficiency virus; MMR = measles, mumps, rubella vaccine.

TABLE 2. Immunizing agents and immunization schedules for health-care workers (HCWs)* — Continued

Generic name	Primary schedule and booster(s)	Indications	Major precautions and contraindications	Special considerations
Rubella live-virus vaccine	One dose SC; no booster	Indicated for HCWs [†] , both men and women, who do not have documentation of having received live vaccine on or after their first birthday or laboratory evidence of immunity. Adults born before 1957, except women who can become pregnant , can be considered immune.	Pregnancy; immunocompromised persons [†] ; history of anaphylactic reaction after administration of neomycin.	The risk for rubella vaccine-associated malformations in the offspring of women pregnant when vaccinated or who become pregnant within 3 months after vaccination is negligible. Such women should be counseled regarding the theoretical basis of concern for the fetus. MMR is the vaccine of choice if recipients are likely to be susceptible to measles or mumps, as well as to rubella.
Varicella zoster live-virus vaccine	Two 0.5 mL doses SC 4-8 weeks apart if ≥13 years of age.	Indicated for HCWs [†] who do not have either a reliable history of varicella or serologic evidence of immunity.	Pregnancy, immunocompromised persons [§] , history of anaphylactic reaction following receipt of neomycin or gelatin. Avoid salicylate use for 6 weeks after vaccination.	Vaccine is available from the manufacturer for certain patients with acute lymphocytic leukemia (ALL) in remission. Because 71%-93% of persons without a history of varicella are immune, serologic testing before vaccination is likely to be cost-effective.
Varicella-zoster immune globulin (VZIG)	Persons <50 kg: 125 u/10 kg IM; persons ≥50 kg: 625 u [¶] .	Persons known or likely to be susceptible (particularly those at high risk for complications, e.g., pregnant women) who have close and prolonged exposure to a contact case or to an infectious hospital staff worker or patient.		Serologic testing may help in assessing whether to administer VZIG. If use of VZIG prevents varicella disease, patient should be vaccinated subsequently.

BCG VACCINATION

Bacille Calmette Guérin(BCG) Vaccine (Tuberculosis)	One percutaneous dose of 0.3 mL; no booster dose recommended.	Should be considered only for HCWs in areas where multi-drug tuberculosis is prevalent, a strong likelihood of infection exists, and where comprehensive infection control precautions have failed to prevent TB transmission to HCWs.	Should not be administered to immunocompromised persons, [§] pregnant women.	In the United States tuberculosis-control efforts are directed towards early identification, treatment of cases, and preventive therapy with isoniazid.
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OTHER IMMUNOBIOLOGICS THAT ARE OR MAY BE INDICATED FOR HEALTH-CARE WORKERS

Generic name	Primary schedule and booster(s)	Indications	Major precautions and contraindications	Special considerations
Immune globulin (Hepatitis A)	Postexposure -One IM dose of 0.02 mL/kg administered ≤2 weeks after exposure.	Indicated for HCWs exposed to feces of infectious patients.	Contraindicated in persons with IgA deficiency; do not administer within 2 weeks after MMR vaccine, or 3 weeks after varicella vaccine. Delay administration of MMR vaccine for ≥3 months and varicella vaccine ≥5 months after administration of IG.	Administer in large muscle mass (deltoid, gluteal).

* Persons who provide health care to patients or work in institutions that provide patient care, e.g., physicians, nurses, emergency medical personnel, dental professionals and students, medical and nursing students, laboratory technicians, hospital volunteers, and administrative and support staff in health-care institutions.

† All HCWs (i.e., medical or nonmedical, paid or volunteer, full-time or part-time, student or nonstudent, with or without patient-care responsibilities) who work in health-care institutions (i.e., inpatient and outpatient, public and private) should be immune to measles, rubella, and varicella.

§ Persons immunocompromised because of immune deficiency diseases, HIV infection (who should primarily not receive BCG, OPV, and yellow fever vaccines), leukemia, lymphoma or generalized malignancy or immunosuppressed as a result of therapy with corticosteroids, alkylating drugs, antimetabolites, or radiation.

¶ Some experts recommend 125 u/10 kg regardless of total body weight.

Abbreviations: IM = intramuscular; HCW = health-care worker; TB = tuberculosis; MMR = measles, mumps, rubella vaccine; HAV = hepatitis A virus; SC = subcutaneous; IgA = immune globulin A.

TABLE 2. Immunizing agents and immunization schedules for health-care workers (HCWs)* — Continued

Generic name	Primary schedule and booster(s)	Indications	Major precautions and contraindications	Special considerations
Hepatitis A vaccine	Two doses of vaccine either 6-12 months apart (HAVRIX®), or 6 months apart (VAQTA®).	Not routinely indicated for HCWs in the United States. Persons who work with HAV-infected primates or with HAV in a research laboratory setting should be vaccinated.	History of anaphylactic hypersensitivity to alum or, for HAVRIX®, the preservative 2-phenoxyethanol. The safety of the vaccine in pregnant women has not been determined; the risk associated with vaccination should be weighed against the risk for hepatitis A in women who may be at high risk for exposure to HAV.	
Meningococcal polysaccharide vaccine (tetravalent A, C, W135, and Y)	One dose in volume and by route specified by manufacturer; need for boosters unknown.	Not routinely indicated for HCWs in the United States.	The safety of the vaccine in pregnant women has not been evaluated; it should not be administered during pregnancy unless the risk for infection is high.	
Typhoid vaccine, IM, SC, and oral	<i>IM vaccine:</i> One 0.5 mL dose, booster 0.5 mL every 2 years. <i>SC vaccine:</i> two 0.5 mL doses, ≥4 weeks apart, booster 0.5 mL SC or 0.1 ID every 3 years if exposure continues. <i>Oral vaccine:</i> Four doses on alternate days. The manufacturer recommends revaccination with the entire four-dose series every 5 years.	Workers in microbiology laboratories who frequently work with <i>Salmonella typhi</i> .	Severe local or systemic reaction to a previous dose. Ty21a (oral) vaccine should not be administered to immunocompromised persons [†] or to persons receiving antimicrobial agents.	Vaccination should not be considered an alternative to the use of proper procedures when handling specimens and cultures in the laboratory.

Vaccinia vaccine (smallpox)	One dose administered with a bifurcated needle; boosters administered every 10 years.	Laboratory workers who directly handle cultures with vaccinia, recombinant vaccinia viruses, or orthopox viruses that infect humans.	The vaccine is contraindicated in pregnancy, in persons with eczema or a history of eczema, and in immunocompromised persons [†] and their household contacts.	Vaccination may be considered for HCWs who have direct contact with contaminated dressings or other infectious material from volunteers in clinical studies involving recombinant vaccinia virus.
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OTHER VACCINE-PREVENTABLE DISEASES

Tetanus and diphtheria (toxoids [Td])	Two IM doses 4 weeks apart; third dose 6-12 months after second dose; booster every 10 years.	All adults.	Except in the first trimester, pregnancy is not a precaution. History of a neurologic reaction or immediate hypersensitivity reaction after a previous dose. History of severe local (Arthus-type) reaction after a previous dose. Such persons should not receive further routine or emergency doses of Td for 10 years.	Tetanus prophylaxis in wound management [§] .
Pneumococcal polysaccharide vaccine (23 valent).	One dose, 0.5 mL, IM or SC; revaccination recommended for those at highest risk ≥ 5 years after the first dose.	Adults who are at increased risk of pneumococcal disease and its complications because of underlying health conditions; older adults, especially those age ≥ 65 who are healthy.	The safety of vaccine in pregnant women has not been evaluated; it should not be administered during pregnancy unless the risk for infection is high. Previous recipients of any type of pneumococcal polysaccharide vaccine who are at highest risk for fatal infection or antibody loss may be revaccinated ≥ 5 years after the first dose.	

* Persons who provide health care to patients or work in institutions that provide patient care, e.g., physicians, nurses, emergency medical personnel, dental professionals and students, medical and nursing students, laboratory technicians, hospital volunteers, and administrative and support staff in health-care institutions.

[†] Persons immunocompromised because of immune deficiency diseases, HIV infection, leukemia, lymphoma or generalized malignancy or immunosuppressed as a result of therapy with corticosteroids, alkylating drugs, antimetabolites, or radiation.

[§] See (15) CDC. Update on adult immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1991;40(No. RR-12):1-94.

Abbreviations: IM = intramuscular; ID = intradermal; SC = subcutaneous.

Vaccine-induced antibodies to HBV decline gradually over time, and $\leq 60\%$ of persons who initially respond to vaccination will lose detectable antibodies over 12 years (28; CDC, unpublished data). Studies among adults have demonstrated that, despite declining serum levels of antibody, vaccine-induced immunity continues to prevent clinical disease or detectable viremic HBV infection (29). Therefore, booster doses are not considered necessary (1). Periodic serologic testing to monitor antibody concentrations after completion of the three-dose series is not recommended. The possible need for booster doses will be assessed as additional data become available.

Asymptomatic HBV infections have been detected in vaccinated persons by means of serologic testing for antibody to hepatitis B core antigen (anti-HBc) (1). However, these infections also provide lasting immunity and are not associated with HBV-related chronic liver disease.

Influenza

During community influenza outbreaks, admitting patients infected with influenza to hospitals has led to nosocomial transmission of the disease (30,31), including transmission from staff to patients (32). Transmission of influenza among medical staff causes absenteeism and considerable disruption of health care (33–36; CDC, unpublished data). In addition, influenza outbreaks have caused morbidity and mortality in nursing homes (36–41). In a recent study of long-term care facilities with uniformly high patient influenza vaccination levels, patients in facilities in which $>60\%$ of the staff had been vaccinated against influenza experienced less influenza-related mortality and illness, compared with patients in facilities with no influenza-vaccinated staff (42).

Measles, Mumps, and Rubella

Measles. Nosocomial measles transmission has been documented in the offices of private physicians, in emergency rooms, and on hospital wards (43–49). Although only 3.5% of all cases of measles reported during 1985–1989 occurred in medical settings, the risk for measles infection in medical personnel is estimated to be thirteenfold that for the general population (45,49–52). During 1990–1991, 1,788 of 37,429 (4.8%) measles cases were reported to have been acquired in medical settings. Of these, 668 (37.4%) occurred among HCWs, 561 (84%) of whom were unvaccinated; 187 (28%) of these HCWs were hospitalized with measles and three died (CDC, unpublished data). Of the 3,659 measles cases reported during 1992–1995, the setting of transmission was known for 2,765; 385 (13.9%) of these cases occurred in medical settings (CDC, unpublished data).

Although birth before 1957 is generally considered acceptable evidence of measles immunity, serologic studies of hospital workers indicate that 5%–9% of those born before 1957 are not immune to measles (53,54). During 1985–1992, 27% of all measles cases among HCWs occurred in persons born before 1957 (CDC, unpublished data).

Mumps. In recent years, a substantial proportion of reported mumps has occurred among unvaccinated adolescents and young adults on college campuses and in the workplace (55–58). Outbreaks of mumps in highly vaccinated populations have been attributed to primary vaccine failure (59,60). During recent years, the overall incidence of mumps has fluctuated only minimally but an increasing proportion of cases has been reported in persons aged ≥ 15 years (61). Mumps transmission in medical set-

tings has been reported nationwide (62, CDC, unpublished data). Programs to ensure that medical personnel are immune to mumps are prudent and are easily linked with measles and rubella control programs (5).

Rubella. Nosocomial rubella outbreaks involving both HCWs and patients have been reported (63). Although vaccination has decreased the overall risk for rubella transmission in all age groups in the United States by $\geq 95\%$, the potential for transmission in hospital and similar settings persists because 10%–15% of young adults are still susceptible (6,64–67). In an ongoing study of rubella vaccination in a health maintenance organization, 7,890 of 92,070 (8.6%) women aged ≥ 29 years were susceptible to rubella (CDC, unpublished data). Although not as infectious as measles, rubella can be transmitted effectively by both males and females. Transmission can occur whenever many susceptible persons congregate in one place. Aggressive rubella vaccination of susceptible men and women with trivalent measles-mumps-rubella (MMR) vaccine can eliminate rubella (as well as measles) transmission (68).

Persons born before 1957 generally are considered to be immune to rubella. However, findings of seroepidemiologic studies indicate that about 6% of HCWs (including persons born in 1957 or earlier) do not have detectable rubella antibody (CDC, unpublished data).

Varicella

Nosocomial transmission of varicella zoster virus (VZV) is well recognized (69–80). Sources for nosocomial exposure of patients and staff have included patients, hospital staff, and visitors (e.g., the children of hospital employees) who are infected with either varicella or zoster. In hospitals, airborne transmission of VZV from persons who had varicella or zoster to susceptible persons who had no direct contact with the index case-patient has occurred (81–85). Although all susceptible hospitalized adults are at risk for severe varicella disease and complications, certain patients are at increased risk: pregnant women, premature infants born to susceptible mothers, infants born at < 28 weeks' gestation or who weigh ≤ 1000 grams regardless of maternal immune status, and immunocompromised persons of all ages (including persons who are undergoing immunosuppressive therapy, have malignant disease, or are immunodeficient).

Varicella Control Strategies

Strategies for managing clusters of VZV infections in hospitals include (16,86–94):

- isolating patients who have varicella and other susceptible patients who are exposed to VZV;
- controlling air flow;
- using rapid serologic testing to determine susceptibility;
- furloughing exposed susceptible personnel or screening these persons daily for skin lesions, fever, and systemic symptoms; and
- temporarily reassigning varicella-susceptible personnel to locations remote from patient-care areas.

Appropriate isolation of hospitalized patients who have confirmed or suspected VZV infection can reduce the risk for transmission to personnel (95).

Identification of the few persons who are susceptible to varicella when they begin employment that involves patient contact is recommended. Only personnel who are immune to varicella should care for patients who have confirmed or suspected varicella or zoster.

A reliable history of chickenpox is a valid measure of VZV immunity. Serologic tests have been used to assess the accuracy of reported histories of chickenpox (76,80,93,95–97). Among adults, 97% to 99% of persons with a positive history of varicella are seropositive. In addition, the majority of adults with negative or uncertain histories are seropositive (range: 71%–93%). Persons who do not have a history of varicella or whose history is uncertain can be considered susceptible, or tested serologically to determine their immune status. In health-care institutions, serologic screening of personnel who have a negative or uncertain history of varicella is likely to be cost effective (8).

If susceptible HCWs are exposed to varicella, they are potentially infective 10–21 days after exposure. They must often be furloughed during this period, usually at substantial cost. Persons in whom varicella develops are infective until all lesions dry and crust (16,35,96–98) (see Other Considerations in Vaccination of Health-Care Workers—Work Restrictions for Susceptible Workers After Exposure).

Administration of varicella zoster immune globulin (VZIG) after exposure can be costly. VZIG does not necessarily prevent varicella, and may prolong the incubation period by a week or more, thus extending the time during which personnel should not work.

Breakthrough Infection and Transmission of Vaccine Virus to Contacts

Varicella virus vaccine protects approximately 70%–90% of recipients against infection and 95% of recipients against severe disease for at least 7–10 years after vaccination. Significant protection is long-lasting. Breakthrough infections (i.e., cases of varicella) have occurred among vaccinees after exposure to natural varicella virus. Data from all trials in which vaccinees of all ages were actively followed for up to 9 years indicated that varicella developed in 1%–4.4% of vaccinees per year, depending on vaccine lot and time interval since vaccination (Merck and Company, Inc., unpublished data). Unvaccinated persons who contract varicella generally are febrile and have several hundred vesicular lesions. Among vaccinees who developed varicella, in contrast, the median number of skin lesions was <50 and lesions were less apt to be vesicular. Most vaccinated persons who contracted varicella were afebrile, and the duration of illness was shorter (Merck and Company, Inc., unpublished data; 99, 100).

The rate of transmission of disease from vaccinees who contract varicella is low for vaccinated children, but has not been studied in adults. Ten different trials conducted during 1981–1989 involved 2,141 vaccinated children. Breakthrough infections occurred in 78 children during the 1–8 year follow-up period of active surveillance, resulting in secondary cases in 11 of 90 (12.2%) vaccinated siblings. Among both index and secondary case-patients, illness was mild. Transmission to a susceptible mother from a vaccinated child in whom breakthrough disease occurred also has been reported (Merck and Company, Inc., unpublished data; 101).

Estimates of vaccine efficacy and persistence of antibody in vaccinees are based on research conducted before widespread use of varicella vaccine began to influence the prevalence of natural VZV infection. Thus, the extent to which boosting from exposure to natural virus increases the protection provided by vaccination remains unclear. Whether longer-term immunity may wane as the circulation of natural VZV decreases also is unknown.

Risk for transmission of vaccine virus was assessed in placebo recipients who were siblings of vaccinated children and among healthy siblings of vaccinated leukemic children (102,103). The findings of these studies indicate that healthy vaccinated persons have a minimal risk (estimated to be <1%) for transmitting vaccine virus to their contacts. This risk may be increased in vaccinees in whom a varicella-like rash develops after vaccination. Tertiary transmission of vaccine virus to a second healthy sibling of a vaccinated leukemic child also has occurred (103).

Several options for managing vaccinated HCWs who may be exposed to varicella are available. Routine serologic testing for varicella immunity after administration of two doses of vaccine is not considered necessary because 99% of persons become seropositive after the second dose. Seroconversion, however, does not always result in full protection against disease. Institutional guidelines are needed for management of exposed vaccinees who do not have detectable antibody and for those who develop clinical varicella. A potentially effective strategy to identify persons who remain at risk for varicella is to test vaccinated persons for serologic evidence of immunity immediately after they are exposed to VZV. Prompt, sensitive, and specific serologic results can be obtained at reasonable cost with a commercially available latex agglutination (LA) test. Many other methods also have been used to detect antibody to VZV (8). The LA test, which uses latex particles coated with VZV glycoprotein antigens, can be completed in 15 minutes (104,105). Persons with detectable antibody are unlikely to become infected with varicella. Persons who do not have detectable antibody can be retested in 5–6 days. If an anamnestic response is present, these persons are unlikely to contract the disease. HCWs who do not have antibody when retested may be furloughed. Alternatively, the clinical status of these persons may be monitored daily and they can be furloughed at the onset of manifestations of varicella.

More information is needed concerning risk for transmission of vaccine virus from vaccinees with and without varicella-like rash after vaccination. The risk appears to be minimal, and the benefits of vaccinating susceptible HCWs outweigh this potential risk. As a safeguard, institutions may wish to consider precautions for personnel in whom a rash develops after vaccination and for other vaccinated personnel who will have contact with susceptible persons at high risk for serious complications.

Vaccination should be considered for unvaccinated HCWs who lack documented immunity if they are exposed to varicella. However, because the effectiveness of postexposure vaccination is unknown, persons vaccinated after an exposure should be managed in the manner recommended for unvaccinated persons.

Tuberculosis and Bacille-Calmette-Guérin Vaccination

In the United States, Bacille Calmette-Guérin (BCG) vaccine has not been recommended for general use because the population risk for infection with *Mycobacterium tuberculosis* (TB) is low and the protective efficacy of BCG vaccine uncertain. The im-

mune response to BCG vaccine also interferes with use of the tuberculin skin test to detect *M. tuberculosis* infection (7). TB prevention and control efforts are focused on interrupting transmission from patients who have active infectious TB, skin testing those at high risk for TB, and administering preventive therapy when appropriate. However, in certain situations, BCG vaccination may contribute to the prevention and control of TB when other strategies are inadequate.

Control of TB

The fundamental strategies for the prevention and control of TB include:

- Early detection and effective treatment of patients with active communicable TB (106).
- Preventive therapy for infected persons. Identifying and treating persons who are infected with *M. tuberculosis* can prevent the progression of latent infection to active infectious disease (107).
- Prevention of institutional transmission. The transmission of TB is a recognized risk in health-care settings and is of particular concern in settings where HIV-infected persons work, volunteer, visit, or receive care (108). Effective TB infection-control programs should be implemented in health-care facilities and other institutional settings, (e.g., shelters for homeless persons and correctional facilities) (16,109,110).

Role of BCG Vaccination in Prevention of TB Among HCWs

In a few geographic areas of the United States, increased risks for TB transmission in health-care facilities (compared with risks observed in health-care facilities in other parts of the United States) occur together with an elevated prevalence among TB patients of *M. tuberculosis* strains that are resistant to both isoniazid and rifampin (111–116). Even in such situations, comprehensive application of infection control practices should be the primary strategy used to protect HCWs and others in the facility from infection with *M. tuberculosis*. BCG vaccination of HCWs should not be used as a primary TB control strategy because a) the protective efficacy of the vaccine in HCWs is uncertain; b) even if BCG vaccination is effective for a particular HCW, other persons in the health-care facility (e.g., patients, visitors, and other HCWs) are not protected against possible exposure to and infection with drug-resistant strains of *M. tuberculosis*; and c) BCG vaccination may complicate preventive therapy because of difficulties in distinguishing tuberculin skin test responses caused by infection with *M. tuberculosis* from those caused by the immune response to vaccination.

Hepatitis C and Other Parenterally Transmitted Non-A, Non-B Hepatitis

Hepatitis C virus (HCV) is the etiologic agent in most cases of parenterally transmitted non-A, non-B hepatitis in the United States (117,118). CDC estimates that the annual number of newly acquired HCV infections has ranged from 180,000 in 1984 to 28,000 in 1995. Of these, an estimated 2%–4% occurred among health-care personnel who were occupationally exposed to blood. At least 85% of persons who contract HCV

infection become chronically infected, and chronic hepatitis develops in an average of 70% of all HCV-infected persons (117–119). Up to 10% of parenterally transmitted non-A, non-B hepatitis may be caused by other bloodborne viral agents not yet characterized (non-ABCDE hepatitis) (117,120).

Serologic enzyme immunoassays (EIA) licensed for the detection of antibody to HCV (anti-HCV) have evolved since their introduction in 1990 and a third version is now available which detects anti-HCV in $\geq 95\%$ of patients with HCV infection. Interpretation of EIA results is limited by several factors. These assays do not detect anti-HCV in all infected persons and do not distinguish among acute, chronic, or resolved infection. In 80% to 90% of HCV-infected persons, seroconversion occurs an average of 10–12 weeks after exposure to HCV. These screening assays also yield a high proportion (up to 50%) of falsely positive results when they are used in populations with a low prevalence of HCV infection (118,121). Although no true confirmatory test has been developed, supplemental tests for specificity are available (such as the licensed Recombinant Immunoblot Assay [RIBA™]), and should always be used to verify repeatedly reactive results obtained with screening assays.

The diagnosis of HCV infection also is possible by detecting HCV RNA with polymerase chain reaction (PCR) techniques. Although PCR assays for HCV RNA are available from several commercial laboratories on a research-use basis, results vary considerably between laboratories. In a recent study in which a reference panel containing known HCV RNA-positive and -negative sera was provided to 86 laboratories worldwide (122), only 50% were considered to have performed adequately (i.e., by failing to detect one weak positive sample), and only 16% reported faultless results. Both false-positive and false-negative results can occur from improper collection, handling, and storage of the test samples. In addition, because HCV RNA may be detectable only intermittently during the course of infection, a single negative PCR test result should not be regarded as conclusive. Tests also have been developed to quantify HCV RNA in serum; however, the applicability of these tests in the clinical setting has not been determined.

Most HCV transmission is associated with direct percutaneous exposure to blood, and HCWs are at occupational risk for acquiring this viral infection (123–131). The prevalence of anti-HCV among hospital-based HCWs and surgeons is about 1% (125–128) and 2% among oral surgeons (129,130). In follow-up studies of HCWs who sustained percutaneous exposures to blood from anti-HCV positive patients through unintentional needlesticks or sharps injuries, the average incidence of anti-HCV seroconversion was 1.8% (range: 0%–7%) (132–137). In the only study that used PCR to measure HCV infection by detecting HCV RNA, the incidence of postinjury infection was 10% (136). Although these follow-up studies have not documented transmission associated with mucous membrane or nonintact skin exposures, one case report describes the transmission of HCV from a blood splash to the conjunctiva (138).

Several studies have examined the effectiveness of prophylaxis with immune globulins (IGs) in preventing posttransfusion non-A, non-B hepatitis (139–141). The findings of these studies are difficult to compare and interpret, because of lack of uniformity in diagnostic criteria, mixed sources of donors (volunteer and commercial), and differing study designs (some studies lacked blinding and placebo controls). In some of these studies, IGs appeared to reduce the rate of clinical disease but not overall infection rates. In one study, data indicated that chronic hepatitis was less likely to

develop in patients who received IG (139). None of these data have been reanalyzed since anti-HCV testing became available. In only one study was the first dose of IG administered after, rather than before, the exposure; the value of IG for postexposure prophylaxis is thus difficult to assess. The heterogeneous nature of HCV and its ability to undergo rapid mutation, however, appear to prevent development of an effective neutralizing immune response (142), suggesting that postexposure prophylaxis using IG is likely to be ineffective. Furthermore, IG is now manufactured from plasma that has been screened for anti-HCV. In an experimental study in which IG manufactured from anti-HCV negative plasma was administered to chimpanzees one hour after exposure to HCV, the IG did not prevent infection or disease (143).

The prevention of HCV infection with antiviral agents (e.g., alpha interferon) has not been studied. Although alpha interferon therapy is safe and effective for the treatment of chronic hepatitis C (144), the mechanisms of the effect are poorly understood. Interferon may be effective only in the presence of an established infection (145). Interferon must be administered by injection and may cause side effects. Based on these considerations, antiviral agents are not recommended for postexposure prophylaxis of HCV infection.

In the absence of effective prophylaxis, persons who have been exposed to HCV may benefit from knowing their infection status so they can seek evaluation for chronic liver disease and treatment. Sustained response rates to alpha interferon therapy generally are low (10%–20% in the United States). The occurrence of mild to moderate side effects in most patients has required discontinuation of therapy in up to 15% of patients. No clinical, demographic, serum biochemical, serologic, or histologic features have been identified that reliably predict which patients will sustain a long-term remission in response to alpha interferon therapy.

Several studies indicate that interferon treatment begun early in the course of HCV infection is associated with an increased rate of resolved infection. Onset of HCV infection among HCWs after exposure could be detected earlier by using PCR to detect HCV RNA than by using EIA to measure anti-HCV. However, PCR is not a licensed assay and its accuracy is highly variable. In addition, no data are available which indicate that treatment begun early in the course of chronic HCV infection is less effective than treatment begun during the acute phase of infection. Furthermore, alpha interferon is approved for the treatment of chronic hepatitis C only.

IG or antiviral agents are not recommended for postexposure prophylaxis of hepatitis C. No vaccine against hepatitis C is available. Health-care institutions should consider implementing policies and procedures to monitor HCWs for HCV infection after percutaneous or permucosal exposures to blood (146). At a minimum, such policies should include:

- For the source, baseline serologic testing for anti-HCV;
- For the person exposed to an anti-HCV positive source, baseline and follow-up (e.g., 6 months) serologic testing for anti-HCV and alanine aminotransferase activity;
- Confirmation by supplemental anti-HCV testing of all anti-HCV results reported as repeatedly reactive by EIA;

- Education of HCWs about the risk for and prevention of occupational transmission of all blood borne pathogens, including hepatitis C, using up-to-date and accurate information.

Other Diseases for Which Immunization of Health-Care Workers Is or May Be Indicated

Diseases are included in this section for one of the following reasons:

- Nosocomial transmission occurs, but HCWs are not at increased risk as a result of occupational exposure (i.e., hepatitis A),
- Occupational risk may be high, but protection via active or passive immunization is not available (i.e., pertussis), or
- Vaccines are available but are not routinely recommended for all HCWs or are recommended only in certain situations (i.e., vaccinia and meningococcal vaccines).

Hepatitis A

Occupational exposure generally does not increase HCWs' risk for hepatitis A virus (HAV) infection. When proper infection control practices are followed, nosocomial HAV transmission is rare. Outbreaks caused by transmission of HAV to neonatal intensive care unit staff by infants infected through transfused blood have occasionally been observed (147–149). Transmission of HAV from adult patients to HCWs is usually associated with fecal incontinence in the patients. However, most patients hospitalized with hepatitis A are admitted after onset of jaundice, when they are beyond the point of peak infectivity (150). Serologic surveys among many types of HCWs have not identified an elevated prevalence of HAV infection compared with other occupational populations (151–153).

Two specific prophylactic measures are available for protection against hepatitis A—administration of immune globulin (IG) and hepatitis A vaccine. When administered within 2 weeks after an exposure, IG is >85% effective in preventing hepatitis A (2). Two inactivated hepatitis A vaccines, which can provide long-term preexposure protection, were recently licensed in the United States: HAVRIX® (manufactured by SmithKline Beecham Biologicals) and VAQTA® (manufactured by Merck & Company, Inc.) (2). The efficacy of these vaccines in preventing clinical disease ranges from 94% to 100%. Data indicate that the duration of clinical protection conferred by VAQTA® is at least 3 years, and that conferred by HAVRIX® at least 4 years. Mathematical models of antibody decay indicate that protection conferred by vaccination may last up to 20 years (2).

Meningococcal Disease

Nosocomial transmission of *Neisseria meningitidis* is uncommon. In rare instances, direct contact with respiratory secretions of infected persons (e.g., during mouth-to-mouth resuscitation) has resulted in transmission from patients with meningococemia or meningococcal meningitis to HCWs. Although meningococcal lower respiratory infections are rare, HCWs may be at increased risk for meningococcal in-

fection if exposed to *N. meningitidis*-infected patients with active productive coughs. HCWs can decrease the risk for infection by adhering to precautions to prevent exposure to respiratory droplets (16,95).

Postexposure prophylaxis is advised for persons who have had intensive, unprotected contact (i.e., without wearing a mask) with infected patients (e.g., intubating, resuscitating, or closely examining the oropharynx of patients)(16). Antimicrobial prophylaxis can eradicate carriage of *N. meningitidis* and prevent infections in persons who have unprotected exposure to patients with meningococcal infections (9). Rifampin is effective in eradicating nasopharyngeal carriage of *N. meningitidis*, but is not recommended for pregnant women, because the drug is teratogenic in laboratory animals. Ciprofloxacin and ceftriaxone in single-dose regimens are also effective in reducing nasopharyngeal carriage of *N. meningitidis*, and are reasonable alternatives to the multidose rifampin regimen (9). Ceftriaxone also can be used during pregnancy.

Although useful for controlling outbreaks of serogroup C meningococcal disease, administration of quadrivalent A,C,Y,W-135 meningococcal polysaccharide vaccines is of little benefit for postexposure prophylaxis (9). The serogroups A and C vaccines, which have demonstrated estimated efficacies of 85%–100% in older children and adults, are useful for control of epidemics (9). The decision to implement mass vaccination to prevent serogroup C meningococcal disease depends on whether the occurrence of more than one case of the disease represents an outbreak or an unusual clustering of endemic meningococcal disease. Surveillance for serogroup C disease and calculation of attack rates can be used to identify outbreaks and determine whether use of meningococcal vaccine is warranted. Recommendations for evaluating and managing suspected serogroup C meningococcal disease outbreaks have been published (9).

Pertussis

Pertussis is highly contagious. Secondary attack rates among susceptible household contacts exceed 80% (154,155). Transmission occurs by direct contact with respiratory secretions or large aerosol droplets from the respiratory tract of infected persons. The incubation period is generally 7–10 days. The period of communicability starts with the onset of the catarrhal stage and extends into the paroxysmal stage. Vaccinated adolescents and adults, whose immunity wanes 5–10 years after the last dose of vaccine (usually administered at age 4–6 years), are an important source of pertussis infection for susceptible infants. The disease can be transmitted from adult patients to close contacts, especially unvaccinated children. Such transmission may occur in households and hospitals.

Transmission of pertussis in hospital settings has been documented in several reports (156–159). Transmission has occurred from a hospital visitor, from hospital staff to patients, and from patients to hospital staff. Although of limited size (range: 2–17 patients and 5–13 staff), documented outbreaks were costly and disruptive. In each outbreak, larger numbers of staff were evaluated for cough illness and required nasopharyngeal cultures, serologic tests, prophylactic antibiotics, and exclusion from work.

During outbreaks that occur in hospitals, the risk for contracting pertussis among patients or staff is often difficult to quantify because exposure is not well defined.

Serologic studies conducted among hospital staff during two outbreaks indicate that exposure to pertussis is much more frequent than the attack rates of clinical disease indicate (154,156–159). Seroprevalence of pertussis agglutinating antibodies correlated with the degree of patient contact and was highest among pediatric house staff (82%) and ward nurses (71%), lowest among nurses with administrative responsibilities (35%) (158).

Prevention of pertussis transmission in health-care settings involves diagnosis and early treatment of clinical cases, respiratory isolation of infectious patients who are hospitalized, exclusion from work of staff who are infectious, and postexposure prophylaxis. Early diagnosis of pertussis, before secondary transmission occurs, is difficult because the disease is highly communicable during the catarrhal stage, when symptoms are still nonspecific. Pertussis should be one of the differential diagnoses for any patient with an acute cough illness of ≥ 7 days duration without another apparent cause, particularly if characterized by paroxysms of coughing, posttussive vomiting, whoop, or apnea. Nasopharyngeal cultures should be obtained if possible.

Precautions to prevent respiratory droplet transmission or spread by close or direct contact should be employed in the care of patients admitted to hospital with suspected or confirmed pertussis (95). These precautions should remain in effect until patients are clinically improved and have completed at least 5 days of appropriate antimicrobial therapy. HCWs in whom symptoms (i.e., unexplained rhinitis or acute cough) develop after known pertussis exposure may be at risk for transmitting pertussis and should be excluded from work (16)(see Other Considerations in Vaccination of Health-Care Workers—Work Restrictions for Susceptible Workers After Exposure).

One acellular pertussis vaccine is immunogenic in adults, but does not increase risk for adverse events when administered with tetanus and diphtheria (Td) toxoids, as compared with administration of Td alone (160). Recommendations for use of licensed diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccines among infants and young children have been published (161). If acellular pertussis vaccines are licensed for use in adults in the future, booster doses of adult formulations of acellular pertussis vaccines may be recommended to prevent the occurrence and spread of the disease in adults, including HCWs. However, acellular pertussis vaccines combined with diphtheria and tetanus toxoids (DTaP) will need to be reformulated for use in adults, because all infant formulations contain more diphtheria toxoid than is recommended for persons aged ≥ 7 years. Recommendations regarding routine vaccination of adults will require additional studies (e.g., studies of the incidence, severity, and cost of pertussis among adults; studies of the efficacy and safety of adult formulations of DTaP; and studies of the effectiveness and cost-effectiveness of a strategy of adult vaccination, particularly for HCWs).

Typhoid

The incidence of typhoid fever declined steadily in the United States from 1900 to 1960 and has remained at a low level. During 1985–1994, the average number of cases reported annually was 441 (CDC, unpublished data). The median age of persons with cases of typhoid was 24 years; 53% were male. Nearly three quarters of patients infected with *Salmonella typhi* reported foreign travel during the 30 days before onset of symptoms. During this ten year period, several cases of laboratory-acquired typhoid fever were reported among microbiology laboratory workers, only one of

whom had been vaccinated (162). *S. typhi* and other enteric pathogens may be nosocomially transmitted via the hands of personnel who are infected. Generally, personal hygiene, particularly hand washing before and after all patient contacts, will minimize risk for transmitting enteric pathogens to patients. If HCWs contract an acute diarrheal illness accompanied by fever, cramps, or bloody stools, they are likely to be excreting large numbers of infective organisms in their feces. Excluding these workers from care of patients until the illness has been evaluated and treated will prevent transmission (16).

Vaccinia

Vaccinia (smallpox) vaccine is a highly effective immunizing agent that brought about the global eradication of smallpox. In 1976, routine vaccinia vaccination of HCWs in the United States was discontinued. More recently, ACIP recommended use of vaccinia vaccine to protect laboratory workers from orthopoxvirus infection (10). Because studies of recombinant vaccinia virus vaccines have advanced to the stage of clinical trials, some physicians and nurses may now be exposed to vaccinia and recombinant vaccinia viruses. Vaccinia vaccination of these persons should be considered in selected instances (e.g., for HCWs who have direct contact with contaminated dressings or other infectious material).

Other Vaccine-Preventable Diseases

HCWs are not at greater risk for diphtheria, tetanus, and pneumococcal disease than the general population. ACIP recommends that all adults be protected against diphtheria and tetanus, and recommends pneumococcal vaccination of all persons aged ≥ 65 years and of younger persons who have certain medical conditions (see Recommendations).

Immunizing Immunocompromised Health-Care Workers

A physician must assess the degree to which an individual health-care worker is immunocompromised. Severe immunosuppression can be the result of congenital immunodeficiency; HIV infection; leukemia; lymphoma; generalized malignancy; or therapy with alkylating agents, antimetabolites, radiation, or large amounts of corticosteroids. All persons affected by some of these conditions are severely immunocompromised, whereas for other conditions (e.g., HIV infection), disease progression or treatment stage determine the degree of immunocompromise. A determination that an HCW is severely immunocompromised ultimately must be made by his or her physician. Immunocompromised HCWs and their physicians should consider the risk for exposure to a vaccine-preventable disease together with the risks and benefits of vaccination.

Corticosteroid Therapy

The exact amount of systemically absorbed corticosteroids and the duration of administration needed to suppress the immune system of an otherwise healthy person are not well defined. Most experts agree that steroid therapy usually does not contraindicate administration of live virus vaccines such as MMR and its component vaccines when therapy is a) short term (i.e., <14 days) low to moderate dose; b) low to

moderate dose administered daily or on alternate days; c) long-term alternate day treatment with short-acting preparations; d) maintenance physiologic doses (replacement therapy); or e) administered topically (skin or eyes), by aerosol, or by intra-articular, bursal, or tendon injection. Although the immunosuppressive effects of steroid treatment vary, many clinicians consider a steroid dose that is equivalent to or greater than a prednisone dose of 20 mg per day sufficiently immunosuppressive to cause concern about the safety of administering live virus vaccines. Persons who have received systemic corticosteroids in excess of this dose daily or on alternate days for an interval of ≥ 14 days should avoid vaccination with MMR and its component vaccines for at least 1 month after cessation of steroid therapy. Persons who have received prolonged or extensive topical, aerosol, or other local corticosteroid therapy that causes clinical or laboratory evidence of systemic immunosuppression also should not receive MMR, its component vaccines, and varicella vaccine for at least 1 month after cessation of therapy. Persons who receive corticosteroid doses equivalent to ≥ 20 mg per day or prednisone during an interval of < 14 days generally can receive MMR or its component vaccines immediately after cessation of treatment, although some experts prefer waiting until 2 weeks after completion of therapy. Persons who have a disease that, in itself, suppresses the immune response and who are also receiving either systemic or locally administered corticosteroids generally should not receive MMR, its component vaccines, or varicella vaccine.

HIV-Infected Persons

In general, symptomatic HIV-infected persons have suboptimal immunologic responses to vaccines (163–167). The response to both live and killed antigens may decrease as the disease progresses (167). Administration of higher doses of vaccine or more frequent boosters to HIV-infected persons may be considered. However, because neither the initial immune response to higher doses of vaccine nor the persistence of antibody in HIV-infected patients has been systematically evaluated, recommendations cannot be made at this time.

Limited studies of MMR immunization in both asymptomatic and symptomatic HIV-infected patients who did not have evidence of severe immunosuppression documented no serious or unusual adverse events after vaccination (168). HIV-infected persons are at increased risk for severe complications if infected with measles. Therefore, MMR vaccine is recommended for all asymptomatic HIV-infected HCWs who do not have evidence of severe immunosuppression. Administration of MMR to HIV-infected HCWs who are symptomatic but do not have evidence of severe immunosuppression also should be considered. However, measles vaccine is not recommended for HIV-infected persons who have evidence of severe immunosuppression because a) a case of progressive measles pneumonia has been reported after administration of MMR vaccine to a person with AIDS and severe immunosuppression (169), b) the incidence of measles in the United States is currently very low (170), c) vaccination-related morbidity has been reported in severely immunocompromised persons who were not HIV-infected (171), and d) a diminished antibody response to measles vaccination occurs among severely immunocompromised HIV-infected persons (172).

RECOMMENDATIONS

Recommendations for administration of vaccines and other immunobiologic agents to HCWs are organized in three broad disease categories:

- those for which active immunization is strongly recommended because of special risks for HCWs (i.e., hepatitis B, influenza, measles, mumps, rubella, and varicella);
- those for which active and/or passive immunization of HCWs may be indicated in certain circumstances (i.e., tuberculosis, hepatitis A, meningococcal disease, typhoid fever, and vaccinia) or in the future (i.e., pertussis); and
- those for which immunization of all adults is recommended (i.e., tetanus, diphtheria, and pneumococcal disease).

Immunization Is Strongly Recommended

ACIP strongly recommends that all HCWs be vaccinated against (or have documented immunity to) hepatitis B, influenza, measles, mumps, rubella, and varicella (Table 2). Specific recommendations for use of vaccines and other immunobiologics to prevent these diseases among HCWs follow.

Hepatitis B

Any HCW who performs tasks involving contact with blood, blood-contaminated body fluids, other body fluids, or sharps should be vaccinated. Hepatitis B vaccine should always be administered by the intramuscular route in the deltoid muscle with a needle 1–1.5 inches long.

Among health-care professionals, risks for percutaneous and permucosal exposures to blood vary during the training and working career of each person but are often highest during the professional training period. Therefore, vaccination should be completed during training in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions, before trainees have contact with blood. In addition, the OSHA Federal Standard requires employers to offer hepatitis B vaccine free of charge to employees who are occupationally exposed to blood or other potentially infectious materials (27).

Prevaccination serologic screening for previous infection is not indicated for persons being vaccinated because of occupational risk unless the hospital or health-care organization considers screening cost-effective. Postexposure prophylaxis with hepatitis B immune globulin (HBIG) (passive immunization) and/or vaccine (active immunization) should be used when indicated (e.g., after percutaneous or mucous membrane exposure to blood known or suspected to be HBsAg-positive [Table 3]).

Needlestick or other percutaneous exposures of unvaccinated persons should lead to initiation of the hepatitis B vaccine series. Postexposure prophylaxis should be considered for any percutaneous, ocular, or mucous membrane exposure to blood in the workplace and is determined by the HBsAg status of the source and the vaccination and vaccine-response status of the exposed person (Table 3) (1, 18).

If the source of exposure is HBsAg-positive and the exposed person is unvaccinated, HBIG also should be administered as soon as possible after exposure

TABLE 3. Recommended postexposure prophylaxis for percutaneous or permucosal exposure to hepatitis B virus, United States

Vaccination and anti-body response status of exposed person	Treatment when source is		
	HBsAg* positive	HBsAg negative	Source not tested or status unknown
Unvaccinated	HBIG [†] x 1; initiate HB vaccine series [§]	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated:			
Known responder [¶]	No treatment	No treatment	No treatment
Known non-responder	HBIG x 2 or HBIG x 1 and initiate revaccination	No treatment	If known high-risk source, treat as if source were HBsAg positive
Antibody response unknown	Test exposed person for anti-HBs** 1. If adequate [¶] , no treatment 2. If inadequate [¶] , HBIG x 1 and vaccine booster	No treatment	Test exposed person for anti-HBs 1. If adequate [¶] , no treatment 2. If inadequate [¶] , initiate revaccination

*Hepatitis B surface antigen.

[†]Hepatitis B immune globulin; dose 0.06 mL/kg intramuscularly.

[§]Hepatitis B vaccine.

[¶]Responder is defined as a person with adequate levels of serum antibody to hepatitis B surface antigen (i.e., anti-HBs \geq 10 mIU/mL); inadequate response to vaccination defined as serum anti-HBs < 10 mIU/mL.

**Antibody to hepatitis B surface antigen.

(preferably within 24 hours) and the vaccine series started. The effectiveness of HBIG when administered >7 days after percutaneous or permucosal exposures is unknown. If the exposed person had an adequate antibody response (\geq 10 mIU/mL) documented after vaccination, no testing or treatment is needed, although administration of a booster dose of vaccine can be considered.

One to 2 months after completion of the 3-dose vaccination series, HCWs who have contact with patients or blood and are at ongoing risk for injuries with sharp instruments or needlesticks should be tested for antibody to hepatitis B surface antigen (anti-HBs). Persons who do not respond to the primary vaccine series should complete a second three-dose vaccine series or be evaluated to determine if they are HBsAg-positive. Revaccinated persons should be retested at the completion of the second vaccine series. Persons who prove to be HBsAg-positive should be counseled accordingly (1,16,121,173). Primary non-responders to vaccination who are HBsAg-negative should be considered susceptible to HBV infection and should be counseled regarding precautions to prevent HBV infection and the need to obtain HBIG prophylaxis for any known or probable parenteral exposure to HBsAg-positive blood (Table 3). Booster doses of hepatitis B vaccine are not considered necessary, and periodic serologic testing to monitor antibody concentrations after completion of the vaccine series is not recommended.

Influenza

To reduce staff illnesses and absenteeism during the influenza season and to reduce the spread of influenza to and from workers and patients, the following HCWs should be vaccinated in the fall of each year:

- Persons who attend patients at high risk for complications of influenza (whether the care is provided at home or in a health-care facility) (3);
- Persons aged ≥ 65 years; and
- Persons with certain chronic medical conditions (e.g., persons who have chronic disorders of the cardiovascular or pulmonary systems; persons who required medical follow-up or hospitalization within the preceding year because of chronic metabolic disease [including diabetes], renal dysfunction, hemoglobinopathies, or immunosuppression [including HIV infection]).
- Pregnant women who will be in the second or third trimester of pregnancy during influenza season.

Measles, Mumps, and Rubella

Persons who work within medical facilities should be immune to measles and rubella. Immunity to mumps is highly desirable for all HCWs. Because any HCW (i.e., medical or nonmedical, paid or volunteer, full time or part time, student or nonstudent, with or without patient-care responsibilities) who is susceptible can, if exposed, contract and transmit measles or rubella, all medical institutions (e.g., inpatient and outpatient, public and private) should ensure that those who work within their facilities* are immune to measles and rubella. Likewise, HCWs have a responsibility to avoid causing harm to patients by preventing transmission of these diseases.

Persons born in 1957 or later can be considered immune to measles, mumps, or rubella[†] only if they have documentation of a) physician-diagnosed measles or mumps disease; or b) laboratory evidence of measles, mumps, or rubella immunity (persons who have an "indeterminate" level of immunity upon testing should be considered nonimmune); or c) appropriate vaccination against measles, mumps, and rubella (i.e., administration on or after the first birthday of two doses of live measles vaccine separated by ≥ 28 days, at least one dose of live mumps vaccine, and at least one dose of live rubella vaccine).

Although birth before 1957 generally is considered acceptable evidence of measles and rubella immunity, health-care facilities should consider recommending a dose of MMR vaccine to unvaccinated workers born before 1957 who are in either of the following categories: a) those who do not have a history of measles disease or laboratory evidence of measles immunity, and b) those who lack laboratory evidence of rubella immunity. Rubella vaccination or laboratory evidence of rubella immunity is particularly important for female HCWs born before 1957 who can become pregnant.

*A possible exception might be an outpatient facility that deals exclusively with elderly patients considered at low risk for measles.

[†]Birth before 1957 is not acceptable evidence of rubella immunity for women who can become pregnant because rubella can occur in some unvaccinated persons born before 1957 and because congenital rubella syndrome can occur in offspring of women infected with rubella during pregnancy.

Serologic screening need not be done before vaccinating against measles and rubella unless the health-care facility considers it cost-effective (174–176). Serologic testing is not necessary for persons who have documentation of appropriate vaccination or other acceptable evidence of immunity to measles and rubella. Serologic testing before vaccination is appropriate only if tested persons identified as nonimmune are subsequently vaccinated in a timely manner, and should **not** be done if the return and timely vaccination of those screened cannot be ensured (176). Likewise, during outbreaks of measles, rubella, or mumps, serologic screening before vaccination is not recommended because rapid vaccination is necessary to halt disease transmission.

Measles-mumps-rubella (MMR) trivalent vaccine is the vaccine of choice. If the recipient has acceptable evidence of immunity to one or more of the components, monovalent or bivalent vaccines may be used. MMR or its component vaccines should not be administered to women known to be pregnant. For theoretical reasons, a risk to the fetus from administration of live virus vaccines cannot be excluded. Therefore, women should be counseled to avoid pregnancy for 30 days after administration of monovalent measles or mumps vaccines and for 3 months after administration of MMR or other rubella-containing vaccines. Routine precautions for vaccinating postpubertal women with MMR or its component vaccines include a) asking if they are or may be pregnant, b) not vaccinating those who say they are or may be pregnant, and c) vaccinating those who state that they are not pregnant after the potential risk to the fetus is explained. If a pregnant woman is vaccinated or if a woman becomes pregnant within 3 months after vaccination, she should be counseled about the theoretical basis of concern for the fetus, but MMR vaccination during pregnancy should not ordinarily be a reason to consider termination of pregnancy. Rubella-susceptible women from whom vaccine is withheld because they state they are or may be pregnant should be counseled about the potential risk for congenital rubella syndrome and the importance of being vaccinated as soon as they are no longer pregnant. Measles vaccine is not recommended for HIV-infected persons with evidence of severe immunosuppression (see Vaccination of HIV-Infected Persons).

Varicella

All HCWs should ensure that they are immune to varicella. Varicella immunization is particularly recommended for susceptible HCWs who have close contact with persons at high risk for serious complications, including a) premature infants born to susceptible mothers, b) infants who are born at <28 weeks of gestation or who weigh $\leq 1,000$ g at birth (regardless of maternal immune status), c) pregnant women, and d) immunocompromised persons.

Serologic screening for varicella immunity need not be done before vaccinating unless the health-care institution considers it cost-effective. Routine postvaccination testing of HCWs for antibodies to varicella is not recommended because $\geq 90\%$ of vaccinees are seropositive after the second dose of vaccine.

Hospitals should develop guidelines for management of vaccinated HCWs who are exposed to natural varicella. Seroconversion after varicella vaccination does not always result in full protection against disease. Therefore, the following measures should be considered for HCWs who are exposed to natural varicella: a) serologic testing for varicella antibody immediately after VZV exposure; b) retesting 5–6 days later

to determine if an anamnestic response is present; and c) possible furlough or re-assignment of personnel who do not have detectable varicella antibody. Whether postexposure vaccination protects adults is not known.

Hospitals also should develop guidelines for managing HCWs after varicella vaccination because of the risk for transmission of vaccine virus. Institutions may wish to consider precautions for personnel in whom a rash develops after vaccination and for other vaccinated HCWs who will have contact with susceptible persons at high risk for serious complications.

Hepatitis C and Other Parenterally Transmitted Non-A, Non-B Hepatitis

No vaccine or other immunoprophylactic measures are available for hepatitis C or other parenterally transmitted non-A, non-B hepatitis. HCWs should follow recommended practices for preventing transmission of all blood borne pathogens (see Background—Hepatitis C and other Parenterally Transmitted Non-A, Non-B Hepatitis).

Other Diseases for Which Immunoprophylaxis Is or May Be Indicated

ACIP does not recommend routine immunization of HCWs against tuberculosis, hepatitis A, pertussis, meningococcal disease, typhoid fever, or vaccinia. However, immunoprophylaxis for these diseases may be indicated for HCWs in certain circumstances.

Tuberculosis and BCG Vaccination of Health-Care Workers in High-Risk Settings

BCG vaccination of HCWs should be considered on an individual basis in health-care settings where **all** of the following conditions are met:

- a high percentage of TB patients are infected with *M. tuberculosis* strains that are resistant to both isoniazid and rifampin; and
- transmission of such drug-resistant *M. tuberculosis* strains to HCWs is likely; and,
- comprehensive TB infection-control precautions have been implemented and have not been successful.

Vaccination with BCG should not be required for employment or for assignment in specific work areas.

BCG is not recommended for use in HIV-infected persons or persons who are otherwise immunocompromised. In health-care settings where there is a high risk for transmission of *M. tuberculosis* strains resistant to both isoniazid and rifampin, employees and volunteers who are infected with HIV or are otherwise immunocompromised should be fully informed about the risk for acquiring TB infection and disease and the even greater risk for development of active TB disease associated with immunosuppression.

HCWs considered for BCG vaccination should be counseled regarding the risks and benefits of both BCG vaccination and preventive therapy. They should be informed about the variable findings of research regarding the efficacy of BCG vaccination, the interference of BCG vaccination with diagnosis of newly acquired *M. tuberculosis* infection, and the possible serious complications of BCG vaccine in immunocompromised persons, especially those infected with HIV. They also should be informed about the lack of data regarding the efficacy of preventive therapy for *M. tuberculosis* infections caused by strains resistant to isoniazid and rifampin and the risks for drug toxicity associated with multidrug preventive-therapy regimens. If requested by the employee, employers should offer (but not compel) a work assignment in which an immunocompromised HCW would have the lowest possible risk for infection with *M. tuberculosis*.

HCWs who contract TB are a source of infection for other health-care personnel and patients. Immunocompromised persons are at increased risk for developing active disease after exposure to TB; therefore, managers of health-care facilities should develop written policies to limit activities that might result in exposure of immunocompromised employees to persons with active cases of TB.

BCG vaccination is not recommended for HCWs in low-risk settings. In most areas of the United States, most *M. tuberculosis* isolates (approximately 90%) are fully susceptible to isoniazid or rifampin or both, and the risk for TB transmission in health-care facilities is very low if adequate infection control practices are maintained.

Hepatitis A

Routine preexposure hepatitis A vaccination of HCWs and routine IG prophylaxis for hospital personnel providing care to patients with hepatitis A are not indicated. Rather, sound hygienic practices should be emphasized. Staff education should emphasize precautions regarding direct contact with potentially infective materials (e.g., hand washing).

In documented outbreaks of hepatitis A, administration of IG to persons who have close contact with infected patients (e.g., HCWs, other patients) is recommended. A single intramuscular dose (0.02 mL per kg) of IG is recommended as soon as possible and ≤ 2 weeks after exposure (2). The usefulness of hepatitis A vaccine in controlling outbreaks in health-care settings has not been investigated.

The following vaccination schedules are recommended for the vaccines available in the United States:

- HAVRIX®: for persons aged >18 years, two doses, the second administered 6–12 months after the first.
- VAQTA® : for persons aged >17 years, two doses, the second administered 6 months after the first.

Meningococcal Disease

Routine vaccination of civilians, including HCWs, is not recommended. HCWs who have intensive contact with oropharyngeal secretions of infected patients, and who do not use proper precautions (95) should receive antimicrobial prophylaxis with rifampin (or sulfonamides, if the organisms isolated are sulfonamide-sensitive). Ciprofloxacin and ceftriaxone are reasonable alternative drugs; ceftriaxone can be ad-

ministered to pregnant women. Vaccination with quadrivalent polysaccharide vaccine should be used to control outbreaks of serogroup C meningococcal disease. Surveillance for serogroup C disease and calculation of attack rates can be used to identify outbreaks and determine whether use of meningococcal vaccine is warranted.

Pertussis

Pertussis vaccines (whole-cell and acellular) are licensed for use only among children aged 6 weeks through 6 years. If acellular pertussis vaccines are licensed for use in adults in the future, booster doses of adult formulations may be recommended to prevent the occurrence and spread of the disease in HCWs.

Typhoid

Workers in microbiology laboratories who frequently work with *S. typhi* should be vaccinated with any one of the three typhoid vaccines distributed in the United States: oral live-attenuated Ty21a vaccine (one enteric-coated capsule taken on alternate days to a total of four capsules), the parenteral heat-phenol inactivated vaccine (two 0.5 mL subcutaneous doses, separated by ≥ 4 weeks), or the capsular polysaccharide parenteral vaccine (one 0.5 mL intramuscular dose). Under conditions of continued or repeated exposure to *S. typhi*, booster doses are required to maintain immunity, every 5 years if the oral vaccine is used, every 3 years if the heat-phenol inactivated parenteral vaccine is used, and every 2 years if the capsular polysaccharide vaccine is used. Live-attenuated Ty21a vaccine should not be used among immunocompromised persons, including those infected with HIV (13).

Vaccinia

Vaccinia vaccine is recommended only for the few persons who work with orthopoxviruses (e.g., laboratory workers who directly handle cultures or animals contaminated or infected with vaccinia, recombinant vaccinia viruses, or other orthopoxviruses that replicate readily in humans [e.g., monkeypox, cowpox, and others]). Other HCWs (e.g., physicians and nurses) whose contact with these viruses is limited to contaminated materials (e.g., dressings) and who adhere to appropriate infection control measures are at lower risk for accidental infection than laboratory workers, but may be considered for vaccination. When indicated, vaccinia vaccine should be administered every 10 years (10). Vaccinia vaccine should not be administered to immunocompromised persons (including persons infected with HIV), persons who have eczema or a history of eczema, or to pregnant women (10).

Other Vaccine-Preventable Diseases

Health-care workers are not at substantially increased risk than the general adult population for acquiring diphtheria, pneumococcal disease, or tetanus. Therefore, they should seek these immunizations from their primary care provider, according to ACIP recommendations (12,14).

Tetanus and Diphtheria

Primary vaccination of previously unvaccinated adults consists of three doses of adult tetanus-diphtheria toxoid (Td): 4–6 weeks should separate the first and second

doses; the third dose should be administered 6–12 months after the second (12). After primary vaccination, a tetanus-diphtheria (Td) booster is recommended for all persons every 10 years. HCWs should be encouraged to receive recommended Td booster doses.

Pneumococcal Disease

Persons for whom pneumococcal vaccine is recommended include:

- Persons aged ≥ 65 years.
- Persons aged ≥ 2 and < 65 years who, because they have certain chronic illnesses, are at increased risk for pneumococcal disease, its complications, or severe disease if they become infected. Included are those who have chronic cardiovascular disease (i.e., congestive heart failure [CHF] or cardiomyopathies), chronic pulmonary disease (i.e., chronic obstructive pulmonary disease [COPD] or emphysema, but not asthma), diabetes mellitus, alcoholism, chronic liver disease (cirrhosis), or cerebrospinal fluid leaks.
- Persons ≥ 2 and < 65 years of age with functional or anatomic asplenia (e.g., sickle cell disease, splenectomy).
- Persons ≥ 2 and < 65 years of age living in special environments or social settings where an increased risk exists for invasive pneumococcal disease or its complications (e.g., Alaska Natives and certain American Indian populations).
- Immunocompromised persons ≥ 2 years of age, including
 - persons infected with HIV and persons who have leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome;
 - persons with other conditions associated with immunosuppression (e.g., organ or bone marrow transplantation); and
 - persons receiving immunosuppressive chemotherapy, including long-term systemic corticosteroids.

Immunization of Immunocompromised Health-Care Workers

ACIP has published recommendations for immunization of immunocompromised persons (177). ACIP recommendations for use of individual vaccines or immune globulins also should be consulted for additional information regarding the epidemiology of the diseases and the safety and the efficacy of the vaccines or immune globulin preparations. Specific recommendations for use of vaccines depend upon the type of immunocompromising condition (Table 4).

Killed or inactivated vaccines do not represent a danger to immunocompromised HCWs and generally should be administered as recommended for workers who are not immunocompromised. Additional vaccines, particularly bacterial polysaccharide vaccines (i.e., *Haemophilus influenzae* type b [Hib] vaccine, pneumococcal vaccine, and meningococcal vaccine), are recommended for persons whose immune function is compromised by anatomic or functional asplenia and certain other conditions. Fre-

TABLE 4. Summary of ACIP recommendations concerning immunization of health-care workers with special conditions

Vaccine	Pregnancy	HIV Infection	Severe Immuno-suppression*	Asplenia	Renal Failure	Diabetes	Alcoholism and Alcoholic Cirrhosis
BCG	C	C	C	UI	UI	UI	UI
Hepatitis A	UI	UI	UI	UI	UI	UI	R [†]
Hepatitis B	R	R	R	R	R	R	R
Influenza	R [§]	R	R	R	R	R	R
Measles, Mumps, Rubella	C	R [¶]	C	R	R	R	R
Meningococcus	UI	UI	UI	R [†]	UI	UI	UI
Poliovirus vaccine, inactivated (IPV)**	UI	UI	UI	UI	UI	UI	UI
Poliovirus vaccine, live, oral (OPV)**	UI	C	C	UI	UI	UI	UI
Pneumococcus [†]	UI	R	R	R	R	R	R
Rabies	UI	UI	UI	UI	UI	UI	UI
Tetanus/diphtheria [†]	R	R	R	R	R	R	R
Typhoid, Inactivated & Vi ^{††}	UI	UI	UI	UI	UI	UI	UI
Typhoid, Ty21a	UI	C	C	UI	UI	UI	UI
Varicella	C	C	C	R	R	R	R
Vaccinia	C	C	C	UI	UI	UI	UI

* Severe immunosuppression can be caused by congenital immunodeficiency, leukemia, lymphoma, generalized malignancy or therapy with alkylating agents, antimetabolites, ionizing radiation, or large amounts of corticosteroids.

[†] Recommendation is based on the person's underlying condition rather than occupation.

[§] Women who will be in the second or third trimester of pregnancy during the influenza season.

[¶] Contraindicated in HIV-infected persons who have evidence of severe immunosuppression.

** Vaccination is recommended for unvaccinated health-care workers who have close contact with patients who may be excreting wild polioviruses. Primary vaccination with IPV is recommended because the risk for vaccine-associated paralysis after administration of OPV is higher among adults than among children. Health care workers who have had a primary series of OPV or IPV who are directly involved with the provision of care to patients who may be excreting poliovirus may receive another dose of either IPV or OPV. Any suspected case of poliomyelitis should be investigated immediately. If evidence suggests transmission of wild poliovirus, control measures to contain further transmission should be instituted immediately, including an OPV vaccination campaign.

^{††} Capsular polysaccharide parenteral vaccine.

Abbreviations: R=Recommended; C= Contraindicated; UI=Use if indicated.

quently, the immune response of immunocompromised persons to these vaccine antigens is not as good as that of nonimmunocompromised persons; higher doses or more frequent boosters may be required. Even with these modifications, the immune response may be suboptimal.

HIV-Infected Persons

Specific recommendations for vaccination of HIV-infected persons have been developed (Table 4). In general, live virus or live bacterial vaccines should not be administered to HIV-infected persons. However, asymptomatic HCWs need not be tested for HIV infection before administering live virus vaccines.

The following recommendations apply to all HCWs infected with HIV:

- MMR vaccine is recommended for all asymptomatic HIV-infected HCWs who do not have evidence of severe immunosuppression. Administration of MMR to HIV-infected HCWs who are symptomatic, but who do not have evidence of severe immunosuppression, should be considered. Measles vaccine is not recommended for HIV-infected persons with evidence of severe immunosuppression.
- Enhanced inactivated poliovirus vaccine (IPV) is the **only** poliovirus vaccine recommended for HIV-infected persons (11). Live oral poliovirus vaccine (OPV) **should not** be administered to immunocompromised persons.
- Influenza and pneumococcal vaccines are indicated for all HIV-infected persons (influenza vaccination for persons aged ≥ 6 months and pneumococcal vaccination for persons aged ≥ 2 years).

OTHER CONSIDERATIONS IN VACCINATION OF HEALTH-CARE WORKERS

Other considerations important to appropriate immunoprophylaxis of HCWs include maintenance of complete immunization records, policies for catch-up vaccination of HCWs, work restrictions for susceptible employees who are exposed to vaccine-preventable diseases, and control of outbreaks of vaccine-preventable disease in health-care settings. Additional vaccines not routinely recommended for HCWs in the United States may be indicated for those who travel to certain other regions of the world to perform research or health-care work (e.g., as medical volunteers in a humanitarian effort).

Immunization Records

An immunization record should be maintained for each HCW. The record should reflect documented disease and vaccination histories as well as immunizing agents administered during employment. At each immunization encounter, the record should be updated and the HCW encouraged to maintain the record as appropriate (15).

Catch-Up Vaccination Programs

Managers of health-care facilities should consider implementing catch-up vaccination programs for HCWs who are already employed, in addition to policies to ensure

that newly hired HCWs receive necessary vaccinations. This strategy will help prevent outbreaks of vaccine preventable diseases (see Outbreak Control). Because education enhances the success of many immunization programs, reference materials should be available to assist in answering questions regarding the diseases, vaccines, and toxoids, and the program or policy being implemented. Conducting educational workshops or seminars several weeks before the initiation of the program may be necessary to ensure acceptance of program goals.

Work Restrictions for Susceptible Workers After Exposure

Postexposure work restrictions ranging from restriction of contact with high-risk patients to complete exclusion from duty are appropriate for HCWs who are not immune to certain vaccine-preventable diseases (Table 5). Recommendations concerning work restrictions in these circumstances have been published (16,35,178).

Outbreak Control

Hospitals should develop comprehensive policies and protocols for management and control of outbreaks of vaccine-preventable disease. Outbreaks of vaccine-preventable diseases are costly and disruptive. Outbreak prevention, by ensuring that all HCWs who have direct contact with patients are fully immunized, is the most effective and cost-effective control strategy. Disease-specific outbreak control measures are described in published ACIP recommendations (Table 1) (1-15) and infection control references (16,35,95, 178-180).

Vaccines Indicated for Foreign Travel

Hospital and other HCWs who perform research or health-care work in foreign countries may be at increased risk for acquiring certain diseases (e.g, hepatitis A, poliomyelitis, Japanese encephalitis, meningococcal disease, plague, rabies, typhoid, or yellow fever). Vaccinations against those diseases should be considered when indicated for foreign travel (181). Elevated risks for acquiring these diseases may stem from exposure to patients in health-care settings (e.g., poliomyelitis, meningococcal disease), but may also arise from circumstances unrelated to patient care (e.g, high endemicity of hepatitis A or exposure to arthropod disease vectors [yellow fever]).

TABLE 5. Work restrictions* for health-care workers (HCWs) exposed to or infected with certain vaccine-preventable diseases

Disease/Problem	Work Restriction	Duration
Diphtheria		
Active	Exclude from duty.	Until antimicrobial therapy is completed and 2 nasopharyngeal cultures obtained ≥ 24 hours apart are negative.
Postexposure (Susceptible HCWs; previously vaccinated HCWs who have not had a Td booster dose within the previous 5 years)	Exclude from duty.	Same as active diphtheria
Asymptomatic carriers	Exclude from duty.	Same as active diphtheria.
Hepatitis A	Restrict from patient contact and food handling.	7 days after onset of jaundice.
Hepatitis B		
HCWs with acute or chronic antigenemia:		
-HCWs who do not perform exposure-prone invasive procedures (21)	Standard precautions should always be observed. No restriction unless epidemiologically linked to transmission of infection.	Universal precautions should always be observed.
-HCWs who perform exposure-prone invasive procedures	These HCWs should not perform exposure-prone invasive procedures until they have sought counsel from an expert review panel which should review and recommend the procedures the worker can perform, taking into account the specific procedure as well as the skill and technique of the worker (30).	Until HBeAg [†] is negative.
Upper respiratory infections		
(Persons at high risk for complications of influenza as defined by ACIP [3])	During particular seasons (e.g., during winter when influenza and/or RSV are prevalent), consider excluding personnel with acute febrile upper respiratory infections (including influenza) from care of high-risk patients.	Until acute symptoms resolve.
Measles		
Active	Exclude from duty	7 days after rash appears.
Postexposure (Susceptible personnel)	Exclude from duty.	5th day after 1st exposure through 21st day after last exposure and/or 7 days after the rash appears.

TABLE 5. Work restrictions* for health-care workers (HCWs) exposed to or infected with certain vaccine-preventable diseases — Continued

Disease/Problem	Work Restriction	Duration
Mumps		
Active	Exclude from duty	9 days after onset of parotitis.
Postexposure (Susceptible personnel)	Exclude from duty.	12th day after 1st exposure through 26th day after last exposure or 9 days after onset of parotitis.
Pertussis		
Active	Exclude from duty	Beginning of catarrhal stage through 3rd week after onset of paroxysms or until 5 days after start of effective antimicrobial therapy.
Postexposure <i>Symptomatic personnel</i>	Exclude from duty	5 days after start of effective antimicrobial therapy.
<i>Asymptomatic personnel</i>	No restriction, on antimicrobial prophylactic therapy.	
Rubella		
Active	Exclude from duty	5 days after the rash appears.
Postexposure (Susceptible personnel)	Exclude from duty.	7th day after 1st exposure through 21st day after last exposure and/or 5 days after rash appears.
Varicella		
Active	Exclude from duty	Until all lesions dry and crust.
Postexposure (Susceptible personnel)	Exclude from duty	10th day after 1st exposure through 21st day (28th day if VZIG administered) after the last exposure; if varicella occurs, until all lesions dry and crust.
Zoster		
(Localized in normal person)	Cover lesions; restrict from care of high-risk patients [§] .	Same as varicella.
Postexposure (Susceptible personnel)	Restrict from patient contact.	

* Adapted from:

- (173) CDC. Recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures. MMWR 1991;40(RR-8):1-8.

- (95) CDC. Guideline for isolation precautions in hospitals. Recommendations of the Hospital Infection Control Practices Advisory Committee (HICPAC) and the National Center for Infectious Diseases. Infect Control Hosp Epidemiol 1996;17:53-80.

- (178) Williams WW: CDC guideline for infection control in hospital personnel. Infect Control 1983;4(Suppl):326-49.

† HBeAg = Hepatitis B e antigen.

§ Patients who are susceptible to varicella and at increased risk for complications of varicella (i.e., neonates and immunocompromised persons of any age.)

References

1. CDC. Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through childhood immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1991;40(No. RR-13):1-25.
2. CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1996;45(No. RR-15):1-30.
3. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1997;46(No. RR-9):1-25.
4. CDC. Measles prevention: recommendations of the Immunization Practices Advisory Committee (ACIP). *MMWR* 1989;(No. S-9):1-18.
5. CDC. Mumps prevention. Recommendations of the Immunization Practices Advisory Committee (ACIP) *MMWR* 1989;38:388-92,397-400.
6. CDC. Rubella prevention. Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1990;39(No. RR-15):1-13.
7. CDC. The role of BCG vaccine in the prevention and control of tuberculosis in the United States: a joint statement by the Advisory Council for the Elimination of Tuberculosis and the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1996;45(No. RR-4):1-18.
8. CDC. Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1996;45(No. RR-11):1-36.
9. CDC. Control and prevention of meningococcal disease and control and prevention of serogroup C meningococcal disease: evaluation and management of suspected outbreaks: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1997;46(No. RR-5):1-21.
10. CDC. Vaccinia (smallpox) vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1991;40(RR-14):1-10.
11. CDC. Poliomyelitis prevention in the United States: introduction of a sequential vaccination schedule of inactivated poliovirus vaccine followed by oral poliovirus vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1997;46(No. RR-3):1-25.
12. CDC. Diphtheria, tetanus, and pertussis: recommendations for vaccine use and other preventive measures: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1991;40(No. RR-10):1-28.
13. CDC. Typhoid immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1994;43(No. RR-14):1-7.
14. CDC. Prevention of pneumococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1997;46(No. RR-8):1-24.
15. CDC. Update on adult immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1991;40(No. RR-12):1-94.
16. CDC. Guidelines for infection control in health care personnel, 1997: recommendations of the Hospital Infection Control Practices Advisory Committee. *Am J Infect Control* 1998 (in press).
17. American Hospital Association. Immunization: management advisory on health care delivery. American Hospital Association; 1992: Chicago, Illinois.
18. CDC. Hepatitis surveillance report No. 56. Atlanta: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention; 1-33, 1996.
19. CDC. Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers: a response to P. L. 100-607, The Health Omnibus Programs Extension Act of 1988. Atlanta, GA.: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control; 1-45, 1989.
20. Shapiro CN. Occupational risk of infection with hepatitis B and hepatitis C virus. *Surg Clin North Am* 1995;75:1047-56.
21. Thomas DL, Factor SH, Gabon D, et al. Viral hepatitis in health care personnel at the Johns Hopkins Hospital. *Arch Intern Med* 1993;153:1705-12.
22. Dienstag JL, Ryan DM. Occupational exposure to hepatitis B virus in hospital personnel: infection or immunization? *Am J Epidemiol* 1982;115:26-39.

23. Shapiro CN, Tokars JI, Chamberland ME, et al. Use of the hepatitis B vaccine and infection with hepatitis B and C among orthopaedic surgeons. *J Bone Joint Surg* 1996;78-A:1791-1800.
24. Gibas A, Blewett DR, Schoenfeld DA, Dienstag JL. Prevalence and incidence of viral hepatitis in health workers in the prehepatitis B vaccination era. *Am J Epidemiol* 1992;136:603-10.
25. Hadler SC, Doto IL, Maynard JE, et al. Occupational risk of hepatitis B infection in hospital workers. *Infection Control* 1985;6:24-31.
26. Department of Labor/Department of Health and Human Services Joint Advisory Notice. Protection against occupational exposure to hepatitis B virus (HBV) and human immunodeficiency virus (HIV). *Federal Register* 1987;52:41818-24.
27. Department of Labor. Bloodborne pathogens: the standard. *Federal Register* 1991;60:64175-82.
28. Stevens CE, Toy PT, Taylor PE, Lee T, Yip H-Y. Prospects for control of hepatitis B virus infection: implications of childhood vaccination and long-term protection. *Pediatrics* 1992;90:170-3.
29. Hadler SC, Margolis HS. Hepatitis B immunization: vaccine types, efficacy, and indications for immunization. In Remington JS, Swartz MN: *Current topics in infectious diseases*. Boston: Blackwell Scientific, 1992:282-308.
30. Balkovic ES, Goodman RA, Rose FB, et al. Nosocomial influenza A(H1N1) infection. *Am J Med Technol* 1980;46:318-20.
31. Van Voris LP, Belshe RB, Shaffer JL. Nosocomial influenza B virus infection in the elderly. *Ann Intern Med* 1982;96:153-8.
32. CDC. Suspected nosocomial influenza cases in an intensive care unit. *MMWR* 1988;37:3.
33. Pachucki CT, Walsh Pappas SA, Fuller GF, Krause SL, Lentino JR, Schaaf DM. Influenza A among hospital personnel and patients: implications for recognition, prevention, and control. *Arch Intern Med* 1990;149:77-80.
34. Hammond GW, Cheang M. Absenteeism among hospital staff during an influenza epidemic: Implications for immunoprophylaxis. *Can Med Assoc J* 1984;131:449-52.
35. Williams WW, Preblud SR, Reichelderfer PS, Hadler SC. Vaccines of importance in the hospital setting. *Infect Dis Clin North Am* 1989;3:701-22.
36. Mast EE, Harmon MW, Gravenstein S, et al. Emergence and possible transmission of amantadine-resistant viruses during nursing home outbreaks of influenza (AH3N2). *Am J Epidemiol* 1991;134:986-97.
37. Horman JT, Stetler HC, Israel E, Sorley D, Schipper MT, Joseph JM. An outbreak of influenza A in a nursing home. *Am J Public Health* 1986;76:501-4.
38. Patriarca PA, Weber JA, Parker RA, et al. Risk factors for outbreaks of influenza in nursing homes: a case-control study. *Am J Epidemiol* 1986;124:114-9.
39. CDC. Outbreak of influenza A in a nursing home—New York, December, 1991–January, 1992. *MMWR* 1992;41:129-31.
40. Gross PA, Rodstein M, LaMontagne JR, et al. Epidemiology of acute respiratory illness during an influenza outbreak in a nursing home. *Arch Intern Med* 1988;148:559-61.
41. Carter ML, Renzullo PO, Helgerson SD, Martin SM, Jekel JF. Influenza outbreaks in nursing homes: how effective is influenza vaccine in the institutionalized elderly? *Infect Control Hosp Epidemiol* 1990;11:473-8.
42. Potter J, Stott DJ, Roberts MA, et al. Influenza vaccination of health care workers in long-term-care hospitals reduces the mortality of elderly patients. *J Infect Dis* 1997;175:1-6.
43. CDC. Measles in HIV-infected children—United States. *MMWR* 1988;37:183-6.
44. CDC. Measles transmitted in a medical office building—New Mexico, 1986. *MMWR* 1987;36:25-7.
45. Davis RM, Orenstein WA, Frank Jr, JA, et al. Transmission of measles in medical settings, 1980 through 1984. *JAMA* 1986;255:1295-8.
46. Istre GR, KcKee PA, West GR, et al. Measles spread in medical settings: an important focus of disease transmission? *Pediatrics* 1987;79:356-8.
47. Sienko DG, Friedman C, McGee HB, et al. A measles outbreak at university medical settings involving health care providers. *Am J Public Health* 1987;77:1222-4.
48. Watkins NM, Smith Jr RP, St.Germain DL, et al. Measles (rubeola) infection in a hospital setting. *Am J Infect Control* 1987;15:201-6.
49. Atkinson WL, Markowitz LE, Adams NC, Seastrom GR. Transmission of measles in medical settings—United States, 1985–1989. *Am J Med* 1991;91(Suppl 3B):320S-4S.

50. CDC. Measles—United States, 1987. *MMWR* 1988;37:527–31.
51. CDC. Measles—United States, 1986. *MMWR* 1987;36:301–5.
52. CDC. Measles—United States, 1985. *MMWR* 1986;35:366–70.
53. Braunstein H, Thomas S, Ito R. Immunity to measles in a large population of varying age. *Am J Dis Child* 1990;144:296–8.
54. Smith E, Welch W, Berhow M, Wong VK. Measles susceptibility of hospital employees as determined by ELISA. *Clin Res* 1990;38:183A.
55. Cochi SL, Preblud SR, Orenstein WA. Perspectives on the relative resurgence of mumps in the United States. *Am J Dis Child* 1988;142:499–507.
56. Kaplan KM, Marder DC, Cochi SL, et al. Mumps in the workplace: further evidence of the changing epidemiology of a childhood vaccine-preventable disease. *JAMA* 1988;260:1434–8.
57. CDC. Mumps outbreaks on university campuses—Illinois, Wisconsin, South Dakota, *MMWR* 1987;36:496–498,503–5.
58. Sosin DM, Cochi SL, Gunn RA, et al. Changing epidemiology of mumps and its impact on university campuses. *Pediatrics* 1989;84:779–84.
59. Hersh BS, Fine PEM, Kent WK, et al. Mumps outbreak in a highly vaccinated population. *J Pediatr* 1991;119:87–93.
60. Briss PA, Fehrs LJ, Parker RA, et al. Sustained transmission of mumps in a highly vaccinated population: assessment of primary vaccine failure and waning vaccine-induced immunity. *J Infect Dis* 1994;169:77–82.
61. van Loon FPL, Holmes SJ, Sirotkin BI, et al. Mumps surveillance—United States, 1988–1993. In: CDC surveillance summaries (August 11). *MMWR* 1995;44(No. SS-3):1–14.
62. Wharton M, Cochi SL, Hutcheson RH, Schaffner W. Mumps transmission in hospitals. *Arch Intern Med* 1990;150:47–9.
63. Greaves WL, Orenstein WA, Stetler HC, et al. Prevention of rubella transmission in medical facilities. *JAMA* 1982;248:861–4.
64. Bart KJ, Orenstein WA, Preblud SR, et al. Elimination of rubella and congenital rubella from the United States. *Pediatr Infect Dis* 1985;4:14–21.
65. CDC. Rubella and congenital rubella—United States, 1984–1986. *MMWR* 1987;36:664–6,671–5.
66. CDC. Increase in rubella and congenital rubella syndrome—United States, 1988–90. *MMWR* 1991;40:93–9.
67. CDC. Congenital rubella among the Amish. *MMWR* 1992;41:468–9,475–6.
68. Crawford GE, Gremillion DH. Epidemic measles and rubella in Air Force recruits: impact of immunization. *J Infect Dis* 1981;144:403–10.
69. Meyers JD, MacQuarrie MB, Merigan TC, Jennison MH. Varicella. Part 1: outbreak in oncology patients at a children's hospital. *West J Med* 1979;130:196–9.
70. Morens DM, Bregman DJ, West CM, et al. An outbreak of varicella-zoster virus infection among cancer patients. *Ann Intern Med* 1980;93:414–9.
71. Baltimore RS. Infections in the pediatric intensive care unit. *Yale J Biol Med* 1984;57:185–97.
72. Gustafson TL, Shehab Z, Brunell PA. Outbreak of varicella in a newborn intensive care nursery. *Am J Dis Child* 1984;138:548–50.
73. Hyams PJ, Stuewe MCS, Heitzer V. Herpes zoster causing varicella (chicken pox) in hospital employees: cost of a casual attitude. *Infect Control* 1984;12:2–5.
74. Shehab ZM, Brunell PA. Susceptibility of hospital personnel to varicella-zoster virus. *J Infect Dis* 1984;150:786.
75. Weitekamp MR, Schan P, Aber RC. An algorithm for the control of varicella-zoster virus. *Am J Infect Control* 1985;13:193–8.
76. Alter SJ, Hammond JA, McVey CJ, Myers MG. Susceptibility to varicella-zoster virus among adults at high risk for exposure. *Infect Control* 1986;7:448–51.
77. Krasinski K, Holzman RS, LaCouture R, Florman A. Hospital experience with varicella-zoster virus. *Infect Control* 1986;7:312–6.
78. Haiduven-Griffiths D, Fecko H. Varicella in hospital personnel: a challenge for the infection control practitioner. *Am J Infect Control* 1987;15:207–11.
79. Weber DJ, Rutala WA, Parham C. Impact and costs of varicella prevention in a university hospital. *Am J Public Health* 1988;78:19–23.
80. McKinney WP, Horowitz MM, Battiola RJ. Susceptibility of hospital-based health care personnel to varicella-zoster virus infections. *Am J Infect Control* 1989;17:26–30.

81. Asano Y, Iwayama S, Miyata T, et al. Spread of varicella in hospitalized children having no direct contact with an indicator zoster case and its prevention by a live vaccine. *Biken J* 1980;23:157-61.
82. Leclair JM, Zaia JA, Levine MJ, Congdon RG, Goldmann DA. Airborne transmission of chickenpox in a hospital. *N Engl J Med* 1980;302:450-3.
83. Gustafson TL, Lavelly GB, Brawner ER, Hutcheson RH, Wright PF, Schaffner W. An outbreak of airborne varicella. *Pediatrics* 1982;70:550-6.
84. Josephson A, Gombert ME. Airborne transmission of nosocomial varicella from localized zoster. *J Infect Dis* 1988;158:238-41.
85. Sawyer MH, Chamberlin CJ, Wu YN, Aintablian N, Wallace MR. Detection of varicella-zoster virus DNA in air samples from hospital room. *J Infect Dis* 1994;169:91-4.
86. Preblud SR. Nosocomial varicella: worth preventing but how? *Am J Public Health* 1988;78:13-5.
87. Myers MG, Rasley DA, Hierholzer WJ. Hospital infection control for varicella zoster virus infection. *Pediatrics* 1982;70:199-202.
88. Steele RW, Coleman MA, Fiser M, Bradsher RW. Varicella-zoster in hospital personnel: skin test reactivity to monitor susceptibility. *Pediatrics* 1982;70:604-8.
89. Anderson JD, Bonner M, Scheifele DW, Schneider BC. Lack of spread of varicella in a pediatric hospital with negative pressure ventilated patient rooms. *Infect Control* 1985;6:120-1.
90. Sayre MR, Lucid EJ. Management of varicella-zoster virus-exposed hospital employees. *Ann Emerg Med* 1987;16:421-4.
91. Stover BH, Cost KM, Hamm C, Adams G, Cook LN. Varicella exposure in a neonatal intensive care unit: case report and control measures. *Am J Infect Control* 1988;16:167-72.
92. Lipton SV, Brunell PA. Management of varicella exposure in a neonatal intensive care unit. *JAMA* 1989;261:1782-4.
93. Ferson MJ, Bell SM, Robertson PW. Determination and importance of varicella immune status of nursing staff in a children's hospital. *J Hosp Infect* 1990;15:347-51.
94. Josephson A, Karanfil L, Gombert ME. Strategies for the management of varicella-susceptible health care workers after a known exposure. *Infect Control Hosp Epidemiol* 1990;11:309-13.
95. CDC. Guideline for isolation precautions in hospitals. Recommendations of the Hospital Infection Control Practices Advisory Committee (HICPAC) and the National Center for Infectious Diseases. *Infect Control Hosp Epidemiol* 1996;17:53-80.
96. Kelly PW, Petruccioli BP, Stehr-Green P, Erickson RL, Mason CJ. The susceptibility of young adult Americans to vaccine-preventable infections. A national serosurvey of US Army recruits. *JAMA* 1991;266:2724-9.
97. Struewing JP, Hyams KC, Tueller JE, Gray GC. The risk of measles, mumps, and varicella among young adults: a serosurvey of US Navy and Marine Corps recruits. *Am J Public Health* 1993;83:1717-20.
98. Polder JA, Tablan OC, Williams WW. Personnel health services. In: Bennett JV, Brachman PS, eds. *Hospital infections*. 3rd ed. Boston: Little, Brown and Company, 1992:31-61.
99. White CJ, Kuter BJ, Ngai A, et al. Modified cases of chickenpox after varicella vaccination: correlation of protection with antibody response. *Pediatr Infect Dis J* 1992;11:19-23.
100. Bernstein HH, Rothstein EP, Watson BM, et al. Clinical survey of natural varicella compared with breakthrough varicella after immunization with live attenuated Oka/Merck varicella vaccine. *Pediatrics* 1993;92:833-7.
101. Watson BM, Piercy SA, Plotkin SA, Starr SE. Modified chickenpox in children immunized with the Oka/Merck varicella vaccine. *Pediatrics* 1993;91:17-22.
102. Weibel RE, Neff BJ, Kuter BJ, et al. Live attenuated varicella vaccine. Efficacy trial in healthy children. *N Engl J Med* 1984;310:1409-15.
103. Tsoia M, Gershon AA, Steinberg SP, Gelb L. Live attenuated varicella vaccine: evidence that the vaccine virus is attenuated and the importance of skin lesions in transmission of varicella-zoster virus. The National Institute of Allergy and Infectious Diseases Varicella Vaccine Collaborative Study Group. *J Pediatr* 1990;116:185-9.
104. Steinberg SP, Gershon AA. Measurement of antibodies to varicella-zoster virus by using a latex agglutination test. *J Clin Microbiol* 1991;29:1527-9.
105. Gershon AA, Steinberg SP, LaRussa PS. Detection of antibody to varicella zoster virus using the latex agglutination assay. *Clin Diagn Virol* 1994; 2:271-8.

106. American Thoracic Society, CDC. Treatment of tuberculosis and tuberculosis infection in adults and children. *Am J Respir Crit Care Med* 1994;149:1359-74.
107. Farer LS. Chemoprophylaxis. *Am Rev Respir Dis* 1982;125(Pt 2):102-7.
108. CDC. Guidelines for preventing the transmission of *M. tuberculosis* in health-care facilities, 1994. *MMWR* 1994;43(RR-13):1-132.
109. CDC. Prevention and control of tuberculosis among homeless persons. *MMWR* 1992;41(RR-5):13-23.
110. CDC. Prevention and control of tuberculosis in correctional facilities: recommendations of the Advisory Council for the Elimination of Tuberculosis. *MMWR* 1996;45:(No.RR-8):1-27.
111. CDC. Nosocomial transmission of multidrug-resistant tuberculosis among HIV-infected persons—Florida and New York, 1988-1991. *MMWR* 1991;40(34): 585-91.
112. Edlin BR, Tokars JI, Grieco MH, et al. An outbreak of multidrug-resistant tuberculosis among hospitalized patients with the acquired immunodeficiency syndrome. *N Engl J Med* 1992;326:1514-21.
113. Pearson ML, Jereb JA, Frieden TR, et al. Nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis*. A risk to patients and health care workers. *Ann Intern Med* 1992;117:191-6.
114. CDC. Multidrug-resistant tuberculosis in a hospital—Jersey City, New Jersey, 1990-1992. *MMWR* 1994;43(22):417-9.
115. CDC. Outbreak of multidrug-resistant tuberculosis at a hospital—New York City, 1991. *MMWR* 1993;42(22):427,433-4.
116. Valway SE, Greifinger RB, Papania M, et al. Multidrug-resistant tuberculosis in the New York State prison system, 1990-1991. *J Infect Dis* 1994;170:151-6.
117. Alter MJ, Margolis HS, Krawczynski K, et al. The natural history of community-acquired hepatitis C in the United States. *N Engl J Med* 1992;327:1899-905.
118. Alter MJ. Epidemiology of hepatitis C in the west. *Semin Liver Dis* 1995;15:5-14.
119. Shakil AO, Conry-Cantilena C, Alter HJ, et al. Volunteer blood donors with antibody to hepatitis C virus: clinical, biochemical, and histologic features. *Ann Intern Med* 1995;123:330-7.
120. Dienstag JL, Katkov WN, Cody H. Evidence for non-A, non-B hepatitis agents besides hepatitis C virus. In Hollinger FB, Lemon SM, Margolis HS (eds). *Viral hepatitis and liver disease*. Baltimore, MD: Williams and Wilkins, 1991:349-56.
121. CDC. Public Health Service inter-agency guidelines for screening donors of blood, plasma, organs, tissues, and semen for evidence of hepatitis B and hepatitis C. *MMWR* 1991;40(RR-4):1-17.
122. Leslie M, Damen HTM, Cuypers HL, et al. International collaborative study on the second Eurohep HCV-RNA reference panel. In: *Proceedings of the IX International Symposium on Viral Hepatitis and Liver Disease*. Rome, 1996: 25.
123. Alter MJ, Gerety RJ, Smallwood L, et al. Sporadic non-A, non-B hepatitis: frequency and epidemiology in an urban United States population. *J Infect Dis* 1982;145:886-93.
124. Seeff LB. Hepatitis C from a needlestick injury [letter]. *Ann Intern Med* 1991;115:411.
125. Cooper BW, Krusell A, Tilton RC, Goodwin R, Levitz RE. Seroprevalence of antibodies to hepatitis C virus in high-risk hospital personnel. *Infect Control Hosp Epidemiol* 1992;13:82-5.
126. Campello C, Majori S, Poli A, Pacini P, Nicolardi L, Pini F. Prevalence of HCV antibodies in health-care workers from northern Italy. *Infection* 1992;20:224-6.
127. Polish LB, Tong MJ, Co RL, Coleman PJ, Alter MJ. Risk factors for hepatitis C virus infection among health care personnel in a community hospital. *Am J Infect Control* 1993;21:196-200.
128. Panlilio AL, Shapiro CN, Schable CA, et al. Serosurvey of human immunodeficiency virus, hepatitis B virus, and hepatitis C virus infection among hospital-based surgeons. *J Am Coll Surg* 1995;180:16-24.
129. Klein RS, Freeman K, Taylor PE, Stevens CE. Occupational risk for hepatitis C virus infection among New York City dentists. *Lancet* 1991;338:1539-42.
130. Thomas DL, Gruninger SE, Siew C, Joy ED, Quinn TC. Occupational risk of hepatitis C infections among general dentists and oral surgeons in North America. *Am J Med* 1996;100:41-5.
131. Tsude K, Fujiyama S, Sato S, Kawano S, Taura Y, Yoshida K, Sato T. Two cases of accidental transmission of hepatitis C to medical staff. *Hepatogastroenterology* 1992;39:73-5.

132. Hernandez ME, Bruguera M, Puyuelo T, Barrera JM, Sanchez Tapias JM, Rodes J. Risk of needle-stick injuries in the transmission of hepatitis C virus in hospital personnel. *J Hepatol* 1992;16:56-8.
133. Zuckerman J, Clewley G, Griffiths P, Cockcroft A. Prevalence of hepatitis C antibodies in clinical health-care workers. *Lancet* 1994;343:1618-20.
134. Petrosillo N, Puro V, Ippolito G. Prevalence of hepatitis C antibodies in health-care workers. Italian Study Group on Blood-borne Occupational Risk in Dialysis. *Lancet* 1994;344:339-40.
135. Lanphear BP, Linnemann CC, Cannon CG, DeRonde MM, Pandy L, Kerley LM. Hepatitis C virus infection in health care workers: risk of exposure and infection. *Infect Control Hosp Epidemiol* 1994;15:745-50.
136. Mitsui T, Iwano K, Masuko K, et al. Hepatitis C virus infection in medical personnel after needlestick accident. *Hepatology* 1992;16:1109-14.
137. Puro V, Petrosillo N, Ippolito G. Risk of hepatitis C seroconversion after occupational exposures in health care workers. Italian Study Group on Occupational Risk of HIV and Other Bloodborne Infections. *Am J Infect Control* 1995;23:273-7.
138. Sartori M, La Terra G, Aglietta M, et al. Transmission of hepatitis C via blood splash into conjunctiva. *Scand J Infect Dis* 1993;25:270-1.
139. Knodell RG, Conrad ME, Ginsburg AL, Bell CJ, Flannery EP. Efficacy of prophylactic gamma globulin in preventing non-A, non-B post-transfusion hepatitis. *Lancet* 1976;1:557-61.
140. Seeff LB, Zimmerman JH, Wright EL, et al. A randomized double-blind controlled trial of the efficacy of immune serum globulin for the prevention of post-transfusion hepatitis. A Veterans Administration cooperative study. *Gastroenterology* 1977;72:111-21.
141. Sanchez-Quijano A, Pineda JA, Lissen E, et al. Prevention of post-transfusion non-A, non-B hepatitis by non-specific immunoglobulin in heart surgery patients. *Lancet* 1988;1:1245-9.
142. Bukh J, Miller RH, Purcell RH. Genetic heterogeneity of hepatitis C virus: quasispecies and genotypes. *Semin Liver Dis* 1995;15:41-63.
143. Krawczynski K, Alter MJ, Tankersley DL, et al. Studies on protective efficacy of hepatitis C immunoglobulins (HCIG) in experimental hepatitis C virus infection [Abstract]. *Hepatology* 1993;18:110A.
144. Hoofnagle JH, Di Bisceglie AM. Drug therapy: the treatment of chronic viral hepatitis. *N Engl J Med* 1997;336:347-56.
145. Peters M, Davis GL, Dooley JS, et al. The interferon system in acute and chronic viral hepatitis. *Prog Liver Dis* 1986;8:453-67.
146. CDC. Recommendations for follow-up of health-care workers after occupational exposure to hepatitis C virus. *MMWR* 1997;46:603-6.
147. Noble RC, Kane MA, Reeves SA, et al. Posttransfusion hepatitis A in a neonatal intensive care unit. *JAMA* 1984;252:2711-5.
148. Klein BS, Michaels JA, Rytel MW, Berg KG, Davis JP. Nosocomial hepatitis A: a multi-nursery outbreak in Wisconsin. *JAMA* 1984;252:2716-21.
149. Rosenblum LS, Villarino ME, Nainan OV, et al. Hepatitis A outbreak in a neonatal intensive care unit: risk factors for transmission and evidence of prolonged viral excretion among pre-term infants. *J Infect Dis* 1991;164: 476-82.
150. Goodman RA. Nosocomial hepatitis A. *Ann Intern Med* 1985;103:452-4.
151. Papaevangelou GJ, Roumeliotou-Karayannis AJ, Contoyannis PC. The risk of hepatitis A and B virus infections from patients under care without isolation precautions. *J Med Virol* 1981;7:143-8.
152. Werzberger A, Mensch B, Kuter B, et al. A controlled trial of a formalin-inactivated hepatitis A vaccine in healthy children. *N Engl J Med* 1992; 327:453-7.
153. Innis B, Snitbhan R, Kunasol P, et al. Field efficacy trial of inactivated hepatitis A vaccine among children in Thailand (an extended abstract). *Vaccine* 1992 10 (Suppl 1):S159.
154. Mortimer EA Jr. Pertussis Vaccine. In: Plotkin SA, Mortimer EA, eds. *Vaccines*, 2nd ed. Philadelphia: W.B. Saunders, 1994: 94.
155. Mortimer EA Jr. Pertussis and its prevention: a family affair. *J Infect Dis* 1990;161:473-9.
156. Christie C, Glover AM, Willke MJ, Marx ML, Reising SF, Hutchinson NM. Containment of pertussis in the regional pediatric hospital during the greater Cincinnati epidemic of 1993. *Infect Control Hosp Epidemiol* 1995;16:556-63.

157. Kurt TL, Yeager AS, Guennette S, Dunlop S. Spread of pertussis by hospital staff. *JAMA* 1972;221:264-7.
158. Linnemann CC, Ramundo N, Perlstein PH, et al. Use of pertussis vaccine in an epidemic involving hospital staff. *Lancet* 1975;2:540-3.
159. Valenti WM, Pincus PH, Messner MK. Nosocomial pertussis: possible spread by a hospital visitor. *Am J Dis Child* 1980;134:520-1.
160. Edwards KM, Decker MD, Graham BS, Mezatesta J, Scott J, Hackell J. Adult immunization with acellular pertussis vaccine. *JAMA*.1993;269:53-6.
161. CDC. Pertussis vaccination: use of acellular pertussis vaccines among infants and young children—recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1997;46(No. RR-7):1-25.
162. Mermin J, Townes J, Gerber M, Dolan N, Mintz E, Tauxe R. Rise of antimicrobial resistant *Salmonella typhi* infections in the United States, 1985-1994 [Abstract]. Proceedings of the 36th Interscience Conference on Antimicrobial Agents and Chemotherapy. Washington, D.C.: American Society for Microbiology, 1996:84.
163. Opravil M, Fierz W, Matter L, et al. Poor antibody response after tetanus and pneumococcal vaccination in immunocompromised, HIV-infected patients. *Clin Exp Immunol* 1991;84(2):185-9.
164. Borkowsky W, Steele CJ, Grubman S, et al. Antibody responses to bacterial toxoids in children infected with human immunodeficiency virus. *J Pediatr* 1987;110:563-6.
165. Huang KL, Ruben FL, Rinaldo CR Jr, et al. Antibody responses after influenza and pneumococcal immunization in HIV-infected homosexual men. *JAMA* 1987; 257:2047-50.
166. Klein RS, Selwyn PA, Maude D, et al. Responses to pneumococcal vaccine among asymptomatic heterosexual partners of persons with AIDS and intravenous drug users infected with human immunodeficiency virus. *J Infect Dis* 1989;160:826-31.
167. Vardinon N, Handsher R, Burke M, et al. Poliovirus vaccination responses in HIV-infected patients: correlation with T4 cell counts. *J Infect Dis* 1990;162:238-41.
168. Onorato IM, Markowitz LE. Immunizations, vaccine-preventable diseases, and HIV infection. In: Wormser GP, ed. *AIDS and other manifestations of HIV infection*. New York: Raven Press, 1992:671-81.
169. CDC. Measles pneumonitis following measles-mumps-rubella vaccination of a patient with HIV infection, 1993. *MMWR* 1996;45:603-6.
170. CDC. Measles, United States, 1995. *MMWR* 1996;45:305-7.
171. Mitus A, Holloway A, Evans AE, Enders JF. Attenuated measles vaccine in children with acute leukemia. *Am J Dis Child* 1962;103:413-8.
172. Bellini WJ, Rota JS, Greer PW, Zaki SR. Measles vaccination death in a child with severe combined immunodeficiency: report of a case. Annual Meeting of United States and Canadian Academy of Pathology, Atlanta, GA, 1992. *Lab Invest* 1992;66:91A.
173. CDC. Recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures. *MMWR* 1991;40(RR-8):1-8.
174. Subbarao EK, Amin S, Kumar ML. Prevacination serologic screening for measles in health care workers. *J Infect Dis* 1991;163:876-8.
175. Sellick Jr. JA, Longbine D, Schifeling R, Mylotte JM. Screening hospital employees for measles immunity is more cost effective than blind immunization. *Ann Intern Med* 1992;116:982-4.
176. Grabowsky M, Markowitz L. Serologic screening, mass immunization, and implications for immunization programs. *J Infect Dis* 1991;164:1237-8.
177. CDC. Use of vaccines and immune globulins in persons with altered immunocompetence—recommendations of the Advisory Committee on Immunization Practices(ACIP). *MMWR* 1993;42(No. RR-4):1-18.
178. Williams WW. CDC guideline for infection control in hospital personnel. *Infect Control* 1983;4(Suppl):326-49.
179. Fedson DS. Immunizations for health care workers and patients in hospitals. In: Wenzel RP, ed. *Prevention and control of nosocomial infections*. Baltimore: Williams & Wilkins, 1992: 214-94.
180. Mayhall CG, ed. *Hospital epidemiology and infection control*. Baltimore: Williams and Wilkins, 1996.

181. CDC. Health information for international travel, 1996–97. Atlanta, GA: Department of Health and Human Services, Centers for Disease Control and Prevention, 1997.

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