

Infection Control Guidelines for Ambulatory Care Settings

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Infection Control Guidelines Ambulatory Care Clinics

Second Edition

Louisiana Office of Public Health

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Section 1

Purpose

Section 1: Purpose

This infection-control document is based on three principal goals for healthcare infection control and prevention programs: 1) protect the client; 2) protect the health care worker, visitors and others in the health care environment; and 3) accomplish these goals in a timely, efficient and cost-effective manner.

These guidelines have been established to:

- Act as a general tool to provide guidelines, procedures, and an exposure control plan for regional and local health department employees and their clients to prevent the spread of infectious diseases, as well as provide for the overall safety and well-being of these individuals.
- Promote safer work practices in caring for clients.
- Indicate when personal protective equipment is necessary.
- Serve as written documentation and reference for administrative purposes.
- Serve as a basis for developing departmental policy statements and in-service education/employee orientation.
- Serve as a reference for future updates/amendments of Office of Public Health (OPH) policies
- Provide recommendations based on the Centers for Disease Control and Prevention Guidelines, Occupational Safety and Health Administration Guidelines and current Office of Public Health policies.
- Be a resource and/or reference document for contractors and health-care providers.

Section 2

Employee Policies

avoid transfer of microorganisms to other clients or environments. This is a key element for prevention of cross-infection in the health care setting. For additional information on Hand Hygiene, refer to MMWR, Recommendations and Reports, Guideline for Hand Hygiene in Health Care Settings, Oct 25, 2002, Vol. 51, No. RR-16 or at the Internet site <http://www.cdc.gov/mmwr>.

Handwashing Facilities

All established clinics must be equipped with handwashing facilities which are readily accessible to employees. Disposable paper towels and soap should be available and within easy reach of the sink. When provisions for handwashing are not feasible, an appropriate antiseptic hand cleanser or towelette approved for use in OPH facilities can be used until hands can be washed with soap and running water.

Note: Proper handwashing is the single most important means of preventing the spread of infection and is a universally accepted standard of hygiene and cleanliness.

Procedure

1. If possible, remove jewelry from hands and wrists.
2. Wet hands under running water. Avoid touching hands to sink surfaces.
3. Lather hands well with soap, hand antiseptic, or surface antiseptic from a dispenser. Wash fingers, in between the fingers, under the fingernails, palms, backs of hands, and wrists, for 15 seconds.
4. Rinse hands thoroughly.
5. Dry hands with paper towels.
6. Use paper towel to turn off the faucet.
7. In the event that handwashing facilities are not available (such as during field/home visits), cleansing towelettes or an instant hand sanitizer may be used if running water and soap are not available.
8. Considerations for the selection and the use of waterless-based hand rubs should include the efficacy as an antiseptic agent, type of dispensing containers, formulations (gel, foam or cream), and formulations containing emollients and acceptable scents.

Key Points

Only a minimum amount of jewelry should be worn during clinic care.

Remove and clean the inside and outside of the dispensing outlet when it needs to be refilled. Keep it free of soap build-up.

Bar soap should be used only if liquid or "soft" soap dispensers are unavailable. Bar soap can harbor bacteria if left undrained. If bar soap is to be used, provide a self-draining soap dish. Run water over the soap briefly before replacing on the soap dish.

Because hand sanitizers are not as effective as soap and water, hands should be washed after every 10 uses or as soon as possible.

Once product selection is considered, these products should be placed in an area where sinks are unavailable (to avoid mix up between soap and waterless-based rub). Placement should be prohibited where safety is a concern.

Reminder: Adverse reactions can develop after use of any hand hygiene products including alcohol-based hand rubs. Skin problems such as dermatitis, allergy or sensitivity as a result of frequent handwashing or use of waterless-based products may result in dry skin. Hand lotion and moisturizers may be indicated.

When to Wash Hands

1. Before and after work.
2. Before and after each significant client contact.*
3. After removing gloves or other personal protective equipment.
4. After contact with objects contaminated with blood or other body substances.
5. After using the toilet, blowing your nose, covering a sneeze/cough or smoking.
6. Before eating, drinking, or handling food.
7. Before preparing and administering injections.**

Rationale for Adherence to Handwashing Hygiene

1. *There are potential risks of transmitting microorganisms from health care providers to clients.*
2. *There are potential risks for colonization or infections caused by microorganisms acquired from the client to health care provider.*
3. *There can be substantial costs associated with the morbidity and mortality of health-care associated/acquired infections.*

* Significant client contact includes, but is not limited to, contact with blood, body substances, mucous membranes, and non-intact skin. Routine contact with a client's intact skin (e.g., taking blood pressures, taking weights, etc.) does not necessitate handwashing.

** Administering injections is considered a significant client contact. In field situations, or other clinic situations where it is not practical to wash hands, antiseptic towelettes or waterless hand sanitizers should be used to cleanse hands between clients.

B. Use of Gloves/Barrier Precautions

Gloves shall be worn when it can be reasonably anticipated the health-care worker may have hand contact with blood, semen, vaginal secretions, urine, feces, saliva, sputum, vomitus, or any body substance.

Note: Throughout the manual, unless otherwise specified, the term “gloves” will refer to disposable latex examination gloves or suitable equivalent such as vinyl gloves or glove liners used underneath the latex gloves if the employee is allergic to latex. Employees who are allergic to latex should not wear latex gloves or inhale powder from latex gloves worn by other staff.

Procedure

1. Gloves shall be used for all procedures where exposure to blood or body substances is expected, including client care, cleaning equipment and environmental surfaces directly contaminated with such substances, or during any “vascular access procedure.”
2. It is recommended that gloves be worn on both hands.
3. If cross-contamination of surfaces and equipment is anticipated, one hand should remain ungloved and not be used to perform the exam.
4. Change gloves between client contacts. Gloves should not be washed or disinfected for continued use. Gloves should not be re-used.
5. If the gloves become torn or punctured, discard them and put on a new pair.
6. If breaks in the skin are present on the hands, additional coverings may be worn under the gloves.
7. For environmental cleaning purposes, heavier reusable household gloves may be used. They can be washed with soap and water after use and hung to dry.
8. Discard the household gloves if they are cracked, peeling, torn, or punctured, or show other signs of deterioration.

Key Points

Disposable gloves should be made available for all staff to wear when contact with body substances is expected. Vascular access procedures include such things as phlebotomy and finger or heel sticks.

When both hands are gloved, be careful not to contaminate equipment and surfaces while performing client exams.

Employees should evaluate their working situations to determine appropriate glove use.

Washing gloves with soap may cause “wicking” (i.e., the enhanced penetration of fluids through undetected holes in the gloves). Disinfecting agents will lead to glove deterioration.

Gloves should be checked for tears and should not replace handwashing.

Glove liners, bandages, gauze, or finger cots can help minimize skin irritations on the hands.

The lightweight examination gloves do not hold up under prolonged exposure to disinfection procedures.

Reminder: Gloves do not provide complete protection against hand contamination and are not intended to replace good handwashing practices; rather, glove use is meant to support and supplement handwashing. Therefore, remove gloves promptly after use, before touching non-contaminated items and environmental surfaces, and before going to another client. Wash hands immediately after gloves are removed to avoid transfer of microorganisms.

C. Management of Natural Rubber Latex Allergy

The use of natural rubber latex (NRL) gloves has proven effective in preventing transmission of many infectious diseases. Unfortunately, use of NRL gloves in this preventive effort has contributed to documented sensitization to NRL allergens of 1 – 6% of the general population. NRL exposure sources in the health care setting may induce sensitization or allergic reactions in health care workers and clients. Allergic reactions can include skin rashes, hives, flushing, itching, and nasal, eye, or sinus symptoms, asthma, and rarely, anaphylactic shock. The primary risk factor in producing sensitization or inducing allergic reaction is exposure to certain NRL proteins. The amount of NRL protein exposure necessary to sensitize an individual is unknown. The powder used in gloves may also cause dermatitis conditions and/or allergic reactions.

Three types of adverse health reactions to gloves and medical products that contain NRL can occur:

- **Irritant Contact Dermatitis:** Produces dry, itchy, irritated areas of the hands/skin. Irritant contact dermatitis is not a true allergy.
- **Allergic contact dermatitis (delayed type hypersensitivity):** Results from specific immune response to the chemical additives to latex during manufacturing and processing of latex products. Can cause skin reactions similar to poison ivy within 24 – 48 hours after contact and progress to blistering and vesicle formation.
- **Latex Allergy:** Certain proteins in latex may cause sensitization whereby reaction can occur within minutes to hours later. Mild allergic reactions involve skin redness, hives, or itching. More severe symptoms involve respiratory symptoms such as runny nose, itchy eyes, scratchy throat, bronchospasm and asthma. Anaphylaxis and death have occurred following latex exposure.

Unfortunately, no one glove is appropriate for every health care provider in every situation. The decision whether or not to use gloves and what type of glove to use should complement existing institutional protocols on managing and preventing occupational health and hazardous exposure. This strategy may reduce costs and improve infection control practices in the health care facility through the education of personnel on appropriate glove choices. Therefore, management of NRL allergy in health care facilities should include:

- A. Management commitment whereby the employer is responsible for managing safety and health at the workplace.
- B. Facility use of lower powder or lower protein or lower allergen NRL gloves, or non-NRL gloves should be used throughout the facility. In addition, the facility manager or other individual as designated by the Regional Manager, should conduct routine maintenance and cleaning of the heating, ventilation, and air conditioning system to reduce NRL protein contamination and improve the general indoor air quality.
- C. Management commitment for the prevention and management of work-related NRL allergy among health care facility employees by:
 1. Educating employees upon employment regarding NRL allergy issues.

2. Asking about any conditions which might require accommodation.
3. Informing employees on how to recognize signs and symptoms of NRL allergy, how exposures can be reduced and to appropriately report to the immediate supervisor after an illness-related exposure.
4. Providing employees diagnosed with NRL sensitivity or allergy with non-NRL gloves or appropriate barriers when in contact with NRL products.
5. Training employees to screen clients for known or potential risk for developing a NRL allergic reaction to products such as gloves, blood pressure cuffs, tourniquets, tape, vascular access devices and other NRL containing materials. Latex-free products and/or powder free gloves should be available as needed to address client procedures performed within health care facilities.

Recommendation: *The employer should annually and periodically screen high risk employees for latex/powder allergy symptoms as a measure for early detection and prevention, and for preventing long term health effects. Individuals considered at high risk for latex hypersensitivity are those who have frequent environmental or occupational exposure to latex products (i.e., gloves, catheters, injection ports).*

D. Use of Additional Personal Protective Equipment (PPE)

Additional forms of barrier protection such as aprons, lab coats, goggles, masks, and gowns are necessary if splattering of blood or other body fluids is anticipated. The use of personal protective equipment (PPE) protects mucous membranes of the eyes, nose and mouth during procedures and client care activities that are likely to generate splashes or sprays of blood, body fluids, and secretions/ excretions. Gowns/lab coats protect the skin and prevent soiling of clothing during client care activities; however, such items cannot be considered PPE if they are not intended to function as protection against a hazard. PPE can be disposable, reusable, semipermeable or nonpermeable and must not permit pass through of the potentially infectious substance to the skin, eyes, nose, mouth or clothes. After an exposure, remove soiled gown or lab coat promptly and wash hands.

Eye protection can consist of goggles, glasses with side shields, or face shields that protect both eyes and face. Masks should be worn in combination with goggles or glasses to protect the face, nasal and oral mucous membranes. Masks can be flat or molded in a cone shape. The type of mask best suited to a particular situation depends on the body substances likely to be encountered and the nature of the activity. Masks protect the mucosal surfaces against large droplets and splashes or sprays and should not be confused with particulate respirators that are recommended for protection from small particles (< 5µm) containing infectious agents transmitted via the airborne route. In routine ambulatory care practices, other types of PPE, such as head or shoe covers are not required. Mouth-to-mask or mouth-to-bag devices with one-way valves should be readily available for resuscitation to avoid exposing the nose and mouth to oral and respiratory fluids during such procedures.

Provision of Personal Protective Equipment

The employer shall provide, at no cost to the employees, necessary personal protective equipment that can be cleaned or replaced as needed. Personal protective equipment should be easily accessible, and the employer shall also provide appropriate training for the use of PPE. In the likelihood that PPE may be infrequently used, a “PPE kit” stocked with these items (along with resuscitation equipment) should be easily transportable and placed in a central location for staff use.

Reminder: PPE, if used properly, can minimize exposure to pathogens. Ambulatory care facilities need to evaluate the tasks performed by staff and then determine what type of PPE are needed to prevent exposures to clients and staff, and when PPE are to be used. Always anticipate your needs!

Table 1. Procedures and Glove, Mask and Goggle Use

Procedure	Glove	Mask	Goggle
1. Drawing blood	Y	N	O
2. Doing finger or heel sticks	Y	N	N
3. Giving immunizations/PPD skin tests	O	O	O
4. Spinning blood in centrifuges	Y	Y	Y
5. Taking oral, ear, or axillary temperatures	N	N	N
6. Taking rectal temperature	Y	N	N
7. Testing urine with dipsticks	Y	N	N
8. Doing Pap smears, testing/Rx for sexually transmitted diseases	Y	O	O
9. Insertion and removal IUDs and IUS	Y	Y	Y
10. Taking blood pressure	N	N	N
11. Taking heights, weights	N	N	N
12. Doing breast exams	N	N	N
13. Changing diapers	Y	O	O
14. Doing an oral exam	Y	N	N
15. Handling/preparing lab specimens	Y	Y	Y
16. Doing physical exams on children	O	O	O
17. Examining a client without touching	N	N	N
18. Verbal interview with client and providing instructions	N	N	N
19. Handling medical waste	Y	O	O

Key to Abbreviations Used

Y = Yes (mandatory for the procedure)

N = No (not required)

O = Optional (base on professional judgment)

Disclaimer: While these examples are not inclusive of all possible events, protective barrier use should be based on judgment for individual situations that may arise.

Examples of Personal Protective Equipment for Protection from Occupational Exposure to Blood and Body Fluids¹

Examples	Disposable Gloves	Gown	Mask	Protective Eyewear
Bleeding control for spurting blood	Yes	Yes	Yes	Yes
Bleeding control with minimal bleeding	Yes	No	No	No
Specimen handling/transport	Yes	Yes	Yes	Yes
Blood drawing	Yes	No	No	No
Handling and cleaning instruments with microbial contamination	Yes	No ²	No	No
Measuring blood pressure	No	No	No	No
Measuring body temperature				
Oral, axillary, ear	No	No	No	No
Rectal	Yes	No	No	No
Giving an injection	No ³	No	No	No

Disclaimer: While these examples are not inclusive of all possible events, PPE use should be based on judgment for individual situations that may arise.

Infection-Control Review

1. Thoroughly wash hands with soap and running water for at least 15 seconds after:
 - significant contact with each client,
 - handling a specimen,
 - contact with a potentially contaminated surface, or
 - removing personal protective equipment.
2. Wear personal protective equipment appropriate to the task being performed.
3. Health-care workers who have exudative lesions/weeping dermatitis or open sores should refrain from direct client care until the condition resolves.
4. Change clothing splashed with blood or body fluids as quickly as possible.
5. Remember that gloves will not provide protection against needle sticks or other percutaneous injuries. Gloves will, however, help to reduce the amount of blood or body substance entering into a wound when the needle penetrates the glove.

¹ Adapted from Centers for Disease Control Guidelines and OSHA standard, Occupational Exposure to Bloodborne Pathogens; Final Rule, December 6, 1991.

² Gowns are not needed unless soiling of clothing is likely.

³ Gloves may be used at an employee's discretion.

III. Employee Immunizations

On the basis of documented nosocomial transmission, personnel in settings with the potential for exposure to clients or infectious materials are considered to be at significant risk for acquiring or transmitting communicable diseases which can be vaccine preventable. Immunizations are an essential part of prevention and infection control programs and should be implemented for all facilities. The Centers for Disease Control and Prevention recommends that health care workers be screened, immunized, and/or preventively treated in order to reduce potential risks of disease transmission as a measure to protect the employee as well as the client within the health care setting. All employees should be in compliance with the following guidelines and maintain an up-to-date immunization status and TB skin tests.

A. Responsibility for OPH Employee Immunizations

It is the responsibility of each Regional Office Medical Director, Regional Administrator, or their designees to ensure that all existing and new employees are offered appropriate vaccinations. To insure compliance with these guidelines, each supervisor should check the record of each employee under his or her supervision yearly at the time of the employee's annual planning and performance rating (PPR). Employees must have on file written verification from their own physician as to having the required immunization and/or tests, or from a parish health unit, including date of administration, type of immunization and/or test.

Procedure

1. Employee immunization guidelines should be adhered to as stated in this document.
2. All positions in which the employee's duties include direct contact with clients, the public, and material from clients with infections will be identified.
3. Employee vaccination, serology, and/or infection history will be documented and reviewed to identify additional vaccinations and tests which are required to meet the criteria of these guidelines.
4. Newly hired employees should be referred to their medical providers to obtain required vaccines, serological tests, or TB screening before their initial work assignment.

Key Points

This document outlines requirements for pre-exposure vaccinations and TB screening and should be discussed with all prospective employees prior to hiring.

Because of their direct contact with clients, or material from clients with infections, health-care employees (physicians, nurses, emergency workers, field responders, disease intervention specialists, medical and nursing students, laboratory technicians, administrative and clerical staff, sanitarians, clinic housekeeping staff, and others) are at increased risk for exposure to and possible transmission of TB and vaccine-preventable diseases.

Vaccination not only protects employees from diseases transmitted by the clients and public they serve but also protects clients and the public from becoming infected through exposure to health-care workers.

Recommended TB screening intervals may vary by risk of exposure. Periodic screening for TB identifies recent converters who would benefit from treatment for latent infection and prevent transmission to clients and staff.

Procedure

5. Employee serological tests will not be inserted in personnel records, but should be maintained in separate files to preserve employee confidentiality.
6. Employee immunizations received at LA OPH or at participating private physician offices will also be recorded in the LA LINKS Immunization System.
7. The Regional Medical Director should review the job duties of employees who are non-responders to Hepatitis B vaccine (e.g., for those who have had their post-vaccination antibody testing status) to determine what modifications or precautions should be taken in the work assignment in the event of a disease exposure.

Key Points

Separate files for immunization records will permit easy access for evaluation as needed. Employee health files can serve this purpose. Such files should be kept in a secure area under lock and key.

The completed vaccination certificate is given to the employee for his/her personal record.

The employee, direct supervisor, and Regional Medical Director will prepare a summary of the immunization problem and any valid medical contraindications. Documentation of the review and outcome will be kept on file with the employee's records.

Vaccines which are required to be offered to health care workers include Hepatitis B, rubella, measles, rabies (for specific workers), and screening for tuberculosis infection. Other vaccines which are not required but recommended include tetanus, diphtheria, influenza, varicella and pneumococcus (for select individuals meeting the vaccine criteria). This policy must be discussed with all prospective employees prior to hiring. If the person is presumed to be susceptible to any of the vaccine-preventable diseases, he/she must be offered the immunization unless standard medical contraindications exist. A statement to applicants outlining specific contraindications is required. (See Refusal of Vaccination and Release from Responsibility form.) Any case in which vaccination is not accepted must be referred to the respective Regional Administrator and Regional Medical Director for discussion and review.

Procedure

Personnel working in Parish Health Units, Regional Offices, and Central Office who have contact with Parish Health unit clients are required to have the following immunizations:

a. Rubella

Immunity to rubella is documented by written record either by a prior rubella immunization, by a prior immune status determination demonstrating immunity to rubella, or by birth prior to 1957 (except for women of childbearing age). If the person is immune to rubella, no further action is needed.

Key Points

If documentation of immunity to rubella is not available, the employee is to receive an injection of rubella vaccine (MMR) without testing. If the employee is pregnant or planning to become pregnant within the next 3 months, the MMR should be postponed until after delivery.

Procedure

Key Points

b. Measles

Immunity to measles is documented by written record by two previous doses of measles vaccine, prior immune status determination documenting immunity to measles, or by birth prior to 1957. If the person is immune to measles, no further action is needed.

If documentation of immunity to measles is not available, the employee is to receive one or two doses of measles vaccine (depending on prior immunization) without testing. If the employee is pregnant or planning to become pregnant within the next 3 months, the MMR should be postponed until after delivery.

c. Hepatitis B

Immunity to Hepatitis B is documented by written record by three prior doses of Hepatitis B vaccine or by a prior immune status determination demonstrating immunity to Hepatitis B. If the person is immune to Hepatitis B, no further action is needed.

If documentation of immunity to Hepatitis B is not available, the employee is to receive doses of Hepatitis B vaccine sufficient to complete a three dose series (including any prior doses). Pre vaccination serologic screening is not indicated for persons being vaccinated because of occupational risk.

As of June 2001, CDC has recommended that health care professionals who have contact with patients or blood and are at ongoing risk for percutaneous injuries should be tested 1--2 months after completion of the 3-dose vaccination series for anti-HBs. If the result of the antibody test is positive, the employee is considered immune.

Persons who do not respond to the primary vaccine series (i.e., anti-HBs < 10 mIU/mL or reported as a negative result) should complete a second 3-dose vaccine series. Revaccinated persons should be retested at the completion of the second vaccine series. Persons who do not respond to an initial 3-dose vaccine series have a 30 – 50% chance of responding to a second 3-dose series.

Nonresponders to vaccination and who are HBsAg negative should be considered susceptible (as for all employees) to HBV infection and should be counseled regarding precautions to prevent HBV infection and the need to obtain HBIG prophylaxis for any known or highly probable parenteral exposure to HBsAg-positive blood. (see *Section 2 IV.B – Protocol for Managing Needlestick Injuries and Other Unintentional Exposures to Blood or Potentially Infectious Body Fluids*)

Procedure

d. Laboratory and other workers with potential exposure to rabies

Laboratory workers and sanitarians who are at risk of exposure to rabies should receive the primary course of the vaccine. Pre-exposure rabies vaccination should be offered according to current CDC recommendations.

Key Points

Information about rabies immunization may be obtained from the Office of Public Health, Infectious Disease Epidemiology Section. The Section must be consulted for the latest recommendations on types of vaccine available, method of procurement, vaccine schedules, and verification of adequate immune response, prior to administering pre-exposure rabies immunizations.

State laboratory workers who conduct rabies tests should receive a primary course of vaccine with serologic testing done annually. Booster vaccination should be given when the antibody level falls below an acceptable level. Sanitarians who receive a primary course of vaccine do not require routine serologic testing or boosters.

The following immunizations are recommended for personnel working in Parish Health Units, Regional Offices, and Central Office:

e. Tetanus/diphtheria

Immunity to tetanus and diphtheria is documented by a written record of a booster within the past ten years.

If a high risk injury is sustained, the Td vaccine booster dose is needed if at least five years have elapsed since the last dose.

If documentation of immunity to tetanus/diphtheria is not available, the employee is to receive one dose of Td vaccine.

f. Varicella

Immunity to varicella is documented by written record either by a history of chickenpox, or one prior dose of varicella vaccine, or by prior immune status determination demonstrating immunity to varicella. If the person is immune to varicella, no further action is needed.

If documentation of immunity to varicella is not available, the employee may receive a series of two injections of varicella vaccine (VAR) without testing. If the employee is pregnant or planning to become pregnant within the next 3 months, the VAR should be postponed until after delivery.

Procedure

Key Points

g. Influenza

Influenza vaccine is recommended yearly for employees who have contact with high-risk clients. High risk clients include adults age 65 and older, individuals with chronic lung or heart problems, adults and children with metabolic diseases such as diabetes, and those who are immune suppressed. Influenza is also recommended for employees who have any of these risk factors themselves.

Any employee may elect to receive influenza vaccine if they wish to avoid influenza disease, depending on vaccine availability and cost. This vaccine is offered yearly during the late fall. Immunization is given yearly because the specific strain of influenza changes slightly each year, requiring new vaccine to be developed each year.

h. Pneumococcal vaccine

Pneumococcal vaccine is recommended for individuals who are at high risk of invasive disease. This includes adults who are 65 years and older or have chronic illnesses, including cardiovascular disease, pulmonary disease, diabetes, alcoholism, cirrhosis, sickle cell disease, or cerebrospinal fluid leaks. It is also recommended for immunocompromised individuals, including those with asplenia, Hodgkin's disease, lymphoma, multiple myeloma, chronic renal failure, nephrotic syndrome, or who have had organ transplantation. It is also recommended for HIV-infected individuals.

Pneumococcal disease accounts for more than 40,000 deaths per year nationally, primarily from pneumonia, bacteremia, and meningitis. At least 83 serotypes of pneumococci have been identified. The current vaccine contains antigens from 23 serotypes.

i. All other personnel

Disease immunity determination and vaccination are not required for employees who do not have contact with health unit clients, laboratory specimens, or sanitarian inspections. However, employees who elect to have any of the vaccinations can be referred to their physicians for consultation. It is recommended that all female employees of childbearing age, whether or not they have contact with clients should have documentation of rubella immunity.

For more information regarding employee immunizations, contact your regional immunization program manager, or the LA OPH Immunization Division at 504-483-1900 or website address <http://www.oph.dhh.state.la.us/immunization>.

NOTE: RESPONDING TO THE MOST RECENT CONCERNS REGARDING BIOTERRORISM (BT) AND THE POSSIBILITY OF INTENTIONAL RELEASE OF VARIOLA (SMALLPOX) VIRUS, SEPARATE GUIDELINES FOR VACCINE USE OR PRIORITY GROUPS FOR BT-RELATED VACCINATION MAY BE COVERED UNDER GUIDELINES ESTABLISHED BY THE OPH BIOTERRORISM SECTION.

B. Employee Tuberculosis Skin Testing

All persons prior to or at the time of employment at any OPH Parish Health Unit or OPH outpatient health care facility shall be free of tuberculosis in a communicable state as evidenced by either: a negative PPD test for tuberculosis, five tuberculin unit strength, given by Mantoux method; a normal chest x-ray if the skin test is positive; or a statement from a licensed physician certifying that the individual is non-infectious if the x-ray is other than normal. The newly hired employee shall not be denied access to work solely on the basis of being infected with tuberculosis, provided the infection is not communicable.

Any employee who has a positive PPD skin test for tuberculosis, five tuberculin unit strength, given by Mantoux method, or a chest x-ray other than normal, in order to remain employed or continue work, shall complete an adequate course of chemotherapy for tuberculosis as prescribed by a Louisiana licensed physician, or shall present a signed statement from a Louisiana licensed physician stating that chemotherapy is not indicated.

Any employee who has a negative PPD skin test for tuberculosis, five tuberculin strength, given by Mantoux method, in order to remain employed or continue work shall be re-tested annually as long as the PPD skin test given by Mantoux method is negative. Any employee converting from a negative to a positive PPD skin test shall be referred to a physician and followed as indicated above. *Note: In a high exposure situation, more frequent testing may be necessary.*

Employees who are found to have a new positive skin test during the annual screening process should be referred to the Tuberculosis Control Program of the Office of Public Health or their regular physician for evaluation. Employees who have documented evidence of a previous positive TB skin test do not require further skin testing, and do not require yearly chest x-rays. However, they should be counseled about the signs and symptoms of tuberculosis (cough lasting more than two weeks, fever, weight loss and night sweats) and informed that they should seek medical evaluation if symptoms suggestive of tuberculosis occur. The OPH supervisor should annually assess these employees for symptoms suggestive of tuberculosis and document their current health status. Questions regarding the administration and interpretation of skin tests, infection control issues or treatment issues may be directed to the OPH Regional TB Disease Intervention Specialist Supervisors at the Regional TB Medical Clinics, or to the OPH TB Control Program staff in New Orleans.

IV. Post-Exposure Management for Occupational Exposure to Blood or Other Potentially Infectious Materials (OPIM)

All accidental exposures of employees or clients to blood, blood products, secretions, or other body substances via percutaneous, parenteral, or mucosal routes shall be reported immediately to an attending supervisor, and appropriate post-exposure evaluation/treatment initiated, as per these guidelines.

Current Estimates – Risk of Becoming Infected After A Single Needlestick From a Known Positive Source

Hepatitis B: 5% - 15%
Hepatitis C: average 3.5%
HIV: ~0.3%

A. Blood Specimen Collection/Handling and Spills

In all OPH facilities, all blood specimens will be taken using proper precautions for the protection of both clients and personnel. Careful skin disinfection and venipuncture or finger sticks with a sterile retractable needle or lancet (or an acceptable safety device) will protect the client. Gloves are required for personnel when exposure to blood or body fluids is likely including venipuncture procedures. Gloves do not need to be used during the administration of immunizations.

Used needles shall not be recapped. All sharps must be disposed of in a puncture-proof container. The container shall be considered “full” at a three-fourths full level. If a sharps container is to be transported during client field visits or for disposal at a hospital or laboratory for incineration, it may be transported by any designated trained public health personnel.

Blood spills on work surfaces should be wiped up carefully with absorbent paper towels and the surface cleaned with a 1:10 dilution of sodium hypochlorite (household bleach) mixed daily, or 70% isopropyl (rubbing) alcohol. ***Reminder: Bloody paper towels are considered infectious waste.*** Plastic goggles or a surgical mask and gloves must be worn when cleaning the spill. Hands must be washed thoroughly with soap and water (or other agent as approved by the State Health Officer) after removing gloves.

*Reminder: NEVER recap, bend or break used needles
NEVER remove needles from disposable syringes
Immediately place sharps in puncture-resistant containers.*

Sharps containers should be accessible by staff, but out of reach of children.

B. Protocol for Managing Needlestick Injuries and Other Unintentional Exposures to Blood or OPIM

1. Evaluation of Exposure and Exposure Source

Health care workers (HCW) are at risk for occupational exposures to Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) through injuries involving needlesticks and other unintentional exposure to blood and body fluids. The most important response to this risk is prevention by strict adherence to the “Universal Precautions,” which minimize the likelihood of such exposures. The guidelines which follow are meant to be used when an exposure of this type does occur in an Office of Public Health (OPH) facility.

Following national guidelines issued by the United States Public Health Service Centers for Disease Control and Prevention (CDC), exposure is:

Contact with blood or body fluids, for which universal precautions apply, from a known or unknown client source, through percutaneous inoculation (such as injury with a hypodermic needle or other “sharps”) or through contact with an open wound, non-intact skin or mucous membranes (splatter into eyes, nose or mouth).

The body fluids for which universal precautions apply are: blood, amniotic fluid, pericardial fluid, peritoneal fluid, pleural fluid, synovial fluid, cerebrospinal fluid, semen, and vaginal secretions. Feces, nasal secretions, saliva, sputum, sweat, tears, urine and vomitus are not considered potentially infectious for HIV, HBV or HCV unless they contain blood. The purpose of this protocol is to guide employees who have had such exposure through the appropriate procedures in assessing risk, taking appropriate prophylaxis, follow-up and reporting the incident.

EVALUATION OF OCCUPATIONAL EXPOSURE SOURCES

Known sources

- Test known sources for HBsAg, anti-HCV and HIV antibody
 - Direct virus assays for routine screening of source clients are not recommended
 - Consider using a rapid HIV antibody test
 - If the source person is not infected with a bloodborne pathogen, baseline testing or further follow-up of the exposed person is not necessary
- For source clients whose infection status remains unknown, e.g., the source client refuses testing, consider medical diagnoses, clinical symptoms and history of risk behaviors
- Do not test discarded needles for blood-borne pathogens

Unknown sources

- For unknown sources, evaluate the likelihood of exposure to a source at high risk of infection
 - Consider likelihood of blood-borne pathogen infection among clients in the exposure setting

2. Immediate Wound Care

Immediately following percutaneous exposure, the site should be washed with soap and water; following a mucous membrane exposure, flush with copious amounts of water, and following exposure to the eye, irrigate with copious amounts of saline solution or other sterile irrigants. There is no data to suggest that use of other antiseptic agents is of additional benefit.

3. Risk Assessment and Prophylaxis

A. HIV

CDC has developed national guidelines for evaluating the risk of HIV infection. These guidelines are to be used as follows:

1. The risk of HIV infection after exposure depends on: a) the nature of the exposure, and b) the HIV status or risk of HIV infection in the source client.

a. The Nature of the Exposure

- The average risk of infection from a percutaneous (e.g., needlestick) exposure to HIV is 0.3% or 3 in a 1000.
- The risk of infection from a mucous membrane exposure to HIV is 0.09% or 9 in 10,000.
- The risk of infection from non-intact skin exposure is estimated to be less than that for mucous membrane exposure.

Employees should assess the type of exposure and amount of blood or fluid involved in the exposure.

b. Determining the HIV Status of the Source Client

This may be done by searching medical records (e.g., STD, Prenatal or Family Planning charts or clinic records) or by requesting a blood sample for an HIV antibody test from the source client. In most circumstances the source client will be willing to provide consent for testing. If the source client refuses and his or her blood has already been drawn for other purposes, under certain circumstances that blood sample may be used to test for HIV after it is used for the reason for which it was originally drawn. **Consult the HIV/AIDS Section or the Infectious Disease Epidemiology Section if this situation occurs.** If it is not possible to determine the HIV status of the source client, it is useful to remember that in general, the type of activities of clients seen in OPH clinics are at very low risk for HIV infection.

For those rare instances in which the source client is known to be HIV+, it is useful to check medical records to estimate his or her severity of disease (presence of AIDS [Acquired Immunodeficiency Syndrome]) and the drugs, including the anti-retroviral drugs being used to treat the disease.

2. Combine the information about the status of the source client and the nature of the exposure to estimate the risk of infection. Employees should then determine whether or not post-exposure prophylaxis (PEP) should be considered or is recommended. Most source clients in OPH

clinics have an unknown HIV status. *In view of the lack of risk factors among most clients in OPH clinics, the guidelines would not suggest nor recommend PEP for HIV infection after a needlestick injury from a source client of unknown status.*

3. Determine whether or not prophylactic medications will be taken. Certain drugs may decrease the risk of HIV infection following an exposure. *These drugs can cause side effects or serious toxicity; toxic effects from an attempt to prevent infection are often far more likely than the risk of HIV infection!* The decision regarding whether these medications should be taken or not should be made by the exposed person after reviewing this information and after consultation with other medical professional persons. Employees and supervisors considering the use of prophylactic drugs should consult immediately with the regional medical director, private physician and/or the medical director of the HIV/AIDS Prevention Program in OPH. Additionally, the advice of an infectious disease medical specialist should be sought. The following should be considered:

- If prophylactic drugs are used, they should be started as soon as possible after exposure, preferably within 1 to 2 hours.
- The drugs should continue to be taken for four weeks.

TABLE 1. Recommended HIV postexposure prophylaxis (PEP) for percutaneous injuries

Exposure type	Infection status of source				
	HIV-positive, class 1*	HIV-positive, class 2*	Source of unknown HIV status†	Unknown source§	HIV-negative
Less severe [¶]	Recommend basic 2-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors††	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings in which exposure to HIV-infected persons is likely	No PEP warranted
More severe ^{§§}	Recommend expanded 3-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors††	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings in which exposure to HIV-infected persons is likely	No PEP warranted

* HIV-positive, class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 ribonucleic acid copies/mL). HIV-positive, class 2 — symptomatic HIV infection, acquired immunodeficiency syndrome, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

† For example, deceased source person with no samples available for HIV testing.

§ For example, a needle from a sharps disposal container.

¶ For example, solid needle or superficial injury.

** The recommendation "consider PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.

†† If PEP is offered and administered and the source is later determined to be HIV-negative, PEP should be discontinued.

§§ For example, large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient's artery or vein.

TABLE 2. Recommended HIV postexposure prophylaxis (PEP) for mucous membrane exposures and nonintact skin* exposures

Exposure type	Infection status of source				
	HIV-positive, class 1 [†]	HIV-positive, class 2 [†]	Source of unknown HIV status [§]	Unknown source [¶]	HIV-negative
Small volume**	Consider basic 2-drug PEP ^{††}	Recommend basic 2-drug PEP	Generally, no PEP warranted ^{§§}	Generally, no PEP warranted	No PEP warranted
Large volume ^{¶¶}	Recommend basic 2-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP ^{††} for source with HIV risk factors ^{§§}	Generally, no PEP warranted; however, consider basic 2-drug PEP ^{††} in settings in which exposure to HIV-infected persons is likely	No PEP warranted

* For skin exposures, follow-up is indicated only if evidence exists of compromised skin integrity (e.g., dermatitis, abrasion, or open wound).
[†] HIV-positive, class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 ribonucleic acid copies/mL). HIV-positive, class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.
[§] For example, deceased source person with no samples available for HIV testing.
[¶] For example, splash from inappropriately disposed blood.
^{**} For example, a few drops.
^{††} The recommendation “consider PEP” indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.
^{§§} If PEP is offered and administered and the source is later determined to be HIV-negative, PEP should be discontinued.
^{¶¶} For example, a major blood splash.

TABLE 3. Primary side effects and toxicities associated with antiretroviral agents used for HIV postexposure prophylaxis, by class and agent

Class and agent	Side effect and toxicity
Nucleoside reverse transcriptase inhibitors (NRTI)	Class warning: all NRTIs have the potential to cause lactic acidosis with hepatic steatosis
Zidovudine (Retrovir [®] ; ZDV, AZT)	Anemia, neutropenia, nausea, headache, insomnia, muscle pain, and weakness
Lamivudine (Epivir [®] ; 3TC)	Abdominal pain, nausea, diarrhea, rash, and pancreatitis
Stavudine (Zerit [™] ; d4T)	Peripheral neuropathy, headache, diarrhea, nausea, insomnia, anorexia, pancreatitis, elevated liver function tests (LFTs), anemia, and neutropenia
Didanosine (Videx [®] ; ddl)	Pancreatitis, lactic acidosis, neuropathy, diarrhea, abdominal pain, and nausea
Emtricitabine (Emtriva, FTC)	Headache, nausea, vomiting, diarrhea, and rash. Skin discoloration (mild hyperpigmentation on palms and soles), primarily among nonwhites
Nucleotide analogue reverse transcriptase inhibitor (NtRTI)	Class warning: All NtRTIs have the potential to cause lactic acidosis with hepatic steatosis
Tenofovir (Viread [®] ; TDF)	Nausea, diarrhea, vomiting, flatulence, and headache
Nonnucleoside reverse transcriptase inhibitors (NNRTIs)	
Efavirenz (Sustiva [®] ; EFV)	Rash (including cases of Stevens-Johnson syndrome), insomnia, somnolence, dizziness, trouble concentrating, abnormal dreaming, and teratogenicity
Protease inhibitor	
Indinavir (Crixivan [®] ; IDV)	Nausea, abdominal pain, nephrolithiasis, and indirect hyperbilirubinemia
Nelfinavir (Viracept [®] ; NFV)	Diarrhea, nausea, abdominal pain, weakness, and rash
Ritonavir (Norvir [®] ; RTV)	Weakness, diarrhea, nausea, circumoral paresthesia, taste alteration, and elevated cholesterol and triglycerides
Saquinavir (Invirase [®] ; SQV)	Diarrhea, abdominal pain, nausea, hyperglycemia, and elevated LFTs
Fosamprenavir (Lexiva [®] ; FOSAPV)	Nausea, diarrhea, rash, circumoral paresthesia, taste alteration, and depression
Atazanavir (Reyataz [®] ; ATV)	Nausea, headache, rash, abdominal pain, diarrhea, vomiting, and indirect hyperbilirubinemia
Lopinavir/ritonavir (Kaletra [®] ; LPV/RTV)	Diarrhea, fatigue, headache, nausea, and increased cholesterol and triglycerides
Fusion inhibitor	
Enfuvirtide (Fuzeon [®] ; T-20)	Local injection site reactions, bacterial pneumonia, insomnia, depression, peripheral neuropathy, and cough

Sources: Package inserts; Panel on Clinical Practices for Treatment of HIV Infection. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents—April 7, 2005. Washington, DC: National Institutes of Health; 2005. Available at http://aidsinfo.nih.gov/guidelines/default_db2.asp?id=50.

TABLE 4. Prescription and over-the-counter drugs that should not be administered with protease inhibitors (PIs) because of drug interactions*

Drug	Comment
Antimycobacterials: rifampin	Decreases plasma concentrations and area under plasma concentration curve of the majority of PIs by approximately 90%, which might result in loss of therapeutic effect and development of resistance
Benzodiazepines: midazolam, triazolam	Contraindicated because of potential for serious or life-threatening events (e.g., prolonged or increased sedation or respiratory depression)
Ergot derivatives: dihydroergotamine, ergotamine, ergonovine, methylergonovine	Contraindicated because of potential for serious or life-threatening events (e.g., acute ergot toxicity characterized by peripheral vasospasm and ischemia of the extremities and other tissues)
Gastrointestinal motility agent: cisapride	Contraindicated because of potential for serious or life-threatening events (e.g., cardiac arrhythmias)
HMG-CoA reductase inhibitors ("statins"): lovastatin, simvastatin	Potential for serious reactions (e.g., myopathy, including rhabdomyolysis); atorvastatin may be used cautiously, beginning with lowest possible starting dose, and monitoring for adverse events
Neuroleptic: pimozide	Contraindicated because of potential for serious or life-threatening events (e.g., cardiac arrhythmias)
Inhaled steroids: fluticasone	Coadministration of fluticasone and ritonavir-boosted protease inhibitors are not recommended unless the potential benefit to the patient outweighs the risk for systemic corticosteroid side effect
Herbal products: St. John's wort (<i>hypericum perforatum</i>), garlic	Coadministration might reduce plasma concentrations of protease inhibitors, which might result in loss of therapeutic effect and development of resistance Garlic might lower saquinavir level

* This table does not list all products that should not be administered with PIs (atazanavir, lopinavir/ritonavir, fosamprenavir, indinavir, nelfinavir, saquinavir). Product labels should be consulted for additional information regarding drug interactions.

Sources: US Department of Health and Human Services. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Washington, DC: US Department of Health and Human Services; 2005. Available at http://www.aidsinfo.nih.gov/guidelines/adult/AA_040705.pdf; University of California at San Francisco Center for HIV Information. Database of antiretroviral drug interactions. Available at <http://hivinsite.ucsf.edu/InSite?page=ar-00-02>.

TABLE 5. Prescription and over-the-counter drugs that should not be administered with efavirenz because of drug interactions*

Drug	Comment
Antifungal: voriconazole	Contraindicated because efavirenz substantially decreases voriconazole plasma concentrations
Benzodiazepines: midazolam, triazolam	Contraindicated because of potential for serious or life-threatening events (e.g., prolonged or increased sedation or respiratory depression)
Ergot derivatives: dihydroergotamine, ergotamine, ergonovine, methylergonovine	Contraindicated because of potential for serious or life-threatening events (e.g., acute ergot toxicity characterized by peripheral vasospasm and ischemia of the extremities and other tissues)
Gastrointestinal motility agent: cisapride	Contraindicated because of potential for serious or life-threatening events (e.g., cardiac arrhythmias)
Herbal products: St. John's wort (<i>hypericum perforatum</i>), garlic	Coadministration might reduce plasma concentrations of protease inhibitors, which might result in loss of therapeutic effect and development of resistance Garlic might lower saquinavir levels

* This table does not list all products that should not be coadministered with efavirenz. Efavirenz product labeling should be consulted for additional information regarding drug interactions.

Sources: US Department of Health and Human Services. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Washington, DC: US Department of Health and Human Services; 2005. Available at http://www.aidsinfo.nih.gov/guidelines/adult/AA_040705.pdf; University of California at San Francisco Center for HIV Information. Database of antiretroviral drug interactions. Available at <http://hivinsite.ucsf.edu/InSite?page=ar-00-02>.

TABLE 6. Reported instances of failure of combination drug postexposure prophylaxis (PEP) to prevent HIV-infection among health-care personnel exposed to HIV-infected blood through percutaneous injury

Year of incident	Device	PEP regimen*	Time to first dose (hrs)	No. of days to onset of retroviral illness	No. of days to document seroconversion†	Source-patient		
						HIV-infection status	On anti retrovirals	Virus resistant to antiretrovirals§
1992 [¶]	Biopsy needle	ZDV, ddl	0.5	23	23	AIDS, terminally ill	Yes	Unknown
1996**	Hollow-bore needle	ZDV, ddl ^{¶¶}	1.5	45	97	Asymptomatic HIV infection	No	Not tested
1997**	Large or hollow-bore needle	ZDV, 3TC, IDV ^{§§}	1.5	40	55	AIDS	Yes	No
1998 ^{¶¶¶}	Hollow-bore needle	ZDV, 3TC, ddl, IDV	0.7	70	83	AIDS	Yes	Yes
1999***	Unknown sharp	ddl, d4T, NVP ^{¶¶¶}	2.0	42	100	AIDS	Yes	Yes
2001 ^{§§§}	Phlebotomy needle	ZDV, 3TC, IDV ^{¶¶¶}	1.6	24	-90	AIDS	Yes	Yes

* ZDV = zidovudine; ddl = didanosine; 3TC = lamivudine; IDV = indinavir; d4T = stavudine; and NVP = nevirapine.

† By enzyme immunoassay for HIV-1 antibody and Western blot.

§ By genotypic or phenotypic resistance testing.

¶ Source: Jochimsen EM. Failures of zidovudine postexposure prophylaxis. *Am J Med* 1997;102(Suppl 5B):52-5.

** Source: Lot F, Abiteboul D. Occupational infections with HIV in France among health-care personnel [French]. *Bull Epi Hebdom* 1999;18:69-70.

¶¶ ZDV and ddl taken for 48 hours and then changed to ZDV alone.

§§ ZDV, 3TC, and IDV taken for 48 hours and then changed to d4T, 3TC, and IDV.

¶¶¶ Source: Perdue B, Wolde Rufael D, Mellors J, Quinn T, Margolick J. HIV-1 transmission by a needlestick injury despite rapid initiation of four-drug postexposure prophylaxis [Abstract no 210]. In: Program and abstracts of the 6th Conference on Retroviruses and Opportunistic Infections. Chicago, IL: Foundation for Retrovirology and Human Health; 1999.

*** Source: Beltrami EM, Luo C-C, de la Torre N, Cardo DM. Transmission of drug-resistant HIV after an occupational exposure despite postexposure prophylaxis with a combination drug regimen. *Infect Control Hosp Epidemiol* 2002;23:345-8; CDC, unpublished data, 1999.

¶¶¶ ZDV and 3TC taken for 1 dose and then changed to ddl, d4T, and NVP; ddl was discontinued after 3 days as a result of severe vomiting.

§§§ Source: Hawkins DA, Asboe D, Barlow K, Evans B. Seroconversion to HIV-1 following a needlestick injury despite combination post-exposure prophylaxis. *J Infect* 2001;43:12-5.

¶¶¶ ZDV, 3TC, and IDV initially and then changed after first dose to d4T, ddl, and NVP; then ddl discontinued after 8 days; and d4T and NVP taken for 4 weeks.

Current guidelines on the use of prophylactic drugs are summarized in the table below.

Basic and Expanded Post-Exposure Prophylaxis Regimens

Regimen category	Application	Drug Regimen
BASIC¶¶	Occupational HIV exposures for which there is a recognized transmission risk	4 weeks (28 days) of both zidovudine (600 mg every day in divided doses (i.e., 300 mg twice a day, 200 mg 3 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 viral titer in blood)	BASIC regimen plus either indinavir 800 mg every 8 hours or nelfinavir 750 mg 3 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., six 8 oz. glasses of water throughout the day); nelfinavir should be taken with meals.

¶ Alternate Basic Regimens such as lamivudine and stavudine or didanosine and stavudine may be considered in consultation with expert authority on treatment of HIV, if resistance to the combination of zidovudine and lamivudine is common in some areas.

¶¶ Alternate expanded regimen, i.e., basic regimen plus one of the following drugs, may be considered in consultation with expert authority on treatment of HIV, if resistance of the organism to a protease inhibitor, such as indinavir or nelfinavir is known or suspected in a source client. These drugs are efavirenz, abacavir, ritonavir, saquinavir, amprenavir, delavirdine, or a combination of lopinavir and ritonavir. NOTE: Nevirapine is generally not recommended for use as PEP.

If exposed employees choose to take these medications, they or their supervisors should contact the regional medical director and/or the HIV/AIDS Prevention Program Medical Director to help obtain the drugs. Arrangements can be made for the drugs to be obtained through the

regional HIV/AIDS clinic or by having prescriptions filled by local pharmacies. If one of these physicians is not available immediately, the employee and/or supervisor should contact their own physician or a physician at the regional HIV/AIDS clinic.

Also, OPH clinical facilities should be stocked with a five day supply of zidovudine and lamivudine. These will be supplied by the OPH pharmacy in unit dose packs and must be kept in the emergency trays or carts in each OPH clinic facility. This supply of drugs can be used if no other is available within the time frame noted (1 to 2 hours after exposure). Staff using these drugs must consult a physician as soon as possible regarding medical follow-up and continuation of the drugs.

Pregnancy in an exposed person is not a contraindication to starting PEP for HIV. The decision to use any anti-retroviral drug during pregnancy should involve discussion between the pregnant woman and her physician regarding the potential benefits and risks to her and her fetus. Certain drugs should be avoided in pregnant women. Because teratogenic effects were observed in primate studies, efavirenz is not recommended during pregnancy. Reports of fatal lactic acidosis in pregnant women treated with a combination of didanosine and stavudine have prompted warnings about these drugs during pregnancy. Because of risk of hyperbilirubinemia in newborns, indinavir should not be administered to pregnant women shortly before delivery.

4. Have a baseline HIV antibody test done. All exposed persons who have experienced an exposure serious enough to consider PEP (regardless of whether or not drugs were actually taken) should be tested for HIV antibodies at the time of exposure. The blood sample for this test should be sent to the OPH Laboratory. Notify the forwarding laboratory immediately regarding the specimen submission so that priority can be given to expedite the post exposure testing process and management.

B. Hepatitis B

All OPH employees with potential occupational exposure to blood or body fluid should be vaccinated against Hepatitis B. Such pre-exposure vaccination is the best protection against Hepatitis B infection in the event of an exposure. Employees with potential occupational exposures who have not already been immunized should consult their supervisors to obtain the Hepatitis B immunization series.

If an exposure to blood or potentially infectious body fluid occurs, the decision regarding whether or not to provide post-exposure Hepatitis B vaccine must include consideration of the likelihood that the source client is positive for Hepatitis B surface antigen (HBsAg) and the likelihood that the exposed person already is protected against Hepatitis B infection. Several items to consider when evaluating this situation are:

- The probability of the source being positive for HBsAg is about 1% in the Louisiana adult population and is about 5-15% in high-risk groups, e.g., men who have sex with men, intravenous drug users.
- Of persons who have not had prior Hepatitis B vaccinations or post-exposure prophylaxis, a needlestick from a needle used on an infected source client may result in an infection rate of up to 62%, the rate in large part depending on the positivity in the source client of both HBsAg and HBeAg.
- In previously unimmunized persons, Hepatitis B vaccines are 70%-75% effective when given

within one week after HBV exposure. Hepatitis B vaccine and Hepatitis B Immune Globulin (HBIG) combination treatment is 85%-95% effective in preventing Hepatitis B following an exposure.

The actions to be taken after an exposure are to:

1. Determine the HBsAg status of the source client. This may be done by searching the medical records or requesting a blood specimen from the source client and sending it to the OPH Laboratory for testing for HBsAg. In most circumstances source clients are willing to consent to have their blood tested. If the source client refuses and his or her blood has already been drawn for other purposes, under certain circumstances the blood may be used to test for HBsAg after it is used for the reason for which it was originally drawn. **Please consult the Epidemiology section if this situation arises.**
2. Determine the Hepatitis B vaccination status and if possible the Hepatitis B antibody status of the exposed person. Vaccination records of exposed persons should be examined to verify whether or not vaccination was initiated and completed, and if post-exposure antibody testing was ever done. If this information is not available, consideration should be given to test the exposed person for Hepatitis B surface antibody (anti-HBs), depending on whether or not this information would influence the vaccination decision following the guidelines given below.
3. Decide whether or not vaccination of the exposed person is recommended. In general, *previously unvaccinated persons* should receive Hepatitis B vaccine for all exposures, because it is advisable for all HCWs to be protected against Hepatitis B. If in addition the source client is known to HBsAg+, the exposed person should be given HBIG in combination with Hepatitis B vaccine. *Previously vaccinated persons* should be managed according to the status of the source client and their own antibody response to the previous Hepatitis B vaccination. Details of the recommendations are presented in the following table:

Recommended Post-Exposure Prophylaxis for Exposure to Hepatitis B Virus

Treatment

Vaccination and Antibody Response Status of Exposed HCW*	Source HBsAg [†] positive	Source HBsAg [†] negative	Source Unknown or not available for testing
Unvaccinated	HBIG § x 1 and initiate Hepatitis B vaccine series¶	Initiate Hepatitis B vaccine series	Initiate Hepatitis B vaccine series
Previously vaccinated Known responder**	No treatment	No treatment	No treatment
Known non-responder ^{††}	HBIG x 1 and initiate revaccination or HBIG x 2§§	No treatment	If known high risk source client, treat as if source client were HBsAg positive
Antibody response unknown	Test exposed person for anti-HBs¶¶ 1. If adequate,** no treatment is necessary 2. If inadequate ^{††} , administer HBIG x 1 and vaccine booster	No treatment	Test exposed person for anti-HBs 1. If adequate¶¶, no treatment is necessary 2. If inadequate¶¶, administer vaccine booster and re-check titer in 1-2 months

* Persons who have previously been infected with HBV are immune to reinfection and do not require post-exposure prophylaxis.

[†] Hepatitis B surface antigen

§ Hepatitis B immune globulin; dose is 0.06 ml/kg intramuscularly

¶ Hepatitis B vaccine

** A responder is a person with adequate levels of serum antibody to HBsAg (i.e., serum anti-HBs \geq 10 mIU/ml)

†† A non-responder is a person with inadequate response to vaccination (i.e., serum anti-HBs less than 10 mIU/ml)

§§ The option of giving one dose of HBIG and re-initiating the vaccine series is preferred for non-responders who have not completed a second three dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.

¶¶ Antibody to HBsAg

If post-exposure vaccination is considered, OPH staff should be aware of the following:

- HBIG should be administered as soon after exposure as possible and within 24 hours.
 - The first dose of Hepatitis B vaccine should be administered at a separate site and can be administered simultaneously with HBIG or within 7 days of exposure.
 - Testing for anti-HBs is available through the OPH Laboratory and through many hospital laboratories. However the test results are not available within 24 hours unless special arrangements are made with the laboratory. If decisions regarding Hepatitis B vaccination are to be made based on these laboratory test results, employees and their supervisors should speak directly with laboratory personnel to arrange for rapid testing.
4. Conduct baseline tests of the exposed person. All employees who are receiving HBIG or Hepatitis B vaccine as prophylaxis for an exposure should be tested before receiving the first dose of vaccine for anti-HBs and HBsAg. The results of these baseline tests can be used later with the results of follow-up testing to assess whether or not an infection occurred from the exposure. Notify the forwarding laboratory immediately regarding the specimen submission so that priority can be given to expedite the post exposure testing process and management.

C. Hepatitis C

The risk of transmission of Hepatitis C following a needlestick from an infected source client is probably greater than the risk for HIV but less than the risk for Hepatitis B. In follow-up studies of HCW's who sustained percutaneous exposure to blood from anti-HCV positive clients, the incidence of anti-HCV seroconversion averaged 3.5%.

Following a needlestick, it is recommended that, if possible, the source client be tested for anti-HCV antibodies. For employees exposed to an anti-HCV positive source client, baseline and follow-up anti-HCV testing are recommended. Anti-HCV testing is now available through the OPH Laboratory; however this test has many false positive results, so employees with positive anti-HCV tests should be referred to their physicians for evaluation and supplemental Hepatitis C testing, e.g., RT-PCR. Notify the forwarding laboratory immediately regarding the specimen submission so that priority can be given to expedite the post exposure testing process and management.

4. **Follow-Up**

A. HIV

Employees with an exposure that is high risk for HIV should be tested for HIV antibodies at

baseline, six weeks, twelve weeks, six months and 12 months after HIV exposure. In rare cases, seroconversion has occurred more than six months after HIV exposure; therefore for severe injuries with a high risk of infection, testing should also be conducted twelve months after exposure. Extended HIV follow-up, e.g., for twelve months, is recommended for any HCW who becomes infected with HCV following exposure to a source client co-infected with HIV and HCV. Whether or not extended follow-up is indicated in other circumstances, e.g., exposure to a source client co-infected with HIV and HCV in the absence of HCV seroconversion or for exposed persons with a medical history suggesting an impaired ability to develop an antibody response to acute infection, is unclear. Although rare instances of delayed HIV seroconversion have been reported in the medical literature, the infrequency of this occurrence does not warrant adding to the anxiety level of the exposed persons by routinely extending the duration of post-exposure follow-up.

Employees who take prophylactic drugs should discuss with the prescribing physician the possibility of tests for medication toxicity at baseline and at the time of the two week follow-up. These tests would be complete blood count, renal and hepatic function tests.

HIV testing should be performed on any exposed person who has an illness that is compatible with an acute retro-viral syndrome, regardless of the interval since exposure. When HIV infection is identified, the person should be referred to a specialist, knowledgeable in the area of HIV treatment and counseling, for medical management.

B. Hepatitis B

Employees of unknown anti-HBs status who begin Hepatitis B vaccination, pending the results of testing and who later are found to have anti-HBs in the baseline blood sample, do not need to complete the Hepatitis B vaccination series, and do not need additional Hepatitis B testing.

Employees who begin Hepatitis B vaccination and do not have measurable anti-HBs in the baseline blood sample should finish off the three dose Hepatitis B vaccine series with the standard one month and six month doses. One to two months after the Hepatitis B series is complete, these employees should be tested for HBsAg and Anti-HBs to assess whether or not an infection occurred and whether or not the employee responded to the vaccination.

C. Hepatitis C

Employees who have had a needlestick injury from anti-HCV positive source client and who are tested at baseline should have follow-up testing for anti-HCV antibodies and liver enzymes (Alanine aminotransferase [ALT]) six months later. This testing can be done by the OPH Laboratory. The purpose of this testing is to document whether or not Hepatitis C infection occurred and to initiate treatment if infection did, indeed, occur. Should such a rare infection happen, then employees should be referred to their own physicians for consultation regarding treatment.

5. **Reporting and Documentation**

A. Forms Needed

- Incident/Accident Reporting Form from the Office of Risk Management (Form DA

2000); website address: http://dhhinet01/OMF/Safetywebpage/dhh_safety_page.htm.

- Employer's Report of Injury/Illness (Form DA 1973 - the above-named form and this form are available from OPH Regional or Central Office Safety Administrator).
- Employee's Report of Exposure to Known or Possible Contaminated Blood or Body Fluids (Form Epi 31).
- HIV Counseling and Testing Form (Lab 100) if HIV antibody testing is done.
- Hepatitis Laboratory Form (Lab 95) if testing for Hepatitis B and/or C.

B. Procedure

- Report the incident of injury or exposure to the supervisor verbally, followed as soon as possible in writing by using the "Incident/Accident Reporting Form" (Form DA-2000) and the "Employer's Report of Injury/Illness" (Form DA-1973 – optional reporting can be done on-line or by paper submission). Forms are not included in this Manual and are available from the Safety Administrator for each Region and for Central Office.
- Complete the forms listed above.
- Notify the Regional Medical Director and/or immediate supervisor of the occurrence; follow the internal organizational command structure.
- Offer the exposed employee confidential pre- and post-test counseling regarding their antibody screenings.
- Complete the first two pages of the Epi-31 (with the exception of the source client's test results) within 24 hours of the incident.
- If the source client is tested for HIV antibodies, complete the HIV counseling and testing forms as per routine procedure.
- Get a baseline test for HBV, HCV, and HIV antibodies on the exposed person and the source client within 48 hours of the incident and enter on the Epi-31 (in Follow-Up section).
- Make sure that consent forms are signed by the source client and the exposed individual. Also validate that the exposed individual signed the Epi-31 form.

C. Supervisor Follow-Up

Contact the employee to assure the follow-up vaccinations and follow-up tests for HIV and Hepatitis B and C are conducted on schedule as described above. Enter the results on the Epi-31 form.

When the Epi-31 form is complete it should be sent to the Regional Nurse Manager and kept on file at the Regional office. Such files should be kept in a secure area under lock and key.

Occupational Exposure Management Resources and References

<p>National Clinicians' Postexposure Prophylaxis Hotline (PEpline)</p> <p>Run by University of California – San Francisco/San Francisco General Hospital Staff; supported by the Health resources and Services Administration Ryan White Care Act, HIV/AIDS Bureau, AIDS Education and Training Centers, and CDC</p>	<p>Phone: 1(888) HIV-4911 1(888) 448-4911 Internet: http://www.ucsf.edu/hivcntr</p>
<p>Needlestick!</p> <p>A website to help clinicians manage and document occupational blood and body fluid exposures. Developed and maintained by the University of California, Los Angeles (UCLA), Emergency Medical Center, UCLA School of Medicine, and funded in part by CDC and the Agency for Healthcare Research and Quality.</p>	<p>Internet: http://www.needlestick.mednet.ucla.edu</p>
<p>Hepatitis Hotline</p>	<p>Phone: 1(888) 443-7232 Internet: http://www.cdc.gov/hepatitis</p>
<p>LSU-Delta Region AIDS Education and Training Center – Clinical Consultation</p> <p>Educational and medical consultative service for HIV infection, AIDS and AIDS-related disorders.</p>	<p>Phone 1(504) 903-0788 Internet: http://www.deltaetc.org</p>
<p>HIV/AIDS Treatment Information Service</p>	<p>Internet: http://www.hivatis.org</p>

C. Employer Provision of Post-Exposure Management

The employer shall ensure that the affected employee receives consultation on medical evaluations, procedures, initial prophylaxis, and counseling as integral for post-exposure management. The exposed employee should consult with a licensed health-care professional(s) to evaluate the exposure and recommended treatment and follow-up. Blood exposure incident reports will be utilized for identification of prevention strategies and for product evaluation purposes.

Source: Gerberding, Julie, M.D., M.P.H. (Feb. 16, 1995). "Management of Occupational Exposures to Blood-Borne Viruses," *New England Journal of Medicine*.

Procedure

1. All employees should be aware of the risks of acquiring an infection from occupational exposures in a health-care setting.

2. All accidental exposures of an employee to client blood or body substances shall be reported to the employee's direct supervisor immediately.

Key Points

Exposure to bloodborne pathogens is defined as parenteral (needlestick or other punctures of the skin with a used needle or other sharp item), mucous membrane (splatters/aerosols into the eyes, nose, or mouth), or direct contamination of an open wound or non-intact skin with a body substance.

If the direct supervisor is unavailable, the incident shall be reported to the next available supervisor or authorized person (e.g., clinic coordinator, nursing director, regional medical director).

Procedure

3. Regardless of the source of exposure, first aid should be given initially to treat the wound or site of exposure.

4. For LA OPH, the employee must fill out the "Employee Report of Exposure to Known or Possible Contaminated Blood or Body Fluids" (EPI 31) and submit this as required. The supervisor is to fill out the "Incident/Accident Investigation Form" (DA2000). The "Employer's Report of Injury/Illness Form" (DA-1973) should be completed and referred to the Office of Risk Management in the event Worker's Compensation claims will be submitted if there is loss time associated with medical care and/or medical expenses incurred.

5. The employee's supervisor is responsible for coordination of post-exposure management.

6. Document on the appropriate forms the route(s) of exposure and the circumstances under which the exposure incident occurred.

7. If post-exposure therapy for HIV is warranted, the first dose should be administered as soon as possible (within one hour of exposure is ideal).

8. Post-exposure counseling will be given within 10 calendar days of the exposure.

9. When required for decisions regarding management of Hepatitis B prophylaxis, employee Hepatitis B surface antibody results should be available within 72 hours. Screening for Hepatitis C may be conducted during this event to obtain baseline Hepatitis C results if not done already.

Key Points

Wash hands or skin with soap and water immediately if contaminated with blood or other body fluids; flush eyes with clear tap water if a splash of blood or body fluid occurs into the eye(s). (Remove contact lens(es) first.) If waterless-based cleansers are used to cleanse skin in an emergency, washing thoroughly with soap and water should follow as soon as possible afterward. Waterless skin disinfectants must never be used in eyes.

Forms can be obtained via website ---
http://dhhinet01/OMF/Safetywebpage/dhh_safety_page.htm

Any and all needlestick exposures should be reported on the "Employee Report of Exposure to Known or Possible Contaminated Blood or Body Fluids" form which can be obtained from rhollowe@dhh.la.gov.

The tasks to be coordinated in post-exposure management include risk assessment, completing the documentation, collecting sera on the employee and the source (if available), HIV-related counseling, referral to an evaluating health-care professional as needed, administering prophylaxis pending the results of serologic follow-up, and ensuring proper medical follow-up.

This information will be important in risk assessment and management of the exposure incident.

Check with the HIV program manager for a list of qualified counselors in the area or region.

Postponing testing of the baseline serum will undermine the success of Hepatitis B intervention. Counseling and referral may be required pending Hepatitis C results.

Procedure

- 10.** An employee may refuse all or part of the recommended post-exposure management procedures. Document on the Epi 31 what step of the process was refused, and have this signed by both employee and supervisor. Attach this documentation to all forms or on the appropriate post-exposure forms specific for bloodborne pathogens.
- 11.** The supervisor shall make available, or ensure it is made available, to the evaluating health-care professional the following information:
 - a.** a copy of the Bloodborne Pathogens Exposure standard;
 - b.** a description of the employee's duties as they relate to the exposure incident;
 - c.** documentation of the route(s) of exposure and the circumstances involved;
 - d.** serologic test results of the source, if available; and
 - e.** employee health records, such as Hepatitis B vaccination and/or serologic status, which may be relevant to the post-exposure treatment.
- 12.** Test results should remain strictly confidential and be filed in the employee's health record.
- 13.** The employer must obtain and provide the employee with a copy of the evaluating health-care professional's written report within 15 days of its completion.
- 14.** Employee health records can be monitored by maintaining records of work-related medical evaluations, screening tests, immunizations, exposures, and post exposure management. The employer should maintain the employee's record for the duration of employment plus 30 years.

Key Points

Despite the employee's decision of refusal to any or all of the postexposure management procedures, be certain that the employee/supervisor follows through with reporting the incident to the Office of Risk Management for documentation of the event.

The employee has the option to select an evaluating health-care professional outside the department. The evaluating health-care professional will review the information provided and determine what prophylaxis may be needed.

Any test, treatment, or follow-up procedure should be documented, but serologic test results should not be put into the employee's personnel file. Health records should be kept in a secure area under lock and key.

This report will document the need, if any, for completion of Hepatitis B vaccine series, and that the employee has been advised of the evaluation's results and any medical conditions that may arise as a consequence of exposure.

The elements of a Bloodborne Pathogen Exposure Control Plan should be explained to workers about the possible risks to their health from infections that can be spread by contact with blood and other body fluids. The premise for which the control plan should address is when body fluids and articles contaminated with blood and body fluids are handled carefully, they are not dangerous in the workplace. Compliance to the exposure control plan includes the following:

1. Use of Standard Precautions as outlined in the manual sections.
2. Engineering Controls – description of methods to reduce hazards – hand hygiene, proper sharps disposal and handling, safety-engineered devices to reduce handling of contaminated needles
3. Work practice controls – task performance as prohibiting re-capping syringes, accessible PPE in the workplace
4. Personnel orientation and training issues as outlined in the manual sections.
5. Labels and signs – biohazard warning labels on items and pertinent refrigerators and freezers
6. Regulated waste management
7. Vaccine preventable diseases associated with risk from blood and body fluids - Hepatitis B vaccination
8. Post-exposure plan and recordkeeping – if an exposure or event did occur – offer on-the-job confidential medical evaluation
9. Housekeeping and Laundry practices – worksite management of blood spills, cleaning schedule, bagging/handling soiled laundry

V. Tuberculosis Exposure Plan

A site-specific tuberculosis control plan is strongly encouraged in the event that a potential TB exposure occurs in an ambulatory care facility, including facilities providing treatment for drug abuse, clinics/laboratories that handle specimens that might contain *Mycobacterium tuberculosis*, and settings that perform high-hazard procedures such as cough-inducing or aerosol-generating procedures. Health care workers must be aware of the risk of tuberculosis in their client population. All newly employed HCWs whose work environment includes sharing of air with clients in the clinic or field shall receive general orientation within 4 weeks of employment with an annual review of TB transmission, symptomatology, and work practices that reduce the likelihood of transmitting *M. tuberculosis*. Refer to the Tuberculosis Control Manual for further program standards on screening, medical evaluation/treatment, and contact exposure.

The following elements of the TB exposure plan should include:

1. Risk assessment of the facility with an adequate ventilation engineering design;
2. Protocol for early identification of individuals with active TB;
3. Medical surveillance of employees, including administration and interpretation of TB skin tests;
4. An outline of the evaluation and management of workers with positive TB skin test, skin test conversion, or those who are exhibiting symptoms of TB. Work restrictions for infectious employees must be enforced and implemented;
5. Description of isolation procedures protocols, including method of placement for individuals with suspected or confirmed TB;

6. Requirements for the use of respiratory protection devices for staff at the facility. N95 masks are the device of choice;
7. Training and information provided to the employees to ensure they are knowledgeable about TB issues; and
8. Installation of ultraviolet lights in appropriate places must be considered. Consultation about this is available from the Tuberculosis Control Program at OPH Central Office.

Follow Up on Exposed Employee, to be completed by Unit Supervisor

Name of Supervisor Completing Follow Up _____

Medications taken (check all that apply): _____ AZT (ZDV, zidovudine)
Remember: AZT + 3TC = "Combivir" _____ 3TC (lamivudine)
 _____ IDV (indinavir)
 _____ nelfinavir

Time interval between exposure and first dose (hours): _____

Medications prescribed by (physician): _____

HIV serology:	Date due	Date drawn	Result
Baseline	___/___/___	___/___/___	_____
6 week follow up	___/___/___	___/___/___	_____
12 week follow up	___/___/___	___/___/___	_____
6 month follow up	___/___/___	___/___/___	_____
12 month follow up	___/___/___	___/___/___	_____

Hepatitis B vaccine: Dose 1 Date ___/___/___ administered by _____
 Dose 2 Date ___/___/___ administered by _____
 Dose 3 Date ___/___/___ administered by _____
 HBIG given: YES [] Date ___/___/___ administered by _____
 NO []

Hepatitis B serology results: HBs	Date due	Date drawn	HbsAg	Anti-
Baseline	___/___/___	___/___/___	_____	_____
Follow up*	___/___/___	___/___/___	_____	_____

*one to two months after vaccination series completed, if vaccinated post-exposure or six months after incident occurred, if employee does not have antibodies at baseline and is not vaccinated post-exposure

Hepatitis C Serology Results:	Date due	Date drawn	Anti-HCV	ALT
Baseline	___/___/___	___/___/___	_____	_____
6 month follow up	___/___/___	___/___/___	_____	_____

Comments: _____

Follow up completed Date ___/___/___ Signature of supervisor _____

Instructions – EPI – 31 Form

Page 1

Employee Last Name: Please print name clearly.

Employee First Name: Please print name clearly.

Home Phone Number: Include Area Code and home telephone number.

Work Phone Number: Include Area Code and work telephone number.

Date of Incident: Write in month, day, and year in the spaces provided.

Place Incident Occurred: Please be as specific as possible; e.g., Immunization Room of X Parish Health Unit

Description of Incident: Please be as specific as possible as to circumstances of incident, including time of day it occurred, and others involved in the incident, e.g., other employees by name and/or patients by name.

Hepatitis B Vaccination Status: Please be as specific as to dates and please do not check unknown unless verification of vaccination history has been impossible to obtain.

Source person: Please complete this section as completely as possible, including laboratory data requested, in a timely manner. Antigen and antibody test results and dates, and medical history of risk should be sought in the source person's medical records as thoroughly as possible.

Baseline Counseling/Testing of Source Patient: Please complete this section as completely as possible and fill in test results as soon as they are obtained back from the testing laboratory.

Note: NA = not applicable, is to be checked only if deemed that testing is not needed at time of exposure incident.

Page 2

Recommendations Regarding Prophylaxis: This must be completed by the parish health unit nursing supervisor, the regional medical director, or a laboratory unit supervisor. The name and title of the person providing the recommendations must be included, and may be, for example, the exposed person's own physician, the regional medical director, and/or an AIDS medical consultant from a medical center or Office of Public Health central office. Include all names and titles of persons consulted regarding recommendations.

Employee Selection of Options: This is an informed consent. Employee's full name must be printed in the blank space in this section. Circle all applicable answers (yes or no) for the Baseline testing and for Prophylactic Vaccination and Medications section. Employee signatures must match the employee name as printed on the form in the blank space, as noted above. The Supervisor's signature should be the person completing the form, as mentioned above, e.g., the parish health unit nursing supervisor, the regional medical director, or a laboratory unit supervisor.

Page 3

Follow Up: The supervisor completing this section should be the same person completing the previous sections, unless there has been a change in supervisors. If so, then that should be explained on the form after the name of the new supervisor has been printed in the space on this page. The appropriate drug names should be checked if applicable, the time interval between exposure and first dose should be expressed in hours, e.g., 1 ½ hours = one hour and thirty minutes, and the name of the physician prescribing the drugs should be printed in the space provided.

The serological testing information requested must be filled out completely; as is also true for the vaccine, immune globulin, and ALT (alanine aminotransferase liver function test) information requested. Dates should be specified by month, day and year in the spaces provided. The follow-up completed date should also be specified by month, day and year in the space provided and the supervisor's signature should be that of the supervisor named at the top of page 3.

DEPARTMENT OF HEALTH AND HOSPITALS
OFFICE OF PUBLIC HEALTH

(Unique ID tracking #)

EMPLOYEE REPORT OF EXPOSURE TO KNOWN OR POSSIBLE CONTAMINATED BLOOD OR BODY FLUIDS
--

REGION

FACILITY

Exposed Employee Data	
Employee Last Name	First Name
Home Phone Number	Office Phone Number
Date of Incident / /	Address Incident Occurred
Occupation	
Description of Incident	
Was the exposure a result of a Needlestick? Yes No (If no then specify how exposed)	
If yes check one of the following. Butterfly Vacutainer Lancet Syringe	

When you have completed the form, please email to Richard Hollowell, Security Coordinator at rhollowe@dhh.la.gov

SUBMIT

CANCEL

Department of Health and Hospitals

REFUSAL OF VACCINATION AND RELEASE FROM RESPONSIBILITY

BE IT KNOWN that on this date, I _____

(Name of employee)

have decided voluntarily to disregard the medical advice of the qualified health professionals attending me on behalf of the Department of Health and Hospitals.

I AM REFUSING TO RECEIVE VACCINATION AGAINST

I HAVE BEEN FULLY INFORMED BY

(Name and Title)

of the possible and probable adverse consequences of my refusal. I understand that my health could be negatively affected and my life possibly endangered by this refusal. The reason for my refusal is

I declare myself to be a person of the full age of majority and to be mentally competent. I hereby assume full responsibility for any and all possible present or future results or complications of my condition due to this refusal.

I do further hereby now and forever free and release the Department of Health and Hospitals and all its agents, attending health care professionals, and other personnel from any and all legal or financial responsibility as a result of this refusal.

I certify that I have read (or had read to me) and that I fully understand this Refusal of Treatment and Release from Responsibility. All explanations were made to me and all blanks filled in before I signed my name. I have refused this vaccination of my own free will.

_____ am/pm
Month Day Year Time

DHH Employee Refusing

Witness

Employee Infection Control Orientation and Annual Update Checklist

Name of Employee _____

Name of Supervisor/Administrator _____

Worksite Location _____ Occupation _____

Date Hired _____

<i>Orientation Tasks</i>	<i>Complete</i>	<i>Date</i>	<i>Comments</i>
<i>I. Standard Precautions</i>			
A. Hand Hygiene Checklist			
1) Rationale for adherence to handwashing			
2) Policy on wearing jewelry & artificial nails			
3) Appropriate use of hand hygiene products			
B. Gloving Policy and Latex allergy			
1) Proper use and disposal of gloves			
2) Changing gloves between client and/or procedures			
3) Types of gloves available and selection for use			
4) WASH hands after glove use			
5) Latex Allergy:	a) Ever experienced hives, swollen mouth/lips, runny nose, eye irritation, swollen throat or wheezing after blowing up a balloon or contact with a rubber product		
	b) Has employee ever been told by a physician that he/she is allergic to rubber		
	c) Ever tested for latex allergy and had a positive reaction		
	d) Ever experienced a rash or persistent itching while wearing rubber gloves		
	e) Have any allergies, asthma or eczema		
	f) Aware of whom to report in the event of allergy development		
	g) Avoid latex products for those allergic to latex – screening employees and clients		
<i>II. Exposure Control Plan</i>			

A. Location and availability of exposure plan				
B. Disease risk and activities that may involve exposure to blood and body substances				
C. Review of infectious diseases and routes of transmission				
D. Personal Protective Equipment (PPE)	1) Appropriate selection for use			
	2) Type of equipment and availability			
	3) Decontamination and disposal			
E. Engineering Controls	1) Handwashing facilities			
	2) Use of sharps disposal containers			
	3) Avoid re-capping or re-sheathing sharps devices			
	4) Usage of needleless system devices			
	5) Other safer medical devices			
F. Work practice controls to protect employee	1) Overview of occupationally acquired infectious diseases			
	2) Management of blood/body spills			
	3) Reporting exposures to spills			
G. Limitations to PPE, devices and practices				
III. Employee Immunizations				
A. Hepatitis B – availability, efficacy and safety				
B. Tetanus-diphtheria				
C. Annual PPD testing				
D. Other (specify)				
IV. Post-Exposure Management for Blood-borne Pathogens and Needlesticks				
A. Exposure definition				
B. Immediate actions				
C. Follow-up actions				
D. Reporting and record-keeping				
V. Signs and Labels				
A. Biohazard symbol and color				
B. Isolation signs				

VI. Disposal of Medical Waste			
A. Disposal of needles/sharps			
B. Segregation of general vs. medical waste			
VII. Disinfection of Clinic Equipment			
A. Environmental/Housekeeping polices			
B. Disinfection of patient equipment for clinic and field use			
VIII. Isolation and Patient Triage			
A. Review Respiratory Etiquette			
B. Review of Isolation Precautions			
C. Management of tuberculosis clients and sputum collection procedures			
IX. Collection, Storage and Transport of Laboratory Specimens			
A. Appropriate use of PPE during specimen collection			
B. Proper storing and packaging of specimens			
C. Shipping requirements for biologic specimens			
X. General Information			
A. Proper wear of lab coats/uniforms for protective measures and laundering			
B. Use of toys in clinic areas including cleaning and appropriateness			
C. Food storage and appropriately labeled refrigerators			
XI. Miscellaneous			

Section 3

Environmental Infection Control and Clinic Equipment Sterilization/Disinfection

Section 3: Environmental Infection Control and Clinic Equipment Sterilization/Disinfection

I. Environmental Infection Control

The worksite should always be maintained in a clean and sanitary condition. Environmental surfaces can be divided into clinical contact surfaces and housekeeping surfaces. Evidence does not support that housekeeping surfaces (e.g., floors, walls, sinks) pose a risk for disease transmission. These surfaces can be decontaminated with less rigorous methods than those used on patient-care items and clinical contact surfaces. Cleaning is the necessary first step of any disinfecting process. Cleaning is a form of decontamination that renders the environmental surface safe by removing organic matter, salts and invisible soils, all of which interfere with microbial inactivation. Schedules and methods for cleaning may vary according to the area (e.g., reception room, laboratory area, bathrooms).

Strategies for cleaning and disinfecting surfaces in patient-care areas should consider the 1) potential for direct patient contact; 2) degree and frequency of hand contact; and 3) potential contamination of the surface with body substances or environmental sources of microorganisms (e.g., soil, dust, or water). Do not use chemical sterilants for disinfection of either noncritical instruments and devices or any environmental surfaces. Use EPA-registered disinfectants in accordance with the manufacturer's instructions.

A. Routine Schedule for Cleaning and Disinfection

The facility will maintain a written schedule for cleaning and disinfection, outlining the surfaces and areas to be cleaned, the cleaners or disinfectants used, and the employees involved in the process.

Procedure

1. Gross organic materials present on environmental surfaces should be removed and cleaned with soap and water. For initial cleanup of blood or other potentially infectious materials, the use of an approved disinfectant chemical germicide should be applied. Dilute solutions of chlorine bleach, or any disinfectant-detergent formulations labeled as registered by the EPA, can be used for cleaning environmental surfaces.
2. If chlorine bleach is used for cleaning/disinfection, a solution of bleach and water will be mixed and put in a labeled opaque spray bottle. The bleach solution must be mixed at 1:100 concentration or 1:10 concentration depending on the bioburden of the environmental surfaces/equipment and the type of material (e.g., non-porous surfaces) to be disinfected.

Key Points

If using an EPA-registered disinfectant-detergent, follow the manufacturer's instructions for use.

Remember that the actual, physical removal of microorganisms and soil by wiping or scrubbing is just as critical, if not more so, than any antimicrobial effect provided by the agent used.

A 1:100 solution should be made fresh on the day of use because the active chlorine is lost gradually over the course of a day once bleach has been diluted.

A 1:10 solution can be made up once a week and is used to decontaminate and disinfect surfaces when a spill of blood, body fluids or feces has occurred.

Procedure

3. Spray disinfectant and wipe the surfaces with a clean cloth at the end of each day and whenever contamination occurs. Rinse the surfaces with plain water and dry.
4. Wear household gloves while cleaning.

Key Points

Do not store the cloth in the solution because organic matter from the cloth accelerates the inactivation of the disinfectant solution.

Rinsing is very important in removing soil and chemical residue. It is especially important when using chlorine-bleach solutions, as residual chlorine can be damaging to metal surfaces.

Reusable gloves should be inspected for tears or holes before using. They should be washed with soap and water and hung to dry after use. Replace the gloves if they are cracked, peeling, torn, etc.

B. Housekeeping Maintenance

Housekeeping surfaces (e.g., floors, walls, counter tops) shall be cleaned as described below. Entrances, lobbies, waiting rooms, hallways should be cleaned on a regular schedule or as needed depending on traffic. Housekeeping practices, if performed correctly through educational presentations, will create an area suitable for the client, visitor and health care worker to enter and be comfortable within the confines of the environment. The proper maintenance of a health care facility increases the awareness of other employees of necessity of good sanitary practices. Good housekeeping practices increase employee morale and public relations.

Procedure

1. Clean and disinfect high-touch surfaces (e.g., doorknobs, bed rails, light switches, and surfaces in and around toilets in clinic rooms) on a more frequent schedule than minimal touch housekeeping surfaces.
2. Clean walls, blinds, and window curtains in patient-care areas when they are visibly dusty or soiled. Spot clean any wall that contains soil.
3. Do not perform disinfectant fogging in patient-care areas; avoid large-surface cleaning methods that produce mists or aerosols, or disperse dust in patient-care areas.

Key Points

Use appropriate dusting methods for patient-care areas by:

- a) wet-dust horizontal surfaces by moistening a cloth with a small amount of an EPA disinfectant; and
- b) avoid dusting methods that disperse dust (e.g., feather dusting).

Procedure

Key Points

4. Hard surface floors

Use a one-step process and an EPA-registered hospital detergent/disinfectant designed for general housekeeping purposes in client-care areas where:

- a) uncertainty exists as to the nature of the soil on the surfaces (e.g., blood or body fluid contamination versus routine dust or dirt); or
- b) uncertainty exists regarding the presence of multi-drug resistant organisms on such surfaces.

Detergent and water are adequate for cleaning surfaces in non-patient care areas (e.g., administrative offices).

Prepare cleaning solutions daily or as needed and replace with fresh solution frequently. Change the mop head at the beginning of each day and after cleaning up large spills of blood or other body substances. Clean mops and cloths after use and allow drying before reuse; or use single-use, disposable mop heads and cloths.

5. Carpeting

Vacuum carpeting in public areas of health care facilities and in general client care areas regularly with well-maintained equipment designed to minimize dust dispersion.

Carpeting is more difficult to clean than nonporous hard-surface flooring, and it cannot be reliably disinfected, especially after spills of blood and body substances.

Follow appropriate procedures for managing spills on carpeting:

- a) spot-clean blood or body substance spills promptly;
- b) if a spill occurs on carpet tiles, replace any tiles contaminated by blood and body fluids or body substances

Periodically perform a thorough, deep cleaning of carpeting by using a method that minimizes the production of aerosols and leaves little or no residue. If blood is spilled on carpeting, make sure you follow the manufacturer's recommendation on type of chemicals that can be used without damaging the fabric.

Thoroughly dry wet carpeting to prevent the growth of fungi; replace carpet that remains wet after 72 hours.

There are no recommendations regarding the routine use of fungicidal or bactericidal treatments for carpeting in public areas of a health care facility or in general patient care areas.

Pest Control

Consider implementing pest control strategies, with emphasis on kitchens, supply rooms, loading areas, construction activities and other areas prone to infestations.

Maintain screens on all windows that open to outside air; keep screens in good repair.

Arrange for routine pest control service by a credentialed pest-control specialist who will tailor the application to the needs of a health care facility.

Counters/Sinks/Tables/Trays/Miscellaneous

All counter tops, sinks, trays, and table tops in patient care areas must be made of impervious materials and should be cleaned routinely with a diluted chlorine-bleach solution or with a registered EPA disinfectant-detergent. Surfaces which are likely to be contaminated with blood or body fluids will be cleaned daily, and must be cleaned and disinfected after contamination.

The American Academy of Pediatrics recommends that toys used in clinic settings that are mouthed or contaminated with body secretions should be cleaned, disinfected and rinsed. Toys frequently touched by infants or toddlers should be cleaned and disinfected daily. All toys, including those items in Denver Developmental Screening Test (DDST) kits, used by clients should be cleaned with a non-toxic germicidal detergent and dried daily. The use of stuffed toys in the clinical facilities is not recommended.

Light fixtures: dust and insects often accumulate on or in light fixtures and on window sills. These areas should be cleaned at least monthly or more often if needed.

C. Cleaning Up Blood and/or Body Secretion Spills

Although no evidence supports that Hepatitis B (HBV), Hepatitis C (HCV) or Human Immunodeficiency Virus (HIV) has been transmitted from a housekeeping surface, prompt removal and surface disinfection of an area contaminated by either blood or OPIM (Other Potentially Infectious Material) are appropriate infection-control practices. Strategies for decontaminating spills of blood and other body fluids differ by setting and volume of the spill. Blood spills on either clinical contact or housekeeping surfaces should be contained and managed as quickly as possible to reduce the risk of contact by patients and personnel. The person assigned to clean the spill should wear gloves and other PPE appropriate for the task. If a spill involves large amounts of blood or body fluids, or if a blood or culture spill occurs in the lab, a 1:10 chlorine-bleach solution or other appropriate EPA-registered disinfectant should be used.

D. Use of Chemical Germicides

Chemical germicides that are registered by the EPA as “hospital disinfectants” and are tuberculocidal are to be used to clean up spills of blood or body secretions. Those disinfectant-detergent formulations not designated as “hospital disinfectants” should be reserved for general cleaning of environmental surfaces. Follow the manufacturer’s instructions for using any EPA disinfectants. The procedures below address cleaning spills with chlorine bleach solution.

<u>Procedure</u>	<u>Key Points</u>
1. When using chlorine bleach, a 1:10 solution of chlorine bleach should always be available in a labeled, opaque spray bottle.	The 1:10 solution of chlorine bleach can be used for up to one week. Make sure the dispensers are labeled clearly so this 1:10 solution is not confused with the 1:100 dilution. Indicate on the label the date the solution was prepared.
2. Put on household gloves and other PPE as appropriate for this task.	
3. Take care not to splash the blood or body secretions into your mouth or eyes. A mask and goggles must be worn.	

Procedure

4. Cover the spill with disposable absorbent toweling. Apply the disinfectant solution by spraying it or pouring it directly onto the covered area.
5. Remove the majority of the spill with disposable absorbent toweling. Place towels in heavy-duty garbage bag, and add absorbent material as needed. Dispose of in waste receptacles marked with the BIOHAZARD label.
6. When dealing with a large spill, reapply disinfectant directly to the cleaned spill area, then remove with absorbent toweling and allow surface to dry.
7. Equipment used in spill cleanup (tongs, dust pans, brooms with plastic bristles), should be decontaminated with the chlorine-bleach solution, washed with soap and water, and hung to dry.
8. Hands should then be washed with soap and water.

Key Points

When using any disinfectant in concentrated form or in large amounts (such as with spill cleanup), always make sure the area is well ventilated.

Heavy-duty garbage bags should be at least 1.2 mil minimum thickness. Examples of absorbent material added to the bags include additional paper towels or kitty litter.

Longer contact times are required when more organic matter is present.

The reusable household gloves should be washed with soap and water and hung to dry after all the spill cleanup equipment has been decontaminated and washed.

II. Clinic Equipment Sterilization/Disinfection

Patient-care items are categorized as critical, semicritical or noncritical, depending on the potential risk for infection associated with their intended use. Critical items (e.g., syringes, venipuncture and surgical devices, scalpels) are those which penetrate soft tissue or bone and have the greatest risk of transmitting infection and should be either sterilized by heat or disposed. Semicritical items (e.g., metal speculum, ear cures) touch the mucous membranes or nonintact skin and have a lower risk of transmission; if the semicritical item is heat tolerant, it should be sterilized by heat and if not, at a minimum be processed with high-level disinfection. Noncritical patient-care items (e.g., blood pressure cuffs, stethoscopes, exam tables) pose the least risk of transmission of infection, contacting only intact skin, which can serve as an effective barrier to microorganisms. In the majority of cases, cleaning, or if visibly soiled, cleaning followed by disinfection with an EPA registered disinfectant is adequate.

A. Exam Tables/Infant & Adult Scales

All exam tables and infant/adult scales should be cleaned daily with an appropriate disinfectant solution, and disposable coverings for exam surfaces should be used.

Procedure

1. Table paper or absorbent pads will be changed on all exam tables, measuring tables and infant scales after use by each patient.

Key Points

This decreases the possibility of tables becoming contaminated with secretions, excretions, and/or blood. Unless there is soil on the table, surface disinfection between patients is not necessary.

Procedure

2. Table paper or absorbent pads with no visible soil or body fluids can be discarded with routine solid waste.
3. If the table or scales become soiled, remove obvious organic soil with disposable towels, soap and water followed immediately with germicidal disinfectant or 1:100 (or 1:10) bleach solution.
4. All exam tables and infant scales should be cleaned at the end of use each day with a chlorine-bleach solution of at least 1:100 concentration, or use an appropriate EPA-registered disinfectant detergent.

Key Points

If the paper or absorbent pad becomes contaminated, the soiled covering must be discarded in waste containers identified with color coding or the BIOHAZARD symbol.

Wear gloves during this cleaning procedure.

A 2% glutaraldehyde solution or other hospital disinfectant is an acceptable substitute, but it is less economical as a routine cleaner. Follow the manufacturer's instructions for use.

Avoid prolonged contact of metal surfaces with chlorine-bleach solution, as bleach is corrosive and may pit the surface. Rinse and dry the treated surface thoroughly.

B. Thermometers

Each thermometer must be designated as being oral, ear, rectal, or axillary. They must not be interchanged. Mercury thermometers must be cleaned and disinfected after each use. Digital and ear thermometers must be cleaned according to manufacturer's instructions. All clinics using standard mercury fever thermometers must purchase plastic slip-on covers to use each time a temperature is taken. If digital thermometers are used regularly, the accuracy of the instrument should be checked at least on a weekly basis. This may be accomplished by taking a temperature with an IVAC or digital thermometer and using a standard mercury fever thermometer on the same patient or staff and compare readings.

Procedure

Mercury Thermometers

1. Thermometers should be placed in containers clearly marked "oral", "ear", "rectal", or "axillary."
2. After a mercury thermometer has been used, wash the thermometer with soap and cool water. Rinse well with water and dry. Do not use hot or warm water. Wash oral, axillary, and rectal thermometers separately.
3. Place the dried mercury thermometer(s) in a 70% alcohol solution or a 1:10 chlorine bleach solution for at least 10 minutes. Soak oral, rectal, and axillary thermometers separately.

Key Points

Certain organic substances, such as blood, pus, and feces, neutralize the disinfectant. Soap and water assure emulsification and dispersion of these substances. Drying the thermometer after it has been rinsed assures there is no dilution of the disinfectant from water left on the surface.

Either ethanol or isopropyl alcohol may be used. Two percent glutaraldehyde solutions are acceptable for use only if 70% alcohol not available. Be sure to use fresh disinfectant solutions daily.

Procedure

4. Rinse the mercury thermometer(s) with water, dry them again, and store them in a dry container.

Key Points

If glutaraldehyde is used, disinfect the thermometers in a covered container. Follow the manufacturer's instructions and be sure to rinse the thermometers well after disinfectant treatment. Contamination with gram-negative bacilli is possible if thermometers are stored in disinfectant.

Digital and Other (Such as Ear) Thermometers

1. When using thermometers with disposable sleeves or sheaths, use a new sleeve or sheath for each patient.
2. Follow manufacturer's instructions for cleaning.

C. Devices Used in Procedures Involving Blood

All devices used in procedures involving blood shall be cleaned, disinfected, or discarded after each use, as directed below.

Procedure

Key Points

Automatic Lancet Devices

1. It is optimal to use a single disposable capillary device or lancet for individual client use.
2. If spring-loaded fingerstick devices (Autolet devices) are used, the platform and lancet should be discarded and replaced after use on each client. Since the device is likely to become contaminated, it should be cleaned and disinfected daily using a 1:100 chlorine bleach solution. The disposable parts of the device should be deposited in an appropriate sharps container.
3. The device itself should be cleaned and disinfected after every use.

Some spring-loaded devices do not have removable parts such as the platform or lancet. These devices are only appropriate for personal use by individual clients and should not be used in clinic settings for multiple client use.

Either ethanol or isopropyl alcohol may be used, providing the material of the device is compatible with the disinfectant.

Vacutainer Sleeves

1. If the sleeve is contaminated with blood, dispose it in the biohazard waste container. Recent recommendations have been made to institute disposable single-use vacutainers as the preferred choice for phlebotomy tasks. If disposable vacutainers are not available, then they should be washed with soap and water, rinsed and dried. Soak it for 10 minutes in 70% alcohol, remove it from solution and dry.
2. No special cleaning procedures are necessary if the sleeve is free of blood.

The alcohol should be changed daily.

Procedure

Key Points

HemoCue Blood Hemoglobin or Glucose Photometer

1. The cuvette holder should be cleaned daily with alcohol or a mild soap solution after having been completely removed from the photometer. It can also be autoclaved.
2. The exterior components of the photometer may also be cleaned and disinfected with alcohol as needed.

Important: Be sure the holder is completely dry before being replaced in the photometer.

D. Gynecological and Surgical Instruments

Disposable instruments must be used whenever possible; however, it should be recognized that manufacturers may only be able to supply re-usable metal instruments suited for the intended need. Re-usable gynecologic and surgical instruments require cleaning care and maintenance to insure that effective and safe instruments are available for use by the clinician as well as eliminate the chance for the instrument to act as a source of infection to a client or health care provider. Re-usable metal instruments available in some clinical facilities serving women's health services (family planning, maternity, etc.) include uterine sound, single tooth tenaculum, forceps (sponge, alligator, mosquito-straight or curved), scissors, and button hook instrument. Disposable speculums are supplied for clinic use and must be discarded after individual use.

Procedure

Key Points

1. Immediately after use, the re-usable instrument can be either put in a container of soap and water that is covered with a lid, or rinsed with warm water and put aside in a sink in a designated cleaning area. This area should have both hot and cold running water and meet all requirements of the LA Sanitary Code.
2. The designated person responsible for this task should wear heavy latex or household gloves, and an apron or other type of protective clothing while cleaning the instruments. The use of face mask or goggles may be necessary if splashing is likely to occur while cleaning. The protective equipment should not be worn in any other clinical areas and be worn only by the individual assigned to this task.

Covered containers will help keep children's hands out of the container

The sink used for cleaning instruments will not be a sink used for any type of food preparation.

The person responsible for cleaning the instruments should be designated by the nursing supervisor.

Any disposable protective gear (masks, gloves, etc) should be disposed of after each use. Disposable masks and/or aprons, and paper towels which have residues of blood, mucus or other body fluids must be considered as infectious waste and be disposed of as such.

Non-disposable goggles will be washed thoroughly with disinfectant or germicidal soap and water and dried with a paper towel after use. If non-disposable aprons or professional smocks are used, they should be professionally dry-cleaned as often as needed. Any apron with residues of blood or other body substances, should not be worn until it is professionally cleaned. An adequate receptacle should be marked for the aprons until transport to the cleaner.

Procedure

3. At the end of the clinic session, disassemble all instruments and rinse with water. Use a stiff “bottle” brush to remove any residue that may adhere on the instrument. Wash manually with a disinfectant soap or antiseptic solution. Be careful not to create splashing. Rinse with hot water and dry with a paper towel. Reassemble the instrument prior to autoclaving or disinfecting.

4. All re-usable metal instruments in the OPH clinical facilities shall be sterilized after washing.

Autoclaving is the preferred method for sterilization of the instruments. Facilities having their own autoclave may sterilize their own instruments.

5. Place the properly wrapped instruments side by side in the autoclave chamber. Do not stack them on top of one another. Place a chemical test strip in between several of the instrument packages. After the cycle, check to see if the strip has changed color. Do not consider as sterile any materials from an autoclave run if the test strips did not change color. Assuming the color of the tape has changed, remove the instruments and restock them in the rooms and exam tables.

Key Points

A small brush or toothbrush, to be used only for cleaning equipment, may be helpful in cleaning the instruments. Bottle brushes should be soaked for at least 5 minutes after use in a 1:10 solution of chlorine bleach and water. After soaking, the brushes should be rinsed with plain water and allowed to dry after use. Store brushes out of the reach of children.

Each rinsed instrument should be placed on a dry paper towel or on a drain board. Air-drying is also acceptable. Avoid cross contaminating “clean” instruments with “unclean” instruments.

In those facilities which have an autoclave, it is the responsibility of the public health nursing supervisor to assure that the autoclave is in proper working order at all times. This responsibility includes consultation with the regional laboratory staff regarding operation of the autoclave.

Single-layer stacking allows the steam to reach all surfaces of the instruments. Follow the manufacturer’s recommendations for proper loading procedures of the autoclave. The strip should be placed in the most difficult area for the steam to reach. These special test strips change color when a temperature of 121°C has been maintained for at least 12 minutes. This will provide an immediate indication that high enough temperature was achieved for a minimum period of time, but it does not assure sterility.

Procedure

6. Facilities lacking an autoclave will wrap each instrument using brown or other wrapping paper and sealed with autoclavable tape. The items to be autoclaved will be transported to the nearest facility (i.e., regional laboratory or clinic) for sterilization.

The type of wrapping paper and tape to be used must be approved by the site facility performing the sterilization. Each wrapped instrument will be clearly labeled using water-resistant ink or laundry marker on a securely attached label or on wrapping paper or tape.

The labeling requirements are: name and type of instrument; name and address of OPH facility; name of person wrapping instrument; date of sterilization.

All unopened and unused sterilized instruments that remain in the inventory stock after one year should be re-wrapped and re-sterilized to maintain the integrity and sterility of the item.

7. Change drawer lining for speculums and other instruments on a weekly basis.
8. Disposable speculums will be discarded into a waste container marked with the BIOHAZARD label.

Key Points

The facility which owns the instruments will arrange for and is responsible for transporting the instruments to the lab/clinic and for picking the instruments up again.

These are considered as "other regulated medical waste."

E. Diaphragm Fitting Rings (DFR)

Diaphragm fitting rings will be disinfected as outlined after each use.

Procedure

1. After use, wash the rings with soap and water, then dry. Wear gloves.
2. Immerse rings in a 2% glutaraldehyde solution, 70% alcohol, or other appropriate disinfectants according to its manufacturer's instructions, to achieve high-level disinfection. Disinfect the rings in a closed container.
3. Remove from solution, rinse well with running water, dry, and store for future use.
4. Do not immerse the rings in boiling water or expose them to excessive heat.

Key Points

The employee will wear gloves to prevent contact with body fluids.

Refer to DFR manufacturer's instructions for appropriate high-level disinfection procedure. High-level disinfection inactivates viruses, fungi, and vegetative bacteria including tubercle bacilli, but will not necessarily inactivate bacterial endospores. Follow the manufacturer's instructions for appropriate handling and use of disinfectants.

F. TB Sputum-Collection Equipment

All sputum-collection equipment that is not disposable should be disinfected as outlined after use each.

Procedure

1. Wearing gloves, dismantle all tubing, mouth-pieces, and components.
2. Wash each piece with soap and water to remove obvious secretions. Rinse with running water.
3. Immerse all parts in 2% glutaraldehyde solution or other disinfectant, according to manufacturer's recommendation, to products. Follow the manufacturer's recommendations to achieve high-level disinfection. Use a closed container.
4. Remove from solution, rinse well with running water, and allow the pieces to air-dry completely.
5. Reassemble and store for future use.

Key Points

This ensures that the cleaning process will be thorough.

A small brush or toothbrush, to be used only for cleaning equipment, may be helpful for cleaning any grooves or crevices. Thoroughly clean and dry the brush after use. Store it out of the reach of children.

Contact time for glutaraldehyde-based disinfectants may vary with different recommendations for disinfectant use. High-level disinfection kills tubercle bacilli. Do not use alcohol to disinfect plastic surfaces of pulmonary-function equipment, as alcohol will damage these surfaces.

Wet surfaces serve as breeding grounds for bacteria.

G. Otoscope/Tonometers/Ophthalmoscope

The plastic attachments are to be cleaned and disinfected as outlined after each use.

Procedure

1. After the piece is removed from the instrument, clean off visible organic matter with a cotton swab. Wash the piece with soap and water, and dry it.
2. Place the cleaned piece(s) in 70% alcohol for 10 minutes.
3. Remove the pieces from the alcohol, rinse well with water, dry, and store in a dry container.

Key Points

Certain substances, such as pus and blood, neutralize the disinfectant. Soap and water assure emulsification and dispersion of these substances. Drying assures there is no dilution of the disinfectant from water left on the pieces.

Either ethanol or isopropyl alcohol is acceptable for use as a disinfectant, but check to make sure that the plastic materials are compatible with alcohol. A 2% glutaraldehyde solution is acceptable for use if 70% alcohol is not available.

Procedure

4. If there is no time to soak the piece(s) between patients, the pieces can be cleaned by first washing with soap and water, then taking an alcohol prep or an alcohol-soaked cotton ball and wiping the piece thoroughly, then rinsing with water and drying. Then, at the end of each day, complete steps 1-3.
5. Disposable specula for ear and nose exams are intended as single-use items and should be discarded after completing each patient's exam.

Key Points

These may be discarded as routine clinic waste, provided that there is no visible blood present on the specula. If blood is present, these should be discarded into a waste receptacle marked with the BIOHAZARD label.

H. Blood-Pressure Equipment

Stethoscope earpieces should be cleaned after each use unless only one person is using the stethoscope. Blood-pressure cuffs should be kept clean and free from obvious debris.

Procedure

1. Earpieces on stethoscopes should be cleaned by using cotton soaked with 70% alcohol or an alcohol swab each time a different person uses the stethoscope.
2. The bell of the stethoscope should be wiped with 70% alcohol or an alcohol swab after use with each patient.
3. Wash the blood-pressure cuffs when they appear to be dirty or when they become soiled with a body substance.
4. Blood-pressure cuffs may be washed in regular laundry detergent after first removing the bladder. The cuffs can be soaked in a sink with detergent and washed by hand.

Key Points

Ideally, the earpieces should be washed with soap and water first to remove obvious debris. This may not be practical in most situations. An alternative procedure would be use a cotton swab to remove visible organic material and follow with alcohol.

How often they are washed depends on how much they are used.

I. Autoclave Operation

Clinic autoclaves will be operated and maintained according to manufacturer's instructions to assure proper function. Clinic autoclaves should be monitored periodically by the clinic's designated or assigned staff person to determine that they are functioning properly (i.e., achieving sterile conditions) for quality assurance. Contact the equipment manufacturer or distributor in the event that the quality assurance standards are not met.

Procedure

1. Make sure that the autoclave is loaded according to the following guidelines:
 - a. Do not overload or crowd items into the chamber.
 - b. Do not allow material to come into contact with the sides or the door of the chamber.
 - c. Separate items or arrange them loosely in the chamber.
 - d. When wrapped and non-wrapped items are loaded together, autoclave them using the run time and temperature guidelines for wrapped items.
2. Do not use an autoclave that is not working properly. Make alternate arrangements for sterilizing materials while the equipment is being repaired.
3. Follow the manufacturer's instructions regarding care and maintenance of the autoclave.
4. Testing procedures to monitor autoclave performance will utilize both physical and biological parameters.
 - a. *Physical Parameters*
Autoclave performance will be monitored each time the equipment is used by including chemical test strips with the load. In addition, log books will be maintained to record the date, type of load, temperature achieved, and length of time at achieved temperature.
 - b. *Biological Parameters*
Autoclave performance will be monitored using a biological or equivalent indicator system, such as a spore test, on a quarterly basis, or more frequently, as needed. In the autoclave log, note the time and date of the run and the results of the spore test.

Key Points

This will ensure that steam reaches all materials adequately during the run.

Check to make sure the drain is kept clear.

These special test strips change color when a temperature of 121°C has been maintained for at least 12 minutes. This will provide an immediate indication that a high enough temperature was achieved for a minimum period of time, but it does not assure sterility. Do not consider any materials sterile if the test strips did not change color.

General Guidelines for Run Times and Temperatures (Refer to the Gynecological and Surgical Instruments section)

Wrapped Items

132°C (270°F): 10 minutes
121°C (250°F): 30 minutes

Non-Wrapped Items

132°C (270°F): 5 minutes
121°C (250°F): 10 minutes

J. Refrigerators and Freezers

Refrigerators and freezers used to store or contain blood or other potentially infectious materials (OPIM) must have a fluorescent orange or orange-red warning label including the BIOHAZARD symbol and word in a contrasting color. These refrigerators and freezers must not be used for food storage. Separate labeled refrigerators/freezers must be used to store food; medications, vaccines and biologic specimens, should be properly and physically separated from each other, and shall be stored in a refrigerator used exclusively for those items.

In those clinic sites that are not open every day to maintain and monitor the refrigeration equipment, an alternative written procedural plan or method should be made available and accessible in the event of a power or refrigerator failure. State regulations can be consulted for any specific temperature monitoring and record-keeping requirements of refrigerators and freezers.

Procedure

1. Refrigerators should be kept clean at all times. They can be wiped out with liquid dish soap and warm water.
2. Comply with safe temperature ranges for specimen, food, medication and lab supplies stored in the refrigerators and freezers.
3. Monitor and chart temperatures at regular intervals, such as each day the clinic is open. The findings should be kept by or on the refrigerator. Note on the chart the acceptable temperature range.
4. Develop a procedure to follow should the temperature fall outside the acceptable range. Describe steps to take and whom to contact on the temperature log. Consult with drug manufacturers or lab supply companies on the efficacy and safety of the medications if outside the acceptable temperature range or the impact of results on affected laboratory reagents, media, etc.
5. Clean and defrost refrigerators/freezers, including staff refrigerators, at regular, defined intervals and when soiled or if a spill occurs.

Key Points

- Be sure to include refrigerator cleaning in the written schedule for routine cleaning and disinfection (housekeeping schedule).
- Use a thermometer inside each refrigerator and freezer.
- If the clinic is part of the Vaccines for Children Program administered through the Office of Public Health, or if the clinic is a state certified Yellow Fever Vaccination Center, additional monitoring requirements may be needed.
- If a refrigerator temperature does not fall within an acceptable range, re-adjust the temperature regulator and re-check the reading on the thermometer in one hour. If the temperature is still not within the acceptable range, notify the supervisor for maintenance servicing.
- A weekly cleaning schedule should be logged on the monitoring record. Expiration dates on drugs and biologic supplies should be checked on a monthly basis. Outdated and expired drugs and supplies should be removed and destroyed.

K. Centrifuges

Centrifugation presents serious hazards from mechanical failure and from generation of aerosols of biohazardous materials or toxic chemicals if improperly used or in absence of good laboratory practices. The operation of a centrifuge shall take place away from clients/employees while spinning. All centrifuges will be cleaned immediately following contamination with blood or other potentially infectious material (OPIM) and also be given a general cleaning once a month. Never use your hands to manually slow down or stop the centrifuge from spinning.

Procedure

1. The exterior surfaces and the interior including the rotor and tube holders should be wiped with 10% bleach to disinfect. If things are heavily soiled, the area may need to be covered with 10% bleach soaked towels for 10-15 minutes or until dirt and debris loosen up to disinfect and then clean with soap and water. Centrifuges should be cleaned routinely, once a month or as often as needed when soiling or spills occur.
2. Wear gloves when cleaning centrifuges.
3. A cloth, small brush, or cotton swab may be needed to get to hard-to-reach areas inside the centrifuge. Rinse with water after using chlorine-bleach solutions.
4. If the centrifuge (or any piece of equipment) becomes contaminated with blood or other body fluids, clean the spill up right away.
5. If tubes of blood or OPIM leak or break during centrifuge operation, close the centrifuge, leave the room for 30 minutes, and post a warning sign on the door.
6. If contaminated equipment cannot be disinfected and cleaned immediately after a spill, a sign or BIOHAZARD label must be posted on the equipment to alert employees that a spill has occurred.
7. If a blood tube or hematocrit (HCT) tube breaks in the centrifuge, use long forceps to remove broken glass. Wear gloves. If a large blood spill results from a tube breaking (where blood has created a pool), soak up the blood using a disposable paper towel, then spray and clean with a 1:10 chlorine bleach solution, let the solution set 10 minutes, then rinse with water.

Key Points

Always unplug the centrifuge prior to cleaning. Do not immerse the unit in water. Always follow the accompanying manufacturer's recommendations for cleaning procedures. A monthly centrifuge cleaning log is recommended in conjunction with recording the RPM and timer calibration check.

The gloves will protect the hands from soil and chemical contact. Remember to wash your hands after glove removal.

Remember that if chlorine bleach is used, these solutions can be corrosive to metal surfaces, so rinsing becomes especially important. Cotton swabs should be discarded in the clinic trash after use. The cloths and brushes should be cleaned thoroughly and allowed to dry.

Spills of blood or OPIM should be decontaminated first with a 1:10 solution of chlorine bleach.

A hazardous aerosol will be created if blood or OPIM spills while the centrifuge is spinning.

The sign should be readily visible and should indicate which parts of the equipment are contaminated.

For disposal of paper towels used to soak up a pool of blood, see "Cleaning Up Blood and/or Body-Secretion Spills."

Keep contact time to a minimum as chlorine bleach solution is corrosive to metals. Rinse metal surfaces thoroughly.

L. Microscopes and Other Laboratory Equipment in the Clinic

Usually microscopes are engineered for long life with a minimum of maintenance required. In general, routine maintenance is limited to keeping the microscope clean. Always protect the microscope with a dust cover when not in use. Any equipment that becomes contaminated with blood or OPIM must be decontaminated. As always, follow the accompanying manufacturer's instructions for cleaning microscopes and other delicate components.

Procedure

1. If the microscope or any piece of clinic equipment becomes contaminated, it should be cleaned/ disinfected as soon as it is practical to do so.
2. To clean the lens surface, remove dust using a soft brush or gauze. To remove finger marks or grease, use a soft cotton cloth, lens tissue or gauze lightly moistened with absolute alcohol (ethanol or methanol) should be used.

For cleaning the objectives only use xylene.

3. Painted surfaces may be cleaned with a dry cloth.

Key Points

Any cleaners or disinfectants used must be compatible with the surface to be cleaned. Follow manufacturer's instructions for cleaning microscopes and other delicate equipment.

Do not leave dust, dirt or finger marks on the lens surface. They will prevent you from clear observation of the specimen image.

Observe sufficient caution for handling alcohol and xylene.

Avoid the use of any organic solvent (e.g., thinner, xylene, ether or alcohol) for cleaning the painted surfaces and plastic parts of the instrument.

M. Hazard Communication for Contaminated Equipment

BIOHAZARD signs or labels must be posted on contaminated equipment if the equipment cannot be decontaminated immediately.

Procedure

1. If the instrument cannot be readily cleaned after contamination with blood or OPIM, a BIOHAZARD sign and label must be posted on the instrument prior to cleanup.
2. The BIOHAZARD sign and label must be attached to contaminated equipment that requires disassembly for cleaning.

Key Points

The sign must be readily visible and must indicate which parts of the instrument are contaminated.

This is important to alert all who handle the equipment, especially off-site repair technicians, as to the nature and extent of the contamination.

N. Ultraviolet Lights

Ultraviolet (UV) lights are to be dusted regularly to keep them dust free. If not used often, dust each time before use.

Procedure

1. Turn off the UV light before cleaning it.
2. Lights and UV bulbs should be dusted regularly with a clean dry cloth as often as necessary to keep them dust-free. If used infrequently, dust before use.
3. UV lights should not be turned on except as used in clinic.
4. UV lights must be installed according to the manufacturer's recommendations so the light is directed away from patients. Once installed, the UV tube should not be visible from any normal position in the room.

Key Points

UV light can cause sunburn and can damage the retina.

Dust on the bulbs interferes with proper function by reducing the amount of effective UV radiation.

UV lights should be on when the room is occupied. The light can be turned off if the room is unoccupied for extended periods of time.

Formulas for Mixing Chlorine Bleach Solution

1:100 Concentration¹

Metric Measurement Volumes			Approximate Household Measurement Volumes		
Bleach	Water	Total	Bleach	Water	Total
2.5 mL	247.5 mL	250 mL	2/3 tsp	1 ¼ cup	10 oz
5 mL	495 mL	500 mL	1 ¼ tsp	2 ½ cups	20 oz
10 mL	990 mL	1 L	2 tsp	1 qt	1 qt
20 mL	1980 mL	2 L	4 tsp	2 qts	2 qts

1:10 Concentration²

Metric Measurement Volumes			Approximate Household Measurement Volumes		
Bleach	Water	Total	Bleach	Water	Total
25 mL	225 mL	250 mL	2 Tbsp	1 cup + 2 Tbsp	10 oz
50 mL	450 mL	500 mL	¼ cup	2 ¼ cups	20 oz
100 mL	900 mL	1 L	6 Tbsp	3 ½ cups	1 qt
200 mL	1800 mL	2 L	¾ cup	7 cups	2 qts

Desired Chlorine Concentration

	5000 ppm	1000 ppm	500 ppm	100 ppm
Dilution of bleach (5.25% NaOCl) Prepared fresh for use within 24 hours	1:10	1:50	1:100	1:500
Dilution of bleach (5.25% NaOCl) Prepared fresh and used for 1 – 30 days	1:5	1:25	1:50	1:250

¹ This solution is used for general cleaning of non-porous environmental surfaces on a routine basis. The solution must be made fresh **daily** because the active ingredient is lost more rapidly in very dilute solutions than in the more concentrated solution.

² This solution is used to decontaminate and disinfect non-porous environmental surfaces when a spill of blood, body fluids or feces has occurred. The solution can be made up **once a week** and dispensed from an opaque spray bottle which has been clearly labeled.

HOUSEKEEPING SERVICES CHECKLIST

(Recommended to be maintained by the Facility Manager or as designated by the Regional Manager)

Location		## times per week	## times per month	## times per year
Floors				
<i>Dust mop all vinyl & ceramic floors in:</i>	<i>Location:</i>			
	<i>a) Waiting room</i>			
	<i>b) Hallways</i>			
	<i>c) Clinic rooms</i>			
	<i>d) Offices</i>			
	<i>e) Conference rooms</i>			
	<i>f) Kitchen</i>			
	<i>g) Restrooms</i>			
<i>Damp mop vinyl & ceramic floors in:</i>	<i>Location:</i>			
	<i>a) Waiting room</i>			
	<i>b) Hallways</i>			
	<i>c) Clinic rooms</i>			
	<i>d) Offices</i>			
	<i>e) Conference rooms</i>			
	<i>f) Kitchen</i>			
	<i>g) Restrooms</i>			
<i>Spray buff vinyl & ceramic floors in:</i>	<i>Location:</i>			
	<i>a) Waiting room</i>			
	<i>b) Hallways</i>			
	<i>c) Clinic rooms</i>			
	<i>d) Offices</i>			
	<i>e) Conference rooms</i>			
	<i>f) Kitchen</i>			
	<i>g) Restrooms</i>			
<i>Strip and wax all vinyl floors in:</i>	<i>Location:</i>			
	<i>a) Waiting room</i>			
	<i>b) Hallways</i>			
	<i>c) Clinic rooms</i>			
	<i>d) Offices</i>			
	<i>e) Conference rooms</i>			
	<i>f) Kitchen</i>			
	<i>g) Restrooms</i>			
	<i>Location:</i>			

<i>Vacuum carpeted floors in:</i>	<i>a) Waiting room</i>			
	<i>b) Hallways</i>			
	<i>c) Clinic rooms</i>			
	<i>d) Offices</i>			
	<i>e) Conference rooms</i>			
	<i>f) Kitchen</i>			
	<i>g) Restrooms</i>			
<i>Shampoo all carpet in:</i>	<i>Location:</i>			
	<i>a) Waiting room</i>			
	<i>b) Hallways</i>			
	<i>c) Clinic rooms</i>			
	<i>d) Offices</i>			
	<i>e) Conference rooms</i>			
	<i>f) Kitchen</i>			
	<i>g) Restrooms</i>			
Restrooms				
<i>Clean & sanitize all fixtures in restrooms and water fountains</i>				
<i>Wash public restroom including walls and fixtures with disinfectant</i>				
<i>Spot clean all walls in restrooms with disinfectant</i>				
<i>Fill receptacles in restrooms</i>				
<i>Empty trash cans and remove trash from building</i>				
Dusting				
<i>Dust areas and remove all spider webs in:</i>	<i>Location:</i>			
	<i>a) Window sills</i>			
	<i>b) Blinds/curtains</i>			
	<i>c) Baseboards</i>			
	<i>d) Doors</i>			
	<i>e) Furniture</i>			
	<i>f) Chair rails</i>			
	<i>g) Fixtures</i>			
	<i>h) Wall fixtures</i>			
	<i>i) Light fixtures/lamps</i>			
<i>j) Shelves</i>				
Light Fixtures and Vents				

<i>Clean all overhead light fixtures</i>			
Clean vents and return A/C air vents			
Clean all windows (in & out)			
Kitchen			
<i>Clean kitchen sinks, counters, outside of cabinets, tables, stove top and inside/outside of microwave</i>			
<i>Clean inside and exterior of refrigerator & freezer</i>			
General			
<i>Empty trash and remove from building</i>			
<i>Empty ash trays</i>			
<i>Spot clean walls</i>			
<i>Fill receptacles in clinic rooms (i.e., soap, paper towels, etc.)</i>			
<i>Remove refuse/debris around building exterior</i>			
Lawn Maintenance			

Special Notes:

Housekeeping service provider must clean all doors, walls, baseboards, furniture and equipment when splashing occurs from mopping, stripping or waxing.

When cleaning restrooms, the following items must be included: toilets, urinals, sinks/fixtures, mirrors, etc.

Clean water must be used when cleaning each restroom.

A daily checklist indicating what work has been completed as per specifications (or contract specifications) must be submitted to _____ (name of designated person to verify work task completion).

Housekeeping staff should maintain inventory of cleaning supplies. (If on contractual services, you may specify that all supplies, labor and equipment must be supplied by the contractual agency.) Included in the supplies should be which agency will supply hand soap, hand disposable towels and toilet tissue.

Section 4

Disposal of Waste

Section 4: Collection and Disposal of Waste

I. Management of Medical Waste

Hazardous biomedical waste materials must be handled properly to avoid accidents and exposures. This is accomplished by safe procedures, wearing personal protective equipment (PPE), and training all employees who routinely or occasionally handle biomedical waste materials. Handling techniques and other procedures designed to minimize contamination or exposures are examples of work practice controls.

Waste which is generated within the clinical facility has a high potential risk for causing infection if improperly handled or treated. All treated and untreated waste will be managed in accordance with: Sanitary Code, State of Louisiana, Part 27, Management of Refuse, Infectious Waste, Medical Waste, and Potentially Infectious Biomedical Waste, Promulgated LSA-R.S. 49:951 et seq. July 1, 1990, amended July 20, 1991. Website address for Title 51 – Public Health – Sanitary Code: <http://www.state.la.us/osr/lac/51v01/51v01.pdf>

NOTE: Refer to the Title 51 Public Health - Sanitary Code, State of Louisiana, Part 27 for further details that may not be covered within the context of this section.

The Regional Medical Director or, in the absence of a Medical Director, the Regional Administrator will appoint within each parish health unit or each regional clinic facility a designated person to monitor quality assurance in the handling and disposal of infectious waste in each facility. Quality assurance means the adherence of the parish health unit or regional facility's staff to this policy.

II. Summary of Waste Management Requirements

1. Sharps and other regulated waste shall be collected in approved containers. Consider using a reusable sharps container system if a hauler is available within your area. Typically, this saves money, can reduce worker exposure and handling, and can significantly improve environmental impacts.
2. Waste may be treated on-site or shipped off-site for treatment and disposal.
 - A. On-site Treatment and Disposal. Any facility planning to treat medical waste onsite will need to obtain a permit and should refer to the LA Department of Health and Hospitals for regulatory compliance prior to start up operations. Large medical facilities, such as hospitals, may choose to treat the potentially infectious biomedical waste on site; smaller clinics and health units typically have this waste transported and treated by permitted transporters and treatment facilities. Facilities that treat potentially infectious biomedical waste on-site must establish an on-site waste treatment operating procedures plan. Records must be maintained documenting on-site treatment and treated waste must be labeled as such before disposal.
 - B. Off-site Treatment and Disposal. Waste shipped off-site for disposal using a permitted medical waste transporter for waste treatment should have an information document on-site which includes how the waste is contained, stored, treated and disposed; records of quantity and type of waste transported; date transported; and the name of the permitted medical waste transporter. Tracking document records, including burn date, should be maintained for at

least 3 years. All OPH clinical and laboratory facilities must ensure that the contractor has a state permit issued by the Department of Health and Hospitals, Office of Public Health Sanitarian Services.

3. Training new and current employees on the facility's commitment to compliance with waste management policies and proper segregation practices is critical for any waste reduction effort as well as generate cost-savings for the facility. It is important for the staff to understand that improper disposal of regulated waste has potentially serious safety threats to the environment, waste haulers and increased liability for the facility.

III. Definitions

If the medical waste management program is to be successful, there must be a clear, succinct definition of medical waste.

Definitions listed below are from the LA Sanitary Code, Part 27:
(For a complete list of definitions, See LA Sanitary Code Part 27)

Generator any person or facility that produces Potentially Infectious Biomedical Waste.

Health Care and Medical Facilities shall include, but not be limited to hospitals, clinics, dialysis facilities, birthing centers, emergency medical services, mental health facilities, physicians' offices, outpatient surgery centers, nursing and extended care facilities, podiatry offices, dental offices and clinics, veterinary medical facilities, medical laboratories, home health care services, diagnostic services, mortuaries, and blood and plasma collection centers and mobile units.

Potentially Infectious Biomedical Waste includes medical waste, infectious waste as defined herein, and as may be defined in other Louisiana law or code, and waste considered likely to be infectious by virtue of what it is or how it may have been generated in the context of health care or health care-like activities. It includes, but is not limited to the following:

1. Cultures and stocks of infectious agents and associated biologicals, including cultures from medical, pathological, research and industrial laboratories.
2. Human pathological waste including tissue, organs, body parts and fluids that are removed during surgery or autopsy.
3. Human blood, human blood products, blood collection bags, tubes and vials.
4. Sharps used or generated in health care or laboratory settings.
5. Bandages, diapers, "blue pads", and other disposable materials IF they have covered infected wounds or have been contaminated by patients isolated to protect others from the spread of infectious diseases.
6. Any other refuse which has been mingled with Potentially Infectious Biomedical Waste.

For purposes of these regulations, eating utensils are excluded from the definition of Potentially Infectious Biomedical Waste.

Infectious Waste is that portion of Potentially Infectious Biomedical Waste which contains pathogens with sufficient virulence and quantity that exposure to the waste by a susceptible host could result in an infectious disease.

Medical Waste is that portion of Potentially Infectious Biomedical Waste that is generated from the operation of medical programs, offices and facilities.

Sharps are needles, syringes, scalpels, scalpel blades, pipettes and other medical instruments capable of puncturing or lacerating skin. This definition also includes glass fragments and other health care and laboratory waste capable of puncturing or lacerating skin.

Labeling to pre-print, mold an impression, write on or affix a sign to a package that is water-resistant, legible and readily visible.

Packaging is the containment of Potentially Infectious Biomedical Waste in disposable or reusable containers in such a manner as to prevent exposure to the waste material.

Storage is the containment of Potentially Infectious Biomedical Waste until treated or transported from the premises of a generator or treatment facility while the material is still potentially infectious.

Transport is the movement of Potentially Infectious Biomedical Waste from the premises of a generator or others involved over more than 0.1 mile of public streets or roadways to places for storage, treatment or disposal.

Transporter is any person or firm who transports large quantities of Potentially Infectious Biomedical Waste or who transports any quantity of such waste generated by another. This definition shall not apply to municipal waste haulers who transport such waste disposed of in household waste.

Treatment in the case of Potentially Infectious Biomedical Wastes other than human bodies; gross anatomical parts such as limbs, torsos and heads; fetal remains; and sharps shall mean any method, technique, or process designed to change the character or composition of any Potentially Infectious Biomedical Waste so as to render the waste non-infectious. Treatment of human bodies, anatomical parts and fetal remains shall be by cremation, burial, or other means specifically authorized by law or regulation. Sharps shall be treated by incineration, encapsulation, or other means by which they are rendered unrecognizable as Potentially Infectious Biomedical Waste or otherwise unusable.

IV. Collection of Sharps and Waste

All sharps and other regulated medical wastes shall be properly collected as outlined below. All sharps will be disposed of in specially designated puncture resistant containers.

A. Sharps Collection

Sharps are of special concern because they present a physical hazard to health care workers and waste handlers. It should be noted that needles and syringes are generally managed uniformly, regardless of whether or not they are contaminated. The successful management of sharps will:

1. Prevent injury from skin punctures or lacerations;
2. Reduce the potential for disease transmission;
3. Comply with requirement that render needles and syringes useless or unavailable for use prior to disposal;
4. Ensure that sharps are destroyed, so they are no longer recognizable; and
5. Comply with federal, state and locals regulations at the lowest possible cost.

Procedure

1. Sharps containers shall be puncture resistant, sealable, leak-proof on sides and bottom, color-coded or labeled clearly with the BIOHAZARD symbol. The container must be tightly closed.

Do NOT discard needles with general waste!
2. Sharps containers shall be placed in clinic settings. All sharps will be placed in these containers immediately after use.
3. Contaminated needles shall not be recapped, bent, sheared, broken, or separated by hand from syringes. Needles and syringes must be discarded into the sharps container as a unit.
4. Broken glassware shall not be picked up directly by hand. Use appropriate mechanical means such as gloves, pliers, broom and dustpan to pick up the debris.
5. Sharps containers will be replaced when they are three-fourths full.
6. Sharps containers will be disposed of by turning it over to a permitted medical waste disposal company or transported by a health unit public health nurse or sanitarian to a medical waste disposal site at a hospital or laboratory.

Key Points

- The BIOHAZARD label must be predominantly fluorescent orange or orange-red with letters or symbols in a contrasting color.
- Make certain that housekeeping staff understands how to pick up sharps from the floor, i.e., needles.
- Place the containers in the areas where sharps are used. These containers must be placed out of the reach of children.
- Twisting, bending, or separating contaminated needles by hand increases the possibility of injury and occupational exposure. One-hand disposal of sharps is recommended.
- Decontaminate and wash equipment as needed after use in picking up contaminated glass.
- Sharps containers must be kept upright, replaced routinely, and not be overfilled.

Note: Under no circumstances are children to be left unattended or unsupervised in clinic areas or in any area where sharps are used.

Under no circumstances shall hand entry into puncture-resistant containers for sharps be allowed.

B. Other Regulated Medical Waste

All regulated medical waste shall be treated and disposed of as outlined below.

<u>Procedure</u>	<u>Key Points</u>
1. All other regulated waste shall be placed in plastic bags or other containers which are impervious to moisture and have the strength sufficient to preclude ripping, tearing, or bursting under normal conditions of usage. Such containers must be securely closed so as to prevent leakage or other loss of contents during handling, storage, transport, and shipping.	Receptacles designated for special waste should be set up in the clinics, readily accessible for staff use.
2. Containers must be labeled or color-coded.	Potentially infectious biomedical waste shall not be mingled with ordinary trash or garbage in any OPH facility.
3. Containers must be closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.	The BIOHAZARD label must be predominantly fluorescent orange or orange-red with letters or symbols in a contrasting color. A red bag or container may be substituted for labels.
4. If outside contamination of the regulated waste container occurs, it shall be placed in a second container which meets the same specifications as the first.	Wear gloves and use mechanical devices as necessary to prevent contamination or injuries to the hands.
5. Clinic personnel shall attend to the proper disposal of sharps and other regulated medical waste. All housekeeping personnel should be aware of what types of waste require regulation.	In conjunction with clinical staff, housekeeping/ janitorial staff should be properly trained to recognize medical waste and requirements in the management in the handling and disposal process.
6. Storage of infectious waste for pick-up must be in a safe area of the facility and not easily accessible to the public. If the storage area is not within the building, it must be secured (locked), and protected from the weather, insects and rodents.	

C. Non-Infectious Clinic Waste and Office Waste

Waste which is generated within the facility and which does not have a high potential for causing infection does not require special precautions concerning handling and disposal. The nonhazardous wastes generated in clinical settings may include glass, plastic, paper, and metal items, cardboard, general trash and liquids. These wastes can usually be disposed of with the general waste streams. Liquid or liquefied Potentially Infectious Biomedical Waste may be directly disposed into a sewage system meeting the requirements of the Louisiana Sanitary Code, Part XIII. Fecal material, urine, blood and other NON-SHARP infectious waste or potentially infectious biomedical waste should be disposed of in a toilet, laboratory sink, or other sink used for no other purposes including handwashing sinks or any sink used for food preparation.

Nevertheless, proper management practices will provide safety for waste handlers, increased recycling of certain wastes, greater efficiency and cost savings

Note: Urine dipsticks and empty urine-specimen cups may be placed in the regular trash. These items do not meet the definition of special waste from health-care related facilities or OSHA's definition of a bloodborne pathogen.

Procedure

1. Exam rooms, clinic areas, and laboratories must have trash cans lined with heavy-duty plastic trash bags.
2. These waste receptacles must also be closable, capable of containing all contents, leakproof, and color-coded or labeled as a BIOHAZARD with the word and symbol.
3. All clinic waste that has not been identified as potentially infectious should be placed into lined trash cans.
4. Clinic trash cans, when filled, should be emptied by taking the plastic-bag lining and the receptacle out with the trash as a unit. Add a new plastic bag to the trash can.
5. If the waste receptacle becomes contaminated, clean and disinfect it using a 1:10 solution of chlorine bleach.

Key Points

Bags of 1.2 mil thickness are less likely to tear and leak. They are used to contain absorbent towels and other disposable clinic supplies stained with small amounts of blood (less than 100 ml) or other organic debris.

The BIOHAZARD label must be fluorescent orange or orange-red, with the symbol and letters on a contrasting background.

Disposable items such as paper gowns, drape sheets, exam-table paper, applicators, cotton or cotton-tipped swabs, tongue blades, used dressings and bandages, urine dipsticks, disposable gloves, cotton balls, hemocult cards, and disposable speculums, if contaminated with <100 ml blood or other potentially infectious materials, fall into this category.

Removal of non-infectious waste from clinic areas may be assigned to the janitorial staff. Make certain that both the clinic personnel and janitorial staff understand that no one is to reach directly into clinic trash receptacles with their bare hands.

This non-infectious waste may be placed with the regular trash.

This should be done as soon as possible.

V. Home Care or Field Visits

If any potential infectious biomedical waste is generated during the course of home care or home visiting of a client, the proper treatment and disposal of that waste is the responsibility of the public health provider. Materials considered as potentially infectious biomedical waste, which may be generated during home care or home visits include, but are not limited to: sharps, body fluids, used or bloody bandages, bandages which have covered infected wounds, urinary catheters and intravenous tubes from clients, who are isolated because of infectious disease.

Procedure

1. Sharps should be handled as previously mentioned in the "Sharps Collection" section.
2. Bandages from infected wounds, urinary catheters and intravenous tubes from isolated clients with an infectious disease must be handled carefully.
3. The solid waste shall then be placed in a plastic bag, closed and attached with a medical waste label.
4. The waste must be transported to a permitted medical waste storage for treatment facility.

Key Points

Note: Residential sharps are not considered regulated waste unless the public health unit worker/staff is in control of its disposal by request of the client or by necessity to be disposed of with the facility's infectious waste.

The label should clearly indicate the name of the OPH facility, the date and type of treatment, name or initials of the person responsible for assuring the proper treatment of the waste.

Public health providers are encouraged to teach clients and their family the proper disposal techniques for infectious waste.

It should be noted that professional public health care providers are subject to infectious waste or potentially infectious biomedical waste regulations. Non-professional household health care givers are not subject to these regulations.

Commercially available labels for medical waste may be purchased if they meet the all of the information requirements for labeling.

Accidental spills of blood or other body fluids

If blood or other body fluids are spilled, the blood or body fluids must be cleaned up (and disinfected) by placing an absorbent paper towel over the spill. A solution of chlorine bleach diluted as stated above should follow to disinfect the area.

It is recommended that personal protective equipment be used in response to the cleanup effort.

Broken glass associated with the accidental spill must be handled with utmost care to prevent injury to the person cleaning the area. Broken glass, as for all other sharps, should be placed in a break-resistant, rigid, puncture-proof container.

Note: Diapers are not classified as infectious waste. Liners and contents of soiled disposable diapers should be flushed in a toilet, when the disposal is under the control of the public health care provider. The outer plastic diaper may be disposed with "regular" trash. Neither tampons, nor sanitary pads are classified as infectious waste, but if the parish health unit staff is in control of its disposal by request of the client or by necessity, the tampon or sanitary pad should be disposed of with the facility's infectious waste.

VI. Storage of Potentially Infectious Biomedical Waste

Infectious waste must be contained to protect patients, healthcare workers, waste handlers, and the general public from exposure to the waste and from puncture/abrasion injury and disease transmission. Infectious waste should be contained from the point of discard until the material is no longer infectious and does not pose a risk of injury. Consequently, the container should be designed to maintain its integrity throughout handling, storage, movement and shipping. Biomedical waste shall be stored in a secure manner and location which affords protection from theft, vandalism, inadvertent human and animal exposure, rain and wind. It shall be managed so as not to provide a breeding place or food for insects or rodents, and not generate noxious odors.

Considerations should be given as to the short term and long term storage of medical waste such as a dedicated area, limited accessibility, adequate ventilation and refrigeration/freezing to limit microbial growth, putrefaction and odor generation. Excessive storage times that result from malfunction of the primary treatment or disposal system can be circumvented by having a backup system or contingency plans.

VII. Transportation of Potentially Infectious Biomedical Waste

There are three types of medical waste transport: collection from the immediate generating area and transport to a temporary storage area in the clinical area, transport from a temporary area to a central storage and collection facility, and transport from the facility to a treatment or disposal site.

Collection at the immediate generation site (e.g., clinic rooms, laboratory areas) is usually done by housekeeping personnel. Waste should be collected at least daily, with the exception of sharps containers, and more frequently if necessary to prevent overfilling of containers. This may be done by carrying the closed waste container to the temporary storage area or by collecting the waste from each generating site using a cart or large trash container on wheels. Medical waste carts are usually dedicated for this purpose and are identified by color coding or labeling.

Packaged medical wastes are usually transported from the temporary storage site in the generating clinic area to the central collection and storage area using carts. Carts should be washable, properly color coded or labeled, and leak proof.

Permitted commercial transporters are commonly used to haul medical waste off-site for treatment and disposal. Trucks are the most common type of vehicle used to pick up and transport medical waste. These trucks should be dedicated to hauling medical waste only, and they should be closed and leak proof. Regardless of the type and size of the vehicles used to haul medical waste, licensure and compliance for transport of medical waste must meet both state and federal Department of Transportation regulations. Each facility must assure within the contractual agreement with medical waste transporters that these criteria have been met.

Section 5

Isolation of Potentially Infectious Clients

Section 5: Isolation of Potentially Infectious Clients

I. Identification/Isolation of Potentially Infectious Clients

The facility staff must recognize that in all areas of ambulatory care, clients at different levels of wellness are clustered in common waiting areas. The range of potentially transmissible infections depends on the population served (case mix) and the type of services offered. These are people who may have or may be:

- a) Young, elderly
- b) Pregnant, antepartum
- c) Immunocompromised
- d) Chronic or debilitating diseases
- e) Active or incubating communicable or infectious diseases *and* their escorts, family members and so forth

A high proportion of people, both health care workers and clients, are at risk for airborne or droplet spread of diseases that are enhanced by close quarters, long waiting periods, and movement between clinical areas. In this setting, droplet-borne or airborne disease transmission (e.g., influenza, measles, chickenpox and TB) poses the most difficult challenge in disease prevention. A key factor to minimize the impact of disease transmission within the ambulatory clinic setting is the quick identification and isolation of any individual with a suspected or confirmed infectious disease that can be transmitted by airborne/droplet spread or direct contact from either the health care worker or the general clinic population.

Ambulatory clinic facilities should utilize specific strategies to control the spread of infectious diseases pertinent to the setting. Any isolation and precaution system implemented must be epidemiologically sound and user friendly. The fundamental components of a facility-specific isolation and precautions protocol should include: hand hygiene; use of barriers (e.g., gloves, gowns and face protection); patient placement (i.e., waiting rooms, examination rooms); and equipment and cleaning.

II. Personnel Training

All health care personnel should be provided with continuing education regarding the epidemiology, modes of transmission, diagnosis and means of preventing the spread of communicable diseases, in accordance to their level of responsibility in preventing health care associated infections. The staff should also be aware of the precautionary measures to implement in the health care setting according to the disease exposure.

In addition to practicing Standard Precautions (See Chapter 2), the employee should be aware of additional precautions designed only for the care of specified patients. These additional "Transmission-Based Precautions" (also known as "Expanded Precautions" – see Table 3) are for patients known or suspected to be infected by potentially transmissible pathogens spread by airborne or droplet route or by contact with dry skin or contaminated surfaces. Transmission-Based Precautions are designed for patients documented or suspected to be infected with highly transmissible pathogens for which additional precautions beyond Standard Precautions are needed to interrupt transmission in the clinical setting. There are three types of Transmission-Based or Expanded Precautions: Airborne Precautions, Droplet Precautions, and Contact Precautions. They may be combined for diseases that have multiple routes of transmission. When used either singularly or in combination, they are to be used in addition to

Standard Precautions.¹ See Common Communicable Diseases in Ambulatory Settings (Table 2) for type of isolation/precautions recommended according to disease.

A. Airborne Precautions: Designed to reduce the risk of airborne transmission of infectious agents. Airborne transmission occurs by dissemination of either airborne droplet nuclei (small-particle residue [5 µm or smaller in size] of evaporated droplets that may remain suspended in the air for long periods of time) or dust particles containing the infectious agent. Microorganisms carried in this manner can be dispersed widely by air currents and may be inhaled by or deposited on a susceptible host within the same room or over a longer distance from the source patient, depending on environmental factors; therefore, special air handling and ventilation are required to prevent airborne transmission. Airborne Precautions apply to patients known or suspected to be infected with potentially transmissible pathogens that can be spread by the airborne route.

B. Droplet Precautions: Designed to reduce the risk of droplet transmission of infectious agents. Droplet transmission involves contact of the conjunctivae or the mucous membranes of the nose or mouth of a susceptible person with large-particle droplets (larger than 5 µm in size) containing microorganisms generated from a person who has a clinical disease or who is a carrier of the micro-organism. Droplets are generated from the source person primarily during coughing, sneezing, or talking and during the performance of certain procedures such as suctioning. Transmission via large-particle droplets requires close contact between source and recipient persons, because droplets do not remain suspended in the air and generally travel only short distances, usually 3 feet or less, through the air. Because droplets do not remain suspended in the air, special air handling and ventilation are not required to prevent droplet transmission. Droplet Precautions apply to any patient known or suspected to be infected with potentially transmissible pathogens that is spread by infectious droplets.

C. Contact Precautions: Designed to reduce the risk of transmission of potentially transmissible microorganisms by direct or indirect contact. Direct-contact transmission involves skin-to-skin contact and physical transfer of microorganisms to a susceptible host from an infected or colonized person, such as occurs when personnel perform patient-care activities that require physical contact. Direct-contact transmission also can occur between two patients (e.g., by hand contact), with one serving as the source of infectious microorganisms and the other as a susceptible host. Indirect-contact transmission involves contact of a susceptible other as a susceptible host. Indirect-contact transmission involves contact of a susceptible host with a contaminated intermediate object, usually inanimate, in the patient's environment. Contact Precautions apply to specified patients known or suspected to be infected or colonized (presence of microorganism in or on patient but without clinical signs and symptoms of infection) with epidemiologically important microorganisms than can be transmitted by direct or indirect contact.

Implementing infection control procedures can prevent the spread of communicable diseases. When a client with respiratory symptoms presents to the clinic facility or outpatient office, there are numerous contact points at which opportunities arise for transmission, including the registration desk, client waiting room, clinical service areas and during movement/transport within the facility. Prevention must begin at the first point at which a person with suspect infectious conditions encounters the healthcare system. Personnel should be trained to ask clients about respiratory symptoms and be familiar with procedures to follow when clients are symptomatic.

¹ Public Health Service, US Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, Georgia. Adapted from Garner JS, Hospital Infection Control Practices Advisory Committee. Guideline for isolation precautions in hospitals. *Infect Control Hosp Epidemiol* 1996;17:53-80, and *Am J Infect Control* 1996;24:24-52, updated February 1997.

As the infected client (or an infected person accompanying the client) waits for care, other persons in the waiting area could be exposed. Steps for preventing exposures may include:

- Posting visual alerts or signs at the entrance to facilities or at the reception or registration desk instructing clients to immediately report symptoms of a respiratory infection and to use “Respiratory Hygiene/ Cough Etiquette” as outlined on page 86.
- Whenever possible, placement without delay in an examination room limits the number of exposed individuals in the common waiting area. Provide separate sick and well client waiting areas
- Creating physical barriers between clients and triage/reception personnel may further reduce the risk of exposure.

Procedure

1. All staff in the clinic should have a basic knowledge of the common communicable diseases that may be present in the clinical setting and be able to implement appropriate isolation and precautionary measures. (See Table 2 for listing of common communicable diseases in ambulatory settings.)
2. Triage and Interventions:
When a client who is suspected of having an infectious illness comes to the clinic, the nurse in charge should be notified, and the client should be taken out of the waiting room immediately and put in an exam room or office with the door closed away from other clients.
Disposable Kleenex tissues should be placed in waiting areas, front offices, or registration areas to offer to clients who are actively coughing and sneezing.
3. Whenever possible, these clients should be seen immediately or moved to an exam room with the door closed. Instruct the client to cough into a tissue or mask the client with a surgical mask.
4. Unless absolutely necessary, schedule clients who are immunosuppressed, or who have a fever or rash, at a time when very few clients are attending clinic.
5. Do not transport the infectious client unnecessarily throughout the clinic facility. Visitors and health care staff should not enter the room unless they have been vaccinated or have previous history of the disease.
6. If the client must be transported to different clinic areas, the client must be masked (and the transporter should be immune).

Key Points

This information should be included as part of the employee’s orientation program.

It is not expected that clinic staff diagnose illness, but rather that they be aware of indications that the client may be infectious. It is particularly important to be aware of persons with rash-associated illness in maternity clinics or facilities that hold maternity clinics. Clerical and other support staff should tell the nurse in charge if they suspect a client is infectious.

This strategy will help to minimize the risk of infectious disease exposure to these client populations.

Be sure to notify any receiving departments or clinical service areas so that immune personnel can be selected to perform any tasks involving the client.

Procedure

7. When the client leaves the room, wash all horizontal surfaces (e.g., examination table, countertops, etc.) with a detergent or disinfectant.
8. It is also important that the Nursing Supervisor is aware of:
 - a. enforcement of work restrictions for health care personnel who are infected or are incubating communicable diseases and
 - b. identification of non-immune health care personnel at risk for communicable diseases.
9. In home care, the health care worker should identify high-risk persons who would benefit from being removed from the home or who should be prohibited from visiting as long as the patient is infectious (e.g., active pulmonary tuberculosis).

Key Points

If no precautions are taken against such diseases such as measles or varicella, it may be appropriate to leave the door closed and not use room for 2 to 4 hours after the client leaves.

Health care personnel who are exposed to a communicable disease and/or are considered “non-immune” should notify the Nursing Supervisor in the event that further intervention is warranted.

Segregation of infected persons during the communicable phase of the illness may be beneficial for prevention of household transmission.

III. Collection of Sputum in the Clinic

Collection of sputum in clinics shall be done in a way to minimize possible exposure of staff and clients.

Procedure

1. Sputum collection should always be done in a room that is well-ventilated. Ideally, the room should be ventilated to the outside of the building.
2. Special areas are to be designated for this purpose. Ultraviolet (UV) lights should be placed in the room and used during and after sputum collection. In addition, if the room has a window that can be opened, it should be opened during collection.
3. If neither UV radiation nor adequate ventilation to the outside is available in the facility or other location, sputum collection may be done outdoors.
4. Follow the manufacturer’s recommendations for use of the sputum-collection equipment.
5. Be sure to give the client full instructions or any necessary information on collecting the specimen before proceeding. The client should be in the room alone when the sputum is collected. It is important, however, to check on the client to be sure that the sputum is being collected correctly and to see if the client has any questions.

Key Points

If used infrequently, the UV light must be dusted before each collection. Ultraviolet lights are remarkably effective in killing airborne tubercle bacilli and serve as a supplement to ventilation in cleaning the air. Airflow in the room should be gentle enough to not cause dust dispersal. The direction of the airflow should be away from occupied areas and air intakes.

It is imperative to disinfect any non-disposable parts of the sputum collection equipment.

Encourage clients to come in for sputum collection in the morning, as this will increase the likelihood of obtaining a good specimen from a more productive cough.

Procedure

6. TB clients, if not known to be sputum negative, who are coughing in the clinic should always be given tissues and asked to cover their mouths when coughing. Alternatively, they should be given masks.

Key Points

Do not schedule a TB clinic immediately prior to or simultaneously with clinics that may serve known immunocompromised clients.

The OPH Tuberculosis Division is reviewing information on the efficacy of masks and particulate respirators. Check with the regional TB program manager for current recommendations.

IV. Respiratory Hygiene/ Cough Etiquette

Because airborne infections spread primarily via respiratory droplets, practicing respiratory etiquette is a simple intervention that confines infectious material at its source. Respiratory hygiene / cough etiquette includes:

- Instructing persons (health care staff, patients, visitors) with symptoms of a respiratory infection to cover their nose and mouth with a tissue when coughing or sneezing.
 - ❖ Provide tissues and no-touch receptacles (i.e., waste container with pedal-operated lid or uncovered waste container) for used tissue disposal
- Making hand hygiene products and tissues available in waiting areas.
 - ❖ Provide conveniently located dispensers of alcohol-based hand rub
 - ❖ Provide soap and disposable towels for hand washing where sinks are available
- Offering masks to symptomatic clients
 - ❖ Provide masks and separate persons with symptoms of respiratory infection from other susceptible clients

During periods of increased respiratory infection in the community, offer masks to persons who are coughing. Either procedure masks (i.e., with ear loops) or surgical masks (i.e., with ties) may be used to contain respiratory secretions; respirators are not necessary. Encourage coughing persons to sit at least 3 feet away from others in common waiting areas. Health care personnel who have a respiratory infection are advised to avoid patient contact when they are actively coughing and producing respiratory secretions. Some facilities may wish to institute this recommendation year-round.

V. Isolation and Precaution Review

1. Reinforce basic infection control practices in healthcare facilities and among healthcare personnel.
2. Early detection and isolation of clients who may be infectious are the most important interventions to prevent the spread of communicable diseases in a healthcare setting. Personnel should be trained to ask clients (and accompanying visitors) about respiratory symptoms.

3. Reinforce education on the recommended procedures for Standard, Contact, and Airborne Infection Isolation Precautions.
4. Educate staff about the importance of strict adherence to and proper use of standard infection control measures, especially hand hygiene (i.e., hand washing or use of an alcohol-based hand rub).
5. Ensure that personnel have access to appropriate PPE, instructions and training in PPE use, and respirator fit-testing as circumstances may arise.
6. Educate the staff and clients in the implementation of isolation and precaution procedures including Respiratory Etiquette procedures.

Table 2. Common Communicable Diseases in Ambulatory Settings[†]

<u>Infection/Condition</u>	<u>Type of Isolation/Precaution*</u>
♦ Acquired immune deficiency syndrome (AIDS)	S
♦ Adenovirus infection in infants and young children	D,C
♦ Anthrax	S
♦ Antibiotic resistant microorganisms (Known)	C
♦ Bacterial meningitis	
Viral	S
<i>H. influenzae</i>	D
<i>N. meningitides</i>	D
♦ Chickenpox	A,C
♦ Conjunctivitis	S
♦ Cytomegalovirus infection, neonatal or immunosuppressed	S
♦ Diphtheria	C,D
♦ Enteroviral infections, infants & young children	
Hand, foot and mouth diseases	S
♦ Gastroenteritis	S
♦ Giardiasis	S
♦ Gonorrhea	S
♦ Hepatitis, Type A, B, C, Viral	S
♦ <i>Herpes zoster</i> (shingles)	
Disseminated	A,C
Localized	S
♦ Human Immunodeficiency virus (HIV)	S
♦ Impetigo	C
♦ Influenza	D
♦ Lice	C
♦ Measles (rubeola)	A
♦ Mumps	D
♦ Parvovirus B19 (Fifth Disease)	D
♦ Pertussis	D
♦ Rashes of unknown source	C,D
♦ Respiratory diseases, infants and young children	C
♦ Ringworm	S
♦ Rubella	D
♦ Scabies	C
♦ Staphylococcal disease (<i>S. aureus</i>)	C,S
♦ Streptococcus, Group A (e.g., strep throat)	D
♦ Syphilis	S
♦ Tuberculosis, pulmonary	A
♦ Upper respiratory infections (especially with fever and productive cough)	A,D

[†] Adapted from Garner, J.S. The Hospital Infection Control Practices Advisory Committee. Guidelines for Isolation precautions in hospitals. Am J Infect Control, 1996; 24:24-52.

* Isolation precautions: C - Contact precautions; D - Droplet precautions; A - Airborne precautions; S - Standard precautions

Table 3. Recommendations for Application of Standard and Expanded Precautions for Patient Care in All Healthcare Settings

Refer to Table 2 – Common Communicable Diseases in Ambulatory Settings for pathogen-specific recommendations, page 87

A. STANDARD PRECAUTIONS: Assume that every person is potentially infected or colonized with an organism that could be transmitted in the health care setting.					
Patient Placement	Use of PPE	Patient Transport	Hand Hygiene	Patient Equipment & Environmental Measures	Discontinue Expanded Precautions
<p>Place patients in an examination room if the patient is at an increased risk of transmission, is likely to contaminate the environment and does not maintain appropriate hygiene, or is at increased risk of acquiring infection or develop adverse outcome following infection.</p> <p>If the individual is coughing, instruct patient and accompanying individuals to follow recommendations for Respiratory Hygiene/ Cough Etiquette.</p>	<p>Gloves: for touching blood, body fluids, secretions, excretions, contaminated items; for touching mucous membranes and non-intact skin.</p> <p>Mask, eye protection & face shield: wear during procedures and patient care activities likely to generate splashes or sprays of blood, body fluids, and secretions.</p> <p>Gown: wear gown during procedures and patient care activities when contact of clothing/exposed skin with blood/body fluids, secretions, and excretions is anticipated.</p>		<p>Observe hand hygiene practices after touching blood, body fluids, secretions, excretions, contaminated items; immediately wash hands after removing gloves; between patient contacts.</p>	<p>Equipment should be handled in a manner that prevents transfer of microorganisms to others and to the environment; wear gloves if visibly contaminated; perform hand hygiene.</p> <p>Develop procedures for routine care, cleaning, and disinfection of environmental surfaces, especially frequently touched surfaces in patient care areas.</p> <p>Needles and sharps should not be re-capped, bent, or broken and used needles should not be hand manipulated. Place used sharps in a puncture - resistant container. Use safety features if available.</p>	<p>Standard Precautions should always be observed and maintained at all times.</p> <p>Expanded Precautions remain in effect for limited periods (while the risk of transmission of the infectious agent persists or for the duration of the illness) for which the duration will be indicated by the known or natural history of the infectious process and its treatment or evidence of eradication of the pathogen.</p>

B. EXPANDED PRECAUTIONS

1. Contact Precautions: Decisions for Contact Precautions are determined on a case-by-case basis and should balance the infection risk to other patients in the clinical and waiting areas with the potential adverse psychosocial impact on the infected or colonized patient.

Patient Placement	Use of PPE	Patient Transport	Hand Hygiene	Patient Equipment & Environmental Measures	Discontinue Expanded Precautions
Place patients who require Contact Precautions in an examination room or cubicle as soon as possible.	<p>Gowns: wear gowns when anticipating that clothing will have direct contact with patient or potentially contaminated environmental surfaces or items. Remove gown and observe hand hygiene after completion of the patient’s care or tasks and/or before leaving the patient’s room.</p> <p>Gloves: wear gloves according to Standard Precautions and whenever touching the patient’s intact skin or surfaces and articles in close proximity to patient (i.e., medical equipment).</p>	Limit transport and movement of patients outside of the designated room to medically necessary purposes. Ensure infected or colonized areas of the patient are contained or covered.	Observe hand hygiene practices and wash hands immediately after removal of gowns and gloves.	<p>Manage patient equipment according to Standard Precautions. Use disposable equipment whenever possible or implement patient-dedicated use of non-critical equipment to avoid sharing between patients. If use of common equipment is unavoidable, clean and disinfect before use on another patient.</p> <p>Home Care: Limit the amount of patient care equipment brought into the home. When possible, leave patient care equipment in the home until discharge from home care services. If non-critical patient care equipment (e.g., stethoscope) cannot remain in the home, clean and disinfect items before taking them from the home or place the reusable item in a plastic bag for transport and subsequent cleaning and disinfection.</p>	<p>Discontinue Contact Precautions after signs and symptoms have resolved or according to pathogen-specific recommendations.</p> <p>Standard Precautions should be observed and maintained at all times.</p>

B. EXPANDED PRECAUTIONS					
2. Droplet Precautions: Droplet Precautions are intended to reduce the risk of droplet transmission of infectious agents from close respiratory or mucous membrane contact (e.g., ≤ 3 feet) with large particle droplets (larger than 5 μm in size).					
Patient Placement	Use of PPE	Patient Transport	Hand Hygiene	Patient Equipment & Environmental Measures	Discontinue Expanded Precautions
<p>Place patients who require Droplet Precautions in an examination room or cubicle as soon as possible. Avoid placing patients nearby the clinical or waiting areas, especially with other clients who may be at increased risk of infection (e.g., immunocompromised patients)</p> <p>Instruct patients and accompanying individuals to follow recommendations for Respiratory Hygiene/ Cough Etiquette.</p>	<p>Mask: a mask should be worn for close patient contact. In the event of contact with a suspected SARS or Avian influenza patient, wear both eye protection (e.g., goggles or face shield) and respiratory protection (e.g., recommended N95 or higher mask).</p>	<p>Limit transport and movement of patients outside of the designated room to medically necessary purposes.</p> <p>Instruct patient to wear a mask and follow Respiratory Hygiene/ Cough Etiquette during transport. (No mask is required for the person handling transport.)</p>	<p>Observe hand hygiene practices as recommended in the guidelines for Standard Precautions.</p>	<p>Manage patient equipment according to Standard Precautions.</p>	<p>Discontinue Contact Precautions after signs and symptoms have resolved or according to pathogen-specific recommendations.</p> <p>Standard Precautions should be observed and maintained at all times.</p>
B. EXPANDED PRECAUTIONS					
3. Airborne Infection Isolation (AII) Precautions: Develop systems (e.g., triage, signs) to identify and segregate patients with known or suspected infections that require AII precautions as soon as possible after entry into a health care setting (e.g., measles, varicella).					
Patient Placement	Use of PPE	Patient Transport	Hand Hygiene	Patient Equipment & Environmental Measures	Discontinue Expanded Precautions
<p>Place a mask on the patient immediately until the patient has been placed in an AII room or in an examination room farthest distance from other clinical rooms (preferably near the end of the ventilation circuit and place a portable HEPA filter in the room)*.</p> <p>Once patient vacates the room, the room should remain vacant for the</p>	<p>Mask: wear a fit-tested, NIOSH approved respiratory protection (N95 respirator or higher) when entering the room or home of a patient who may have suspected or confirmed: 1) pulmonary or laryngeal tuberculosis or draining tuberculous skin lesions or 2) smallpox (vaccinated and unvaccinated), SARS, and viral hemorrhagic fevers.</p>	<p>Restrict susceptible health care personnel from entering the room of patients with suspected measles, varicella or smallpox if other immune health care personnel are available.</p> <p>Limit transport and movement of patients outside of the designated room to medically necessary purposes.</p>	<p>Observe hand hygiene practices as recommended in the guidelines for Standard Precautions.</p>	<p>Manage patient equipment according to Standard Precautions.</p>	<p>Discontinue AII Precautions after signs and symptoms have resolved or according to pathogen-specific recommendations.</p> <p>For additional precautions for preventing transmission of tuberculosis in health care settings, refer to the CDC’s “Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities”.</p>

Patient Placement	Use of PPE	Patient Transport	Hand Hygiene	Patient Equipment & Environmental Measures	Discontinue Expanded Precautions
<p>appropriate time according to the number of air exchanges per hour, usually one hour, to allow for a full exchange of air.</p> <p>*HEPA filters may not be readily available in ambulatory facilities. Implementation of this recommendation should be discussed further in consideration with bioterrorism activity recommendations.</p>	<p>Wear nose/mouth protection upon entering the room or home of a patient known or suspected of having measles, varicella, or disseminated zoster for consistency and because of difficulties in establishing definite immunity in all health care personnel.</p> <p>NOTE: Respiratory protection is recommended even when health care personnel have had a “documented take” after smallpox vaccination due to the risk of a genetically engineered virus against which the vaccine may not provide protection, or of exposure to a very large viral load.</p>	<p>If transport or movement outside of the room is necessary, place a surgical mask on the patient. For patients with skin lesions caused by <i>M. tuberculosis</i>, varicella or smallpox, cover the patient to prevent aerosolization or contact with the infectious agent present in skin lesions.</p> <p>For persons transporting the patient, wear respiratory protection.</p>			<p>Standard Precautions should be observed and maintained at all times.</p>

C. OTHER CONSIDERATIONS: All healthcare settings constitute important environments for the emergence and transmission of antimicrobial resistant microbes (also known as multidrug resistant organisms – MRDOs), although it has been well documented in acute care facilities. Patient-to-patient transmission in healthcare settings, usually via hands of healthcare personnel has been a major factor accounting for the increase in MDRO incidence and prevalence.

Patient Placement	Use of PPE	Patient Transport	Hand Hygiene	Patient Equipment & Environmental Measures	Discontinue Expanded Precautions
<p>Observe Standard Precautions during all patient encounters in all settings where healthcare is delivered under the assumption that any patient could be colonized or infected with an MDRO.</p>	<p>No recommendations for routine use of gloves and/or gowns to prevent MDRO transmission in ambulatory or home settings.</p>		<p>Observe hand hygiene practices as recommended in the guidelines for Standard Precautions.</p>	<p>Follow recommended routine cleaning, sterilization and disinfection procedures for maintaining patient care areas and critical and non-critical devices and equipment.</p>	<p>Standard Precautions should be observed and maintained at all times.</p>

Patient Placement	Use of PPE	Patient Transport	Hand Hygiene	Patient Equipment & Environmental Measures	Discontinue Expanded Precautions
<p>On a case-by-case basis, Contact Precautions should be implemented for patients known to be infected or colonized with target MDROs when the nature of the HCW-patient interaction or the risk of acquisition and associated adverse outcomes to other patients in the areas indicates a need to intensify use of barriers to prevent transmission (e.g., MDRO patient with uncontrolled secretions, stool incontinence) or immunocompromised patients are in the same clinic area.</p>				<p>Home Care: Limit the amount of patient care equipment brought into the home. When possible, leave patient care equipment in the home until discharge from home care services. If non-critical patient care equipment (e.g., stethoscope) cannot remain in the home, clean and disinfect items before taking them from the home or place the reusable item in a plastic bag for transport and subsequent cleaning and disinfection.</p>	

Summarized from CDC Draft: Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings – Recommendations of the Healthcare Infection Control Practices Advisory Committee, 2004.

Section 6

Storage and Handling of Equipment, Supplies, and Biological Specimens

Section 6. Storage and Handling of Equipment, Supplies, and Biological Specimens

I. Laboratory Specimen Collection and Standard Precautions

It is important to recognize the infectious potential of any biologic specimen and to use standard precautions when handling specimens or other material that comes in contact with specimens to prevent HBV, HIV, or other infectious diseases. Standard precautions should be used at all times when handling client samples and related materials. All personnel should wear protective clothing including laboratory coats and gloves when handling laboratory specimens. Face shields may be worn at the discretion of the individual, if splashing may occur while handling the specimen. WASH hands immediately after handling the specimens.

Specimens that warrant the use of standard precautions are:

- a. Blood and blood products, serum, plasma – these are the most important source of HIV and HBV infections
- b. Saliva, semen and vaginal secretions – these are known to contain HIV and HBV virus and have been epidemiologically implicated as a means of disease transmission, however, they have not been shown to cause transmission from occupational exposures
- c. Tissue, CSF, synovial fluid, peritoneal fluid, pleural fluid, amniotic fluid and pericardial fluid – the risk of occupational exposure is not known, however, it is considered to be real
- d. Concentrated HIV or HBV viral cultures
- e. Any specimen of any type that contains visible traces of blood

II. Biologic Specimen Storage, Handling, and Transport

The purpose of proper preservation, storage and transportation of laboratory specimens is to:

1. Ensure that the integrity of the biologic sample is not compromised;
2. Assure that all biological materials shipped to the laboratory that could contain etiologic agents are packaged, handled and transported in a manner that minimize the potential for leakage and possibly contamination of the environment or exposure to those handling packages in transit;
3. Confirm shipment, delivery, and receipt of those packages in an appropriate and timely manner; and
4. Provide information necessary to determine the correct handling, disposal or treatment of packages that may have broken or leaked in transit.

Submitters are responsible for shipping specimens in conformity with all safety and labeling regulations. Be aware that many commercial carriers no longer accept specimens. When using any carrier, including the inter-city bus service or the U.S. Postal Service, specimens should be packaged to avoid leakage or breakage. All specimen mailing containers supplied by the bureau must meet U.S. Postal Service requirements. Specimens must be packed in triple containment with sufficient absorbent material enclosed to absorb the entire volume of liquids. Personnel who package and ship these specimens must be concerned with the protection and safety of persons who handle the specimen after packaging and shipment.

The OPH laboratory provides specimen mailing containers to physicians and regional public health laboratories upon request. The containers are the property of the state and must not be used for any purpose other than the shipment of specimens to a state health laboratory. Each container may contain specimen identification forms and special instructions, if applicable, or a “master copy” form should be used. The completed forms must accompany the specimen to avoid delays. **The patient’s name on the specimen identification form and on the specimen must be the same. If they are not the same, the specimen will not be tested. Please be sure that the laboratory acquisition slips that accompany the specimens are packed separate from the specimen or use a biohazard bag so that the paperwork is not in contact with the specimen (s) in the event of breakage or leakage from the collected sample during transport.**

Procedure

1. Specimens of blood or OPIM must be placed in containers which prevent leakage during collection, handling, storage, processing, or transport.
2. Be sure to add enough absorbent material to absorb the entire contents of the primary container in case of breakage or leakage.
3. The outer container used for storing or shipping specimens must be color coded or labeled with the BIOHAZARD symbol and word.
4. All procedures involving blood or OPIM must be performed in such a manner as to minimize splashing, spraying, spattering, and the creation of aerosols of these materials.
5. Mouth pipetting/suctioning of blood or OPIM is prohibited.

Key Points

Triple containers, required by postal regulations, are supplied by the Laboratories. All containers must be closed tightly prior to shipping the specimens.

The OSHA Bloodborne Pathogens standard states that the BIOHAZARD label is to be affixed to all tertiary containers of specimens leaving the facility for testing. The BIOHAZARD label is not placed on outer containers sent through U.S. mail. Postal regulations have priority over OSHA regulations in this case. Contact other carriers for their specific protocols.

Procedure

6. Specimens must also be in leakproof containers separate from vaccines or other biologicals during storage in the refrigerator. The containers should be disinfected at least once a week with a 1:10 solution of chlorine bleach or other EPA-registered hospital disinfectant.
7. Dried blood spots collected on the filter paper laboratory forms used in newborn screening for the Genetics Program must also comply with carrier packaging requirements and labeled with the BIOHAZARD symbol and word. The package should also be marked "Dried Clinical Specimen".

Key Points

Remember to list these tasks as part of the written schedule for clinic housekeeping.

A follow-up confirmatory test that may be required by the Genetics Program usually involves the collection of whole blood or sera. These specimens must also abide by all shipping and transport regulations. Refer to the OPH Genetics Program for further instructions.

Regulations, effective December 17, 1989, altered the requirements for the submission of diagnostic specimens through the U.S. Postal Services system. The primary changes are:

1. Clinical specimens, including blood specimens, that "contain or can reasonably be expected to contain an etiological agent" must be transported in a triple container (see Diagram on page 99);
2. A limit of 50 ml total volume per outside shipping unit or container has been established;
3. Container must contain sufficient absorbent materials to absorb the entire content of primary container in case of breakage or leakage; and
4. Outside shipping container must be properly labeled.

III. Equipment and Supplies

All equipment and supplies, including those in boxes, will be stored in properly designated storage areas.

Procedure

1. Unpack supplies when received and place them on shelves or in cabinets immediately.
2. Keep supplies off the floor to avoid contamination from soil and bacteria.

Key Points

As an aid to rotating stock supplies, place the new supplies towards the back of the shelf and move the older supplies towards the front.

A. Sterile Equipment

All expiration dates on sterile equipment will be checked routinely. Outdated equipment and supplies should be removed from the inventory and either be disposed or returned to the originating source (if allowed) for exchange.

B. Cotton Balls

Cotton balls will not be stored in alcohol unless they are to be used that day.

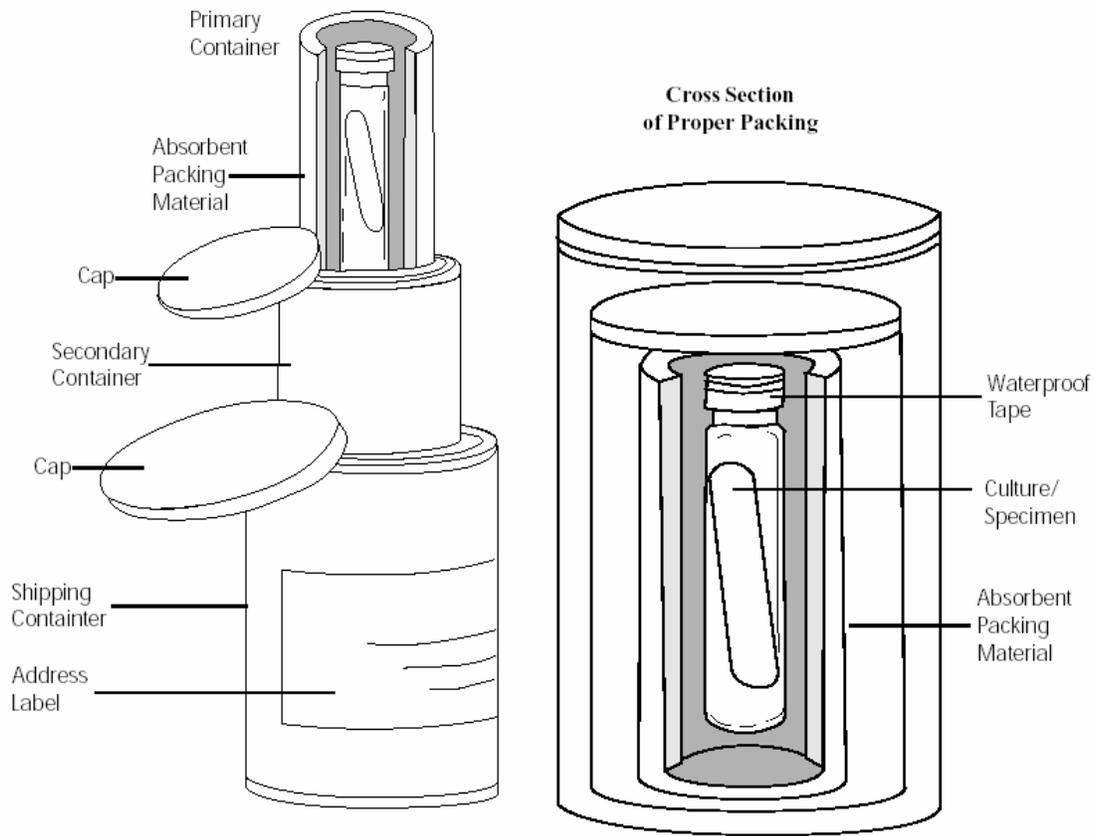
Procedure

1. Cotton balls are to be soaked with 70% alcohol at the time they are used. Only a one-day supply should be put into a container and moistened with alcohol. Discard the leftover ones at the end of the day. Cotton ball and alcohol containers should be kept clean.

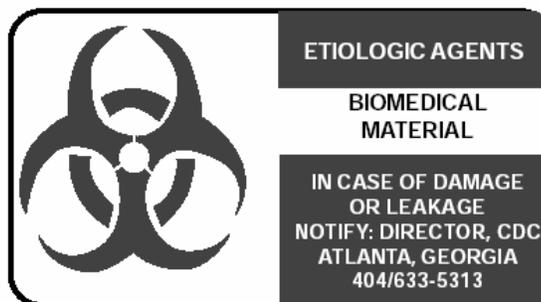
Key Points

Unless the solution is changed daily, the alcohol begins to lose its effectiveness. The moist cotton can then become a breeding ground for certain organisms. Alcohol is the most convenient chemical germicide for use in this situation, but other germicides may be used, provided they are chemically compatible with the surface to be wiped or are not too irritating to the skin.

Packaging And Labeling of Etiologic Agents



(Red on White)



Section 7

Miscellaneous Activities in Clinic Settings

Section 7: Miscellaneous Activities in Clinic Settings

I. Infection Control and Safe Injection Practices

The improper use of needles and syringes and contamination of multidose medication vials can result in the transmission of bloodborne pathogens (e.g., hepatitis B virus {HBV} and human immunodeficiency virus {HIV}) and other infectious agents from patient-to-patient. Bacteria can survive in and have been transmitted to patients through contaminated multidose vials and syringes. Outbreaks have been associated with health care workers not adhering to fundamental principles related to safe injection practices and breaches in aseptic techniques. The following infection control principles should be adhered to by health care providers and all persons who administer parenteral substances by injection. The same principles should be used when applying topical products from a multidose container.

<u>Procedure</u>	<u>Key Points</u>
1. Use a sterile, single-use, disposable needle and syringe for each injection and discard intact in an appropriate sharps container after use. The same recommendation applies to the use of a swab and multidose topical applications (e.g., Trichloroacetic acid {TCA} used for treatment of genital warts commonly caused by human papillomaviruses {HPV}).	All hypodermic needles, as well as lumens of syringes used to administer parenteral substances, should be sterile. Use aseptic technique to avoid contamination of sterile injection equipment and medication. A needle/syringe or swab that has been previously used to inoculate or topically treat a patient is considered contaminated and should not be re-used to aspirate medication or vaccine from a multidose vial or re-dip the swab in the multidose container if any of the contents of the vial will subsequently be administered to another patient.
2. Use single dose medication vials, prefilled syringes, and ampules when possible.	Do not administer medications from single-dose vials to multiple patients or combine leftover contents for later use.
3. If multidose vials or bottles of liquid medication are used, restrict them to a centralized medication area or for single patient use. NEVER re-enter a vial with a needle/syringe or swab used on one patient if that vial will be used to withdraw medication for another patient.	Store vials or bottles of liquid medication in accordance to manufacturer's recommendations and discard if sterility is compromised.

These principles should be reviewed with frequent in-service education for health care staff and their practices should be monitored as part of the institutional oversight process.

II. Laundry

Clinic smocks, laboratory coats, or other reusable personal protective equipment made of cloth will be cleaned and repaired at no cost to the employee. The method of handling, transporting and laundering of soiled textiles are determined by organizational policy and any applicable regulations.

Key Points

Procedure

1. Reusable personal protective equipment made of cloth will be laundered and repaired, as needed, at no cost to the employee.
2. Employees must remove their clinic coats or smocks before leaving the clinic or lab area.
3. A container that is labeled with the BIOHAZARD symbol and word, or color coded, must be available to collect clothing contaminated with blood or OPIM.
4. Employees will use universal precautions when handling contaminated laundry.
5. If using a contract service for laundry, BIOHAZARD labeling and color-coding provisions will apply.

If the contaminated clothing is wet and leakage is possible, the container must be leakproof.

Gloves and other personal protective equipment will be necessary when handling contaminated laundry.

When laundering occurs outside of a health care facility, the clean items must be packaged to prevent contamination with outside air or construction dust that could contain infectious fungal spores that are at risk for immunocompromised patients.

III. Toys

All toys provided for patients to play with will be washable and will be kept clean.

Procedure

1. Toys should be cleaned with soap and water and dried as needed during the course of the day.
2. At the end of each day, all toys that have been used will be washed with soap and water, rinsed, and dried.
3. Toys that are used in the clinics must be safe, easily maintained, and kept clean. They must be made of impervious materials.
4. Throughout the day, make sure that clinic toys do not clutter the entrances, exits, hallways, and walkways.

Key Points

Do not use toys that can't be washed. Be sure to include this cleaning process in the written schedule for routine cleaning and housekeeping.

Avoid toys with sharp edges, lead-based paints, beads, heavy hard balls that can be thrown, cloth toys, or toys with small removable parts. If buying toys, note the recommended age suitability of the toy on the container and use accordingly in waiting or examining rooms.

IV. Food

Employee food will be stored separately from vaccines, biologicals, medications, and specimens.

Procedure

1. Food and biologicals will not be stored in the same refrigerator. Food cannot be stored in a refrigerator along with specimens.
2. Food shall not be eaten in the clinic or laboratory areas.

Key Points

The following activities are also not permitted in the patient-treatment areas or laboratory areas:

- smoking or drinking,
- applying cosmetics or lip balm, or
- handling contact lenses without washing hands.

V. Client Loaner Equipment

Any equipment that is distributed through a client loaner program for home or field use (e.g., breast pumps) should be visibly inspected and cleaned/disinfected with an appropriate cleaning/disinfecting agent as well as be inspected for proper functionality between client usage. Review and refer to the manufacturer's recommendations on the proper handling, storage and terminal cleaning of equipment used for client purposes. It is recommended that any returned equipment be placed in a single plastic bag for transport to the reprocessing location.

VI. First Aid and Safety for Chemical Exposures

All health care facilities should ensure a safe workplace for employees with regards to occupational exposures and hazards to chemicals such as disinfectants, commercial/industrial cleaning agents, liquid topical medications or other potential corrosive agents. Each agency should evaluate the potential hazards of chemicals present in the workplace and communicate information concerning hazards and appropriate protective measures to employees. Essential components of a written communication plan should include the provisions for container labeling, a chemical inventory and the associated MSDSs that include information on material identification; ingredients and hazards; physical data; fire and explosion data; reactivity data; health hazard, spill, leak and disposal precautions; and comments as well as an annual employee training program. Exposure control and protection measures should be targeted to chemical exposures with the potential for causing eye and skin irritation and tissue corrosion.

Examples of measures include:

- 1) Wear suitable protective clothing, gloves and eye/face protection in preventing eye and skin contact;
- 2) Use chemicals in well ventilated areas;
- 3) Avoid chemical contact with skin, eye and clothing;
- 4) Wash hands thoroughly after handling any chemical substances;
- 5) Safety showers/eye wash stations should be located close to operations that involve frequent use of chemicals;
- 6) If necessary, flush affected areas immediately with large amounts of water; direct water under contaminated clothing while removing the clothing so that any corrosive acid is quickly removed;
- 7) Provide a medical plan for referral for further treatment and follow-up; and
- 8) Have the phone number of the Louisiana Poison Control Center (1-800-256-9822) available for immediate consultation.

Section 8

Appendices*

*** While the references contained in this “Appendices - Section 8” are current as of this manual development, these policies and recommendations may be updated in the future and will need further exploration towards the application to this document.**

APPENDIX A

Disclaimer:

Some of the information in the following appendix may be out of date regarding HIV. For the most up to date information refer to Appendix B



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MMWRTM
MORBIDITY AND MORTALITY
WEEKLY REPORT

*Recommendations
and
Reports*

Inside: Continuing Education Examination

**Updated U.S. Public Health Service
Guidelines for the Management
of Occupational Exposures
to HBV, HCV, and HIV
and Recommendations
for Postexposure Prophylaxis**

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



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Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis

Summary

This report updates and consolidates all previous U.S. Public Health Service recommendations for the management of health-care personnel (HCP) who have occupational exposure to blood and other body fluids that might contain hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV).

Recommendations for HBV postexposure management include initiation of the hepatitis B vaccine series to any susceptible, unvaccinated person who sustains an occupational blood or body fluid exposure. Postexposure prophylaxis (PEP) with hepatitis B immune globulin (HBIG) and/or hepatitis B vaccine series should be considered for occupational exposures after evaluation of the hepatitis B surface antigen status of the source and the vaccination and vaccine-response status of the exposed person. Guidance is provided to clinicians and exposed HCP for selecting the appropriate HBV PEP.

Immune globulin and antiviral agents (e.g., interferon with or without ribavirin) are not recommended for PEP of hepatitis C. For HCV postexposure management, the HCV status of the source and the exposed person should be determined, and for HCP exposed to an HCV positive source, follow-up HCV testing should be performed to determine if infection develops.

Recommendations for HIV PEP include a basic 4-week regimen of two drugs (zidovudine [ZDV] and lamivudine [3TC]; 3TC and stavudine [d4T]; or didanosine [ddI] and d4T) for most HIV exposures and an expanded regimen that includes the addition of a third drug for HIV exposures that pose an increased risk for transmission. When the source person's virus is known or suspected to be resistant to one or more of the drugs considered for the PEP regimen, the selection of drugs to which the source person's virus is unlikely to be resistant is recommended.

In addition, this report outlines several special circumstances (e.g., delayed exposure report, unknown source person, pregnancy in the exposed person, resistance of the source virus to antiretroviral agents, or toxicity of the PEP regimen) when consultation with local experts and/or the National Clinicians' Post-Exposure Prophylaxis Hotline ([PEPline] 1-888-448-4911) is advised.

Occupational exposures should be considered urgent medical concerns to ensure timely postexposure management and administration of HBIG, hepatitis B vaccine, and/or HIV PEP.

An exposure that might place HCP at risk for HBV, HCV, or HIV infection is defined as a percutaneous injury (e.g., a needlestick or cut with a sharp object) or contact of mucous membrane or nonintact skin (e.g., exposed skin that is chapped, abraded, or afflicted with dermatitis) with blood, tissue, or other body fluids that are potentially infectious (16,17).

In addition to blood and body fluids containing visible blood, semen and vaginal secretions also are considered potentially infectious. Although semen and vaginal secretions have been implicated in the sexual transmission of HBV, HCV, and HIV, they have not been implicated in occupational transmission from patients to HCP. The following fluids also are considered potentially infectious: cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. The risk for transmission of HBV, HCV, and HIV infection from these fluids is unknown; the potential risk to HCP from occupational exposures has not been assessed by epidemiologic studies in health-care settings. Feces, nasal secretions, saliva, sputum, sweat, tears, urine, and vomitus are not considered potentially infectious unless they contain blood. The risk for transmission of HBV, HCV, and HIV infection from these fluids and materials is extremely low.

Any direct contact (i.e., contact without barrier protection) to concentrated virus in a research laboratory or production facility is considered an exposure that requires clinical evaluation. For human bites, the clinical evaluation must include the possibility that both the person bitten and the person who inflicted the bite were exposed to bloodborne pathogens. Transmission of HBV or HIV infection only rarely has been reported by this route (18–20) (CDC, unpublished data, 1998).

BACKGROUND

This section provides the rationale for the postexposure management and prophylaxis recommendations presented in this report. Additional details concerning the risk for occupational bloodborne pathogen transmission to HCP and management of occupational bloodborne pathogen exposures are available elsewhere (5,12,13,21–24).

Occupational Transmission of HBV

Risk for Occupational Transmission of HBV

HBV infection is a well recognized occupational risk for HCP (25). The risk of HBV infection is primarily related to the degree of contact with blood in the work place and also to the hepatitis B e antigen (HBeAg) status of the source person. In studies of HCP who sustained injuries from needles contaminated with blood containing HBV, the risk of developing clinical hepatitis if the blood was both hepatitis B surface antigen (HBsAg)- and HBeAg-positive was 22%–31%; the risk of developing serologic evidence of HBV infection was 37%–62%. By comparison, the risk of developing clinical hepatitis from a needle contaminated with HBsAg-positive, HBeAg-negative blood was 1%–6%, and the risk of developing serologic evidence of HBV infection, 23%–37% (26).

Although percutaneous injuries are among the most efficient modes of HBV transmission, these exposures probably account for only a minority of HBV infections among HCP. In several investigations of nosocomial hepatitis B outbreaks, most infected HCP could not recall an overt percutaneous injury (27,28), although in some studies, up to one third of infected HCP recalled caring for a patient who was HBsAg-positive (29,30). In addition, HBV has been demonstrated to survive in dried blood at room temperature on

environmental surfaces for at least 1 week (31). Thus, HBV infections that occur in HCP with no history of nonoccupational exposure or occupational percutaneous injury might have resulted from direct or indirect blood or body fluid exposures that inoculated HBV into cutaneous scratches, abrasions, burns, other lesions, or on mucosal surfaces (32–34). The potential for HBV transmission through contact with environmental surfaces has been demonstrated in investigations of HBV outbreaks among patients and staff of hemodialysis units (35–37).

Blood contains the highest HBV titers of all body fluids and is the most important vehicle of transmission in the health-care setting. HBsAg is also found in several other body fluids, including breast milk, bile, cerebrospinal fluid, feces, nasopharyngeal washings, saliva, semen, sweat, and synovial fluid (38). However, the concentration of HBsAg in body fluids can be 100–1000-fold higher than the concentration of infectious HBV particles. Therefore, most body fluids are not efficient vehicles of transmission because they contain low quantities of infectious HBV, despite the presence of HBsAg.

In serologic studies conducted in the United States during the 1970s, HCP had a prevalence of HBV infection approximately 10 times higher than the general population (39–42). Because of the high risk of HBV infection among HCP, routine preexposure vaccination of HCP against hepatitis B and the use of standard precautions to prevent exposure to blood and other potentially infectious body fluids have been recommended since the early 1980s (43). Regulations issued by the Occupational Safety and Health Administration (OSHA) (2) have increased compliance with these recommendations. Since the implementation of these recommendations, a sharp decline has occurred in the incidence of HBV infection among HCP.

PEP for HBV

Efficacy of PEP for HBV. The effectiveness of hepatitis B immune globulin (HBIG) and/or hepatitis B vaccine in various postexposure settings has been evaluated by prospective studies. For perinatal exposure to an HBsAg-, HBeAg-positive mother, a regimen combining HBIG and initiation of the hepatitis B vaccine series at birth is 85%–95% effective in preventing HBV infection (44,45). Regimens involving either multiple doses of HBIG alone or the hepatitis B vaccine series alone are 70%–75% effective in preventing HBV infection (46). In the occupational setting, multiple doses of HBIG initiated within 1 week following percutaneous exposure to HBsAg-positive blood provides an estimated 75% protection from HBV infection (47–49). Although the postexposure efficacy of the combination of HBIG and the hepatitis B vaccine series has not been evaluated in the occupational setting, the increased efficacy of this regimen observed in the perinatal setting, compared with HBIG alone, is presumed to apply to the occupational setting as well. In addition, because persons requiring PEP in the occupational setting are generally at continued risk for HBV exposure, they should receive the hepatitis B vaccine series.

Safety of PEP for HBV. Hepatitis B vaccines have been found to be safe when administered to infants, children, or adults (12,50). Through the year 2000, approximately 100 million persons have received hepatitis B vaccine in the United States. The most common side effects from hepatitis B vaccination are pain at the injection site and mild to moderate fever (50–55). Studies indicate that these side effects are reported no more frequently among persons vaccinated than among those receiving placebo (51,52).

Approximately 45 reports have been received by the Vaccine Adverse Event Reporting System (VAERS) of alopecia (hair loss) in children and adults after administration of

plasma-derived and recombinant hepatitis B vaccine; four persons sustained hair loss following vaccination on more than one occasion (56). Hair loss was temporary for approximately two thirds of persons who experienced hair loss. An epidemiologic study conducted in the Vaccine Safety Datalink found no statistical association between alopecia and receipt of hepatitis B vaccine in children (CDC, unpublished data, 1998). A low rate of anaphylaxis has been observed in vaccine recipients based on reports to VAERS; the estimated incidence is 1 in 600,000 vaccine doses distributed. Although none of the persons who developed anaphylaxis died, anaphylactic reactions can be life-threatening; therefore, further vaccination with hepatitis B vaccine is contraindicated in persons with a history of anaphylaxis after a previous dose of vaccine.

Hepatitis B immunization programs conducted on a large scale in Taiwan, Alaska, and New Zealand have observed no association between vaccination and the occurrence of serious adverse events. Furthermore, in the United States, surveillance of adverse events following hepatitis B vaccination has demonstrated no association between hepatitis B vaccine and the occurrence of serious adverse events, including Guillain-Barré syndrome, transverse myelitis, multiple sclerosis, optic neuritis, and seizures (57-59) (CDC, unpublished data, 1991). However, several case reports and case series have claimed an association between hepatitis B vaccination and such syndromes and diseases as multiple sclerosis, optic neuritis, rheumatoid arthritis, and other autoimmune diseases (57,60-66). Most of these reported adverse events have occurred in adults, and no report has compared the frequency of the purported vaccine-associated syndrome/disease with the frequency in an unvaccinated population. In addition, recent case-control studies have demonstrated no association between hepatitis B vaccination and development or short-term risk of relapse of multiple sclerosis (67,68), and reviews by international panels of experts have concluded that available data do not demonstrate a causal association between hepatitis B vaccination and demyelinating diseases, including multiple sclerosis (69).

HBIG is prepared from human plasma known to contain a high titer of antibody to HBsAg (anti-HBs). The plasma from which HBIG is prepared is screened for HBsAg and antibodies to HIV and HCV. The process used to prepare HBIG inactivates and eliminates HIV from the final product. Since 1996, the final product has been free of HCV RNA as determined by the polymerase chain reaction (PCR), and, since 1999, all products available in the United States have been manufactured by methods that inactivate HCV and other viruses. No evidence exists that HBV, HCV, or HIV have ever been transmitted by HBIG commercially available in the United States (70,71).

Serious adverse effects from HBIG when administered as recommended have been rare. Local pain and tenderness at the injection site, urticaria and angioedema might occur; anaphylactic reactions, although rare, have been reported following the injection of human immune globulin (IG) preparations (72). Persons with a history of anaphylactic reaction to IG should not receive HBIG.

PEP for HBV During Pregnancy. No apparent risk exists for adverse effects to developing fetuses when hepatitis B vaccine is administered to pregnant women (CDC, unpublished data, 1990). The vaccine contains noninfectious HBsAg particles and should pose no risk to the fetus. HBV infection during pregnancy might result in severe disease for the mother and chronic infection for the newborn. Therefore, neither pregnancy nor lactation should be considered a contraindication to vaccination of women. HBIG is not contraindicated for pregnant or lactating women.

Occupational Transmission of HCV

Risk for Occupational Transmission of HCV

HCV is not transmitted efficiently through occupational exposures to blood. The average incidence of anti-HCV seroconversion after accidental percutaneous exposure from an HCV-positive source is 1.8% (range: 0%–7%) (73–76), with one study indicating that transmission occurred only from hollow-bore needles compared with other sharps (75). Transmission rarely occurs from mucous membrane exposures to blood, and no transmission in HCP has been documented from intact or nonintact skin exposures to blood (77,78). Data are limited on survival of HCV in the environment. In contrast to HBV, the epidemiologic data for HCV suggest that environmental contamination with blood containing HCV is not a significant risk for transmission in the health-care setting (79,80), with the possible exception of the hemodialysis setting where HCV transmission related to environmental contamination and poor infection-control practices have been implicated (81–84). The risk for transmission from exposure to fluids or tissues other than HCV-infected blood also has not been quantified but is expected to be low.

Postexposure Management for HCV

In several studies, researchers have attempted to assess the effectiveness of IG following possible exposure to non-A, non-B hepatitis. These studies have been difficult to interpret because they lack uniformity in diagnostic criteria and study design, and, in all but one study, the first dose of IG was administered before potential exposure (48,85,86). In an experiment designed to model HCV transmission by needlestick exposure in the health-care setting, high anti-HCV titer IG administered to chimpanzees 1 hour after exposure to HCV-positive blood did not prevent transmission of infection (87). In 1994, the Advisory Committee on Immunization Practices (ACIP) reviewed available data regarding the prevention of HCV infection with IG and concluded that using IG as PEP for hepatitis C was not supported (88). This conclusion was based on the following facts:

- No protective antibody response has been identified following HCV infection.
- Previous studies of IG use to prevent posttransfusion non-A, non-B hepatitis might not be relevant in making recommendations regarding PEP for hepatitis C.
- Experimental studies in chimpanzees with IG containing anti-HCV failed to prevent transmission of infection after exposure.

No clinical trials have been conducted to assess postexposure use of antiviral agents (e.g., interferon with or without ribavirin) to prevent HCV infection, and antivirals are not FDA-approved for this indication. Available data suggest that an established infection might need to be present before interferon can be an effective treatment. Kinetic studies suggest that the effect of interferon on chronic HCV infection occurs in two phases. During the first phase, interferon blocks the production or release of virus from infected cells. In the second phase, virus is eradicated from the infected cells (89); in this later phase, higher pretreatment alanine aminotransferase (ALT) levels correlate with an increasing decline in infected cells, and the rapidity of the decline correlates with viral clearance. In contrast, the effect of antiretrovirals when used for PEP after exposure to HIV is based on inhibition of HIV DNA synthesis early in the retroviral replicative cycle.

In the absence of PEP for HCV, recommendations for postexposure management are intended to achieve early identification of chronic disease and, if present, referral for evaluation of treatment options. However, a theoretical argument is that intervention with antivirals when HCV RNA first becomes detectable might prevent the development of chronic infection. Data from studies conducted outside the United States suggest that a short course of interferon started early in the course of acute hepatitis C is associated with a higher rate of resolved infection than that achieved when therapy is begun after chronic hepatitis C has been well established (90–92). These studies used various treatment regimens and included persons with acute disease whose peak ALT levels were 500–1,000 IU/L at the time therapy was initiated (2.6–4 months after exposure).

No studies have evaluated the treatment of acute infection in persons with no evidence of liver disease (i.e., HCV RNA-positive <6 months duration with normal ALT levels); among patients with chronic HCV infection, the efficacy of antivirals has been demonstrated only among patients who also had evidence of chronic liver disease (i.e., abnormal ALT levels). In addition, treatment started early in the course of chronic HCV infection (i.e., 6 months after onset of infection) might be as effective as treatment started during acute infection (13). Because 15%–25% of patients with acute HCV infection spontaneously resolve their infection (93), treatment of these patients during the acute phase could expose them unnecessarily to the discomfort and side effects of antiviral therapy.

Data upon which to base a recommendation for therapy of acute infection are insufficient because a) no data exist regarding the effect of treating patients with acute infection who have no evidence of disease, b) treatment started early in the course of chronic infection might be just as effective and would eliminate the need to treat persons who will spontaneously resolve their infection, and c) the appropriate regimen is unknown.

Occupational Transmission of HIV

Risk for Occupational Transmission of HIV

In prospective studies of HCP, the average risk of HIV transmission after a percutaneous exposure to HIV-infected blood has been estimated to be approximately 0.3% (95% confidence interval [CI] = 0.2%–0.5%) (94) and after a mucous membrane exposure, approximately 0.09% (95% CI = 0.006%–0.5%) (95). Although episodes of HIV transmission after nonintact skin exposure have been documented (96), the average risk for transmission by this route has not been precisely quantified but is estimated to be less than the risk for mucous membrane exposures (97). The risk for transmission after exposure to fluids or tissues other than HIV-infected blood also has not been quantified but is probably considerably lower than for blood exposures (98).

As of June 2000, CDC had received voluntary reports of 56 U.S. HCP with documented HIV seroconversion temporally associated with an occupational HIV exposure. An additional 138 episodes in HCP are considered possible occupational HIV transmissions. These workers had a history of occupational exposure to blood, other infectious body fluids, or laboratory solutions containing HIV, and no other risk for HIV infection was identified, but HIV seroconversion after a specific exposure was not documented (99).

Epidemiologic and laboratory studies suggest that several factors might affect the risk of HIV transmission after an occupational exposure. In a retrospective case-control study of HCP who had percutaneous exposure to HIV, the risk for HIV infection was found

to be increased with exposure to a larger quantity of blood from the source person as indicated by a) a device visibly contaminated with the patient's blood, b) a procedure that involved a needle being placed directly in a vein or artery, or c) a deep injury (100). The risk also was increased for exposure to blood from source persons 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). 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 (101).

The use of source person viral load as a surrogate measure of viral titer for assessing transmission risk has not yet been established. Plasma viral load (e.g., HIV RNA) reflects only the level of cell-free virus in the peripheral blood; latently infected cells might transmit infection in the absence of viremia. Although a lower viral load (e.g., <1,500 RNA copies/mL) or one that is below the limits of detection probably indicates a lower titer exposure, it does not rule out the possibility of transmission.

Some evidence exists regarding host defenses possibly influencing the risk for HIV infection. A study of HIV-exposed but uninfected HCP demonstrated an HIV-specific cytotoxic T-lymphocyte (CTL) response when peripheral blood mononuclear cells were stimulated *in vitro* with HIV-specific antigens (102). Similar CTL responses have been observed in other groups who experienced repeated HIV exposure without resulting infection (103–108). Among several possible explanations for this observation is that the host immune response sometimes might prevent establishment of HIV infection after a percutaneous exposure; another is that the CTL response simply might be a marker for exposure. In a study of 20 HCP with occupational exposure to HIV, a comparison was made of HCP treated with zidovudine (ZDV) PEP and those not treated. The findings from this study suggest that ZDV blunted the HIV-specific CTL response and that PEP might inhibit early HIV replication (109).

Rationale for HIV PEP

Considerations that influence the rationale and recommendations for PEP include

- the pathogenesis of HIV infection, particularly the time course of early infection;
- the biological plausibility that infection can be prevented or ameliorated by using antiretroviral drugs;
- direct or indirect evidence of the efficacy of specific agents used for prophylaxis; and
- the risk and benefit of PEP to exposed HCP.

The following discussion considers each of these concerns.

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 postexposure antiretroviral intervention might modify or prevent viral replication. 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. Over 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 (110). Theoretically, initiation of antiretroviral PEP soon after exposure might prevent or inhibit systemic infection by limiting the proliferation of virus in the initial target cells or lymph nodes.

Efficacy of Antiretrovirals for PEP in Animal Studies. Data from animal studies have been difficult to interpret, in part, because of problems identifying an animal model that is comparable to humans. In early 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) made extrapolation of the results to humans difficult. Recently, refinements in methodology have facilitated more relevant studies; in particular, the viral inocula used in animal studies have been reduced to levels more analogous to human exposures but sufficient to cause infection in control animals (111–113). These studies provide encouraging evidence of postexposure chemoprophylactic efficacy.

Studies among primates and in murine and feline animal models have demonstrated that larger viral inocula decrease prophylactic efficacy (114–117). In addition, delaying initiation, shortening the duration, or decreasing the antiretroviral dose of PEP, individually or in combination, decreased prophylactic efficacy (113,118–124). For example, when (R)-9-(2-phosphonylmethoxypropyl) adenine (tenofovir) 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 (122). A subsequent study confirmed the efficacy of tenofovir PEP when administered 24 hours after intravenous inoculation of a dose of SIV that uniformly results in infection in untreated macaques. In the same study, protection was incomplete if the tenofovir administration was delayed to 48 or 72 hours postexposure or if the total duration of treatment was curtailed to 3 or 10 days (123).

Efficacy of Antiretrovirals for PEP in Human Studies. Little information exists from which the efficacy of PEP in humans can be assessed. Seroconversion is infrequent following an occupational exposure to HIV-infected blood; therefore, several thousands of exposed HCP would need to enroll in a prospective trial to achieve the statistical power necessary to directly demonstrate PEP efficacy (125).

In the retrospective case-control study of HCP, after controlling for other risk factors for HIV transmission, use of ZDV as PEP was associated with a reduction in the risk of HIV infection by approximately 81% (95% CI = 43%–94%) (100). Although the results of this study suggest PEP efficacy, its limitations include the small number of cases studied and the use of cases and controls from different cohorts.

In a multicenter trial 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% (126). Only part of the protective effect of ZDV was explained by reduction of the HIV viral load in the maternal blood, suggesting that ZDV prophylaxis, in part, involves a mechanism other than the reduction of maternal viral burden (127,128). Since 1998, studies have highlighted the importance of PEP for prevention of perinatal HIV transmission. In Africa, the use of ZDV in combination with lamivudine (3TC) decreased perinatal HIV transmission by 50% when administered during pregnancy, labor, and for 1 week postpartum, and by 37% when started at the onset of labor and continued for 1 week postpartum (129). Studies in the United States and Uganda also have demonstrated that rates of perinatal HIV transmission have been reduced with the use of abbreviated PEP regimens started intrapartum or during the first 48–72 hours of life (130–132).

The limitations of all of these studies with animals and humans 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 might not be directly applicable to PEP in HCP.

Reports of Failure of PEP. Failure of PEP to prevent HIV infection in HCP has been reported in at least 21 instances (78, 133–139). In 16 of the cases, ZDV was used alone as a single agent; in two cases, ZDV and didanosine (ddI) were used in combination (133, 138); and in three cases, ≥ 3 drugs were used for PEP (137–139). Thirteen of the source persons were known to have been treated with antiretroviral therapy before the exposure. Antiretroviral resistance testing of the virus from the source person was performed in seven instances, and in four, the HIV infection transmitted was found to have decreased sensitivity to ZDV and/or other drugs used for PEP. In addition to possible exposure to an antiretroviral-resistant strain of HIV, other factors that might have contributed to these apparent failures might 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 responsiveness) and/or to the source person's virus (e.g., presence of syncytia-forming strains) (133). Details regarding the cases of PEP failure involving combinations of antiretroviral agents are included in this report (Table 1).

Antiretroviral Agents for PEP

Antiretroviral agents from three classes of drugs are available for the treatment of HIV infection. These agents include the nucleoside reverse transcriptase inhibitors (NRTIs), nonnucleoside reverse transcriptase inhibitors (NNRTIs), and protease inhibitors (PIs). Only antiretroviral agents that have been approved by FDA for treatment of HIV infection are discussed in these guidelines.

Determining which agents and how many to use or when to alter a PEP regimen is largely empiric. Guidelines for the treatment of HIV infection, a condition usually involving a high total body burden of HIV, include recommendations for the use of three drugs (140); however, the applicability of these recommendations to PEP remains unknown. In HIV-infected patients, combination regimens have proved superior to monotherapy regimens in reducing HIV viral load, reducing the incidence of opportunistic infections and death, and delaying onset of drug resistance (141, 142). A combination of drugs with activity at different stages in the viral replication cycle (e.g., nucleoside analogues with a PI) theoretically could offer an additional preventive effect in PEP, particularly for occupational exposures that pose an increased risk of transmission. Although the use of a three-drug regimen might be justified for exposures that pose an increased risk of transmission, whether the potential added toxicity of a third drug is justified for lower-risk exposures is uncertain. Therefore, the recommendations at the end of this document provide guidance for two- and three-drug PEP regimens that are based on the level of risk for HIV transmission represented by the exposure.

NRTI combinations that can be considered for PEP include ZDV and 3TC, 3TC and stavudine (d4T), and ddI and d4T. In previous PHS guidelines, a combination of ZDV and 3TC was considered the first choice for PEP regimens (3). Because ZDV and 3TC are available in a combination formulation (Combivir™, manufactured by Glaxo Wellcome, Inc., Research Triangle Park, NC), the use of this combination might be more convenient for HCP. However, recent data suggest that mutations associated with ZDV and 3TC resistance might be common in some areas (143). Thus, individual clinicians might prefer other NRTIs or combinations based on local knowledge and experience in treating HIV infection and disease.

TABLE 1. Reported instances of failure of combination drug postexposure prophylaxis to prevent HIV infection in health-care personnel exposed to HIV-infected blood

Report no.	Source of injury	Regimen*	Hours to first dose	Days to onset of retroviral illness	Days to seroconversions [†]	Source patient on antiretrovirals
1 [§]	Biopsy needle	ZDV, ddl	0.50	23	23	yes
2 [¶]	Hollow needle	ZDV, ddl**	1.50	45	97	no
3 [¶]	Large-bore hollow needle	3-drugs ^{††}	1.50	40	55	yes ^{§§}
4 ^{¶¶}	Hollow needle	ZDV, 3TC ddl, IDV	0.67	70	83	yes ^{***}
5 ^{†††}	Unknown sharp	ddl, d4T NVP ^{§§§}	2.00	42	100	yes ^{***}

* ZDV = zidovudine, ddl = didanosine, 3TC = lamivudine, IDV = indinavir, d4T = stavudine, and NVP = nevirapine

[†] By enzyme immunoassay for HIV-1 antibody and Western blot.

[§] Jochimsen EM. Failures of zidovudine postexposure prophylaxis. *Am J Med* 1997;102(suppl 5B):52-5.

[¶] Lot F, Abiteboul D. Occupational HIV infection in France [Abstract WP-25]. In: Keynote addresses and abstracts of the 4th ICOH International Conference on Occupational Health for Health Care Workers. Montreal, Canada, 1999.

** Report 2: ZDV and ddl taken for 48 hours then changed to ZDV alone.

^{††} Report 3: ZDV, 3TC, and IDV taken for 48 hours then changed to d4T, 3TC, and IDV.

^{§§} HIV isolate tested and determined to be sensitive to antiretroviral agent(s).

^{¶¶} Perdue B, Wolderufael D, Mellors J, Quinn T, Margolick J. HIV-1 transmission by a needlestick injury despite rapid initiation of four-drug postexposure prophylaxis [Abstract 210]. In: Program and abstracts of the 6th Conference on Retroviruses and Opportunistic Infections. Chicago, IL: Foundation for Retrovirology and Human Health in scientific collaboration with the National Institute of Allergy and Infectious Diseases and CDC, 1999:107.

^{***} HIV isolate tested and determined to be resistant to antiretroviral agent(s).

^{†††} Beltrami EM, Luo C-C, Dela Torre N, Cardo DM. HIV transmission after an occupational exposure despite postexposure prophylaxis with a combination drug regimen [Abstract P-S2-62]. In: Program and abstracts of the 4th Decennial International Conference on Nosocomial and Healthcare-Associated Infections in conjunction with the 10th Annual Meeting of SHEA. Atlanta, GA: CDC, 2000:125-6.

^{§§§} Report 5: ZDV and 3TC taken for one dose then changed to ddl, d4T, and NVP; ddl was discontinued after 3 days because of severe vomiting.

The addition of a third drug for PEP following high-risk exposures is based on demonstrated effectiveness in reducing viral burden in HIV-infected persons. Previously, indinavir (IDV) or nelfinavir (NFV) were recommended as first-choice agents for inclusion in an expanded PEP regimen (5). Since the publication of the 1998 PEP guidelines, efavirenz (EFV), an NNRTI; abacavir (ABC), a potent NRTI; and Kaletra™, a PI, have been approved by FDA. Although side effects might be common with the NNRTIs, EFV might be considered for expanded PEP regimens, especially when resistance to PIs in the source person's virus is known or suspected. ABC has been associated with dangerous hypersensitivity reactions but, with careful monitoring, may be considered as a third drug for PEP. Kaletra, a combination of lopinavir and ritonavir, is a potent HIV inhibitor that, with expert consultation, may be considered in an expanded PEP regimen.

Toxicity and Drug Interactions of Antiretroviral Agents. When administering PEP, an important goal is completion of a 4-week PEP regimen when PEP is indicated. 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 (Table 2). However, studies of adverse events have been conducted primarily with persons who have advanced disease (and longer treatment courses) and who therefore might not reflect the experience in persons who are uninfected (144).

Several primary side effects are associated with antiretroviral agents (Table 2). Side effects associated with many of the NRTIs are chiefly gastrointestinal (e.g., nausea or diarrhea); however, ddI has been associated with cases of fatal and nonfatal pancreatitis among HIV-infected patients treated for >4 weeks. The use of PIs has been associated with new onset diabetes mellitus, hyperglycemia, diabetic ketoacidosis, exacerbation of preexisting diabetes mellitus, and dyslipidemia (145–147). Nephrolithiasis has been associated with IDV use; however, the incidence of this potential complication might be limited by drinking at least 48 ounces (1.5 L) of fluid per 24-hour period (e.g., six 8-ounce glasses of water throughout the day) (148). NFV has been associated with the development of diarrhea; however, this side effect might respond to treatment with antimotility agents that can be prescribed for use, if necessary, at the time the drug is recommended for PEP. The NNRTIs have been associated with severe skin reactions, including life-threatening cases of Stevens-Johnson syndrome and toxic epidermal necrolysis. Hepatotoxicity, including fatal hepatic necrosis, has occurred in patients treated with nevirapine (NVP); some episodes began during the first few weeks of therapy (FDA, unpublished data, 2000). EFV has been associated with central nervous system side effects, including dizziness, somnolence, insomnia, and abnormal dreaming.

All of the approved antiretroviral agents might have potentially serious drug interactions when used with certain other drugs (Appendix C). Careful evaluation of concomitant medications used by an exposed person is required before PEP is prescribed, and close monitoring for toxicity is also needed. Further information about potential drug interactions can be found in the manufacturer's package insert.

Toxicity Associated with PEP. Information from the National Surveillance System for Health Care Workers (NaSH) and the HIV Postexposure Registry indicates that nearly 50% of HCP experience adverse symptoms (e.g., nausea, malaise, headache, anorexia, and headache) while taking PEP and that approximately 33% stop taking PEP because of adverse signs and symptoms (6,7,10,11). Some studies have demonstrated that side effects and discontinuation of PEP are more common among HCP taking three-drug

TABLE 2. Primary side effects associated with antiretroviral agents

Antiretroviral class/agent	Primary side effects and toxicities
Nucleoside reverse transcriptase inhibitors (NRTIs)	
Zidovudine (Retrovir™; ZDV; AZT)	anemia, neutropenia, nausea, headache, insomnia, muscle pain, and weakness
Lamivudine (Epivir™; 3TC)	abdominal pain, nausea, diarrhea, rash, and pancreatitis
Stavudine (Zerit™; d4T)	peripheral neuropathy, headache, diarrhea, nausea, insomnia, anorexia, pancreatitis, increased liver function tests (LFTs), anemia, and neutropenia
Didanosine (Videx™; ddl)	pancreatitis, lactic acidosis, neuropathy, diarrhea, abdominal pain, and nausea
Abacavir (Ziagen™; ABC)	nausea, diarrhea, anorexia, abdominal pain, fatigue, headache, insomnia, and hypersensitivity reactions
Nonnucleoside reverse transcriptase inhibitors (NNRTIs)	
Nevirapine (Viramune™; NVP)	rash (including cases of Stevens-Johnson syndrome), fever, nausea, headache, hepatitis, and increased LFTs
Delavirdine (Rescriptor™; DLV)	rash (including cases of Stevens-Johnson syndrome), nausea, diarrhea, headache, fatigue, and increased LFTs
Efavirenz (Sustiva™; EFV)	rash (including cases of Stevens-Johnson syndrome), insomnia, somnolence, dizziness, trouble concentrating, and abnormal dreaming
Protease inhibitors (PIs)	
Indinavir (Crixivan™; IDV)	nausea, abdominal pain, nephrolithiasis, and indirect hyperbilirubinemia
Nelfinavir (Viracept™; NFV)	diarrhea, nausea, abdominal pain, weakness, and rash
Ritonavir (Norvir™; RTV)	weakness, diarrhea, nausea, circumoral paresthesia, taste alteration, and increased cholesterol and triglycerides
Saquinavir (Fortovase™; SQV)	diarrhea, abdominal pain, nausea, hyperglycemia, and increased LFTs
Amprenavir (Agenerase™; AMP)	nausea, diarrhea, rash, circumoral paresthesia, taste alteration, and depression
Lopinavir/Ritonavir (Kaletra™)	diarrhea, fatigue, headache, nausea, and increased cholesterol and triglycerides

combination regimens for PEP compared with HCP taking two-drug combination regimens (7,10). Although similar rates of side effects were observed among persons who took PEP after sexual or drug use exposures to HIV in the San Francisco Post-Exposure Prevention Project, 80% completed 4 weeks of therapy (149). Participants in the San Francisco Project were followed at 1, 2, 4, 26, and 52 weeks postexposure and received medication adherence counseling; most participants took only two drugs for PEP.

Serious side effects, including nephrolithiasis, hepatitis, and pancytopenia have been reported with the use of combination drugs for PEP (6,7,150,151). One case of NVP-associated fulminant liver failure requiring liver transplantation and one case of hypersensitivity syndrome have been reported in HCP taking NVP for HIV PEP (152). Including these two cases, from March 1997 through September 2000, FDA received reports of 22 cases of serious adverse events related to NVP taken for PEP (153). These events included 12 cases of hepatotoxicity, 14 cases of skin reaction (including one documented and two possible cases of Stevens-Johnson syndrome), and one case of rhabdomyolysis; four cases involved both hepatotoxicity and skin reaction, and one case involved both rhabdomyolysis and skin reaction.

Resistance to Antiretroviral Agents. Known or suspected resistance of the source virus to antiretroviral agents, particularly to agents that might be included in a PEP regimen, is a concern for persons making decisions about PEP. Resistance to HIV infection occurs with all of the available antiretroviral agents, and cross-resistance within drug classes is frequent (154). Recent studies have demonstrated an emergence of drug-resistant HIV among source persons for occupational exposures (143,155). A study conducted at seven U.S. sites during 1998–1999 found that 16 (39%) of 41 source persons whose virus was sequenced had primary genetic mutations associated with resistance to RTIs, and 4 (10%) had primary mutations associated with resistance to PIs (143). In addition, occupational transmission of resistant HIV strains, despite PEP with combination drug regimens, has been reported (137,139). In one case, a hospital worker became infected after an HIV exposure despite a PEP regimen that included ddI, d4T, and NVP (139). The transmitted HIV contained two primary genetic mutations associated with resistance to NNRTIs (the source person was taking EFV at the time of the exposure). Despite recent studies and case reports, the relevance of exposure to a resistant virus is still not well understood.

Empiric decisions about the presence of antiretroviral drug resistance are often difficult to make because patients generally take more than one antiretroviral agent. Resistance should be suspected in source persons when they are experiencing clinical progression of disease or a persistently increasing viral load, and/or decline in CD4 T-cell count, despite therapy or a lack of virologic response to therapy. However, resistance testing of the source virus at the time of an exposure is not practical because the results will not be available in time to influence the choice of the initial PEP regimen. Furthermore, in this situation, whether modification of the PEP regimen is necessary or will influence the outcome of an occupational exposure is unknown. No data exist to suggest that modification of a PEP regimen after receiving results from resistance testing (usually a minimum of 1–2 weeks) improves efficacy of PEP.

Antiretroviral Drugs During Pregnancy. Data are limited on the potential effects of antiretroviral drugs on the developing fetus or neonate (156). Carcinogenicity and/or mutagenicity is evident in several in vitro screening tests for ZDV and all other FDA-licensed NRTIs. The relevance of animal data to humans is unknown; however, because

teratogenic effects were observed in primates at drug exposures similar to those representing human therapeutic exposure, the use of EFV should be avoided in pregnant women (140). IDV is associated with infrequent side effects in adults (i.e., hyperbilirubinemia and renal stones) that could be problematic for a newborn. Because the half-life of IDV in adults is short, these concerns might be relevant only if the drug is administered shortly before delivery.

In a recent study in France of perinatal HIV transmission, two cases of progressive neurologic disease and death were reported in uninfected infants exposed to ZDV and 3TC (157). Laboratory studies of these children suggested mitochondrial dysfunction. In a careful review of deaths in children followed in U.S. perinatal HIV cohorts, no deaths attributable to mitochondrial disease have been found (158).

Recent reports of fatal and nonfatal lactic acidosis in pregnant women treated throughout gestation with a combination of d4T and ddI have prompted warnings about use of these drugs during pregnancy (159). Although the case-patients were HIV-infected women taking the drugs for >4 weeks, pregnant women and their providers should be advised to consider d4T and ddI only when the benefits of their use outweigh the risks.

PEP Use in Hospitals in the United States. Analysis of data from NaSH provides information on the use of PEP following occupational exposures in 47 hospitals in the United States. A total of 11,784 exposures to blood and body fluids was reported from June 1996 through November 2000 (CDC, unpublished data, 2001). For all exposures with known sources, 6% were to HIV-positive sources, 74% to HIV-negative sources, and 20% to sources with an unknown HIV status. Sixty-three percent of HCP exposed to a known HIV-positive source started PEP, and 54% of HCP took it for at least 20 days, whereas 14% of HCP exposed to a source person subsequently found to be HIV-negative initiated PEP, and 3% of those took it for at least 20 days. Information recorded about HIV exposures in NaSH indicates that 46% of exposures involving an HIV-positive source warranted only a two-drug PEP regimen (i.e., the exposure was to mucous membranes or skin or was a superficial percutaneous injury and the source person did not have end-stage AIDS or acute HIV illness); however, 53% of these exposed HCP took ≥ 3 drugs (CDC, unpublished data, 2000). Similarly, the National Clinicians' Post-Exposure Prophylaxis Hotline (PEpline) reported that PEpline staff recommended stopping or not starting PEP for approximately one half of the HCP who consulted them about exposures (D. Bangsberg, San Francisco General Hospital, unpublished data, September 1999). The observation that some HCP exposed to HIV-negative source persons take PEP from several days to weeks following their exposures suggests that strategies be employed such as the use of a rapid HIV antibody assay, which could minimize exposure to unnecessary PEP (11). A recent study demonstrated that use of a rapid HIV test for evaluation of source persons after occupational exposures not only resulted in decreased use of PEP, but also was cost-effective compared with use of the standard enzyme immunoassay (EIA) test for source persons subsequently found to be HIV-negative (160).

RECOMMENDATIONS FOR THE MANAGEMENT OF HCP POTENTIALLY EXPOSED TO HBV, HCV, or HIV

Exposure prevention remains the primary strategy for reducing occupational bloodborne pathogen infections; however, occupational exposures will continue to occur. Health-care organizations should make available to their personnel a system that includes written protocols for prompt reporting, evaluation, counseling, treatment, and

follow-up of occupational exposures that might place HCP at risk for acquiring a bloodborne infection. HCP should be educated concerning the risk for and prevention of bloodborne infections, including the need to be vaccinated against hepatitis B (17,21,161–163). Employers are required to establish exposure-control plans that include postexposure follow-up for their employees and to comply with incident reporting requirements mandated by the 1992 OSHA bloodborne pathogen standard (2). Access to clinicians who can provide postexposure care should be available during all working hours, including nights and weekends. HBIG, hepatitis B vaccine, and antiretroviral agents for HIV PEP should be available for timely administration (i.e., either by providing access on-site or by creating linkages with other facilities or providers to make them available off-site). Persons responsible for providing postexposure management should be familiar with evaluation and treatment protocols and the facility's plans for accessing HBIG, hepatitis B vaccine, and antiretroviral drugs for HIV PEP.

HCP should be educated to report occupational exposures immediately after they occur, particularly because HBIG, hepatitis B vaccine, and HIV PEP are most likely to be effective if administered as soon after the exposure as possible. HCP who are at risk for occupational exposure to bloodborne pathogens should be familiarized with the principles of postexposure management as part of job orientation and ongoing job training.

Hepatitis B Vaccination

Any person who performs tasks involving contact with blood, blood-contaminated body fluids, other body fluids, or sharps should be vaccinated against hepatitis B (2,21). Pre vaccination 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.

Hepatitis B vaccine should always be administered by the intramuscular route in the deltoid muscle with a needle 1–1.5 inches long. Hepatitis B vaccine can be administered at the same time as other vaccines with no interference with antibody response to the other vaccines (164). If the vaccination series is interrupted after the first dose, the second dose should be administered as soon as possible. The second and third doses should be separated by an interval of at least 2 months. If only the third dose is delayed, it should be administered when convenient. HCP who have contact with patients or blood and are at ongoing risk for percutaneous injuries should be tested 1–2 months after completion of the 3-dose vaccination series for anti-HBs (21). Persons who do not respond to the primary vaccine series (i.e., anti-HBs <10 mIU/mL) should complete a second 3-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 do not respond to an initial 3-dose vaccine series have a 30%–50% chance of responding to a second 3-dose series (165). Persons who prove to be HBsAg-positive should be counseled regarding how to prevent HBV transmission to others and regarding the need for medical evaluation (12,163,166). Nonresponders 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. Booster doses of hepatitis B vaccine are not necessary, and periodic serologic testing to monitor antibody concentrations after completion of the vaccine series is not recommended. Any blood or body fluid exposure sustained by an unvaccinated, susceptible person should lead to the initiation of the hepatitis B vaccine series.

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. No evidence exists that using antiseptics for wound care or expressing fluid by squeezing the wound further reduces the risk of bloodborne pathogen 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.

Exposure Report

If an occupational exposure occurs, the circumstances and postexposure management should be recorded in the exposed person's confidential medical record (usually on a form the facility designates for this purpose) (Box 1). In addition, employers should follow all federal (including OSHA) and state requirements for recording and reporting occupational injuries and exposures.

BOX 1. Recommendations for the contents of the occupational exposure report

- date and time of exposure;
- details of the procedure being performed, including where and how the exposure occurred; if related to a sharp device, the type and brand 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; for a skin or mucous membrane exposure, the estimated volume of material and the condition of the skin [e.g., chapped, abraded, intact]);
- details about the exposure source (e.g., whether the source material contained HBV, HCV, or HIV; if the source is HIV-infected, the stage of disease, history of antiretroviral therapy, viral load, and antiretroviral resistance information, if known);
- details about the exposed person (e.g., hepatitis B vaccination and vaccine-response status); and
- details about counseling, postexposure management, and follow-up.

Evaluation of the Exposure and the Exposure Source

Evaluation of the Exposure

The exposure should be evaluated for the potential to transmit HBV, HCV, and HIV based on the type of body substance involved and the route and severity of the exposure (Box 2). 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 can be infectious for bloodborne viruses. Exposures to

these 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 virus transmission and require further evaluation. For HCV and HIV, 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. In addition, any direct contact (i.e., personal protective equipment either was not present or was ineffective in protecting skin or mucous membranes) with concentrated virus in a research laboratory or production facility is considered an exposure that requires clinical evaluation.

For skin exposure, follow-up is indicated only if it involves exposure to a body fluid previously listed and evidence exists of compromised skin integrity (e.g., dermatitis, abrasion, or open wound). In the clinical evaluation for human bites, possible exposure of both the person bitten and the person who inflicted the bite must be considered. If a bite results in blood exposure to either person involved, postexposure follow-up should be provided.

BOX 2. Factors to consider in assessing the need for follow-up of occupational exposures

- **Type of exposure**
 - Percutaneous injury
 - Mucous membrane exposure
 - Nonintact skin exposure
 - Bites resulting in blood exposure to either person involved
- **Type and amount of fluid/tissue**
 - Blood
 - Fluids containing blood
 - Potentially infectious fluid or tissue (semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids)
 - Direct contact with concentrated virus
- **Infectious status of source**
 - Presence of HBsAg
 - Presence of HCV antibody
 - Presence of HIV antibody
- **Susceptibility of exposed person**
 - Hepatitis B vaccine and vaccine response status
 - HBV, HCV, and HIV immune status

Evaluation of the Exposure Source

The person whose blood or body fluid is the source of an occupational exposure should be evaluated for HBV, HCV, and HIV infection (Box 3). Information available in the medical record at the time of exposure (e.g., laboratory test results, admitting diagnosis, or previous medical history) or from the source person, might confirm or exclude bloodborne virus infection.

If the HBV, HCV, and/or HIV infection status of the source is unknown, the source person should be informed of the incident and tested for serologic evidence of bloodborne virus infection. Procedures should be followed for testing source persons, including obtaining informed consent, in accordance with applicable state and local laws. Any persons determined to be infected with HBV, HCV, or HIV should be referred for appropriate counseling and treatment. Confidentiality of the source person should be maintained at all times.

Testing to determine the HBV, HCV, and HIV infection status of an exposure source should be performed as soon as possible. Hospitals, clinics and other sites that manage exposed HCP should consult their laboratories regarding the most appropriate test to use to expedite obtaining these results. An FDA-approved rapid HIV-antibody test kit should be considered for use in this situation, particularly if testing by EIA cannot be completed within 24–48 hours. Repeatedly reactive results by EIA or rapid HIV-antibody tests are considered to be 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 to make initial decisions about postexposure management but should be done to complete the testing process and before informing the source person. Repeatedly reactive results by EIA for anti-HCV should be confirmed by a supplemental test (i.e., recombinant immunoblot assay [RIBA™] or HCV PCR). Direct virus assays (e.g., HIV p24 antigen EIA or tests for HIV RNA or HCV RNA) for routine HIV or HCV screening of source persons are not recommended.

If the exposure source is unknown or cannot be tested, information about where and under what circumstances the exposure occurred should be assessed epidemiologically for the likelihood of transmission of HBV, HCV, or HIV. Certain situations as well as the type of exposure might suggest an increased or decreased risk; an important consideration is the prevalence of HBV, HCV, or 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 injection-drug use is prevalent or involves a needle discarded in a drug-treatment facility would be considered epidemiologically to have a higher risk for transmission than an exposure that occurs in a nursing home for the elderly.

Testing of needles or other sharp instruments implicated in 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, and testing might be hazardous to persons handling the sharp instrument.

Examples of information to consider when evaluating an exposure source for possible HBV, HCV, or HIV infection include laboratory information (e.g., previous HBV, HCV, or HIV test results or results of immunologic testing [e.g., CD4+ T-cell count]) or liver enzymes (e.g., ALT), clinical symptoms (e.g., acute syndrome suggestive of primary HIV infection or undiagnosed immunodeficiency disease), and history of recent (i.e., within 3 months) possible HBV, HCV, or HIV exposures (e.g., injection-drug use or sexual contact

with a known positive partner). Health-care providers should be aware of local and state laws governing the collection and release of HIV serostatus information on a source person, following an occupational exposure.

If the source person is known to have HIV infection, available information about this person's stage of infection (i.e., asymptomatic, symptomatic, or AIDS), CD4+ T-cell count, results of viral load testing, current and previous antiretroviral therapy, and results of any genotypic or phenotypic viral resistance testing 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. Reevaluation of exposed HCP should be considered within 72 hours postexposure, especially as additional information about the exposure or source person becomes available.

If the source person is HIV seronegative and has no clinical evidence of AIDS or symptoms of HIV infection, no further testing of the person for HIV infection is indicated. The likelihood of the source person being in the "window period" of HIV infection in the absence of symptoms of acute retroviral syndrome is extremely small.

BOX 3. Evaluation of occupational exposure sources

Known sources

- Test known sources for HBsAg, anti-HCV, and HIV antibody
 - Direct virus assays for routine screening of source patients are **not** recommended
 - Consider using a rapid HIV-antibody test
 - If the source person is **not** infected with a bloodborne pathogen, baseline testing or further follow-up of the exposed person is **not** necessary
- For sources whose infection status remains unknown (e.g., the source person refuses testing), consider medical diagnoses, clinical symptoms, and history of risk behaviors
- Do not test discarded needles for bloodborne pathogens

Unknown sources

- For unknown sources, evaluate the likelihood of exposure to a source at high risk for infection
 - Consider likelihood of bloodborne pathogen infection among patients in the exposure setting

Management of Exposures to HBV

For percutaneous or mucosal exposures to blood, several factors must be considered when making a decision to provide prophylaxis, including the HBsAg status of the source and the hepatitis B vaccination and vaccine-response status of the exposed person. Such exposures usually involve persons for whom hepatitis B vaccination is recommended.

Any blood or body fluid exposure to an unvaccinated person should lead to initiation of the hepatitis B vaccine series.

The hepatitis B vaccination status and the vaccine-response status (if known) of the exposed person should be reviewed. A summary of prophylaxis recommendations for percutaneous or mucosal exposure to blood according to the HBsAg status of the exposure source and the vaccination and vaccine-response status of the exposed person is included in this report (Table 3).

When HBIG is indicated, it should be administered as soon as possible after exposure (preferably within 24 hours). The effectiveness of HBIG when administered >7 days after exposure is unknown. When hepatitis B vaccine is indicated, it should also be administered as soon as possible (preferably within 24 hours) and can be administered simultaneously with HBIG at a separate site (vaccine should always be administered in the deltoid muscle).

For exposed persons who are in the process of being vaccinated but have not completed the vaccination series, vaccination should be completed as scheduled, and HBIG should be added as indicated (Table 3). Persons exposed to HBsAg-positive blood or body fluids who are known not to have responded to a primary vaccine series should receive a single dose of HBIG and reinitiate the hepatitis B vaccine series with the first dose of the hepatitis B vaccine as soon as possible after exposure. Alternatively, they should receive two doses of HBIG, one dose as soon as possible after exposure, and the second dose 1 month later. The option of administering one dose of HBIG and reinitiating the vaccine series is preferred for nonresponders who did not complete a second 3-dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.

Management of Exposures to HCV

Individual institutions should establish policies and procedures for testing HCP for HCV after percutaneous or mucosal exposures to blood and ensure that all personnel are familiar with these policies and procedures. The following are recommendations for follow-up of occupational HCV exposures:

- For the source, perform testing for anti-HCV.
- For the person exposed to an HCV-positive source
 - perform baseline testing for anti-HCV and ALT activity; and
 - perform follow-up testing (e.g., at 4–6 months) for anti-HCV and ALT activity (if earlier diagnosis of HCV infection is desired, testing for HCV RNA may be performed at 4–6 weeks).
- Confirm all anti-HCV results reported positive by enzyme immunoassay using supplemental anti-HCV testing (e.g., recombinant immunoblot assay [RIBA™]) (13).

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 PEP after exposure to HCV-positive blood. In addition, no guidelines exist for administration of therapy during the acute

TABLE 3. Recommended postexposure prophylaxis for exposure to hepatitis B virus

Vaccination and antibody response status of exposed workers*	Treatment		
	Source HBsAg [†] positive	Source HBsAg [†] negative	Source unknown or not available for testing
Unvaccinated	HBIG [‡] x 1 and initiate HB vaccine series [¶]	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated			
Known responder**	No treatment	No treatment	No treatment
Known nonresponder ^{††}	HBIG x 1 and initiate revaccination or HBIG x 2 ^{§§}	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 is necessary 2. If inadequate, ^{††} administer HBIG x 1 and vaccine booster	No treatment	Test exposed person for anti-HBs 1. If adequate, [¶] no treatment is necessary 2. If inadequate, [¶] administer vaccine booster and recheck titer in 1–2 months

* Persons who have previously been infected with HBV are immune to reinfection and do not require postexposure prophylaxis.

[†] Hepatitis B surface antigen.

[‡] Hepatitis B immune globulin; dose is 0.06 mL/kg intramuscularly.

[¶] Hepatitis B vaccine.

** A responder is a person with adequate levels of serum antibody to HBsAg (i.e., anti-HBs ≥ 10 mIU/mL).

^{††} A nonresponder is a person with inadequate response to vaccination (i.e., serum anti-HBs < 10 mIU/mL).

^{§§} The option of giving one dose of HBIG and reinitiating the vaccine series is preferred for nonresponders who have not completed a second 3-dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.

^{¶¶} Antibody to HBsAg.

phase of HCV infection. However, limited data indicate that antiviral therapy might be beneficial when started early in the course of HCV infection. When HCV infection is identified early, the person should be referred for medical management to a specialist knowledgeable in this area.

Counseling for HCP Exposed to Viral Hepatitis

HCP exposed to HBV- or HCV-infected blood do not need to take any special precautions to prevent secondary transmission during the follow-up period (12,13); however, they should refrain from donating blood, plasma, organs, tissue, or semen. The exposed person does not need to modify sexual practices or refrain from becoming pregnant. If an exposed woman is breast feeding, she does not need to discontinue.

No modifications to an exposed person's patient-care responsibilities are necessary to prevent transmission to patients based solely on exposure to HBV- or HCV-positive blood. If an exposed person becomes acutely infected with HBV, the person should be evaluated according to published recommendations for infected HCP (165). No recommendations exist regarding restricting the professional activities of HCP with HCV infection (13). As recommended for all HCP, those who are chronically infected with HBV or HCV should follow all recommended infection-control practices, including standard precautions and appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments (162).

Management of Exposures to HIV

Clinical Evaluation and Baseline Testing of Exposed HCP

HCP exposed to HIV should be evaluated within hours (rather than days) after their exposure and should be tested for HIV at baseline (i.e., to establish infection status at the time of exposure). If the source person is seronegative for HIV, baseline testing or further follow-up of the exposed person normally is not necessary. Serologic testing should be made available to all HCP who are concerned that they might have been occupationally infected with HIV. For purposes of considering HIV PEP, the evaluation also should include information about medications the exposed person might be taking and any current or underlying medical conditions or circumstances (i.e., pregnancy, breast feeding, or renal or hepatic disease) that might influence drug selection.

PEP for HIV

The following recommendations (Tables 4 and 5) apply to situations when a person has been exposed to a source person with HIV infection or when information suggests the likelihood that the source person is HIV-infected. These recommendations are based on the risk for HIV infection after different types of exposure and on 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. To assist with the initial management of an HIV exposure, health-care facilities should have drugs for an initial PEP regimen selected and available for use. When possible, these recommendations should be implemented in consultation with persons who have expertise in antiretroviral therapy and HIV transmission (Box 4).

TABLE 4. Recommended HIV postexposure prophylaxis for percutaneous injuries

Exposure type	Infection status of source				
	HIV-Positive Class 1*	HIV-Positive Class 2*	Source of unknown HIV status [†]	Unknown source [§]	HIV-Negative
Less severe [†]	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors ^{††}	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings where exposure to HIV-infected persons is likely	No PEP warranted
More severe ^{§§}	Recommend expanded 3-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors ^{††}	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings where exposure to HIV-infected persons is likely	No PEP warranted

* HIV-Positive, Class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 RNA copies/mL). HIV-Positive, Class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

[†] Source of unknown HIV status (e.g., deceased source person with no samples available for HIV testing).

[§] Unknown source (e.g., a needle from a sharps disposal container).

[†] Less severe (e.g., solid needle and superficial injury).

** The designation “consider PEP” indicates that PEP is optional and should be based on an individualized decision between the exposed person and the treating clinician.

^{††} If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.

^{§§} More severe (e.g., large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient’s artery or vein).

TABLE 5. Recommended HIV postexposure prophylaxis for mucous membrane exposures and nonintact skin* exposures

Exposure type	Infection status of source				
	HIV-Positive Class 1 [†]	HIV-Positive Class 2 [†]	Source of unknown HIV status [§]	Unknown source [¶]	HIV-Negative
Small volume**	Consider basic 2-drug PEP ^{††}	Recommend basic 2-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP ^{††} for source with HIV risk factors ^{§§}	Generally, no PEP warranted; however, consider basic 2-drug PEP ^{††} in settings where exposure to HIV-infected persons is likely	No PEP warranted
Large volume ^{¶¶}	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP ^{††} for source with HIV risk factors ^{§§}	Generally, no PEP warranted; however, consider basic 2-drug PEP ^{††} in settings where exposure to HIV-infected persons is likely	No PEP warranted

* For skin exposures, follow-up is indicated only if there is evidence of compromised skin integrity (e.g., dermatitis, abrasion, or open wound).

[†] HIV-Positive, Class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 RNA copies/mL). HIV-Positive, Class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

[§] Source of unknown HIV status (e.g., deceased source person with no samples available for HIV testing).

[¶] Unknown source (e.g., splash from inappropriately disposed blood).

** Small volume (i.e., a few drops).

^{††} The designation, “consider PEP,” indicates that PEP is optional and should be based on an individualized decision between the exposed person and the treating clinician.

^{§§} If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.

^{¶¶} Large volume (i.e., major blood splash).

Timing and Duration of PEP. PEP should be initiated as soon as possible. The interval within which PEP should be initiated for optimal efficacy is not known. Animal studies have demonstrated the importance of starting PEP soon after an exposure (111,112,118). If questions exist about which antiretroviral drugs to use or whether to use a basic or expanded regimen, starting the basic regimen immediately rather than delaying PEP administration is probably better. Although animal studies suggest that PEP probably is substantially less effective when started more than 24–36 hours postexposure (112,119,122), the interval after which no benefit is gained 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 week) might be considered for exposures that represent an increased risk for transmission. The optimal duration of PEP is unknown. Because 4 weeks of ZDV appeared protective in occupational and animal studies (100,123), PEP probably should be administered for 4 weeks, if tolerated.

Use of PEP When HIV Infection Status of Source Person is Unknown. If the source person's HIV infection status is unknown at the time of 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 (Tables 4 and 5). If these considerations suggest a possibility for HIV transmission and HIV testing of the source person is pending, initiating a two-drug PEP regimen until laboratory results have been obtained and later modifying or discontinuing the regimen accordingly is reasonable. The following are recommendations regarding HIV postexposure prophylaxis:

- If indicated, start PEP as soon as possible after an exposure.
- Reevaluation of the exposed person should be considered within 72 hours postexposure, especially as additional information about the exposure or source person becomes available.
- Administer PEP for 4 weeks, if tolerated.
- If a source person is determined to be HIV-negative, PEP should be discontinued.

PEP for Pregnant HCP. If the exposed person is pregnant, the evaluation of risk of infection and need for PEP should be approached as with any other person 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(s) regarding the potential benefits and risks to her and her fetus.

Certain drugs should be avoided in pregnant women. Because teratogenic effects were observed in primate studies, EFV is not recommended during pregnancy. Reports of fatal lactic acidosis in pregnant women treated with a combination of d4T and ddI have prompted warnings about these drugs during pregnancy. Because of the risk of hyperbilirubinemia in newborns, IDV should not be administered to pregnant women shortly before delivery.

Recommendations for the Selection of Drugs for HIV PEP

Health-care providers must strive to balance the risk for infection against the potential toxicity of the agent(s) used when selecting a drug regimen for HIV PEP. Because PEP is potentially toxic, its use is not justified for exposures that pose a negligible risk for

transmission (Tables 4 and 5). Also, insufficient evidence exists to support recommending a three-drug regimen for all HIV exposures. Therefore, two regimens for PEP are provided (Appendix C): 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 (Tables 4 and 5). When possible, the regimens should be implemented in consultation with persons who have expertise in antiretroviral treatment and HIV transmission.

Most HIV exposures will warrant a two-drug regimen using two nucleoside analogues (e.g., ZDV and 3TC; or 3TC and d4T; or d4T and ddI). The addition of a third drug should be considered for exposures that pose an increased risk for transmission. 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-cell counts, viral load measurements, and current disease stage. When the source person's virus is known or suspected to be resistant to one or more of the drugs considered for the PEP regimen, the selection of drugs to which the source person's virus is unlikely to be resistant is recommended; expert consultation is advised. 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. Reevaluation of the exposed person should be considered within 72 hours postexposure, especially as additional information about the exposure or source person becomes available.

Follow-up of HCP Exposed to HIV

Postexposure Testing. HCP 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). Extended HIV follow-up (e.g., for 12 months) is recommended for HCP who become infected with HCV following exposure to a source coinfecting with HIV and HCV. Whether extended follow-up is indicated in other circumstances (e.g., exposure to a source coinfecting with HIV and HCV in the absence of HCV seroconversion or for exposed persons with a medical history suggesting an impaired ability to develop an antibody response to acute infection) is unclear. Although rare instances of delayed HIV seroconversion have been reported (167, 168), the infrequency of this occurrence does not warrant adding to the anxiety level of the exposed persons by routinely extending the duration of postexposure follow-up. However, this recommendation should not preclude a decision to extend follow-up in an individual situation based on the clinical judgement of the exposed person's health-care provider. HIV testing should be performed on any exposed person who has an illness that is compatible with an acute retroviral syndrome, regardless of the interval since exposure. When HIV infection is identified, the person should be referred to a specialist knowledgeable in the area of HIV treatment and counseling for medical management.

HIV-antibody testing with EIA should be used to monitor for seroconversion. The routine use of direct virus assays (e.g., HIV p24 antigen EIA or tests for HIV RNA) to detect infection in exposed HCP generally is not recommended (169). The high rate of false-positive results of these tests in this setting could lead to unnecessary anxiety and/or treatment (170, 171). Despite the ability of direct virus assays to detect HIV infection a few days earlier than EIA, the infrequency of occupational seroconversion and increased costs of these tests do not warrant their routine use in this setting.

- HIV-antibody testing should be performed for at least 6 months postexposure.
- Direct virus assays for routine follow-up of HCP are not recommended.
- HIV testing should be performed on any exposed person who has an illness compatible with an acute retroviral syndrome.

Monitoring and Management of PEP Toxicity. If PEP is used, HCP should be monitored for drug toxicity by testing at baseline and again 2 weeks after starting PEP. The scope of testing should be based on medical conditions in the exposed person and the toxicity of drugs included in the PEP regimen. Minimally, lab monitoring for toxicity should include a complete blood count and renal and hepatic function tests. Monitoring for evidence of hyperglycemia should be included for HCP whose regimens include any PI; if the exposed person 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.

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

HCP 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 with antimotility and antiemetic agents or other medications that target the specific symptoms without changing the regimen. 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), might facilitate adherence to the regimen. Serious adverse events should be reported to FDA's MedWatch Program.

Counseling and Education. Although HIV infection following an occupational exposure occurs infrequently, the emotional effect of an exposure often is substantial (172–174). In addition, HCP are given seemingly conflicting information. Although HCP are told that a low risk exists for HIV transmission, a 4-week regimen of PEP might be recommended, and they are asked to commit to behavioral measures (e.g., sexual abstinence or condom use) to prevent secondary transmission, all of which influence their lives for several weeks to months (172). Therefore, access to persons who are knowledgeable about occupational HIV transmission and who can deal with the many concerns an HIV exposure might generate for the exposed person is an important element of postexposure management. HIV-exposed HCP should be advised to use the following measures to prevent secondary transmission during the follow-up period, especially the first 6–12 weeks after the exposure when most HIV-infected persons are expected to seroconvert: exercise sexual abstinence or use condoms to prevent sexual transmission and to avoid pregnancy; and refrain from donating blood, plasma, organs, tissue, or semen. If an exposed woman is breast feeding, she should be counseled about the risk of HIV transmission through breast milk, and discontinuation of breast feeding should be considered, especially for high-risk exposures. Additionally, NRTIs are known to pass into breast milk, as is NVP; whether this also is true for the other approved antiretroviral drugs is unknown.

The patient-care responsibilities of an exposed person do not need to be modified, based solely on an HIV exposure, to prevent transmission to patients. If HIV seroconversion is detected, the person should be evaluated according to published recommendations for infected HCP (175).

Exposed HCP 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, might be indicative of acute HIV infection but also might be indicative of a drug reaction or another medical condition.

For exposures for which PEP is considered appropriate, HCP should be informed that a) knowledge about the efficacy of drugs used for PEP is limited; b) experts recommend combination drug regimens because of increased potency and concerns about drug-resistant virus; c) data regarding toxicity of antiretroviral drugs in persons without HIV infection or in pregnant women are limited; d) although the short-term toxicity of antiretroviral drugs is usually limited, serious adverse events have occurred in persons taking PEP; and e) any or all drugs for PEP may be declined or stopped by the exposed person. HCP who experience 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.

Guidelines for counseling and educating HCP with HIV exposure include

- Exposed HCP should be advised to use precautions to prevent secondary transmission during the follow-up period.
- For exposures for which PEP is prescribed, HCP should be informed about possible drug toxicities and the need for monitoring, and possible drug interactions.

Occupational Exposure Management Resources

Several resources are available that provide guidance to HCP regarding the management of occupational exposures. These resources include PEPline; the Needlestick! website; the Hepatitis Hotline; CDC (receives reports of occupationally acquired HIV infections and failures of PEP); the HIV Antiretroviral Pregnancy Registry; FDA (receives reports of unusual or severe toxicity to antiretroviral agents); and the HIV/AIDS Treatment Information Service (Box 5).

BOX 4. Situations for which expert* consultation for HIV postexposure prophylaxis is advised

- Delayed (i.e., later than 24–36 hours) exposure report
 - the interval after which there is no benefit from postexposure prophylaxis (PEP) is undefined
- Unknown source (e.g., needle in sharps disposal container or laundry)
 - decide use of PEP on a case-by-case basis
 - consider the severity of the exposure and the epidemiologic likelihood of HIV exposure
 - do not test needles or other sharp instruments for HIV
- Known or suspected pregnancy in the exposed person
 - does not preclude the use of optimal PEP regimens
 - do not deny PEP solely on the basis of pregnancy
- Resistance of the source virus to antiretroviral agents
 - influence of drug resistance on transmission risk is unknown
 - selection of drugs to which the source person's virus is unlikely to be resistant is recommended, if the source person's virus is known or suspected to be resistant to ≥ 1 of the drugs considered for the PEP regimen
 - resistance testing of the source person's virus at the time of the exposure is not recommended
- Toxicity of the initial PEP regimen
 - adverse symptoms, such as nausea and diarrhea are common with PEP
 - symptoms often can be managed without changing the PEP regimen by prescribing antimotility and/or antiemetic agents
 - modification of dose intervals (i.e., administering a lower dose of drug more frequently throughout the day, as recommended by the manufacturer), in other situations, might help alleviate symptoms

*Local experts and/or the National Clinicians' Post-Exposure Prophylaxis Hotline (PEpline [1-888-448-4911]).

BOX 5. Occupational exposure management resources**National Clinicians' Postexposure Prophylaxis Hotline (PEpline)**

Run by University of California–San Francisco/San Francisco General Hospital staff; supported by the Health Resources and Services Administration Ryan White CARE Act, HIV/AIDS Bureau, AIDS Education and Training Centers, and CDC.

Phone: (888) 448-4911

Internet: <<http://www.ucsf.edu/hivcntr>>

Needlestick!

A website to help clinicians manage and document occupational blood and body fluid exposures. Developed and maintained by the University of California, Los Angeles (UCLA), Emergency Medicine Center, UCLA School of Medicine, and funded in part by CDC and the Agency for Healthcare Research and Quality.

Internet: <[http://](http://www.needlestick.mednet.ucla.edu)

www.needlestick.mednet.ucla.edu>

Hepatitis Hotline.

Phone: (888) 443-7232

Internet: <<http://www.cdc.gov/hepatitis>>

Reporting to CDC: Occupationally acquired HIV infections and failures of PEP.

Phone: (800) 893-0485

HIV Antiretroviral Pregnancy Registry.

Phone:(800) 258-4263

Fax: (800) 800-1052

Address:

1410 Commonwealth Drive

Suite 215

Wilmington, NC 28405

Internet:

<http://www.glaxowellcome.com/preg_reg/antiretroviral>

BOX 5. (Continued) Occupational exposure management resources**Food and Drug Administration**

Report unusual or severe toxicity
to antiretroviral agents.

Phone: (800) 332-1088

Address:

MedWatch

HF-2, FDA

5600 Fishers Lane

Rockville, MD 20857

Internet:

<<http://www.fda.gov/medwatch>>

**HIV/AIDS Treatment Information
Service.**

Internet: <<http://www.hivatis.org>>

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APPENDIX A.

Practice Recommendations for Health-Care Facilities Implementing the U.S. Public Health Service Guidelines for Management of Occupational Exposures to Bloodborne Pathogens

Practice recommendation	Implementation checklist
Establish a bloodborne pathogen policy.	<p>All institutions where health-care personnel (HCP) might experience exposures should have a written policy for management of exposures.</p> <p>The policy should be based on the U.S. Public Health Service (PHS) guidelines.</p> <p>The policy should be reviewed periodically to ensure that it is consistent with PHS recommendations.</p>
Implement management policies.	<p>Health-care facilities (HCF) should provide appropriate training to all personnel on the prevention of and response to occupational exposures.</p> <p>HCF should establish hepatitis B vaccination programs.</p> <p>HCF should establish exposure-reporting systems.</p> <p>HCF should have personnel who can manage an exposure readily available at all hours of the day.</p> <p>HCF should have ready access to postexposure prophylaxis (PEP) for use by exposed personnel as necessary.</p>
Establish laboratory capacity for bloodborne pathogen testing.	<p>HCF should provide prompt processing of exposed person and source person specimens to guide management of occupational exposures.</p> <p>Testing should be performed with appropriate counseling and consent.</p>

Practice recommendation	Implementation checklist
Select and use appropriate PEP regimens.	<p>HCF should develop a policy for the selection and use of PEP antiretroviral regimens for HIV exposures within their institution.</p> <p>Hepatitis B vaccine and HBIG should be available for timely administration.</p> <p>HCF should have access to resources with expertise in the selection and use of PEP.</p>
Provide access to counseling for exposed HCP.	<p>HCF should provide counseling for HCP who might need help dealing with the emotional effect of an exposure.</p> <p>HCF should provide medication adherence counseling to assist HCP in completing HIV PEP as necessary.</p>
Monitor for adverse effects of PEP.	<p>HCP taking antiretroviral PEP should be monitored periodically for adverse effects of PEP through baseline and testing (every 2 weeks) and clinical evaluation.</p>
Monitor for seroconversion.	<p>HCF should develop a system to encourage exposed HCP to return for follow-up testing.</p> <p>Exposed HCP should be tested for HCV and HIV.</p>
Monitor exposure management programs.	<p>HCF should develop a system to monitor reporting and management of occupational exposures to ensure timely and appropriate response.</p>
	<p>Evaluate</p> <ul style="list-style-type: none"> • exposure reports for completeness and accuracy, • access to care (i.e., the time of exposure to the time of evaluation), and • laboratory result reporting time.
	<p>Review</p> <ul style="list-style-type: none"> • exposures to ensure that HCP exposed to sources not infected with bloodborne pathogens do not receive PEP or that PEP is stopped.
	<p>Monitor</p> <ul style="list-style-type: none"> • completion rates of HBV vaccination and HIV PEP and • completion of exposure follow-up.

APPENDIX B.

Management of Occupational Blood Exposures

Provide immediate care to the exposure site.

- Wash wounds and skin with soap and water.
- Flush mucous membranes with water.

Determine risk associated with exposure by

- type of fluid (e.g., blood, visibly bloody fluid, other potentially infectious fluid or tissue, and concentrated virus) and
- type of exposure (i.e., percutaneous injury, mucous membrane or nonintact skin exposure, and bites resulting in blood exposure).

Evaluate exposure source.

- Assess the risk of infection using available information.
- Test known sources for HBsAg, anti-HCV, and HIV antibody (consider using rapid testing).
- For unknown sources, assess risk of exposure to HBV, HCV, or HIV infection.
- Do not test discarded needles or syringes for virus contamination.

Evaluate the exposed person.

- Assess immune status for HBV infection (i.e., by history of hepatitis B vaccination and vaccine response).

Give PEP for exposures posing risk of infection transmission.

- HBV: See Table 3.
- HCV: PEP not recommended.
- HIV: See Tables 4 and 5.
 - Initiate PEP as soon as possible, preferably within hours of exposure.
 - Offer pregnancy testing to all women of childbearing age not known to be pregnant.
 - Seek expert consultation if viral resistance is suspected.
 - Administer PEP for 4 weeks if tolerated.

Perform follow-up testing and provide counseling.

- Advise exposed persons to seek medical evaluation for any acute illness occurring during follow-up.

HBV exposures

- Perform follow-up anti-HBs testing in persons who receive hepatitis B vaccine.
 - Test for anti-HBs 1–2 months after last dose of vaccine.
 - Anti-HBs response to vaccine cannot be ascertained if HBIG was received in the previous 3–4 months.

HCV exposures

- Perform baseline and follow-up testing for anti-HCV and alanine aminotransferase (ALT) 4–6 months after exposures.
- Perform HCV RNA at 4–6 weeks if earlier diagnosis of HCV infection desired.
- Confirm repeatedly reactive anti-HCV enzyme immunoassays (EIAs) with supplemental tests.

HIV exposures

- Perform HIV-antibody testing for at least 6 months postexposure (e.g., at baseline, 6 weeks, 3 months, and 6 months).
- Perform HIV antibody testing if illness compatible with an acute retroviral syndrome occurs.
- Advise exposed persons to use precautions to prevent secondary transmission during the follow-up period.
- Evaluate exposed persons taking PEP within 72 hours after exposure and monitor for drug toxicity for at least 2 weeks.

APPENDIX C.

Basic and Expanded HIV Postexposure Prophylaxis Regimens

BASIC REGIMEN

- **Zidovudine (RETROVIR™; ZDV; AZT) + Lamivudine (EPIVIR™; 3TC); available as COMBIVIR™**
 - ZDV: 600 mg per day, in two or three divided doses, and
 - 3TC: 150 mg twice daily.

Advantages

- ZDV is associated with decreased risk of HIV transmission in the CDC case-control study of occupational HIV infection.
- ZDV has been used more than the other drugs for PEP in HCP.
- Serious toxicity is rare when used for PEP.
- Side effects are predictable and manageable with antimotility and antiemetic agents.
- Probably a safe regimen for pregnant HCP.
- Can be given as a single tablet (COMBIVIR™) twice daily.

Disadvantages

- Side effects are common and might result in low adherence.
- Source patient virus might have resistance to this regimen.
- Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

ALTERNATE BASIC REGIMENS

- **Lamivudine (3TC) + Stavudine (ZERIT™; d4T)**
 - 3TC: 150 mg twice daily, and
 - d4T: 40 mg (if body weight is <60 kg, 30 mg twice daily) twice daily.

Advantages

- well tolerated in patients with HIV infection, resulting in good adherence,
- serious toxicity appears to be rare, and
- twice daily dosing might improve adherence.

Disadvantages

- Source patient virus might be resistant to this regimen.
- Potential for delayed toxicity (oncogenic/teratogenic) is unknown.
- **Didanosine (VIDEX™, chewable/dispersable buffered tablet; VIDEX™ EC, delayed-release capsule; ddl) + Stavudine (d4T)**
 - ddl: 400 mg (if body weight is <60 kg, 125 mg twice daily) daily, on an empty stomach.
 - d4T: 40 mg (if body weight is <60 kg, 30 mg twice daily) twice daily.

Advantages

- Likely to be effective against HIV strains from source patients who are taking ZDV and 3TC.

Disadvantages

- ddl is difficult to administer and unpalatable.
- Chewable/dispersable buffered tablet formulation of ddl interferes with absorption of some drugs (e.g., quinolone antibiotics, and indinavir).
- Serious toxicity (e.g., neuropathy, pancreatitis, or hepatitis) can occur. Fatal and nonfatal pancreatitis has occurred in HIV-positive, treatment-naïve patients. Patients taking ddl and d4T should be carefully assessed and closely monitored for pancreatitis, lactic acidosis, and hepatitis.
- Side effects are common; anticipate diarrhea and low adherence.
- Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

EXPANDED REGIMEN

Basic regimen plus one of the following:

- **Indinavir (CRIXIVAN™; IDV)**
 - 800 mg every 8 hours, on an empty stomach.

Advantages

- Potent HIV inhibitor.

Disadvantages

- Serious toxicity (e.g., nephrolithiasis) can occur; must take 8 glasses of fluid per day.
- Hyperbilirubinemia common; must avoid this drug during late pregnancy.

- Requires acid for absorption and cannot be taken simultaneously with ddi in chewable/dispersable buffered tablet formulation (doses must be separated by at least 1 hour).
- Concomitant use of astemizole, terfenadine, dihydroergotamine, ergotamine, ergonovine, methylergonovine, rifampin, cisapride, St. John's Wort, lovastatin, simvastatin, pimozone, midazolam, or triazolam is not recommended.
- Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

- **Nelfinavir (VIRACEPT™; NFV)**

- 750 mg three times daily, with meals or snack, or
- 1250 mg twice daily, with meals or snack.

Advantages

- potent HIV inhibitor, and
- twice dosing per day might improve adherence.

Disadvantages

- Concomitant use of astemizole, terfenadine, dihydroergotamine, ergotamine, ergonovine, methylergonovine, rifampin, cisapride, St. John's Wort, lovastatin, simvastatin, pimozone, midazolam, or triazolam is not recommended.
- Might accelerate the clearance of certain drugs, including oral contraceptives (requiring alternative or additional contraceptive measures for women taking these drugs).
- Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

- **Efavirenz (SUSTIVA™; EFV)**

- 600 mg daily, at bedtime.

Advantages

- Does not require phosphorylation before activation and might be active earlier than other antiretroviral agents (note: this might be only a theoretical advantage of no clinical benefit.)
- One dose daily might improve adherence.

Disadvantages

- Drug is associated with rash (early onset) that can be severe and might rarely progress to Stevens-Johnson syndrome.

- Differentiating between early drug-associated rash and acute seroconversion can be difficult and cause extraordinary concern for the exposed person.
 - Nervous system side effects (e.g., dizziness, somnolence, insomnia, and/or abnormal dreaming) are common. Severe psychiatric symptoms are possible (dosing before bedtime might minimize these side effects).
 - Should not be used during pregnancy because of concerns about teratogenicity.
 - Concomitant use of astemizole, cisapride, midazolam, triazolam, ergot derivatives, or St. John's Wort is not recommended because inhibition of the metabolism of these drugs could create the potential for serious and/or life-threatening adverse events (e.g., cardiac arrhythmias, prolonged sedation, or respiratory depression).
 - Potential for oncogenic toxicity is unknown.
- **Abacavir (ZIAGEN™; ABC); available as TRIZIVIR™, a combination of ZDV, 3TC, and ABC**
 - 300 mg twice daily.

Advantages

- potent HIV inhibitor, and
- well tolerated in patients with HIV infection.

Disadvantages

- Severe hypersensitivity reactions can occur, usually within the first 6 weeks of treatment.
- Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

ANTIRETROVIRAL AGENTS FOR USE AS PEP ONLY WITH EXPERT CONSULTATION

- **Ritonavir (NORVIR™; RTV)**

Disadvantages

- difficult to take (requires dose escalation),
- poor tolerability, and
- many drug interactions.

- **Saquinavir (FORTOVASE™, soft-gel formulation; SQV)**

Disadvantages

- Bioavailability is relatively poor, even with new formulation.

- **Amprenavir (AGENERASE™; AMP)**

Disadvantages

- Dosage consists of eight large pills taken twice daily.
- Many drug interactions.

- **Delavirdine (RESCRIPTOR™; DLV)**

Disadvantages

- Drug is associated with rash (early onset) that can be severe and progress to Stevens-Johnson syndrome.
- Many drug interactions.

- **Lopinavir/Ritonavir (KALETRA™)**

- 400/100 mg twice daily.

Advantages

- potent HIV inhibitor, and
- well tolerated in patients with HIV infection.

Disadvantages

- Concomitant use of flecainide, propafenone, astemizole, terfenadine, dihydroergotamine, ergotamine, ergonovine, methylergonovine, rifampin, cisapride, St. John's Wort, lovastatin, simvastatin, pimozone, midazolam, or triazolam is not recommended because inhibition of the metabolism of these drugs could create the potential for serious and/or life-threatening adverse events (e.g., cardiac arrhythmias, prolonged sedation, or respiratory depression).
- May accelerate the clearance of certain drugs, including oral contraceptives (requiring alternative or additional contraceptive measures for women taking these drugs).
- Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

ANTIRETROVIRAL AGENTS GENERALLY NOT RECOMMENDED FOR USE AS PEP

- **Nevirapine (VIRAMUNE™; NVP)**

- 200 mg daily for 2 weeks, then 200 mg twice daily.

Disadvantages

- Associated with severe hepatotoxicity (including at least one case of liver failure requiring liver transplantation in an exposed person taking PEP),
- Associated with rash (early onset) that can be severe and progress to Stevens-Johnson syndrome,
- Differentiating between early drug-associated rash and acute seroconversion can be difficult and cause extraordinary concern for the exposed person, and
- Concomitant use of St. John's Wort is not recommended because this might result in suboptimal antiretroviral drug concentrations.

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Appendix B



MMWRTM

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Recommendations and Reports

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Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis

INSIDE: Continuing Education Examination

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION**

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Disclosure of Relationship

CDC, our planners, and our content experts wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters.

The antiretroviral agents mentioned in the article do not have an approved indication by the FDA for postexposure prophylaxis. The material presented is based on expert review and does not reflect the views of the FDA.

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis

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Summary

This report updates U.S. Public Health Service recommendations for the management of health-care personnel (HCP) who have occupational exposure to blood and other body fluids that might contain human immunodeficiency virus (HIV). Although the principles of exposure management remain unchanged, recommended HIV postexposure prophylaxis (PEP) regimens have been changed. This report emphasizes adherence to HIV PEP when it is indicated for an exposure, expert consultation in management of exposures, follow-up of exposed workers to improve adherence to PEP, and monitoring for adverse events, including seroconversion. To ensure timely postexposure management and administration of HIV PEP, clinicians should consider occupational exposures as urgent medical concerns.

Introduction

Although preventing exposures to blood and body fluids is the primary means of preventing occupationally acquired human immunodeficiency virus (HIV) infection, appropriate postexposure management is an important element of workplace safety. In 1996, the first U.S. Public Health Service (PHS) recommendations for the use of postexposure prophylaxis (PEP) after occupational exposure to HIV were published; these recommendations have been updated twice (1–3). Since publication of the most recent guidelines in 2001, new antiretroviral agents have been approved by the Food and Drug Administration (FDA), and additional information has become available regarding the use and safety of HIV PEP. In August 2003, CDC convened a meeting of a PHS interagency working group* and consultants to assess use of HIV PEP.

* This interagency working group included representatives from CDC, FDA, the Health Resources and Services Administration, and the National Institutes of Health. Information included in these recommendations might not represent FDA approval or approved labeling for the particular product or indications in question. Specifically, the terms “safe” and “effective” might not be synonymous with the FDA-defined legal standard for product approval.

The material in this report originated in the National Center for Infectious Diseases, Anne Schuchat, MD, Acting Director; Division of Healthcare Quality Promotion, Denise M. Cardo, MD, Director. **Corresponding preparer:** Adelisa L. Panlilio, MD, MPH, Division of Healthcare Quality Promotion, National Center for Infectious Diseases, CDC, 1600 Clifton Rd., NE, MS E-68, Atlanta, GA 30333. Telephone: 404-498-1265; Fax: 404-498-1244; E-mail: alp4@cdc.gov.

On the basis of this discussion, the PHS working group decided that updated recommendations for the management of occupational exposure to HIV were warranted.

This report modifies and expands the list of antiretroviral medications that can be considered for use as PEP. This report also emphasizes prompt management of occupational exposures, selection of tolerable regimens, attention to potential drug interactions involving drugs that could be included in HIV PEP regimens and other medications, consultation with experts for postexposure management strategies (especially determining whether an exposure has actually occurred) and selection of HIV PEP regimens, use of HIV rapid testing, and counseling and follow-up of exposed personnel.

Recommendations on the management of occupational exposures to hepatitis B virus or hepatitis C virus have been published previously (3) and are not included in this report. Recommendations for nonoccupational (e.g., sexual, pediatric, and perinatal) HIV exposures also have been published previously (4–6).

Definition of Health-Care Personnel and Exposure

The definitions of health-care personnel (HCP) and occupational exposures are unchanged from those used in 2001 (3). The term HCP refers to all paid and unpaid persons working in health-care settings who have the potential for exposure to infectious materials (e.g., blood, tissue, and specific body fluids and medical supplies, equipment, or environmental

surfaces contaminated with these substances). HCP might include, but are not limited to, emergency medical service personnel, dental personnel, laboratory personnel, autopsy personnel, nurses, nursing assistants, physicians, technicians, therapists, pharmacists, students and trainees, contractual staff not employed by the health-care facility, and persons not directly involved in patient care but potentially exposed to blood and body fluids (e.g., clerical, dietary, housekeeping, maintenance, and volunteer personnel). The same principles of exposure management could be applied to other workers who have potential for occupational exposure to blood and body fluids in other settings.

An exposure that might place HCP at risk for HIV infection is defined as a percutaneous injury (e.g., a needlestick or cut with a sharp object) or contact of mucous membrane or nonintact skin (e.g., exposed skin that is chapped, abraded, or afflicted with dermatitis) with blood, tissue, or other body fluids that are potentially infectious. In addition to blood and visibly bloody body fluids, semen and vaginal secretions also are considered potentially infectious. Although semen and vaginal secretions have been implicated in the sexual transmission of HIV, they have not been implicated in occupational transmission from patients to HCP. The following fluids also are considered potentially infectious: cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. The risk for transmission of HIV infection from these fluids is unknown; the potential risk to HCP from occupational exposures has not been assessed by epidemiologic studies in health-care settings. Feces, nasal secretions, saliva, sputum, sweat, tears, urine, and vomitus are not considered potentially infectious unless they are visibly bloody; the risk for transmission of HIV infection from these fluids and materials is low (7).

Any direct contact (i.e., contact without barrier protection) to concentrated virus in a research laboratory or production facility requires clinical evaluation. For human bites, clinical evaluation must include the possibility that both the person bitten and the person who inflicted the bite were exposed to bloodborne pathogens. Transmission of HIV infection by this route has been reported rarely, but not after an occupational exposure (8–12).

Risk for Occupational Transmission of HIV

The risks for occupational transmission of HIV have been described; risks vary with the type and severity of exposure (2,3,7). In prospective studies of HCP, the average risk for HIV transmission after a percutaneous exposure to HIV-infected blood has been estimated to be approximately 0.3%

(95% confidence interval [CI] = 0.2%–0.5%) (7) and after a mucous membrane exposure, approximately 0.09% (CI = 0.006%–0.5%) (3). Although episodes of HIV transmission after nonintact skin exposure have been documented, the average risk for transmission by this route has not been precisely quantified but is estimated to be less than the risk for mucous membrane exposures. The risk for transmission after exposure to fluids or tissues other than HIV-infected blood also has not been quantified but is probably considerably lower than for blood exposures.

Epidemiologic and laboratory studies suggest that multiple factors might affect the risk for HIV transmission after an occupational exposure (3). In a retrospective case-control study of HCP who had percutaneous exposure to HIV, increased risk for HIV infection was associated with exposure to a larger quantity of blood from the source person as indicated by 1) a device (e.g., a needle) visibly contaminated with the patient's blood, 2) a procedure that involved a needle being placed directly in a vein or artery, or 3) a deep injury. The risk also was increased for exposure to blood from source persons with terminal illness, possibly reflecting either the higher titer of HIV in blood late in the course of acquired immunodeficiency syndrome (AIDS) or other factors (e.g., the presence of syncytia-inducing strains of HIV). 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 (3).

The use of source-person viral load as a surrogate measure of viral titer for assessing transmission risk has not yet been established. Plasma viral load (e.g., HIV RNA) reflects only the level of cell-free virus in the peripheral blood; latently infected cells might transmit infection in the absence of viremia. Although a lower viral load (e.g., <1,500 RNA copies/mL) or one that is below the limits of detection probably indicates a lower titer exposure, it does not rule out the possibility of transmission.

Antiretroviral Agents for PEP

Antiretroviral agents from five classes of drugs are currently available to treat HIV infection (13,14). These include the nucleoside reverse transcriptase inhibitors (NRTIs), nucleotide reverse transcriptase inhibitors (NtRTIs), nonnucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), and a single fusion inhibitor. Only antiretroviral agents approved by FDA for treatment of HIV infection are included in these guidelines. The recommendations in this report provide guidance for two- or-more drug PEP regimens on the basis of the level of risk for HIV transmission represented by the exposure (Tables 1 and 2; Appendix).

TABLE 1. Recommended HIV postexposure prophylaxis (PEP) for percutaneous injuries

Exposure type	Infection status of source				
	HIV-positive, class 1*	HIV-positive, class 2*	Source of unknown HIV status†	Unknown source§	HIV-negative
Less severe¶	Recommend basic 2-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors††	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings in which exposure to HIV-infected persons is likely	No PEP warranted
More severe§§	Recommend expanded 3-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors††	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings in which exposure to HIV-infected persons is likely	No PEP warranted

* HIV-positive, class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 ribonucleic acid copies/mL). HIV-positive, class 2 — symptomatic HIV infection, acquired immunodeficiency syndrome, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

† For example, deceased source person with no samples available for HIV testing.

§ For example, a needle from a sharps disposal container.

¶ For example, solid needle or superficial injury.

** The recommendation "consider PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.

†† If PEP is offered and administered and the source is later determined to be HIV-negative, PEP should be discontinued.

§§ For example, large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient's artery or vein.

TABLE 2. Recommended HIV postexposure prophylaxis (PEP) for mucous membrane exposures and nonintact skin* exposures

Exposure type	Infection status of source				
	HIV-positive, class 1†	HIV-positive, class 2†	Source of unknown HIV status§	Unknown source¶	HIV-negative
Small volume**	Consider basic 2-drug PEP††	Recommend basic 2-drug PEP	Generally, no PEP warranted§§	Generally, no PEP warranted	No PEP warranted
Large volume¶¶	Recommend basic 2-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP†† for source with HIV risk factors§§	Generally, no PEP warranted; however, consider basic 2-drug PEP†† in settings in which exposure to HIV-infected persons is likely	No PEP warranted

* For skin exposures, follow-up is indicated only if evidence exists of compromised skin integrity (e.g., dermatitis, abrasion, or open wound).

† HIV-positive, class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 ribonucleic acid copies/mL). HIV-positive, class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

§ For example, deceased source person with no samples available for HIV testing.

¶ For example, splash from inappropriately disposed blood.

** For example, a few drops.

†† The recommendation "consider PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.

§§ If PEP is offered and administered and the source is later determined to be HIV-negative, PEP should be discontinued.

¶¶ For example, a major blood splash.

Toxicity and Drug Interactions of Antiretroviral Agents

Persons receiving PEP should complete a full 4-week regimen (3). However, as a result of toxicity and side effects among HCP, a substantial proportion of HCP have been unable to complete a full 4-week course of HIV PEP (15–20). Because all antiretroviral agents have been associated with side effects (Table 3), the toxicity profile of these agents, including the frequency, severity, duration, and reversibility of side effects, is an important consideration in selection of an HIV PEP regimen. The majority of data concerning adverse events have been reported primarily for persons with established HIV infection receiving prolonged antiretroviral therapy and therefore might not reflect the experience of uninfected persons who take PEP. Anecdotal evidence from clinicians knowledgeable about HIV treatment indicates that antiretroviral agents are tolerated more poorly among HCP taking HIV PEP than among HIV-infected patients on antiretroviral medications.

a substantial (range: 17%–47%) proportion of HCP taking PEP after occupational exposures to HIV-positive sources did not complete a full 4-week course of therapy because of inability to tolerate the drugs (15–17,19,20). Data from the National Surveillance System for Health Care Workers (NaSH), CDC's occupational surveillance system for occupational exposures and infections in hospitals, for June 1995–December 2004 indicate that 401 (46.9%) of 921 HCP with at least one follow-up visit after starting PEP experienced one or more symptoms. The symptom reported most frequently was nausea (26.5%), followed by malaise and fatigue (22.8%) (CDC, unpublished data, 2005). Of 503 HCP who stopped HIV PEP prematurely (<28 days), 361 (24.0%) did so because of adverse effects of the drugs. Similar data have been reported from the Italian Registry of Antiretroviral Postexposure Prophylaxis, which includes data primarily on HCP taking PEP but also collects data on those taking PEP after nonoccupational exposures (18). In multivariate analysis, those taking regimens that include PI were more likely to

TABLE 3. Primary side effects and toxicities associated with antiretroviral agents used for HIV postexposure prophylaxis, by class and agent

Class and agent	Side effect and toxicity
Nucleoside reverse transcriptase inhibitors (NRTI)	Class warning: all NRTIs have the potential to cause lactic acidosis with hepatic steatosis
Zidovudine (Retrovir [®] ; ZDV, AZT)	Anemia, neutropenia, nausea, headache, insomnia, muscle pain, and weakness
Lamivudine (EpiVir [®] , 3TC)	Abdominal pain, nausea, diarrhea, rash, and pancreatitis
Stavudine (Zerit [™] ; d4T)	Peripheral neuropathy, headache, diarrhea, nausea, insomnia, anorexia, pancreatitis, elevated liver function tests (LFTs), anemia, and neutropenia
Didanosine (Videx [®] ; ddI)	Pancreatitis, lactic acidosis, neuropathy, diarrhea, abdominal pain, and nausea
Emtricitabine (Emtriva, FTC)	Headache, nausea, vomiting, diarrhea, and rash. Skin discoloration (mild hyperpigmentation on palms and soles), primarily among nonwhites
Nucleotide analogue reverse transcriptase inhibitor (NtRTI)	Class warning: All NtRTIs have the potential to cause lactic acidosis with hepatic steatosis
Tenofovir (Viread [®] ; TDF)	Nausea, diarrhea, vomiting, flatulence, and headache
Nonnucleoside reverse transcriptase inhibitors (NNRTIs)	
Efavirenz (Sustiva [®] ; EFV)	Rash (including cases of Stevens-Johnson syndrome), insomnia, somnolence, dizziness, trouble concentrating, abnormal dreaming, and teratogenicity
Protease inhibitor	
Indinavir (Crixivan [®] ; IDV)	Nausea, abdominal pain, nephrolithiasis, and indirect hyperbilirubinemia
Nelfinavir (Viracept [®] ; NFV)	Diarrhea, nausea, abdominal pain, weakness, and rash
Ritonavir (Norvir [®] ; RTV)	Weakness, diarrhea, nausea, circumoral paresthesia, taste alteration, and elevated cholesterol and triglycerides
Saquinavir (Invirase [®] ; SQV)	Diarrhea, abdominal pain, nausea, hyperglycemia, and elevated LFTs
Fosamprenavir (Lexiva [®] ; FOSAPV)	Nausea, diarrhea, rash, circumoral paresthesia, taste alteration, and depression
Atazanavir (Reyataz [®] ; ATV)	Nausea, headache, rash, abdominal pain, diarrhea, vomiting, and indirect hyperbilirubinemia
Lopinavir/ritonavir (Kaletra [®] ; LPV/RTV)	Diarrhea, fatigue, headache, nausea, and increased cholesterol and triglycerides
Fusion inhibitor	
Enfuvirtide (Fuzeon [®] ; T-20)	Local injection site reactions, bacterial pneumonia, insomnia, depression, peripheral neuropathy, and cough

Sources: Package inserts; Panel on Clinical Practices for Treatment of HIV Infection. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents—April 7, 2005. Washington, DC: National Institutes of Health; 2005. Available at http://aidsinfo.nih.gov/guidelines/default_db2.asp?id=50.

Side effects have been reported frequently by persons taking antiretroviral agents as PEP (15–23). In multiple instances,

experience PEP-associated side effects and to discontinue PEP prematurely (<28 days). Because side effects are frequent and

particularly because they are cited as a major reason for not completing PEP regimens as prescribed, the selection of regimens should be heavily influenced toward those that are tolerable for short-term use.

In addition, all approved antiretroviral agents might have potentially serious drug interactions when used with certain other drugs, requiring careful evaluation of concomitant medications, including over-the-counter medications and supplements (e.g., herbals), used by an exposed person before prescribing PEP and close monitoring for toxicity of anyone receiving these drugs (24–33) (Tables 3–5). PIs and NNRTIs have the greatest potential for interactions with other drugs. Information regarding potential drug interactions has been published (13,24–33). Additional information is included in the manufacturers' package inserts. Because of interactions, certain drugs should not be administered concomitantly with PIs or with efavirenz (EFV) (Tables 4 and 5). Consultation with a pharmacist might be considered.

Selection of HIV PEP Regimens

Determining which agents and how many to use or when to alter a PEP regimen is primarily empiric (34). Guidelines for treating HIV infection, a condition typically involving a high total body burden of HIV, recommend use of three or more drugs (13,14); however, the applicability of these recommendations to PEP is unknown. Among HIV-infected patients, combination regimens with three or more antiretroviral agents have proved superior to monotherapy and dual-therapy regimens in reducing HIV viral load, reducing incidence of opportunistic infections and death, and delaying

onset of drug resistance (13,14). In theory, a combination of drugs with activity at different stages in the viral replication cycle (e.g., nucleoside analogues with a PI) might offer an additive preventive effect in PEP, particularly for occupational exposures that pose an increased risk for transmission or for transmission of a resistant virus. Although use of a three- (or more) drug regimen might be justified for exposures that pose an increased risk for transmission, whether the potential added toxicity of a third or fourth drug is justified for lower-risk exposures is uncertain, especially in the absence of data supporting increased efficacy of more drugs in the context of occupational PEP. Offering a two-drug regimen is a viable option, primarily because the benefit of completing a full course of this regimen exceeds the benefit of adding the third agent and risking noncompletion (35). In addition, the total body burden of HIV is substantially lower among exposed HCP than among persons with established HIV infection. For these reasons, the recommendations in this report provide guidance for two- and three- (or more) drug PEP regimens on the basis of the level of risk for HIV transmission represented by the exposure (Tables 1 and 2; Appendix).

Resistance to Antiretroviral Agents

Known or suspected resistance of the source virus to antiretroviral agents, particularly those that might be included in a PEP regimen, is a concern for persons making decisions about PEP (36). Drug resistance to all available antiretroviral agents has been reported, and cross-resistance within drug classes is frequent (37). Although occupational transmission of drug-resistant HIV strains has been reported despite PEP

TABLE 4. Prescription and over-the-counter drugs that should not be administered with protease inhibitors (PIs) because of drug interactions*

Drug	Comment
Antimycobacterials: rifampin	Decreases plasma concentrations and area under plasma concentration curve of the majority of PIs by approximately 90%, which might result in loss of therapeutic effect and development of resistance
Benzodiazepines: midazolam, triazolam	Contraindicated because of potential for serious or life-threatening events (e.g., prolonged or increased sedation or respiratory depression)
Ergot derivatives: dihydroergotamine, ergotamine, ergonovine, methylergonovine	Contraindicated because of potential for serious or life-threatening events (e.g., acute ergot toxicity characterized by peripheral vasospasm and ischemia of the extremities and other tissues)
Gastrointestinal motility agent: cisapride	Contraindicated because of potential for serious or life-threatening events (e.g., cardiac arrhythmias)
HMG-CoA reductase inhibitors ("statins"): lovastatin, simvastatin	Potential for serious reactions (e.g., myopathy, including rhabdomyolysis); atorvastatin may be used cautiously, beginning with lowest possible starting dose, and monitoring for adverse events
Neuroleptic: pimozide	Contraindicated because of potential for serious or life-threatening events (e.g., cardiac arrhythmias)
Inhaled steroids: fluticasone	Coadministration of fluticasone and ritonavir-boosted protease inhibitors are not recommended unless the potential benefit to the patient outweighs the risk for systemic corticosteroid side effect
Herbal products: St. John's wort (<i>hypericum perforatum</i>), garlic	Coadministration might reduce plasma concentrations of protease inhibitors, which might result in loss of therapeutic effect and development of resistance Garlic might lower saquinavir level

* This table does not list all products that should not be administered with PIs (atazanavir, lopinavir/ritonavir, fosamprenavir, indinavir, nelfinavir, saquinavir). Product labels should be consulted for additional information regarding drug interactions.

Sources: US Department of Health and Human Services. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Washington, DC: US Department of Health and Human Services; 2005. Available at http://www.aidsinfo.nih.gov/guidelines/adult/AA_040705.pdf; University of California at San Francisco Center for HIV Information. Database of antiretroviral drug interactions. Available at <http://hivinsite.ucsf.edu/InSite?page=ar-00-02>.

TABLE 5. Prescription and over-the-counter drugs that should not be administered with efavirenz because of drug interactions*

Drug	Comment
Antifungal: voriconazole	Contraindicated because efavirenz substantially decreases voriconazole plasma concentrations
Benzodiazepines: midazolam, triazolam	Contraindicated because of potential for serious or life-threatening events (e.g., prolonged or increased sedation or respiratory depression)
Ergot derivatives: dihydroergotamine, ergotamine, ergonovine, methylergonovine	Contraindicated because of potential for serious or life-threatening events (e.g., acute ergot toxicity characterized by peripheral vasospasm and ischemia of the extremities and other tissues)
Gastrointestinal motility agent: cisapride	Contraindicated because of potential for serious or life-threatening events (e.g., cardiac arrhythmias)
Herbal products: St. John's wort (<i>hypericum perforatum</i>), garlic	Coadministration might reduce plasma concentrations of protease inhibitors, which might result in loss of therapeutic effect and development of resistance Garlic might lower saquinavir levels

* This table does not list all products that should not be coadministered with efavirenz. Efavirenz product labeling should be consulted for additional information regarding drug interactions.

Sources: US Department of Health and Human Services. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Washington, DC: US Department of Health and Human Services; 2005. Available at http://www.aidsinfo.nih.gov/guidelines/adult/AA_040705.pdf; University of California at San Francisco Center for HIV Information. Database of antiretroviral drug interactions. Available at <http://hivinsite.ucsf.edu/InSite?page=ar-00-02>.

with combination drug regimens (36,38–40), the effect of exposure to a resistant virus on transmission and transmissibility is not well understood.

Since publication of the previous guidelines, an additional report of an occupational HIV seroconversion despite combination HIV PEP has been published (Table 6) (38), bringing the total number of reports worldwide to six. The exposure was a percutaneous injury sustained by a nurse performing a phlebotomy on a heavily treatment-experienced patient. At the time of the exposure, the source patient was failing treat-

ment with stavudine (d4T), lamivudine (3TC), ritonavir (RTV), and saquinavir (SQV) and had a history of previous treatment with zidovudine (ZDV) and zalcitabine (ddC). Genotypic resistance testing performed within 1 month of the exposure suggested resistance to ZDV and 3TC. Phenotypic testing confirmed resistance to 3TC but demonstrated relative susceptibility to ZDV and d4T. The source virus demonstrated no evidence of resistance to nevirapine (NVP) or other NNRTIs. The initial HIV PEP regimen started within 95 minutes of the exposure was ZDV, 3TC, and indinavir.

TABLE 6. Reported instances of failure of combination drug postexposure prophylaxis (PEP) to prevent HIV-infection among health-care personnel exposed to HIV-infected blood through percutaneous injury

Year of incident	Device	PEP regimen*	Time to first dose (hrs)	No. of days to onset of retroviral illness	No. of days to document seroconversion†	Source-patient		
						HIV-infection status	On anti-retrovirals	Virus resistant to antiretrovirals§
1992¶	Biopsy needle	ZDV, ddl	0.5	23	23	AIDS, terminally ill	Yes	Unknown
1996**	Hollow-bore needle	ZDV, ddl††	1.5	45	97	Asymptomatic HIV infection	No	Not tested
1997**	Large or hollow-bore needle	ZDV, 3TC, IDV§§	1.5	40	55	AIDS	Yes	No
1998¶¶	Hollow-bore needle	ZDV, 3TC, ddl, IDV	0.7	70	83	AIDS	Yes	Yes
1999***	Unknown sharp	ddl, d4T, NVP†††	2.0	42	100	AIDS	Yes	Yes
2001§§§	Phlebotomy needle	ZDV, 3TC, IDV¶¶¶	1.6	24	~90	AIDS	Yes	Yes

* ZDV = zidovudine; ddl = didanosine; 3TC = lamivudine; IDV = indinavir; d4T = stavudine; and NVP = nevirapine.

† By enzyme immunoassay for HIV-1 antibody and Western blot.

§ By genotypic or phenotypic resistance testing.

¶ **Source:** Jochimsen EM. Failures of zidovudine postexposure prophylaxis. *Am J Med* 1997;102(Suppl 5B):52–5.

** **Source:** Lot F, Abiteboul D. Occupational infections with HIV in France among health-care personnel [French]. *Bull Epi Hebdom* 1999;18:69–70.

†† ZDV and ddl taken for 48 hours and then changed to ZDV alone.

§§ ZDV, 3TC, and IDV taken for 48 hours and then changed to d4T, 3TC, and IDV.

¶¶ **Source:** Perdue B, Wolde Rufael D, Mellors J, Quinn T, Margolick J. HIV-1 transmission by a needlestick injury despite rapid initiation of four-drug postexposure prophylaxis [Abstract no 210]. In: Program and abstracts of the 6th Conference on Retroviruses and Opportunistic Infections. Chicago, IL: Foundation for Retrovirology and Human Health; 1999.

*** **Source:** Beltrami EM, Luo C-C, de la Torre N, Cardo DM. Transmission of drug-resistant HIV after an occupational exposure despite postexposure prophylaxis with a combination drug regimen. *Infect Control Hosp Epidemiol* 2002;23:345–8; CDC, unpublished data, 1999.

††† ZDV and 3TC taken for 1 dose and then changed to ddl, d4T, and NVP; ddl was discontinued after 3 days as a result of severe vomiting.

§§§ **Source:** Hawkins DA, Asboe D, Barlow K, Evans B. Seroconversion to HIV-1 following a needlestick injury despite combination post-exposure prophylaxis. *J Infect* 2001;43:12–5.

¶¶¶ ZDV, 3TC, and IDV initially and then changed after first dose to d4T, ddl, and NVP; then ddl discontinued after 8 days; and d4T and NVP taken for 4 weeks.

The worker was referred to a hospital where the regimen was changed within 6 hours of the exposure to didanosine (ddI), d4T, and NVP because of concerns regarding possible drug resistance to certain or all of the components of the initial PEP regimen. The exposed worker stopped ddI after 8 days because of symptoms but continued to take d4T and NVP, stopping at day 24 because of a generalized macular pruritic rash and mild thrombocytopenia. Seroconversion was documented at 3 months. Sequencing of viruses from the source and exposed worker demonstrated their close relatedness. Virus from the worker demonstrated the same resistance patterns as those in the source patient. In addition, the worker's virus had a mutation suggesting resistance to the NNRTI class (38).

Empiric decisions regarding the presence of antiretroviral drug resistance are often difficult because patients frequently take more than one antiretroviral agent. Resistance should be suspected in a source patient when clinical progression of disease or a persistently increasing viral load or decline in CD4+ T-cell count occurs despite therapy, or when no virologic response to therapy occurs. However, resistance testing of the source virus at the time of an exposure is impractical because the results will not be available in time to influence the choice of the initial PEP regimen. No data suggest that modification of a PEP regimen after resistance testing results become available (usually 1–2 weeks) improves efficacy of PEP (41).

Antiretroviral Drugs During Pregnancy

Data regarding the potential effects of antiretroviral drugs on the developing fetus or neonate are limited (3). Carcinogenicity and mutagenicity are evident in certain *in vitro* screening tests for ZDV and all other FDA-licensed NRTIs. The relevance of animal data to humans is unknown; however, because teratogenic effects were reported among primates at drug exposures similar to those representing human therapeutic exposure, pregnant women should not use efavirenz (EFV). Indinavir (IDV) is associated with infrequent side effects in adults (i.e., hyperbilirubinemia and renal stones) that could be problematic for a newborn. Because the half-life of IDV in adults is short, these concerns might be relevant only if the drug is administered shortly before delivery. Other concerns regarding use of PEP during pregnancy have been raised by reports of mitochondrial dysfunction leading to neurologic disease and death among uninfected children whose mothers had taken antiretroviral drugs to prevent perinatal HIV transmission and of fatal and nonfatal lactic acidosis in pregnant women treated throughout gestation with a combination of d4T and ddI (3).

Management of Occupational Exposure by Emergency Physicians

Although PHS guidelines for the management of occupational exposures to HIV were first published in 1985 (42), HCP often are not familiar with these guidelines. Focus groups conducted among emergency department (ED) physicians in 2002 indicated that of 71 participants, >95% had not read the 2001 guidelines before being invited to participate (43). All physicians participating in these focus groups had managed occupational exposures to blood or body fluids. They cited three challenges in exposure management most frequently: evaluation of an unknown source patient or a source patient who refused testing, inexperience in managing occupational HIV exposures, and counseling of exposed workers in busy EDs.

Occupational HIV Exposure Management and PEP Use in U.S. Hospitals

Analysis of NaSH data for June 1995–December 2004 provides information regarding the management of occupational exposure to HIV in a convenience sample of 95 U.S. hospitals. These data indicate improved adherence to PHS recommendations concerning use of HIV PEP after occupational exposures. A total of 28,010 exposures to blood and body fluids were reported by these hospitals (CDC, unpublished data, 2005). For all 25,510 exposures with known sources, 1,350 (5.3%) were to HIV-positive sources, 15,301 (60.0%) to HIV-negative sources, and 8,859 (34.7%) to sources of unknown HIV status. Of 1,350 HCP exposed to a known HIV-positive source, 788 (58.4%) started PEP, and 317 (49%) of 647 for whom follow-up information was available took PEP for ≥ 21 days. The overall median duration of HIV PEP after exposure to an HIV-positive source was 27 days, increasing from 10 days in 1995 to 26.5 days in 2004; the overall median duration of HIV PEP after exposure to an HIV-negative source was 2 days, decreasing from 7.5 days in 1995 to 1 day in 2004. The use of rapid HIV tests for evaluation of source patients has increased; during 1995–1997, none of 25 NaSH facilities used rapid HIV tests, whereas in 2004, a total of 21 (84%) did (CDC, unpublished data, 2005). Rapid HIV tests could result in decreased use of PEP and spare personnel both undue anxiety and adverse effects of antiretroviral PEP (44–47). The annual median time to initiation of PEP was consistent (2 hours). Of 1,350 HCP with exposures to HIV-positive sources, 909 (67.1%) had at least one follow-up serologic test recorded, but only 289 (31.8%) had tests recorded at 4–6 months (CDC, unpublished data, 2005).

In 1996, of 24 HCP taking PEP after exposure to HIV-positive sources, 10 (42%) took a three-drug PEP regimen compared with 30 (76.9%) of 39 in 2004 (CDC, unpublished data, 2005). After 227 HIV exposures for which only a two-drug PEP regimen was recommended (i.e., the exposure was to mucous membranes or skin or was a superficial percutaneous injury and the source person did not have end-stage AIDS or acute HIV illness), 104 (45.8%) HCP initiated a three-drug HIV PEP regimen. The National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline)[†] reports similar findings. PEPline staff recommended changing or discontinuing PEP regimens for 45 (38%) of 118 exposures involving source patients with known viral load or CD4 cell count concerning which they were consulted during April 2002–March 2003 (48; R. Goldschmidt, PEPline, personal communication, 2004). For 14 (11.9%) HCP, the recommendation was to decrease the number of drugs in the PEP regimens; for 22 (18.7%) HCP, the recommendation was to increase the number of drugs; and for nine (7.6%), the recommendation was to change the PEP regimen, keeping the same number of drugs.

Recommendations for the Management of HCP Potentially Exposed to HIV

Exposure prevention remains the primary strategy for reducing occupational bloodborne pathogen infections. However, occupational exposures will continue to occur, and PEP will remain an important element of exposure management.

HIV PEP

The recommendations provided in this report (Tables 1 and 2; Appendix) apply to situations in which HCP have been exposed to a source person who either has or is considered likely to have HIV infection. These recommendations are based on the risk for HIV infection after different types of exposure and on limited data regarding efficacy and toxicity of PEP. If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued. Although concerns have been expressed regarding HIV-negative sources being in the window period for seroconversion, no case of transmission involving an exposure source during the window period has been reported in the United States (39). Rapid HIV testing of source patients can facilitate making timely

decisions regarding use of HIV PEP after occupational exposures to sources of unknown HIV status. Because the majority of occupational HIV exposures do not result in transmission of HIV, potential toxicity must be considered when prescribing PEP. Because of the complexity of selecting HIV PEP regimens, when possible, these recommendations should be implemented in consultation with persons having expertise in antiretroviral therapy and HIV transmission. Reevaluation of exposed HCP should be strongly encouraged within 72 hours postexposure, especially as additional information about the exposure or source person becomes available.

Timing and Duration of PEP

PEP should be initiated as soon as possible, preferably within hours rather than days of exposure. If a question exists concerning which antiretroviral drugs to use, or whether to use a basic or expanded regimen, the basic regimen should be started immediately rather than delay PEP administration. The optimal duration of PEP is unknown. Because 4 weeks of ZDV appeared protective in occupational and animal studies, PEP should be administered for 4 weeks, if tolerated (49–52).

Recommendations for the Selection of Drugs for HIV PEP

The selection of a drug regimen for HIV PEP must balance the risk for infection against the potential toxicities of the agent(s) used. Because PEP is potentially toxic, its use is not justified for exposures that pose a negligible risk for transmission (Tables 1 and 2). The initial HIV PEP regimens recommended in these guidelines should be viewed as suggestions that can be changed if additional information is obtained concerning the source of the occupational exposure (e.g., possible treatment history or antiretroviral drug resistance) or if expert consultation is provided. Given the complexity of choosing and administering HIV PEP, whenever possible, consultation with an infectious diseases consultant or another physician who has experience with antiretroviral agents is recommended, but it should not delay timely initiation of PEP.

Consideration should be given to the comparative risk represented by the exposure and information regarding the exposure source, including history of and response to antiretroviral therapy based on clinical response, CD4+ T-cell counts, viral load measurements, and current disease stage. When the source person's virus is known or suspected to be resistant to one or more of the drugs considered for the PEP regimen, the selection of drugs to which the source person's virus is unlikely to be resistant is recommended; expert consultation is advised. If this information is not immediately available, initiation of PEP, if indicated, should not be delayed; changes

[†] Administered by staff members from the University of California at San Francisco and San Francisco General Hospital; supported by the Health Resources and Services Administration Ryan White CARE Act and AIDS Education and Training Centers, and by CDC.

in the regimen can be made after PEP has started, as appropriate. For HCP who initiate PEP, re-evaluation of the exposed person should occur within 72 hours postexposure, especially if additional information about the exposure or source person becomes available.

PHS continues to recommend stratification of HIV PEP regimens based on the severity of exposure and other considerations (e.g., concern for antiretroviral drug resistance in the exposure source). The majority of HIV exposures will warrant a two-drug regimen, using two NRTIs or one NRTI and one NtRTI (Tables 1 and 2; Appendix). Combinations that can be considered for PEP include ZDV and 3TC or emtricitabine (FTC); d4T and 3TC or FTC; and tenofovir (TDF) and 3TC or FTC. In the previous PHS guidelines, a combination of d4T and ddI was considered one of the first-choice PEP regimens; however, this regimen is no longer recommended because of concerns about toxicity (especially neuropathy and pancreatitis) and the availability of more tolerable alternative regimens (3).

The addition of a third (or even a fourth) drug should be considered for exposures that pose an increased risk for transmission or that involve a source in whom antiretroviral drug resistance is likely. The addition of a third drug for PEP after a high-risk exposure is based on demonstrated effectiveness in reducing viral burden in HIV-infected persons. However, no definitive data exist that demonstrate increased efficacy of three- compared with two-drug HIV PEP regimens. Previously, IDV, nelfinavir (NFV), EFV, or abacavir (ABC) were recommended as first-choice agents for inclusion in an expanded PEP regimen (3).

PHS now recommends that expanded PEP regimens be PI-based. The PI preferred for use in expanded PEP regimens is lopinavir/ritonavir (LPV/RTV). Other PIs acceptable for use in expanded PEP regimens include atazanavir, fosamprenavir, RTV-boosted IDV, RTV-boosted SQV, or NFV (Appendix). Although side effects are common with NNRTIs, EFV may be considered for expanded PEP regimens, especially when resistance to PIs in the source person's virus is known or suspected. Caution is advised when EFV is used in women of childbearing age because of the risk of teratogenicity.

Drugs that may be considered as alternatives to the expanded regimens, with warnings about side effects and other adverse events, are EFV or PIs as noted in the Appendix in combination with ddI and either 3TC or FTC. The fusion inhibitor enfuvirtide (T20) has theoretic benefits for use in PEP because its activity occurs before viral-host cell integration; however, it is not recommended for routine HIV PEP because of the mode of administration (subcutaneous injection twice daily). Furthermore, use of T20 has the potential for

production of anti-T20 antibodies that cross react with HIV gp41. This could result in a false-positive, enzyme immunoassay (EIA) HIV antibody test among HIV-uninfected patients. A confirmatory Western blot test would be expected to be negative in such cases. T20 should only be used with expert consultation.

Antiviral drugs not recommended for use as PEP, primarily because of the higher risk for potentially serious or life-threatening adverse events, include ABC, delavirdine, ddC, and, as noted previously, the combination of ddI and d4T. NVP should not be included in PEP regimens except with expert consultation because of serious reported side effects, including hepatotoxicity (with one instance of fulminant liver failure requiring liver transplantation), rhabdomyolysis, and hypersensitivity syndrome (53–55).

Because of the complexity of selection of HIV PEP regimens, consultation with persons having expertise in antiretroviral therapy and HIV transmission is strongly recommended. Certain institutions have required consultation with a hospital epidemiologist or infectious diseases consultant when HIV PEP use is under consideration. This can be especially important in management of a pregnant or breastfeeding worker or a worker who has been exposed to a heavily treatment-experienced source (Box 1).

Resources for consultation are available from the following sources:

- PEPLine at <http://www.ucsf.edu/hivcntr/Hotlines/PEPLine>; telephone 888-448-4911;
- HIV Antiretroviral Pregnancy Registry at <http://www.apregistry.com/index.htm>; Address: Research Park, 1011 Ashes Drive, Wilmington, NC 28405. Telephone: 800-258-4263; Fax: 800-800-1052; E-mail: registry@nc.crl.com;
- FDA (for reporting unusual or severe toxicity to antiretroviral agents) at <http://www.fda.gov/medwatch>; telephone: 800-332-1088; address: MedWatch, HF-2, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857;
- CDC (for reporting HIV infections in HCP and failures of PEP) at telephone 800-893-0485; and
- HIV/AIDS Treatment Information Service at <http://aidsinfo.nih.gov>.

Follow-Up of Exposed HCP

Postexposure Testing

HCP with occupational exposure to HIV should receive follow-up counseling, postexposure testing, and medical evaluation regardless of whether they receive PEP. HIV-antibody

BOX 1. Situations for which expert consultation* for HIV postexposure prophylaxis (PEP) is advised

- Delayed (i.e., later than 24–36 hours) exposure report
 - Interval after which lack of benefit from PEP undefined
- Unknown source (e.g., needle in sharps disposal container or laundry)
 - Use of PEP to be decided on a case-by-case basis
 - Consider severity of exposure and epidemiologic likelihood of HIV exposure
 - Do not test needles or other sharp instruments for HIV
- Known or suspected pregnancy in the exposed person
 - Use of optimal PEP regimens not precluded
 - PEP not denied solely on basis of pregnancy
- Breastfeeding in the exposed person
 - Use of optimal PEP regimens not precluded
 - PEP not denied solely on basis of breastfeeding
- Resistance of the source virus to antiretroviral agents
 - Influence of drug resistance on transmission risk unknown
 - If source person's virus is known or suspected to be resistant to one or more of the drugs considered for PEP, selection of drugs to which the source person's virus is unlikely to be resistant recommended
 - Resistance testing of the source person's virus at the time of the exposure not recommended
 - Initiation of PEP not to be delayed while awaiting any results of resistance testing
- Toxicity of the initial PEP regimen
 - Adverse symptoms (e.g., nausea and diarrhea) common with PEP
 - Symptoms often manageable without changing PEP regimen by prescribing antimotility or antiemetic agents
 - In other situations, modifying the dose interval (i.e., taking drugs after meals or administering a lower dose of drug more frequently throughout the day, as recommended by the manufacturer) might help alleviate symptoms when they occur

* Either with local experts or by contacting the National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline), telephone 888-448-4911.

testing by enzyme immunoassay should be used to monitor HCP for seroconversion for >6 months after occupational HIV exposure. After baseline testing at the time of exposure, follow-up testing could be performed at 6 weeks, 12 weeks, and 6 months after exposure. Extended HIV follow-up (e.g., for 12 months) is recommended for HCP who become infected with HCV after exposure to a source coinfecting with HIV and HCV. Whether extended follow-up is indicated in other

circumstances (e.g., exposure to a source co-infected with HIV and HCV in the absence of HCV seroconversion or for exposed persons with a medical history suggesting an impaired ability to mount an antibody response to acute infection) is unclear. Although rare instances of delayed HIV seroconversion have been reported (56,57), the infrequency of this occurrence does not warrant adding to exposed persons' anxiety by routinely extending the duration of postexposure follow-up. However, this should not preclude a decision to extend follow-up in a particular situation based on the clinical judgment of the exposed person's health-care provider. The routine use of direct virus assays (e.g., HIV p24 antigen EIA or tests for HIV ribonucleic acid) to detect infection among exposed HCP usually is not recommended (58). Despite the ability of direct virus assays to detect HIV infection a few days earlier than EIA, the infrequency of occupational seroconversion and increased costs of these tests do not warrant their routine use in this setting. In addition, the relatively high rate of false-positive results of these tests in this setting could lead to unnecessary anxiety or treatment (59,60). Nevertheless, HIV testing should be performed on any exposed person who has an illness compatible with an acute retroviral syndrome, regardless of the interval since exposure. A person in whom HIV infection is identified should be referred for medical management to a specialist with expertise in HIV treatment and counseling. Health-care providers caring for persons with occupationally acquired HIV infection can report these cases to CDC at telephone 800-893-0485 or to their state health departments.

Monitoring and Management of PEP Toxicity

If PEP is used, HCP should be monitored for drug toxicity by testing at baseline and again 2 weeks after starting PEP. The scope of testing should be based on medical conditions in the exposed person and the toxicity of drugs included in the PEP regimen. Minimally, laboratory monitoring for toxicity should include a complete blood count and renal and hepatic function tests. Monitoring for evidence of hyperglycemia should be included for HCP whose regimens include any PI; if the exposed person 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 might be indicated.

Exposed HCP 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 drugs that should not be taken with PEP, side effects of prescribed drugs, measures to minimize side effects, and methods of clinical monitoring for toxicity

during the follow-up period. HCP should be advised that evaluation of certain symptoms (e.g., rash, fever, back or abdominal pain, pain on urination or blood in the urine, or symptoms of hyperglycemia (e.g., increased thirst or frequent urination) should not be delayed.

HCP often fail to complete the recommended regimen often because they experience side effects (e.g., nausea or diarrhea). These symptoms often can be managed with antimotility and antiemetic agents or other medications that target specific symptoms without changing the regimen. 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) might facilitate adherence to the regimen. Serious adverse events[§] should be reported to FDA's MedWatch program.

Although recommendations for follow-up testing, monitoring, and counseling of exposed HCP are unchanged from those published previously (3), greater emphasis is needed on improving follow-up care provided to exposed HCP (Box 2). This might result in increased adherence to HIV PEP regimens, better management of associated symptoms with ancillary medications or regimen changes, improved detection of serious adverse effects, and serologic testing among a larger proportion of exposed personnel to determine if infection is transmitted after occupational exposures. Closer follow-up should in turn reassure HCP who become anxious after these events (61,62). The psychologic impact on HCP of needlesticks or exposure to blood or body fluid should not be underestimated. Providing HCP with psychologic counseling should be an essential component of the management and care of exposed HCP.

Reevaluation and Updating of HIV PEP Guidelines

As new antiretroviral agents for treatment of HIV infection and additional information concerning early HIV infection and prevention of HIV transmission become available, the PHS Interagency Working Group will assess the need to update these guidelines. Updates will be published periodically as appropriate.

[§] Defined by FDA as follows: "Any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition" (63).

BOX 2. Follow-up of health-care personnel (HCP) exposed to known or suspected HIV-positive sources

- Exposed HCP should be advised to use precautions (e.g., avoid blood or tissue donations, breastfeeding, or pregnancy) to prevent secondary transmission, especially during the first 6–12 weeks postexposure.
- For exposures for which PEP is prescribed, HCP should be informed regarding
 - possible drug toxicities and the need for monitoring,
 - possible drug interactions, and
 - the need for adherence to PEP regimens.
- Consider reevaluation of exposed HCP 72 hours postexposure, especially after additional information about the exposure or source person becomes available.

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APPENDIX

Basic and Expanded HIV Postexposure Prophylaxis Regimens

BASIC REGIMEN

- **Zidovudine (Retrovir™; ZDV; AZT) + lamivudine (Epivir®; 3TC); available as Combivir™**

Preferred dosing

- ZDV: 300 mg twice daily or 200 mg three times daily, with food; total: 600 mg daily
- 3TC: 300 mg once daily or 150 mg twice daily
- Combivir: one tablet twice daily

Dosage forms

- ZDV: 100 mg capsule, 300 mg tablet
- 3TC: 150 or 300 mg tablet
- Combivir: tablet, 300 mg ZDV + 150 mg 3TC

Advantages

- ZDV associated with decreased risk for HIV transmission
- ZDV used more often than other drugs for PEP for health-care personnel (HCP)
- Serious toxicity rare when used for PEP

- Side effects predictable and manageable with antimotility and antiemetic agents
- Can be used by pregnant HCP
- Can be given as a single tablet (COMBIVIR™) twice daily

Disadvantages

- Side effects (especially nausea and fatigue) common and might result in low adherence
- Source-patient virus resistance to this regimen possible
- Potential for delayed toxicity (oncogenic/teratogenic) unknown

- **Zidovudine (Retrovir®; ZDV; AZT) + emtricitabine (Emtriva™; FTC)**

Preferred dosing

- ZDV: 300 mg twice daily or 200 mg three times daily, with food; total: 600 mg/day, in 2–3 divided doses
- FTC: 200 mg (one capsule) once daily

Dosage forms

- ZDV: see above
- FTC: 200 mg capsule

FTC general comments

- Nucleoside analogue; same structure as 3TC, except fluoride residue at position 5 on pyrimidine ring
- Same resistance and safety profile as 3TC
- No apparent advantage over 3TC; tolerability and virologic response rates appear better than regimens containing ddI + d4T

Advantages

- ZDV: see above.
- FTC
 - o Convenient (once daily)
 - o Well tolerated
 - o Long intracellular half-life (~40 hours)

Disadvantages

- ZDV: see above.
- FTC
 - o Rash perhaps more frequent than with 3TC
 - o No long-term experience with this drug
 - o Cross resistance to 3TC
 - o Hyperpigmentation among non-Caucasians with long-term use: 3%

- **Tenofovir DF (Viread®; TDF) + lamivudine (Epivir®; 3TC)**

Preferred dosing

- TDF: 300 mg once daily
- 3TC: 300 mg once daily or 150 mg twice daily

Dosage forms

- TDF: 300 mg tablet
- 3TC: see above

Advantages

- 3TC: see above
- TDF
 - o Convenient dosing (single pill once daily)
 - o Resistance profile activity against certain thymidine analogue mutations
 - o Well tolerated

Disadvantages

- TDF
 - o Same class warnings as nucleoside reverse transcriptase inhibitors (NRTIs)
 - o Drug interactions
 - o Increased TDF concentrations among persons taking atazanavir and lopinavir/ritonavir; need to monitor patients for TDF-associated toxicities
- Preferred dosage of atazanavir if used with TDF: 300 mg + ritonavir 100 mg once daily + TDF 300 mg once daily

- **Tenofovir DF (Viread®; TDF) + emtricitabine (Emtriva™; FTC); available as Truvada™**

Preferred dosing

- TDF: 300 mg once daily
- FTC: 200 mg once daily
- As Truvada™: one tablet daily

Dosage forms

- TDF: 300 mg tablet
- FTC: see FTC
- Truvada™ (TDF 300 mg plus FTC 200 mg)

Advantages

- FTC: see above
- TDF
 - o Convenient dosing (single pill once daily)
 - o Resistance profile activity against certain thymidine analogue mutations
 - o Well tolerated

Disadvantages

- TDF
 - o Same class warnings as NRTIs
 - o Drug interactions
 - o Increased TDF concentrations among persons taking atazanavir and lopinavir/ritonavir; need to monitor patients for TDF-associated toxicities
 - o Preferred dosing of atazanavir if used with TDF: 300 mg + ritonavir 100 mg once daily + TDF 300 mg once daily

ALTERNATE BASIC REGIMENS

- **Lamivudine (Epivir®; 3TC) + stavudine (Zerit®; d4T)**

Preferred dosing

- 3TC: 300 mg once daily or 150 mg twice daily
- d4T: 40 mg twice daily (can use lower doses of 20–30 mg twice daily if toxicity occurs; equally effective but less toxic among HIV-infected patients with peripheral neuropathy); 30 mg twice daily if body weight is <60 kg

Dosage forms

- 3TC: see above
- d4T: 15, 20, 30, and 40 mg tablet

Advantages

- 3TC: see above
- d4T: gastrointestinal (GI) side effects rare

Disadvantages

- Possibility that source-patient virus is resistant to this regimen
- Potential for delayed toxicity (oncogenic/teratogenic) unknown

• **Emtricitabine (Emtriva™; FTC) + stavudine (Zerit®; d4T)**

Preferred dosing

- FTC: 200 mg daily
- d4T: 40 mg twice daily (can use lower doses of 20–30 mg twice daily if toxicity occurs; equally effective but less toxic among HIV-infected patients who developed peripheral neuropathy); if body weight is <60 kg, 30 mg twice daily

Dosage forms

- FTC: see above
- d4T: see above

Advantages

- 3TC and FTC: see above; d4T's GI side effects rare

Disadvantages

- Potential that source-patient virus is resistant to this regimen
- Unknown potential for delayed toxicity (oncogenic/teratogenic) unknown

• **Lamivudine (Epivir®; 3TC) + didanosine (Videx®; ddI)**

Preferred dosing

- 3TC: 300 mg once daily or 150 mg twice daily
- ddI: Videx® chewable/dispersible buffered tablets can be administered on an empty stomach as either 200 mg twice daily or 400 mg once daily. Patients must take at least two of the appropriate strength tablets at each dose to provide adequate buffering and prevent gastric acid degradation of ddI. Because of the need for adequate buffering, the 200-mg strength tablet should be used only as a component of a once-daily regimen. The dose is either 200 mg twice daily or 400 mg once daily for patients weighing >60 kg and 125 mg twice daily or 250 mg once daily for patients weighing >60 kg.

Dosage forms

- 3TC: 150 or 300 mg tablets
- ddI: 25, 50, 100, 150, or 200 mg buffered white tablets

Advantages

- ddI: once daily dosing option
- 3TC: see above

Disadvantages

- Tolerability: diarrhea more common with buffered preparation than with enteric-coated preparation
- Associated with toxicity: peripheral neuropathy, pancreatitis, and lactic acidosis
- Must be taken on empty stomach except with TDF
- Drug interactions
- 3TC: see above

• **Emtricitabine (Emtriva™; FTC) + didanosine (Videx®; ddI)**

Preferred dosing

- FTC: 200 mg once daily
- ddI: see above

Dosage forms

- ddI: see above
- FTC: see above

Advantages

- ddI: see above
- FTC: see above

Disadvantages

- Tolerability: diarrhea more common with buffered than with enteric-coated preparation
- Associated with toxicity: peripheral neuropathy, pancreatitis, and lactic acidosis
- Must be taken on empty stomach except with TDF
- Drug interactions
- FTC: see above

PREFERRED EXPANDED REGIMEN

Basic regimen plus:

• **Lopinavir/ritonavir (Kaletra®; LPV/RTV)**

Preferred dosing

- LPV/RTV: 400/100 mg = 3 capsules twice daily with food

Dosage form

- LPV/RTV: 133/33 mg capsules

Advantages

- Potent HIV protease inhibitor
- Generally well-tolerated

Disadvantages

- Potential for serious or life-threatening drug interactions (see Table 4)
- Might accelerate clearance of certain drugs, including oral contraceptives (requiring alternative or additional contraceptive measures for women taking these drugs)
- Can cause severe hyperlipidemia, especially hypertriglyceridemia
- GI (e.g., diarrhea) events common

ALTERNATE EXPANDED REGIMENS

Basic regimen plus one of the following:

• **Atazanavir (Reyataz®; ATV) ± ritonavir (Norvir®; RTV)**

Preferred dosing

- ATV: 400 mg once daily, unless used in combination with TDF, in which case ATV should be boosted with RTV, preferred dosing of ATV 300 mg + RTV: 100 mg once daily

Dosage forms

- ATV: 100, 150, and 200 mg capsules
- RTV: 100 mg capsule

Advantages

- Potent HIV protease inhibitor
- Convenient dosing – once daily
- Generally well tolerated

Disadvantages

- Hyperbilirubinemia and jaundice common
- Potential for serious or life-threatening drug interactions (see Table 4)
- Avoid coadministration with proton pump inhibitors
- Separate antacids and buffered medications by 2 hours and H₂-receptor antagonists by 12 hours to avoid decreasing ATV levels
- Caution should be used with ATV and products known to induce PR prolongation (e.g., diltiazem)

• **Fosamprenavir (Lexiva®; FOSAPV) ± ritonavir (Norvir®; RTV)**

Preferred dosing

- FOSAPV: 1400 mg twice daily (without RTV)
- FOSAPV: 1400 mg once daily + RTV 200 mg once daily
- FOSAPV: 700 mg twice daily + RTV 100 mg twice daily

Dosage form

- FOSAPV: 700 mg tablets
- RTV: 100 mg capsule

Advantages

- Once daily dosing when given with ritonavir

Disadvantages

- Tolerability: GI side effects common
- Multiple drug interactions. Oral contraceptives decrease fosamprenavir concentrations
- Incidence of rash in healthy volunteers, especially when used with low doses of ritonavir. Differentiating between early drug-associated rash and acute seroconversion can be difficult and cause extraordinary concern for the exposed person

• **Indinavir (Crixivan®; IDV) ± ritonavir (Norvir®; RTV)**

Preferred dosing

- IDV 800 mg + RTV 100 mg twice daily without regard to food

Alternative dosing

- IDV: 800 mg every 8 hours, on an empty stomach

Dosage forms

- IDV: 200 mg, 333, and 400 mg capsule
- RTV: 100 mg capsule

Advantages

- Potent HIV inhibitor

Disadvantages

- Potential for serious or life-threatening drug interactions (see Table 4)
- Serious toxicity (e.g., nephrolithiasis) possible; consumption of 8 glasses of fluid/day required
- Hyperbilirubinemia common; must avoid this drug during late pregnancy
- Requires acid for absorption and cannot be taken simultaneously with ddl, chewable/dispersible buffered tablet formulation (doses must be separated by ≥1 hour)

• **Saquinavir (Invirase®; SQV) + ritonavir (Norvir®; RTV)**

Preferred dosing

- SQV: 1,000 mg (given as Invirase) + RTV 100 mg, twice daily
- SQV : five capsules twice daily + RTV: one capsule twice daily

Dosage forms

- SQV (Invirase): 200 mg capsule
- RTV: 100 mg capsule

Advantages

- Generally well-tolerated, although GI events common

Disadvantages

- Potential for serious or life-threatening drug interactions (see Table 4)
- Substantial pill burden

• **Nelfinavir (Viracept®; NFV)**

Preferred dosing

- NFV: 1,250 mg (2 x 625 mg or 5 x 250 mg tablets), twice daily with a meal

Dosage forms

- NFV: 250 or 625 mg tablet

Advantages

- Generally well-tolerated

Disadvantages

- Diarrhea or other GI events common
- Potential for serious and/or life-threatening drug interactions (see Table 4)

• **Efavirenz (Sustiva®; EFV)**

Preferred dosing

- EFV: 600 mg daily, at bedtime

Dosage forms

- EFV: 50, 100, 200 capsules
- EFV: 600 mg tablet

Advantages

- Does not require phosphorylation before activation and might be active earlier than other antiretroviral agents (a theoretic advantage of no demonstrated clinical benefit)
- Once daily dosing

Disadvantages

- Drug associated with rash (early onset) that can be severe and might rarely progress to Stevens-Johnson syndrome
- Differentiating between early drug-associated rash and acute seroconversion can be difficult and cause extraordinary concern for the exposed person
- Central nervous system side effects (e.g., dizziness, somnolence, insomnia, or abnormal dreaming) common; severe psychiatric symptoms possible (dosing before bedtime might minimize these side effects)
- Teratogen; should not be used during pregnancy
- Potential for serious or life-threatening drug interactions (see Table 5)

ANTIRETROVIRAL AGENTS GENERALLY NOT RECOMMENDED FOR USE AS PEP• **Nevirapine (Viramune®; NVP)***Disadvantages*

- Associated with severe hepatotoxicity (including at least one case of liver failure requiring liver transplantation in an exposed person taking PEP)
- Associated with rash (early onset) that can be severe and progress to Stevens-Johnson syndrome
- Differentiating between early drug-associated rash and acute seroconversion can be difficult and cause extraordinary concern for the exposed person
- Drug interactions: can lower effectiveness of certain antiretroviral agents and other commonly used medicines

• **Delavirdine (Rescriptor®; DLV)***Disadvantages*

- Drug associated with rash (early onset) that can be severe and progress to Stevens-Johnson syndrome
- Multiple drug interactions

• **Abacavir (Ziagen®; ABC)***Disadvantages*

- Severe hypersensitivity reactions can occur, usually within the first 6 weeks
- Differentiating between early drug-associated rash/hypersensitivity and acute seroconversion can be difficult

• **Zalcitabine (Hivid®; ddC)***Disadvantages*

- Three times a day dosing
- Tolerability
- Weakest antiretroviral agent

ANTIRETROVIRAL AGENT FOR USE AS PEP ONLY WITH EXPERT CONSULTATION• **Enfuvirtide (Fuzeon™; T20)***Preferred dosing*

- T20: 90 mg (1 ml) twice daily by subcutaneous injection

Dosage forms

- T20: Single-dose vial, reconstituted to 90 mg/ml

Advantages

- New class
- Unique viral target; to block cell entry
- Prevalence of resistance low

Disadvantages

- Twice-daily injection
- Safety profile: local injection site reactions
- Never studied among antiretroviral-naïve or HIV-negative patients
- False-positive EIA HIV antibody tests might result from formation of anti-T20 antibodies that cross-react with anti-gp41 antibodies

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Appendix C



MMWRTM

Morbidity and Mortality Weekly Report

Recommendations and Reports

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Guideline for Hand Hygiene in Health-Care Settings

**Recommendations of the Healthcare Infection Control Practices
Advisory Committee and the HICPAC/SHEA/APIC/IDSA
Hand Hygiene Task Force**

INSIDE: Continuing Education Examination

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Guideline for Hand Hygiene in Health-Care Settings

Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force

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Summary

The Guideline for Hand Hygiene in Health-Care Settings provides health-care workers (HCWs) with a review of data regarding handwashing and hand antisepsis in health-care settings. In addition, it provides specific recommendations to promote improved hand-hygiene practices and reduce transmission of pathogenic microorganisms to patients and personnel in health-care settings. This report reviews studies published since the 1985 CDC guideline (Garner JS, Favero MS. CDC guideline for handwashing and hospital environmental control, 1985. Infect Control 1986;7:231–43) and the 1995 APIC guideline (Larson EL, APIC Guidelines Committee. APIC guideline for handwashing and hand antisepsis in health care settings. Am J Infect Control 1995;23:251–69) were issued and provides an in-depth review of hand-hygiene practices of HCWs, levels of adherence of personnel to recommended handwashing practices, and factors adversely affecting adherence. New studies of the in vivo efficacy of alcohol-based hand rubs and the low incidence of dermatitis associated with their use are reviewed. Recent studies demonstrating the value of multidisciplinary hand-hygiene promotion programs and the potential role of alcohol-based hand rubs in improving hand-hygiene practices are summarized. Recommendations concerning related issues (e.g., the use of surgical hand antiseptics, hand lotions or creams, and wearing of artificial fingernails) are also included.

Part I. Review of the Scientific Data Regarding Hand Hygiene

Historical Perspective

For generations, handwashing with soap and water has been considered a measure of personal hygiene (1). The concept of cleansing hands with an antiseptic agent probably emerged in the early 19th century. As early as 1822, a French pharmacist demonstrated that solutions containing chlorides of lime or soda could eradicate the foul odors associated with human corpses and that such solutions could be used as disinfectants and antiseptics (2). In a paper published in 1825, this pharmacist stated that physicians and other persons attending patients with contagious diseases would benefit from moistening their hands with a liquid chloride solution (2).

In 1846, Ignaz Semmelweis observed that women whose babies were delivered by students and physicians in the First Clinic at the General Hospital of Vienna consistently had a

higher mortality rate than those whose babies were delivered by midwives in the Second Clinic (3). He noted that physicians who went directly from the autopsy suite to the obstetrics ward had a disagreeable odor on their hands despite washing their hands with soap and water upon entering the obstetrics clinic. He postulated that the puerperal fever that affected so many parturient women was caused by “cadaverous particles” transmitted from the autopsy suite to the obstetrics ward via the hands of students and physicians. Perhaps because of the known deodorizing effect of chlorine compounds, as of May 1847, he insisted that students and physicians clean their hands with a chlorine solution between each patient in the clinic. The maternal mortality rate in the First Clinic subsequently dropped dramatically and remained low for years. This intervention by Semmelweis represents the first evidence indicating that cleansing heavily contaminated hands with an antiseptic agent between patient contacts may reduce health-care-associated transmission of contagious diseases more effectively than handwashing with plain soap and water.

In 1843, Oliver Wendell Holmes concluded independently that puerperal fever was spread by the hands of health personnel (1). Although he described measures that could be taken to limit its spread, his recommendations had little impact on

The material in this report originated in the National Center for Infectious Diseases, James M. Hughes, M.D., Director; and the Division of Healthcare Quality Promotion, Steve Solomon, M.D., Acting Director.

obstetric practices at the time. However, as a result of the seminal studies by Semmelweis and Holmes, handwashing gradually became accepted as one of the most important measures for preventing transmission of pathogens in health-care facilities.

In 1961, the U. S. Public Health Service produced a training film that demonstrated handwashing techniques recommended for use by health-care workers (HCWs) (4). At the time, recommendations directed that personnel wash their hands with soap and water for 1–2 minutes before and after patient contact. Rinsing hands with an antiseptic agent was believed to be less effective than handwashing and was recommended only in emergencies or in areas where sinks were unavailable.

In 1975 and 1985, formal written guidelines on handwashing practices in hospitals were published by CDC (5,6). These guidelines recommended handwashing with non-antimicrobial soap between the majority of patient contacts and washing with antimicrobial soap before and after performing invasive procedures or caring for patients at high risk. Use of waterless antiseptic agents (e.g., alcohol-based solutions) was recommended only in situations where sinks were not available.

In 1988 and 1995, guidelines for handwashing and hand antisepsis were published by the Association for Professionals in Infection Control (APIC) (7,8). Recommended indications for handwashing were similar to those listed in the CDC guidelines. The 1995 APIC guideline included more detailed discussion of alcohol-based hand rubs and supported their use in more clinical settings than had been recommended in earlier guidelines. In 1995 and 1996, the Healthcare Infection Control Practices Advisory Committee (HICPAC) recommended that either antimicrobial soap or a waterless antiseptic agent be used for cleaning hands upon leaving the rooms of patients with multidrug-resistant pathogens (e.g., vancomycin-resistant enterococci [VRE] and methicillin-resistant *Staphylococcus aureus* [MRSA]) (9,10). These guidelines also provided recommendations for handwashing and hand antisepsis in other clinical settings, including routine patient care. Although the APIC and HICPAC guidelines have been adopted by the majority of hospitals, adherence of HCWs to recommended handwashing practices has remained low (11,12).

Recent developments in the field have stimulated a review of the scientific data regarding hand hygiene and the development of new guidelines designed to improve hand-hygiene practices in health-care facilities. This literature review and accompanying recommendations have been prepared by a Hand Hygiene Task Force, comprising representatives from HICPAC, the Society for Healthcare Epidemiology of America (SHEA), APIC, and the Infectious Diseases Society of America (IDSA).

Normal Bacterial Skin Flora

To understand the objectives of different approaches to hand cleansing, a knowledge of normal bacterial skin flora is essential. Normal human skin is colonized with bacteria; different areas of the body have varied total aerobic bacterial counts (e.g., 1×10^6 colony forming units (CFUs)/cm² on the scalp, 5×10^5 CFUs/cm² in the axilla, 4×10^4 CFUs/cm² on the abdomen, and 1×10^4 CFUs/cm² on the forearm) (13). Total bacterial counts on the hands of medical personnel have ranged from 3.9×10^4 to 4.6×10^6 (14–17). In 1938, bacteria recovered from the hands were divided into two categories: transient and resident (14). Transient flora, which colonize the superficial layers of the skin, are more amenable to removal by routine handwashing. They are often acquired by HCWs during direct contact with patients or contact with contaminated environmental surfaces within close proximity of the patient. Transient flora are the organisms most frequently associated with health-care-associated infections. Resident flora, which are attached to deeper layers of the skin, are more resistant to removal. In addition, resident flora (e.g., coagulase-negative staphylococci and diphtheroids) are less likely to be associated with such infections. The hands of HCWs may become persistently colonized with pathogenic flora (e.g., *S. aureus*), gram-negative bacilli, or yeast. Investigators have documented that, although the number of transient and resident flora varies considerably from person to person, it is often relatively constant for any specific person (14,18).

Physiology of Normal Skin

The primary function of the skin is to reduce water loss, provide protection against abrasive action and microorganisms, and act as a permeability barrier to the environment. The basic structure of skin includes, from outer- to innermost layer, the superficial region (i.e., the stratum corneum or horny layer, which is 10- to 20- μ m thick), the viable epidermis (50- to 100- μ m thick), the dermis (1- to 2-mm thick), and the hypodermis (1- to 2-mm thick). The barrier to percutaneous absorption lies within the stratum corneum, the thinnest and smallest compartment of the skin. The stratum corneum contains the corneocytes (or horny cells), which are flat, polyhedral-shaped nonnucleated cells, remnants of the terminally differentiated keratinocytes located in the viable epidermis. Corneocytes are composed primarily of insoluble bundled keratins surrounded by a cell envelope stabilized by cross-linked proteins and covalently bound lipid. Interconnecting the corneocytes of the stratum corneum are polar structures (e.g., corneodesmosomes), which contribute to stratum corneum cohesion.

The intercellular region of the stratum corneum is composed of lipid primarily generated from the exocytosis of lamellar bodies during the terminal differentiation of the keratinocytes. The intercellular lipid is required for a competent skin barrier and forms the only continuous domain. Directly under the stratum corneum is a stratified epidermis, which is composed primarily of 10–20 layers of keratinizing epithelial cells that are responsible for the synthesis of the stratum corneum. This layer also contains melanocytes involved in skin pigmentation; Langerhans cells, which are important for antigen presentation and immune responses; and Merkel cells, whose precise role in sensory reception has yet to be fully delineated. As keratinocytes undergo terminal differentiation, they begin to flatten out and assume the dimensions characteristic of the corneocytes (i.e., their diameter changes from 10–12 μm to 20–30 μm , and their volume increases by 10- to 20-fold). The viable epidermis does not contain a vascular network, and the keratinocytes obtain their nutrients from below by passive diffusion through the interstitial fluid.

The skin is a dynamic structure. Barrier function does not simply arise from the dying, degeneration, and compaction of the underlying epidermis. Rather, the processes of cornification and desquamation are intimately linked; synthesis of the stratum corneum occurs at the same rate as loss. Substantial evidence now confirms that the formation of the skin barrier is under homeostatic control, which is illustrated by the epidermal response to barrier perturbation by skin stripping or solvent extraction. Circumstantial evidence indicates that the rate of keratinocyte proliferation directly influences the integrity of the skin barrier. A general increase in the rate of proliferation results in a decrease in the time available for 1) uptake of nutrients (e.g., essential fatty acids), 2) protein and lipid synthesis, and 3) processing of the precursor molecules required for skin-barrier function. Whether chronic but quantitatively smaller increases in rate of epidermal proliferation also lead to changes in skin-barrier function remains unclear. Thus, the extent to which the decreased barrier function caused by irritants is caused by an increased epidermal proliferation also is unknown.

The current understanding of the formation of the stratum corneum has come from studies of the epidermal responses to perturbation of the skin barrier. Experimental manipulations that disrupt the skin barrier include 1) extraction of skin lipids with apolar solvents, 2) physical stripping of the stratum corneum using adhesive tape, and 3) chemically induced irritation. All of these experimental manipulations lead to a decreased skin barrier as determined by transepidermal water loss (TEWL). The most studied experimental system is the treatment of mouse skin with acetone. This experiment

results in a marked and immediate increase in TEWL, and therefore a decrease in skin-barrier function. Acetone treatment selectively removes glycerolipids and sterols from the skin, which indicates that these lipids are necessary, though perhaps not sufficient in themselves, for barrier function. Detergents act like acetone on the intercellular lipid domain. The return to normal barrier function is biphasic: 50%–60% of barrier recovery typically occurs within 6 hours, but complete normalization of barrier function requires 5–6 days.

Definition of Terms

Alcohol-based hand rub. An alcohol-containing preparation designed for application to the hands for reducing the number of viable microorganisms on the hands. In the United States, such preparations usually contain 60%–95% ethanol or isopropanol.

Antimicrobial soap. Soap (i.e., detergent) containing an antiseptic agent.

Antiseptic agent. Antimicrobial substances that are applied to the skin to reduce the number of microbial flora. Examples include alcohols, chlorhexidine, chlorine, hexachlorophene, iodine, chloroxylenol (PCMX), quaternary ammonium compounds, and triclosan.

Antiseptic handwash. Washing hands with water and soap or other detergents containing an antiseptic agent.

Antiseptic hand rub. Applying an antiseptic hand-rub product to all surfaces of the hands to reduce the number of microorganisms present.

Cumulative effect. A progressive decrease in the numbers of microorganisms recovered after repeated applications of a test material.

Decontaminate hands. To Reduce bacterial counts on hands by performing antiseptic hand rub or antiseptic handwash.

Detergent. Detergents (i.e., surfactants) are compounds that possess a cleaning action. They are composed of both hydrophilic and lipophilic parts and can be divided into four groups: anionic, cationic, amphoteric, and nonionic detergents. Although products used for handwashing or antiseptic handwash in health-care settings represent various types of detergents, the term “soap” is used to refer to such detergents in this guideline.

Hand antiseptis. Refers to either antiseptic handwash or antiseptic hand rub.

Hand hygiene. A general term that applies to either handwashing, antiseptic handwash, antiseptic hand rub, or surgical hand antiseptis.

Handwashing. Washing hands with plain (i.e., non-antimicrobial) soap and water.

Persistent activity. Persistent activity is defined as the prolonged or extended antimicrobial activity that prevents or inhibits the proliferation or survival of microorganisms after application of the product. This activity may be demonstrated by sampling a site several minutes or hours after application and demonstrating bacterial antimicrobial effectiveness when compared with a baseline level. This property also has been referred to as “residual activity.” Both substantive and nonsubstantive active ingredients can show a persistent effect if they substantially lower the number of bacteria during the wash period.

Plain soap. Plain soap refers to detergents that do not contain antimicrobial agents or contain low concentrations of antimicrobial agents that are effective solely as preservatives.

Substantivity. Substantivity is an attribute of certain active ingredients that adhere to the stratum corneum (i.e., remain on the skin after rinsing or drying) to provide an inhibitory effect on the growth of bacteria remaining on the skin.

Surgical hand antisepsis. Antiseptic handwash or antiseptic hand rub performed preoperatively by surgical personnel to eliminate transient and reduce resident hand flora. Antiseptic detergent preparations often have persistent antimicrobial activity.

Visibly soiled hands. Hands showing visible dirt or visibly contaminated with proteinaceous material, blood, or other body fluids (e.g., fecal material or urine).

Waterless antiseptic agent. An antiseptic agent that does not require use of exogenous water. After applying such an agent, the hands are rubbed together until the agent has dried.

Food and Drug Administration (FDA) product categories. The 1994 FDA Tentative Final Monograph for Health-Care Antiseptic Drug Products divided products into three categories and defined them as follows (19):

- **Patient preoperative skin preparation.** A fast-acting, broad-spectrum, and persistent antiseptic-containing preparation that substantially reduces the number of microorganisms on intact skin.
- **Antiseptic handwash or HCW handwash.** An antiseptic-containing preparation designed for frequent use; it reduces the number of microorganisms on intact skin to an initial baseline level after adequate washing, rinsing, and drying; it is broad-spectrum, fast-acting, and if possible, persistent.
- **Surgical hand scrub.** An antiseptic-containing preparation that substantially reduces the number of microorganisms on intact skin; it is broad-spectrum, fast-acting, and persistent.

Evidence of Transmission of Pathogens on Hands

Transmission of health-care-associated pathogens from one patient to another via the hands of HCWs requires the following sequence of events:

- Organisms present on the patient’s skin, or that have been shed onto inanimate objects in close proximity to the patient, must be transferred to the hands of HCWs.
- These organisms must then be capable of surviving for at least several minutes on the hands of personnel.
- Next, handwashing or hand antisepsis by the worker must be inadequate or omitted entirely, or the agent used for hand hygiene must be inappropriate.
- Finally, the contaminated hands of the caregiver must come in direct contact with another patient, or with an inanimate object that will come into direct contact with the patient.

Health-care-associated pathogens can be recovered not only from infected or draining wounds, but also from frequently colonized areas of normal, intact patient skin (20–31). The perineal or inguinal areas are usually most heavily colonized, but the axillae, trunk, and upper extremities (including the hands) also are frequently colonized (23,25,26,28,30–32). The number of organisms (e.g., *S. aureus*, *Proteus mirabilis*, *Klebsiella* spp., and *Acinetobacter* spp.) present on intact areas of the skin of certain patients can vary from 100 to 10⁶/cm² (25,29,31,33). Persons with diabetes, patients undergoing dialysis for chronic renal failure, and those with chronic dermatitis are likely to have areas of intact skin that are colonized with *S. aureus* (34–41). Because approximately 10⁶ skin squames containing viable microorganisms are shed daily from normal skin (42), patient gowns, bed linen, bedside furniture, and other objects in the patient’s immediate environment can easily become contaminated with patient flora (30,43–46). Such contamination is particularly likely to be caused by staphylococci or enterococci, which are resistant to desiccation.

Data are limited regarding the types of patient-care activities that result in transmission of patient flora to the hands of personnel (26,45–51). In the past, attempts have been made to stratify patient-care activities into those most likely to cause hand contamination (52), but such stratification schemes were never validated by quantifying the level of bacterial contamination that occurred. Nurses can contaminate their hands with 100–1,000 CFUs of *Klebsiella* spp. during “clean” activities (e.g., lifting a patient; taking a patient’s pulse, blood pressure, or oral temperature; or touching a patient’s hand, shoulder, or groin) (48). Similarly, in another study, hands were cultured of nurses who touched the groins of patients heavily colonized with *P. mirabilis* (25); 10–600 CFUs/mL of this

organism were recovered from glove juice samples from the nurses' hands. Recently, other researchers studied contamination of HCWs' hands during activities that involved direct patient-contact wound care, intravascular catheter care, respiratory-tract care, and the handling of patient secretions (51). Agar fingertip impression plates were used to culture bacteria; the number of bacteria recovered from fingertips ranged from 0 to 300 CFUs. Data from this study indicated that direct patient contact and respiratory-tract care were most likely to contaminate the fingers of caregivers. Gram-negative bacilli accounted for 15% of isolates and *S. aureus* for 11%. Duration of patient-care activity was strongly associated with the intensity of bacterial contamination of HCWs' hands.

HCWs can contaminate their hands with gram-negative bacilli, *S. aureus*, enterococci, or *Clostridium difficile* by performing "clean procedures" or touching intact areas of the skin of hospitalized patients (26,45,46,53). Furthermore, personnel caring for infants with respiratory syncytial virus (RSV) infections have acquired RSV by performing certain activities (e.g., feeding infants, changing diapers, and playing with infants) (49). Personnel who had contact only with surfaces contaminated with the infants' secretions also acquired RSV by contaminating their hands with RSV and inoculating their oral or conjunctival mucosa. Other studies also have documented that HCWs may contaminate their hands (or gloves) merely by touching inanimate objects in patient rooms (46,53–56). None of the studies concerning hand contamination of hospital personnel were designed to determine if the contamination resulted in transmission of pathogens to susceptible patients.

Other studies have documented contamination of HCWs' hands with potential health-care-associated pathogens, but did not relate their findings to the specific type of preceding patient contact (15,17,57–62). For example, before glove use was common among HCWs, 15% of nurses working in an isolation unit carried a median of 1×10^4 CFUs of *S. aureus* on their hands (61). Of nurses working in a general hospital, 29% had *S. aureus* on their hands (median count: 3,800 CFUs), whereas 78% of those working in a hospital for dermatology patients had the organism on their hands (median count: 14.3×10^6 CFUs). Similarly, 17%–30% of nurses carried gram-negative bacilli on their hands (median counts: 3,400–38,000 CFUs). One study found that *S. aureus* could be recovered from the hands of 21% of intensive-care-unit personnel and that 21% of physician and 5% of nurse carriers had >1,000 CFUs of the organism on their hands (59). Another study found lower levels of colonization on the hands of personnel working in a neurosurgery unit, with an average of 3 CFUs of *S. aureus* and 11 CFUs of gram-negative bacilli (16). Serial

cultures revealed that 100% of HCWs carried gram-negative bacilli at least once, and 64% carried *S. aureus* at least once.

Models of Hand Transmission

Several investigators have studied transmission of infectious agents by using different experimental models. In one study, nurses were asked to touch the groins of patients heavily colonized with gram-negative bacilli for 15 seconds — as though they were taking a femoral pulse (25). Nurses then cleaned their hands by washing with plain soap and water or by using an alcohol hand rinse. After cleaning their hands, they touched a piece of urinary catheter material with their fingers, and the catheter segment was cultured. The study revealed that touching intact areas of moist skin of the patient transferred enough organisms to the nurses' hands to result in subsequent transmission to catheter material, despite handwashing with plain soap and water.

The transmission of organisms from artificially contaminated "donor" fabrics to clean "recipient" fabrics via hand contact also has been studied. Results indicated that the number of organisms transmitted was greater if the donor fabric or the hands were wet upon contact (63). Overall, only 0.06% of the organisms obtained from the contaminated donor fabric were transferred to recipient fabric via hand contact. *Staphylococcus saprophyticus*, *Pseudomonas aeruginosa*, and *Serratia* spp. were also transferred in greater numbers than was *Escherichia coli* from contaminated fabric to clean fabric after hand contact (64). Organisms are transferred to various types of surfaces in much larger numbers (i.e., $>10^4$) from wet hands than from hands that are thoroughly dried (65).

Relation of Hand Hygiene and Acquisition of Health-Care-Associated Pathogens

Hand antisepsis reduces the incidence of health-care-associated infections (66,67). An intervention trial using historical controls demonstrated in 1847 that the mortality rate among mothers who delivered in the First Obstetrics Clinic at the General Hospital of Vienna was substantially lower when hospital staff cleaned their hands with an antiseptic agent than when they washed their hands with plain soap and water (3).

In the 1960s, a prospective, controlled trial sponsored by the National Institutes of Health and the Office of the Surgeon General demonstrated that infants cared for by nurses who did not wash their hands after handling an index infant colonized with *S. aureus* acquired the organism more often and more rapidly than did infants cared for by nurses who used hexachlorophene to clean their hands between infant

contacts (68). This trial provided evidence that, when compared with no handwashing, washing hands with an antiseptic agent between patient contacts reduces transmission of health-care-associated pathogens.

Trials have studied the effects of handwashing with plain soap and water versus some form of hand antiseptics on health-care-associated infection rates (69,70). Health-care-associated infection rates were lower when antiseptic handwashing was performed by personnel (69). In another study, antiseptic handwashing was associated with lower health-care-associated infection rates in certain intensive-care units, but not in others (70).

Health-care-associated infection rates were lower after antiseptic handwashing using a chlorhexidine-containing detergent compared with handwashing with plain soap or use of an alcohol-based hand rinse (71). However, because only a minimal amount of the alcohol rinse was used during periods when the combination regimen also was in use and because adherence to policies was higher when chlorhexidine was available, determining which factor (i.e., the hand-hygiene regimen or differences in adherence) accounted for the lower infection rates was difficult. Investigators have determined also that health-care-associated acquisition of MRSA was reduced when the antimicrobial soap used for hygienic handwashing was changed (72,73).

Increased handwashing frequency among hospital staff has been associated with decreased transmission of *Klebsiella* spp. among patients (48); these studies, however, did not quantify the level of handwashing among personnel. In a recent study, the acquisition of various health-care-associated pathogens was reduced when hand antiseptics was performed more frequently by hospital personnel (74); both this study and another (75) documented that the prevalence of health-care-associated infections decreased as adherence to recommended hand-hygiene measures improved.

Outbreak investigations have indicated an association between infections and understaffing or overcrowding; the association was consistently linked with poor adherence to hand hygiene. During an outbreak investigation of risk factors for central venous catheter-associated bloodstream infections (76), after adjustment for confounding factors, the patient-to-nurse ratio remained an independent risk factor for bloodstream infection, indicating that nursing staff reduction below a critical threshold may have contributed to this outbreak by jeopardizing adequate catheter care. The understaffing of nurses can facilitate the spread of MRSA in intensive-care settings (77) through relaxed attention to basic control measures (e.g., hand hygiene). In an outbreak of *Enterobacter cloacae* in a neonatal intensive-care unit (78), the daily number of

hospitalized children was above the maximum capacity of the unit, resulting in an available space per child below current recommendations. In parallel, the number of staff members on duty was substantially less than the number necessitated by the workload, which also resulted in relaxed attention to basic infection-control measures. Adherence to hand-hygiene practices before device contact was only 25% during the workload peak, but increased to 70% after the end of the understaffing and overcrowding period. Surveillance documented that being hospitalized during this period was associated with a fourfold increased risk of acquiring a health-care-associated infection. This study not only demonstrates the association between workload and infections, but it also highlights the intermediate cause of antimicrobial spread: poor adherence to hand-hygiene policies.

Methods Used To Evaluate the Efficacy of Hand-Hygiene Products

Current Methods

Investigators use different methods to study the in vivo efficacy of handwashing, antiseptic handwash, and surgical hand antiseptics protocols. Differences among the various studies include 1) whether hands are purposely contaminated with bacteria before use of test agents, 2) the method used to contaminate fingers or hands, 3) the volume of hand-hygiene product applied to the hands, 4) the time the product is in contact with the skin, 5) the method used to recover bacteria from the skin after the test solution has been used, and 6) the method of expressing the efficacy of the product (i.e., either percent reduction in bacteria recovered from the skin or log reduction of bacteria released from the skin). Despite these differences, the majority of studies can be placed into one of two major categories: studies focusing on products to remove transient flora and studies involving products that are used to remove resident flora from the hands. The majority of studies of products for removing transient flora from the hands of HCWs involve artificial contamination of the volunteer's skin with a defined inoculum of a test organism before the volunteer uses a plain soap, an antimicrobial soap, or a waterless antiseptic agent. In contrast, products tested for the preoperative cleansing of surgeons' hands (which must comply with surgical hand-antiseptics protocols) are tested for their ability to remove resident flora from without artificially contaminating the volunteers' hands.

In the United States, antiseptic handwash products intended for use by HCWs are regulated by FDA's Division of Over-the-Counter Drug Products (OTC). Requirements for in vitro and in vivo testing of HCW handwash products and surgical

hand scrubs are outlined in the FDA Tentative Final Monograph for Healthcare Antiseptic Drug Products (TFM) (19). Products intended for use as HCW handwashes are evaluated by using a standardized method (19). Tests are performed in accordance with use directions for the test material. Before baseline bacterial sampling and before each wash with the test material, 5 mL of a standardized suspension of *Serratia marcescens* are applied to the hands and then rubbed over the surfaces of the hands. A specified volume of the test material is dispensed into the hands and is spread over the hands and lower one third of the forearms. A small amount of tap water is added to the hands, and hands are completely lathered for a specified time, covering all surfaces of the hands and the lower third of the forearms. Volunteers then rinse hands and forearms under 40°C tap water for 30 seconds. Ten washes with the test formulation are required. After the first, third, seventh, and tenth washes, rubber gloves or polyethylene bags used for sampling are placed on the right and left hands, and 75 mL of sampling solution is added to each glove; gloves are secured above the wrist. All surfaces of the hand are massaged for 1 minute, and samples are obtained aseptically for quantitative culture. No neutralizer of the antimicrobial is routinely added to the sampling solution, but if dilution of the antimicrobial in the sampling fluid does not result in demonstrable neutralization, a neutralizer specific for the test formulation is added to the sampling solution. For waterless formulations, a similar procedure is used. TFM criteria for efficacy are as follows: a 2- \log_{10} reduction of the indicator organism on each hand within 5 minutes after the first use, and a 3- \log_{10} reduction of the indicator organism on each hand within 5 minutes after the tenth use (19).

Products intended for use as surgical hand scrubs have been evaluated also by using a standardized method (19). Volunteers clean under fingernails with a nail stick and clip their fingernails. All jewelry is removed from hands and arms. Hands and two thirds of forearms are rinsed with tap water (38°C–42°C) for 30 seconds, and then they are washed with a non-antimicrobial soap for 30 seconds and are rinsed for 30 seconds under tap water. Baseline microbial hand counts can then be determined. Next, a surgical scrub is performed with the test formulation using directions provided by the manufacturer. If no instructions are provided with the formulation, two 5-minute scrubs of hands and forearms followed by rinsing are performed. Reduction from baseline microbial hand counts is determined in a series of 11 scrubs conducted during 5 days. Hands are sampled at 1 minute, 3 hours, and 6 hours after the first scrubs on day 1, day 2, and day 5. After washing, volunteers wear rubber gloves; 75 mL of sampling solution are then added to one glove, and all surfaces of the hands are massaged

for 1 minute. Samples are then taken aseptically and cultured quantitatively. The other glove remains on the other hand for 6 hours and is sampled in the same manner. TFM requires that formulations reduce the number of bacteria 1 \log_{10} on each hand within 1 minute of product application and that the bacterial cell count on each hand does not subsequently exceed baseline within 6 hours on day 1; the formulation must produce a 2- \log_{10} reduction in microbial flora on each hand within 1 minute of product application by the end of the second day of enumeration and a 3- \log_{10} reduction of microbial flora on each hand within 1 minute of product use by the end of the fifth day when compared with the established baseline (19).

The method most widely used in Europe to evaluate the efficacy of hand-hygiene agents is European Standard 1500–1997 (EN 1500—Chemical disinfectants and antiseptics. Hygienic hand-rub test method and requirements) (79). This method requires 12–15 test volunteers and an 18- to 24-hour growth of broth culture of *E. coli* K12. Hands are washed with a soft soap, dried, and then immersed halfway to the metacarpals in the broth culture for 5 seconds. Hands are removed from the broth culture, excess fluid is drained off, and hands are dried in the air for 3 minutes. Bacterial recovery for the initial value is obtained by kneading the fingertips of each hand separately for 60 seconds in 10 mL of tryptic soy broth (TSB) without neutralizers. The hands are removed from the broth and disinfected with 3 mL of the hand-rub agent for 30 seconds in a set design. The same operation is repeated with total disinfection time not exceeding 60 seconds. Both hands are rinsed in running water for 5 seconds and water is drained off. Fingertips of each hand are kneaded separately in 10 mL of TSB with added neutralizers. These broths are used to obtain the final value. \log_{10} dilutions of recovery medium are prepared and plated out. Within 3 hours, the same volunteers are tested with the reference disinfectant (60% 2-propanol [isopropanol]) and the test product. Colony counts are performed after 24 and 48 hours of incubation at 36°C. The average colony count of both left and right hand is used for evaluation. The log-reduction factor is calculated and compared with the initial and final values. The reduction factor of the test product should be superior or the same as the reference alcohol-based rub for acceptance. If a difference exists, then the results are analyzed statistically using the Wilcoxon test. Products that have log reductions substantially less than that observed with the reference alcohol-based hand rub (i.e., approximately 4 \log_{10} reduction) are classified as not meeting the standard.

Because of different standards for efficacy, criteria cited in FDA TFM and the European EN 1500 document for establishing alcohol-based hand rubs vary (1, 19, 79). Alcohol-based

hand rubs that meet TFM criteria for efficacy may not necessarily meet the EN 1500 criteria for efficacy (80). In addition, scientific studies have not established the extent to which counts of bacteria or other microorganisms on the hands need to be reduced to minimize transmission of pathogens in health-care facilities (1,8); whether bacterial counts on the hands must be reduced by 1 log₁₀ (90% reduction), 2 log₁₀ (99%), 3 log₁₀ (99.9%), or 4 log₁₀ (99.99%) is unknown. Several other methods also have been used to measure the efficacy of antiseptic agents against various viral pathogens (81–83).

Shortcomings of Traditional Methodologies

Accepted methods of evaluating hand-hygiene products intended for use by HCWs require that test volunteers wash their hands with a plain or antimicrobial soap for 30 seconds or 1 minute, despite the observation in the majority of studies that the average duration of handwashing by hospital personnel is <15 seconds (52,84–89). A limited number of investigators have used 15-second handwashing or hygienic hand-wash protocols (90–94). Therefore, almost no data exist regarding the efficacy of plain or antimicrobial soaps under conditions in which they are actually used by HCWs. Similarly, certain accepted methods for evaluating waterless antiseptic agents for use as antiseptic hand rubs require that 3 mL of alcohol be rubbed into the hands for 30 seconds, followed by a repeat application for the same duration. This type of protocol also does not reflect actual usage patterns among HCWs. Furthermore, volunteers used in evaluations of products are usually surrogates for HCWs, and their hand flora may not reflect flora found on the hands of personnel working in health-care settings. Further studies should be conducted among practicing HCWs using standardized protocols to obtain more realistic views of microbial colonization and risk of bacterial transfer and cross-transmission (51).

Review of Preparations Used for Hand Hygiene

Plain (Non-Antimicrobial) Soap

Soaps are detergent-based products that contain esterified fatty acids and sodium or potassium hydroxide. They are available in various forms including bar soap, tissue, leaflet, and liquid preparations. Their cleaning activity can be attributed to their detergent properties, which result in removal of dirt, soil, and various organic substances from the hands. Plain soaps have minimal, if any, antimicrobial activity. However, handwashing with plain soap can remove loosely adherent transient flora. For example, handwashing with plain soap and water for 15 seconds reduces bacterial counts on the skin by 0.6–1.1 log₁₀, whereas washing for 30 seconds reduces counts

by 1.8–2.8 log₁₀ (1). However, in several studies, handwashing with plain soap failed to remove pathogens from the hands of hospital personnel (25,45). Handwashing with plain soap can result in paradoxical increases in bacterial counts on the skin (92,95–97). Non-antimicrobial soaps may be associated with considerable skin irritation and dryness (92,96,98), although adding emollients to soap preparations may reduce their propensity to cause irritation. Occasionally, plain soaps have become contaminated, which may lead to colonization of hands of personnel with gram-negative bacilli (99).

Alcohols

The majority of alcohol-based hand antiseptics contain either isopropanol, ethanol, n-propanol, or a combination of two of these products. Although n-propanol has been used in alcohol-based hand rubs in parts of Europe for many years, it is not listed in TFM as an approved active agent for HCW handwashes or surgical hand-scrub preparations in the United States. The majority of studies of alcohols have evaluated individual alcohols in varying concentrations. Other studies have focused on combinations of two alcohols or alcohol solutions containing limited amounts of hexachlorophene, quaternary ammonium compounds, povidone-iodine, triclosan, or chlorhexidine gluconate (61,93,100–119).

The antimicrobial activity of alcohols can be attributed to their ability to denature proteins (120). Alcohol solutions containing 60%–95% alcohol are most effective, and higher concentrations are less potent (120–122) because proteins are not denatured easily in the absence of water (120). The alcohol content of solutions may be expressed as percent by weight (w/w), which is not affected by temperature or other variables, or as percent by volume (vol/vol), which can be affected by temperature, specific gravity, and reaction concentration (123). For example, 70% alcohol by weight is equivalent to 76.8% by volume if prepared at 15°C, or 80.5% if prepared at 25°C (123). Alcohol concentrations in antiseptic hand rubs are often expressed as percent by volume (19).

Alcohols have excellent *in vitro* germicidal activity against gram-positive and gram-negative vegetative bacteria, including multidrug-resistant pathogens (e.g., MRSA and VRE), *Mycobacterium tuberculosis*, and various fungi (120–122,124–129). Certain enveloped (lipophilic) viruses (e.g., herpes simplex virus, human immunodeficiency virus [HIV], influenza virus, respiratory syncytial virus, and vaccinia virus) are susceptible to alcohols when tested *in vitro* (120,130,131) (Table 1). Hepatitis B virus is an enveloped virus that is somewhat less susceptible but is killed by 60%–70% alcohol; hepatitis C virus also is likely killed by this percentage of alcohol (132). In a porcine tissue carrier model used to study antiseptic activity, 70% ethanol and 70% isopropanol were found to

TABLE 1. Virucidal activity of antiseptic agents against enveloped viruses

Ref. no.	Test method	Viruses	Agent	Results
(379)	Suspension	HIV	19% EA	LR = 2.0 in 5 minutes
(380)	Suspension	HIV	50% EA 35% IPA	LR > 3.5 LR > 3.7
(381)	Suspension	HIV	70% EA	LR = 7.0 in 1 minute
(382)	Suspension	HIV	70% EA	LR = 3.2B 5.5 in 30 seconds
(383)	Suspension	HIV	70% IPA/0.5% CHG 4% CHG	LR = 6.0 in 15 seconds LR = 6.0 in 15 seconds
(384)	Suspension	HIV	Chloroxylenol Benzalkonium chloride	Inactivated in 1 minute Inactivated in 1 minute
(385)	Suspension	HIV	Povidone-iodine Chlorhexidine	Inactivated Inactivated
(386)	Suspension	HIV	Detergent/0.5% PCMX	Inactivated in 30 seconds
(387)	Suspension/dried plasma chimpanzee challenge	HBV	70% IPA	LR = 6.0 in 10 minutes
(388)	Suspension/plasma chimpanzee challenge	HBV	80% EA	LR = 7.0 in 2 minutes
(389)	Suspension	HSV	95% EA 75% EA 95% IPA 70% EA + 0.5% CHG	LR > 5.0 in 1 minute LR > 5.0 LR > 5.0 LR > 5.0
(130)	Suspension	RSV	35% IPA 4% CHG	LR > 4.3 in 1 minute LR > 3.3
(141)	Suspension	Influenza Vaccinia	95% EA 95% EA	Undetectable in 30 seconds Undetectable in 30 seconds
(141)	Hand test	Influenza Vaccinia	95% EA 95% EA	LR > 2.5 LR > 2.5

Note: HIV = human immunodeficiency virus, EA = ethanol, LR = Log_{10} reduction, IPA = isopropanol, CHG = chlorhexidine gluconate, HBV = hepatitis B virus, RSV = respiratory syncytial virus, HSV = herpes simplex virus, HAV = hepatitis A virus, and PCMX = chloroxylenol.

reduce titers of an enveloped bacteriophage more effectively than an antimicrobial soap containing 4% chlorhexidine gluconate (133). Despite its effectiveness against these organisms, alcohols have very poor activity against bacterial spores, protozoan oocysts, and certain nonenveloped (nonlipophilic) viruses.

Numerous studies have documented the *in vivo* antimicrobial activity of alcohols. Alcohols effectively reduce bacterial counts on the hands (14,121,125,134). Typically, log reductions of the release of test bacteria from artificially contaminated hands average 3.5 log_{10} after a 30-second application and 4.0–5.0 log_{10} after a 1-minute application (1). In 1994, the FDA TFM classified ethanol 60%–95% as a Category I agent (i.e., generally safe and effective for use in antiseptic handwash or HCW hand-wash products) (19). Although TFM placed isopropanol 70%–91.3% in category IIIIE (i.e., insufficient data to classify as effective), 60% isopropanol has subse-

quently been adopted in Europe as the reference standard against which alcohol-based hand-rub products are compared (79). Alcohols are rapidly germicidal when applied to the skin, but they have no appreciable persistent (i.e., residual) activity. However, regrowth of bacteria on the skin occurs slowly after use of alcohol-based hand antiseptics, presumably because of the sublethal effect alcohols have on some of the skin bacteria (135,136). Addition of chlorhexidine, quaternary ammonium compounds, octenidine, or triclosan to alcohol-based solutions can result in persistent activity (1).

Alcohols, when used in concentrations present in alcohol-based hand rubs, also have *in vivo* activity against several nonenveloped viruses (Table 2). For example, 70% isopropanol and 70% ethanol are more effective than medicated soap or nonmedicated soap in reducing rotavirus titers on fingerpads (137,138). A more recent study using the same test methods evaluated a commercially available product containing 60%

TABLE 2. Virucidal activity of antiseptic agents against nonenveloped viruses

Ref. no.	Test method	Viruses	Antiseptic	Result
(390)	Suspension	Rotavirus	4% CHG 10% Povidone-Iodine 70% IPA/0.1% HCP	LR < 3.0 in 1 minute LR > 3.0 LR > 3.0
(141)	Hand test	Adenovirus Poliovirus Coxsackie	95% EA 95% EA 95% EA	LR > 1.4 LR = 0.2–1.0 LR = 1.1–1.3
	Finger test	Adenovirus Poliovirus Coxsackie	95% EA 95% EA 95% EA	LR > 2.3 LR = 0.7–2.5 LR = 2.9
(389)	Suspension	ECHO virus	95% EA 75% EA 95% IPA 70% IPA + 0.5% CHG	LR > 3.0 in 1 minute LR ≤ 1.0 LR = 0 LR = 0
(140)	Finger pad	HAV	70% EA 62% EA foam plain soap 4% CHG 0.3% Triclosan	87.4% reduction 89.3% reduction 78.0% reduction 89.6% reduction 92.0% reduction
(105)	Finger tips	Bovine Rotavirus	n-propanol + IPA 70% IPA 70% EA 2% triclosan water (control) 7.5% povidone-iodine plain soap 4% CHG	LR = 3.8 in 30 seconds LR = 3.1 LR = 2.9 LR = 2.1 LR = 1.3 LR = 1.3 LR = 1.2 LR = 0.5
(137)	Finger pad	Human Rotavirus	70% IPA plain soap	98.9% decrease in 10 seconds 77.1%
(138)	Finger pad	Human Rotavirus	70% IPA 2% CHG plain soap	99.6% decrease in 10 seconds 80.3% 72.5%
(81)	Finger pad	Rotavirus Rhinovirus Adenovirus	60% EA gel 60% EA gel 60% EA gel	LR > 3.0 in 10 seconds LR > 3.0 LR > 3.0
(139)	Finger pad	Poliovirus	70% EA 70% IPA	LR = 1.6 in 10 seconds LR = 0.8
(200)	Finger tips	Poliovirus	Plain soap 80% EA	LR = 2.1 LR = 0.4

Note: HIV = human immunodeficiency virus, EA = ethanol, LR = Log₁₀ reduction, IPA = isopropanol, CHG = chlorhexidine gluconate, HBV = hepatitis B virus, RSV = respiratory syncytial virus, HSV = herpes simplex virus, and HAV = hepatitis A virus.

ethanol and found that the product reduced the infectivity titers of three nonenveloped viruses (i.e., rotavirus, adenovirus, and rhinovirus) by >3 logs (81). Other nonenveloped viruses such as hepatitis A and enteroviruses (e.g., poliovirus) may require 70%–80% alcohol to be reliably inactivated (82,139). However, both 70% ethanol and a 62% ethanol foam product with emollients reduced hepatitis A virus titers on whole hands or fingertips more than nonmedicated soap; both were equally as effective as antimicrobial soap containing 4% chlorhexidine gluconate in reducing reduced viral counts on hands (140). In the same study, both 70% ethanol and the 62% ethanol foam product demonstrated greater virucidal activity against poliovirus than either non-antimicrobial

soap or a 4% chlorhexidine gluconate-containing soap (140). However, depending on the alcohol concentration, the amount of time that hands are exposed to the alcohol, and viral variant, alcohol may not be effective against hepatitis A and other nonlipophilic viruses. The inactivation of nonenveloped viruses is influenced by temperature, disinfectant-virus volume ratio, and protein load (141). Ethanol has greater activity against viruses than isopropanol. Further in vitro and in vivo studies of both alcohol-based formulations and antimicrobial soaps are warranted to establish the minimal level of virucidal activity that is required to interrupt direct contact transmission of viruses in health-care settings.

Alcohols are not appropriate for use when hands are visibly dirty or contaminated with proteinaceous materials. However, when relatively small amounts of proteinaceous material (e.g., blood) are present, ethanol and isopropanol may reduce viable bacterial counts on hands more than plain soap or antimicrobial soap (142).

Alcohol can prevent the transfer of health-care-associated pathogens (25,63,64). In one study, gram-negative bacilli were transferred from a colonized patient's skin to a piece of catheter material via the hands of nurses in only 17% of experiments after antiseptic hand rub with an alcohol-based hand rinse (25). In contrast, transfer of the organisms occurred in 92% of experiments after handwashing with plain soap and water. This experimental model indicates that when the hands of HCWs are heavily contaminated, an antiseptic hand rub using an alcohol-based rinse can prevent pathogen transmission more effectively than can handwashing with plain soap and water.

Alcohol-based products are more effective for standard handwashing or hand antisepsis by HCWs than soap or antimicrobial soaps (Table 3) (25,53,61,93,106–112,119,143–152). In all but two of the trials that compared alcohol-based solutions with antimicrobial soaps or detergents, alcohol reduced bacterial counts on hands more than washing hands with soaps or detergents containing hexachlorophene, povidone-iodine, 4% chlorhexidine, or triclosan. In studies exam-

ining antimicrobial-resistant organisms, alcohol-based products reduced the number of multidrug-resistant pathogens recovered from the hands of HCWs more effectively than did handwashing with soap and water (153–155).

Alcohols are effective for preoperative cleaning of the hands of surgical personnel (1,101,104,113–119,135,143,147,156–159) (Tables 4 and 5). In multiple studies, bacterial counts on the hands were determined immediately after using the product and again 1–3 hours later; the delayed testing was performed to determine if regrowth of bacteria on the hands is inhibited during operative procedures. Alcohol-based solutions were more effective than washing hands with plain soap in all studies, and they reduced bacterial counts on the hands more than antimicrobial soaps or detergents in the majority of experiments (101,104,113–119,135,143,147,157–159). In addition, the majority of alcohol-based preparations were more effective than povidone-iodine or chlorhexidine.

The efficacy of alcohol-based hand-hygiene products is affected by several factors, including the type of alcohol used, concentration of alcohol, contact time, volume of alcohol used, and whether the hands are wet when the alcohol is applied. Applying small volumes (i.e., 0.2–0.5 mL) of alcohol to the hands is not more effective than washing hands with plain soap and water (63,64). One study documented that 1 mL of alcohol was substantially less effective than 3 mL (91). The ideal volume of product to apply to the hands is not known

TABLE 3. Studies comparing the relative efficacy (based on log₁₀ reductions achieved) of plain soap or antimicrobial soaps versus alcohol-based antiseptics in reducing counts of viable bacteria on hands

Ref. no.	Year	Skin contamination	Assay method	Time (sec)	Relative efficacy
(143)	1965	Existing hand flora	Finger-tip agar culture	60	Plain soap < HCP < 50% EA foam
(119)	1975	Existing hand flora	Hand-rub broth culture	—	Plain soap < 95% EA
(106)	1978	Artificial contamination	Finger-tip broth culture	30	Plain soap < 4% CHG < P-I < 70% EA = alc. CHG
(144)	1978	Artificial contamination	Finger-tip broth culture	30	Plain soap < 4% CHG < 70% EA
(107)	1979	Existing hand flora	Hand-rub broth culture	120	Plain soap < 0.5% aq. CHG < 70% EA < 4% CHG < alc.CHG
(145)	1980	Artificial contamination	Finger-tip broth culture	60–120	4% CHG < P-I < 60% IPA
(53)	1980	Artificial contamination	Finger-tip broth culture	15	Plain soap < 3% HCP < P-I < 4% CHG < 70% EA
(108)	1982	Artificial contamination	Glove juice test	15	P-I < alc. CHG
(109)	1983	Artificial contamination	Finger-tip broth culture	120	0.3–2% triclosan = 60% IPA = alc. CHG < alc. triclosan
(146)	1984	Artificial contamination	Finger-tip agar culture	60	Phenolic < 4% CHG < P-I < EA < IPA < n-P
(147)	1985	Existing hand flora	Finger-tip agar culture	60	Plain soap < 70% EA < 95% EA
(110)	1986	Artificial contamination	Finger-tip broth culture	60	Phenolic = P-I < alc. CHG < n-P
(93)	1986	Existing hand flora	Sterile-broth bag technique	15	Plain soap < IPA < 4% CHG = IPA-E = alc. CHG
(61)	1988	Artificial contamination	Finger-tip broth culture	30	Plain soap < triclosan < P-I < IPA < alc. CHG < n-P
(25)	1991	Patient contact	Glove-juice test	15	Plain soap < IPA-E
(148)	1991	Existing hand flora	Agar-plate/image analysis	30	Plain soap < 1% triclosan < P-I < 4% CHG < IPA
(111)	1992	Artificial contamination	Finger-tip agar culture	60	Plain soap < IPA < EA < alc. CHG
(149)	1992	Artificial contamination	Finger-tip broth culture	60	Plain soap < 60% n-P
(112)	1994	Existing hand flora	Agar-plate/image analysis	30	Plain soap < alc. CHG
(150)	1999	Existing hand flora	Agar-plate culture	N.S.	Plain soap < commercial alcohol mixture
(151)	1999	Artificial contamination	Glove-juice test	20	Plain soap < 0.6% PCMX < 65% EA
(152)	1999	Artificial contamination	Finger-tip broth culture	30	4% CHG < plain soap < P-I < 70% EA

Note: Existing hand flora = without artificially contaminating hands with bacteria, alc. CHG = alcoholic chlorhexidine gluconate, aq. CHG = aqueous chlorhexidine gluconate, 4% CHG = chlorhexidine gluconate detergent, EA = ethanol, HCP = hexachlorophene soap/detergent, IPA = isopropanol, IPA-E = isopropanol + emollients, n-P = n-propanol, PCMX = chloroxylenol detergent, P-I = povidone-iodine detergent, and N.S. = not stated.

TABLE 4. Studies comparing the relative efficacy of plain soap or antimicrobial soap versus alcohol-containing products in reducing counts of bacteria recovered from hands immediately after use of products for pre-operative cleansing of hands

Ref. no.	Year	Assay method	Relative efficacy
(143)	1965	Finger-tip agar culture	HCP < 50% EA foam + QAC
(157)	1969	Finger-tip agar culture	HCP < P-I < 50% EA foam + QAC
(101)	1973	Finger-tip agar culture	HCP soap < EA foam + 0.23% HCP
(135)	1974	Broth culture	Plain soap < 0.5% CHG < 4% CHG < alc. CHG
(119)	1975	Hand-broth test	Plain soap < 0.5% CHG < 4% CHG < alc. CHG
(118)	1976	Glove-juice test	0.5% CHG < 4% CHG < alc. CHG
(114)	1977	Glove-juice test	P-I < CHG < alc. CHG
(117)	1978	Finger-tip agar culture	P-I = 46% EA + 0.23% HCP
(113)	1979	Broth culture of hands	Plain soap < P-I < alc. CHG < alc. P-I
(116)	1979	Glove-juice test	70% IPA = alc. CHG
(147)	1985	Finger-tip agar culture	Plain soap < 70% - 90% EA
(115)	1990	Glove-juice test, modified	Plain soap < triclosan < CHG < P-I < alc. CHG
(104)	1991	Glove-juice test	Plain soap < 2% triclosan < P-I < 70% IPA
(158)	1998	Finger-tip broth culture	70% IPA < 90% IPA = 60% n-P
(159)	1998	Glove-juice test	P-I < CHG < 70% EA

Note: QAC = quaternary ammonium compound, alc. CHG = alcoholic chlorhexidine gluconate, CHG = chlorhexidine gluconate detergent, EA = ethanol, HCP = hexachlorophene detergent, IPA = isopropanol, and P-I = povidone-iodine detergent.

TABLE 5. Efficacy of surgical hand-rub solutions in reducing the release of resident skin flora from clean hands

Study	Rub	Concentration* (%)	Time (min)	Mean log reduction	
				Immediate	Sustained (3 hr)
1	n-Propanol	60	5	2.9 [†]	1.6 [†]
2			5	2.7 [†]	NA
3			5	2.5 [†]	1.8 [†]
4			5	2.3 [†]	1.6 [†]
5			3	2.9 [§]	NA
4	Isopropanol	90	3	2.0 [†]	1.0 [†]
4			1	1.1 [†]	0.5 [†]
6			3	2.4 [§]	1.4 [§]
6			3	2.3 [§]	1.2 [§]
7			5	2.4 [†]	2.1 [†]
4			5	2.1 [†]	1.0 [†]
6			3	2.0 [§]	0.7 [§]
5			3	1.7 ^c	NA
4			3	1.5 [†]	0.8 [†]
8			2	1.2	0.8
4	1	0.7 [†]	0.2		
9	1	0.8	NA		
10	Isopropanol + chlorhexidine gluc. (w/v)	60	5	1.7	1.0
7			5	2.5 [†]	2.7 [†]
8	Ethanol	70 + 0.5	2	1.0	1.5
11			2	2.1	NA
5			3	2.4 [§]	NA
12			2	1.5	NA
8			2	1.0	0.6
13	Ethanol + chlorhexidine gluc. (w/v)	95 + 0.5	2	1.7	NA
14			5	2.0	1.5 [¶]
8			2	0.7	1.4
8	Chlorhexidine gluc. (aq. Sol., w/v)	0.5	2	0.4	1.2
15			5	1.9 [†]	0.8 [†]
16	Peracetic acid (w/v)	0.5	5	1.9	NA

Note: NA = not available.

Source: Rotter M. Hand washing and hand disinfection [Chapter 87]. In: Mayhall CG, ed. Hospital epidemiology and infection control. 2nd ed. Philadelphia, PA: Lippincott Williams & Wilkins, 1999. Table 5 is copyrighted by Lippincott Williams & Wilkins; it is reprinted here with their permission and permission from Manfred Rotler, M.D., Professor of Hygiene and Microbiology, Klinisches Institute für Hygiene der Universität Wien, Germany.

* Volume/volume unless otherwise stated.

[†] Tested according to Deutsche Gesellschaft für Hygiene, and Mikrobiologic (DGHM)-German Society of Hygiene and Microbiology method.

[§] Tested according to European Standard prEN.

[¶] After 4 hours.

and may vary for different formulations. However, if hands feel dry after rubbing hands together for 10–15 seconds, an insufficient volume of product likely was applied. Because alcohol-impregnated towelettes contain a limited amount of alcohol, their effectiveness is comparable to that of soap and water (63,160,161).

Alcohol-based hand rubs intended for use in hospitals are available as low viscosity rinses, gels, and foams. Limited data are available regarding the relative efficacy of various formulations. One field trial demonstrated that an ethanol gel was slightly more effective than a comparable ethanol solution at reducing bacterial counts on the hands of HCWs (162). However, a more recent study indicated that rinses reduced bacterial counts on the hands more than the gels tested (80). Further studies are warranted to determine the relative efficacy of alcohol-based rinses and gels in reducing transmission of health-care-associated pathogens.

Frequent use of alcohol-based formulations for hand antisepsis can cause drying of the skin unless emollients, humectants, or other skin-conditioning agents are added to the formulations. The drying effect of alcohol can be reduced or eliminated by adding 1%–3% glycerol or other skin-conditioning agents (90,93,100,101,106,135,143,163,164). Moreover, in several recent prospective trials, alcohol-based rinses or gels containing emollients caused substantially less skin irritation and dryness than the soaps or antimicrobial detergents tested (96,98,165,166). These studies, which were conducted in clinical settings, used various subjective and objective methods for assessing skin irritation and dryness. Further studies are warranted to establish whether products with different formulations yield similar results.

Even well-tolerated alcohol hand rubs containing emollients may cause a transient stinging sensation at the site of any broken skin (e.g., cuts and abrasions). Alcohol-based hand-rub preparations with strong fragrances may be poorly tolerated by HCWs with respiratory allergies. Allergic contact dermatitis or contact urticaria syndrome caused by hypersensitivity to alcohol or to various additives present in certain alcohol hand rubs occurs only rarely (167,168).

Alcohols are flammable. Flash points of alcohol-based hand rubs range from 21°C to 24°C, depending on the type and concentration of alcohol present (169). As a result, alcohol-based hand rubs should be stored away from high temperatures or flames in accordance with National Fire Protection Agency recommendations. In Europe, where alcohol-based hand rubs have been used extensively for years, the incidence of fires associated with such products has been low (169). One recent U.S. report described a flash fire that occurred as a result of an unusual series of events, which included an HCW applying an alcohol gel to her hands, immediately removing a

polyester isolation gown, and then touching a metal door before the alcohol had evaporated (170). Removing the polyester gown created a substantial amount of static electricity that generated an audible static spark when the HCW touched the metal door, igniting the unevaporated alcohol on her hands (170). This incident emphasizes the need to rub hands together after application of alcohol-based products until all the alcohol has evaporated.

Because alcohols are volatile, containers should be designed to minimize evaporation. Contamination of alcohol-based solutions has seldom been reported. One report documented a cluster of pseudo-infections caused by contamination of ethyl alcohol by *Bacillus cereus* spores (171).

Chlorhexidine

Chlorhexidine gluconate, a cationic bisbiguanide, was developed in England in the early 1950s and was introduced into the United States in the 1970s (8,172). Chlorhexidine base is only minimally soluble in water, but the digluconate form is water-soluble. The antimicrobial activity of chlorhexidine is likely attributable to attachment to, and subsequent disruption of, cytoplasmic membranes, resulting in precipitation of cellular contents (1,8). Chlorhexidine's immediate antimicrobial activity occurs more slowly than that of alcohols. Chlorhexidine has good activity against gram-positive bacteria, somewhat less activity against gram-negative bacteria and fungi, and only minimal activity against tubercle bacilli (1,8,172). Chlorhexidine is not sporicidal (1,172). It has in vitro activity against enveloped viruses (e.g., herpes simplex virus, HIV, cytomegalovirus, influenza, and RSV) but substantially less activity against nonenveloped viruses (e.g., rotavirus, adenovirus, and enteroviruses) (130,131,173). The antimicrobial activity of chlorhexidine is only minimally affected by the presence of organic material, including blood. Because chlorhexidine is a cationic molecule, its activity can be reduced by natural soaps, various inorganic anions, nonionic surfactants, and hand creams containing anionic emulsifying agents (8,172,174). Chlorhexidine gluconate has been incorporated into a number of hand-hygiene preparations. Aqueous or detergent formulations containing 0.5% or 0.75% chlorhexidine are more effective than plain soap, but they are less effective than antiseptic detergent preparations containing 4% chlorhexidine gluconate (135,175). Preparations with 2% chlorhexidine gluconate are slightly less effective than those containing 4% chlorhexidine (176).

Chlorhexidine has substantial residual activity (106,114–116,118,135,146,175). Addition of low concentrations (0.5%–1.0%) of chlorhexidine to alcohol-based preparations results in greater residual activity than alcohol alone (116,135). When used as recommended, chlorhexidine has a good safety

record (172). Minimal, if any, absorption of the compound occurs through the skin. Care must be taken to avoid contact with the eyes when using preparations with $\geq 1\%$ chlorhexidine, because the agent can cause conjunctivitis and severe corneal damage. Ototoxicity precludes its use in surgery involving the inner or middle ear. Direct contact with brain tissue and the meninges should be avoided. The frequency of skin irritation is concentration-dependent, with products containing 4% most likely to cause dermatitis when used frequently for antiseptic handwashing (177); allergic reactions to chlorhexidine gluconate are uncommon (118,172). Occasional outbreaks of nosocomial infections have been traced to contaminated solutions of chlorhexidine (178–181).

Chloroxylenol

Chloroxylenol, also known as parachlorometaxylenol (PCMX), is a halogen-substituted phenolic compound that has been used as a preservative in cosmetics and other products and as an active agent in antimicrobial soaps. It was developed in Europe in the late 1920s and has been used in the United States since the 1950s (182).

The antimicrobial activity of PCMX likely is attributable to inactivation of bacterial enzymes and alteration of cell walls (1). It has good in vitro activity against gram-positive organisms and fair activity against gram-negative bacteria, mycobacteria, and certain viruses (1,7,182). PCMX is less active against *P. aeruginosa*, but addition of ethylenediaminetetraacetic acid (EDTA) increases its activity against *Pseudomonas* spp. and other pathogens.

A limited number of articles focusing on the efficacy of PCMX-containing preparations intended for use by HCWs have been published in the last 25 years, and the results of studies have sometimes been contradictory. For example, in studies in which antiseptics were applied to abdominal skin, PCMX had the weakest immediate and residual activity of any of the agents studied (183). However, when 30-second handwashes were performed using 0.6% PCMX, 2% chlorhexidine gluconate, or 0.3% triclosan, the immediate effect of PCMX was similar to that of the other agents. When used 18 times per day for 5 consecutive days, PCMX had less cumulative activity than did chlorhexidine gluconate (184). When PCMX was used as a surgical scrub, one report indicated that 3% PCMX had immediate and residual activity comparable to 4% chlorhexidine gluconate (185), whereas two other studies demonstrated that the immediate and residual activity of PCMX was inferior to both chlorhexidine gluconate and povidone-iodine (176,186). The disparity between published studies may be associated with the various concentrations of PCMX included in the preparations evaluated and with other aspects of the formulations tested, including the

presence or absence of EDTA (7,182). PCMX is not as rapidly active as chlorhexidine gluconate or iodophors, and its residual activity is less pronounced than that observed with chlorhexidine gluconate (7,182). In 1994, FDA TFM tentatively classified PCMX as a Category III SE active agent (i.e., insufficient data are available to classify this agent as safe and effective) (19). Further evaluation of this agent by the FDA is ongoing.

The antimicrobial activity of PCMX is minimally affected by the presence of organic matter, but it is neutralized by non-ionic surfactants. PCMX, which is absorbed through the skin (7,182), is usually well-tolerated, and allergic reactions associated with its use are uncommon. PCMX is available in concentrations of 0.3%–3.75%. In-use contamination of a PCMX-containing preparation has been reported (187).

Hexachlorophene

Hexachlorophene is a bisphenol composed of two phenolic groups and three chlorine moieties. In the 1950s and early 1960s, emulsions containing 3% hexachlorophene were widely used for hygienic handwashing, as surgical scrubs, and for routine bathing of infants in hospital nurseries. The antimicrobial activity of hexachlorophene results from its ability to inactivate essential enzyme systems in microorganisms. Hexachlorophene is bacteriostatic, with good activity against *S. aureus* and relatively weak activity against gram-negative bacteria, fungi, and mycobacteria (7).

Studies of hexachlorophene as a hygienic handwash and surgical scrub demonstrated only modest efficacy after a single handwash (53,143,188). Hexachlorophene has residual activity for several hours after use and gradually reduces bacterial counts on hands after multiple uses (i.e., it has a cumulative effect) (1,101,188,189). With repeated use of 3% hexachlorophene preparations, the drug is absorbed through the skin. Infants bathed with hexachlorophene and personnel regularly using a 3% hexachlorophene preparation for handwashing have blood levels of 0.1–0.6 ppm hexachlorophene (190). In the early 1970s, certain infants bathed with hexachlorophene developed neurotoxicity (vacuolar degeneration) (191). As a result, in 1972, the FDA warned that hexachlorophene should no longer be used routinely for bathing infants. However, after routine use of hexachlorophene for bathing infants in nurseries was discontinued, investigators noted that the incidence of health-care-associated *S. aureus* infections in hospital nurseries increased substantially (192,193). In several instances, the frequency of infections decreased when hexachlorophene bathing of infants was reinstated. However, current guidelines still recommend against the routine bathing of neonates with hexachlorophene because of its potential neurotoxic effects (194). The agent is classified by FDA TFM as not

generally recognized as safe and effective for use as an antiseptic handwash (19). Hexachlorophene should not be used to bathe patients with burns or extensive areas of susceptible, sensitive skin. Soaps containing 3% hexachlorophene are available by prescription only (7).

Iodine and Iodophors

Iodine has been recognized as an effective antiseptic since the 1800s. However, because iodine often causes irritation and discoloring of skin, iodophors have largely replaced iodine as the active ingredient in antiseptics.

Iodine molecules rapidly penetrate the cell wall of microorganisms and inactivate cells by forming complexes with amino acids and unsaturated fatty acids, resulting in impaired protein synthesis and alteration of cell membranes (195). Iodophors are composed of elemental iodine, iodide or triiodide, and a polymer carrier (i.e., the complexing agent) of high molecular weight. The amount of molecular iodine present (so-called “free” iodine) determines the level of antimicrobial activity of iodophors. “Available” iodine refers to the total amount of iodine that can be titrated with sodium thiosulfate (196). Typical 10% povidone-iodine formulations contain 1% available iodine and yield free iodine concentrations of 1 ppm (196). Combining iodine with various polymers increases the solubility of iodine, promotes sustained release of iodine, and reduces skin irritation. The most common polymers incorporated into iodophors are polyvinyl pyrrolidone (i.e., povidone) and ethoxylated nonionic detergents (i.e., poloxamers) (195,196). The antimicrobial activity of iodophors also can be affected by pH, temperature, exposure time, concentration of total available iodine, and the amount and type of organic and inorganic compounds present (e.g., alcohols and detergents).

Iodine and iodophors have bactericidal activity against gram-positive, gram-negative, and certain spore-forming bacteria (e.g., clostridia and *Bacillus* spp.) and are active against mycobacteria, viruses, and fungi (8,195,197–200). However, in concentrations used in antiseptics, iodophors are not usually sporicidal (201). In vivo studies have demonstrated that iodophors reduce the number of viable organisms that are recovered from the hands of personnel (113,145,148,152,155). Povidone-iodine 5%–10% has been tentatively classified by FDA TFM as a Category I agent (i.e., a safe and effective agent for use as an antiseptic handwash and an HCW handwash) (19). The extent to which iodophors exhibit persistent antimicrobial activity after they have been washed off the skin is unclear. In one study, persistent activity was noted for 6 hours (176); however, several other studies demonstrated persistent activity for only 30–60 minutes after washing hands with an iodophor (61,117,202). In studies in which bacterial counts

were obtained after gloves were worn for 1–4 hours after washing, iodophors have demonstrated poor persistent activity (1,104,115,189,203–208). The in vivo antimicrobial activity of iodophors is substantially reduced in the presence of organic substances (e.g., blood or sputum) (8).

The majority of iodophor preparations used for hand hygiene contain 7.5%–10% povidone-iodine. Formulations with lower concentrations also have good antimicrobial activity because dilution can increase free iodine concentrations (209). However, as the amount of free iodine increases, the degree of skin irritation also may increase (209). Iodophors cause less skin irritation and fewer allergic reactions than iodine, but more irritant contact dermatitis than other antiseptics commonly used for hand hygiene (92). Occasionally, iodophor antiseptics have become contaminated with gram-negative bacilli as a result of poor manufacturing processes and have caused outbreaks or pseudo-outbreaks of infection (196).

Quaternary Ammonium Compounds

Quaternary ammonium compounds are composed of a nitrogen atom linked directly to four alkyl groups, which may vary in their structure and complexity (210). Of this large group of compounds, alkyl benzalkonium chlorides are the most widely used as antiseptics. Other compounds that have been used as antiseptics include benzethonium chloride, cetrimide, and cetylpyridium chloride (1). The antimicrobial activity of these compounds was first studied in the early 1900s, and a quaternary ammonium compound for preoperative cleaning of surgeons' hands was used as early as 1935 (210). The antimicrobial activity of this group of compounds likely is attributable to adsorption to the cytoplasmic membrane, with subsequent leakage of low molecular weight cytoplasmic constituents (210).

Quaternary ammonium compounds are primarily bacteriostatic and fungistatic, although they are microbicidal against certain organisms at high concentrations (1); they are more active against gram-positive bacteria than against gram-negative bacilli. Quaternary ammonium compounds have relatively weak activity against mycobacteria and fungi and have greater activity against lipophilic viruses. Their antimicrobial activity is adversely affected by the presence of organic material, and they are not compatible with anionic detergents (1,210). In 1994, FDA TFM tentatively classified benzalkonium chloride and benzethonium chloride as Category III SE active agents (i.e., insufficient data exists to classify them as safe and effective for use as an antiseptic handwash) (19). Further evaluation of these agents by FDA is in progress.

Quaternary ammonium compounds are usually well tolerated. However, because of weak activity against

gram-negative bacteria, benzalkonium chloride is prone to contamination by these organisms. Several outbreaks of infection or pseudoinfection have been traced to quaternary ammonium compounds contaminated with gram-negative bacilli (211–213). For this reason, in the United States, these compounds have been seldom used for hand antisepsis during the last 15–20 years. However, newer handwashing products containing benzalkonium chloride or benzethonium chloride have recently been introduced for use by HCWs. A recent study of surgical intensive-care unit personnel found that cleaning hands with antimicrobial wipes containing a quaternary ammonium compound was about as effective as using plain soap and water for handwashing; both were less effective than decontaminating hands with an alcohol-based hand rub (214). One laboratory-based study reported that an alcohol-free hand-rub product containing a quaternary ammonium compound was efficacious in reducing microbial counts on the hands of volunteers (215). Further studies of such products are needed to determine if newer formulations are effective in health-care settings.

Triclosan

Triclosan (chemical name: 2,4,4'-trichloro-2'-hydroxydiphenyl ether) is a nonionic, colorless substance that was developed in the 1960s. It has been incorporated into soaps for use by HCWs and the public and into other consumer products. Concentrations of 0.2%–2% have antimicrobial activity. Triclosan enters bacterial cells and affects the cytoplasmic membrane and synthesis of RNA, fatty acids, and proteins (216). Recent studies indicate this agent's antibacterial activity is attributable to binding to the active site of enoyl-acyl carrier protein reductase (217,218).

Triclosan has a broad range of antimicrobial activity, but it is often bacteriostatic (1). Minimum inhibitory concentrations (MICs) range from 0.1 to 10 µg/mL, whereas minimum bactericidal concentrations are 25–500 µg/mL. Triclosan's activity against gram-positive organisms (including MRSA) is greater than against gram-negative bacilli, particularly *P. aeruginosa* (1,216). The agent possesses reasonable activity against mycobacterial and *Candida* spp., but it has limited activity against filamentous fungi. Triclosan (0.1%) reduces bacterial counts on hands by 2.8 log₁₀ after a 1-minute hygienic handwash (1). In several studies, log reductions have been lower after triclosan is used than when chlorhexidine, iodophors, or alcohol-based products are applied (1,61,149,184,219). In 1994, FDA TFM tentatively classified triclosan ≤1.0% as a Category II/III active agent (i.e., insufficient data exist to classify this agent as safe and effective for use as an antiseptic handwash) (19). Further evaluation of this agent by the FDA is underway. Like chlorhexidine, triclosan has persistent activity on the skin. Its activity in

hand-care products is affected by pH, the presence of surfactants, emollients, or humectants and by the ionic nature of the particular formulation (1,216). Triclosan's activity is not substantially affected by organic matter, but it can be inhibited by sequestration of the agent in micelle structures formed by surfactants present in certain formulations. The majority of formulations containing <2% triclosan are well-tolerated and seldom cause allergic reactions. Certain reports indicate that providing hospital personnel with a triclosan-containing preparation for hand antisepsis has led to decreased MRSA infections (72,73). Triclosan's lack of potent activity against gram-negative bacilli has resulted in occasional reports of contamination (220).

Other Agents

Approximately 150 years after puerperal-fever-related maternal mortality rates were demonstrated by Semmelweis to be reduced by use of a hypochlorite hand rinse, the efficacy of rubbing hands for 30 seconds with an aqueous hypochlorite solution was studied once again (221). The solution was demonstrated to be no more effective than distilled water. The regimen used by Semmelweis, which called for rubbing hands with a 4% [w/w] hypochlorite solution until the hands were slippery (approximately 5 minutes), has been revisited by other researchers (222). This more current study indicated that the regimen was 30 times more effective than a 1-minute rub using 60% isopropanol. However, because hypochlorite solutions are often irritating to the skin when used repeatedly and have a strong odor, they are seldom used for hand hygiene.

Certain other agents are being evaluated by FDA for use in health-care-related antiseptics (19). However, the efficacy of these agents has not been evaluated adequately for use in handwashing preparations intended for use by HCWs. Further evaluation of these agents is warranted. Products that use different concentrations of traditional antiseptics (e.g., low concentrations of iodophor) or contain novel compounds with antiseptic properties are likely to be introduced for use by HCWs. For example, preliminary studies have demonstrated that adding silver-containing polymers to an ethanol carrier (i.e., Surfacine®) results in a preparation that has persistent antimicrobial activity on animal and human skin (223). New compounds with good in vitro activity must be tested in vivo to determine their abilities to reduce transient and resident skin flora on the hands of HCWs.

Activity of Antiseptic Agents Against Spore-Forming Bacteria

The widespread prevalence of health-care-associated diarrhea caused by *Clostridium difficile* and the recent occurrence

in the United States of human *Bacillus anthracis* infections associated with contaminated items sent through the postal system has raised concern regarding the activity of antiseptic agents against spore-forming bacteria. None of the agents (including alcohols, chlorhexidine, hexachlorophene, iodophors, PCMX, and triclosan) used in antiseptic handwash or antiseptic hand-rub preparations are reliably sporicidal against *Clostridium* spp. or *Bacillus* spp. (120,172,224,225). Washing hands with non-antimicrobial or antimicrobial soap and water may help to physically remove spores from the surface of contaminated hands. HCWs should be encouraged to wear gloves when caring for patients with *C. difficile*-associated diarrhea (226). After gloves are removed, hands should be washed with a non-antimicrobial or an antimicrobial soap and water or disinfected with an alcohol-based hand rub. During outbreaks of *C. difficile*-related infections, washing hands with a non-antimicrobial or antimicrobial soap and water after removing gloves is prudent. HCWs with suspected or documented exposure to *B. anthracis*-contaminated items also should be encouraged to wash their hands with a non-antimicrobial or antimicrobial soap and water.

Reduced Susceptibility of Bacteria to Antiseptics

Reduced susceptibility of bacteria to antiseptic agents can either be an intrinsic characteristic of a species or can be an acquired trait (227). Several reports have described strains of bacteria that appear to have acquired reduced susceptibility (when defined by MICs established in vitro) to certain antiseptics (e.g., chlorhexidine, quaternary ammonium compounds, and triclosan) (227–230). However, because the antiseptic concentrations that are actually used by HCWs are often substantially higher than the MICs of strains with reduced antiseptic susceptibility, the clinical relevance of the in vitro findings is questionable. For example, certain strains of MRSA have chlorhexidine and quaternary ammonium compound MICs that are several-fold higher than methicillin-susceptible strains, and certain strains of *S. aureus* have elevated MICs to triclosan (227,228). However, such strains were readily inhibited by the concentrations of these antiseptics that are actually used by practicing HCWs (227,228). The description of a triclosan-resistant bacterial enzyme has raised the question of whether resistance to this agent may develop more readily than to other antiseptic agents (218). In addition, exposing *Pseudomonas* strains containing the MexAB-OprM efflux system to triclosan may select for mutants that are resistant to multiple antibiotics, including fluoroquinolones (230). Further studies are needed to determine whether reduced susceptibility to antiseptic agents is of epidemiologic

significance and whether resistance to antiseptics has any influence on the prevalence of antibiotic-resistant strains (227).

Surgical Hand Antisepsis

Since the late 1800s, when Lister promoted the application of carbolic acid to the hands of surgeons before procedures, preoperative cleansing of hands and forearms with an antiseptic agent has been an accepted practice (231). Although no randomized, controlled trials have been conducted to indicate that surgical-site infection rates are substantially lower when preoperative scrubbing is performed with an antiseptic agent rather than a non-antimicrobial soap, certain other factors provide a strong rationale for this practice. Bacteria on the hands of surgeons can cause wound infections if introduced into the operative field during surgery (232); rapid multiplication of bacteria occurs under surgical gloves if hands are washed with a non-antimicrobial soap. However, bacterial growth is slowed after preoperative scrubbing with an antiseptic agent (14,233). Reducing resident skin flora on the hands of the surgical team for the duration of a procedure reduces the risk of bacteria being released into the surgical field if gloves become punctured or torn during surgery (1,156,169). Finally, at least one outbreak of surgical-site infections occurred when surgeons who normally used an antiseptic surgical scrub preparation began using a non-antimicrobial product (234).

Antiseptic preparations intended for use as surgical hand scrubs are evaluated for their ability to reduce the number of bacteria released from hands at different times, including 1) immediately after scrubbing, 2) after wearing surgical gloves for 6 hours (i.e., persistent activity), and 3) after multiple applications over 5 days (i.e., cumulative activity). Immediate and persistent activity are considered the most important in determining the efficacy of the product. U.S. guidelines recommend that agents used for surgical hand scrubs should substantially reduce microorganisms on intact skin, contain a nonirritating antimicrobial preparation, have broad-spectrum activity, and be fast-acting and persistent (19,235).

Studies have demonstrated that formulations containing 60%–95% alcohol alone or 50%–95% when combined with limited amounts of a quaternary ammonium compound, hexachlorophene, or chlorhexidine gluconate, lower bacterial counts on the skin immediately postscrub more effectively than do other agents (Table 4). The next most active agents (in order of decreasing activity) are chlorhexidine gluconate, iodophors, triclosan, and plain soap (104,119,186,188,203,204,206,208,236). Because studies of PCMX as a surgical scrub have yielded contradictory results, further studies are needed to establish how the efficacy of this compound compares with the other agents (176,185,186).

Although alcohols are not considered to have persistent antimicrobial activity, bacteria appear to reproduce slowly on the hands after a surgical scrub with alcohol, and bacterial counts on hands after wearing gloves for 1–3 hours seldom exceed baseline (i.e., prescrub) values (1). However, a recent study demonstrated that a formulation containing 61% ethanol alone did not achieve adequate persistent activity at 6 hours postscrub (237). Alcohol-based preparations containing 0.5% or 1% chlorhexidine gluconate have persistent activity that, in certain studies, has equaled or exceeded that of chlorhexidine gluconate-containing detergents (1,118,135,237).*

Persistent antimicrobial activity of detergent-based surgical scrub formulations is greatest for those containing 2% or 4% chlorhexidine gluconate, followed by hexachlorophene, triclosan, and iodophors (1,102,113–115,159,189,203,204,206–208,236). Because hexachlorophene is absorbed into the blood after repeated use, it is seldom used as a surgical scrub.

Surgical staff have been traditionally required to scrub their hands for 10 minutes preoperatively, which frequently leads to skin damage. Several studies have demonstrated that scrubbing for 5 minutes reduces bacterial counts as effectively as a 10-minute scrub (117,238,239). In other studies, scrubbing for 2 or 3 minutes reduced bacterial counts to acceptable levels (156,205,207,240,241).

Studies have indicated that a two-stage surgical scrub using an antiseptic detergent, followed by application of an alcohol-containing preparation, is effective. For example, an initial 1- or 2-minute scrub with 4% chlorhexidine gluconate or povidone-iodine followed by application of an alcohol-based product has been as effective as a 5-minute scrub with an antiseptic detergent (114,242).

Surgical hand-antiseptic protocols have required personnel to scrub with a brush. But this practice can damage the skin of personnel and result in increased shedding of bacteria from the hands (95,243). Scrubbing with a disposable sponge or combination sponge-brush has reduced bacterial counts on the hands as effectively as scrubbing with a brush (244–246). However, several studies indicate that neither a brush nor a

sponge is necessary to reduce bacterial counts on the hands of surgical personnel to acceptable levels, especially when alcohol-based products are used (102,117,159,165,233,237,247,248). Several of these studies performed cultures immediately or at 45–60 minutes postscrub (102,117,233,247,248), whereas in other studies, cultures were obtained 3 and 6 hours postscrub (159,237). For example, a recent laboratory-based study using volunteers demonstrated that brushless application of a preparation containing 1% chlorhexidine gluconate plus 61% ethanol yielded lower bacterial counts on the hands of participants than using a sponge/brush to apply a 4% chlorhexidine-containing detergent preparation (237).

Relative Efficacy of Plain Soap, Antiseptic Soap/Detergent, and Alcohols

Comparing studies related to the *in vivo* efficacy of plain soap, antimicrobial soaps, and alcohol-based hand rubs is problematic, because certain studies express efficacy as the percentage reduction in bacterial counts achieved, whereas others give \log_{10} reductions in counts achieved. However, summarizing the relative efficacy of agents tested in each study can provide an overview of the *in vivo* activity of various formulations intended for handwashing, hygienic handwash, antiseptic hand rub, or surgical hand antiseptics (Tables 2–4).

Irritant Contact Dermatitis Resulting from Hand-Hygiene Measures

Frequency and Pathophysiology of Irritant Contact Dermatitis

In certain surveys, approximately 25% of nurses report symptoms or signs of dermatitis involving their hands, and as many as 85% give a history of having skin problems (249). Frequent and repeated use of hand-hygiene products, particularly soaps and other detergents, is a primary cause of chronic irritant contact dermatitis among HCWs (250). The potential of detergents to cause skin irritation can vary considerably and can be ameliorated by the addition of emollients and humectants. Irritation associated with antimicrobial soaps may be caused by the antimicrobial agent or by other ingredients of the formulation. Affected persons often complain of a feeling of dryness or burning; skin that feels “rough;” and erythema, scaling, or fissures. Detergents damage the skin by causing denaturation of stratum corneum proteins, changes in intercellular lipids (either depletion or reorganization of lipid moieties), decreased corneocyte cohesion, and decreased stratum corneum water-binding capacity (250,251). Damage

* In a recent randomized clinical trial, surgical site infection rates were monitored among patients who were operated on by surgical personnel who cleaned their hands preoperatively either by performing a traditional 5-minute surgical hand scrub using 4% povidone-iodine or 4% antiseptic antimicrobial soap, or by washing their hands for 1 minute with a non-antimicrobial soap followed by a 5-minute hand-rubbing technique using an alcohol-based hand rinse containing 0.2% mectronium eilsulfate. The incidence of surgical site infections was virtually identical in the two groups of patients. (Source: Parienti JJ, Thibon P, Heller R, et al. for Members of the Antiseptie Chirurgicale des Mains Study Group. Hand-rubbing with an aqueous alcoholic solution vs traditional surgical hand-scrubbing and 30-day surgical site infection rates: a randomized equivalence study. JAMA 2002;288:722–7).

to the skin also changes skin flora, resulting in more frequent colonization by staphylococci and gram-negative bacilli (17,90). Although alcohols are among the safest antiseptics available, they can cause dryness and irritation of the skin (1,252). Ethanol is usually less irritating than n-propanol or isopropanol (252).

Irritant contact dermatitis is more commonly reported with iodophors (92). Other antiseptic agents that can cause irritant contact dermatitis (in order of decreasing frequency) include chlorhexidine, PCMX, triclosan, and alcohol-based products. Skin that is damaged by repeated exposure to detergents may be more susceptible to irritation by alcohol-based preparations (253). The irritancy potential of commercially prepared hand-hygiene products, which is often determined by measuring transepidermal water loss, may be available from the manufacturer. Other factors that can contribute to dermatitis associated with frequent handwashing include using hot water for handwashing, low relative humidity (most common in winter months), failure to use supplementary hand lotion or cream, and the quality of paper towels (254,255). Shear forces associated with wearing or removing gloves and allergy to latex proteins may also contribute to dermatitis of the hands of HCWs.

Allergic Contact Dermatitis Associated with Hand-Hygiene Products

Allergic reactions to products applied to the skin (i.e., contact allergies) may present as delayed type reactions (i.e., allergic contact dermatitis) or less commonly as immediate reactions (i.e., contact urticaria). The most common causes of contact allergies are fragrances and preservatives; emulsifiers are less common causes (256–259). Liquid soaps, hand lotions or creams, and “udder ointments” may contain ingredients that cause contact allergies among HCWs (257,258).

Allergic reactions to antiseptic agents, including quaternary ammonium compounds, iodine or iodophors, chlorhexidine, triclosan, PCMX, and alcohols have been reported (118,167,172,256,260–265). Allergic contact dermatitis associated with alcohol-based hand rubs is uncommon. Surveillance at a large hospital in Switzerland, where a commercial alcohol hand rub has been used for >10 years, failed to identify a single case of documented allergy to the product (169). In late 2001, a Freedom of Information Request for data in the FDA’s Adverse Event Reporting System regarding adverse reactions to popular alcohol hand rubs in the United States yielded only one reported case of an erythematous rash reaction attributed to such a product (John M. Boyce, M.D., Hospital of St. Raphael, New Haven, Connecticut, personal communication, 2001). However, with increasing use of such products by HCWs, true allergic reactions to such products likely will be encountered.

Allergic reactions to alcohol-based products may represent true allergy to alcohol, allergy to an impurity or aldehyde metabolite, or allergy to another constituent of the product (167). Allergic contact dermatitis or immediate contact urticarial reactions may be caused by ethanol or isopropanol (167). Allergic reactions can be caused by compounds that may be present as inactive ingredients in alcohol-based hand rubs, including fragrances, benzyl alcohol, stearyl or isostearyl alcohol, phenoxyethanol, myristyl alcohol, propylene glycol, parabens, and benzalkonium chloride (167,256,266–270).

Proposed Methods for Reducing Adverse Effects of Agents

Potential strategies for minimizing hand-hygiene-related irritant contact dermatitis among HCWs include reducing the frequency of exposure to irritating agents (particularly anionic detergents), replacing products with high irritation potential with preparations that cause less damage to the skin, educating personnel regarding the risks of irritant contact dermatitis, and providing caregivers with moisturizing skin-care products or barrier creams (96,98,251,271–273). Reducing the frequency of exposure of HCWs to hand-hygiene products would prove difficult and is not desirable because of the low levels of adherence to hand-hygiene policies in the majority of institutions. Although hospitals have provided personnel with non-antimicrobial soaps in hopes of minimizing dermatitis, frequent use of such products may cause greater skin damage, dryness, and irritation than antiseptic preparations (92,96,98). One strategy for reducing the exposure of personnel to irritating soaps and detergents is to promote the use of alcohol-based hand rubs containing various emollients. Several recent prospective, randomized trials have demonstrated that alcohol-based hand rubs containing emollients were better tolerated by HCWs than washing hands with non-antimicrobial soaps or antimicrobial soaps (96,98,166). Routinely washing hands with soap and water immediately after using an alcohol hand rub may lead to dermatitis. Therefore, personnel should be reminded that it is neither necessary nor recommended to routinely wash hands after each application of an alcohol hand rub.

Hand lotions and creams often contain humectants and various fats and oils that can increase skin hydration and replace altered or depleted skin lipids that contribute to the barrier function of normal skin (251,271). Several controlled trials have demonstrated that regular use (e.g., twice a day) of such products can help prevent and treat irritant contact dermatitis caused by hand-hygiene products (272,273). In one study, frequent and scheduled use of an oil-containing lotion improved skin condition, and thus led to a 50% increase in

handwashing frequency among HCWs (273). Reports from these studies emphasize the need to educate personnel regarding the value of regular, frequent use of hand-care products.

Recently, barrier creams have been marketed for the prevention of hand-hygiene-related irritant contact dermatitis. Such products are absorbed to the superficial layers of the epidermis and are designed to form a protective layer that is not removed by standard handwashing. Two recent randomized, controlled trials that evaluated the skin condition of caregivers demonstrated that barrier creams did not yield better results than did the control lotion or vehicle used (272,273). As a result, whether barrier creams are effective in preventing irritant contact dermatitis among HCWs remains unknown.

In addition to evaluating the efficacy and acceptability of hand-care products, product-selection committees should inquire about the potential deleterious effects that oil-containing products may have on the integrity of rubber gloves and on the efficacy of antiseptic agents used in the facility (8,236).

Factors To Consider When Selecting Hand-Hygiene Products

When evaluating hand-hygiene products for potential use in health-care facilities, administrators or product-selection committees must consider factors that can affect the overall efficacy of such products, including the relative efficacy of antiseptic agents against various pathogens (Appendix) and acceptance of hand-hygiene products by personnel (274,275). Soap products that are not well-accepted by HCWs can be a deterrent to frequent handwashing (276). Characteristics of a product (either soap or alcohol-based hand rub) that can affect acceptance by personnel include its smell, consistency (i.e., “feel”), and color (92,277,278). For soaps, ease of lathering also may affect user preference.

Because HCWs may wash their hands from a limited number of times per shift to as many as 30 times per shift, the tendency of products to cause skin irritation and dryness is a substantial factor that influences acceptance, and ultimate usage (61,98,274,275,277,279). For example, concern regarding the drying effects of alcohol was a primary cause of poor acceptance of alcohol-based hand-hygiene products in hospitals in the United States (5,143). However, several studies have demonstrated that alcohol-based hand rubs containing emollients are acceptable to HCWs (90,93,98,100,101,106,143,163,164,166). With alcohol-based products, the time required for drying may also affect user acceptance.

Studies indicate that the frequency of handwashing or antiseptic handwashing by personnel is affected by the accessibility of hand-hygiene facilities (280–283). In certain health-care

facilities, only one sink is available in rooms housing several patients, or sinks are located far away from the door of the room, which may discourage handwashing by personnel leaving the room. In intensive-care units, access to sinks may be blocked by bedside equipment (e.g., ventilators or intravenous infusion pumps). In contrast to sinks used for handwashing or antiseptic handwash, dispensers for alcohol-based hand rubs do not require plumbing and can be made available adjacent to each patient’s bed and at many other locations in patient-care areas. Pocket carriage of alcohol-based hand-rub solutions, combined with availability of bedside dispensers, has been associated with substantial improvement in adherence to hand-hygiene protocols (74,284). To avoid any confusion between soap and alcohol hand rubs, alcohol hand-rub dispensers should not be placed adjacent to sinks. HCWs should be informed that washing hands with soap and water after each use of an alcohol hand rub is not necessary and is not recommended, because it may lead to dermatitis. However, because personnel feel a “build-up” of emollients on their hands after repeated use of alcohol hand gels, washing hands with soap and water after 5–10 applications of a gel has been recommended by certain manufacturers.

Automated handwashing machines have not been demonstrated to improve the quality or frequency of handwashing (88,285). Although technologically advanced automated handwashing devices and monitoring systems have been developed recently, only a minimal number of studies have been published that demonstrate that use of such devices results in enduring improvements in hand-hygiene adherence among HCWs. Further evaluation of automated handwashing facilities and monitoring systems is warranted.

Dispenser systems provided by manufacturers or vendors also must be considered when evaluating hand-hygiene products. Dispensers may discourage use by HCWs when they 1) become blocked or partially blocked and do not deliver the product when accessed by personnel, and 2) do not deliver the product appropriately onto the hands. In one hospital where a viscous alcohol-based hand rinse was available, only 65% of functioning dispensers delivered product onto the caregivers’ hands with one press of the dispenser lever, and 9% of dispensers were totally occluded (286). In addition, the volume delivered was often suboptimal, and the product was sometimes squirted onto the wall instead of the caregiver’s hand.

Only limited information is available regarding the cost of hand-hygiene products used in health-care facilities (165,287). These costs were evaluated in patient-care areas at a 450-bed community teaching hospital (287); the hospital spent \$22,000 (\$0.72 per patient-day) on 2% chlorhexidine-containing preparations, plain soap, and an alcohol hand rinse. (287) When

hand-hygiene supplies for clinics and nonpatient care areas were included, the total annual budget for soaps and hand antiseptic agents was \$30,000 (approximately \$1 per patient-day). Annual hand-hygiene product budgets at other institutions vary considerably because of differences in usage patterns and varying product prices. One researcher (287) determined that if non-antimicrobial liquid soap were assigned an arbitrary relative cost of 1.0, the cost per liter would be 1.7 times as much for 2% chlorhexidine gluconate detergent, 1.6–2.0 times higher for alcohol-based hand-rub products, and 4.5 times higher for an alcohol-based foam product. A recent cost comparison of surgical scrubbing with an antimicrobial soap versus brushless scrubbing with an alcohol-based hand rub revealed that costs and time required for preoperative scrubbing were less with the alcohol-based product (165). In a trial conducted in two critical-care units, the cost of using an alcohol hand rub was half as much as using an antimicrobial soap for handwashing (\$0.025 versus \$0.05 per application, respectively) (166).

To put expenditures for hand-hygiene products into perspective, health-care facilities should consider comparing their budget for hand-hygiene products to estimated excess hospital costs resulting from health-care-associated infections. The excess hospital costs associated with only four or five health-care-associated infections of average severity may equal the entire annual budget for hand-hygiene products used in inpatient-care areas. Just one severe surgical site infection, lower respiratory tract infection, or bloodstream infection may cost the hospital more than the entire annual budget for antiseptic agents used for hand hygiene (287). Two studies provided certain quantitative estimates of the benefit of hand-hygiene-promotion programs (72,74). One study demonstrated a cost saving of approximately \$17,000 resulting from reduced use of vancomycin after the observed decrease in MRSA incidence in a 7-month period (72). In another study that examined both direct costs associated with the hand-hygiene promotion program (increased use of hand-rub solution and poster production) and indirect costs associated with health-care-personnel time (74), costs of the program were an estimated \$57,000 or less per year (an average of \$1.42 per patient admitted). Supplementary costs associated with the increased use of alcohol-based hand-rub solution averaged \$6.07 per 100 patient-days. Based on conservative estimates of \$2,100 saved per infection averted and on the assumption that only 25% of the observed reduction in the infection rate was associated with improved hand-hygiene practice, the program was substantially cost-effective. Thus, hospital administrators must consider that by purchasing more effective or more acceptable hand-hygiene products to improve hand-hygiene practices, they

will avoid the occurrence of nosocomial infections; preventing only a limited number of additional health-care-associated infections per year will lead to savings that will exceed any incremental costs of improved hand-hygiene products.

Hand-Hygiene Practices Among HCWs

In observational studies conducted in hospitals, HCWs washed their hands an average of five times per shift to as many as 30 times per shift (Table 6) (17,61,90,98,274,288); certain nurses washed their hands ≤ 100 times per shift (90). Hospitalwide surveillance of hand hygiene reveals that the average number of handwashing opportunities varies markedly between hospital wards. For example, nurses in pediatric wards had an average of eight opportunities for hand hygiene per hour of patient care compared with an average of 20 for nurses in intensive-care units (11). The duration of handwashing or hygienic handwash episodes by HCWs has averaged 6.6–24.0 seconds in observational studies (Table 7) (17,52,59,84–87,89,249,279). In addition to washing their

TABLE 6. Handwashing frequency among health-care workers

Ref. no.	Year	Avg. no./time period	Range	Avg. no./hr
(61)	1988	5/8 hour	N.S.	
(89)	1984	5–10/shift	N.S.	
(96)	2000	10/shift	N.S.	
(273)	2000	12–18/day	2–60	
(98)	2000	13–15/8 hours	5–27	1.6–1.8/hr
(90)	1977	20–42/8 hours	10–100	
(391)	2000	21/12 hours	N.S.	
(272)	2000	22/day	0–70	
(88)	1991			1.7–2.1/hr
(17)	1998			2.1/hr
(279)	1978			3/hr
(303)	1994			3.3/hr

Note: N.S. = Not Stated.

TABLE 7. Average duration of handwashing by health-care workers

Ref. no.	Year	Mean/median time
(392)	1997	4.7–5.3 seconds
(303)	1994	6.6 seconds
(52)	1974	8–9.3 seconds
(85)	1984	8.6 seconds
(86)	1994	<9 seconds
(87)	1994	9.5 seconds
(88)	1991	<10 seconds
(294)	1990	10 seconds
(89)	1984	11.6 seconds
(300)	1992	12.5 seconds
(59)	1988	15.6–24.4 seconds
(17)	1998	20.6 seconds
(279)	1978	21 seconds
(293)	1989	24 seconds

hands for limited time periods, personnel often fail to cover all surfaces of their hands and fingers (288).

Adherence of HCWs to Recommended Hand-Hygiene Practices

Observational Studies of Hand-Hygiene Adherence. Adherence of HCWs to recommended hand-hygiene procedures has been poor, with mean baseline rates of 5%–81% (overall average: 40%) (Table 8) (71,74,86,87,276,280,281,283,285,289–313). The methods used for defining adherence (or non-adherence) and those used for conducting observations vary considerably among studies, and reports do not provide

detailed information concerning the methods and criteria used. The majority of studies were conducted with hand-hygiene adherence as the major outcome measure, whereas a limited number measured adherence as part of a broader investigation. Several investigators reported improved adherence after implementing various interventions, but the majority of studies had short follow-up periods and did not confirm whether behavioral improvements were long-lasting. Other studies established that sustained improvements in handwashing behavior occurred during a long-term program to improve adherence to hand-hygiene policies (74,75).

TABLE 8. Hand-hygiene adherence by health-care workers (1981–2000)

Ref. no.	Year	Setting	Before/after	Adherence baseline	Adherence after intervention	Intervention
(280)	1981	ICU	A	16%	30%	More convenient sink locations
(289)	1981	ICU	A	41%	—	
		ICU	A	28%	—	
(290)	1983	All wards	A	45%	—	
(281)	1986	SICU	A	51%	—	
		MICU	A	76%	—	
(276)	1986	ICU	A	63%	92%	Performance feedback
(291)	1987	PICU	A	31%	30%	Wearing overgown
(292)	1989	MICU	B/A	14%/28%*	73%/81%	Feedback, policy reviews, memo, and posters
		MICU	B/A	26%/23%	38%/60%	
(293)	1989	NICU	A/B	75%/50%	—	
(294)	1990	ICU	A	32%	45%	Alcohol rub introduced
(295)	1990	ICU	A	81%	92%	Inservices first, then group feedback
(296)	1990	ICU	B/A	22%	30%	
(297)	1991	SICU	A	51%	—	
(298)	1991	Pedi OPDs	B	49%	49%	Signs, feedback, and verbal reminders to physicians
(299)	1991	Nursery and NICU	B/A†	28%	63%	Feedback, dissemination of literature, and results of environmental cultures
(300)	1992	NICU/others	A	29%	—	
(71)	1992	ICU	N.S.	40%	—	
(301)	1993	ICUs	A	40%	—	
(87)	1994	Emergency Room	A	32%	—	
(86)	1994	All wards	A	32%	—	
(285)	1994	SICU	A	22%	38%	Automated handwashing machines available
(302)	1994	NICU	A	62%	60%	No gowning required
(303)	1994	ICU Wards	AA	30%/29%	—	
(304)	1995	ICU Oncol Ward	A	56%	—	
(305)	1995	ICU	N.S.	5%	63%	Lectures, feedback, and demonstrations
(306)	1996	PICU	B/A	12%/11%	68%/65%	Overt observation, followed by feedback
(307)	1996	MICU	A	41%	58%	Routine wearing of gowns and gloves
(308)	1996	Emergency Dept	A	54%	64%	Signs/distributed review paper
(309)	1998	All wards	A	30%	—	
(310)	1998	Pediatric wards	B/A	52%/49%	74%/69%	Feedback, movies, posters, and brochures
(311)	1999	MICU	B/A	12%/55%	—	
(74)	2000	All wards	B/A	48%	67%	Posters, feedback, administrative support, and alcohol rub
(312)	2000	MICU	A	42%	61%	Alcohol hand rub made available
(283)	2000	MICU	B/A	10%/22%	23%/48%	Education, feedback, and alcohol gel made available
		CTICU	B/A	4%/13%	7%/14%	
(313)	2000	Medical wards	A	60%	52%	Education, reminders, and alcohol gel made available

Note: ICU = intensive care unit, SICU = surgical ICU, MICU = medical ICU, PICU = pediatric ICU, NICU = neonatal ICU, Emerg = emergency, Oncol = oncology, CTICU = cardiothoracic ICU, and N.S. = not stated.

* Percentage compliance before/after patient contact.

† After contact with inanimate objects.

Factors Affecting Adherence. Factors that may influence hand hygiene include those identified in epidemiologic studies and factors reported by HCWs as being reasons for lack of adherence to hand-hygiene recommendations. Risk factors for poor adherence to hand hygiene have been determined objectively in several observational studies or interventions to improve adherence (11,12,274,292,295,314–317). Among these, being a physician or a nursing assistant, rather than a nurse, was consistently associated with reduced adherence (Box 1).

In the largest hospitalwide survey of hand-hygiene practices among HCWs (11), predictors of poor adherence to recommended hand-hygiene measures were identified. Predictor variables included professional category, hospital ward, time of day/week, and type and intensity of patient care, defined as the number of opportunities for hand hygiene per hour of patient care. In 2,834 observed opportunities for hand hygiene, average adherence was 48%. In multivariate analysis, nonadherence was lowest among nurses and during weekends

BOX 1. Factors influencing adherence to hand-hygiene practices*

Observed risk factors for poor adherence to recommended hand-hygiene practices

- Physician status (rather than a nurse)
- Nursing assistant status (rather than a nurse)
- Male sex
- Working in an intensive-care unit
- Working during the week (versus the weekend)
- Wearing gowns/gloves
- Automated sink
- Activities with high risk of cross-transmission
- High number of opportunities for hand hygiene per hour of patient care

Self-reported factors for poor adherence with hand hygiene

- Handwashing agents cause irritation and dryness
- Sinks are inconveniently located/shortage of sinks
- Lack of soap and paper towels
- Often too busy/insufficient time
- Understaffing/overcrowding
- Patient needs take priority
- Hand hygiene interferes with health-care worker relationships with patients
- Low risk of acquiring infection from patients
- Wearing of gloves/beliefs that glove use obviates the need for hand hygiene
- Lack of knowledge of guidelines/protocols
- Not thinking about it/forgetfulness
- No role model from colleagues or superiors
- Skepticism regarding the value of hand hygiene
- Disagreement with the recommendations
- Lack of scientific information of definitive impact of improved hand hygiene on health-care–associated infection rates

Additional perceived barriers to appropriate hand hygiene

- Lack of active participation in hand-hygiene promotion at individual or institutional level
- Lack of role model for hand hygiene
- Lack of institutional priority for hand hygiene
- Lack of administrative sanction of noncompliers/rewarding compliers
- Lack of institutional safety climate

* Source: Adapted from Pittet D. Improving compliance with hand hygiene in hospitals. *Infect Control Hosp Epidemiol* 2000;21:381–6.

(Odds Ratio [OR]: 0.6; 95% confidence interval [CI] = 0.4–0.8). Nonadherence was higher in intensive-care units compared with internal medicine wards (OR: 2.0; 95% CI = 1.3–3.1), during procedures that carried a high risk of bacterial contamination (OR: 1.8; 95% CI = 1.4–2.4), and when intensity of patient care was high (21–40 handwashing opportunities — OR: 1.3; 95% CI = 1.0–1.7; 41–60 opportunities — OR: 2.1; 95% CI = 1.5–2.9; >60 opportunities — OR: 2.1; 95% CI = 1.3–3.5). The higher the demand for hand hygiene, the lower the adherence; on average, adherence decreased by 5% (\pm 2%) for each increase of 10 opportunities per hour when the intensity of patient care exceeded 10 opportunities per hour. Similarly, the lowest adherence rate (36%) was found in intensive-care units, where indications for hand hygiene were typically more frequent (on average, 20 opportunities per patient-hour). The highest adherence rate (59%) was observed in pediatrics wards, where the average intensity of patient care was lower than in other hospital areas (an average of eight opportunities per patient-hour). The results of this study indicate that full adherence to previous guidelines may be unrealistic, and that facilitated access to hand hygiene could help improve adherence (11,12,318).

Perceived barriers to adherence with hand-hygiene practice recommendations include skin irritation caused by hand-hygiene agents, inaccessible hand-hygiene supplies, interference with HCW-patient relationships, priority of care (i.e., the patients' needs are given priority over hand hygiene), wearing of gloves, forgetfulness, lack of knowledge of the guidelines, insufficient time for hand hygiene, high workload and understaffing, and the lack of scientific information indicating a definitive impact of improved hand hygiene on health-care-associated infection rates (11,274,292,295,315–317). Certain perceived barriers to adherence with hand-hygiene guidelines have been assessed or quantified in observational studies (12,274,292,295,314–317) (Box 1).

Skin irritation by hand-hygiene agents constitutes a substantial barrier to appropriate adherence (319). Because soaps and detergents can damage skin when applied on a regular basis, HCWs must be better informed regarding the possible adverse effects associated with hand-hygiene agents. Lack of knowledge and education regarding this subject is a barrier to motivation. In several studies, alcohol-based hand rubs containing emollients (either isopropanol, ethanol, or n-propanol in 60%–90% vol/vol) were less irritating to the skin than the soaps or detergents tested. In addition, the alcohol-based products containing emollients that were tested were at least as tolerable and efficacious as the detergents tested. Also, studies demonstrate that several hand lotions have reduced skin scaling and cracking, which may reduce microbial shedding from the hands (67,272,273).

Easy access to hand-hygiene supplies, whether sink, soap, medicated detergent, or alcohol-based hand-rub solution, is essential for optimal adherence to hand-hygiene recommendations. The time required for nurses to leave a patient's bedside, go to a sink, and wash and dry their hands before attending the next patient is a deterrent to frequent handwashing or hand antisepsis (11,318). Engineering controls could facilitate adherence, but careful monitoring of hand-hygiene behavior should be conducted to exclude the possible negative effect of newly introduced handwashing devices (88).

The impact of wearing gloves on adherence to hand-hygiene policies has not been definitively established, because published studies have yielded contradictory results (87,290,301,320). Hand hygiene is required regardless of whether gloves are used or changed. Failure to remove gloves after patient contact or between "dirty" and "clean" body-site care on the same patient must be regarded as nonadherence to hand-hygiene recommendations (11). In a study in which experimental conditions approximated those occurring in clinical practice (321), washing and reusing gloves between patient contacts resulted in observed bacterial counts of 0–4.7 log on the hands after glove removal. Therefore, this practice should be discouraged; handwashing or disinfection should be performed after glove removal.

Lack of 1) knowledge of guidelines for hand hygiene, 2) recognition of hand-hygiene opportunities during patient care, and 3) awareness of the risk of cross-transmission of pathogens are barriers to good hand-hygiene practices. Furthermore, certain HCWs believe they have washed their hands when necessary, even when observations indicate they have not (89,92,295,296,322).

Perceived barriers to hand-hygiene behavior are linked not only to the institution, but also to HCWs' colleagues. Therefore, both institutional and small-group dynamics need to be considered when implementing a system change to secure an improvement in HCWs' hand-hygiene practice.

Possible Targets for Hand-Hygiene Promotion

Targets for the promotion of hand hygiene are derived from studies assessing risk factors for nonadherence, reported reasons for the lack of adherence to recommendations, and additional factors perceived as being important to facilitate appropriate HCW behavior. Although certain factors cannot be modified (Box 1), others can be changed.

One factor that must be addressed is the time required for HCWs to clean their hands. The time required for traditional handwashing may render full adherence to previous guidelines unrealistic (11,12,318) and more rapid access to hand-hygiene materials could help improve adherence. One study conducted in an intensive-care unit demonstrated that it took

nurses an average of 62 seconds to leave a patient's bedside, walk to a sink, wash their hands, and return to patient care (318). In contrast, an estimated one fourth as much time is required when using alcohol-based hand rub placed at each patient's bedside. Providing easy access to hand-hygiene materials is mandatory for appropriate hand-hygiene behavior and is achievable in the majority of health-care facilities (323). In particular, in high-demand situations (e.g., the majority of critical-care units), under hectic working conditions, and at times of overcrowding or understaffing, HCWs may be more likely to use an alcohol-based hand rub than to wash their hands (323). Further, using alcohol-based hand rubs may be a better option than traditional handwashing with plain soap and water or antiseptic handwash, because they not only require less time (166,318) but act faster (1) and irritate hands less often (1,67,96,98,166). They also were used in the only program that reported a sustained improvement in hand-hygiene adherence associated with decreased infection rates (74). However, making an alcohol-based hand rub available to personnel without providing ongoing educational and motivational activities may not result in long-lasting improvement in hand-hygiene practices (313). Because increased use of hand-hygiene agents might be associated with skin dryness, the availability of free skin-care lotion is recommended.

Education is a cornerstone for improvement with hand-hygiene practices. Topics that must be addressed by educational programs include the lack of 1) scientific information for the definitive impact of improved hand hygiene on health-care-associated infection and resistant organism transmission rates; 2) awareness of guidelines for hand hygiene and insufficient knowledge concerning indications for hand hygiene during daily patient care; 3) knowledge concerning the low average adherence rate to hand hygiene by the majority of HCWs; and 4) knowledge concerning the appropriateness, efficacy, and understanding of the use of hand-hygiene and skin-care-protection agents.

HCWs necessarily evolve within a group that functions within an institution. Possible targets for improvement in hand-hygiene behavior not only include factors linked to individual HCWs, but also those related to the group(s) and the institution as a whole (317,323). Examples of possible targets for hand-hygiene promotion at the group level include education and performance feedback on hand-hygiene adherence; efforts to prevent high workload, downsizing, and understaffing; and encouragement and provision of role models from key members in the work unit. At the institutional level, targets for improvement include 1) written guidelines, hand-hygiene agents, skin-care promotions and agents, or hand-hygiene facilities; 2) culture or tradition of adherence; and 3)

administrative leadership, sanction, support, and rewards. Several studies, conducted in various types of institutions, reported modest and even low levels of adherence to recommended hand-hygiene practices, indicating that such adherence varied by hospital ward and by type of HCW. These results indicate educational sessions may need to be designed specifically for certain types of personnel (11,289,290,294,317,323).

Lessons Learned from Behavioral Theories

In 1998, the prevailing behavioral theories and their applications with regard to the health professions were reviewed by researchers in an attempt to better understand how to target more successful interventions (317). The researchers proposed a hypothetical framework to enhance hand-hygiene practices and stressed the importance of considering the complexity of individual and institutional factors when designing behavioral interventions.

Although behavioral theories and secondary interventions have primarily targeted individual workers, this practice might be insufficient to produce sustained change (317,324,325). Interventions aimed at improving hand-hygiene practices must account for different levels of behavior interaction (12,317,326). Thus, the interdependence of individual factors, environmental constraints, and the institutional climate must be taken into account in the strategic planning and development of hand-hygiene campaigns. Interventions to promote hand hygiene in hospitals should consider variables at all these levels. Various factors involved in hand-hygiene behavior include intention, attitude towards the behavior, perceived social norm, perceived behavioral control, perceived risk for infection, hand-hygiene practices, perceived role model, perceived knowledge, and motivation (317). The factors necessary for change include 1) dissatisfaction with the current situation, 2) perception of alternatives, and 3) recognition, both at the individual and institutional level, of the ability and potential to change. Although the latter implies education and motivation, the former two necessitate a system change.

Among the reported reasons for poor adherence with hand-hygiene recommendations (Box 1), certain ones are clearly associated with the institution or system (e.g., lack of institutional priority for hand hygiene, administrative sanctions, and a safety climate). Although all of these reasons would require a system change in the majority of institutions, the third requires management commitment, visible safety programs, an acceptable level of work stress, a tolerant and supportive attitude toward reported problems, and belief in the efficacy

of preventive strategies (12,317,325,327). Most importantly, an improvement in infection-control practices requires 1) questioning basic beliefs, 2) continuous assessment of the group (or individual) stage of behavioral change, 3) intervention(s) with an appropriate process of change, and 4) supporting individual and group creativity (317). Because of the complexity of the process of change, single interventions often fail. Thus, a multimodal, multidisciplinary strategy is likely necessary (74,75,317,323,326).

Methods Used To Promote Improved Hand Hygiene

Hand-hygiene promotion has been challenging for >150 years. In-service education, information leaflets, workshops and lectures, automated dispensers, and performance feedback on hand-hygiene adherence rates have been associated with transient improvement (291,294–296,306,314).

Several strategies for promotion of hand hygiene in hospitals have been published (Table 9). These strategies require education, motivation, or system change. Certain strategies are based on epidemiologic evidence, others on the authors' and other investigators' experience and review of current knowledge. Some strategies may be unnecessary in certain circumstances, but may be helpful in others. In particular, changing the hand-hygiene agent could be beneficial in institutions or hospital wards with a high workload and a high demand for hand hygiene when alcohol-based hand rubs are not available (11,73,78,328). However, a change in the recommended hand-hygiene agent could be deleterious if introduced during winter, at a time of higher hand-skin irritability, and if not accompanied by the provision of skin-care products (e.g., pro-

TECTIVE creams and lotions). Additional specific elements should be considered for inclusion in educational and motivational programs (Box 2).

Several strategies that could potentially be associated with successful promotion of hand hygiene require a system change (Box 1). Hand-hygiene adherence and promotion involve factors at both the individual and system level. Enhancing individual and institutional attitudes regarding the feasibility of making changes (self-efficacy), obtaining active participation of personnel at both levels, and promoting an institutional safety climate represent challenges that exceed the current perception of the role of infection-control professionals.

Whether increased education, individual reinforcement technique, appropriate rewarding, administrative sanction, enhanced self-participation, active involvement of a larger number of organizational leaders, enhanced perception of health threat, self-efficacy, and perceived social pressure (12,317,329,330), or combinations of these factors can improve HCWs' adherence with hand hygiene needs further investigation. Ultimately, adherence to recommended hand-hygiene practices should become part of a culture of patient safety where a set of interdependent quality elements interact to achieve a shared objective (331).

On the basis of both these hypothetical considerations and successful, actual experiences in certain institutions, strategies to improve adherence to hand-hygiene practices should be both multimodal and multidisciplinary. However, strategies must be further researched before they are implemented.

TABLE 9. Strategies for successful promotion of hand hygiene in hospitals

Strategy	Tool for change*	Selected references†
Education	E (M, S)	(74,295,306,326,393)
Routine observation and feedback	S (E, M)	(74,294,306,326,393)
Engineering control		
Make hand hygiene possible, easy, and convenient	S	(74,281,326,393)
Make alcohol-based hand rub available	S	(74)
(at least in high-demand situations)	S	(74,283,312)
Patient education	S (M)	(283,394)
Reminders in the workplace	S	(74,395)
Administrative sanction/rewarding	S	(12,317)
Change in hand-hygiene agent	S (E)	(11,67,71,283,312)
Promote/facilitate skin care for health-care-workers' hands	S (E)	(67,74,274,275)
Obtain active participation at individual and institutional level	E, M, S	(74,75,317)
Improve institutional safety climate	S (M)	(74,75,317)
Enhance individual and institutional self-efficacy	S (E, M)	(74,75,317)
Avoid overcrowding, understaffing, and excessive workload	S	(11,74,78,297,396)
Combine several of above strategies	E, M, S	(74,75,295,306,317,326)

* The dynamic of behavioral change is complex and involves a combination of education (E), motivation (M), and system change (S).

† Only selected references have been listed; readers should refer to more extensive reviews for exhaustive reference lists (1,8,317,323,397).

BOX 2. Elements of health-care worker educational and motivational programs**Rationale for hand hygiene**

- Potential risks of transmission of microorganisms to patients
- Potential risks of health-care worker colonization or infection caused by organisms acquired from the patient
- Morbidity, mortality, and costs associated with health-care–associated infections

Indications for hand hygiene

- Contact with a patient’s intact skin (e.g., taking a pulse or blood pressure, performing physical examinations, lifting the patient in bed) (25,26,45,48,51,53)
- Contact with environmental surfaces in the immediate vicinity of patients (46,51,53,54)
- After glove removal (50,58,71)

Techniques for hand hygiene

- Amount of hand-hygiene solution
- Duration of hand-hygiene procedure
- Selection of hand-hygiene agents
 - Alcohol-based hand rubs are the most efficacious agents for reducing the number of bacteria on the hands of personnel. Antiseptic soaps and detergents are the next most effective, and non-antimicrobial soaps are the least effective (1,398).
 - Soap and water are recommended for visibly soiled hands.
 - Alcohol-based hand rubs are recommended for routine decontamination of hands for all clinical indications (except when hands are visibly soiled) and as one of the options for surgical hand hygiene.

Methods to maintain hand skin health

- Lotions and creams can prevent or minimize skin dryness and irritation caused by irritant contact dermatitis
- Acceptable lotions or creams to use
- Recommended schedule for applying lotions or creams

Expectations of patient care managers/administrators

- Written statements regarding the value of, and support for, adherence to recommended hand-hygiene practices
- Role models demonstrating adherence to recommended hand hygiene practices (399)

Indications for, and limitations of, glove use

- Hand contamination may occur as a result of small, undetected holes in examination gloves (321,361)
- Contamination may occur during glove removal (50)
- Wearing gloves does not replace the need for hand hygiene (58)
- Failure to remove gloves after caring for a patient may lead to transmission of microorganisms from one patient to another (373).

Efficacy of Promotion and Impact of Improved Hand Hygiene

The lack of scientific information of the definitive impact of improved hand hygiene on health-care–associated infection rates is a possible barrier to appropriate adherence with hand-hygiene recommendations (Box 1). However, evidence supports the belief that improved hand hygiene can reduce health-care–associated infection rates. Failure to perform appropriate hand hygiene is considered the leading cause of

health-care–associated infections and spread of multiresistant organisms and has been recognized as a substantial contributor to outbreaks.

Of nine hospital-based studies of the impact of hand hygiene on the risk of health-care–associated infections (Table 10) (48,69–75,296), the majority demonstrated a temporal relationship between improved hand-hygiene practices and reduced infection rates.

In one of these studies, endemic MRSA in a neonatal intensive-care unit was eliminated 7 months after introduction of a new

TABLE 10. Association between improved adherence with hand-hygiene practice and health-care-associated infection rates

Year	Ref. no.	Hospital setting	Results	Duration of follow-up
1977	(48)	Adult ICU	Reduction in health-care-associated infections caused by endemic <i>Klebsiella</i> spp.	2 years
1982	(69)	Adult ICU	Reduction in health-care-associated infection rates	N.S.
1984	(70)	Adult ICU	Reduction in health-care-associated infection rates	N.S.
1990	(296)	Adult ICU	No effect (average hand hygiene adherence improvement did not reach statistical significance)	11 months
1992	(71)	Adult ICU	Substantial difference between rates of health-care-associated infection between two different hand-hygiene agents	8 months
1994	(72)	NICU	Elimination of MRSA, when combined with multiple other infection-control measures. Reduction of vancomycin use	9 months
1995	(73)	Newborn nursery	Elimination of MRSA, when combined with multiple other infection-control measures	3.5 years
2000	(75)	MICU/NICU	85% relative reduction of VRE rate in the intervention hospital; 44% relative reduction in control hospital; no change in MRSA	8 months
2000	(74)	Hospitalwide	Substantial reduction in the annual overall prevalence of health-care-associated infections and MRSA cross-transmission rates. Active surveillance cultures and contact precautions were implemented during same period	5 years

Note: ICU = intensive care unit, NICU = neonatal ICU, MRSA = methicillin-resistant *Staphylococcus aureus*, MICU = medical ICU, and N.S. = not stated.

hand antiseptic (1% triclosan); all other infection-control measures remained in place, including the practice of conducting weekly active surveillance by obtaining cultures (72). Another study reported an MRSA outbreak involving 22 infants in a neonatal unit (73). Despite intensive efforts, the outbreak could not be controlled until a new antiseptic was added (i.e., 0.3% triclosan); all previously used control measures remained in place, including gloves and gowns, cohorting, and obtaining cultures for active surveillance.

The effectiveness of a longstanding, hospitalwide program to promote hand hygiene at the University of Geneva hospitals was recently reported (74). Overall adherence to hand-hygiene guidelines during routine patient care was monitored during hospitalwide observational surveys. These surveys were conducted biannually during December 1994–December 1997, before and during implementation of a hand-hygiene campaign that specifically emphasized the practice of bedside, alcohol-based hand disinfection. Individual-sized bottles of hand-rub solution were distributed to all wards, and custom-made holders were mounted on all beds to facilitate access to hand disinfection. HCWs were also encouraged to carry bottles in their pockets, and in 1996, a newly designed flat (instead of round) bottle was made available to further facilitate pocket carriage. The promotional strategy was multimodal and involved a multidisciplinary team of HCWs, the use of wall posters, the promotion of antiseptic hand rubs located at bed-sides throughout the institution, and regular performance feedback to all HCWs (see <http://www.hopisafe.ch> for further

details on methodology). Health-care-associated infection rates, attack rates of MRSA cross-transmission, and consumption of hand-rub disinfectant were measured. Adherence to recommended hand-hygiene practices improved progressively from 48% in 1994 to 66% in 1997 ($p < 0.001$). Whereas recourse to handwashing with soap and water remained stable, frequency of hand disinfection markedly increased during the study period ($p < 0.001$), and the consumption of alcohol-based hand-rub solution increased from 3.5 to 15.4 liters per 1,000 patient-days during 1993–1998 ($p < 0.001$). The increased frequency of hand disinfection was unchanged after adjustment for known risk factors of poor adherence. During the same period, both overall health-care-associated infection and MRSA transmission rates decreased (both $p < 0.05$). The observed reduction in MRSA transmission may have been affected by both improved hand-hygiene adherence and the simultaneous implementation of active surveillance cultures for detecting and isolating patients colonized with MRSA (332). The experience from the University of Geneva hospitals constitutes the first report of a hand-hygiene campaign with a sustained improvement over several years. An additional multimodal program also yielded sustained improvements in hand-hygiene practices over an extended period (75); the majority of studies have been limited to a 6- to 9-month observation period.

Although these studies were not designed to assess the independent contribution of hand hygiene on the prevention of health-care-associated infections, the results indicate that

improved hand-hygiene practices reduce the risk of transmission of pathogenic microorganisms. The beneficial effects of hand-hygiene promotion on the risk of cross-transmission also have been reported in surveys conducted in schools and day care centers (333–338), as well as in a community setting (339–341).

Other Policies Related to Hand Hygiene

Fingernails and Artificial Nails

Studies have documented that subungual areas of the hand harbor high concentrations of bacteria, most frequently coagulase-negative staphylococci, gram-negative rods (including *Pseudomonas* spp.), Corynebacteria, and yeasts (14,342,343). Freshly applied nail polish does not increase the number of bacteria recovered from periungual skin, but chipped nail polish may support the growth of larger numbers of organisms on fingernails (344,345). Even after careful handwashing or the use of surgical scrubs, personnel often harbor substantial numbers of potential pathogens in the subungual spaces (346–348).

Whether artificial nails contribute to transmission of health-care-associated infections is unknown. However, HCWs who wear artificial nails are more likely to harbor gram-negative pathogens on their fingertips than are those who have natural nails, both before and after handwashing (347–349). Whether the length of natural or artificial nails is a substantial risk factor is unknown, because the majority of bacterial growth occurs along the proximal 1 mm of the nail adjacent to subungual skin (345,347,348). Recently, an outbreak of *P. aeruginosa* in a neonatal intensive care unit was attributed to two nurses (one with long natural nails and one with long artificial nails) who carried the implicated strains of *Pseudomonas* spp. on their hands (350). Patients were substantially more likely than controls to have been cared for by the two nurses during the exposure period, indicating that colonization of long or artificial nails with *Pseudomonas* spp. may have contributed to causing the outbreak. Personnel wearing artificial nails also have been epidemiologically implicated in several other outbreaks of infection caused by gram-negative bacilli and yeast (351–353). Although these studies provide evidence that wearing artificial nails poses an infection hazard, additional studies are warranted.

Gloving Policies

CDC has recommended that HCWs wear gloves to 1) reduce the risk of personnel acquiring infections from patients, 2) prevent health-care worker flora from being transmitted to patients, and 3) reduce transient contamination of the hands

of personnel by flora that can be transmitted from one patient to another (354). Before the emergence of the acquired immunodeficiency syndrome (AIDS) epidemic, gloves were worn primarily by personnel caring for patients colonized or infected with certain pathogens or by personnel exposed to patients with a high risk of hepatitis B. Since 1987, a dramatic increase in glove use has occurred in an effort to prevent transmission of HIV and other bloodborne pathogens from patients to HCWs (355). The Occupational Safety and Health Administration (OSHA) mandates that gloves be worn during all patient-care activities that may involve exposure to blood or body fluids that may be contaminated with blood (356).

The effectiveness of gloves in preventing contamination of HCWs' hands has been confirmed in several clinical studies (45,51,58). One study found that HCWs who wore gloves during patient contact contaminated their hands with an average of only 3 CFUs per minute of patient care, compared with 16 CFUs per minute for those not wearing gloves (51). Two other studies, involving personnel caring for patients with *C. difficile* or VRE, revealed that wearing gloves prevented hand contamination among the majority of personnel having direct contact with patients (45,58). Wearing gloves also prevented personnel from acquiring VRE on their hands when touching contaminated environmental surfaces (58). Preventing heavy contamination of the hands is considered important, because handwashing or hand antisepsis may not remove all potential pathogens when hands are heavily contaminated (25,111).

Several studies provide evidence that wearing gloves can help reduce transmission of pathogens in health-care settings. In a prospective controlled trial that required personnel to routinely wear vinyl gloves when handling any body substances, the incidence of *C. difficile* diarrhea among patients decreased from 7.7 cases/1,000 patient discharges before the intervention to 1.5 cases/1,000 discharges during the intervention (226). The prevalence of asymptomatic *C. difficile* carriage also decreased substantially on "glove" wards, but not on control wards. In intensive-care units where VRE or MRSA have been epidemic, requiring all HCWs to wear gloves to care for all patients in the unit (i.e., universal glove use) likely has helped control outbreaks (357,358).

The influence of glove use on the hand-hygiene habits of personnel is not clear. Several studies found that personnel who wore gloves were less likely to wash their hands upon leaving a patient's room (290,320). In contrast, two other studies found that personnel who wore gloves were substantially more likely to wash their hands after patient care (87,301).

The following caveats regarding use of gloves by HCWs must be considered. Personnel should be informed that gloves

do not provide complete protection against hand contamination. Bacterial flora colonizing patients may be recovered from the hands of $\leq 30\%$ of HCWs who wear gloves during patient contact (50,58). Further, wearing gloves does not provide complete protection against acquisition of infections caused by hepatitis B virus and herpes simplex virus (359,360). In such instances, pathogens presumably gain access to the caregiver's hands via small defects in gloves or by contamination of the hands during glove removal (50,321,359,361).

Gloves used by HCWs are usually made of natural rubber latex and synthetic nonlatex materials (e.g., vinyl, nitrile, and neoprene [polymers and copolymers of chloroprene]). Because of the increasing prevalence of latex sensitivity among HCWs and patients, FDA has approved several powdered and powder-free latex gloves with reduced protein contents, as well as synthetic gloves that can be made available by health-care institutions for use by latex-sensitive employees. In published studies, the barrier integrity of gloves varies on the basis of type and quality of glove material, intensity of use, length of time used, manufacturer, whether gloves were tested before or after use, and method used to detect glove leaks (359,361–366). In published studies, vinyl gloves have had defects more frequently than latex gloves, the difference in defect frequency being greatest after use (359,361,364,367). However, intact vinyl gloves provide protection comparable to that of latex gloves (359). Limited studies indicate that nitrile gloves have leakage rates that approximate those of latex gloves (368–371). Having more than one type of glove available is desirable, because it allows personnel to select the type that best suits their patient-care activities. Although recent studies indicate that improvements have been made in the quality of gloves (366), hands should be decontaminated or washed after removing gloves (8,50,58,321,361). Gloves should not be washed or reused (321,361). Use of petroleum-based hand lotions or creams may adversely affect the integrity of latex gloves (372). After use of powdered gloves, certain alcohol hand rubs may interact with residual powder on the hands of personnel, resulting in a gritty feeling on the hands. In facilities where powdered gloves are commonly used, various alcohol-based hand rubs should be tested after removal of powdered gloves to avoid selecting a product that causes this undesirable reaction. Personnel should be reminded that failure to remove gloves between patients may contribute to transmission of organisms (358,373).

Jewelry

Several studies have demonstrated that skin underneath rings is more heavily colonized than comparable areas of skin on fingers without rings (374–376). One study found that 40% of nurses harbored gram-negative bacilli (e.g., *E. cloacae*, *Klebsiella*, and *Acinetobacter*) on skin under rings and that certain nurses carried the same organism under their rings for several months (375). In a more recent study involving >60 intensive care unit nurses, multivariable analysis revealed that rings were the only substantial risk factor for carriage of gram-negative bacilli and *S. aureus* and that the concentration of organisms recovered correlated with the number of rings worn (377). Whether the wearing of rings results in greater transmission of pathogens is unknown. Two studies determined that mean bacterial colony counts on hands after handwashing were similar among persons wearing rings and those not wearing rings (376,378). Further studies are needed to establish if wearing rings results in greater transmission of pathogens in health-care settings.

Hand-Hygiene Research Agenda

Although the number of published studies concerning hand hygiene has increased considerably in recent years, many questions regarding hand-hygiene products and strategies for improving adherence of personnel to recommended policies remain unanswered. Several concerns must still be addressed by researchers in industry and by clinical investigators (Box 3).

Web-Based Hand-Hygiene Resources

Additional information regarding improving hand hygiene is available at <http://www.hopisafe.ch>
University of Geneva Hospitals, Geneva, Switzerland
<http://www.cdc.gov/ncidod/hip>
CDC, Atlanta, Georgia
<http://www.jr2.ox.ac.uk/bandolier/band88/b88-8.html>
Bandolier journal, United Kingdom
<http://www.med.upenn.edu>
University of Pennsylvania, Philadelphia, Pennsylvania

BOX 3. Hand-hygiene research agenda**Education and promotion**

- Provide health-care workers (HCWs) with better education regarding the types of patient care activities that can result in hand contamination and cross-transmission of microorganisms.
- Develop and implement promotion hand-hygiene programs in pregraduate courses.
- Study the impact of population-based education on hand-hygiene behavior.
- Design and conduct studies to determine if frequent glove use should be encouraged or discouraged.
- Determine evidence-based indications for hand cleansing (considering that it might be unrealistic to expect HCWs to clean their hands after every contact with the patient).
- Assess the key determinants of hand-hygiene behavior and promotion among the different populations of HCWs.
- Develop methods to obtain management support.
- Implement and evaluate the impact of the different components of multimodal programs to promote hand hygiene.

Hand-hygiene agents and hand care

- Determine the most suitable formulations for hand-hygiene products.
- Determine if preparations with persistent antimicrobial activity reduce infection rates more effectively than do preparations whose activity is limited to an immediate effect.
- Study the systematic replacement of conventional handwashing by the use of hand disinfection.
- Develop devices to facilitate the use and optimal application of hand-hygiene agents.
- Develop hand-hygiene agents with low irritancy potential.
- Study the possible advantages and eventual interaction of hand-care lotions, creams, and other barriers to help minimize the potential irritation associated with hand-hygiene agents.

Laboratory-based and epidemiologic research and development

- Develop experimental models for the study of cross-contamination from patient to patient and from environment to patient.
- Develop new protocols for evaluating the in vivo efficacy of agents, considering in particular short application times and volumes that reflect actual use in health-care facilities.
- Monitor hand-hygiene adherence by using new devices or adequate surrogate markers, allowing frequent individual feedback on performance.
- Determine the percentage increase in hand-hygiene adherence required to achieve a predictable risk reduction in infection rates.
- Generate more definitive evidence for the impact on infection rates of improved adherence to recommended hand-hygiene practices.
- Provide cost-effectiveness evaluation of successful and unsuccessful promotion campaigns.

Part II. Recommendations**Categories**

These recommendations are designed to improve hand-hygiene practices of HCWs and to reduce transmission of pathogenic microorganisms to patients and personnel in health-care settings. This guideline and its recommendations are not intended for use in food processing or food-service establishments, and are not meant to replace guidance provided by FDA's Model Food Code.

As in previous CDC/HICPAC guidelines, each recommendation is categorized on the basis of existing scientific data, theoretical rationale, applicability, and economic impact. The CDC/HICPAC system for categorizing recommendations is as follows:

Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.

Category IB. Strongly recommended for implementation and supported by certain experimental, clinical, or epidemiologic studies and a strong theoretical rationale.

Category IC. Required for implementation, as mandated by federal or state regulation or standard.

Category II. Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale.

No recommendation. Unresolved issue. Practices for which insufficient evidence or no consensus regarding efficacy exist.

Recommendations

1. Indications for handwashing and hand antisepsis
 - A. When hands are visibly dirty or contaminated with proteinaceous material or are visibly soiled with blood or other body fluids, wash hands with either a non-antimicrobial soap and water or an antimicrobial soap and water (IA) (66).
 - B. If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in all other clinical situations described in items 1C–J (IA) (74,93,166,169,283,294,312,398). Alternatively, wash hands with an antimicrobial soap and water in all clinical situations described in items 1C–J (IB) (69-71,74).
 - C. Decontaminate hands before having direct contact with patients (IB) (68,400).
 - D. Decontaminate hands before donning sterile gloves when inserting a central intravascular catheter (IB) (401,402).
 - E. Decontaminate hands before inserting indwelling urinary catheters, peripheral vascular catheters, or other invasive devices that do not require a surgical procedure (IB) (25,403).
 - F. Decontaminate hands after contact with a patient's intact skin (e.g., when taking a pulse or blood pressure, and lifting a patient) (IB) (25,45,48,68).
 - G. Decontaminate hands after contact with body fluids or excretions, mucous membranes, nonintact skin, and wound dressings if hands are not visibly soiled (IA) (400).
 - H. Decontaminate hands if moving from a contaminated-body site to a clean-body site during patient care (II) (25,53).
 - I. Decontaminate hands after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient (II) (46,53,54).
 - J. Decontaminate hands after removing gloves (IB) (50,58,321).
 - K. Before eating and after using a restroom, wash hands with a non-antimicrobial soap and water or with an antimicrobial soap and water (IB) (404-409).
 - L. Antimicrobial-impregnated wipes (i.e., towelettes) may be considered as an alternative to washing hands with non-antimicrobial soap and water. Because they are not as effective as alcohol-based hand rubs or washing hands with an antimicrobial soap and water for reducing bacterial counts on the hands of HCWs, they are not a substitute for using an alcohol-based hand rub or antimicrobial soap (IB) (160,161).
 - M. Wash hands with non-antimicrobial soap and water or with antimicrobial soap and water if exposure to *Bacillus anthracis* is suspected or proven. The physical action of washing and rinsing hands under such circumstances is recommended because alcohols, chlorhexidine, iodophors, and other antiseptic agents have poor activity against spores (II) (120,172,224,225).
 - N. No recommendation can be made regarding the routine use of nonalcohol-based hand rubs for hand hygiene in health-care settings. Unresolved issue.
2. Hand-hygiene technique
 - A. When decontaminating hands with an alcohol-based hand rub, apply product to palm of one hand and rub hands together, covering all surfaces of hands and fingers, until hands are dry (IB) (288,410). Follow the manufacturer's recommendations regarding the volume of product to use.
 - B. When washing hands with soap and water, wet hands first with water, apply an amount of product recommended by the manufacturer to hands, and rub hands together vigorously for at least 15 seconds, covering all surfaces of the hands and fingers. Rinse hands with water and dry thoroughly with a disposable towel. Use towel to turn off the faucet (IB) (90-92,94,411). Avoid using hot water, because repeated exposure to hot water may increase the risk of dermatitis (IB) (254,255).
 - C. Liquid, bar, leaflet or powdered forms of plain soap are acceptable when washing hands with a non-antimicrobial soap and water. When bar soap is used, soap racks that facilitate drainage and small bars of soap should be used (II) (412-415).
 - D. Multiple-use cloth towels of the hanging or roll type are not recommended for use in health-care settings (II) (137,300).
3. Surgical hand antisepsis
 - A. Remove rings, watches, and bracelets before beginning the surgical hand scrub (II) (375,378,416).
 - B. Remove debris from underneath fingernails using a nail cleaner under running water (II) (14,417).

- C. Surgical hand antisepsis using either an antimicrobial soap or an alcohol-based hand rub with persistent activity is recommended before donning sterile gloves when performing surgical procedures (IB) (115,159,232,234,237,418).
 - D. When performing surgical hand antisepsis using an antimicrobial soap, scrub hands and forearms for the length of time recommended by the manufacturer, usually 2–6 minutes. Long scrub times (e.g., 10 minutes) are not necessary (IB) (117,156,205,207,238-241).
 - E. When using an alcohol-based surgical hand-scrub product with persistent activity, follow the manufacturer's instructions. Before applying the alcohol solution, prewash hands and forearms with a non-antimicrobial soap and dry hands and forearms completely. After application of the alcohol-based product as recommended, allow hands and forearms to dry thoroughly before donning sterile gloves (IB) (159,237).
4. Selection of hand-hygiene agents
- A. Provide personnel with efficacious hand-hygiene products that have low irritancy potential, particularly when these products are used multiple times per shift (IB) (90,92,98,166,249). This recommendation applies to products used for hand antisepsis before and after patient care in clinical areas and to products used for surgical hand antisepsis by surgical personnel.
 - B. To maximize acceptance of hand-hygiene products by HCWs, solicit input from these employees regarding the feel, fragrance, and skin tolerance of any products under consideration. The cost of hand-hygiene products should not be the primary factor influencing product selection (IB) (92,93,166,274,276-278).
 - C. When selecting non-antimicrobial soaps, antimicrobial soaps, or alcohol-based hand rubs, solicit information from manufacturers regarding any known interactions between products used to clean hands, skin care products, and the types of gloves used in the institution (II) (174,372).
 - D. Before making purchasing decisions, evaluate the dispenser systems of various product manufacturers or distributors to ensure that dispensers function adequately and deliver an appropriate volume of product (II) (286).
 - E. Do not add soap to a partially empty soap dispenser. This practice of “topping off” dispensers can lead to bacterial contamination of soap (IA) (187,419).
5. Skin care
- A. Provide HCWs with hand lotions or creams to minimize the occurrence of irritant contact dermatitis associated with hand antisepsis or handwashing (IA) (272,273).
 - B. Solicit information from manufacturers regarding any effects that hand lotions, creams, or alcohol-based hand antiseptics may have on the persistent effects of antimicrobial soaps being used in the institution (IB) (174,420,421).
6. Other Aspects of Hand Hygiene
- A. Do not wear artificial fingernails or extenders when having direct contact with patients at high risk (e.g., those in intensive-care units or operating rooms) (IA) (350–353).
 - B. Keep natural nails tips less than 1/4-inch long (II) (350).
 - C. Wear gloves when contact with blood or other potentially infectious materials, mucous membranes, and nonintact skin could occur (IC) (356).
 - D. Remove gloves after caring for a patient. Do not wear the same pair of gloves for the care of more than one patient, and do not wash gloves between uses with different patients (IB) (50,58,321,373).
 - E. Change gloves during patient care if moving from a contaminated body site to a clean body site (II) (50,51,58).
 - F. No recommendation can be made regarding wearing rings in health-care settings. Unresolved issue.
7. Health-care worker educational and motivational programs
- A. As part of an overall program to improve hand-hygiene practices of HCWs, educate personnel regarding the types of patient-care activities that can result in hand contamination and the advantages and disadvantages of various methods used to clean their hands (II) (74,292,295,299).
 - B. Monitor HCWs' adherence with recommended hand-hygiene practices and provide personnel with information regarding their performance (IA) (74,276,292,295,299,306,310).
 - C. Encourage patients and their families to remind HCWs to decontaminate their hands (II) (394,422).
8. Administrative measures
- A. Make improved hand-hygiene adherence an institutional priority and provide appropriate

- administrative support and financial resources (IB) (74,75).
- B. Implement a multidisciplinary program designed to improve adherence of health personnel to recommended hand-hygiene practices (IB) (74,75).
 - C. As part of a multidisciplinary program to improve hand-hygiene adherence, provide HCWs with a readily accessible alcohol-based hand-rub product (IA) (74,166,283,294,312).
 - D. To improve hand-hygiene adherence among personnel who work in areas in which high workloads and high intensity of patient care are anticipated, make an alcohol-based hand rub available at the entrance to the patient's room or at the bedside, in other convenient locations, and in individual pocket-sized containers to be carried by HCWs (IA) (11,74,166,283,284,312,318,423).
 - E. Store supplies of alcohol-based hand rubs in cabinets or areas approved for flammable materials (IC).

Part III. Performance Indicators

1. The following performance indicators are recommended for measuring improvements in HCWs' hand-hygiene adherence:
 - A. Periodically monitor and record adherence as the number of hand-hygiene episodes performed by personnel/number of hand-hygiene opportunities, by ward or by service. Provide feedback to personnel regarding their performance.
 - B. Monitor the volume of alcohol-based hand rub (or detergent used for handwashing or hand antisepsis) used per 1,000 patient-days.
 - C. Monitor adherence to policies dealing with wearing of artificial nails.
 - D. When outbreaks of infection occur, assess the adequacy of health-care worker hand hygiene.

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Appendix

Antimicrobial Spectrum and Characteristics of Hand-Hygiene Antiseptic Agents*

Group	Gram-positive bacteria	Gram-negative bacteria	Mycobacteria	Fungi	Viruses	Speed of action	Comments
Alcohols	+++	+++	+++	+++	+++	Fast	Optimum concentration 60%–95%; no persistent activity
Chlorhexidine (2% and 4% aqueous)	+++	++	+	+	+++	Intermediate	Persistent activity; rare allergic reactions
Iodine compounds	+++	+++	+++	++	+++	Intermediate	Causes skin burns; usually too irritating for hand hygiene
Iodophors	+++	+++	+	++	++	Intermediate	Less irritating than iodine; acceptance varies
Phenol derivatives	+++	+	+	+	+	Intermediate	Activity neutralized by nonionic surfactants
Tricolsan	+++	++	+	—	+++	Intermediate	Acceptability on hands varies
Quaternary ammonium compounds	+	++	—	—	+	Slow	Used only in combination with alcohols; ecologic concerns

Note: +++ = excellent; ++ = good, but does not include the entire bacterial spectrum; + = fair; — = no activity or not sufficient.

* Hexachlorophene is not included because it is no longer an accepted ingredient of hand disinfectants.

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Appendix D



SEVERE ACUTE RESPIRATORY SYNDROME

Public Health Guidance for Community-Level Preparedness and Response to Severe Acute Respiratory Syndrome (SARS) Version 2

Supplement C: Preparedness and Response in Healthcare Facilities

IV. Recommended Preparedness and Response Activities in Healthcare Facilities

Components of Preparedness and Response in Healthcare Facilities

- Surveillance and Triage
- Clinical Evaluation
- Infection Control and Respiratory Hygiene
- Patient Isolation and Cohorting
- Engineering and Environmental Controls
- Exposure Reporting and Evaluation
- Staffing Needs and Personnel Policies
- Hospital Access Controls
- Supplies and Equipment
- Communication and Reporting

A. *Surveillance and Triage*

As with any disease control effort, surveillance for cases of SARS-CoV disease is the basis for control. SARS case surveillance, including surveillance in healthcare facilities, is also discussed in Supplement B and in the SARS response matrices for healthcare facilities (Appendix C1). Some key surveillance activities specific to healthcare facilities are described below.

Objective 1: *In the absence of SARS-CoV transmission worldwide*, establish surveillance aimed at early detection of cases and clusters of severe unexplained respiratory infections (i.e., pneumonia) that might signal the re-emergence of SARS-CoV.

Activities

- Participate in surveillance activities to detect new cases of SARS-CoV disease, in accordance with public health guidelines (See Supplement B).
- Consider SARS-CoV disease in patients who require hospitalization for radiographically confirmed pneumonia or acute respiratory distress syndrome of unknown etiology and who have one of the following risk factors in the 10 days before illness onset:

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Recommended Preparedness and Response Activities in Healthcare Facilities

(continued from previous page)

- Travel to mainland China, Hong Kong, or Taiwan,¹ or close contact² with an ill person with a history of recent travel to one of these areas, *OR*
- Employment in an occupation associated with a risk for SARS-CoV exposure (e.g., healthcare worker with direct patient contact; worker in a laboratory that contains live SARS-CoV), *OR*
- Part of a cluster of cases of atypical pneumonia without an alternative diagnosis
- Be alert for clusters of pneumonia among two or more healthcare workers who work in the same facility.
- Post visual alerts (in appropriate languages) at the entrances to all outpatient facilities (emergency departments, physicians' offices, clinics) instructing patients to inform healthcare personnel of lower respiratory symptoms when they first register for care and to practice "respiratory hygiene/cough etiquette" precautions (detailed below).
- Ensure that clinicians know where and how to promptly report a potential SARS case to hospital and public health officials (See Supplement B).

Objective 2: In the presence of person-to-person SARS-CoV transmission anywhere in the world, establish surveillance to promptly identify and report all new U.S. cases of SARS-CoV disease in persons who present for evaluation at the facility.

Basic Activities

- Continue to implement case detection and reporting efforts as detailed above and in Supplement B.
- Develop a strategy and assign responsibility for regularly updating clinicians and intake and triage staff on the status of SARS-CoV transmission locally, nationally, and internationally.
- Train intake and triage staff on how to assess for SARS risks and to use any applicable screening tools.
- Educate clinical healthcare providers about the signs and symptoms of and current risk factors for SARS-CoV disease (e.g., locations where there is SARS-CoV transmission).
- Institute a strategy to identify, evaluate, and monitor the health of staff and patients who are potentially exposed to SARS-CoV.
- Determine the threshold at which screening of persons entering the facility will be initiated and at what point screening will escalate from passive (e.g., signs at the entrance) to active (e.g., direct questioning). Screening will likely need to be coordinated with access controls (see Section H: Access Controls). In addition to visual alerts, other potential screening measures include:
 - Priority triage of persons with lower respiratory symptoms
 - Triage stations outside the facility to screen patients before they enter
 - Telephone screening of patients with appointments
- Report cases that meet the screening criteria, in accordance with health department instructions.

¹ The 2003 SARS-CoV outbreak likely originated in mainland China, and neighboring areas such as Taiwan and Hong Kong are thought to be at higher risk due to the large volume of travelers from mainland China. Although less likely, SARS-CoV may also reappear from other previously affected areas. Therefore, clinicians should obtain a complete travel history. If clinicians have concerns about the possibility of SARS-CoV disease in a patient with a history of travel to other previously affected areas (e.g., while traveling abroad, had close contact with another person with pneumonia of unknown etiology or spent time in a hospital in which patients with acute respiratory disease were treated), they should contact the health department.

² Close contact: A person who has cared for or lived with a person with SARS-CoV disease or had a high likelihood of direct contact with respiratory secretions and/or body fluids of a person with SARS-CoV disease. Examples of close contact include kissing or hugging, sharing eating or drinking utensils, talking within 3 feet, and direct touching. Close contact does not include activities such as walking by a person or briefly sitting across a waiting room or office.

Recommended Preparedness and Response Activities in Healthcare Facilities
(continued from previous page)

Enhanced Activities

- Develop plans to actively screen all persons entering the facility.
- Determine at what point the facility will open a designated "SARS evaluation center" for evaluation of possible SARS patients, to separate potential SARS patients from other patients seeking care at the healthcare facility (see Section E: Engineering and Environmental Controls).

Objective 3: Conduct surveillance of healthcare workers caring for SARS patients.

Activities

- Healthcare workers caring for SARS patients are at increased risk for becoming infected with SARS-CoV and disseminating the virus to others. Use of personal protective equipment (PPE) will help to minimize this risk, but healthcare workers may not always be aware of minor breaches in PPE. Therefore, healthcare workers who are in close contact with SARS patients should undergo daily monitoring for symptoms suggestive of SARS-CoV disease. Because of their high risk of exposure to SARS-CoV, the clinical criteria for healthcare workers who are in close contact with SARS patients should be expanded to include, in addition to fever or lower respiratory symptoms, the presence of two or more of the other early symptoms of SARS-CoV disease (subjective fever, chills, rigors, myalgia, headache, diarrhea, sore throat, rhinorrhea).

B. Clinical Evaluation of Symptomatic Persons

To date, no specific clinical or laboratory findings can distinguish SARS-CoV disease from other respiratory illnesses reliably and rapidly enough to inform management decisions that must be made soon after a patient presents to the healthcare system. Therefore, *early clinical recognition of SARS-CoV disease still relies on a combination of clinical and epidemiologic features.* Although exposure history is a main factor in the diagnosis, many SARS patients do share some suggestive clinical characteristics. These include: presence of fever and other systemic symptoms 2 to 7 days before onset of a dry cough and dyspnea, infrequent presence of upper respiratory tract symptoms, presence of radiographic evidence of pneumonia in most patients by day 7 to 10 of illness, and lymphopenia.

The clinical set point for considering SARS-CoV disease will vary by likelihood and level of risk of exposure. Potential sources of exposure will vary by the status of SARS-CoV transmission locally, nationally, and globally. Potential SARS patients need to be evaluated and managed in a way that protects healthcare workers, other patients, and visitors.

Objective 1: Ensure that potential SARS patients are evaluated using safe work practices.

Activities

- Assign only trained and respirator fit-tested emergency staff to evaluate possible SARS patients.
- Instruct staff to wear appropriate PPE (see Supplement I).

Objective 2: In the *absence of SARS-CoV transmission worldwide*, perform a routine evaluation of patients with respiratory illnesses and maintain a low index of suspicion for SARS-CoV disease.

In the absence of person-to-person SARS-CoV transmission anywhere in the world, the overall likelihood that a patient with fever or respiratory illness has SARS-CoV disease will be exceedingly

Recommended Preparedness and Response Activities in Healthcare Facilities

(continued from previous page)

low unless there are both typical clinical findings and some accompanying epidemiologic evidence that raises the suspicion of exposure to SARS-CoV. Therefore, the diagnosis should be considered only in patients who require hospitalization for radiographically confirmed pneumonia (or acute respiratory distress syndrome) of unknown etiology and who have an epidemiologic history that raises the suspicion for SARS-CoV disease.

Activities

- Evaluate patients requiring hospitalization for radiographically confirmed pneumonia (or acute respiratory distress syndrome) of unknown etiology according to the algorithm (Figure 1) in *Clinical Guidance on the Identification and Evaluation of Possible SARS-CoV Disease among Persons Presenting with Community-Acquired Illness* (www.cdc.gov/ncidod/sars/clinicalguidance.htm).
- In the absence of SARS-CoV transmission worldwide, evaluation and management for possible SARS-CoV disease should be considered only for adults, unless special circumstances make the clinician and health department consider a child to be at potentially higher risk.

Objective 3: *In the presence of person-to-person SARS-CoV transmission worldwide,* increase the index of suspicion as appropriate based on the patient's symptoms and epidemiologic risk factors.

Activities

- Once person-to-person SARS-CoV transmission has been documented anywhere in the world, a diagnosis of SARS-CoV disease should still be considered in patients who require hospitalization for radiographically confirmed pneumonia (or acute respiratory distress syndrome) of unknown etiology and who have an epidemiologic history that raises the suspicion for exposure to SARS-CoV (see above).
- In addition, all patients with fever or lower respiratory symptoms should be questioned about recent close contact with persons suspected to have SARS-CoV disease and about exposure to locations in which recent SARS-CoV transmission is known or suspected to have occurred. Persons with such an exposure history should be evaluated according to the algorithm (Figure 2) in *Clinical Guidance on the Identification and Evaluation of Possible SARS-CoV Disease among Persons Presenting with Community-Acquired Illness* (www.cdc.gov/ncidod/sars/clinicalguidance.htm).
- For persons with a high risk of exposure to SARS-CoV (e.g., persons previously identified through contact tracing or self-identified as close contacts of a laboratory-confirmed case of SARS-CoV disease; persons who are epidemiologically linked to a laboratory-confirmed case of SARS-CoV disease), the clinical criteria should be expanded to include, in addition to fever or lower respiratory symptoms, the presence of other early symptoms of SARS-CoV disease (subjective fever, chills, rigors, myalgia, headache, diarrhea, sore throat, rhinorrhea). The more common early symptoms include chills, rigors, myalgia, and headache. In some patients, myalgia and headache may precede the onset of fever by 12-24 hours. However, diarrhea, sore throat, and rhinorrhea may also be early symptoms of SARS-CoV disease.

Recommended Preparedness and Response Activities in Healthcare Facilities

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- Establish procedures for managing symptomatic healthcare workers. Healthcare workers who have cared for or been exposed to a SARS patient and who develop symptoms(s) within 10 days after exposure or patient care should immediately:
 - o Contact infection control, occupational health, or a designee in each facility where they work, and
 - o Report to the predetermined location for clinical evaluation.
- Manage symptomatic healthcare workers according to the algorithm (Figure 2) in Clinical Guidance on the Identification and Evaluation of Possible SARS-CoV Disease among Persons Presenting with Community-Acquired Illness (www.cdc.gov/ncidod/sars/clinicalguidance.htm). Decisions on return to work should be guided by policies or regulations defined by the facility and/or health department.
- Typical symptoms of SARS-CoV disease may not always be present in elderly patients and those with underlying chronic illnesses. Therefore, the diagnosis should be considered for almost any change in health status when such patients have strong risk factors.
- Once SARS-CoV transmission has been documented, the evaluation algorithm established for adults can be used in children with the following caveats:
 - o Both the rate of development of radiographically confirmed pneumonia and the timing of development of such radiographic changes in children are unknown.
 - o The positive predictive value of rapid virus antigen detection tests (e.g., RSV) "in season" will be higher in a pediatric population.
 - o Pneumococcal and legionella urinary antigen testing are not recommended for routine diagnostic use in children.

C. Infection Control and Respiratory Hygiene/Cough Etiquette

Objective 1: Reinforce basic infection control practices in the healthcare facility.

SARS highlights the risks of nosocomial transmission of respiratory pathogens and provides an opportunity to improve overall infection control in healthcare facilities. During the 2003 epidemic, public health authorities quickly recognized infection control as a primary means for containing SARS-CoV. All healthcare facilities need to re-emphasize the importance of basic infection control measures for the control of SARS-CoV transmission.

Activities

- Educate staff about the importance of strict adherence to and proper use of standard infection control measures, especially hand hygiene and isolation (see Supplement I).
- Reinforce education on the recommended procedures for Standard, Contact, and Airborne Infection Isolation precautions (www.cdc.gov/ncidod/hip/ISOLAT/Isolat.htm and Supplement I).
- Ensure that healthcare workers have access to respirator fit-testing and instructions on respirator use.
- Determine how infection control training and education will be provided for all hospital personnel and visitors who may be exposed to SARS-CoV.
- Develop posters and instructional materials designed to: 1) teach appropriate hand hygiene and Standard Precautions, 2) teach the correct sequence and methods for donning and removing PPE, 3) instruct on actions to take after an exposure, 4) instruct visitors and patients with symptoms and SARS risk factors to report to a specified screening and evaluation site.

Recommended Preparedness and Response Activities in Healthcare Facilities

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Objective 2: Emphasize the importance of respiratory hygiene/cough etiquette practices to help decrease transmission of respiratory infections.

Many viral and some bacterial respiratory pathogens (e.g., influenza, adenovirus, respiratory syncytial virus, *Mycoplasma pneumoniae*) share transmission characteristics with SARS-CoV and are also frequently transmitted in healthcare settings. Implementation of “respiratory hygiene/cough etiquette” practices can decrease the risk of transmission from unrecognized SARS patients and also control the spread of other, more common respiratory pathogens.

Activities

- Educate patients about the importance of respiratory hygiene/cough etiquette practices for preventing the spread of respiratory illnesses.
- Consider initiating a standard “respiratory hygiene/cough etiquette strategy” for the facility as described in the box below.

Respiratory Hygiene/Cough Etiquette Strategy for Healthcare Facilities

Respiratory hygiene/cough etiquette

To contain respiratory secretions, all persons with signs and symptoms of a respiratory infection, regardless of presumed cause, should be instructed to:

- Cover the nose/mouth when coughing or sneezing.
- Use tissues to contain respiratory secretions.
- Dispose of tissues in the nearest waste receptacle after use.
- Perform hand hygiene after contact with respiratory secretions and contaminated objects/materials.

Healthcare facilities should ensure the availability of materials for adhering to respiratory hygiene/cough etiquette in waiting areas for patients and visitors:

- Provide tissues and no-touch receptacles for used tissue disposal
- Provide conveniently located dispensers of alcohol-based hand rub
- Provide soap and disposable towels for hand washing where sinks are available

Masking and separation of persons with symptoms of respiratory infection

During periods of increased respiratory infection in the community, offer masks to persons who are coughing. Either procedure masks (i.e., with ear loops) or surgical masks (i.e., with ties) may be used to contain respiratory secretions; respirators are not necessary. Encourage coughing persons to sit at least 3 feet away from others in common waiting areas. Some facilities may wish to institute this recommendation year-round.

Droplet precautions

Healthcare workers should practice Droplet Precautions (i.e., wear a surgical or procedure mask for close contact), in addition to Standard Precautions, when examining a patient with symptoms of a respiratory infection. Droplet Precautions should be maintained until it is determined that they are no longer needed (www.cdc.gov/ncidod/hip/ISOLAT/Isolat.htm).

Recommended Preparedness and Response Activities in Healthcare Facilities

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D. Patient Placement, Isolation, and Cohorting

Appropriate patient placement is a significant component of effective SARS control. Each healthcare facility should develop a strategy and procedures to: 1) quickly separate potential SARS patients from other patients, and 2) implement appropriate isolation precautions.

Objective 1: Develop strategies for triage and admission that minimize the risk of transmission to staff, patients, and visitors.

Activities

- Determine where and how possible SARS patients will be triaged, evaluated, diagnosed, and isolated.
- Admit patients only when medically indicated or if appropriate isolation in the community is not possible.
- If a patient with SARS symptoms and risk factors does not meet the criteria for admission and is to be sent home, discuss the case with the health department to ensure adequate home isolation and follow-up (See Supplement D).
- Review admission procedures, and determine how they can be streamlined to limit the number of patient encounters for healthcare personnel.
- Determine a method for tracking and monitoring all SARS patients in the facility.

Objective 2: Develop a patient transport plan to safely move SARS patients within the facility.

Activities

- Identify appropriate paths, separated from main traffic routes as much as possible, for entry and movement of SARS patients in the facility, and determine how these pathways will be controlled (e.g., dedicated SARS patient corridors, elevators).
- Optimize necessary patient transport (see Supplement I).

Objective 3: Ensure optimal strategies for isolation of possible SARS patients in the healthcare facility.

Although most SARS-CoV transmission appears to occur through droplet and contact exposures, transmission by fomites and by the airborne route remain possibilities. Therefore, patients who require hospitalization should be admitted to an Airborne Infection Isolation room (AIIR) or specially adapted SARS unit or ward where they can be managed safely. In some settings, a lack of AIIRs and/or a need to concentrate infection control efforts and resources within the facility may lead to a strategy of cohorting patients in individual rooms on the same floor, rather than placing them in AIIRs throughout the hospital. This strategy physically isolates SARS patients from non-SARS patients and also makes it possible to dedicate resources and appropriately trained staff to their care. Experience in some settings in Taiwan and Toronto demonstrated that cohorting SARS patients, without use of AIIRs, effectively interrupted transmission. Thus, although single AIIRs are recommended for SARS isolation, other strategies may provide effective overall infection control.

Recommended Preparedness and Response Activities in Healthcare Facilities

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Basic Activities

- As possible, admit patients with possible SARS-CoV disease to an AIIR (See Supplement I). An AIIR is a single-patient room in which environmental factors are controlled to minimize the possibility of airborne transmission of infectious agents. These rooms have specific requirements for controlled ventilation, negative pressure, and air filtration and monitoring, which are detailed in the *Guideline for Environmental Infection Control in Health-Care Facilities, 2003* (www.cdc.gov/ncidod/hip/enviro/guide.htm).
- If there is a lack of AIIRs and/or a need to concentrate infection control resources, or if AIIRs are available only in locations housing immunosuppressed patients (e.g., bone marrow transplant wards), patients may be cohorted in single rooms on nursing units that have been modified to accommodate SARS patients (see Section E: Engineering and Environmental Controls, and Supplement I).
- Even if a facility has chosen to cohort SARS patients, AIIRs are preferred for: 1) patients who are known to have transmitted SARS-CoV to other persons and 2) patients in whom the risk of SARS is being assessed (to avoid putting non-SARS-CoV-infected patients on a SARS unit).
- Determine where SARS patients will have various procedures (e.g., collection of respiratory specimens) performed. Whenever possible, perform procedures/tests in the patient's room (see Supplement I).

Enhanced Activities

- Determine at what point the facility will designate a special SARS nursing unit, and determine how that unit would be modified to accommodate SARS patients (see Section E: Engineering and Environmental Controls).
- In the context of significant SARS-CoV transmission in the facility, high patient volume, or frequent unprotected exposures, devise and implement a plan for cohorting patients and healthcare workers. Patients might be divided into the following cohorts: 1) patients who are exposed and asymptomatic; 2) patients who are exposed and symptomatic but do not meet the SARS case definition; 3) patients who meet the case definition; 4) non-exposed patients.
- Consider the need/practicality of a designated SARS hospital. In some areas during the 2003 outbreak, a logical expansion of a SARS unit was designation of certain facilities as SARS hospitals. This decision facilitated cohorting of staff and focused resources on one or a few hospitals. As shown by the experience in Toronto and Taiwan, however, designation of SARS hospitals is a difficult policy to implement. Hospitals that were not seriously affected did not want to become the repository of all SARS cases for fear of liability, negative public relations and financial impact. Even where this policy was successful, patients with SARS still presented to other facilities. Thus, all hospitals still needed to be vigilant for SARS and able to handle the initial triage, stabilization, and transfer of patients. The decision to create a SARS hospital requires the involvement of hospital leadership, health departments, and other community officials. The ultimate decision-making authority may vary by jurisdiction. The decision must also take into account the availability of specialty services, both at the designated facility and at other facilities in the area.

Recommended Preparedness and Response Activities in Healthcare Facilities

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E. Engineering and Environmental Controls

Optimal functioning and maintenance of the facility's environment are important components of SARS control.

Objective 1: Ensure that the capacity of rooms and units that will be used to house SARS patients is adequate for isolation and infection control.

Activities

- Determine the current capacity for isolating SARS patients in ICU and non-ICU settings.
- Ensure that AIIRs are functioning properly and are maintained in accordance with current recommendations (www.cdc.gov/ncidod/hip/enviro/guide.htm).
- Determine how non-AIIR rooms designated for SARS patient care might be modified to achieve appropriate airflow direction and/or air exchanges.
- Determine the best location in the hospital for a SARS unit in which patients and the staff caring for them can be cohorted. Determine how to modify existing rooms/units/floors as needed to meet the engineering requirements for a SARS unit. Ideally this location would have the following characteristics:
 - An air-handling system that allows the unit to be made negative pressure to surrounding areas and allows for a pressure gradient with air flow from the "cleanest" (nurses' station) to the "least clean" (patient room) area.
 - Rooms that can be converted to negative pressure in relation to the hallway
- Identify a designated space for a SARS evaluation center, which may be a temporary structure or make use of existing structures. The purpose is to separate potential SARS patients from other patients seeking care at the healthcare facility during triage and initial evaluation.
 - Determine needed ventilation, imaging, laboratory, and restroom facilities, water supply, etc., for the evaluation center.
 - Determine appropriate traffic routes and modes of transport for patients who must be transported from the evaluation center to the healthcare facility.
- Designate an environmental/housekeeping specialist to verify that cleaning and disinfection methods and staff are appropriately prepared to provide SARS patient care at the facility (see Supplement I).

F. Exposure Reporting and Evaluation

Unrecognized patients were a significant source of transmission during the 2003 SARS outbreak. Thus, rapid reporting and evaluation of persons exposed to SARS-CoV will be an important measure in early identification and isolation. Although healthcare facilities may play an active role in the follow-up of exposed patients and healthcare workers, it will be important for such follow-up to be coordinated with the health department.

Objective 1: Ensure that staff members understand the risks of SARS-CoV exposure, the importance of reporting exposures and illness, and the procedures for reporting exposures and illness.

Activities

- Establish an exposure reporting process that includes various methods for identifying exposed personnel (e.g., self-reporting by employees, logs of personnel entering SARS patient rooms).

Recommended Preparedness and Response Activities in Healthcare Facilities

(continued from previous page)

Include a mechanism for sharing information with the health department on exposed patients who are being discharged and also on exposed healthcare workers.

- Establish procedures for managing unprotected high-risk exposures. These occur when a healthcare worker is in a room with a SARS patient during a high-risk aerosol-generating procedure or event and the recommended infection control precautions are either absent or breached. If a healthcare worker has an unprotected high-risk exposure but has no symptoms of SARS-CoV disease, the worker:
 - Should be excluded from duty (e.g., administrative leave) for 10 days after the date of the last high-risk exposure.
 - Should be actively monitored for the development of symptoms for 10 days after the date of the last high-risk exposure. Because a healthcare worker with an unprotected high-risk exposure has been exposed to a known SARS patient, the worker should be monitored not only for fever or lower respiratory symptoms but also for the presence of the other early symptoms of SARS-CoV disease (subjective fever, chills, rigors, myalgia, headache, diarrhea, sore throat, rhinorrhea).

Decisions regarding activity restrictions (e.g., quarantine, home/work restrictions) outside the facility should be discussed with the health department, in accordance with the recommendations in Supplement D.

- Establish procedures for managing **unprotected exposures that are not high risk**. These occur when a healthcare worker is in a room or patient-care area with a SARS patient (not during a high-risk procedure) and the recommended infection control precautions are either absent or breached. If a healthcare worker has an unprotected, non-high-risk exposure and has **no symptoms of SARS**, the healthcare worker:
 - Need not be excluded from duty.
 - Should be actively monitored for the development of fever or respiratory symptoms for 10 days after the date of the last exposure. Because a healthcare worker with an unprotected, non-high-risk exposure has been exposed to a known SARS patient, the worker should be monitored not only for fever or lower respiratory symptoms but also for the presence of the other early symptoms of SARS-CoV disease (subjective fever, chills, rigors, myalgia, headache, diarrhea, sore throat, rhinorrhea).

Decisions regarding activity restrictions (e.g., quarantine, home/work restrictions) outside the facility should be discussed with the health department in accordance with the recommendations in Supplement D.

- Healthcare workers who develop symptoms during the follow-up period should:
 - Contact infection control, occupational health, or a designee in each facility where they work and
 - Be evaluated in accordance with the SARS clinical algorithm (www.cdc.gov/ncidod/sars/clinicalguidance.htm).

G. Staffing Needs and Personnel Policies

A SARS outbreak challenges a healthcare facility's ability to meet staffing, organizational, and resource needs. During an outbreak of any size, existing staffing shortages may be amplified by illness among staff members, fear and concern about SARS, and isolation and quarantine of exposed staff or ill/exposed family members. Staffing shortages are also likely to escalate as an outbreak progresses.

Recommended Preparedness and Response Activities in Healthcare Facilities

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During the preparedness period, it is important to plan for how staffing services might be provided, as some strategies might require changes in policy or even in legislation. To address staffing shortages, healthcare workers may need to be relocated to different settings or modify the type of services they usually provide. The strain involved in the prolonged use of PPE may intensify staffing challenges. Healthcare personnel will need special training in the details of SARS preparedness planning, infection control, crisis management, exposure management, and skills required for a mass-casualty response. Non-healthcare workers, retired healthcare workers, and volunteers may be potential resources. However, use of alternative staffing resources will require training and support.

Experience from other countries has shown that healthcare workers are likely to experience significant physical and emotional stress both during and after an outbreak of SARS. These issues must also be addressed.

Objective 1: Develop strategies to meet the range of staffing needs that might be required to manage a SARS outbreak.

Activities

- Determine the minimum number and categories of personnel needed to care for a single patient or small group of patients on a given day. Given the high burden of wearing SARS PPE (especially prolonged respirator wear), staffing may need to be increased to allow PPE-free time.
- Determine whether a small group of staff, including ancillary staff (perhaps divided into multiple teams), could be assigned responsibility for providing initial care for SARS patients. These staff members would be well trained in infection control practices, would be respirator fit-tested in advance (preferably to multiple manufacturers' models), and would serve as a resource to other staff when additional patients are admitted. Examples of such teams include:
 - Initial care team of medical, nursing, housekeeping, and ancillary staff
 - Emergency response team to provide resuscitation, intubation, and emergency care to possible or known SARS patients using appropriate PPE (see Supplement I for PPE recommendations for respiratory procedures)
 - Respiratory procedures team (e.g., bronchoscopy, sputum induction) using appropriate PPE (see Supplement I for PPE recommendations for respiratory procedures)
- For teaching hospitals, determine what role, if any, students and other trainees (e.g., residents, fellows) will play in the care of SARS patients.
- Determine how staffing needs will be met as the number of SARS patients increases and/or staff become ill or are quarantined.

Objective 2: Ensure that infection control staffing is adequate.

Activities

- Ensure the availability of a sufficient number of infection control practitioners (ICPs) to allow for daily monitoring and assessment of all SARS patient-care areas. ICPs should continue not only to implement appropriate infection control measures but also to stop practices that are ineffective. Designees who can help ICPs during outbreaks should be identified.
- When patients are isolated, designate staff members to formally monitor and reinforce compliance with PPE measures.

Objective 3: Develop personnel policies for exposure management, work restrictions, and compliance.

Recommended Preparedness and Response Activities in Healthcare Facilities

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Activities

- Inform healthcare workers that they are expected to comply with all infection control and public health recommendations. Alert them that recommendations may change as an outbreak progresses.
- Develop criteria for work restrictions for healthcare workers.
- Develop systems for follow-up of healthcare workers after unprotected exposures to SARS patients.
- Instruct healthcare workers to notify each facility at which they work if any of those facilities is providing care to SARS patients.
- If quarantine is used as an exposure-management tool, some healthcare workers may be placed on "working quarantine" to ensure sufficient staffing levels. Healthcare workers on working quarantine should travel only between home and the healthcare facility for the duration of the restriction. Limitations on alternative employment will be needed.

Objective 4: Provide needed assistance and resources to help healthcare workers cope with the stresses of responding to a SARS outbreak.

Activities

- Arrange to provide assistance to healthcare workers on work quarantine with activities of daily life, including obtaining food, running errands, and providing child care.
- Arrange to provide healthcare workers with access to mental health professionals as needed to cope with the stresses of an outbreak.

H. Access Controls

When SARS-CoV is present in the community surrounding a healthcare facility, preventing unrecognized SARS patients from entering the facility will be essential. Appropriate surveillance and screening measures are detailed in the surveillance section of this document and in Supplement B. Restricting access to the facility will increase the efficacy of surveillance and screening measures.

Objective: Develop criteria and plans for limiting access to the healthcare facility.

Activities

- Establish criteria and protocols for limiting admissions, transfers, and discharges in accordance with local/state recommendations and regulations in the event that nosocomial transmission of SARS-CoV occurs in the healthcare facility.
- Establish criteria and protocols for closing the facility to new admissions and transfers if necessary.
- Establish criteria and protocols for limiting visitors.
- Determine when and how to involve security services to enforce access controls.
- Consider meeting with local law enforcement officials in advance to determine what assistance they might be able to provide.

I. Supplies and Equipment

SARS patient care requires both consumable (e.g., PPE) and durable (e.g., ventilators) supplies. Experience in other countries indicates that a SARS outbreak not only can strain a facility's supply of these resources but also can affect the ability to order replacement supplies.

Recommended Preparedness and Response Activities in Healthcare Facilities

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Objective 1: Determine the current availability of and anticipated need for supplies and equipment that would be used in a SARS outbreak.

Basic Activity

- Assess anticipated needs for consumable and durable resources that will be required to provide care for various numbers of SARS patients, and determine at what point extra resources will be ordered.

Consumable resources include:

- Hand hygiene supplies (antimicrobial soap and alcohol-based waterless hand hygiene products)
- Disposable particulate respirators (N-95 or higher level)
- Personal air-purifying respirator (PAPR) hoods and power packs (if applicable)
- Goggles and face shields (disposable or reusable)
- Gowns
- Gloves
- Surgical masks

Durable resources include:

- Ventilators
- Portable HEPA filtration units
- Portable x-ray units

Enhanced activity

- Establish back-up plans in the event of limited supplies.

J. Communication and Reporting

A SARS outbreak will generate a need for rapid analysis of the status of patients and transmission in the healthcare facility and reporting of this information to public health officials and to the public, press, and political leaders. These needs can overwhelm resources that are essential to other response activities.

Objective 1: Communicate regularly with the health department about SARS-related activities.

Activities

- Establish a mechanism for regular contact with the local health department to report SARS activity in the facility and receive information on SARS activity in the community.
- Establish a reporting process to review discharge planning of SARS patients and information on exposed patients and healthcare workers with health department officials to ensure appropriate follow-up and case management in the community.
- Discuss jurisdictional and procedural issues for the investigation of nosocomial SARS outbreaks.

Objective 2: Communicate with facility staff and the public.

Activities

- Determine how to provide daily updates to the infection control staff and the hospital administration regarding SARS activity in the facility and the community.

Recommended Preparedness and Response Activities in Healthcare Facilities

(continued from previous page)

- Determine the preferred flow and release of information related to SARS patient care or transmission in the facility. Public relations/media staff should work with the SARS coordinator or designee to ensure clarity and accuracy. Prepare plans for: 1) internal notification and communication with patients and healthcare workers, 2) external communication with the media and the public, coordinated with local public health officials, and 3) development of templates for frequently asked questions, notifications, press releases, and other communication tools.
- Determine whether and how the facility will establish a SARS hotline for public inquiries, if needed.

For more information, visit www.cdc.gov/ncidod/sars or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

Appendix E

Title 51
PUBLIC HEALTH-SANITARY CODE

Part XXVII. Management of Refuse, Infectious Waste, Medical Waste, and Potentially Infectious Biomedical Waste

Chapter 1. Refuse Management
[formerly Chapter XXVII Part 1]

§101. Definitions
[formerly paragraph 27:001]

A. Unless otherwise specifically provided herein, the following words and terms used in Part XXVII of the Sanitary Code and all other Parts which are adopted or may be adopted, are defined for the purposes thereof as follows:

Ashes—include the solid residue resulting from the combustion of all fuels, including those used for heating, cooking, and the production of energy in any public or private establishment, institution, or residence.

Garbage—the putrescible components of refuse which are subject to spoilage, rot, or decomposition. It includes wastes from the preparation and consumption of food, vegetable matter, and animal offal and carcasses.

Offal—waste parts especially of a butchered animal including, but not limited to, bones, cartilage, fatty tissue and gristle.

Refuse—any garbage, rubbish, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility. It also includes other discarded material such as solid, liquid, semi-solid, or contained gaseous material resulting from either industrial, commercial, mining, or agricultural operations, or from community activities. It does not include solid or dissolved material in domestic sewage, irrigation return flows, industrial discharges which are point sources, or radioactive wastes.

Rubbish—includes all non-putrescible waste matter, except ashes, from any public or private establishments, institution, or residence. It also includes construction and demolition wastes.

Stable Refuse—includes animal feces and urine, any material contaminated by animal body discharges, and waste feed stuff.

Trash—rubbish.

AUTHORITY NOTE: The first source of authority for promulgation of the Sanitary Code is in R.S. 36:258(B), with more particular provisions found in Chapters 1 and 4 of Title 40 of the Louisiana Revised Statutes. This Part is promulgated in accordance with R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1449 (June 2002).

§103. Accumulation and Collection of Refuse
[formerly paragraph 27:002]

A. No owner or lessee of any public or private property or premises nor agent of such owner or lessee shall permit garbage to accumulate upon the property or premises except in tightly covered containers constructed of such material and in such a manner as to be strong, watertight, not easily corroded, and rodent and insect-proof. When garbage and other types of refuse are collected separately, separate containers may be required by the state health officer.

B. [Formerly paragraph 27:003] Refuse shall not be allowed to remain in any house or other building, cellar, or outhouse, or on any premises long enough to cause a nuisance or health hazard.

C. [Formerly paragraph 27:004] The bodies of vehicles used for the collection and transportation of garbage shall be watertight and easily cleaned. Such bodies shall be covered except when being loaded and unloaded.

D. [Formerly paragraph 27:005] No person shall throw, deposit, or allow to fall upon any public or private property any refuse of any kind.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1450 (June 2002).

§105. Swine Feeding
[formerly paragraph 27:006]

A. No garbage, either cooked or raw, shall be disposed of by feeding said garbage to swine.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1450 (June 2002).

§107. Disposal of Carcasses
[formerly paragraph 27:007]

A. Animal offal and the carcasses of animals shall be buried or cremated or shall be cooked (rendered) at minimum temperature of 250 degrees Fahrenheit, which temperature shall be maintained for at least 30 minutes. The apparatus and method or methods used in rendering shall be approved by the Livestock Sanitary Board and the state health officer, and rendering shall not be carried out in any establishment except as required in the Louisiana Administrative Code, Title 7, Volume 2, Louisiana Department of Agriculture and Animals, and under the

provisions of a permit issued by such representative, as required in Part XI of this Code.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1450 (June 2002).

§109. Stable Refuse
[formerly paragraph 27:008]

A. Every owner, lessee, manager (or other agent of an owner or lessee) of any stable, barn, stall, or any other establishment in the built-up part of any community, in which horses, cattle, dogs, fowl, or any other animals are quartered or in which stable refuse may accumulate shall cause such stable refuse to be removed therefrom, and shall at all times keep, or cause to be kept, such stable, barn, stall, or quarters, and the yards, drains, and appurtenances in a clean and sanitary condition so that no offensive odors shall be allowed to escape therefrom. Manure shall be kept in covered containers, or shall be treated to prevent the breeding of flies.

B. [Formerly paragraph 27:009] It shall be the duty of every owner, lessee, manager (or other agent of an owner or lessee) of any stable, barn, stall, or other establishment used for quartering animals or fowl to cause all stable refuse to be removed daily from such stable, or stable premises, unless the refuse is pressed bales, barrels or boxes. The removal and disposal of stable refuse without a written permit from the state health officer is prohibited.

C. [Formerly paragraph 27:010] Vehicles used for the removal of stable refuse shall be loaded within the premise, and not upon the street or sidewalk.

D. [Formerly paragraph 27:011] No stable refuse vault or receptacle shall be built, or used, on any premises except pursuant to the terms of a permit granted therefore by the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1450 (June 2002).

Chapter 3. Management of Infectious Waste, Medical Waste and Potentially Infectious Biomedical Waste
[formerly Chapter XXVII Part 2]

§301. Definitions
[formerly paragraph 27:020]

A. Unless otherwise specifically provided herein, the following words and terms used in this Part of the Sanitary Code are defined for the purposes thereof as follows.

Generator—any person or facility that produces Potentially Infectious Biomedical Waste.

Health Care and Medical Facilities—shall include, but not be limited to hospitals, clinics, dialysis facilities, birthing

centers, emergency medical services, mental health facilities, physicians' offices, outpatient surgery centers, nursing and extended care facilities, podiatry offices, dental offices and clinics, veterinary medical facilities, medical laboratories, home health care services, diagnostic services, mortuaries, and blood and plasma collection centers and mobile units.

Infectious Waste—that portion of Potentially Infectious Biomedical Waste which contains pathogens with sufficient virulence and quantity that exposure to the waste by a susceptible host could result in an infectious disease.

Labeling—to pre-print, mold an impression, write on or affix a sign to a package that is water resistant, legible and readily visible.

Large Health Care and Medical Facility Generator—a health facility generating 25 or more kilograms (55 pounds) of Potentially Infectious Biomedical Waste, not including sharps, or 5 or more kilograms (11 pounds) of sharps per month.

Medical Waste—that portion of Potentially Infectious Biomedical Waste that is generated from the operation of medical programs, offices and facilities.

Packaging—containing of Potentially Infectious Biomedical Waste in disposable or reusable containers in such a manner as to prevent exposure to the waste material.

Potentially Infectious Biomedical Waste—includes medical waste, infectious waste as defined herein, and as may be defined in other Louisiana law or code, and waste considered likely to be infectious by virtue of that it is or how it may have been generated in the context of health care or health care like activities. It includes, but is not limited to the following:

a. cultures and stocks of infectious agents and associated biologicals, including cultures from medical and pathological laboratories, from research and industrial laboratories;

b. human pathological wastes including tissue, organs, body parts and fluids that are removed during surgery or autopsy;

c. human blood, human blood products, blood collection bags, tubes and vials;

d. sharps used or generated in health care or laboratory settings;

e. bandages, diapers, "blue pads", and other disposable materials if they have covered infected wounds or have been contaminated by patients isolated to protect others from the spread of infectious diseases;

f. any other refuse which has been mingled with Potentially Infectious Biomedical Waste.

B. For purposes of these regulations, eating utensils are excluded from the definition of Potentially Infectious Biomedical Waste.

C. Also excluded are animal carcasses and bedding as regulated under §§107.A through 109.D of these regulations,

and very small quantities of uninfected human and animal surgical waste as specified in §303E.

D. Once treated in accordance with the provisions of §1101 of these regulations, the waste shall be deemed not to be potentially infectious, and may be handled and treated in accordance with those regulations governing the management of other municipal and industrial waste.

Sharps—are needles, syringes, scalpels, scalpel blades, pipettes and other medical instruments capable of puncturing or lacerating skin. This definition also includes glass fragments and other health care and laboratory waste capable of puncturing or lacerating skin.

Small Health Care and Medical Facility Generator—a health facility generating less than 25 kilograms (55 pounds) of Potentially Infectious Biomedical waste, not including sharps, or less than 5 kilograms (11 pounds) of sharps per month.

Small Quantity of Potentially Infectious Biomedical Waste—a single package containing less than 5 kilograms (11 pounds) of such waste not including sharps, or less than 1 kilogram (2.2 pounds) of sharps.

Storage—the containment of Potentially Infectious Biomedical Waste until treated or transported from the premises of a generator or treatment facility while the material is still potentially infectious.

Transport—the movement of Potentially Infectious Biomedical Waste from the premises of a generator or others involved over more than 0.1 mile of public streets or roadways to places for storage, treatment or disposal.¹

Transporter—any person or firm who transports large quantities of Potentially Infectious Biomedical Waste or who transports any quantity of such waste generated by another. This definition shall not apply to municipal waste haulers who transport such waste disposed of in household waste under the provisions of §501(D).

Treatment, in the case of Potentially Infectious Biomedical Wastes other than human bodies; gross anatomical parts such as limbs, torsos and heads; fetal remains; and sharps—any method, technique, or process designed to change the character or composition of any Potentially Infectious Biomedical Waste so as to render the waste non-infectious. Treatment of human bodies, anatomical parts and fetal remains shall be by cremation, burial, or other means specifically authorized by law or regulation. Sharps shall be treated by incineration, encapsulation, or other means by which they are rendered unrecognizable as Potentially Infectious Biomedical Waste or otherwise unusable.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1450 (June 2002).

§303. Requirements for Large Health Care and Medical Facility Generators of Potentially Infectious Biomedical Waste [formerly paragraph 27:021]

A. [Formerly paragraph 27:021-1] If Potentially Infectious Biomedical Waste is not segregated from other wastes at the point of origin, all wastes commingled with the Potentially Infectious Biomedical Waste must be managed as Potentially Infectious Biomedical Waste.

B. [Formerly paragraph 27:021-2] Potentially Infectious Biomedical Waste must be packaged as defined in §301(A). Liquid wastes require sturdy, leak resistant containment. For sharps, this is to be a break resistant, rigid, puncture resistant container, the openings of which must be tightly closed prior to storage or transport. Plastic bags and other containers used for Potentially Infectious Biomedical Waste must be clearly labeled, impervious to moisture and have a strength sufficient to preclude ripping, tearing, or bursting under normal conditions of usage. Such containers must be securely closed so as to prevent leakage or other loss of contents during storage and transport. Potentially Infectious Biomedical Wastes to be stored outside prior to treatment require a second level of containment. The outer containers must be constructed of such material and in such a manner as to be strong, watertight, not easily corroded, and rodent and insect-proof.

C. [Formerly paragraph 27:021-3] Liquid or liquefied Potentially Infectious Biomedical Waste may be directly disposed into a sewage system meeting the requirements of Part XIII.

D. [Formerly paragraph 27:021-4] Animal cadavers, and tissue and waste from large animals (e.g. livestock and horses) that are potentially infectious to human hosts may be disposed of in accordance with Livestock Sanitary Board Regulations, or treated and disposed as Potentially Infectious Biomedical Waste. Cadavers, tissues and waste from companion animals (e.g. cats and dogs) that are potentially infectious to human hosts may be buried, rendered, incinerated or otherwise appropriately treated in accordance with these regulations by, or on the order of, a licensed veterinarian involved with the case.

E. [Formerly paragraph 27:021-5] Very small quantities of human or animal tissue, reasonably estimated as less than 250 grams (about half a pound) and associated surgical dressings and non-sharp surgical wastes from clean surgical procedures from persons or animals not known or suspected to be infected with a disease communicable to humans, need not be disinfected prior to disposal, but must be disposed of in tightly closed plastic bags or other impervious containers.

F. [Formerly paragraph 27:021-6] Sharps shall be packaged as defined in §303(B). Every sharps container shall be labeled as defined in §301(A) and as specified in §303(G). The contents of the container will be treated as specified in §1101 prior to disposal.

G. [Formerly paragraph 27:021-7] All bags and other containers of Potentially Infectious Biomedical Waste shall be labeled as defined in §301(A) and as follows:

1. Each package shall be prominently identified as "Potentially Infectious Biomedical Waste", "Medical Waste", or "Infectious Waste", with or without the universal biohazard symbol.

2. Untreated, Potentially Infectious Biomedical Waste that leaves the premises of the generator must bear the name and address of the generator or transporter. If not labeled as to generator, the transporter must maintain a tracking system that can identify the generator of every package of Potentially Infectious Biomedical Waste.

3. Treated, but still recognizable Potentially Infectious Biomedical Waste shall carry a supplemental label or marking to specify the treatment method used and the name or initials of the person responsible for assurance of treatment.

H. [Formerly paragraph 27:021-8] Storage of Potentially Infectious Biomedical Waste shall be in a secure manner and location which affords protection from theft, vandalism, inadvertent human and animal exposure, rain and wind. It shall be managed so as not to provide a breeding place or food for insects or rodents, and not generate noxious odors.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1451 (June 2002).

§305. Transportation of Potentially Infectious Biomedical Waste
[formerly paragraph 27:021-9]

A. Transportation of potentially infectious biomedical waste shall be as follows:

1. A generator who transports large quantities of untreated or treated but still recognizable Potentially Infectious Biomedical Waste off site must register as a transporter and meet all the requirements specified in §701 of these regulations.

2. Generators shall transfer custody of Potentially Infectious Biomedical Waste only to transporters who are registered with the state health officer for this purpose as set forth in §701.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1452 (June 2002).

§307. Disposal of Potentially Infectious Biomedical Wastes
[formerly paragraph 27:021-10]

A. Disposal of Potentially Infectious Biomedical Wastes shall be in accordance with the provisions of §1301.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1452 (June 2002).

§309. Contingency Plans
[formerly paragraph 27:021-11]

A. Generators who normally depend upon on site incineration or other on site treatment and destruction of Potentially Infectious Biomedical Waste shall prepare and annually update written contingency plans for management of such waste when the incinerator or other means of on site destruction becomes inoperative for any reason. Such contingency plans shall be developed for periods of one day, seven to 29 days, and more than 30 days.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1452 (June 2002).

Chapter 5. Requirements for Small Health Care and Medical Facilities, Household and Other Small Quantity Generators of Potentially Infectious Medical Waste
[formerly paragraph 27:022]

§501. General Provisions
[formerly paragraph 27:022-1]

A. A physician, dentist, veterinarian or nurse or, in the case of households, patient or family member, is authorized to transport small quantities of properly packaged sharps and other Potentially Infectious Biomedical Waste, generated as a result of professional or self administered health care services, from the place of original generation of the waste to an approved large quantity generator, permitted storage facility, or permitted treatment facility without having to meet the requirements of §701 or 1101 of these regulations.

B. [Formerly paragraph 27:022-2] Small quantity generators shall package, label and store Potentially Infectious Biomedical Wastes as defined and specified in §303 of these regulations.

C. [Formerly paragraph 27:022-3] Small quantity generators may handle liquid, animal and very small quantity wastes as specified in §303(C), (D), and (E).

D. [Formerly paragraph 27:022-4] Small quantities of Potentially Infectious Biomedical Waste generated as a result of self-administered or non-professional health care or veterinary care services in a household or other non health-care facility may be disposed of in ordinary municipal waste without treatment, provided that such waste is packaged to assure no loss of contents, should the integrity of the original package be violated. This shall generally be interpreted to mean placing the original plastic bag or rigid container into a second bag or rigid disposal container. Sharps must be encased as specified in §1101 or placed in a sharps disposal container of standard manufacture or other

similar container of a type approved by the state health officer. This sharps container should then be placed within another bag or rigid container containing a greater volume of non-infectious waste.¹

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1452 (June 2002).

Chapter 7. Transportation

§701. Requirements for Transporters of Potentially Infectious Biomedical Waste [formerly paragraph 27:023]

A. [Formerly paragraph 27:023-1] This section shall apply to all transportation of Potentially Infectious Biomedical Waste within, into, out of or through the State of Louisiana.

B. [Formerly paragraph 27:023-2] A generator that transports large quantities of untreated, or treated but still recognizable Potentially Infectious Biomedical Waste must secure a permit as required in this section.

C. [Formerly paragraph 27:023-3] Arrangements between a generator and transporter for the transport of Potentially Infectious Biomedical Waste must be in the form of written contract which specifies that both parties fully understand and are fully committed to compliance with the provision of these regulations.

D. [Formerly paragraph 27:023-4] Potentially Infectious Biomedical Waste to be transported from the point of generation to an off-site treatment or disposal facility must meet the packaging and labeling requirements specified in §303.

E. [Formerly paragraph 27:023-5] The transporter shall deliver Potentially Infectious Biomedical Waste only to facilities that are permitted to transfer, store, treat or otherwise receive such wastes in accordance with these regulations. In the event that Potentially Infectious Biomedical Waste is transported out of state, the transporter shall deliver such waste to a facility demonstrating full compliance with all pertinent federal, state and local laws, rules and regulations.

F. [Formerly paragraph 27:023-6] Vehicles used by transporters shall meet the following minimum requirements:

1. The vehicle must have a fully enclosed cargo carrying body or compartment which is an integral part of the vehicle or firmly attached thereto and which affords protection from theft, vandalism, inadvertent human and animal exposure, rain, rodents and insects. The cargo body or compartment shall be separated by a solid barrier from the driver and passengers.

2. Provision shall be made for the containment within the body or compartment of any liquid which might leak from the packaged waste.

3. The cargo body or compartment shall be maintained in good sanitary condition and must be secured if left unattended.

4. The cargo body or vehicle containing the cargo compartment shall be identified on both sides with the name of the transporter and on both sides and the rear with the words "Medical Waste", "Infectious Waste", "Regulated Medical Waste", or "Potentially Infectious Biomedical Waste" in letters at least 3 inches high on contrasting background. In addition, a current permit decal issued by the Department of Health and Hospitals shall be affixed to the lower front section of the left side of the cargo body or to the driver's side door of the vehicle.¹

G [Formerly paragraph 27:023-7] Any person transporting Potentially Infectious Biomedical Waste for a generator other than himself shall secure a permit from the state health officer or his duly authorized representative by submitting each of the following:

1. [Formerly paragraph 27:023-7(1)] A completed and signed permit application form provided by the Louisiana Department of Health and Hospitals. The forms shall contain the following:

- a. a statement certifying that the permittee understands and will comply with the applicable requirements of this Part;

- b. a list of all vehicles and containers to be used by the permittee for transporting potentially infectious medical waste, and

- c. a copy of a certificate of insurance;

- d. a commitment that insurance coverage will be fully maintained for the duration of the permit.

2. [Formerly paragraph 27:023-7(2)] An operation plan for the handling and transport of Potentially Infectious Biomedical Waste. The operation plan shall include the following, each of which shall be subject to approval by the state health officer or his designee.

- a. The method(s) to be used for handling Potentially Infectious Biomedical Waste separately from other waste which prevents unauthorized persons from having access to or contact with the waste;

- b. The method(s) to be used for labeling each package of Potentially Infectious Biomedical Waste, and, if needed, the method(s) for tracking such waste, if the name, address and phone number of the generator is not to appear on the outer package, as specified in §303(G)(2) of these regulations.

- c. The method(s) to be used for loading and unloading of such wastes which limits the number of persons handling the wastes and minimizes the possibility of exposure of employees and the public to Potentially Infectious Biomedical Waste;

- d. The method(s) to be used for decontaminating emptied reusable Potentially Infectious Biomedical waste containers, transport vehicles and facility equipment which

are known or believed to have been contaminated with Potentially Infectious Biomedical Waste;

e. The provision and required use of clean protective gloves and uniforms for persons manually loading or unloading containers of Potentially Infectious Biomedical Waste on or from transport vehicles. Soiled protective gear shall be laundered or otherwise properly treated;

f. The management of any person having had bodily contact with Potentially Infectious Biomedical Waste.

g. Except as specified in §501, and single small quantity packages of Potentially Infectious Biomedical Waste, Compactor vehicles shall not be used for the transport of Potentially Infectious Biomedical Waste.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1453 (June 2002).

Chapter 9.Storage

§901. Storage of Potentially Infectious Biomedical Waste [formerly paragraph 27:024]

A. [Formerly paragraph 24:024-1] Storage of Potentially Infectious Biomedical Waste shall be in a secure manner and location which affords protection from theft, vandalism, inadvertent human and animal exposure, rain and wind. It shall be managed so as not to provide a breeding place or food for insects or rodents, and not generate noxious odors.

B. [Formerly paragraph 24:024-2] Compactors shall not be used for the storage of Potentially Infectious Biomedical Waste.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1454 (June 2002).

Chapter 11. Treatment

§1101. Treatment of Potentially Infectious Biomedical Waste [formerly paragraph 27:025]

A. Treatment shall be by one of the following.

1. [Formerly paragraph 27:025-1] *Incineration*-to consume waste by burning under conditions in conformance with the standards prescribed by the Louisiana Department of Environmental Quality and other laws, rule and regulations as may apply.

2. [Formerly paragraph 27:025-2] *Steam Sterilization*-autoclaving at a temperature of at least 120° C., (248° F.), and a pressure of at least 15 pounds per square inch for at least 30 minutes. Longer times are required depending on the amount of waste, the presence of water and

the type of container used. Alternate patterns of temperature, pressure and time may be used if compatible with the sterilization equipment being used and demonstrably sufficient to kill disease causing microorganisms.

3. [Formerly paragraph 27:025-3] Disposal as a liquid, with or without other treatment, into a sewage treatment system meeting the requirements of Part XIII of this Code.

4. [Formerly paragraph 27:025-4] *Thermal Inactivation*-dry heat of at least 160° C., (320° F.), at atmospheric pressure for at least two hours. This relates to time of exposure after attaining the specific temperature and does not include lag time.

5. [Formerly paragraph 27:025-5] *Chemical Disinfection*-the use of a chemical agent only in accordance with the written approval of the state health officer, except for hypochlorite bleach, diluted with water to no less than 5,000 ppm of chlorine (generally one part liquid household bleach, nine parts water). If chemically disinfected wastes are to be disposed into a sewage treatment system, the written permission of the operating authority of the sewage treatment system must be secured.

6. [Formerly paragraph 27:025-6] *Irradiation Sterilization*-the use of gamma rays, xrays, or other forms of radiation to treat Potentially Infectious Biomedical Waste may be used only with the written approval of the state health officer.

7. [Formerly paragraph 27:025-7] Treatment and disposition of human bodies, gross anatomical parts and fetal remains shall be by burial, cremation, or other means specifically authorized in law or regulation. Extracted human teeth may be disposed of by these means, or as sharps.

8. [Formerly paragraph 27:025-8] Treatment and disposition of sharps shall be by incineration, encasement in plaster within a tightly closed container, encasement in other substances within a tightly closed container, as approved by the state health officer or by other treatment that renders them unrecognizable as medical sharps, and, for all practical purposes, precludes the release of recognizable needles and syringes if compacted. Small health care and medical facility generators, as defined in §301 of these regulations may dispose of sharps by encasement, as described above, without prior sterilization, inactivation or disinfection. Large health care and medical facility generators, as defined in §301 of these regulations may apply to the state health officer for authority to dispose of sharps by encasement without prior sterilization, inactivation or disinfection.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1454 (June 2002).

Chapter 13. Disposal

§1301. Disposal of Potentially Infectious Biomedical Waste [formerly paragraph 27:026]

A. [Formerly paragraph 27:026-1] Once treated, as specified in §1101, Potentially Infectious Biomedical Waste may be disposed as non-infectious waste in a permitted sanitary landfill in accordance with the Solid Waste Regulations of the Department of Environmental Quality.

B. [Formerly paragraph 27:026-2] Treated, but still recognizable Potentially Infectious Biomedical Waste shall carry a supplemental label or marking to specify the treatment method used, date and name or initials of the person responsible for assurance of treatment.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1454 (June 2002).

Chapter 15. Treatment Facilities

§1501. General Provisions [formerly paragraph 27:027]

A. [Formerly paragraph 27:027-1] A generator may store its own Potentially Infectious Biomedical Wastes without a separate permit as otherwise required in this section, but must fully comply with all other provisions of this section.

B. [Formerly paragraph 27:027-2] Any generator operating its own incinerator or any other person operating a storage or treatment facility shall secure a permit from the state health officer by submitting each of the following.

1. A completed and signed permit application form provided by the State Health Officer. The forms shall contain the following:

a. a statement certifying that the permittee understands and will comply with the applicable requirements of this chapter; and

b. proof of all appropriate permits as required by the Louisiana Department of Environmental Quality and other state and federal agencies;

c. written arrangements between the storage and treatment facility and transporters which specify that both parties fully understand and are fully committed to compliance with the provisions of these regulations.

2. An operation plan for the management of Potentially Infectious Biomedical Waste. The operation plan shall include the following:

a. Methods of receiving wastes, unloading, storing and processing them, which ensure that all requirements specified in §§303.A, 303.H, 901, 1101, and 1301 are fully addressed.

b. A proposed method of decontaminating emptied reusable Potentially Infectious Biomedical Waste containers, transport vehicles and facility equipment which are known or believed to have been contaminated with Potentially Infectious Biomedical Waste.

c. The provision and required use of protective gloves and uniforms to protect employees against exposure to Potentially Infectious Biomedical Waste. Soiled protective gear shall be laundered or otherwise appropriately treated.

d. The management of any person having had bodily contact with Potentially Infectious Biomedical Waste.

C. Section 1501 shall not apply to municipal and other sewage treatment facilities permitted in accordance with Part XIII.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1454 (June 2002).

Chapter 17. Enforcement [formerly paragraph 27:028]

§1701. General Provisions

A. The Office of Public Health shall enforce the provisions of this Part in accordance with the provisions of the State Sanitary Code.

B. [Formerly paragraph 27:029] Effective Dates

1. [Formerly paragraph 27:029-1] These regulations shall take effect July 1, 1990.

C. Notes

1. ¹Sections revised July 20, 1991

2. [Sections 27:025-9, 27:026-3, 27:029-2 were deleted July 20, 1991]

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(b) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1455 (June 2002).

Appendix F

Friday
December 6, 1991

federal register

Part II (Excerpts)

Department of Labor

Occupational Safety and Health
Administration

29 CFR Part 1910.1030
Occupational Exposure to Bloodborne
Pathogens; Final Rule

XI. The Standard

General Industry

Part 1910 of title 29 of the Code of Federal Regulations is amended as follows:

PART 1910 -- [AMENDED]

Subpart Z -- [Amended]

1. The general authority citation for subpart of 29 CFR part 1910 continues to read as follows and a new citation for §1910.1030 is added:

Authority: Secs. 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657, Secretary of Labor's Orders Nos. 12-71 (36 FR 8754), 8-76 (41 FR 25059), or 9-83 (48 FR 35736), as applicable; and 29 CFR part 1911.

* * * *

Section 1910.1030 also issued under 29 U.S.C 653.

* * * *

2. Section 1910.1030 is added to read as follows:

§ 1910.1030 Bloodborne Pathogens.

(a) Scope and Application.

This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

(b) Definitions. For purposes of this section, the following shall apply:

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

Blood means human blood, human blood components, and products made from human blood.

Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, Hepatitis B

virus (HBV) and human immunodeficiency virus (HIV).

Clinical Laboratory means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

Contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Laundry means laundry which has been soiled with blood or other potentially infectious material or may contain sharps.

Contaminated Sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

Engineering Controls means controls (e.g., sharps disposal containers, self-sheathing needles) that isolate or remove the bloodborne pathogens hazard from the workplace.

Exposure Incident means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

Handwashing Facilities

means a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

Licensed Healthcare Professional is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

HBV means Hepatitis B virus.

HIV means human immunodeficiency virus.

Occupational Exposure

means 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.

Other Potentially Infectious Materials means

(1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

(2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral means piercing mucous membranes or the skin barrier through such events

as needle sticks, human bites, cuts, and abrasions.

Personal Protective Equipment is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

Production Facility means a facility engaged in industrial-scale, large volume or high concentration production of HIV or HBV.

Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Research Laboratory means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

Source Individual means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment

facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

Sterilize means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other blood-borne pathogens.

Work Practice Controls means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

(c) Exposure control-- (1) Exposure Control Plan. (i) Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

(ii) The Exposure Control Plan shall contain at least the following elements:

(A) The exposure determination required by paragraph (c)(2);

(B) The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard; and

(C) The procedure for the evaluation of circumstances surrounding exposure inci-

dents as required by paragraph (f)(3)(i) of this standard.

(iii) Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.20(e).

(iv) The Exposure Control Plan shall be reviewed and updated at least annually 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.

(v) The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.

(2) Exposure determination.

(i) Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

(A) A list of all job classifications in which all employees in those job classifications have occupational exposure;

(B) A list of job classifications in which some employees have occupational exposure; and

(C) A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

(ii) This exposure determination shall be made without regard to the use of personal protective equipment.

(d) Methods of compliance-- (1) General-- Universal pre-

cautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

(2) *Engineering and work practice controls.* (i) Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

(ii) Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

(iii) Employers shall provide handwashing facilities which are readily accessible to employees.

(iv) When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleaners or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

(v) Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

(vi) Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or

other potentially infectious materials.

(vii) Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.

(A) Contaminated needles and other contaminated sharps shall not be recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical procedure.

(B) Such recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

(viii) Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

(A) Puncture resistant;

(B) Labeled or color-coded in accordance with this standard;

(C) Leakproof on the sides and bottom; and

(D) In accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

(ix) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

(x) Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.

(xi) All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

(xii) Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

(xiii) Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

(A) The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped.

When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.

(B) If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.

(C) If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

(xiv) Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

(A) A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated.

(B) The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

(3) Personal protective equipment:

(i) Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

(ii) Use. The employer shall ensure that the employee

uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgment, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

(iii) Accessibility. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the work site or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

(iv) Cleaning, Laundering, and Disposal. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee.

(v) Repair and Replacement. The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

(vi) If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

(vii) All personal protective equipment shall be removed prior to leaving the work area.

(viii) When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

(iv) Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

(A) Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

(B) Disposable (single use) gloves shall not be washed or decontaminated for re-use.

(C) Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

(D) If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall:

(1) Periodically reevaluate this policy;

(2) Make gloves available to all employees who wish to use them for phlebotomy;

(3) Not discourage the use of gloves for phlebotomy; and

(4) Require that gloves be used for phlebotomy in the following circumstances:

- (i) When the employee has cuts, scratches, or other breaks in his or her skin;
 - (ii) When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and
 - (iii) When the employee is receiving training in phlebotomy.
- (x) **Masks, Eye Protection, and Face Shields.** Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.
- (xi) **Gowns, Aprons, and Other Protective Body Clothing.** Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.
- (xii) **Surgical caps or hoods and/or shoe covers or boots** shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).

(4) **Housekeeping.** (i) General. Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type

of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

(ii) All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

(A) Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

(B) Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the work shift if they may have become contaminated during the shift.

(C) All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

(D) Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.

(E) Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

(iii) **Regulated Waste.**

(A) **Contaminated Sharps Discarding and Containment.** (1) Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

- (i) Closable;
 - (ii) Puncture resistant;
 - (iii) Leakproof on sides and bottom; and
 - (iv) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.
- (2) During use, containers for contaminated sharps shall be:
- (i) Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);
 - (ii) Maintained upright throughout use; and
 - (iii) Replaced routinely and not be allowed to overfill.
- (3) When moving containers of contaminated sharps from the area of use, the containers shall be:
- (i) Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;
 - (ii) Placed in a secondary container if leakage is possible. The second container shall be:
- (A) Closable;
 - (B) Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and

- (C) Labeled or color-coded according to paragraph (g)(1)(i) of this standard.
- (4) Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.
- (B) Other Regulated Waste Containment. (1) Regulated waste shall be placed in containers which are:
- (i) Closable;
 - (ii) Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;
 - (iii) Labeled or color-coded in accordance with paragraph (g)(1)(i) this standard; and
 - (iv) Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
- (2) If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be:
- (i) Closable;
 - (ii) Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;
 - (iii) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and
 - (iv) Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
- (C) Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.
- (iv) Laundry.
- (A) Contaminated laundry shall be handled as little as possible with a minimum of agitation. (1) Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.
- (2) Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.
- (3) Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.
- (B) The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.
- (C) When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).
- (e) *HIV and HBV Research Laboratories and Production Facilities.*
- (1) This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.
- (2) Research laboratories and production facilities shall meet the following criteria:
- (i) Standard microbiological practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.
 - (ii) Special practices.
 - (A) Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.
 - (B) Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.
 - (C) Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.
 - (D) When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this standard.
 - (E) All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these

other potentially infectious materials shall be conducted on the open bench.

(F) Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

(G) Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

(H) Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

(I) Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

(J) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly

placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.

(K) All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

(L) A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

(M) A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

(iii) Containment equipment.

(A) Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

(B) Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

(3) HIV and HBV research laboratories shall meet the following criteria:

(i) Each laboratory shall contain a facility for handwashing and an eye wash facility which is readily available within the work area.

(ii) An autoclave for decontamination of regulated waste shall be available.

(4) HIV and HBV production facilities shall meet the following criteria:

(i) The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

(ii) The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

(iii) Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

(iv) Access doors to the work area or containment module shall be self-closing.

(v) An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

(vi) A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The

exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

(5) *Training Requirements.* Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

(f) *Hepatitis B vaccination and post-exposure evaluation and follow-up--(1) General.* (i) The employer shall make available the Hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

(ii) The employer shall ensure that all medical evaluations and procedures including the Hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

(A) Made available at no cost to the employee;

(B) Made available to the employee at a reasonable time and place;

(C) Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

(D) Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

(iii) The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

(2) *Hepatitis B Vaccination.* (i) Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete Hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

(ii) The employer shall not make participation in a pre-screening program a prerequisite for receiving Hepatitis B vaccination.

(iii) If the employee initially declines Hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available Hepatitis B vaccination at that time.

(iv) The employer shall assure that employees who decline to accept Hepatitis B vaccination offered by the employer sign the statement in appendix A.

(v) If a routine booster dose(s) of Hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

(3) *Post-exposure Evaluation and Follow-up.* Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

(i) Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

(ii) Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

(A) The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

(B) When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

(C) Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

(iii) Collection and testing of blood for HBV and HIV serological status;

(A) The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

(B) If the employee consent to baseline blood collection, but does not give consent at the time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

(iv) Post-exposure prophylaxis, when medically indi-

cated, as recommended by the U.S. Public Health Service;

(v) Counseling; and

(vi) Evaluation of reported illnesses.

(4) Information Provided to the Healthcare Professional.

(i) The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

(ii) The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

(A) A copy of this regulation;

(B) A description of the exposed employee's duties as they relate to the exposure incident;

(C) Documentation of the route(s) of exposure and circumstances under which exposure occurred;

(D) Results of the source individual's blood testing, if available; and

(E) All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

(5) Healthcare Professional's Written Opinion. The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

(i) The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

(ii) The healthcare professional's written opinion for

post-exposure evaluation and follow-up shall be limited to the following information:

(A) That the employee has been informed of the results of the evaluation; and

(B) That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

(iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report.

(6) Medical Recordkeeping. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

(g) Communication of hazards to employees— (1) Labels and signs. (i) Labels. (A) Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

(B) Labels required by this section shall include the following legend:

BIOHAZARD

(C) These labels shall be fluorescent orange or orange-red or predominantly so, with lettering or symbols in a contrasting color.

(D) Labels required by affixed as close as feasible to the container by string, wire, adhesive, or other method that pre-

vents their loss or unintentional removal.

(E) Red bags or red containers may be substituted for labels.

(F) Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

(G) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

(H) Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

(I) Regulated waste that has been decontaminated need not be labeled or color-coded.

(ii) Signs. (A) The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:

BIOHAZARD

(Name of the Infectious Agent)

(Special requirements for entering the area)

(Name, telephone number of the laboratory director or other responsible person.)

(B) These signs shall be fluorescent orange-red or predominantly so, with lettering or symbols in a contrasting color.

(2) *Information and Training.*

(i) Employers shall ensure that all employees with occupational exposure participate in a training program which must be provided at no cost to the employee and during working hours.

(ii) Training shall be provided as follows:

(A) At the time of initial assignment to tasks where occupational exposure may take place;

(B) Within 90 days after the effective date of the standard; and

(C) At least annually thereafter.

(iii) For employees who have received training on bloodborne pathogens in the year preceding the effective date of the standard, only training with respect to the provisions of the standard which were not included need be provided.

(iv) Annual training for all employees shall be provided within one year of their previous training.

(v) Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

(vi) Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

(vii) The training program shall contain at a minimum the following elements:

(A) An accessible copy of the regulatory text of this standard and an explanation of its contents;

(B) A general explanation of the epidemiology and symptoms of bloodborne diseases;

(C) An explanation of the modes of transmission of bloodborne pathogens;

(D) An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

(E) An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

(F) 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;

(G) Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

(H) An explanation of the basis for selection of personal protective equipment;

(I) Information on the Hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

(J) Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

(K) 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;

(L) Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

(M) An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and

(N) An opportunity for interactive questions and answers with the person conducting the training session.

(viii) The person conducting the training shall 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.

(ix) Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

(A) The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

(B) The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

(C) The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

- (h) *Recordkeeping – (1) Medical Records.* (i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.20
- (ii) This record shall include:
- (A) The name and social security number of the employee;
- (B) A copy of the employee's Hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);
- (C) A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);
- (D) The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and
- (E) A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).
- (iii) Confidentially. The employer shall ensure that employee medical records required by paragraph (h)(1) are:
- (A) Kept confidential; and
- (B) Are not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.
- (iv) The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.20
- (2) *Training Records.* (i) *Training records shall include the following information:*
- (A) The dates of the training sessions;
- (B) The contents or a summary of the training sessions;
- (C) The names and qualifications of persons conducting the training; and
- (D) The names and job titles of all persons attending the training sessions.
- (ii) Training records shall be maintained for 3 years from the date on which the training occurred.
- (3) *Availability.* (i) The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary of the Director for examination and copying.
- (ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.20.
- (iii) Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.20.
- (4) *Transfer of Records.* (i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.20(h).
- (ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period.
- (i) *Dates - (1) Effective Date.* The standard shall become effective on March 6, 1992.
- (2) The Exposure Control Plan required by paragraph (c)(2) of this section shall be completed on or before May 5, 1992.
- (3) Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on or before June 4, 1992.
- (4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs, shall take effect July 6, 1992.

Appendix A to Section 1910.1030 -- Hepatitis B Vaccine Declination (Mandatory)

I understand that due to my occupational exposure to blood or other potentially infectious material I may be at risk of acquiring Hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with Hepatitis B vaccine, at no charge to myself. However, I decline Hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring Hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with Hepatitis B vaccine, I can receive the vaccination series at no charge to me.

[FR Doc. 91-28886 Filed 12-2-91; 8:45 am]

Appendix G

Special Report

Guideline for Isolation Precautions in Hospitals

Julia S. Garner, RN, MN; the Hospital Infection Control Practices Advisory Committee

PART I: EVOLUTION OF ISOLATION PRACTICES

INTRODUCTION

To assist hospitals in maintaining up-to-date isolation practices, the Centers for Disease Control and Prevention (CDC) and the Hospital Infection Control Practices Advisory Committee¹ (HICPAC) have revised the "CDC Guideline for Isolation Precautions in Hospitals." HICPAC was established in 1991 to provide advice and guidance to the Secretary, Department of Health and Human Services (DHHS); the Assistant Secretary for Health, DHHS; the Director, CDC; and the Director, National Center for Infectious Diseases, regarding the practice of hospital infection control and strategies for surveillance, prevention, and control of nosocomial infections in US hospitals. HICPAC also advises the CDC on periodic updating of guidelines and other policy statements regarding prevention of nosocomial infections.

The revised guideline contains two parts. Part I, "Evolution of Isolation Practices," reviews the evolution of isolation practices in US hospitals, including their advantages, disadvantages, and controversial aspects, and provides the background for the HICPAC-consensus recommendations contained in Part II, "Recommendations for Isolation Precautions in Hospitals." The guideline supersedes previous CDC recommendations for isolation precautions in hospitals.^{2,4}

The guideline recommendations are based on the latest epidemiologic information on transmission of infection in hospitals. The recommendations are intended primarily for use in the care of patients in acute-care hospitals, although some of the recom-

mendations may be applicable for some patients receiving care in subacute-care or extended-care facilities. The recommendations are not intended for use in daycare, well care, or domiciliary care programs. Because there have been few studies to test the efficacy of isolation precautions and gaps still exist in the knowledge of the epidemiology and modes of transmission of some diseases, disagreement with some of the recommendations is expected. A working draft of the guideline was reviewed by experts in infection control and published in the *Federal Register* for public comment. However, all recommendations in the guideline may not reflect the opinions of all reviewers.

HICPAC recognizes that the goal of preventing transmission of infections in hospitals can be accomplished by multiple means and that hospitals will modify the recommendations according to their needs and circumstances and as directed by federal, state, or local regulations. Modification of the recommendations is encouraged if (1) the principles of epidemiology and disease transmission are maintained, and (2) precautions are included to interrupt spread of infection by all routes that are likely to be encountered in the hospital.

SUMMARY

The "Guideline for Isolation Precautions in Hospitals" was revised to meet the following objectives: (1) to be epidemiologically sound; (2) to recognize the importance of all body fluids, secretions, and excretions in the transmission of nosocomial pathogens; (3) to contain adequate precautions for infections transmitted by the airborne, droplet, and contact routes of transmission; (4) to be as simple

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and user friendly as possible; and, (5) to use new terms to avoid confusion with existing infection control and isolation systems.

The revised guideline contains two tiers of precautions. In the first, and most important, tier are those precautions designed for the care of all patients in hospitals regardless of their diagnosis or presumed infection status. Implementation of these "Standard Precautions" is the primary strategy for successful nosocomial infection control. In the second tier are precautions designed only for the care of specified patients. These additional "Transmission-Based Precautions" are used for patients known or suspected to be infected or colonized with epidemiologically important pathogens that can be transmitted by airborne or droplet transmission or by contact with dry skin or contaminated surfaces.

Standard Precautions synthesize the major features of Universal (Blood and Body Fluid) Precautions (designed to reduce the risk of transmission of bloodborne pathogens) and Body Substance Isolation (designed to reduce the risk of transmission of pathogens from moist body substances). Standard Precautions apply to (1) blood; (2) all body fluids, secretions, and excretions *except sweat*, regardless of whether or not they contain visible blood; (3) nonintact skin; and, (4) mucous membranes. Standard Precautions are designed to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection in hospitals.

Transmission-Based Precautions are designed for patients documented or suspected to be infected or colonized with highly transmissible or epidemiologically important pathogens for which additional precautions beyond Standard Precautions are needed to interrupt transmission in hospitals. There are three types of Transmission-Based Precautions: Airborne Precautions, Droplet Precautions, and Contact Precautions. They may be combined for diseases that have multiple routes of transmission. When used either singularly or in combination, they are to be used in addition to Standard Precautions.

The revised guideline also lists specific clinical syndromes or conditions in both adult and pediatric patients that are highly suspicious for infection and identifies appropriate Transmission-Based Precautions to use on an empiric, temporary basis until a diagnosis can be made; these empiric, temporary precautions are also to be used in addition to Standard Precautions.

EARLY ISOLATION PRACTICES

The first published recommendations for isolation precautions in the United States appeared as

early as 1877, when a hospital handbook recommended placing patients with infectious diseases in separate facilities,⁵ which ultimately became known as infectious disease hospitals. Although this practice segregated infected patients from noninfected patients, nosocomial transmission continued to occur because infected patients were not separated from each other according to their disease, and few, if any, aseptic procedures were practiced. Personnel in infectious disease hospitals began to combat problems of nosocomial transmission by setting aside a floor or ward for patients with similar diseases⁶ and by practicing aseptic procedures recommended in nursing textbooks published from 1890 to 1900.⁵

In 1910, isolation practices in US hospitals were altered by the introduction of the cubicle system of isolation, which placed patients in multiple-bed wards.⁶ With the cubicle system, hospital personnel used separate gowns, washed their hands with antiseptic solutions after patient contact, and disinfected objects contaminated by the patient. These nursing procedures, designed to prevent transmission of pathogenic organisms to other patients and personnel, became known as "barrier nursing." Use of the cubicle system of isolation and barrier nursing procedures provided general hospitals with an alternative to placing some patients in infectious disease hospitals.

During the 1950s, US infectious disease hospitals, except those designated exclusively for tuberculosis, began to close. In the mid-1960s, tuberculosis hospitals also began to close, partly because general hospital or outpatient treatment became preferred for patients with tuberculosis. Thus, by the late 1960s, patients with infectious diseases were housed in wards in general hospitals, either in specially designed, single-patient isolation rooms or in regular single or multiple-patient rooms.

CDC ISOLATION SYSTEMS

CDC Isolation Manual

In 1970, CDC published a detailed manual entitled *Isolation Techniques for Use in Hospitals* to assist general hospitals with isolation precautions.² A revised edition appeared in 1975.³ The manual could be applied in small community hospitals with limited resources, as well as in large, metropolitan, university-associated medical centers.

The manual introduced the category system of isolation precautions. It recommended that hospitals use one of seven isolation categories (Strict Isolation, Respiratory Isolation, Protective Isolation, Enteric Precautions, Wound and Skin Precautions,

Discharge Precautions, and Blood Precautions). The precautions recommended for each category were determined almost entirely by the epidemiologic features of the diseases grouped in the category, primarily their routes of transmission. Certain isolation techniques, believed to be the minimum necessary to prevent transmission of all diseases in the category, were indicated for each isolation category. Because all diseases in a category did not have the same epidemiology (ie, were not spread by exactly the same combination of modes of transmission), with some requiring fewer precautions than others, more precautions were suggested for some diseases than were necessary. This disadvantage of "over-isolation" for some diseases was offset by the convenience of having a small number of categories. More importantly, the simple system required personnel to learn only a few established routines for applying isolation precautions. To make the system even more user friendly, instructions for each category were printed on color-coded cards and placed on the doors, beds, or charts of patients on isolation precautions.

By the mid-1970s, 93% of US hospitals had adopted the isolation system recommended in the manual.⁷ However, neither the efficacy of the category approach in preventing spread of infections nor the costs of using the system were evaluated by empirical studies.

By 1980, hospitals were experiencing new endemic and epidemic nosocomial infection problems, some caused by multidrug-resistant microorganisms and others caused by newly recognized pathogens, which required different isolation precautions from those specified by any existing isolation category. There was increasing need for isolation precautions to be directed more specifically at nosocomial transmission in special-care units, rather than at the intrahospital spread of infectious diseases acquired in the community.⁸ Infection control professionals and nursing directors in hospitals with particularly sophisticated nursing staffs increasingly were calling for new isolation systems that would tailor precautions to the modes of transmission for each infection and avoid the over-isolation inherent in the category-specific approach. Further, new facts about the epidemiology and modes of transmission of some diseases made it necessary for CDC to revise the isolation manual. Toward that end, during 1981 to 1983, CDC Hospital Infections Program personnel consulted with infectious disease specialists in medicine, pediatrics, and surgery; hospital epidemiologists; and infection control practitioners about revising the manual.

CDC Isolation Guideline

In 1983, the *CDC Guideline for Isolation Precautions in Hospitals*⁴ (hereafter referred to as the isolation guideline) was published to take the place of the 1975 isolation manual; it contained many important changes. One of the most important was the increased emphasis on decision making on the part of users. Unlike the 1975 manual, which encouraged few decisions on the part of users, the isolation guideline encouraged decision making at several levels.^{9,10} First, hospital infection control committees were given a choice of selecting between category-specific or disease-specific isolation precautions or using the guideline to develop a unique isolation system appropriate to their hospitals' circumstances and environments. Second, personnel who placed a patient on isolation precautions were encouraged to make decisions about the individual precautions to be taken (eg, whether the patient's age, mental status, or condition indicated that a private room was needed to prevent sharing of contaminated articles). Third, personnel taking care of patients on isolation precautions were encouraged to decide whether they needed to wear a mask, gown, or gloves based on the likelihood of exposure to infective material. Such decisions were deemed necessary to isolate the infection, but not the patient, and to reduce the costs associated with unnecessary isolation precautions.

In the category-specific section of the guideline, existing categories were modified, new categories were added, and many infections were reassigned to different categories. The old category of Blood Precautions, primarily directed toward patients with chronic carriage of hepatitis B virus (HBV), was renamed Blood and Body Fluid Precautions and was expanded to include patients with AIDS and body fluids other than blood. The old category of Protective Isolation was deleted because of studies demonstrating its lack of efficacy in general clinical practice in preventing the acquisition of infection by the immunocompromised patient for whom it had been described originally.^{11,12} The 1983 guideline contained the following categories of isolation: Strict Isolation, Contact Isolation, Respiratory Isolation, Tuberculosis (acid-fast bacilli [AFB]) Isolation, Enteric Precautions, Drainage/Secretion Precautions, and Blood and Body Fluid Precautions. As with the category approach in the former CDC isolation manuals, these categories tended to over-isolate some patients.

In the disease-specific section of the guideline, the epidemiology of each infectious disease was considered individually by advocating only those precautions (eg, private room, mask, gown, and gloves) needed to interrupt transmission of the infection. In

place of the categories and signs of the category-specific approach, a chart listed all diseases posing the threat of in-hospital transmission, with checks in columns indicating which precautions were required for each. Because precautions were individualized for each disease, hospitals using the system were encouraged to provide more initial training and inservice education and to encourage a much higher level of attention from patient-care personnel. Although disease-specific isolation precautions eliminated over-isolation, personnel might be prone to mistakes in applying the precautions, particularly if the disease was not seen regularly in the hospital,^{9,10} if there was a delay in diagnosis, or if there was a misdiagnosis. Placing disease-specific isolation precautions in a hospital computerized information system resulted in more accurate use of the system.¹³

Because gaps existed in the knowledge of the epidemiology of some diseases, disagreement was expected, and occurred, regarding the placement of individual diseases within given categories, especially diseases with a respiratory component of transmission.¹⁴ Placing measles in Respiratory Isolation (designed to prevent transmission of large-particle droplets) rather than in a category that had provisions for preventing transmission by airborne droplet nuclei and placing rubella and respiratory syncytial virus (RSV) infection in Contact Isolation were controversial.¹⁵ There also was disagreement about the lack of a recommendation for adult patients with influenza, the need for private rooms for pediatric patients with RSV infections, and the length of time that precautions should be maintained.¹⁵ The lack of empiric studies on the efficacy and costs of implementing the recommendations contributed to the disagreements.

As new epidemiologic data became available, several subsequent CDC reports¹⁶⁻¹⁸ updated portions of the isolation guideline. Updated recommendations for management of patients with suspected hemorrhagic fever were published in 1988.¹⁶ The recommendation for Respiratory Isolation for acute erythema infectiosum was superseded by a 1989 report that recommended Respiratory Isolation for human parvovirus B19 (the causative agent for erythema infectiosum) only when infected patients were in transient aplastic crisis or had immunodeficiency and chronic human parvovirus B19 infection.¹⁷

Recommendations for Tuberculosis (AFB) Isolation were updated in 1990¹⁸ because of heightened concern about nosocomial transmission of multidrug-resistant tuberculosis,^{19,20} particularly in settings where persons with human immunodeficiency virus (HIV) infection were receiving care. The 1990 tuberculosis guidelines emphasized (1) placing a hospital

patient with confirmed or suspected tuberculosis in a private room that has lower, or negative, air pressure compared with surrounding areas; (2) reducing mycobacterial contamination of air by dilution and removal of airborne contaminants; and, (3) wearing particulate respirators, rather than standard surgical masks, when hospital personnel shared air space with an infectious tuberculosis patient. Subsequent recommendations reemphasized the importance of early diagnosis and treatment of tuberculosis.²¹ In 1993, a second edition of the guidelines for preventing the transmission of tuberculosis in healthcare facilities was published in draft for public comment.²² After review of written comments, the guidelines were modified and published.²³

UNIVERSAL PRECAUTIONS

In 1985, largely because of the HIV epidemic, isolation practices in the United States were altered dramatically by the introduction of a new strategy for isolation precautions, which became known as Universal Precautions (UP). Following the initial reports of hospital personnel becoming infected with HIV through needlesticks and skin contamination with patients' blood, a widespread outcry created the urgent need for new isolation strategies to protect hospital personnel from bloodborne infections. The subsequent modification of isolation precautions in some hospitals produced several major strategic changes and sacrificed some measures of protection against patient-to-patient transmission in the process of adding protection against patient-to-personnel transmission. In acknowledgment of the fact that many patients with bloodborne infections are not recognized, the new UP approach for the first time placed emphasis on applying Blood and Body Fluid Precautions universally to all persons regardless of their presumed infection status.²⁴ Until this time, most patients placed on isolation precautions were those for whom a diagnosis of an infectious disease had been made or was suspected. This provision led to the new name of Universal Precautions.

In addition to emphasizing prevention of needlestick injuries and the use of traditional barriers such as gloves and gowns, UP expanded Blood and Body Fluid Precautions to include use of masks and eye coverings to prevent mucous membrane exposures during certain procedures and the use of individual ventilation devices when the need for resuscitation was predictable. This approach, and particularly the techniques for preventing mucous membrane exposures, was reemphasized in subsequent CDC reports that contained recommendations for prevention of HIV transmission in healthcare settings.²⁵⁻²⁸

In 1987, one of these reports²⁷ stated that implementation of UP for all patients eliminated the need for the isolation category of Blood and Body Fluid Precautions for patients known or suspected to be infected with bloodborne pathogens; however, the report stated that other category- or disease-specific isolation precautions recommended in the CDC isolation guideline⁴ should be used as necessary if infections other than bloodborne infections were diagnosed or suspected.

The 1987 report was updated by a 1988 report²⁸ that emphasized two important points: (1) blood was the single most important source of HIV, HBV, and other bloodborne pathogens in the occupational setting, and (2) infection control efforts for preventing transmission of bloodborne pathogens in healthcare settings must focus on preventing exposures to blood, as well as on delivery of HBV immunization. The report stated that UP applied to blood, to body fluids that had been implicated in the transmission of bloodborne infections (semen and vaginal secretions), to body fluids from which the risk of transmission was unknown (amniotic, cerebrospinal, pericardial, peritoneal, pleural, and synovial fluids), and to any other body fluid visibly contaminated with blood, but not to feces, nasal secretions, sputum, sweat, tears, urine, or vomitus unless they contained visible blood. Although HIV and HBV surface antigen (HBsAg) had been found in some of the fluids, secretions, or excretions to which UP did not apply, epidemiologic studies in the healthcare and community settings had not implicated these substances in the transmission of HIV and HBV infections. However, the report noted that some of the fluids, secretions, and excretions not covered under UP represented a potential source for nosocomial and community-acquired infections with other pathogens and referred readers to the CDC isolation guideline.

BODY SUBSTANCE ISOLATION

In 1987, a new system of isolation, called Body Substance Isolation (BSI), was proposed after 3 years of study by infection control personnel at the Harborview Medical Center in Seattle, Washington, and the University of California at San Diego, California, as an alternative to diagnosis-driven isolation systems.²⁹ BSI focused on the isolation of all moist and potentially infectious body substances (blood, feces, urine, sputum, saliva, wound drainage, and other body fluids) from all patients, regardless of their presumed infection status, primarily through the use of gloves. Personnel were instructed to put on clean gloves just before contact with mucous membranes and nonintact skin, and to wear gloves

for anticipated contact with moist body substances. In addition, a "Stop Sign Alert" was used to instruct persons wishing to enter the room of some patients with infections transmitted exclusively, or in part, by the airborne route to check with the floor nurse, who would determine whether a mask should be worn. Personnel were to be immune to or immunized against selected infectious diseases transmitted by airborne or droplet routes (measles, mumps, rubella, and varicella), or they were not to enter the rooms housing patients with these diseases. Other issues related to implementing BSI in a university teaching hospital were described.³⁰

Among the advantages cited for BSI were that it was a simple, easy to learn and administer system, that it avoided the assumption that individuals without known or suspected diagnoses of transmissible infectious diseases were free of risk to patients and personnel, and that only certain body fluids were associated with transmission of infections. The disadvantages of BSI included the added cost of increased use of barrier equipment, particularly gloves³¹; the difficulty in maintaining routine application of the protocol for all patients; the uncertainty about the precautions to be taken when entering a room with a "Stop Sign Alert"; and the potential for misapplication of the protocol to overprotect personnel at the expense of the patient.³²

In a prospective study,³³ a combination use of gown and glove protocols similar to BSI led to lower infection rates in a pediatric intensive care unit (ICU), and, in other studies, similar combinations of barriers were associated with lower rates of nosocomial RSV infection in a pediatric ICU³⁴ and of resistant gram-negative organisms in an acute-care hospital.³⁵ However, in none of these studies, initiated before publication of BSI, nor were the authors attempting to evaluate BSI, nor were they able to separate the effect of gloves from that of gowns or from gloves and gowns used in combination.

Controversial aspects of BSI have been summarized.^{15,36} BSI appeared to replace some, but not all, of the isolation precautions necessary to prevent transmission of infection. BSI did not contain adequate provisions to prevent (1) droplet transmission of serious infections in pediatric populations (eg, invasive *Haemophilus influenzae*, *Neisseria meningitidis* meningitis and pneumonia, and pertussis); (2) direct or indirect contact transmission of epidemiologically important microorganisms from dry skin or environmental sources (eg, *Clostridium difficile* and vancomycin-resistant enterococci); or, (3) true airborne transmission of infections transmitted over long distances by floating droplet nuclei. Although BSI emphasized that

a private room was indicated for some patients with some diseases transmitted exclusively, or in part, by the true airborne route, it did not emphasize the need for special ventilation for patients known or suspected of having pulmonary tuberculosis or other diseases transmitted by airborne droplet nuclei. The lack of emphasis on special ventilation was of particular concern to CDC in the early 1990s because of multidrug-resistant tuberculosis.^{18,19}

BSI and UP shared many similar features designed to prevent the transmission of bloodborne pathogens in hospitals. However, there was an important difference in the recommendation for glove use and handwashing. Under UP, gloves were recommended for anticipated contact with blood and specified body fluids, and hands were to be washed immediately after gloves were removed.^{27,28} Under BSI, gloves were recommended for anticipated contact with any moist body substance, but handwashing after glove removal was not required unless the hands visibly were soiled.²⁹ The lack of emphasis on handwashing after glove removal was cited as one of the theoretical disadvantages of BSI.^{15,37,38} Using gloves as a protective substitute for handwashing may have provided a false sense of security, resulted in less handwashing, increased the risk of nosocomial transmission of pathogens, because hands can become contaminated even when gloves are used³⁹ and are contaminated easily in the process of removing gloves, and contributed to skin problems and allergies associated with the use of gloves.^{40,41} On the other hand, proponents of BSI have noted that studies of handwashing have indicated that there is relatively low compliance by hospital personnel,^{42,43} that glove use may have been easier to manage than handwashing, and that frequent handwashing may have led to eczema, skin cracking, or, in some persons, clinical damage to the skin of the hands.⁴⁴ Although use of gloves may have been better than no handwashing, the efficacy of using gloves as a substitute for handwashing has not been demonstrated.

OSHA BLOODBORNE PATHOGENS REGULATIONS

In 1989, the Occupational Safety and Health Administration (OSHA) published a proposed rule regarding occupational exposure to bloodborne pathogens in hospitals and other healthcare settings.⁴⁵ The proposed rule, based on the concept of UP, raised concerns in the infection control community. Among them were concerns about the use of "visibly bloody" as a marker for the infectious risk of certain body fluids and substances, the imbalance toward precautions to protect personnel and away

from protection for patients, the lack of proven efficacy of UP, and the costs for implementing the proposed regulations.⁴⁶⁻⁵⁰ After a series of OSHA public hearings and the review of written comments, the proposed rule was modified, and the final rule on occupational exposure to bloodborne pathogens was published in 1991.⁵¹ Although the final rule was expected to improve occupational safety in the care of patients infected with bloodborne pathogens, its impact on the cost of patient care and on nosocomial infection control has remained undefined. Information on complying with the OSHA final rule has been made available by the American Hospital Association⁵² and others.⁵³

THE NEED FOR A NEW ISOLATION GUIDELINE

By the early 1990s, isolation had become an infection control conundrum.⁵⁴ Although many hospitals had incorporated all or portions of UP into their category- or disease-specific isolation system and others had adopted all or portions of BSI,^{55,56} there was much local variation in the interpretation and use of UP and BSI, and a variety of combinations was common. Further, there was considerable confusion about which body fluids or substances required precautions under UP and BSI. Many hospitals espousing UP really were using BSI and vice versa. Moreover, there was continued lack of agreement about the importance of handwashing when gloves were used^{14,15,27-29,37,38,57,58} and the need for additional precautions beyond BSI to prevent airborne, droplet, and contact transmission.^{14,15,27-29,31,36,59,60} Some hospitals had not implemented appropriate guidelines for preventing transmission of tuberculosis, including multidrug-resistant tuberculosis.⁶¹ As other multidrug-resistant microorganisms^{62,63} were emerging, some hospitals failed to recognize them as new problems and to add appropriate precautions that would contain them.

In view of these problems and concerns, no simple adjustment to any of the existing approaches—UP, BSI, the CDC isolation guideline, or other isolation systems—appeared likely to solve the conundrum. Clearly what was needed was a new synthesis of the various systems that would provide a guideline with logistically feasible recommendations for preventing the many infections that occur in hospitals through diverse modes of transmission. To achieve this, the new guideline would (1) have to be epidemiologically sound; (2) have to recognize the importance of all body fluids, secretions, and excretions in the transmission of nosocomial pathogens; (3) have to contain adequate precautions for infections transmitted by the airborne, droplet, and con-

tact routes of transmission; (4) have to be as simple and user friendly as possible; and, (5) have to use new terms to avoid confusion with existing systems.

Based on these considerations, this guideline subsequently was developed. It contains three important changes from previous recommendations. First, it synthesizes the major features of UP^{27,28} and BSI^{29,30} into a single set of precautions to be used for the care of all patients in hospitals regardless of their presumed infection status. These precautions, called Standard Precautions, are designed to reduce the risk of transmission of bloodborne and other pathogens in hospitals. As a result of this synthesis, a large number of patients with diseases or conditions that previously required category- or disease-specific precautions in the 1983 CDC isolation guideline⁴ now are covered under Standard Precautions and do not require additional precautions. Second, it collapses the old categories of isolation precautions (Strict Isolation, Contact Isolation, Respiratory Isolation, Tuberculosis Isolation, Enteric Precautions, and Drainage/Secretion Precautions) and the old disease-specific precautions into three sets of precautions based on routes of transmission for a smaller number of specified patients known or suspected to be infect-

ed or colonized with highly transmissible or epidemiologically important pathogens. These Transmission-Based Precautions, designed to reduce the risk of airborne, droplet, and contact transmission in hospitals, are to be used in addition to Standard Precautions. Third, it lists specific syndromes in both adult and pediatric patients that are highly suspicious for infection and identifies appropriate Transmission-Based Precautions to use on an empiric, temporary basis until a diagnosis can be made. These empiric, temporary precautions also are designed to be used in addition to Standard Precautions. The details of the guideline recommendations are presented in Part II, "Recommendations for Isolation Precautions in Hospitals."

In summary, this new guideline is another step in the evolution of isolation practices in US hospitals. It now is recommended for review and use by hospitals with the following provision. No guideline can address all of the needs of the more than 6,000 US hospitals, which range in size from five beds to more than 1,500 beds and serve very different patient populations. Hospitals are encouraged to review the recommendations and to modify them according to what is possible, practical, and prudent.

PART II: RECOMMENDATIONS FOR ISOLATION PRECAUTIONS IN HOSPITALS

Hospital Infection Control Practices Advisory Committee

RATIONALE FOR ISOLATION PRECAUTIONS IN HOSPITALS

Transmission of infection within a hospital requires three elements: a source of infecting microorganisms, a susceptible host, and a means of transmission for the microorganism.

Source

Human sources of the infecting microorganisms in hospitals may be patients, personnel, or, on occasion, visitors, and may include persons with acute disease, persons in the incubation period of a disease, persons who are colonized by an infectious agent but have no apparent disease, or persons who are chronic carriers of an infectious agent. Other sources of infecting microorganisms can be the patient's own endogenous flora, which may be difficult to control, and inanimate environmental objects that have become contaminated, including equipment and medications.

Host

Resistance among persons to pathogenic microorganisms varies greatly. Some persons may be immune to infection or may be able to resist colonization by an infectious agent; others exposed to the same agent may establish a commensal relationship with the infecting microorganism and become asymptomatic carriers; still others may develop clinical disease. Host factors such as age; underlying diseases; certain treatments with antimicrobials, corticosteroids, or other immunosuppressive agents; irradiation; and breaks in the first line of defense mechanisms caused by such factors as surgical operations, anesthesia, and indwelling catheters may render patients more susceptible to infection.

Transmission

Microorganisms are transmitted in hospitals by several routes, and the same microorganism may be transmitted by more than one route. There are five main routes of transmission—contact, droplet, airborne, common vehicle, and vectorborne. For the purpose of this guideline, common vehicle and vectorborne transmission will be discussed only briefly, because neither play a significant role in typical nosocomial infections.

- (1) *Contact transmission*, the most important and frequent mode of transmission of nosocomial infections, is divided into two subgroups: direct-contact transmission and indirect-contact transmission.
 - (a) Direct-contact transmission involves a direct body surface-to-body surface contact and physical transfer of microorganisms between a susceptible host and an infected or colonized person, such as occurs when a person turns a patient, gives a patient a bath, or performs other patient-care activities that require direct personal contact. Direct-contact transmission also can occur between two patients, with one serving as the source of the infectious microorganisms and the other as a susceptible host.
 - (b) Indirect-contact transmission involves contact of a susceptible host with a contaminated intermediate object, usually inanimate, such as contaminated instruments, needles, or dressings, or contaminated hands that are not washed and gloves that are not changed between patients.
- (2) *Droplet transmission*, theoretically, is a form of contact transmission. However, the mechanism of transfer of the pathogen to the host is quite distinct from either direct- or indirect-contact transmission. Therefore, droplet transmission will be considered a separate route of transmission in this guideline. Droplets are generated from the source person primarily during coughing, sneezing, and talking, and during the performance of certain procedures such as suctioning and bronchoscopy. Transmission occurs when droplets containing microorganisms generated from the infected person are propelled a short distance through the air and deposited on the host's conjunctivae, nasal mucosa, or mouth. Because droplets do not remain suspended in the air, special air handling and ventilation are not required to prevent droplet transmission; that is, droplet transmission *must not* be confused with airborne transmission.
- (3) *Airborne Transmission* occurs by dissemination of either airborne droplet nuclei (small-particle residue [5 μm or smaller in size] of evaporated droplets containing microorganisms that remain suspended in the air for long periods of time) or dust particles containing the infectious agent. Microorganisms carried in this manner can be dispersed widely by air currents and may become inhaled by a susceptible host within the same room or over a longer distance from the source patient, depending on environmental fac-

tors; therefore, special air handling and ventilation are required to prevent airborne transmission. Microorganisms transmitted by airborne transmission include *Mycobacterium tuberculosis* and the rubeola and varicella viruses.

- (4) *Common Vehicle Transmission* applies to microorganisms transmitted by contaminated items such as food, water, medications, devices, and equipment.
- (5) *Vectorborne Transmission* occurs when vectors such as mosquitoes, flies, rats, and other vermin transmit microorganisms; this route of transmission is of less significance in hospitals in the United States than in other regions of the world.

Isolation precautions are designed to prevent transmission of microorganisms by these routes in hospitals. Because agent and host factors are more difficult to control, interruption of transfer of microorganisms is directed primarily at transmission. The recommendations presented in this guideline are based on this concept.

Placing a patient on isolation precautions, however, often presents certain disadvantages to the hospital, patients, personnel, and visitors. Isolation precautions may require specialized equipment and environmental modifications that add to the cost of hospitalization. Isolation precautions may make frequent visits by nurses, physicians, and other personnel inconvenient, and they may make it more difficult for personnel to give the prompt and frequent care that sometimes is required. The use of a multi-patient room for one patient uses valuable space that otherwise might accommodate several patients. Moreover, forced solitude deprives the patient of normal social relationships and may be psychologically harmful, especially to children. These disadvantages, however, must be weighed against the hospital's mission to prevent the spread of serious and epidemiologically important microorganisms in the hospital.

FUNDAMENTALS OF ISOLATION PRECAUTIONS

A variety of infection control measures are used for decreasing the risk of transmission of microorganisms in hospitals. These measures make up the fundamentals of isolation precautions.

Handwashing and Gloving

Handwashing frequently is called the single most important measure to reduce the risks of transmitting microorganisms from one person to another or from one site to another on the same patient. The scientific rationale, indications, methods, and prod-

ucts for handwashing have been delineated in other publications.⁶⁴⁻⁷²

Washing hands as promptly and thoroughly as possible between patient contacts and after contact with blood, body fluids, secretions, excretions, and equipment or articles contaminated by them is an important component of infection control and isolation precautions. In addition to handwashing, gloves play an important role in reducing the risks of transmission of microorganisms.

Gloves are worn for three important reasons in hospitals. First, gloves are worn to provide a protective barrier and to prevent gross contamination of the hands when touching blood, body fluids, secretions, excretions, mucous membranes, and nonintact skin²⁷⁻²⁹; the wearing of gloves in specified circumstances to reduce the risk of exposures to blood-borne pathogens is mandated by the OSHA Bloodborne Pathogens final rule.⁵¹ Second, gloves are worn to reduce the likelihood that microorganisms present on the hands of personnel will be transmitted to patients during invasive or other patient-care procedures that involve touching a patient's mucous membranes and nonintact skin. Third, gloves are worn to reduce the likelihood that hands of personnel contaminated with microorganisms from a patient or a fomite can transmit these microorganisms to another patient. In this situation, gloves must be changed between patient contacts and hands should be washed after gloves are removed.

Wearing gloves does not replace the need for handwashing, because gloves may have small, inapparent defects or may be torn during use, and hands can become contaminated during removal of gloves.^{14,15,39,72-76} Failure to change gloves between patient contacts is an infection control hazard.³²

Patient Placement

Appropriate patient placement is a significant component of isolation precautions. A private room is important to prevent direct- or indirect-contact transmission when the source patient has poor hygienic habits, contaminates the environment, or cannot be expected to assist in maintaining infection control precautions to limit transmission of microorganisms (ie, infants, children, and patients with altered mental status). When possible, a patient with highly transmissible or epidemiologically important microorganisms is placed in a private room with handwashing and toilet facilities, to reduce opportunities for transmission of microorganisms.

When a private room is not available, an infected patient is placed with an appropriate roommate. Patients infected by the same microorganism usually

can share a room, provided they are not infected with other potentially transmissible microorganisms and the likelihood of reinfection with the same organism is minimal. Such sharing of rooms, also referred to as cohorting patients, is useful especially during outbreaks or when there is a shortage of private rooms. When a private room is not available and cohorting is not achievable or recommended,²³ it is very important to consider the epidemiology and mode of transmission of the infecting pathogen and the patient population being served in determining patient placement. Under these circumstances, consultation with infection control professionals is advised before patient placement. Moreover, when an infected patient shares a room with a noninfected patient, it also is important that patients, personnel, and visitors take precautions to prevent the spread of infection and that roommates are selected carefully.

Guidelines for construction, equipment, air handling, and ventilation for isolation rooms have been delineated in other publications.⁷⁷⁻⁷⁹ A private room with appropriate air handling and ventilation is particularly important for reducing the risk of transmission of microorganisms from a source patient to susceptible patients and other persons in hospitals when the microorganism is spread by airborne transmission. Some hospitals use an isolation room with an anteroom as an extra measure of precaution to prevent airborne transmission. Adequate data regarding the need for an anteroom, however, is not available. Ventilation recommendations for isolation rooms housing patients with pulmonary tuberculosis have been delineated in other CDC guidelines.²³

Transport of Infected Patients

Limiting the movement and transport of patients infected with virulent or epidemiologically important microorganisms and ensuring that such patients leave their rooms only for essential purposes reduces opportunities for transmission of microorganisms in hospitals. When patient transport is necessary, it is important that (1) appropriate barriers (eg, masks, impervious dressings) are worn or used by the patient to reduce the opportunity for transmission of pertinent microorganisms to other patients, personnel, and visitors and to reduce contamination of the environment; (2) personnel in the area to which the patient is to be taken are notified of the impending arrival of the patient and of the precautions to be used to reduce the risk of transmission of infectious microorganisms; and, (3) patients are informed of ways by which they can assist in preventing the transmission of their infectious microorganisms to others.

Masks, Respiratory Protection, Eye Protection, Face Shields

Various types of masks, goggles, and face shields are worn alone or in combination to provide barrier protection. A mask that covers both the nose and the mouth, and goggles or a face shield are worn by hospital personnel during procedures and patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions to provide protection of the mucous membranes of the eyes, nose, and mouth from contact transmission of pathogens. The wearing of masks, eye protection, and face shields in specified circumstances to reduce the risk of exposures to bloodborne pathogens is mandated by the OSHA bloodborne pathogens final rule.⁵¹ A surgical mask generally is worn by hospital personnel to provide protection against spread of infectious large-particle droplets that are transmitted by close contact and generally travel only short distances (up to 3 ft) from infected patients who are coughing or sneezing.

An area of major concern and controversy over the last several years has been the role and selection of respiratory protection equipment and the implications of a respiratory protection program for prevention of transmission of tuberculosis in hospitals. Traditionally, although the efficacy was not proven, a surgical mask was worn for isolation precautions in hospitals when patients were known or suspected to be infected with pathogens spread by the airborne route of transmission. In 1990, however, the CDC tuberculosis guidelines¹⁸ stated that surgical masks may not be effective in preventing the inhalation of droplet nuclei and recommended the use of disposable particulate respirators, despite the fact that the efficacy of particulate respirators in protecting persons from the inhalation of *M tuberculosis* had not been demonstrated. By definition, particulate respirators included dust-mist (DM), dust-fume-mist (DFM), or high-efficiency particulate air (HEPA) filter respirators certified by the CDC National Institute for Occupational Safety and Health (NIOSH); because the generic term "particulate respirator" was used in the 1990 guidelines, the implication was that any of these respirators provided sufficient protection.⁸⁰

In 1993, a draft revision of the CDC tuberculosis guidelines²² outlined performance criteria for respirators and stated that some DM or DFM respirators might not meet these criteria. After review of public comments, the guidelines were finalized in October 1994,²³ with the draft respirator criteria unchanged. At that time, the only class of respirators that were known to consistently meet or exceed the performance crite-

ria outlined in the 1994 tuberculosis guidelines and that were certified by NIOSH (as required by OSHA) were HEPA filter respirators. Subsequently, NIOSH revised the testing and certification requirements for all types of air-purifying respirators, including those used for tuberculosis control.⁸¹ The new rule, effective in July 1995, provides a broader range of certified respirators that meet the performance criteria recommended by CDC in the 1994 tuberculosis guidelines. NIOSH has indicated that the N95 (N category at 95% efficiency) meets the CDC performance criteria for a tuberculosis respirator. The new respirators are likely to be available in late 1995. Additional information on the evolution of respirator recommendations, regulations to protect hospital personnel, and the role of various federal agencies in respiratory protection for hospital personnel has been published.⁸⁰

Gowns and Protective Apparel

Various types of gowns and protective apparel are worn to provide barrier protection and to reduce opportunities for transmission of microorganisms in hospitals. Gowns are worn to prevent contamination of clothing and to protect the skin of personnel from blood and body fluid exposures. Gowns especially treated to make them impermeable to liquids, leg coverings, boots, or shoe covers provide greater protection to the skin when splashes or large quantities of infective material are present or anticipated. The wearing of gowns and protective apparel under specified circumstances to reduce the risk of exposures to bloodborne pathogens is mandated by the OSHA Bloodborne Pathogens final rule.⁵¹

Gowns also are worn by personnel during the care of patients infected with epidemiologically important microorganisms to reduce the opportunity for transmission of pathogens from patients or items in their environment to other patients or environments; when gowns are worn for this purpose, they are removed before leaving the patient's environment, and hands are washed. Adequate data regarding the efficacy of gowns for this purpose, however, is not available.

Patient-Care Equipment and Articles

Many factors determine whether special handling and disposal of used patient-care equipment and articles are prudent or required, including the likelihood of contamination with infective material; the ability to cut, stick, or otherwise cause injury (needles, scalpels, and other sharp instruments [sharps]); the severity of the associated disease; and the environmental stability of the pathogens involved.^{27,51,82-84} Some used articles are enclosed in

containers or bags to prevent inadvertent exposures to patients, personnel, and visitors and to prevent contamination of the environment. Used sharps are placed in puncture-resistant containers; other articles are placed in a bag. One bag is adequate if the bag is sturdy and the article can be placed in the bag without contaminating the outside of the bag⁸⁵; otherwise, two bags are used.

The scientific rationale, indications, methods, products, and equipment for reprocessing patient-care equipment have been delineated in other publications.^{68,84,86-91} Contaminated, reusable critical medical devices or patient-care equipment (ie, equipment that enters normally sterile tissue or through which blood flows) or semicritical medical devices or patient-care equipment (ie, equipment that touches mucous membranes) are sterilized or disinfected (reprocessed) after use to reduce the risk of transmission of microorganisms to other patients; the type of reprocessing is determined by the article and its intended use, the manufacturer's recommendations, hospital policy, and any applicable guidelines and regulations.

Noncritical equipment (ie, equipment that touches intact skin) contaminated with blood, body fluids, secretions, or excretions is cleaned and disinfected after use, according to hospital policy. Contaminated disposable (single-use) patient-care equipment is handled and transported in a manner that reduces the risk of transmission of microorganisms and decreases environmental contamination in the hospital; the equipment is disposed of according to hospital policy and applicable regulations.

Linen and Laundry

Although soiled linen may be contaminated with pathogenic microorganisms, the risk of disease transmission is negligible if it is handled, transported, and laundered in a manner that avoids transfer of microorganisms to patients, personnel, and environments. Rather than rigid rules and regulations, hygienic and common sense storage and processing of clean and soiled linen are recommended.^{27,83,92,93} The methods for handling, transporting, and laundering of soiled linen are determined by hospital policy and any applicable regulations.

Dishes, Glasses, Cups, and Eating Utensils

No special precautions are needed for dishes, glasses, cups, or eating utensils. Either disposable or reusable dishes and utensils can be used for patients on isolation precautions. The combination of hot water and detergents used in hospital dishwashers is sufficient to decontaminate dishes, glasses, cups, and eating utensils.

Routine and Terminal Cleaning

The room, or cubicle, and bedside equipment of patients on Transmission-Based Precautions are cleaned using the same procedures used for patients on Standard Precautions, unless the infecting microorganism(s) and the amount of environmental contamination indicate special cleaning. In addition to thorough cleaning, adequate disinfection of bedside equipment and environmental surfaces (eg, bedrails, bedside tables, carts, commodes, door-knobs, faucet handles) is indicated for certain pathogens, especially enterococci, which can survive in the inanimate environment for prolonged periods of time.⁹⁴ Patients admitted to hospital rooms that previously were occupied by patients infected or colonized with such pathogens are at increased risk of infection from contaminated environmental surfaces and bedside equipment if they have not been cleaned and disinfected adequately. The methods, thoroughness, and frequency of cleaning and the products used are determined by hospital policy.

HICPAC ISOLATION PRECAUTIONS

There are two tiers of HICPAC isolation precautions. In the first, and most important, tier are those precautions designed for the care of all patients in hospitals, regardless of their diagnosis or presumed infection status. Implementation of these "Standard Precautions" is the primary strategy for successful nosocomial infection control. In the second tier are precautions designed only for the care of specified patients. These additional "Transmission-Based Precautions" are for patients known or suspected to be infected by epidemiologically important pathogens spread by airborne or droplet transmission or by contact with dry skin or contaminated surfaces.

Standard Precautions

Standard Precautions synthesize the major features of UP (Blood and Body Fluid Precautions)^{27,28} (designed to reduce the risk of transmission of blood-borne pathogens) and BSI^{29,30} (designed to reduce the risk of transmission of pathogens from moist body substances) and applies them to all patients receiving care in hospitals, regardless of their diagnosis or presumed infection status. Standard Precautions apply to (1) blood; (2) all body fluids, secretions, and excretions *except sweat*, regardless of whether or not they contain visible blood; (3) nonintact skin; and, (4) mucous membranes. Standard Precautions are designed to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection in hospitals.

Transmission-Based Precautions

Transmission-Based Precautions are designed for patients documented or suspected to be infected with highly transmissible or epidemiologically important pathogens for which additional precautions beyond Standard Precautions are needed to interrupt transmission in hospitals. There are three types of Transmission-Based Precautions: Airborne Precautions, Droplet Precautions, and Contact Precautions. They may be combined for diseases that have multiple routes of transmission. When used either singularly or in combination, they are to be used in addition to Standard Precautions.

Airborne Precautions are designed to reduce the risk of airborne transmission of infectious agents. Airborne transmission occurs by dissemination of either airborne droplet nuclei (small-particle residue [5 μm or smaller in size] of evaporated droplets that may remain suspended in the air for long periods of time) or dust particles containing the infectious agent. Microorganisms carried in this manner can be dispersed widely by air currents and may become inhaled by or deposited on a susceptible host within the same room or over a longer distance from the source patient, depending on environmental factors; therefore, special air handling and ventilation are required to prevent airborne transmission. Airborne Precautions apply to patients known or suspected to be infected with epidemiologically important pathogens that can be transmitted by the airborne route.

Droplet Precautions are designed to reduce the risk of droplet transmission of infectious agents. Droplet transmission involves contact of the conjunctivae or the mucous membranes of the nose or mouth of a susceptible person with large-particle droplets (larger than 5 μm in size) containing microorganisms generated from a person who has a clinical disease or who is a carrier of the microorganism. Droplets are generated from the source person primarily during coughing, sneezing, or talking and during the performance of certain procedures such as suctioning and bronchoscopy. Transmission via large-particle droplets requires close contact between source and recipient persons, because droplets do not remain suspended in the air and generally travel only short distances, usually 3 ft or less, through the air. Because droplets do not remain suspended in the air, special air handling and ventilation are not required to prevent droplet transmission. Droplet Precautions apply to any patient known or suspected to be infected with epidemiologically important pathogens that can be transmitted by infectious droplets.

Contact Precautions are designed to reduce the risk of transmission of epidemiologically important

microorganisms by direct or indirect contact. Direct-contact transmission involves skin-to-skin contact and physical transfer of microorganisms to a susceptible host from an infected or colonized person, such as occurs when personnel turn patients, bathe patients, or perform other patient-care activities that require physical contact. Direct-contact transmission also can occur between two patients (eg, by hand contact), with one serving as the source of infectious microorganisms and the other as a susceptible host. Indirect-contact transmission involves contact of a susceptible host with a contaminated intermediate object, usually inanimate, in the patient's environment. Contact Precautions apply to specified patients known or suspected to be infected or colonized (presence of microorganism in or on patient but without clinical signs and symptoms of infection) with epidemiologically important microorganisms that can be transmitted by direct or indirect contact.

A synopsis of the types of precautions and the patients requiring the precautions is listed in Table 1.

EMPIRIC USE OF AIRBORNE, DROPLET, OR CONTACT PRECAUTIONS

In many instances, the risk of nosocomial transmission of infection may be highest before a definitive diagnosis can be made and before precautions based on that diagnosis can be implemented. The routine use of Standard Precautions for all patients should reduce greatly this risk for conditions other than those requiring Airborne, Droplet, or Contact Precautions. While it is not possible to prospectively identify all patients needing these enhanced precautions, certain clinical syndromes and conditions carry a sufficiently high risk to warrant the empiric addition of enhanced precautions while a more definitive diagnosis is pursued. A listing of such conditions and the recommended precautions beyond Standard Precautions is presented in Table 2.

The organisms listed under the column "Potential Pathogens" are not intended to represent the complete or even most likely diagnoses, but rather possible etiologic agents that require additional precautions beyond Standard Precautions until they can be ruled out. Infection control professionals are encouraged to modify or adapt this table according to local conditions. To ensure that appropriate empiric precautions are implemented always, hospitals must have systems in place to evaluate patients routinely according to these criteria as part of their preadmission and admission care.

TABLE 1

SYNOPSIS OF TYPES OF PRECAUTIONS AND PATIENTS REQUIRING THE PRECAUTIONS*

Standard Precautions

Use Standard Precautions for the care of all patients

Airborne Precautions

In addition to Standard Precautions, use Airborne Precautions for patients known or suspected to have serious illnesses transmitted by airborne droplet nuclei. Examples of such illnesses include:

- Measles
- Varicella (including disseminated zoster)[†]
- Tuberculosis[‡]

Droplet Precautions

In addition to Standard Precautions, use Droplet Precautions for patients known or suspected to have serious illnesses transmitted by large particle droplets. Examples of such illnesses include:

- Invasive *Haemophilus influenzae* type b disease, including meningitis, pneumonia, epiglottitis, and sepsis
- Invasive *Neisseria meningitidis* disease, including meningitis, pneumonia, and sepsis
- Other serious bacterial respiratory infections spread by droplet transmission, including:

- Diphtheria (pharyngeal)
- Mycoplasma pneumonia
- Pertussis
- Pneumonic plague
- Streptococcal pharyngitis, pneumonia, or scarlet fever in infants and young children

Serious viral infections spread by droplet transmission, including:

- Adenovirus[†]
- Influenza
- Mumps
- Parvovirus B19
- Rubella

Contact Precautions

In addition to Standard Precautions, use Contact Precautions for patients known or suspected to have serious illnesses easily transmitted by direct patient contact or by contact with items in the patient's environment. Examples of such illnesses include:

- Gastrointestinal, respiratory, skin, or wound infections or colonization with multidrug-resistant bacteria judged by the infection control program, based on current state, regional, or national recommendations, to be of special clinical and epidemiologic significance

Enteric infections with a low infectious dose or prolonged environmental survival, including:

- Clostridium difficile*

For diapered or incontinent patients: enterohemorrhagic *Escherichia coli* O157:H7, *Shigella*, hepatitis A, or rotavirus

Respiratory syncytial virus, parainfluenza virus, or enteroviral infections in infants and young children

Skin infections that are highly contagious or that may occur on dry skin, including:

- Diphtheria (cutaneous)
- Herpes simplex virus (neonatal or mucocutaneous)
- Impetigo
- Major (noncontained) abscesses, cellulitis, or decubiti
- Pediculosis
- Scabies
- Staphylococcal furunculosis in infants and young children
- Zoster (disseminated or in the immunocompromised host)[†]

Viral/hemorrhagic conjunctivitis

Viral hemorrhagic infections (Ebola, Lassa, or Marburg)*

* See Appendix A for a complete listing of infections requiring precautions, including appropriate footnotes.

[†] Certain infections require more than one type of precaution.[‡] See CDC "Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Facilities."²³

TABLE 2
CLINICAL SYNDROMES OR CONDITIONS WARRANTING ADDITIONAL EMPIRIC PRECAUTIONS TO PREVENT TRANSMISSION OF EPIDEMIOLOGICALLY IMPORTANT PATHOGENS PENDING CONFIRMATION OF DIAGNOSIS*

Clinical Syndrome or Condition†	Potential Pathogens‡	Empiric Precautions
Diarrhea		
Acute diarrhea with a likely infectious cause in an incontinent or diapered patient	Enteric pathogens§	Contact
Diarrhea in an adult with a history of recent antibiotic use	<i>Clostridium difficile</i>	Contact
Meningitis	<i>Neisseria meningitidis</i>	Droplet
Rash or exanthems, generalized, etiology unknown		
Petechial/ecchymotic with fever	<i>Neisseria meningitidis</i>	Droplet
Vesicular	Varicella	Airborne and contact
Maculopapular with coryza and fever	Rubeola (measles)	Airborne
Respiratory infections		
Cough/fever/upper lobe pulmonary infiltrate in an HIV-negative patient or a patient at low risk for HIV infection	<i>Mycobacterium tuberculosis</i>	Airborne
Cough/fever/pulmonary infiltrate in any lung location in an HIV-infected patient or a patient at high risk for HIV infection ²³	<i>Mycobacterium tuberculosis</i>	Airborne
Paroxysmal or severe persistent cough during periods of pertussis activity	<i>Bordetella pertussis</i>	Droplet
Respiratory infections, particularly bronchiolitis and croup, in infants and young children	Respiratory syncytial or parainfluenza virus	Contact
Risk of multidrug-resistant microorganisms		
History of infection or colonization with multidrug-resistant organisms¶	Resistant bacteria	Contact
Skin, wound, or urinary tract infection in a patient with a recent hospital or nursing home stay in a facility where multidrug-resistant organisms are prevalent	Resistant bacteria	Contact
Skin or Wound Infection		
Abscess or draining wound that cannot be covered	<i>Staphylococcus aureus</i> , Group A streptococcus	Contact

* Infection control professionals are encouraged to modify or adapt this table according to local conditions. To ensure that appropriate empiric precautions are implemented always, hospitals must have systems in place to evaluate patients routinely according to these criteria as part of their preadmission and admission care.

† Patients with the syndromes or conditions listed below may present with atypical signs or symptoms (eg, pertussis in neonates and adults may not have paroxysmal or severe cough). The clinician's index of suspicion should be guided by the prevalence of specific conditions in the community, as well as clinical judgment.

‡ The organisms listed under the column "Potential Pathogens" are not intended to represent the complete, or even most likely, diagnoses, but rather possible etiologic agents that require additional precautions beyond Standard Precautions until they can be ruled out.

§ These pathogens include enterohemorrhagic *Escherichia coli* O157:H7, *Shigella*, hepatitis A, and rotavirus.

¶ Resistant bacteria judged by the infection control program, based on current state, regional, or national recommendations, to be of special clinical or epidemiological significance.

IMMUNOCOMPROMISED PATIENTS

Immunocompromised patients vary in their susceptibility to nosocomial infections, depending on the severity and duration of immunosuppression. They generally are at increased risk for bacterial, fungal, parasitic, and viral infections from both endogenous and exogenous sources. The use of Standard Precautions for all patients and Transmission-Based Precautions for specified patients, as recommended in this guideline, should reduce the acquisition by these patients of institutionally acquired bacteria from other patients and environments.

It is beyond the scope of this guideline to address the various measures that may be used for immuno-

compromised patients to delay or prevent acquisition of potential pathogens during temporary periods of neutropenia. Rather, the primary objective of this guideline is to prevent transmission of pathogens from infected or colonized patients in hospitals. Users of this guideline, however, are referred to the "Guideline for Prevention of Nosocomial Pneumonia"^{95,96} for the HIC-PAC recommendations for prevention of nosocomial aspergillosis and Legionnaires' disease in immunocompromised patients.

RECOMMENDATIONS

The recommendations presented below are categorized as follows:

Category IA. Strongly recommended for all hospitals and strongly supported by well-designed experimental or epidemiologic studies.

Category IB. Strongly recommended for all hospitals and reviewed as effective by experts in the field and a consensus of HICPAC based on strong rationale and suggestive evidence, even though definitive scientific studies have not been done.

Category II. Suggested for implementation in many hospitals. Recommendations may be supported by suggestive clinical or epidemiologic studies, a strong theoretical rationale, or definitive studies applicable to some, but not all, hospitals.

No recommendation; unresolved issue. Practices for which insufficient evidence or consensus regarding efficacy exists.

The recommendations are limited to the topic of isolation precautions. Therefore, they must be supplemented by hospital policies and procedures for other aspects of infection and environmental control, occupational health, administrative and legal issues, and other issues beyond the scope of this guideline.

I. Administrative Controls

A. Education

Develop a system to ensure that hospital patients, personnel, and visitors are educated about use of precautions and their responsibility for adherence to them. *Category IB*

B. Adherence to Precautions

Periodically evaluate adherence to precautions, and use findings to direct improvements. *Category IB*

II. Standard Precautions

Use Standard Precautions, or the equivalent, for the care of all patients. *Category IB*

A. Handwashing

(1) Wash hands after touching blood, body fluids, secretions, excretions, and contaminated items, whether or not gloves are worn. Wash hands immediately after gloves are removed, between patient contacts, and when otherwise indicated to avoid transfer of microorganisms to other patients or environments. It may be necessary to wash hands between tasks and procedures on the same patient to prevent cross-contamination of different body sites. *Category IB*

(2) Use a plain (nonantimicrobial) soap for routine handwashing. *Category IB*

(3) Use an antimicrobial agent or a waterless antiseptic agent for specific circumstances (eg, control of outbreaks or hyperendemic infections), as defined by the infection control

program. *Category IB* (See Contact Precautions for additional recommendations on using antimicrobial and antiseptic agents.)

B. Gloves

Wear gloves (clean, nonsterile gloves are adequate) when touching blood, body fluids, secretions, excretions, and contaminated items. Put on clean gloves just before touching mucous membranes and nonintact skin. Change gloves between tasks and procedures on the same patient after contact with material that may contain a high concentration of microorganisms. Remove gloves promptly after use, before touching noncontaminated items and environmental surfaces, and before going to another patient, and wash hands immediately to avoid transfer of microorganisms to other patients or environments.

Category IB

C. Mask, Eye Protection, Face Shield

Wear a mask and eye protection or a face shield to protect mucous membranes of the eyes, nose, and mouth during procedures and patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions, and excretions. *Category IB*

D. Gown

Wear a gown (a clean, nonsterile gown is adequate) to protect skin and to prevent soiling of clothing during procedures and patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions. Select a gown that is appropriate for the activity and amount of fluid likely to be encountered. Remove a soiled gown as promptly as possible, and wash hands to avoid transfer of microorganisms to other patients or environments. *Category IB*

E. Patient-Care Equipment

Handle used patient-care equipment soiled with blood, body fluids, secretions, and excretions in a manner that prevents skin and mucous membrane exposures, contamination of clothing, and transfer of microorganisms to other patients and environments. Ensure that reusable equipment is not used for the care of another patient until it has been cleaned and reprocessed appropriately. Ensure that single-use items are discarded properly. *Category IB*

F. Environmental Control

Ensure that the hospital has adequate procedures for the routine care, cleaning, and disinfection of environmental surfaces, beds, bedrails, bedside equipment, and other fre-

quently touched surfaces, and ensure that these procedures are being followed. *Category IB*

G. Linen

Handle, transport, and process used linen soiled with blood, body fluids, secretions, and excretions in a manner that prevents skin and mucous membrane exposures and contamination of clothing, and that avoids transfer of microorganisms to other patients and environments. *Category IB*

H. Occupational Health and Bloodborne Pathogens

(1) Take care to prevent injuries when using needles, scalpels, and other sharp instruments or devices; when handling sharp instruments after procedures; when cleaning used instruments; and when disposing of used needles. Never recap used needles, or otherwise manipulate them using both hands, or use any other technique that involves directing the point of a needle toward any part of the body; rather, use either a one-handed "scoop" technique or a mechanical device designed for holding the needle sheath. Do not remove used needles from disposable syringes by hand, and do not bend, break, or otherwise manipulate used needles by hand. Place used disposable syringes and needles, scalpel blades, and other sharp items in appropriate puncture-resistant containers, which are located as close as practical to the area in which the items were used, and place reusable syringes and needles in a puncture-resistant container for transport to the reprocessing area. *Category IB*

(2) Use mouthpieces, resuscitation bags, or other ventilation devices as an alternative to mouth-to-mouth resuscitation methods in areas where the need for resuscitation is predictable. *Category IB*

I. Patient Placement

Place a patient who contaminates the environment or who does not (or cannot be expected to) assist in maintaining appropriate hygiene or environmental control in a private room. If a private room is not available, consult with infection control professionals regarding patient placement or other alternatives. *Category IB*

III. Airborne Precautions

In addition to Standard Precautions, use Airborne Precautions, or the equivalent, for patients known or suspected to be infected with microorganisms transmitted by airborne droplet nuclei (small-particle residue [$5 \mu\text{m}$ or smaller in

size] of evaporated droplets containing microorganisms that remain suspended in the air and that can be dispersed widely by air currents within a room or over a long distance). *Category IB*

A. Patient Placement

Place the patient in a private room that has (1) monitored negative air pressure in relation to the surrounding areas, (2) 6 to 12 air changes per hour, and (3) appropriate discharge of air outdoors or monitored high-efficiency filtration of room air before the air is circulated to other areas in the hospital.²³ Keep the room door closed and the patient in the room. When a private room is not available, place the patient in a room with a patient who has active infection with the same microorganism, unless otherwise recommended,²³ but with no other infection. When a private room is not available and cohorting is not desirable, consultation with infection control professionals is advised before patient placement. *Category IB*

B. Respiratory Protection

Wear respiratory protection when entering the room of a patient with known or suspected infectious pulmonary tuberculosis.^{23,81} Susceptible persons should not enter the room of patients known or suspected to have measles (rubeola) or varicella (chickenpox) if other immune caregivers are available. If susceptible persons must enter the room of a patient known or suspected to have measles (rubeola) or varicella, they should wear respiratory protection.⁸¹ Persons immune to measles (rubeola) or varicella need not wear respiratory protection. *Category IB*

C. Patient Transport

Limit the movement and transport of the patient from the room to essential purposes only. If transport or movement is necessary, minimize patient dispersal of droplet nuclei by placing a surgical mask on the patient, if possible. *Category IB*

D. Additional Precautions for Preventing Transmission of Tuberculosis

Consult CDC "Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Facilities"²³ for additional prevention strategies.

IV. Droplet Precautions

In addition to Standard Precautions, use Droplet Precautions, or the equivalent, for a patient known or suspected to be infected with microorganisms transmitted by droplets (large-particle droplets [larger than $5 \mu\text{m}$ in size] that can be generated by the patient during coughing, sneez-

ing, talking, or the performance of procedures).

Category IB

A. Patient Placement

Place the patient in a private room. When a private room is not available, place the patient in a room with a patient(s) who has active infection with the same microorganism but with no other infection (cohorting). When a private room is not available and cohorting is not achievable, maintain spatial separation of at least 3 ft between the infected patient and other patients and visitors. Special air handling and ventilation are not necessary, and the door may remain open. *Category IB*

B. Mask

In addition to standard precautions, wear a mask when working within 3 ft of the patient. (Logistically, some hospitals may want to implement the wearing of a mask to enter the room.) *Category IB*

C. Patient Transport

Limit the movement and transport of the patient from the room to essential purposes only. If transport or movement is necessary, minimize patient dispersal of droplets by masking the patient, if possible. *Category IB*

V. Contact Precautions

In addition to Standard Precautions, use Contact Precautions, or the equivalent, for specified patients known or suspected to be infected or colonized with epidemiologically important microorganisms that can be transmitted by direct contact with the patient (hand or skin-to-skin contact that occurs when performing patient-care activities that require touching the patient's dry skin) or indirect contact (touching) with environmental surfaces or patient-care items in the patient's environment. *Category IB*

A. Patient Placement

Place the patient in a private room. When a private room is not available, place the patient in a room with a patient(s) who has active infection with the same microorganism but with no other infection (cohorting). When a private room is not available and cohorting is not achievable, consider the epidemiology of the microorganism and the patient population when determining patient placement. Consultation with infection control professionals is advised before patient placement. *Category IB*

B. Gloves and Handwashing

In addition to wearing gloves as outlined under Standard Precautions, wear gloves

(clean, nonsterile gloves are adequate) when entering the room. During the course of providing care for a patient, change gloves after having contact with infective material that may contain high concentrations of microorganisms (fecal material and wound drainage). Remove gloves before leaving the patient's environment and wash hands immediately with an antimicrobial agent or a waterless antiseptic agent.^{72,94} After glove removal and handwashing, ensure that hands do not touch potentially contaminated environmental surfaces or items in the patient's room to avoid transfer of microorganisms to other patients or environments. *Category IB*

C. Gown

In addition to wearing a gown as outlined under Standard Precautions, wear a gown (a clean, nonsterile gown is adequate) when entering the room if you anticipate that your clothing will have substantial contact with the patient, environmental surfaces, or items in the patient's room, or if the patient is incontinent or has diarrhea, an ileostomy, a colostomy, or wound drainage not contained by a dressing. Remove the gown before leaving the patient's environment. After gown removal, ensure that clothing does not contact potentially contaminated environmental surfaces to avoid transfer of microorganisms to other patients or environments. *Category IB*

D. Patient Transport

Limit the movement and transport of the patient from the room to essential purposes only. If the patient is transported out of the room, ensure that precautions are maintained to minimize the risk of transmission of microorganisms to other patients and contamination of environmental surfaces or equipment. *Category IB*

E. Patient-Care Equipment

When possible, dedicate the use of noncritical patient-care equipment to a single patient (or cohort of patients infected or colonized with the pathogen requiring precautions) to avoid sharing between patients. If use of common equipment or items is unavoidable, then adequately clean and disinfect them before use for another patient. *Category IB*

F. Additional Precautions for Preventing the Spread of Vancomycin Resistance

Consult the HICPAC report on preventing the spread of vancomycin resistance for additional prevention strategies.⁹⁴

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APPENDIX A

Type and Duration of Precautions Needed for Selected Infections and Conditions

Infection/Condition	Precautions	
	Type*	Duration [†]
Abscess		
Draining, major [‡]	C	DI
Draining, minor or limited [‡]	S	
Acquired immunodeficiency syndrome [‡]	S	
Actinomycesis	S	
Adenovirus infection, in infants and young children	D, C	DI
Amebiasis	S	
Anthrax		
Cutaneous	S	
Pulmonary	S	
Antibiotic-associated colitis (see <i>Clostridium difficile</i>)		
Arthropodborne viral encephalitides (eastern, western, Venezuelan equine encephalomyelitis; St Louis, California encephalitis)	S [‡]	
Arthropodborne viral fevers (dengue, yellow fever, Colorado tick fever)	S [‡]	
Ascariasis	S	
Aspergillosis	S	
Babesiosis	S	
Blastomycosis, North American, cutaneous or pulmonary	S	

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APPENDIX A (continued)

Type and Duration of Precautions Needed for Selected Infections and Conditions

Infection/Condition	Precautions	
	Type*	Duration†
Botulism	S	
Bronchiolitis (see respiratory infections in infants and young children)		
Brucellosis (undulant, Malta, Mediterranean fever)	S	
<i>Campylobacter</i> gastroenteritis (see gastroenteritis)		
Candidiasis, all forms including mucocutaneous	S	
Cat-scratch fever (benign inoculation lymphoreticulosis)	S	
Cellulitis, uncontrolled drainage	C	DI
Chancroid (soft chancre)	S	
Chickenpox (varicella; see F ⁵ for varicella exposure)	A, C	F ⁵
<i>Chlamydia trachomatis</i>		
Conjunctivitis	S	
Genital	S	
Respiratory	S	
Cholera (see gastroenteritis)		
Closed-cavity infection		
Draining, limited or minor	S	
Not draining	S	
<i>Clostridium</i>		
<i>C. botulinum</i>	S	
<i>C. difficile</i>	C	DI
<i>C. perfringens</i>		
Food poisoning	S	
Gas gangrene	S	
Coccidioidomycosis (valley fever)		
Draining lesions	S	
Pneumonia	S	
Colorado tick fever	S	
Congenital rubella	C	F ⁶
Conjunctivitis		
Acute bacterial	S	
<i>Chlamydia</i>	S	
Gonococcal	S	
Acute viral (acute hemorrhagic)	C	DI
Coxsackievirus disease (see enteroviral infection)		
Creutzfeldt-Jakob disease	S ⁷	
Croup (see respiratory infections in infants and young children)		
Cryptococcosis	S	
Cryptosporidiosis (see gastroenteritis)		
Cysticercosis	S	
Cytomegalovirus infection, neonatal or immunosuppressed	S	
Decubitus ulcer, infected		
Major ¹	C	DI
Minor or limited ²	S	
Dengue	S ⁴	
Diarrhea, acute— <i>infective etiology suspected</i> (see gastroenteritis)		
Diphtheria		
Cutaneous	C	CN ⁸
Pharyngeal	D	CN ⁸

Type and Duration of Precautions Needed for Selected Infections and Conditions

Infection/Condition	Precautions	
	Type*	Duration†
Ebola viral hemorrhagic fever	C ⁹	DI
Echinococcosis (hydatidosis)	S	
Echovirus (see enteroviral infection)		
Encephalitis or encephalomyelitis (see specific etiologic agents)		
Endometritis	S	
Enterobiasis (pinworm disease, oxyuriasis)	S	
<i>Enterococcus</i> species (see multidrug-resistant organisms if epidemiologically significant or vancomycin resistant)		
Enterocolitis, <i>Clostridium difficile</i>	C	DI
Enteroviral infections		
Adults	S	
Infants and young children	C	DI
Epiglottitis, due to <i>Haemophilus influenzae</i>	D	U ^{24 hrs}
Epstein-Barr virus infection, including infectious mononucleosis	S	
Erythema infectiosum (also see Parvovirus B19)	S	
<i>Escherichia coli</i> gastroenteritis (see gastroenteritis)		
Food poisoning		
Botulism	S	
<i>Clostridium perfringens</i> or <i>welchii</i>	S	
Staphylococcal	S	
Furunculosis—staphylococcal		
Infants and young children	C	DI
Gangrene (gas gangrene)	S	
Gastroenteritis		
<i>Campylobacter</i> species	S ¹⁰	
Cholera	S ¹⁰	
<i>Clostridium difficile</i>	C	DI
<i>Cryptosporidium</i> species	S ¹⁰	
<i>Escherichia coli</i>		
Enterohemorrhagic O157:H7	S ¹⁰	
Diapered or incontinent	C	DI
Other species	S ¹⁰	
<i>Giardia lamblia</i>	S ¹⁰	
Rotavirus	S ¹⁰	
Diapered or incontinent	C	DI
<i>Salmonella</i> species (including <i>S typhi</i>)	S ¹⁰	
<i>Shigella</i> species	S ¹⁰	
Diapered or incontinent	C	DI
<i>Vibrio parahaemolyticus</i>	S ¹⁰	
Viral (if not covered elsewhere)	S ¹⁰	
<i>Yersinia enterocolitica</i>	S ¹⁰	
German measles (rubella)	D	F ²²
Giardiasis (see gastroenteritis)		
Gonococcal ophthalmia neonatorum (gonorrhoeal ophthalmia, acute conjunctivitis of newborn)	S	
Gonorrhea	S	
Granuloma inguinale (donovanosis, granuloma venereum)	S	

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APPENDIX A (continued)

Type and Duration of Precautions Needed for Selected Infections and Conditions

Infection/Condition	Precautions	
	Type*	Duration†
Guillain-Barré syndrome	S	
Hand, foot, and mouth disease (see enteroviral infection)		
<i>Hantavirus</i> pulmonary syndrome	S	
<i>Helicobacter pylori</i>	S	
Hemorrhagic fevers (for example, Lassa and Ebola)	C ⁹	DI
Hepatitis, viral		
Type A	S	
Diapered or incontinent patients	C	F ¹¹
Type B—HBsAg positive	S	
Type C and other unspecified non-A, non-B	S	
Type E	S	
Herpangina (see enteroviral infection)		
Herpes simplex (<i>Herpesvirus hominis</i>)		
Encephalitis	S	
Neonatal ¹² (see F ¹² for neonatal exposure)	C	DI
Mucocutaneous, disseminated or primary, severe	C	DI
Mucocutaneous, recurrent (skin, oral, genital)	S	
Herpes zoster (varicella-zoster)		
Localized in immunocompromised patient, or disseminated	A, C	D ¹³
Localized in normal patient	S ¹³	
Histoplasmosis	S	
HIV (see human immunodeficiency virus)	S	
Hookworm disease (ancylostomiasis, uncinariasis)	S	
Human immunodeficiency virus (HIV) infection ³	S	
Impetigo	C	U ²⁴ hrs
Infectious mononucleosis	S	
Influenza	D ¹⁴	DI
Kawasaki syndrome	S	
Lassa fever	C ⁹	DI
Legionnaires' disease	S	
Leprosy	S	
Leptospirosis	S	
Lice (pediculosis)	C	U ²⁴
Listeriosis	S	
Lyme disease	S	
Lymphocytic choriomeningitis	S	
Lymphogranuloma venereum	S	
Malaria	S ¹	
Marburg virus disease	C ⁹	DI
Measles (rubeola), all presentations	A	DI
Melioidosis, all forms	S	
Meningitis	S	
Aseptic (nonbacterial or viral meningitis [also see enteroviral infections])		
Bacterial, gram-negative enteric, in neonates	S	
Fungal	S	
<i>Haemophilus influenzae</i> , known or suspected	D	U ²⁴ hrs
<i>Listeria monocytogenes</i>	S	
<i>Neisseria meningitidis</i> (meningococcal) known or suspected	D	U ²⁴ hrs

APPENDIX A (continued)

Type and Duration of Precautions Needed for Selected Infections and Conditions

Infection/Condition	Precautions	
	Type*	Duration†
Pneumococcal	S	
Tuberculosis ¹⁵	S	
Other diagnosed bacterial	S	
Meningococcal pneumonia	D	U ²⁴ hrs
Meningococemia (meningococcal sepsis)	D	U ²⁴ hrs
<i>Molluscum contagiosum</i>	S	
Mucormycosis	S	
Multidrug-resistant organisms, infection or colonization ¹⁶		
Gastrointestinal	C	CN
Respiratory	C	CN
Pneumococcal	S	
Skin, wound, or burn	C	CN
Mumps (infectious parotitis)	D	F ¹⁷
Mycobacteria, nontuberculosis (atypical)		
Pulmonary	S	
Wound	S	
<i>Mycoplasma pneumoniae</i>	D	DI
Necrotizing enterocolitis	S	
Nocardiosis, draining lesions or other presentations	S	
Norwalk agent gastroenteritis (see viral gastroenteritis)		
Orf	S	
Parainfluenza virus infection, respiratory in infants and young children	C	DI
Parvovirus B19	D	F ¹⁸
Pediculosis (lice)	C	U ²⁴ hrs
Pertussis (whooping cough)	D	F ¹⁹
Pinworm infection	S	
Plague		
Bubonic	S	
Pneumonic	D	U ⁷² hrs
Pleurodynia (see enteroviral infection)		
Pneumonia		
Adenovirus	D, C	DI
Bacterial not listed elsewhere (including gram-negative bacterial)	S	
<i>Burkholderia cepacia</i> in cystic fibrosis (CF) patients, including respiratory tract colonization	S ²⁰	
<i>Chlamydia</i>	S	
Fungal	S	
<i>Haemophilus influenzae</i>		
Adults	S	
Infants and children (any age)	D	U ²⁴ hrs
<i>Legionella</i>	S	
Meningococcal	D	U ²⁴ hrs
Multidrug-resistant bacterial (see multidrug-resistant organisms)		
<i>Mycoplasma</i> (primary atypical pneumonia)	D	DI
Pneumococcal		
Multidrug-resistant (see multidrug-resistant organisms)		
<i>Pneumocystis carinii</i>	S ²¹	
<i>Pseudomonas cepacia</i> (see <i>Burkholderia cepacia</i>)	S ²¹	
<i>Staphylococcus aureus</i>	S	

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APPENDIX A (continued)

Type and Duration of Precautions Needed for Selected Infections and Conditions

Infection/Condition	Precautions	
	Type*	Duration†
<i>Streptococcus</i> , Group A		
Adults	S	
Infants and young children	D	U ^{24 hrs}
Viral		
Adults	S	
Infants and young children (see respiratory infectious disease, acute)		
Poliomyelitis	S	
Psittacosis (ornithosis)	S	
Q fever	S	
Rabies	S	
Rat-bite fever (<i>Streptobacillus moniliformis</i> disease, <i>Spirillum minus</i> disease)	S	
Relapsing fever	S	
Resistant bacterial infection or colonization (see multidrug-resistant organisms)		
Respiratory infectious disease, acute (if not covered elsewhere)		
Adults	S	
Infants and young children ³	C	DI
Respiratory syncytial virus infection, in infants and young children, and immunocompromised adults	C	DI
Reye's syndrome	S	
Rheumatic fever	S	
Rickettsial fevers, tickborne (Rocky Mountain spotted fever, tickborne typhus fever)	S	
Rickettsialpox (vesicular rickettsiosis)	S	
Ringworm (dermatophytosis, dermatomycosis, tinea)	S	
Ritter's disease (staphylococcal scalded skin syndrome)	S	
Rocky Mountain spotted fever	S	
Roseola infantum (exanthem subitum)	S	
Rotavirus infection (see gastroenteritis)		
Rubella (German measles; also see congenital rubella)	D	F ²²
Salmonellosis (see gastroenteritis)		
Scabies	C	U ^{24 hrs}
Scalded skin syndrome, staphylococcal (Ritter's disease)	S	
Schistosomiasis (bilharziasis)	S	
Shigellosis (see gastroenteritis)		
Sporotrichosis	S	
<i>Spirillum minus</i> disease (rat-bite fever)	S	
Staphylococcal disease (<i>S aureus</i>)		
Skin, wound, or burn		
Major ¹	C	DI
Minor or limited ²	S	
Enterocolitis	S ¹⁰	
Multidrug-resistant (see multidrug-resistant organisms)		
Pneumonia	S	
Scalded skin syndrome	S	
Toxic shock syndrome	S	
<i>Streptobacillus moniliformis</i> disease (rat-bite fever)	S	
Streptococcal disease (group A streptococcus)		
Skin, wound, or burn		
Major ¹	C	U ^{24 hrs}
Minor or limited ²	S	

APPENDIX A (continued)

Type and Duration of Precautions Needed for Selected Infections and Conditions

Infection/Condition	Precautions	
	Type*	Duration [†]
Endometritis (puerperal sepsis)	S	
Pharyngitis in infants and young children	D	U ²⁴ hrs
Pneumonia in infants and young children	D	U ²⁴ hrs
Scarlet fever in infants and young children	D	U ²⁴ hrs
Streptococcal disease (group B streptococcus), neonatal	S	
Streptococcal disease (not group A or B) unless covered elsewhere	S	
Multidrug-resistant (see multidrug-resistant organisms)	S	
Strongyloidiasis	S	
Syphilis	S	
Skin and mucous membrane, including congenital, primary, secondary	S	
Latent (tertiary) and seropositivity without lesions	S	
Tapeworm disease	S	
<i>Hymenolepis nana</i>	S	
<i>Taenia solium</i> (pork)	S	
Other	S	
Tetanus	S	
Tinea (fungus infection dermatophytosis, dermatomycosis, ringworm)	S	
Toxoplasmosis	S	
Toxic shock syndrome (staphylococcal disease)	S	
Trachoma, acute	S	
Trench mouth (Vincent's angina)	S	
Trichinosis	S	
Trichomoniasis	S	
Trichuriasis (whipworm disease)	S	
Tuberculosis	S	
Extrapulmonary, draining lesion (including scrofula)	S	
Extrapulmonary, meningitis ¹⁵	A	F ²³
Pulmonary, confirmed or suspected or laryngeal disease	S	
Skin-test positive with no evidence of current pulmonary disease	S	
Tularemia	S	
Draining lesion	S	
Pulmonary	S	
Typhoid (<i>Salmonella typhi</i>) fever (see gastroenteritis)	S	
Typhus, endemic and epidemic	S	
Urinary tract infection (including pyelonephritis), with or without urinary catheter	A, C	F ⁵
Varicella (chickenpox)	S	
<i>Vibrio parahaemolyticus</i> (see gastroenteritis)	S	
Vincent's angina (trench mouth)	S	
Viral diseases		
Respiratory (if not covered elsewhere)	S	
Adults		
Infants and young children (see respiratory infectious disease, acute)	D	F ¹²
Whooping cough (pertussis)		
Wound infections	C	D1
Major ¹	S	
Minor or limited ²		
<i>Yersinia enterocolitica</i> gastroenteritis (see gastroenteritis)		
Localized in immunocompromised patient, disseminated	A, C	D1 ¹³
Localized in normal patient	S ¹³	
Zygomycosis (phycomycosis, mucormycosis)	S	
Zoster (varicella-zoster)		

(Continued on page 80)

Appendix H

List of Abbreviations

ALT – alanine aminotransferase
ANTI-HBS – Hepatitis B surface antibody
ANTI-HCV – antibody to Hepatitis C
APIC – Association for Professionals in Infection Control and Epidemiology, Inc.
AZT - Zidovudine
BT - Bioterrorism
CDC – Centers for Disease Control and Prevention
CFR – Code of Federal Regulations
CSF – Cerebral Spinal Fluid
DFR – Diaphragm Fitting Rings
DDST – Denver Developmental Screening Test
EPA – Environmental Protection Agency
HBIG – Hepatitis B Immune Globulin
HBsAG – Hepatitis B Surface Antigen
HBV – Hepatitis B Virus
HCT - Hematocrit
HCV – Hepatitis C Virus
HICPAC – Healthcare Infection Control Practices Advisory Committee
HIV – Human Immunodeficiency Virus
IDSA – Infectious Diseases Society of America
IDV - Indinavir
LA - Louisiana
LINKS – Louisiana Immunization Information Network for Kids Statewide
MMR – Measles, Mumps, rubella vaccine
MMWR – Morbidity and Mortality Weekly Report
NACL – Sodium chloride
NRL – Natural Rubber Latex

OMF – Office of Management and Finance
OPH – Office of Public Health
OPIM – Other Potentially Infectious Materials
OSHA – Occupational Safety and Health Administration
PEP – Post exposure prophylaxis
PPE – Personal protective equipment
PPD – Purified Protein Derivative
PPR – Performance Planning Review
SARS – Severe Acute Respiratory Syndrome
SHEA – The Society for Healthcare Epidemiology of America, Inc.
STD – Sexually transmitted disease
TB - Tuberculosis
TD – Tetanus-diphtheria
UV - Ultraviolet
VAR – Varicella vaccine

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