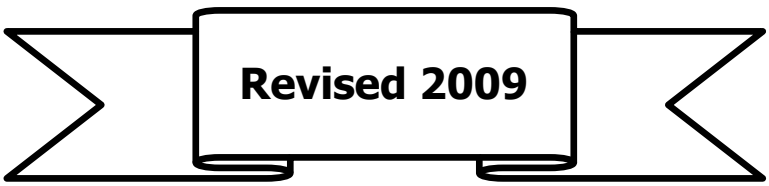
Strong Memorial Hospital
Rochester, NY

presents

INFECTION CONTROL

Self-Study Training Program

(64 pages)



INFECTION CONTROL
Self-Study Training Program

The content of this training curriculum is established by the New York State Department of Health and the New York State Department of Education, and meets the requirements for mandatory infection control training of health-care professionals in the State of New York, pursuant to Chapter 786 of the Laws of 1992.

Specific questions on **content** of this self-study training program should be directed to:

June Rank, BS, RN, CIC
Gail Quinlan, RN, BS, CIC
Lynn Fine, MPH, PhD

Infection Control Program, Strong Memorial Hospital
Rochester, New York

(585) 275-7716

Program hours are Monday through Friday; 8:00 a.m. to 4:30 p.m.

Questions about test results or issuing of certificates should be directed to:
University of Rochester Office of Continuing Professional Education
(585) 275-4392

This self-study syllabus was developed by the Infection Control Programs at several Rochester area hospitals:

Strong Memorial Hospital
Highland Hospital
Via Health System - Rochester General Hospital
Unity Health System - Park Ridge Hospital
and
the membership of APIC Rochester / Finger Lakes Chapter 107

Editor: Paul S. Graman, MD
Hospital Epidemiologist, Strong Memorial Hospital
University of Rochester Medical Center

New York State Department of Health
And
New York State Education Department

Infection Control Training
Self Study

The content of this self-study handbook is established by the New York State Department of Health and the New York Education Department and meets the licensure renewal requirement for mandatory Infection Control Training of Health Care Professionals in the State of New York.

APIC Rochester Finger Lakes
Chapter 107
Original content established 1994
Revised 1998, 2002, 2006, and 2009

CONTENTS

ELEMENT I

PROFESSIONAL RESPONSIBILITY FOR INFECTION CONTROL

All health-care professionals share responsibility to adhere to scientifically accepted principles and practices of infection control, and to monitor the performance of those for whom they are responsible

Learning Objectives:

- Describe benefits to patients and health-care workers of adhering to scientifically accepted principles and practices of infection control;
- Describe the professional's responsibility to adhere to these practices, and the consequences of failing to comply;
- Describe the professional's responsibility to monitor infection control practices of persons for whom he/she is responsible

Definitions:

- **Universal Precautions (Standard Precautions):** precautions that are applicable to <u>all</u> patients, including use of barriers, such as gloves, gowns, masks, and/or protective eyewear, and proper disposal of sharps, to prevent skin and mucous membrane exposure to bloodborne pathogens and all other moist and potentially infectious body substances.
- **Standard of Care:** established criteria for the performance of individuals in similar circumstances.
- **OSHA:** Occupational Safety and Health Administration, a branch of the U. S. Department of Labor

I. Standards of care in infection control

A. **Prevention of Bloodborne Diseases:** evidence suggests that the transmission of human immunodeficiency virus (HIV) , hepatitis B virus (HBV) and hepatitis C virus (HCV) through medical and dental procedures is preventable through the strict adherence to good infection control practices. **Standard Precautions** decrease the opportunity for blood exposures among health-care workers and patients, and have become the standard of care in all health care settings since 1985.

B. Other standards of care for infection control include:
   1. practices to prevent spread of airborne diseases (e.g., tuberculosis, measles, chickenpox, smallpox, Severe Acute Respiratory Syndrome (SARS));
   2. practices, such as hand hygiene, aseptic technique, and use of barrier methods, especially gloves, to prevent contact spread of most bacterial infections (e.g., staph and strep) and some viruses (herpes, cold viruses, CMV) in health-care settings;
   3. appropriate cleaning, disinfection, and sterilization of medical devices and equipment; and
   4. occupational health practices for prevention and control of communicable diseases in health-care workers (e.g. TB skin testing and immunizations against hepatitis B, measles, and rubella).

II. Standards of professional conduct as they apply to infection control

A. Mandated NY State and Federal standards of professional conduct

1. **New York State:** 1992 legislation formally established scientifically accepted infection control practices as standards of professional conduct. The NY State Department of Health and NY State Education Department require that **all licensed health care professionals in New York must complete mandatory course work in infection control before July 1, 1994 and every 4 years thereafter.** Documentation of this training is required for hospital-credentialing of physicians, and for state licensing or registration of non-physicians.
2. **OSHA** (US Dept of Labor): in 1991 the OSHA Bloodborne Pathogens Standard took effect, requiring enforcement of Universal Precautions (Standard Precautions) and training of all personnel (with potential blood or body fluid exposure) in infection control techniques. The Standard also mandates the availability of appropriate protective equipment and barriers, and requires procedures for follow-up after an exposure.

B. Implications of professional conduct standards

1. All health care professionals bear responsibility to adhere to infection control standards. By law in New York State, **unprofessional conduct includes** *"failing to use scientifically accepted infection prevention techniques appropriate to each profession for the cleaning and sterilization or disinfection of instruments, devices, materials, and work surfaces, utilization of protective garb, use of covers for contamination-prone equipment and the handling of sharp instruments"....* and *"failure to use scientifically accepted infection control practices to prevent transmission of disease pathogens from patient to patient, professional to patient, employee to patient, and patient to employee..."*
2. All health-care professionals have a **responsibility to monitor the practices of others** to assure the safety of all patients and personnel.
3. Consequences of failure to follow accepted standards of infection control include:

    a. subjecting self, coworkers, and/or patients to increased risk of communicable disease

    b. subjecting oneself to charges of unprofessional conduct.

        1) **Mechanisms for reporting unprofessional conduct:** patients, family members, or co-workers can file charges against a health professional through their institution (e.g., hospital or employer) or directly to the New York State Department of Health (Office of Health Systems Management, OHSM);
        2) **investigation** of the complaint is carried out by the hospital, employer, or OHSM;
        3) **possible outcomes**, depending on the severity of misconduct, include:

            - disciplinary action,
            - revocation of professional license, or
            - **professional liability**: since infection control practices are considered standard of care, failure to adhere to these standards may be grounds for professional liability.

ELEMENT II

TRANSMISSION AND CONTROL OF INFECTION IN HEALTH CARE SETTINGS

Learning Objectives:

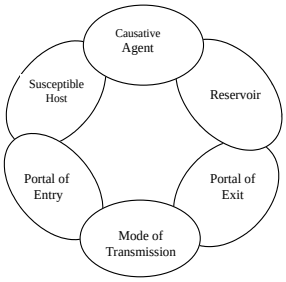
- Describe how pathogenic organisms may be spread in health care settings;
- Identify the factors which influence the outcome of an exposure;
- List strategies for prevention of transmission of pathogenic organisms;
- Describe how infection control concepts are applied in professional practice.

Definitions:

- **Pathogen** or **Infectious Agent**: a microorganism capable of causing disease.
- **Transmission**: any mechanism by which a pathogen is spread by a source or reservoir to a host.
- **Reservoir**: any person, animal, insect, plant, soil or substance (or combination of these) in which an infectious agent normally lives and multiplies, on which it depends for survival, and where it reproduces itself in such a manner that it can be transmitted to a susceptible host.
- **Susceptible Host**: a person or animal lacking effective resistance to a particular infectious agent.
- **Common Vehicle:** contaminated material, product, or substance that serves as an intermediate means by which an infectious agent is transported to two or more susceptible hosts.
- **Nosocomial Infection**: any infection which is acquired in a health care setting; manifestation of clinical illness may occur during or after discharge from the hospital or other health care facility, depending on the incubation period of the infection.
- **Incubation Period**: the time between exposure to an infectious agent and the onset of disease, ranging from hours to years.
- **Colonization**: presence of an infectious agent on skin, mucous membranes (nose, throat, vagina, intestinal tract) or wounds, or in urine, stool or secretions, without causing illness. The colonizing agent may later cause disease, or may be transmitted to other persons.
- **Carrier**: a person who is colonized or infected by an infectious agent for an extended time, often without symptoms, and may transmit infection to others.

I. Transmission of infections

A. **"The Chain of Infection"**: the pattern of spread of infection from one host to another susceptible host, or from the environment to a susceptible host. This chain requires a *pathogen*, a source or *reservoir*, a *mode of transmission*, a *susceptible host*, and a *portal of entry*. With acquisition of the infectious agent, the new host may become ill, may remain asymptomatic (but may be a carrier), or develop an illness which resolves but may be followed by a prolonged carrier state. Many infections are spread from person-to-person (e.g., influenza, SARS, measles, chickenpox, tuberculosis, colds, strep throat, staph, HIV, hepatitis A, B, and C, typhoid, gastroenteritis), whereas others are spread from environment-to-person without further spread between people (e.g., Legionnaire's Disease, Anthrax and several fungal infections).



B. Presence of a pathogen:

1. **Bacteria**: examples are staph, strep, *E. coli, Pseudomonas,* anaerobes, *rickettsia, mycoplasma, chlamydia,* and mycobacteria such as TB.
2. **Viruses:** examples are influenza, common cold viruses, measles, mumps, chickenpox (varicella), smallpox (Variola), hepatitis A, B, and C, and HIV.
3. **Fungi:** include yeasts (e.g., Candida) and molds (e.g., Aspergillus).
4. **Parasites:** include protozoa (e.g., malaria, toxoplasmosis, pneumocystis), worms, and insects (e.g., lice and scabies).
5. **Prions:** include Kuru (shivering disease) CJD(mad cow disease), Germann-Straussler-Scheinker (GSS) fatal familial insomnia (FFI) and atypical dementias (prion dementia without spongiform disease).
6. Pathogens vary in their illness-causing potential, depending on virulence, survival outside the host, host and organ specificity (tendency to infect one type of human or animal host or a particular organ system), and ability to mutate. Mutations allow microorganisms to become more virulent; to develop resistance to antimicrobial drugs, and to avoid normal host defenses.

C. Reservoirs include:

1. Animate

a) **People**:

- **Patients and health-care personnel;**
- **Infected or colonized persons;**
- **Ill persons or asymptomatic carriers.**

Persons who are asymptomatic may readily transmit infection if they are colonized, are incubating an infection, or are chronic carriers of the infectious agent.
Examples: Many health-care workers carry ***Staph aureus*** in their noses and may transmit it to patients; SARS, **chickenpox** and **hepatitis A** can be transmitted during their incubation periods, before illness occurs; **hepatitis B** can be transmitted (via blood, body fluids, sex, or birth) during an asymptomatic incubation period lasting up to 6 months, and 10% of those infected become chronic carriers who may transmit the infection indefinitely; **HIV** is transmissible (via blood, body fluids, sex, or birth) during the asymptomatic incubation period lasting up to 10 or more years, and throughout the period of illness. Hepatitis C can be transmitted (via blood, body fluids, sex, or birth) during an incubation period ranging from 2 weeks to 6 months. The period of communicability may remain indefinitely in persons chronically infected.

b) **Insects or animals**

Examples: skunks, fox, and bats are reservoirs of **rabies**; mice and deer are reservoirs of **Lyme Disease**, which is transmitted to humans from these animals by ticks

2. Inanimate Environment: water, soil, food, counter tops, sinks, medical equipment

Examples: soil and water (including home and hospital hot water tanks) are reservoirs of Legionella, the cause of Legionnaire's Disease; stagnant water is a reservoir of Pseudomonas and other serious pathogens in hospitals; soil and dust are reservoirs of Aspergillus, a serious pathogen in immunocompromised hosts; soil is a reservoir of tetanus, anthrax and other anaerobic infections.

D. **Portals of exit**: routes and mechanisms by which pathogens exit the body

1. coughing, sneezing, respiratory and oral secretions;
2. draining skin lesions or wounds;
3. feces (diarrhea or formed stool);
4. urine;
5. drainage of blood and other body fluids.

E. Modes by which pathogens are transmitted:

1. **Contact** with an infected/colonized person or their contaminated environment.

   a) **direct contact**: touching a person or direct contact with their blood or secretions
   b) **indirect contact**: handling of environment or objects ("fomites") contaminated with infected blood or secretions; or carriage of infection from one patient to another on the health-care workers' hands
   c) **large droplet**: close-range (within 3 feet) exposure to droplets generated by coughing or sneezing

2. **Airborne**: infections acquired by inhalation of aerosols composed of small infectious particles. Infectious aerosols are generated from coughing/sneezing/laughing/talking persons, or from the environment (water, soil, dust). Infection may spread widely in a room, corridor, or through a ventilation system.

   Examples: tuberculosis, chickenpox, measles, aspergillus, histoplasmosis

3. **Common vehicle**: contaminated food, water, medication, intravenous fluid or other product which transmits infection to 2 or more persons.
4. **Vector-borne**: transmission via an insect or animal carrier.

   Examples: mosquitoes are vectors of **malaria and West Nile Virus**; ticks are vectors of **Lyme Disease**.

F. **Portals of Entry**: routes and mechanisms by which pathogens are introduced:

1. Entry sites: non-intact skin, mucous membranes; GI, respiratory, and genitourinary tracts; across placenta to fetus
2. Mechanisms: via ingestion, inhalation, endotracheal tube, bladder catheter, percutaneous injury (e.g., needlestick), vascular access, surgical incision, etc.

G. Factors which influence the outcome of an exposure:

1. **Host susceptibility**: Immunity from past infection or immunization (e.g, measles, rubella) decreases susceptibility. Impairment of host defenses, e.g., due to advanced age, prematurity, chronic disease, malignancy, malnutrition, injury, or chemotherapy increases susceptibility. Impairment of defense is mediated by alteration in:

    a. Natural barriers to infection, e.g., intact skin, stomach acid, respiratory tract cilia, and cough mechanism; tears and normal flora.
    b. Immune system, e.g., humoral immunity (antibodies), cell-mediated immunity (lymphocytes, macrophages), inflammatory response.
    c. Presence of a foreign body/invasive device.

2. **Agent factors**

    a. Infectivity
    b. Pathogenicity or the ability of an agent to cause disease in a susceptible host.
    c. Virulence of the pathogen: invasiveness, ability to cause disease;
    d. Inoculum size: amount of the infectious agent in the exposure;
    e. Route of exposure: some routes more likely to cause infection;
    f. Duration of exposure

3. **Contamination factors**

    a. Contamination of environment
    b. Contamination of equipment

II. Prevention Strategies: Breaking the "Chain of Transmission"

Consider all patients to be potentially infected with a bloodborne pathogen

B. For organisms other than bloodborne pathogens

1. Recognize, diagnose, and treat persons with transmissible disease. *Examples*: tuberculosis, whooping cough, meningococcal meningitis.
2. Eliminate or control inanimate reservoirs of pathogenic organisms. *Example*: eliminate stagnant water sources in health care setting, treat hot water systems for *Legionella*.

C. Interrupt routes of transmission:

1. **Hand Hygiene** is the single most important means of preventing spread of infection:

    a. Washing with a non-antimicrobial soap or an antimicrobial soap, running water and friction for a minimum 15 seconds when hands are visibly dirty or grossly contaminated with proteinaceous material effectively removes organisms from the hands.
    b. If hands are not visibly soiled an alcohol-based waterless antiseptic agent for routine decontamination of hands may be used. Apply product to palm of one-hand and rub hands together, covering all surfaces of hands and fingers until hands are dry.
    c. To improve hand hygiene adherence among personnel especially in instances where high workloads and high intensity of patient care are anticipated, make available at convenient locations, an alcohol-based waterless antiseptic agent.
    d. An antimicrobial soap may be preferred before surgical or invasive procedures, before contact in ICU settings, and after contact with blood, secretions, excretions, drainage, or contaminated articles.
    e. Care must be taken to avoid re-contamination of hands from soap containers, sink handles, standing water in sink or on counter. Bar soap should not be used.

2. **Use of barriers** (gloves, gowns, masks, goggles): see Element IV.
3. **Sterilization and disinfection** of patient care equipment: see Element V.
4. **Isolation or cohorting:**

    a. Standard Precautions synthesize Universal (Blood and Body fluid Precautions) and Body Substance Isolation and apply them to all patients receiving care regardless of 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) non-intact 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.
        - These precautions require the use of barrier protection (gloves, gowns, goggles and masks) and safe work practices (safe disposal of sharps and regulated wastes).

    b. Expanded Precautions:

        - Designed for patients suspected or documented to be infected with highly transmissible or epidemiologically important pathogens for which additional precautions beyond Standard Precautions are needed. There are three types of Transmission-based precautions:
        - Contact precautions-used when a patient is known or suspected to be infected or colonized epidemiologically important microorganisms transmitted by direct contact with the patient or indirect contact with environmental surfaces or patient equipment.

- Droplet precautions are used when patient are known or suspected to be infected with microorganisms transmitted by droplet (large particle droplets) that can be generated by the patient when coughing, sneezing, talking or the performance of procedures. A surgical mask must be worn when within 3 feet of the patient.
- **Airborne precautions** are used when patients are known/suspected to be infected with microorganisms transmitted by airborne droplet nuclei (smaller-particle residue 5 microns or smaller in size) of evaporated droplets that remain suspended in the air and that can be dispersed widely by air currents within a room or over long distance and long periods of time.
- **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.

5. Environmental practices:

A. Housekeeping: maintaining a clean environment;
B. Ventilation: special room ventilation is required for patients with TB (or suspected TB), SARS, Chickenpox and certain other airborne infections;
C. Waste management: proper disposal of sharps and infectious waste;
D. Linen and laundry management.

6. Engineering controls

a. Safer devices

7. Work practice controls

a. Modification in techniques

D. Protection of the host:

1. Vaccination:

- Personnel: immunity against measles (rubeola) and rubella is required of health-care workers (HCWs) either by vaccination or history of natural disease. Vaccination against hepatitis B is highly recommended. Annual influenza vaccination is advised for all HCWs to prevent illness and transmission of influenza to patients.
- Patients: should receive vaccinations appropriate to their age and risk group (e.g. influenza and pneumococcal vaccine for patients or with chronic disease).

2. Pre-and **post-exposure prophylaxis** = preventative treatment or vaccination given after exposure to an infectious agent, in order to prevent infection or illness. Examples:
    - Antibiotics (rifampin) given after specific identified exposure to meningococcal disease;
    - Antiviral drugs (combination of 2-3 agents) given after known significant exposures to HIV-infected blood/body fluid;
    - Hepatitis B vaccine and hepatitis B immune globulin given after exposure of an unvaccinated person to hepatitis B-infected blood;

- Varicella-zoster immune globulin (VZIG) given to a susceptible, immunocompromised host after exposure to chickenpox.
- Antivirals (Amantidine, Rimantidine, Oseltamivir) given after Influenza exposure to prevent disease or mitigate disease severity

3. **Protect skin** from breakdown
4. **Avoid unnecessary use**, or excessive duration of placement, of intravenous lines, bladder catheters, and other invasive devices.

E. Training and education of health care workers

Training should be directly linked to the implementation of professional and regulatory standards as well as facility policies and procedures.

Examples include: OSHA Bloodborne Pathogen Training when beginning employment and then yearly training for all "at risk" healthcare workers yearly. Ongoing infection control education to comply with policies and procedures.

ELEMENT III

USE OF ENGINEERING AND WORK PRACTICE CONTROLS TO REDUCE THE OPPORTUNITY FOR PATIENT AND HEALTH-CARE WORKER EXPOSURE TO POTENTIALLY INFECTIOUS MATERIAL

Learning Objectives:

- Define "engineering controls" and "work practice controls";
- Identify a hierarchy of exposure prevention strategies;
- Describe specific practices and settings which increase the opportunity for exposure of health-care workers and patients to infectious material;
- Identify where engineering or work practice controls can be utilized to prevent exposure.

Definitions:

- **Engineering Controls** are use of equipment, devices, or instruments that remove or isolate a hazard. *Example*: use of needle-less intravenous devices.
- **Work Practice Controls** are alterations in the performance of a task in such a manner as to reduce or eliminate the likelihood of exposure. *Example*: no re-capping of needles.
- **Personal Protective Equipment (PPE)** include gloves, gowns, masks, and goggles. Their use is discussed in Element IV.

I. High risk practices and procedures: Circumstances and practices which *increase* opportunities for exposure to bloodborne and contact pathogens

A. **Percutaneous exposures** = exposures that occur through the skin

1. Injury occurs by handling, disassembly, disposal of, or reprocessing of needles and other sharps. *Examples*:

    - manipulating needles and sharps by hand;
    - recapping needles using both hands;
    - removing scalpel blades by hand;
    - handling broken glass or exposed ends of dental wires.

Procedures in which there is opportunity for injury, particularly where there is poor visualization which can expose the patient as well as the HCW. *Examples*:

- blind suturing (suturing by feel);
- using a non-dominant hand next to a sharp;
- working with bone spicules or metal fragments.

B. **Mucous membrane or non-intact skin exposures** (exposures through eyes, mouth, nose, cuts, rashes, dermatitis) occur via:

1. direct contact with blood or body fluid, e.g., by handling a contaminated instrument or cleaning up a blood spill.

2. sprays or splashes of blood or body fluid, e.g., during a surgical or dental procedure, or during suctioning of a patient.

C. Parenteral exposures (exposure via the blood stream), may occur by injection with infectious material;

1. infusion of contaminated blood products;
2. transplantation of contaminated organs or tissue

II. Evaluation/Surveillance of exposure incidents

A. Identify who is at risk

Direct care providers

- MD, RN, LPN, dentists, dental hygienists;
- Assistants: Nursing assistants, technicians, orderlies
- Ancillary personnel: respiratory therapists, physical therapists, housekeepers, laundry staff;
- Patients

B. Identify the devices causing exposure : needles, scalpels, lancets , etc.

C. Devices with higher disease transmission risk such as a hollow bore needle

D. Devices with higher injury rate such as the recoil effect from butterfly phlebotomy needles

E. Identify areas or settings where exposures are occurring.

1. Patient room
2. Operating room
3. Treatment rooms
4. Physicians' offices

F. Circumstances by which exposures are occurring

1. Recapping;
2. Transferring a body fluid between containers
3. Failing to properly dispose of used needles in puncture-resistant sharps containers
4. Failure to activate the engineered safety device

III. **Engineering controls which eliminate or isolate the hazard:**

A. Use safer devices whenever possible to prevent sharps injuries: strategies are to:

1. Passive (i.e., automatic) safety features are preferred. *Examples*: needle-less IV systems and self-sheathing syringes are currently available
2. Provide a mechanism to safely cover the sharp immediately and permanently after use.
3. Integrate safety devices rather than accessory devices.

4. Provide education and training on the use of safer devices
5. Eliminate the traditional, non-safety alternative whenever possible.

B. Puncture resistant, durable, leakproof containers for disposal and transport of needles and other sharps (scalpel blades, lancets, slides, broken glass, surgical staples, orthodontic wires, etc.) [For more information on Sharps Disposal Containers refer to the NIOSH published guidelines]

1. employers must provide sharps disposal containers which are accessible to employees and as close as feasible to the area of sharps use;

- **containers must be red in color or labeled with biohazard sign;**
- **containers must be removed for disposal before becoming overfilled.**

C. Splatter shields on medical equipment, e.g. locking centrifuge lids, or a biosafety cabinet for laboratory procedures.

IV. Work practice controls to eliminate or reduce the likelihood of exposure to potentially infectious material

A. General Practices

1. Wash your hands
   a. Use alcohol-based handwash for routine handwashing
   b. Soap and water wash for visibly soiled hands

2. Avoid unnecessary use of needles and other sharps;
   - **Choose a safety device when available**
     a. Always activate appropriately
     b. DO NOT circumvent the safety feature.

3. Use special care in handling and disposal of sharps:

   - **Do not recap needles or, if absolutely necessary, use a one-handed recapping technique:**

     a. place needle-cap on flat surface;
     b. take hand away from cap and away from needle;
     c. holding only the syringe, guide needle into cap and scoop up the cap;
     d. lift up syringe so cap is sitting on needle hub;
     e. secure needle-cap into place.

   - **in surgery, dentistry, or emergencies, pass sharps using an area or basin or tray designated as a "safe zone" (not hand-to-hand);**
   - **only disassemble sharp equipment using forceps or other devices.**
   - **always dispose of sharps you have used: NEVER leave sharps behind on trays, counters, or beds for someone else to pick up.**
   - **watch out for overfilled sharps containers when disposing of sharps.**

4. Modify procedures to avoid injury:

    - **use forceps, suture holders or other instruments for suturing;**
    - **do not use fingers to hold tissue when suturing;**
    - **never leave sharps in a surgical field;**
    - **do not reach into trash to retrieve items;**
    - **do not reach into a sink or basin of water to retrieve contaminated instruments**

5. Promptly clean blood and body fluid spills:

    - **wear gloves and use approved disinfectant;**
    - **discard all contaminated materials in the appropriate biohazard waste container (or laundry container for contaminated laundry)**

6. Do not eat, drink, smoke, apply cosmetics or handle contact lenses in work areas where there is risk of exposure to blood or body fluids.

V. Prevention and control of airborne pathogens

A. Circumstances which *increase* opportunities for exposure include:

1. Inadequate ventilation;
2. Lack of source control:
3. Failure to institute respiratory precautions for known or suspected cases of TB or other airborne diseases

Unrecognized cases:

1. Failure to consider the diagnosis of TB or other airborne disease, resulting in delayed recognition, isolation, and treatment of cases.
2. Transmission to HCWs and other patients may follow.

Prolonged exposure.

D. Engineering controls for prevention of airborne transmission

1. Appropriate air exchange (number of complete air replacements per hour)

    a. **A minimum of 6 air exchanges per hour** are required in rooms housing patients with known or suspected TB or other airborne diseases; high rates of air exchange remove contaminated air more quickly and dilute the concentration of airborne organisms with fresh air.
    b. Air from these rooms must be exhausted to the outside, or appropriately filtered (HEPA filtration) before recirculation to other areas.

2. Negative-pressure rooms: special isolation rooms which have air pressure below the corridor air pressure, causing air to flow from the corridor into the room, and limiting flow of contaminated air out into the corridor. Doors to these rooms must be kept closed. Patients with active pulmonary TB should be isolated in negative-pressure rooms.

3. HEPA filters: high-efficiency-particulate-air filters remove infectious particles from the air. Isolation booths, tents, and portable filtration units utilizing HEPA filters can be used to minimize airborne transmission in isolation rooms or during procedures such as sputum induction and aerosolized pentamidine treatments.
4. Ultraviolet (UV) lights are a supplemental measure for control of airborne pathogens.

E. Source control

1. Early identification
2. Teach source (patient) to cover mouth when coughing or sneezing, and to appropriately discard tissues.
3. Possibly infectious patients should be triaged early and isolated from others at risk, e.g., in an emergency department, clinic, or office. In an office setting, possibly infectious patients can be scheduled for the end of the day, or taken directly to a treatment room without exposing waiting patients.
4. Close doors on identified/suspected patients rooms.
5. Perform PPD surveillance every six months in high-risk areas; annually for others.
6. Provide patient/family education.

F. Personal Protective Equipment (masks, particulate respirators): see Element IV

G. Special Considerations

1. Operating Suites must have positive air pressure; therefore
    a. Elective procedures should be postponed until patient is noninfectious
    b. For procedures unable to be postponed – contact your facility's Infection Control Department
2. Procedures associated with aerosol transmission of extrapulmonary TB.
3. Potentially infectious patients must wear a surgical mask during transportation.

VI. Safe injection practices and procedures designed to prevent disease transmission from patient to patient and healthcare worker to patient

1. Unsafe injection practices have resulted in one or more of the following:
    a. Transmission of bloodborne viruses, including hepatitis B and C viruses to patients;
    b. Notification of thousands of patients of possible exposure to bloodborne pathogens and recommendation that they be tested for hepatitis B and C viruses and human immunodeficiency virus (HIV);
    c. Referral of providers to licensing boards for disciplinary action; and
    d. Malpractice suits filed by patients.
2. Pathogens including HCV, HBV, and HIV can be present in sufficient quantities to produce infection in the absence of visible blood.
    a. Bacteria and other microbes can be present without clouding or other visible evidence of contamination.
    b. The absence of visible blood or signs of contamination in a used syringe, IV tubing, multi-dose medication vial, or blood glucose monitoring device does NOT mean the item is free from potentially infectious agents.
    c. All used injection supplies and materials are potentially contaminated and should be discarded.

3. Providers should:
    a. Maintain aseptic technique throughout all aspects of injection preparation and administration:
        1) Medications should be drawn up in a designated "clean" medication area that is not adjacent to areas where potentially contaminated items are placed.
        2) Use a new sterile syringe and needle to draw up medications whole preventing contact between the injection materials and the non-sterile environment.
        3) Ensure proper hand hygiene before handling medications.
        4) If a medication vial has already been opened, the rubber septum should be disinfected with alcohol prior to piercing it.
        5) Never leave a needle or other devise (e.g. "spikes") inserted into a medication vial septum or IV bag/bottle for multiple uses. This provides a direct route for microorganisms to enter the vial and contaminate the fluid.
        6) Medication vials should be discarded upon expiration or any time there are concerns regarding the sterility of the medication.
    b. Never administer medications from the same syringe to than one patient, even if the needle is changed.
    c. Never use the same syringe or needle to administer IV medications to more than one patient even if the medication is administered into the IV tubing, regardless of the distance from the IV insertion site.
        1) All infusion components from the infusate to the patient's catheter are a single interconnected unit.
        2) All of the components are directly or indirectly exposed to the patient's blood and cannot be used for another patient.
        3) Syringes and needles that intersect through any port in the IV system also become contaminated and cannot be used for another patient or used to re-enter a non-patient specific multi-dose vial.
        4) Separation from the patient's IV by distance, gravity and/or positive infusion pressure does not ensure that small amounts of blood are not present in these items.
    d. Never enter a vial with a syringe or needle that has been used for a patient if the same medication vial might be used for another patient.
    e. Dedicate vials of medication to a single patient.
        1) Medications packaged as single-use must never be used for more than one patient:
            i. Never combine leftover contents for later use;
            ii. Medications packaged as multi-use should be assigned to a single patient whenever possible;
            iii. Never use bags or bottles of intravenous solution as a common source of supply for more than one patient.

    f. Never use peripheral capillary blood monitoring devices packaged as single-patient use on more than one patient:
        1) Restricted use of peripheral capillary blood-sampling devices to individual patients.
        2) Never reuse lancets. Consider selecting single-use lancets that permanently retract upon puncture.

ELEMENT IV

SELECTION AND USE OF BARRIERS AND PERSONAL PROTECTIVE EQUIPMENT

Learning Objectives:

- Describe the circumstances which require the use of barriers and personal protective equipment (PPE) to prevent patient and health-care worker (HCW) contact with potentially infectious material;
- Identify specific barriers and PPE for patient and HCW protection

Definitions:

- **Personal Protective Equipment (PPE)**: specialized clothing or equipment (e.g., gloves, gowns, masks, goggles) worn by a health-care worker (HCW) for protection against a hazard.
- **Barrier**: an object that separates a person from a hazard (e.g., dressing or drape).

I. Types of PPE and barriers and criteria for selection

A. Gloves:

1. **When to be worn**: gloves must be worn for all anticipated hand contact with 1) blood, 2) all body fluids, excretions, and secretions *except sweat* (e.g., urine, stool, saliva, cerebrospinal fluid, wound drainage, etc), 3) mucous membranes (oropharynx, GI, respiratory, and genitourinary tracts), and 4) non-intact skin, wounds, rash or burns and when handling items contaminated with blood, body fluids, excretions, or secretions. Gloves must be worn during all invasive procedures and all vascular access procedures, including all phlebotomies and insertion of IV's or other vascular catheters.

   Gloves are not to be washed, disinfected, or sterilized for reuse (except utility gloves). Gloves must be changed between patients, and hands must be sanitized after gloves are removed.

2. Sterile and non-sterile gloves:

   a. **Sterile gloves** are required to prevent transmission of infection from HCW to patient **in surgery and in other procedures** associated with a high risk of infection due to interruption of normal host defenses. *Examples*: insertion of central venous catheters, urinary catheterization, surgical dressing changes, and tracheal suctioning.
   b. **Non-sterile gloves** are used to reduce transmission of infection when sterility is not required (e.g.: oral or vaginal examination, cleaning a spill, emptying suction containers, urine drainage bags, or bedpans) or where sterile technique does not necessitate sterile gloves (*e.g.*: phlebotomy, peripheral IV insertion).

3. Glove Material:

    a. **Vinyl or latex gloves** are used for most medical, dental, and laboratory procedures discussed above. Since gloves can be torn, they should be inspected prior to use. Disposable single use gloves must be replaced as soon as practical if contaminated, punctured or damaged during use. **Double-gloving** or **puncture-resistant liners** can be used to decrease the risk of percutaneous injury and exposure to blood/body fluids. If it is anticipated that there will be exposure to a large volume of blood or body fluids, then latex or nitrile gloves rather than vinyl gloves should be worn.
    b. **Rubber utility gloves** are used for heavy-duty housekeeping chores. They may be decontaminated and reused unless they are cracked, peeling, torn, or punctured.
    c. Hypoallergenic (latex free) gloves, glove liners, and powderless gloves are available.

B. Cover garb = protective attire to prevent contamination of skin, mucous membranes, work clothes, and undergarments. (Regular work clothes, uniforms, and surgical scrubs are not considered protective attire.)

1. Types of cover garb:

    a. **Gowns** (with sleeves) are worn:
        - in surgery and obstetrics,
        - when splashing, spraying, spattering of blood/body fluids is anticipated, or
        - when blood/body fluid contamination of arms is anticipated.
    b. **Aprons** (no sleeves) may be worn for lesser degrees of exposure
    c. **Laboratory coats** are worn in laboratory setting.

2. Permeability characteristics:

    a. **impervious** = fluids will not pass through
    b. **fluid resistant** = fluids will not readily pass through
    c. **permeable** = easily penetrated by fluids

3. **Choice of gown or apron** depends on the level of blood or body fluid exposure anticipated. **Fluid resistant** gowns are suitable for most situations; extra fluid resistant sleeves can be worn over a gown, and/or an impervious apron can be worn under a gown, to improve protection against soak-through during prolonged or high-blood-loss surgical procedures. **Impervious gowns** may be preferable for procedures with the highest risk of blood exposure. Impervious gowns may be less comfortable since the material does not breathe well.

C. Masks

1. Types of masks:

   a. **Surgical mask**: purpose is to protect the patient by preventing discharge of contaminated nasal and oral secretions from the wearer during a procedure, and thereby reduce risk of wound infection.
   b. Masks to protect the wearer:

      - Protect wearer's nose/mouth from exposure to splattered or splashed blood or body fluids. Standard surgical masks are appropriate for this purpose.
      - Masks to protect wearer from inhalation of airborne aerosolized infectious particles (e.g., TB, influenza, and measles).

      Masks for protection against organisms spread via the airborne route such as TB, Chickenpox and novel agents such as SARS, Avian flu include **N95 respirators,** also called Particulate Respirators, and **HEPA filter** respirators in disposable and reusable types. **N95 respirators** must filter out particles as small as 1 micron in size with at least 95% efficiency, and allow no more than 10% leakage of air around the mask. **HEPA** filters provide the highest level of filtering ability (0.3 micron size with 99.7% efficiency). Powered air-purifying respirators (**PAPR**) are an alternative for protection against TB.

   N95 respirators, HEPA respirators and PAPRs are accepted by OSHA for protection of the wearer against airborne organisms.

2. Characteristics of masks:
   a. **Filtration** characteristics of the material: surgical masks may effectively block discharge of large droplets into the air, but the material is not an effective filter to prevent inhalation of very small, aerosolized particles characteristic of TB and airborne viral diseases. N95 and HEPA respirators provide increased levels of filtration. A wet mask is no longer effective.
   b. **Face seal**: a tight seal around the edges of a particulate respirator is essential to its effectiveness. If loose fitting, contaminated air is drawn in around the edges of the mask with each inhalation, instead of the air being drawn through the filter. Acceptable protection requires that face-seal leakage be no more than 10%. See **Respirator Fit-testing and Training** below (section III. A. 3.).

D. **Face shields** protect eyes, nose, and mouth from exposure to blood or body fluids via splash, splatter, or spray. Protection against airborne pathogens requires the addition of an appropriate mask.
E. **Eye protection (goggles, safety glasses, or face shield)** should be worn during all major surgical procedures and whenever splashes/sprays of blood or body fluid may be generated. **Ordinary glasses are not acceptable** unless a solid side shield is added to the eyewear.
F. **Shoe covers, leg covers, boots, and head covers** are appropriate attire whenever heavy exposure to blood/body fluids is anticipated, usually in surgery. Most such situations involve surgical procedures in which caps or hoods are already required for sterility. Shoe/leg and head covers should be removed or discarded before leaving the room.
G. Other barriers, such as wound dressings, reduce the risk of exposure to blood/body fluids.

II. Choice of PPE and barriers is based on reasonably anticipated exposure of the HCW and on the need for patient protection:

A. Selection of PPE/barriers based on anticipated exposure of **HCW:**

1. Contact with minimal bleeding or drainage: use gloves plus gown or apron.
2. The possibility of blood/body fluid splashes, sprays, splatters exists: use gloves, fluid resistant gown, mask, and eye protection or faceshield. Appropriate in surgery, obstetrics, and dentistry.
3. Contact with large volume bleeding or drainage (likely to soak through): use the above, (select vinyl or nitrile gloves) with fluid resistant gown, and add shoe covers, leg covers, and/or boots; consider impervious gown.
4. Large droplet vs. airborne (aerosol) pathogen: a faceshield, or surgical mask plus eye protection, will protect against inoculation of large droplets or splatter into mouth, nose, and eyes. Optimal protection against airborne disease (e.g., TB) requires a particulate respirator.

B. Selection of PPE/barriers based on need for **patient** protection:

1. Select sterile barriers and PPE for invasive procedures. *Example*: sterile gowns, gloves, dressings in surgery.
2. Select surgical masks for prevention of droplet contamination of patients' wounds. Most particulate respirators will also prevent droplet contamination from HCW to patient. **Exception**: exhalation valves (to allow easier breathing) on some particulate respirators will permit respiratory droplets to escape from the wearer; masks with exhalation valves should not be worn in surgery.
3. HCWs with skin lesions or nail infections must wear dressings and/or gloves to protect patients from exposure to HCW's blood/body fluid.

III. Proper and effective use of PPE and barriers:

A. Proper fit:

1. **Gloves**: too small may tear; too large are clumsy.
2. **Gowns**: should cover skin and clothes.
3. **Mask**: must fit snugly around mouth and nose, with metal band molded across bridge of nose, and straps or ties in place. When wearing a N95 particulate respirator mask, a fit check should be done after applying the mask and before going in the room.

    a) **Respirator Fit-testing and Training:** HCWs who care for patients with known or suspected infectious TB are evaluated for ability to wear a particulate respirator (N95 mask or HEPA mask), fit-tested with the designated mask, and educated regarding TB transmission and precautions. Successful fit testing requires that face-seal leakage be no more than 10%. HCWs who have not been fit-tested and trained (or who cannot achieve adequate face seal due to facial contours or the presence of facial hair) for the appropriate respirator do not enter rooms being used for TB isolation. Powered air-purifying particulate respirators (**PAPRs**) are an alternative for respiratory protection of persons who have not or cannot be fit-tested successfully with an N95 mask but proper training for its use must occur.

B. **Integrity of barrier**: check for holes, tears, and damage before use.

1. Inspect gloves for tears or holes before use. Replace gloves as soon as practical if damaged during use. Gloves need to be changed between patients and during care of the same patient if going from a dirty to clean task (e.g. perineal care to checking an IV site).
2. Masks should be replaced if damaged or wet.

C. Disposable vs. reusable barriers and PPE:
1. Disposable items should not be reused.
2. Reusable items must be properly cleaned and reprocessed before reuse.
3. Surgical masks are replaced after each use, and discarded promptly between patients. Particulate respirators (N95 and HEPA respirators) are often used for longer periods of time, but must be replaced if damaged, soiled, or wet.
4. All PPE, whether disposable or reusable, must be removed before leaving the patient room or work area, and hands must be sanitized.

D. Potential for cross-contamination if PPE is not changed between patients

1. Gloves, gowns, aprons, and surgical masks must be changed between patient contacts. Never wear the same gloves, gowns, etc. from patient-to-patient.
2. Hands must be sanitized after gloves are removed. Gloves do not completely prevent penetration of bacteria and viruses, and the moist environment inside a glove can promote growth of bacteria on the skin.
3. Reusable goggles should not be shared, and should be cleaned when soiled.

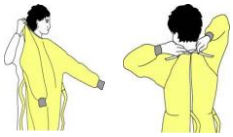
E. Under- and over-utilization of barriers and PPE:

1. Under-utilization places HCWs and patients at unnecessary risk.
2. Over-utilization wastes resources, may intimidate patients, and may interfere with patient care.

F. The proper sequence for putting on and removing PPE is as follows:

Putting on PPE

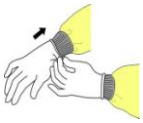
1. Gown
   - Fully cover torso from neck to knees, arms to end of wrists, and fully wrap around the back
   - Fasten in back of neck and waist



2. Mask or Respirator
   - Secure ties or elastic bands at middle of head and neck
   - Fit flexible band to nose bridge
   - Fit snug to face and below chin
   - Fit-check respirator

3. Goggles or Face Shield
   - Place over face and eyes and adjust to fit

4. Gloves
   - Extend to cover wrist of isolation gown



Removing PPE

1. Gloves
   - Outside of gloves is contaminated!
   - Grasp outside of glove with opposite gloved hand, peel off
   - Hold removed glove in gloved hand
   - Slide fingers of ungloved hand under remaining glove at wrist
   - Peel glove off over first glovet
   - Discard gloves in waste container

2. Goggles or Face Shield
   - Outside of goggles or face shield is contaminated !
   - To remove, handle by head band or ear pieces
   - Place in designated receptacle for reprocessing or in waste container


3. Gown
   - Gown front and sleeves are contaminated !
   - Unfasten ties
   - Pull away from neck and shoulders, touching inside of gown only
   - Turn gown inside out
   - Fold or roll into a bundle and discard


4. Masks or Respirator
   - Front of mask/respirator is contaminated – DO NOT TOUCH !
   - Grasp bottom, then top ties or elastics and remove
   - Discard in waste container


http://www.cdc.gov/handhygiene/download/hand_hygiene_supplement.ppt

IV. Dentists and dental hygienists:

- See: Centers for Disease Control (CDC). **Recommended infection control practices for dentistry, 1993.** *MMWR* 1993; 42(No. RR-8): 1-12 (May 28, 1993).

ELEMENT V

PRINCIPLES AND PRACTICES FOR CLEANING, DISINFECTION, AND STERILIZATION

Learning Objectives:

- Recognize the importance of the correct application of reprocessing methods for assuring the safety and integrity of patient care equipment.
- Identify the individual's professional responsibility for maintaining a safe patient care environment.
- Recognize strategies for effective pre-cleaning, chemical disinfection, and sterilization of instruments and devices.

Definitions:

- **Cleaning**: The removal of all foreign material (e.g., soil, organic debris) from objects.
- **Contamination**: The presence of microorganisms on inanimate objects (e.g. clothing, surgical instruments) or in substances (e.g. water, food, milk).
- **Decontamination**: The process of removing disease-producing microorganisms and rendering the object safe for handling.
- **Disinfection**: A process that results in the elimination of many or all pathogenic microorganisms on inanimate objects, with the exception of bacterial endospores.
    - **High-level disinfection** - kills bacteria, *Mycobacteria* (TB), fungi, viruses, and some bacterial spores.
    - **Intermediate-level disinfection** - kills bacteria, *Mycobacteria* (TB), most fungi, and most viruses. Does not kill resistant bacterial spores.
    - **Low-level disinfection** - kills most bacteria, some fungi, and some viruses. Will not kill bacterial spores and is less active against some gram-negative rods (e.g., *Pseudomonas*) and *Mycobacteria*.
- **Sterilization**: A process that completely eliminates all forms of microbial life.

I. General Information:

A. Cleaning, disinfection, and sterilization play an important role in prevention of infections related to exogenous introduction of microorganisms.

B. The major risk from breaks in infection control practice is to patients.

1. Infections may occur at any body site when medical supplies or equipment are contaminated.
2. The infection potential is greatest when invasive procedures are performed.

C. Additional risk exists for personnel who may become colonized/infected during processing of equipment.

D. Every health care setting should establish policies for the disposal and/or reprocessing of supplies, to include:

1. Procedure for reprocessing reusable equipment or supplies appropriate for each type of material and its intended use in patient care.
2. Workflow patterns *from* soiled/contaminated *to* clean/sterile areas.
3. Procedure for receiving and storing clean/sterile supplies and to provide for rotation to avoid outdating of supplies.
4. Procedure for recall of products from commercial suppliers and from in-house preparation.

E. Every health care setting should develop monitoring systems, to include:

1. Monitoring of the sterilization process with results recorded in a permanent log or record.
2. Recall of items if monitors indicate sterilization is not complete.
3. Criteria for sterility assurance
   - **Shelf life –** the length of time the item is considered sterile. Pre-packaged sterile items may have an expiration date determined by the manufacturer.
   - **Event-related Sterility –** sterility of a package depends on the packaging material used, the number of times it is handled and the conditions of storage (cleanliness, temperature, humidity).
4. The healthcare professional is responsible for checking supplies based on shelf life or event-related sterility.

II. Evidence of disease transmission by contaminated equipment is well documented.

A. Examples:

Vascular access devices (IV cannulas, arterial pressure monitors, cardiac and vascular prostheses, A-V shunts for hemodialysis): contamination of devices at time of insertion, or subsequent contamination, may result in blood stream infection, site of entry infection, or remote infection.
Genito-urinary tract devices: contaminated urinary drainage systems or cystoscopes can cause nosocomial urinary tract infection and subsequent blood stream infection.
Respiratory tract devices: contaminated fluid nebulizers, ventilators, or bronchoscopes may cause nosocomial pneumonia.

B. Factors that have contributed to contamination in reported cases include:

1. **Inadequate cleaning.** *Examples*: inadequately cleaned commodes contributing to transmission of *Clostridium difficile* colitis; inadequate clean up of blood spills contributing to transmission of hepatitis B.
2. **Inadequate disinfection/sterilization processes.** *Example*: inadequately sterilized instruments increasing post-operative wound infection rates.
3. **Contamination of disinfectant or rinse solution.** *Example*: *Pseudomonas*- contaminated disinfectant causing contamination of bronchoscopes; *C. difficile*-contaminated endoscopes.
4. **Reuse of disposable equipment.** *Example*: reuse of disposable platforms on glucometers linked with transmission of Hepatitis B.
5. **Failure to reprocess or dispose of equipment between patients.** *Example*: transmission of *S. aureus*, hepatitis B and numerous other pathogens.

III. Points in reprocessing or handling where breaks in infection control practices can compromise the integrity of equipment or devices.

A. General Principles of Cleaning:

1. Soil protects microbes from contact with lethal agents (disinfectants, sterilants), and may directly inactivate these agents.
2. Physical cleaning eliminates large numbers of organisms associated with gross soil.
3. Sound cleaning practices, in addition to their aesthetic benefits, reduce the microbial load on environmental surfaces.
4. Manufacturer's recommendations for operation of cleaning equipment and use of cleaning supplies must be followed carefully.

B. Handling and cleaning contaminated items, e.g.:

1. **Pre-soaking instruments** vs. immediate transport to a central reprocessing area. Pre-soaking in detergent-disinfectant solution is preferred when delays in reprocessing are unavoidable.
2. **Thoroughness of internal and external physical cleaning** is vital to the process. Adequate disinfection cannot be achieved without first completing thorough cleaning and rinsing of the item, since organic debris and residual detergent may inactivate the disinfectant. More complex equipment creates opportunities for breaks in this process. *Example*: multiple internal channels in endoscopic equipment must be thoroughly washed and rinsed prior to disinfection.

C. Choice of reprocessing method should be based on the:

1. intended use of the equipment or device,
2. desired level of antimicrobial activity (high, intermediate, low), and
3. manufacturer's recommendations for reprocessing.

The CDC recommendations for reprocessing are presented in **TABLE 1**.

D. **Reprocessing and Re-use**

Definitions

Single-use disposable – a single use device that is intended to be used on one patient during a single procedure. It is not intended to be reprocessed (i.e. cleaned and disinfected/sterilized) and used on another patient. The labeling may or may not identify the device as single-use or disposable and does not include instructions for reprocessing.

Opened but unused single-use device – a disposable single-use device whose sterility has been breached or compromised or whose sterile package was opened but which has not been used on a patient (i.e. has not been in contact with blood or bodily fluids).

Reprocessing: Includes all operations performed to render a contaminated reusable or single-use device patient-ready. (see Steps of Reprocessing below)

Re-sterilization: The repeated application of a terminal process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility assurance level to a device that has previously undergone a sterilization process.

Reuse: The repeated use of multiple uses of any medical device, including devices intended for reuse or single-use with reprocessing (cleaning, disinfection or sterilization) between uses.
Disposable devices: Medical devices that are required to be sterile and are supplied by the manufacturers as for "single-use only." A wide range of items used for diagnosis and treatment are marketed as disposable devices such as syringes to cardiac pacemakers.
Endotoxin: A high-molecular-weight complex associated with the outer membrane of gram-negative bacteria. Endotoxins are pyrogenic and increase capillary permeability regardless of the species of bacteria.
Original equipment manufacturers (OEM): The company that originally manufactures a device prior to its first use.
Outsourcing: The process in healthcare facilities of contracting reprocessing activities to a company that specializes in re-sterilization.
Pyrogen: A fever-producing substance.
Reposable: Recommended Practices for Endoscopy and Minimally Invasive Surgery from the Association of perioperative registered Nurses (AORN) defines a reposable device as an instrument with a combination of reusable and disposable components.
Reusable devices: Medical devices intended to be used and reprocessed multiple times. For a device to be labeled as "reusable," the manufacturer must show that the device retains its safety and efficacy after reprocessing. Usually fabricated from metal, glass, rubber or woven textiles, these items are collected after use, cleaned, inspected, packaged and sterilized in the hospital by ETO or steam sterilization.
Third-party reprocessor: The Association of Medical Device Reprocessors (AMDR) defines a third-party reprocessor as an entity that, at the request of a customer, inspects, functionally tests, cleans, packages and sterilizes medical devices labeled for single use in a way that does not significantly affect the quality, physical characteristics or performance functions of the device and keeps the device safe and effective for its appropriate clinical use.

Potential complications associated with reuse:

- Infection
- Endotoxic reactions
- Toxic residues
- Bio-compatibility
- Complications associated with device integrity.

Regulatory Issues

- The FDA will regulate hospitals and third-party reprocessors in the same manner that it regulates device manufacturers. Organizations will be required to seek FDA approval prior to reprocessing.
- If an outside reprocessing company is used, it is the responsibility of the reuse facility to select a competent company, monitor its performance and ensure that the reprocessed devices meet quality control standards. Selection and monitoring of an outside reprocessing company may include site visits, evaluation of the reprocessing company's protocols and procedures and assurance of outside independent testing.

Reprocessing

- Includes all operations performed to render a contaminated reusable or single-use devise patient-ready.

Steps of Reprocessing

1. Pre-Cleaning
    A. Removes soil, debris, lubricants from internal and external surfaces
    B. To be done as soon as possible after use
2. Cleaning
    A. Manual (e.g., scrubbing with brushes)
    B. Mechanical (e.g., automated washers)
    C. Appropriate use and reprocessing of cleaning equipment (e.g., do not reuse disposable cleaning equipment)
    D. Frequency of solution changes
3. Disinfection requires sufficient contact time with chemical solution.
4. Sterilization requires sufficient exposure time to heat , chemicals, or gases.
5. Choice/Level of reprocessing sequence
    A. Based on intended use
        1. Critical instruments and medical devices require sterilization.
        2. Semi critical instruments and medical devices minimally require high level disinfection.
        3. Noncritical instruments and medical devices minimally require cleaning low level disinfection.
    B. Based on manufacturer's recommendation
        1. Compatibility among equipment components, materials and chemicals used
        2. Equipment heat and pressure tolerance
        3. Time and temperature requirements for reprocessing
6. Effectiveness of reprocessing instruments, medical devices and equipment
    A. Cleaning prior to disinfection
    B. Disinfection
        1. Selection and use of disinfectants
            a) Surface products
            b) Immersion products
            c) Presence of organic matter
            d) Presence of biofilms
            e) Monitoring
                i. Activity and stability of disinfectant
                ii. Contact time with internal and external components
                iii. Record keeping/tracking of instrument usage and reprocessing
            f) Post-disinfection handling and storage.

TABLE 1: Equipment Reprocessing Guidelines

Risk of Infection	Usage of Medical Device	Examples of Medical Devices	Procedure to Use Before Each Use
Critical	enters normally sterile tissue or vascular system	surgical instruments, cardiac catheters; implants; pertinent components of heart-lung oxygenators, blood component of hemodialyzers; laparoscopes; arthroscopes; bronchoscopes	Sterilize
Semi-Critical	Contacts intact mucous membranes, does not ordinarily penetrate body surfaces	non-invasive flexible and rigid fiberoptic endoscopes, endotracheal tubes; anesthesia breathing circuits; cystoscopes	sterilize if feasible or at least high level disinfection
Non-Critical	does not ordinarily touch the patient or touches only intact skin	crutches; bed boards; blood pressure cuffs	intermediate to low-level disinfection

Note: The CDC recommends that scopes be sterilized, if feasible; and if sterilization is not feasible, high level disinfection should be utilized. There is currently no data to prove that sterilization of scopes reduces the risk of infection as compared to proper cleaning and high level disinfection. However, since there is also no data to prove that proper cleaning and high level disinfection eliminates the potential for cross- contamination, sterilization following cleaning is the preferred method.

IV. Effectiveness of the *disinfection* process is dependent on three factors:

- Selection and use of disinfecting products,
- Monitoring activity of disinfectants, and
- Post-disinfection handling and storage of the equipment or device.

A. General principles regarding use of any chemical disinfectant include:

1. Read the label for activity and use instructions.
2. All items must be thoroughly cleaned before disinfecting.
3. All items must be thoroughly rinsed and dried after disinfecting. Care must be taken not to re-contaminate the items.
4. Only surfaces in direct contact with the solution will be disinfected (instruments must be opened, disassembled, and completely submerged for the required period of time).
5. Items should be dry before submerging to avoid diluting the solution to inactive levels.
6. Disinfectants are designed for inanimate objects and are damaging to the skin. Gloves should always be worn to protect the hands. Goggles may be advisable to protect eyes from splashes. Generally, the more effective against microbes, the more toxic to humans.
7. Disinfectants should be used in well-ventilated rooms.

V. Sterilization

A. **Types of sterilization methods**

1. Heat

a. <u>Steam</u>

Steam continues to be the method of choice for sterilization of heat- all moisture-stable items. The CDC Guideline for Handwashing and Hospital Environmental Control states that steam sterilization should be used unless the object to be sterilized will be damaged by high pressure or moisture or is otherwise inappropriate for steam sterilization.

Flash sterilization is the process of sterilizing items that are needed for immediate use. This process also requires the use of saturated steam. This process destroys most vegetative bacteria and viruses if the bioburden is low and no or matter is evident. Flash sterilization should not be used as a routine sterilization process because of its minimal time, temperature and per requirements; the lack of biological indicators appropriate for rapid sterilization; the absence of protective packaging, and the possibility of contamination during transport. *Implantable items should not be flash sterilized.*

b. <u>Dry Heat</u>

This process has been used for the sterilization of glass, instruments and other items that cannot be sterilized by steam sterilization. However, it is considered a less efficient process than moist heat. Furthermore, the parameters for dry heat are difficult to determine and the process is quite lengthy.

2. Gas

    a. **ETO** is a colorless gas that is highly reactive with other chemicals. The ETO cycle involves preconditioning and humidification, gas introduction, exposure, evacuation and air washes. The process, excluding aeration time, is approximately 2 to 3 hours. ETO penetrates materials and, therefore, mechanical aeration is needed to remove the toxic ETO residue.
    b. **Formaldehyde** can be used as a disinfectant (liquid form) or a sterilant (gas form). It is primarily used for decontamination of biological safety cabinets, high-efficiency particulate filter units.

    c. **Peroxide gas plasma**

        - Low-temperature sterilization method
        - Utilizes hydrogen peroxide in vapor phase and low-temperature gas plasma

    d. **Peracetic acid gas plasma** process (Plazlyte) cleared for use on selected instruments without small lumens.

        - Can form a toxic salt when sterilization materials interact with copper, brass or zinc.

    e. **Vapor-phase hydrogen peroxide** uses a deep vacuum to pull 30% liquid hydrogen peroxide from a disposable cartridge through a heated vaporizer.

3. Chemical Sterilants

    - Glutaraldehyde
    - Hydrogen peroxide
    - Peracetic acid
    - Peracetic acid with hydrogen peroxide

4. Other Methods
    a. Chlorine dioxide
    b. Filtration
    c. Ozone

TABLE 2: Summary of Chemical Sterilants Used Primarily as High-Level Disinfectants

Agent	Advantages	Disadvantages	Cleared by FDA?
Glutaraldehyde (≥=2.0%)	Good compatibility Fairly inexpensive	Respiratory irritant; can coagulate blood and fix tissues to surfaces Activation required Slow mycobacterial activity	Yes
Hydrogen peroxide (7.5%)	No activation required May facilitate removal of organisms and organic material No specific disposal necessary Compatible with metals, plastics and elastomers No odor Does not coagulate blood or fix tissues to surfaces Inactivates *Cryptosporidium*	Compatibility concern with brass, copper, zinc and nickel-silver plating Can cause serious eye damage	Yes
Peracetic acid (0.2%)	Broad spectrum Rapid activity Environment-friendly by-products	Can corrode copper, brass, bronze, plain steel and galvanized iron Unstable when diluted Can cause serious eye and skin damage	Yes

Agent	Advantages	Disadvantages	Cleared by FDA?
Peracetic acid with hydrogen peroxide (0.8% ,1%)	No activation Mild odor	Some concerns about compatibility with lead, brass, copper and zinc (both cosmetic and functional) Limited clinical use	Yes

B. Sterilization monitoring systems are meant to assure that equipment and devices labeled sterile are in fact sterile. Such systems take one of two forms: product control or process control.

1. **Product control** = sterility testing; use of biological indicators (i.e. spore samples placed in sterilizer to document sterilization).
2. **Process control** = assessing the sterilization process; e.g.:
   - **a.** mechanical indicators (time/temperature charts & pressure gauges);
   - **b.** chemical indicators of temperature/humidity.

C. Post-sterilization handling and storage procedures are important to prevent contamination:

1. **Provide sterile storage** in procedure areas (closed cabinets, wrappers) to avoid:

   - **a.** contamination from patient secretions or body fluids,
   - **b.** hand contamination by employees obtaining extra supplies, and
   - **c.** contamination from supplies being returned to stock after use.

2. Store packages to prevent disruption of package integrity:

   - **a.** covered storage to prevent moisture damage,
   - **b.** keep storage off the floor, and
   - **c.** protect from insects and other pests.

3. Rotate stock so that items are used on a timely basis and to avoid having to discard unused, outdated items.
4. Designate separate area for mixing of medications or solutions.
5. **Refrigerate products** according to manufacturer's requirements.
6. Appropriate storage conditions for sterile packs include:

   - limited access to storage area and/or closed cabinets,
   - clean supplies should be stored separately from sterile supplies,
   - area must be clean, dry, dust free, lint free,
   - temperature 18^{o}-22^{o} C (65^{o} -72^{o} F),
   - relative humidity 35-50%.

7. Check package integrity:

   - Is the package free of tears, dampness, excessive dust, and gross soil?
   - Is there a chemical indicator on the outside of the package?
   - Has the expiration date (if applicable) been reached or passed?
   - If heat-sealed, has the seal been maintained?

III. Recognizing potential sources of cross-contamination in the health care environment

A. Identification of surfaces or equipment requiring between-patient cleaning:

1. All items having contact with mucous membranes must be cleaned and disinfected between patient use. *Example*: reusable thermometers.
2. Items having contact with intact skin, such as blood pressure cuffs and stethoscopes, need periodic cleaning.
3. Any environmental surface, equipment, or device contaminated with blood or body fluids should be cleaned and disinfected immediately.

B. Identification of practices which contribute to touch contamination and the potential for cross-contamination:

1. Clean and dirty work areas should be separated to reduce cross-contamination of supplies.
2. Environmental cleaning must be performed on a regular basis to reduce microbial load on surfaces (e.g., commodes contaminated with feces may be a vehicle for spread of *C. difficile* between patients).
3. Gloves must be removed and hands washed after touching contaminated surfaces or equipment (e.g., urinary collection devices, bedpans, dressings).

V. Appropriate levels of knowledge of disinfection/sterilization methods and agents are based on the area of professional practice and scope of responsibility

A. Knowledge expectations of health professionals who practice in organizations where the responsibility for handling, cleaning and reprocessing equipment or devices is designated to another department should include:

1. Basic concepts and principles of cleaning, disinfection, and sterilization described above.
2. Appropriate application of safe practices for handling devices and equipment in the specific area of professional practice (e.g., ophthalmology, dentistry).

B. Knowledge expectations of individuals who have primary or supervisory responsibilities for equipment or device reprocessing should include:

1. Core concepts and principles of cleaning, disinfection and sterilization described above.
2. Detailed information on the following:

a. properties and uses of chemical disinfectants
b. methods for achieving sterilization
c. sterilization equipment and packaging devices
d. methods for monitoring sterilization processes and current recommendations for monitoring frequency

Additional references for persons responsible for Sterilization /Disinfection procedures:

Guidelines for Infection Control in Dental Health-Care Settings---2003
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5217a1.htm

Guideline for Environmental Infection Control in Health-Care Facilities,2003
http://www.cdc.govncidod/dhqp/glenvironinfection.html

ELEMENT VI

PREVENTION AND CONTROL OF INFECTIOUS AND COMMUNICABLE DISEASES IN HEALTH-CARE WORKERS

Learning Objectives:

- List occupational health strategies for protecting health-care workers (HCWs) and patients;
- List non-specific disease findings which should prompt evaluation of HCWs;
- Identify occupational health strategies for preventing HIV, hepatitis B (HBV), hepatitis C (HCV) and tuberculosis (TB) in health-care workers;
- Identify resources for evaluation of HCWs infected with HIV, HBV, and/or HCV

Definitions:

- **Infectious Disease**: a clinically manifest disease resulting from infection.
- **Communicable Disease**: an illness due to a specific infectious agent which is acquired through transmission of that agent from an infected person, animal, or inanimate reservoir to a susceptible host.
- **Occupational Health Strategies:** as applied to infection control, a set of activities intended to assess, prevent, and control infections and communicable diseases in HCWs.

I. Overview of occupational health strategies for infection control

A. **Goals** of occupational health strategies:

1. Prevent disease transmission from HCWs to patients and staff.
2. Protect susceptible HCWs from infectious or communicable diseases.

B. Strategies to assess HCWs for disease risks:

1. **Pre-employment**: review of overall health and immunization status, TB testing (PPD) before employment (2-step if no documentation of negative PPD within past year), chest x-ray and medical assessment for PPD positive employees, administration of necessary vaccinations (i.e. rubella, rubeola, varicella, tetanus/diphtheria).

   Periodic (annual) health assessments: review of overall health status and assessment for possible communicable disease exposure, TB screening (PPD or blood assay), or medical assessment and screening for signs/symptoms of TB activation (i.e. fever, chills, night sweats, fatigue, anorexia, cough) for PPD or blood assay positive employees.

2. **Immunization/screening programs** are targeted at several diseases:

   a. **tuberculosis (TB):** TB screening is required at least annually; more often for high-risk positions.
   b. **hepatitis B (HBV): HBV** vaccination is highly recommended; must be offered at no charge to all HCWs whose work involves risk of exposure to blood/body fluids.

c. **rubeola (measles):** documentation of immunity (2 doses of vaccine or a history of illness) is **required** of all HCWs born in 1957 or later.
d. **rubella (German measles)** documentation of immunity (1 dose of vaccine or a positive serologic test) is **required** of all HCWs.
e. **Mumps:** screening for history of illness (and/or a blood test to confirm immunity or susceptibility) is often performed; vaccination is recommended for susceptible HCWs.
f. **varicella (chickenpox):** screening for history of illness (and/or a blood test to confirm immunity or susceptibility) is often done; vaccination is recommended for susceptible HCWs.
g. **influenza:** annual influenza vaccination is highly recommended for all HCWs; vaccination is required to be offered to all employees in long term care facilities, home care, adult day care programs etc.
h. **pneumovax**: vaccination is required to be offered to all employees in long term care facilities, home care, adult day care programs etc.; it is highly recommended for anyone at risk as identified in ACIP guidelines

Some of the above screenings and immunizations are **required** by NY State or Federal mandates; others are highly **recommended**. Immunity to rubeola and rubella are required by the NY State Department of Health. Offering hepatitis B vaccine at no charge is required by the U.S. Department of Labor (OSHA). Periodic TB screening (PPD) is required by both the NY State Department of Health and OSHA.

3. Evaluation of acute or incubating illnesses in HCWs:

a. **HCWs exhibiting any of these symptoms** should be promptly evaluated for fitness to work (i.e., risk of transmitting to patients, staff, visitors):
   - fever, chills
   - cough, sputum production
   - sore throat
   - exanthema (rash), vesicles
   - skin lesions, weeping dermatitis
   - draining wounds, sores
   - diarrhea or vomiting
   - eye infection or drainage

b. **Post-exposure evaluation**: susceptible HCWs who have been exposed to the following diseases should also be evaluated:
   - tuberculosis
   - varicella (chickenpox or herpes zoster, shingles)
   - rubeola
   - rubella
   - pertussis (whooping cough)
   - mumps
   - meningococcal infection (close contact)
   - scabies
   - parvovirus B19 (Fifth disease)

- *Example*: if a HCW is exposed to a personal family member or patient with active TB, the HCW must be evaluated for symptoms of active TB and tested for TB infection (PPD skin test). If infection is present, a chest x-ray is performed and treatment is begun.

c. **Management of ill or exposed HCWs** with acute or incubating communicable disease. Goal is to prevent potential transmission to susceptible patients and staff.

1) **Limit contact** with susceptible patients and staff. *Example*: temporary job re-assignment.
2) **Furlough from work** until HCW is no longer infectious or risk of contracting infection (post-exposure) has passed.

- *Example*: a susceptible (non-immune) HCW who has been exposed to chickenpox is usually furloughed from work beginning the 10^{th} day through the 21^{st} day after exposure (the incubation period for chickenpox).

3) **Treatment** as needed. *Examples*:

- HCW with active pulmonary tuberculosis is treated with multiple anti-tuberculosis drugs, and may return to work after symptoms have resolved and sputum smears show clearing of TB.
- HCW with a newly positive PPD skin test (indicating TB infection) but no evidence of active TB (TB illness), is treated with isoniazid (INH) for 6-12 months to prevent active TB from developing.
- HCW with draining skin lesions due to staph or strep (impetigo) may be treated with antibiotics until lesions heal.

d. **Reportable diseases**: the NY State Department of Health requires that cases of certain communicable diseases be reported to county and state health departments so that screening and/or treatment can be provided to contacts, and for epidemiological analysis. Diseases on the list include TB, rubeola, rubella, mumps, pertussis, syphilis, gonorrhea, and many others. Physicians, infection control practitioners, laboratories, hospitals, nursing homes, school nurses, and day care directors are responsible for reporting these diseases.

II. Prevention and control of bloodborne pathogen transmission

B. Risk of bloodborne pathogens to HCWs:

1. **Occupational exposure** is defined as work-related contact to blood and other potentially infectious material via percutaneous exposure (needlestick, injection, cut), mucous membrane exposure (eye, nose, mouth), or non-intact skin exposure (wound, abrasion, dermatitis).

   Potentially infectious material includes blood, semen, vaginal secretions, spinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, fluids contaminated with blood, and any unknown fluid.

2. Risks of specific pathogens

   a. **HIV**: the risk of acquiring HIV infection, following a needlestick contaminated with HIV-infected blood, is approximately 0.4% (1 in 250). Occupational infections have occurred via mucous membrane or non-intact skin exposures, but the risk from these exposures is much lower. Infection with HIV nearly always progresses to AIDS after an asymptomatic incubation period of several years. HIV infection can be transmitted to others via sexual contact, blood contact, and perinatally (to the newborn).

   b. **Hepatitis B virus (HBV)**: *percutaneous exposure to HBV results in a 6-30% risk of HBV infection.* After an asymptomatic incubation period of 2-6 months, 50% of infected persons develop clinical hepatitis with jaundice, and the other 50% remain asymptomatic. 5-10% of HBV infected persons become chronic carriers who never clear the infection and can transmit HBV to others indefinitely (via sex, blood contact, or perinatally). 25% of chronic carriers develop chronic hepatitis with associated risk of cirrhosis, liver cancer, and death.

   c. **Hepatitis C virus (HCV)**: Hepatitis C virus (HCV): exposure to HCV via needlestick results in a 1.8% risk for HCV infection. After an incubation period of 2 weeks to 6 months (usually 6-9 weeks), only 30-40% of persons with acute HCV will develop symptoms (anorexia, fatigue, nausea and vomiting, abdominal pain and jaundice). 85% of infected individuals will become chronic. These chronically infected persons are at risk for developing chronic liver disease such as liver cancer and cirrhosis. There is no treatment for acute HCV. Persons with chronic HCV may be evaluated for treatment with interferon and ribaviron to reduce the viral load and the protect the liver from further damage. There is no vaccine for HCV.

B. Hepatitis B prevention through vaccination:

1. HBV vaccine is highly effective and safe.
   - **Vaccination consists of 3 injections in the arm over a 6-month period.**
   - **Immunity develops in 80-95% of persons vaccinated.**
   - **Side effects may include soreness, slight swelling, and redness at the injection site; malaise and mild fever are uncommon reactions.**
   - **HBV vaccine is a recombinant product made from yeast (contains no live virus and no human serum or other human substances).**

- **Vaccination is contraindicated in persons allergic to yeast or thimerosal (a preservative).**

2. **HBV vaccination is highly recommended** and must be offered by employers at no charge to employees whose work entails risk of exposure to blood and body fluids. Consent is required, and persons refusing vaccination must sign a declination statement.

C. Post-exposure management of blood or body fluid exposures:

1. Every step in this process must be executed with maximum confidentiality for the patient and HCW involved.
2. **First, clean the affected area.** Cleanse skin with soap and water. For a needlestick, cut, or exposure through broken skin, wash affected area with soap and water, then rinse with waterless alcohol hand product , hydrogen peroxide, chlorhexidine, or iodophor (betadine). For oral exposure, rinse mouth well with hydrogen peroxide and then water. For eyes, rinse well with sterile saline (after removing contact lenses).
3. **HCWs must promptly report blood/body fluid exposures** to infection control, occupational health, or a supervisor in accordance with the Exposure Control Plan at their hospital, clinic, or office practice. **It is recommended that medical assessment be completed immediately or shortly after the exposure (i.e. within hours of the occurrence).**
4. **Evaluation of the exposure** includes documentation of:
   a. date, time, and location of exposure;
   b. route of exposure and type of potentially infectious material;
   c. detail of exposure incident, task being performed, etc.;
   d. identification of the source person, if known.

5. The **source person** is informed of the exposure and the importance of HIV, HBV, and HCV testing for blood-borne pathogens. **HIV, HBV, and HCV testing of the source** is performed after appropriate consent is obtained; informed, written consent and counseling are required for HIV testing. Persons already known to be HIV+, HBV+ and/or HCV+ infected need not be retested for that pathogen.

6. Medical evaluation, treatment and follow-up of the exposed HCW includes:
   a. review of HBV vaccination status;
   b. baseline serologic testing for HBV, HCV and HIV (after counseling and written consent);
   c. counseling about the risk of infection resulting from the exposure, recommended post-exposure treatment and follow-up, and precautions to prevent possible HIV transmission to others.
   d. post-exposure prophylaxis. *Examples*:

      - **HBV exposure**: HBV vaccination and HBV immune globulin (HBIG) are recommended for unvaccinated HCWs, as soon as possible (preferably within 24 hours but up to 7 days of exposure); previously vaccinated HCWs may require a booster of HBV vaccine.
      - **HIV exposure**: post-exposure prophylaxis (PEP) with antiviral drugs (combinations of 2 or 3 agents) should be considered following significant HIV exposures. Post-exposure prophylaxis is based on the level of risk and exposure (i.e. amount and type) vs. the risk/benefit from PEP. If indicated, PEP should be initiated as soon as possible.
      - **HCV exposure:** there is no known post-exposure treatment or vaccination at this time.

   e. post-exposure follow-up:

      - report acute illness during 12 weeks after exposure, especially if characterized by fever, rash, muscle aches, malaise, or lymph node enlargement, which may signify recent HIV infection;
      - following a documented or suspected HIV exposure, repeat HIV testing of the HCW is recommended at baseline and periodically for at least 6 months post-exposure (e.g., 6 weeks, 3 months, and 6 months).
      - following blood exposure, test the employee for baseline HCV, ALT and repeat testing at 4-6 months. (Anti-HCV is recommended for routine testing of asymptomatic persons, and should include use of both EIA to test for anti-HCV and supplemental or confirmatory testing with an additional, more specific assay Use of supplemental antibody testing (i.e., RIBATM) for all positive anti-HCV results by EIA is preferred, particularly in settings where clinical services are not provided directly.

7. Post-exposure management when the source is a HCW:
   a. when a patient or HCW sustains a blood/body fluid exposure and the source is a HCW, the hospital/clinic/practice has an ethical obligation to notify the exposed patient or HCW.
   b. the exposed patient or HCW, and the source HCW, are approached for counseling, consent, testing, treatment, and follow-up in the same manner as described above for a source patient and exposed HCW.

III. Evaluation of HCWs infected with HIV, HBV, HCV or other bloodborne pathogens (see Appendix A)

A. NY State Department of Health policy on HIV testing of HCWs

1. Mandatory HIV screening of HCWs is discouraged;
2. *Voluntary HIV and HBV screening of HCWs at risk for infection is encouraged* so they may benefit from medical intervention; all HCWs who have been potentially exposed to HIV or HBV through personal risk behavior, blood products or occupational accidents should be strongly advised to seek testing.
3. *HCWs are not required to inform patients or employers if they are HIV or HBV positive.* Employers should be informed if infection results in impairment affecting job performance. A patient should be informed if that patient has sustained a significant exposure to the HCWs blood.

B. Evaluation of infected HCWs for risk of transmission

1. HIV or HBV infection alone does not justify limiting a HCWs professional duties.
2. **Limitations**, if any, should be determined on a case-by-case basis considering the factors that influence transmission risk, including:

    a. Nature and scope of professional practice:

        - techniques used in invasive procedures which may pose a risk to patients;
        - compliance with infection control standards.

    b. Presence of weeping dermatitis or skin lesions.
    c. Overall health status: physical and cognitive function.

3. **Expert panel**: each hospital or institution must establish an expert panel to confidentially evaluate cases of HIV/HBV-infected HCWs with respect to work-related issues. An expert panel of the NY State Department of Health can also perform this evaluation. A panel can recommend practice limitations, modifications or restrictions where the evidence suggests there is a significant risk to patients.
4. Any **modification of work practice** must seek to impose the least restrictive alternative in accordance with federal disability laws.

New York State Health Department
And the
New York State Education Department

Laws Pertaining to HIV/HBV Infection Control Training Standards

HIV AND HEPATITIS B - INFECTION CONTROL

STANDARDS AND TRAINING

LAW OF NEW YORK, 1992
CHAPTER 786

AN ACT to amend the Public Health Law and the Education Law, relating to preventing transmission of human immunodeficiency virus (HIV) and hepatitis B (HBV) in health care settings.
Became a law August 7, 1992, with the approval of the Governor. Passed on message of necessity pursuant to Article 111, section 14 of the Constitution by a majority vote, three-fifths being present.

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:
§1. The Public Health Law is amended by adding a new section 230-a to read as follows:

§ 230-**A. INFECTION CONTROL STANDARDS.** Notwithstanding any law to the contrary, including section sixty-five hundred thirty-two of the Education Law, the department shall promulgate rules or regulations describing scientifically accepted barrier precautions and infection control practices as standards of professional medical conduct for persons licensed under Articles one hundred thirty-one and one hundred thirty-one B of the Education Law. 'Me department shall consult with the Education Department to ensure that regulatory standards for scientifically acceptable barrier precautions and infection prevention techniques promulgated pursuant to this section are consistent, as far as appropriate with such standards adopted by the Education Department applicable to persons licensed under the Education Law other than Articles one hundred thirty-one and one hundred thirty-one B of such law.
§ 2. Article 2 of the Public Health Law is amended by adding a new title II-E to read as follow:

TITLE II-E
HIV/HBV PREVENTION TRAINING
SECTION 239. COURSE WORK OR TRAINING IN INFECTION CONTROL PRACTICES.

§ 239. COURSE WORK OR TRAINING IN INFECTION CONTROL PRACTICES. Every physician, physician assistant and specialist assisting practicing in the State shall, on or before July first, nineteen hundred ninety-four and every four years thereafter, (A) complete course work or training, appropriate to the professional's practice, approved by the department regarding infection control and barrier precautions, including engineering and work practice controls, in accordance with regulatory standards promulgated by the department in consultation with the Department of Education, to prevent the transmission of HIV or HBV in the course of professional practice and (B) so document to the department, provided however, that physicians subject to the provisions of paragraph (F) of subdivision one of section twenty-eight hundred five-K of this Chapter shall not be required to report to the department. The department shall provide an exemption from this requirement to anyone who requests such an exemption and who (1) clearly demonstrates to the department's satisfaction that there would be no need for him or her to complete such course work or training because of the nature of his or *her* practice or (11) that he or she has completed course work or training deemed by the department to be equivalent to the standards for course work or training approved by the department pursuant to this section. The department shall consult with organizations representative of professions, institutions and those with expertise in infection control HIV and HBV with respect to the regulatory standards promulgated pursuant to this section.

ARTICLE 27-DD
STATE ADVISORY PANEL ON HIV/HBV INFECTED HEALTHCARE WORKERS
SECTION 2760. ADVISORY PANEL ESTABLISHED.
§2761 FUNCTION, POWERS AND DUTIES.

§2760.ADVISORY PANEL ESTABLISHED. 1. A State advisory panel for the evaluation of health care workers with human immunodeficiency virus (HIV) or Hepatitis B (HBV) (Hereinafter referred to in this Article as HI V/HBV) is hereby established in the department. This panel shall be known as the Health Care Worker HIV/HBV Advisory Panel and shall be composed to five members. The commissioner shall appoint three members for a term *of* two years: a state or local public health officer, an infectious disease expert and an expert in infection control or epidemiology. For the purpose of the panel's deliberations on a specific case: (A) the commissioner may appoint a health professional with expertise relevant to procedures performed by the health care worker, provided however, that the commissioner shall appoint such professional if the health care worker so requests; and (B) the commissioner shall, at the health care worker's request, appoint the health care worker's personal physician. The commissioner shall appoint the chairman of the panel. A vacancy occurring during a term shall be filled by appointment by the commissioner for the unexpired term. Any member may be removed from the panel at the pleasure of the commissioner.

2. Each member of the panel shall receive up to one hundred and fifty dollars as prescribed by the commissioner for each day devoted
to panel work not to exceed forty-five hundred dollars in any one year, and shall be reimbursed for actual and necessary incurred in the performance of his/her duties.
3. The department of health shall advise the panel members of statutory and regulatory confidentiality provisions and restrictions on disclosure of information which are applicable to the panel members and to panel operations.

§ **2761. FUNCTION, POWERS AND DUIPIES. 1.** The *Health Care Worker HIV/HBV Advisory Panel* shall only evaluate and advise an HIV/HBV infected health care worker who voluntarily seeks the panel's review of the risk of HIV/HBV transmission to others through his/her workplace practice. Prior to the panel's evaluation of the worker, the panel must fully advise worker of the panel's authority to investigate, to recommend practice restrictions or modifications, to advise facilities of such restrictions and to refer cases to professional licensing, registration and certification boards. If the health care worker is affiliated with or employed at a facility licensed by the department, the panel may evaluate and advise the worker only after such facility has completed its review of the scope of practice of the worker. This institutional review may be conducted through the facility's existing quality assurance program as required under section twenty-eight hundred five-J of this Chapter, and need not require the creation of a separate facility **HIV/HBV** panel. Notwithstanding any other provision of law, rule or regulation, the panel may request and shall be entitled to receive patient records and other documents or information reasonably necessary for and relevant to the panel's deliberations and the implementation of this Article including information and reports available to the department under section twenty-eight hundred five-M of this Chapter, provided that the panel may only request records with patient names if essential to the panel's complete review of the case and provided further that employees of the department, other than the panel, shall redact patient names before panel review of such records. Any such information and reports provided to the panel that are subject to section two thousand eight hundred five-M of this Chapter shall remain subject to the limitations on disclosure provided by such section. The panel may seek the advice of professionals with relevant expertise. The panel shall give the health care worker an opportunity to meet with the panel. The health care worker may be accompanied by a union or other representative at such meeting. Only when evidence indicates that the health care worker's practice poses a significant risk of harm to patients, the panel shall make appropriate recommendations that are least restrictive with respect to the health care worker's practice including, but not limited to, training or monitoring, or, if necessary, reassignment or practice restrictions.

2. The panel shall evaluate an **HIV/HBV** infected health care worker pursuant to comprehensive medical criteria, including:

(A) Physical or mental condition that interferes with or is significantly likely to interfere with the worker's ability to perform assigned tasks or regular duties;

(B) Lack of compliance with established guidelines to prevent transmission of disease and/or documentation or evidence of previous transmission of bloodborne pathogens;

(C) The appropriateness of techniques as related to performance of procedures;
and

(D) Any health condition that would pose a significant risk to others.

3. When the panel recommends training, monitoring, reassignment, any similar action, or practice restrictions, the health care worker shall provide written assurance to the panel that he/she has informed facilities licensed by the department where the worker provides patient care of the panel's recommendations and shall identify the person or persons at the facilities so informed. If the health care worker fails to inform facilities licensed by the department where he/she provides patient care of the panel's recommendations, the panel shall so notify such facilities. If the health care worker fails to comply with the panel's recommendations or compliance cannot be determined by the panel after reasonable effort, the pastel shall disclose the nature of its recommendations to the professional licensing, registration or certification boards relevant to the health care worker. The panel may periodically monitor and reevaluate the worker, with the worker's consent, at a frequency and through a mechanism to be determined by agreement between the worker and the panel.

4. The information received by the panel, the record of deliberations of the panel, and the decisions of the panel are not disclosable pursuant to Article Six of the Public Officers Law. If the health care worker fails to comply with the recommendations of the panel or compliance cannot be determined by the panel after reasonable effort, information held by the panel, the panel's deliberations and recommendations may be disclosed to and utilized by the office of Professional Medical Conduct, the Office of Professional Discipline and appropriate disciplinary bodies. °fhe meetings of the panel are not subject to Article seven of the Public Officers Law. The members of the panel are bound by Article six-A of the Public Officers Law (Personal Privacy Protection Law).

5. A health care worker's petition to the panel shall not prevent or preclude the worker from seeking relief in any other forum at any time.

6. The commissioner may promulgate regulations implementing this Article.

4. Subdivision 8 of section 2780 of the Public Health Law, as amended by Chapter 193 of the Laws of 1991, is amended to read as follows:

8. "Health or social service" means any public or private care, treatment, clinical laboratory test, counseling or educational service for adults or children, and acute, chronic. custodial, residential, outpatient. home or other health care provided pursuant to this Chapter or the Social Service Law; public assistance or care as defined in Article one of the Social Services Law; employment-related services, housing services, foster care, shelter, protective services, day care, or preventive services provided pursuant to the Social

Services Law; services for the mentally disabled as defined in Article one of the Mental Hygiene Law; probation services, provided pursuant to Articles twelve and twelve-A of the Executive Law; parole services, provided pursuant to Article twelve-B of the Executive Law; correctional services, provided pursuant to the Correction Law; and detention and rehabilitative services provided pursuant to Article nineteen-G of the Executive Law; and the activities of the health care worker HIV/HBV advisory panel pursuant to Article twenty-seven-DD of this Chapter.

§ 5. Section 2782 of the Public Health Law is amended by adding a new subdivision 9 to read as follows:

9. Confidential HIV related information shall be disclosed upon the request of the health care worker HIV/HBV advisory panel, established pursuant to Article Twenty Seven-DD of this Chapter, to the panel or its designee only when reasonably necessary for the evaluation of a worker who has voluntarily sought the panel's review.

§ 6. Paragraph (1) of subdivision I of section 2805-k of the Public Health Law is re-lettered paragraph (g) and a new paragraph (f) is added to read as follows:

(F) Documentation that the physician, dentist or podiatrist has completed this course work or training as mandated by section two hundred thirty-eight of this Chapter or section six thousand five hundred five-B of the Education Law. A hospital or facility shall not grant or renew professional privileges or association to the physician, dentist, or podiatrist who has not completed such course work or training.

7. THE EDUCATION LAW IS AMENDED BY ADDING A NEW SECTION 6505-B TO READ AS FOLLOWS:

§ 6505-B. COURSE WORK OR TRAINING IN INFECTION CONTROL PRACTICES. Every dentist, registered nurse, licensed practical nurse, podiatrist, optometrist and dental hygienist practicing in the state shall, on or before July first, nineteen hundred ninety-four and every four years thereafter, complete course work or training appropriate to the professional's practice approved by the department regarding infection control and barrier precautions, including engineering and work practice controls, in accordance with regulatory standards promulgated by the department, in consultation with the department of health, which shall be consistent, as far as appropriate, with such standards adopted by the department of health pursuant to section two hundred thirty-eight of the public health law to prevent the transmission of HIV/HBV in the course of professional practice. Each such professional shall document to the department at the time of registration commencing with the first registration after July first, nineteen hundred ninety-four that the professional has completed course work or training in accordance with is section, provided, however that a professional subject to the provisions of paragraph (f) of subdivision one of section twenty-eight hundred five-k of the public health law shall not be required to so document. The department shall provide an exemption from this requirement to anyone who requests exemption and who (i) clearly demonstrates to the department's satisfaction that there would be no need for him or her to complete such course work or training because of the nature of his or her practice or (ii) that he or she has completed course work or training deemed by the department to be equivalent to the course work or training approved by the department pursuant to this section. the department shall consult with organizations representative of professions, institutions and those with expertise in infection control and HBV with respect to the regulatory standards promulgated pursuant to this section.

§ 8. Section 6509 of the Education Law is amended by adding a new subdivision I I to read as follows:

11. A violation of section six thousand five hundred five-b of this chapter by a professional other than a professional subject to the provisions of paragraph (f) of subdivision one of section twenty-eight hundred five-k of the public health law.

§ 9. Section 6530 of the Education Law is amended by adding two new subdivisions 46 and 47 to read as follows:

46. A violation of section two hundred thirty-eight of the public health law by a professional other than a professional subject to the provisions of paragraph (f) of subdivision one of section twenty-eight hundred five-k of the public health law. -

47. Failure to use scientifically accepted barrier precautions and infection control practices as established by the department of health pursuant to section two hundred thirty-a of the public health law.

§ 10. This act shall take effect February 1, 1993, provided, however, that the commissioners of health and education may immediately take such steps as are necessary in order to ensure that this act is fully implemented on such effective date.

NEW YORK STATE EDUCATION DEPARTMENT
ULES OF THE BOARD OF REGENTS
SECTION 29.2(a)(33)
UNPROFESSIONAL CONDUCT IN THE AREA OF
INFECTION CONTROL

29.2 General provisions for health professionals. (a) Unprofessional conduct should also include, in the professions of:

medicine, acupuncture, physical therapy, physician's assistant, specialist's assistant, chiropractic, dentistry, dental hygiene, pharmacy, podiatry, optometry, ophthalmic dispensing, psychology, social work, massage, occupational therapy, speech pathology, audiology, nursing (registered professional nurse, licensed practical nurse):

(13) failing to use scientifically accepted infection prevention techniques appropriate to each profession for the cleaning and sterilization or disinfection of instruments, devices, materials and work surfaces, utilization of protective garb, use of covers for contamination-prone equipment and the handling of sharp instruments. Such techniques shall include but not be limited to:

(i) wearing of appropriate protective gloves at all times when touching blood, saliva, other body fluids or secretions, mucous membranes, non-intact skin, blood-soiled items or bodily fluid-soiled items, contaminated surfaces, and sterile body areas, and during instrument cleaning and decontamination procedures;

(ii) discarding gloves used following treatment of a patient and changing to new gloves if tom or damaged during treatment of a patient; washing hands and donning new gloves prior to performing services for another patient; and washing hands and other skin surfaces immediately if contaminated with blood or other body fluids;

(iii) wearing of appropriate masks, gowns or aprons, and protective eye wear or chin length plastic face shields whenever splashing or spattering of blood or other body fluids is likely to occur*

(iv) sterilization equipment and devices that enter the patient`s vascular system or other normally sterile areas of the body;

(v) sterilizing equipment and devices that touch intact mucous membranes but do not penetrate the patient's body or using high-level disinfection for equipment and devices which cannot be sterilized prior to use for a patient;

(vi) using appropriate agents including but not limited to detergents for cleaning all equipment and devices prior to sterilization or disinfection;

(vii) cleaning, by the use of appropriate agents including but not limited to detergents, equipment and devices which do not touch the patient or that only touch the intact skin of the patient;

(viii) maintaining equipment and devices used for sterilization according to the manufacturer's instructions;

(ix) adequately monitoring the performance of all personnel, licensed or unlicensed, for whom the licensee is responsible regarding infection control techniques;

(x) placing disposable used syringes, needles, scalpel blades, and other sharp instruments in appropriate puncture-resistant containers for disposal; and placing reusable needles, scalpel blades, and other sharp instruments in appropriate puncture resistant containers until appropriately cleaned and sterilized;

(xi) maintaining appropriate ventilation devices to minimize the need for emergency mouth-to-mouth resuscitation;

(xii) refraining from all direct patient care and handling of patient care equipment when the *health care* professional has exudative lesions or weeping dermatitis and the condition has not been medically evaluated and determined to be safe or capable of being safely protected against in providing direct patient care or in handling patient care equipment, and

(xiii) placing all specimens of blood and body fluids in well-constructed containers with secure lids to prevent leaking; and cleaning any spill of blood or other body fluid with an appropriate detergent and appropriate chemical germicide.

CHAPTER II COMMSSIONER'S REGULATIONS

PART 58

APPROVAL OF COURSE WORK OR TRAINING IN INFECTION CONTROL PRACTICES AND BARRIER PRECAUTIONS

(Statutory Authority: Education Law, §§ 207, 212, 6501, 6504, 6505-b, 6507)

Sec.
58.1 Purpose
58.2 Definitions
58.3 Approval of course work or training
58.4 Standards for approval of course work or training
58.5 Responsibilities of providers of course work or training

Sec.
58.6 Application for approval of course work or training
58.7 Term of approval of course work or training
58.8 Review of course work or training
58.9 Exemption

Historical Note

Part (§§ 58.1-58.9) filed June 29, 1993 as emergency measure eff. June 29, 1993

58.1 Purpose. The purpose of this Part is to set forth standards for the approval and the approval process for course work or training regarding infection control and barrier precautions for dentists, registered professional nurses, licensed practical nurses, podiatrists, optometrists and dental hygienists practicing in the State, as required *by* section 6505-b of the Education Law.

B. **Historical Note**

Sec. filed June 29, 1993 as emergency measure
eff. June 29, 1993

58.2 Definitions. As used in this Part:

(a) Course work or training means course work or training in infection control and barrier precautions.

(b) Provider means a Department of Health regulated facility; or a college or university which is authorized to offer programs leading to licensure in a profession subject to the requirements of section 6505-b of the Education Law or section 239 of the Public Health Law or to offer post-licensure degree programs in these fields; or any other organization or government entity that has as a purpose the provision of education or training on health care related issues to licensed professionals subject to the requirements of section 6505-b of the Education Law or section 239 of the Public Health Law.

C. **Historical Note**

Sec. filed June 29, 1993 as emerge
eff. June *29, 1993*

58.3 Approval of course work or training. Course work or training included as part of a program leading to licensure in a profession regulated by title VIII of the Education Law shall be approved by the department pursuant to Part 52 of this Title. Unless otherwise exempted, all other course work or training shall be approved by the commissioner pursuant to this Part.

D. **Historical Note**

Sec. filed June *29,* 1993 as emergency measure
Eff. June 29, 1993

58.4 Standards for approval of course work or training. (a) Course work or training shall be offered by a provider.

(b) Course work or training shall include, but not be limited to, the core elements specified in the syllabus prepared by the department in consultation with the Department of Health, regarding infection control and barrier precautions, including engineering and work practice controls, to

prevent the transmission of Human Immunodeficiency Virus/Hepatitis B Virus (HIV/HBV) in the course of professional practice.

(c) Course work or training shall be taught by instructors who have demonstrated by training, education, and experience their competence to teach the course content prescribed in subdivision (b) of this section.
(d) Course work or training shall be supported by adequate facilities, equipment, and other physical resources.

Historical Note

Sec. Filed une 29, 1993 as emergency measure
eff. June 9, 1993

58.5 Responsibilities of providers of course work or training. (a) A provider of course work or training shall execute a certification of completion for each person completing the course work or training.

(b) Within 21 calendar days of the completion of coarse work or training, the provider shall submit a certification of completion to the person completing the course work or training for that person's use in documenting such completion.

(c) The provider shall retain a copy of the certification of completion in the provider's files for not less than six years date of completion of course work or training.

(d) In the event that a provider discontinues offering course work or training, all copies of certifications of completion issued within the six years prior to such discontinuance shall be transferred to the department.

Historical Note

Sec. filed June 29, 1993 " emergency measure eff. June 29, 1993

58.6 Applications for approval of course work or training. (a) Providers seeking approval of course work or training pursuant to this Part shall submit to the commissioner an application on forms prescribed by the commissioner and a fee of $600 for the review of such course work or training.

(b) The commissioner shall review the information contained in such application and may request and review additional information and may conduct a site visit to ensure compliance with the requirements of this Pail.

Historical Note

Sec. filed June 29, 1993 as emergency measure
eff. June 29, 1993

58.7 Term of approval of course work or training. (a) Course work or training shall be approved for a period of six years, except that the approved status of such course work or training may be terminated during this term by- the department in accordancewith section 58.8 of this Part.

(b) At the expiration of said term, a provider may reapply to the department for approval of course work or training following the requirements of section 58.6 of this Part, including payment of the required fee.

E. **Historical Note**

Sec, filed June 29, 1993 as emergency measure
eff. June 29, 1993

58.8 Review of the course work or training. (a) The department may review approved course work or training during the term of oval to ensure compliance with the requirements of this Part and may request information from a provider and may conduct a site visit, pursuant to such review.

(b) A determination by the department that the course work or training offered by a provider is inadequate, incomplete, or otherwise unsatisfactory pursuant to the standards set forth in this Part shall result in the denial or termination of the approved status of that course work or training.

F. **Historical Note**

Sec, filed June 29, 1993 as emergency measure
eff. June 29, 1993

58.9 Exemption. Course work or training in infection control and barrier precautions that is offered by Department of Health regulated facility and is approved by the Comissioner of Health in accordance with regulations of the Commissioner of Health shall be deem approved pursuant to this part.

G. **Historical Note**

Sec, filed June 29, 1993 as emergency measure
eff. June 29, 1993

59.13 Training regarding infection control practices. (a) Commencing July 2, 1994, all persons applying for the issuance of a license or renewal of a registration in dentistry, registered professional nursing, licensed practical nursing, podiatry, optometry, dental hygiene, or any other profession subject to the requirements of section 6505-b of the Education Law shall affirm to the department, and maintain and/or submit such documentation as the department may require, that they have competed, in the four years immediately preceding such application, course work or training in infection control and barrier precautions which is approved by the department, pursuant to Part 58 of this Title, or which is approved as part of a program registered pursuant to Part 52 of this Title. As provided in subdivision (b) of this section, an applicant may be exempted from the infection control and barrier precautions course work or training requirements; or as provided in subdivision (c) of this section, may be exempted from the requirement to document the completion of such course work or training.

(b) The department may exempt an applicant for registration from the course work or training required pursuant to subdivision (a) of this section either upon receipt of-

(1) a written application for such exemption establishing that there be no need to complete the course work or training because the nature of the applicant's/licensee's practice does not require the use of infection control techniques or barrier precautions; or

(2) documentation satisfactory to the department that the applicant/licensee has completed course work or training equivalent to that approved by the department, pursuant to Part 58 of this Title.

(c) Maintenance or submittal of documentation pursuant to subdivision (a) of this section is not required of any dentist or podiatrist who is subject to the provisions of paragraph (f) of subdivision (1) of section 2805-k of the Public Health Law and who attests at the time of registration that documentation requirements have been met as required in the Public Health Law.

(d) If there are changes in the nature of the practice of a licensee who has been granted an exemption under paragraph (b)(1) of this section and such changes require the licensee to use infection control techniques or barrier precautions, the licensee shall notify the department in writing of the change within 30 days of such change. If the licensee has not taken approved course work or training in infection control and barrier precautions during the four years immediately preceding the change in practice, the licensee shall obtain such course work or training within 90 days of the change in practice.

Historical Note
Sec. filed June 29, 1993 as emergency measure
Eff. June 29, 1993.

SUBPART 92-1

PHYSICIAN'S, REGISTERED PHYSICIAN ASSISTANTS AND SPECIALIST ASSISTANTS: REQUIRED COURSE WORK OR TRAINING IN INFECTION CONTROL AND BARRIER PRECAUTIONS

(Statutory Authority: Public Health Law, Section 230a)

Section 92-1.1 Course work or training. Course work or training in infection control and barrier precautions for physicians, registered physician assistants (PAs) and specialist assistants (SAs) as sufficient to satisfy the requirement of Public Health Law section 239, shall contain the core content which is specified in a syllabus prepared by the Department of Health (DOH) in consultation with the Department of Education, including course work or training in basic concepts of disease transmission, scientifically accepted principles and practices for infection control and engineering and work practice controls.

92-1.2 Application. Persons or organizations, other than DOH regulated health care facilities, including home health care agencies, wishing to provide such course work or training to physicians, PAs, and SAs must submit an application to DOH far review and approval, on forms prescribed b) the commissioner. The department may request additional information from the applicant and conduct site visits. DOH regulated health care facilities, including home health care agencies, wishing to provide such course work or training to physicians, PAs and SAs must inform the department in a manner as prescribed by the commissioner.

92-1.3 Provider competency. Persons or organizations seeking approval, other than DOH regulated health care facilities, including home health care agencies, shall document their expertise and competence to communicate the course materials and document that course work or training shall be supported by adequate facilities, equipment and other physical resources. Such facilities and agencies are deemed competent to provide training and education on infection control, unless they are subject to a denial or termination as provided for in section 92-1.5 of this Subpart.

92-1.4 Approval period. The department may approve for a six-year period the course work or training as submitted by an organization or person.

92-1.5 Denial or termination. A determination by the department that course work or training offered is inadequate or incomplete shall result in the denial or termination of departmental approval.

92-1.6 Certificate of completion. Persons or organizations engaged in training and education pursuant to this Subpart shall supply each participant who has completed a course with a certificate of completion, as specified by the Commissioner, within 21 days and shall maintain a record for six years of participants who complete the work or training.

92-1.7 Certificate of retention. In the event that an approved person or organization discontinues offering course work or training, a record of certifications shall be retained in a manner approved by the department for six years from the date of issuance.

92-1.8 Submission of documentation to the department. Physicians, PAs and SAs must submit documentation of course completion to DOH, except that such persons holding privileges or affiliated with or employed by DOH regulated health care facilities, including home health care agencies, need not submit documentation of course completion to the department. DOH regulated health

care facilities, including home health care agencies, shall maintain documentation in credentialing or employment files of such infection control training and education of physicians, PAs and SAs.

92-1.9 Exemptions. The department may grant an exemption from such training and education to: physicians, PAs and SAs when the professional demonstrates to the department's satisfaction that:

(1) no need exists to complete the course work or training due to the nature of his/her practice, or

(2) he/she has completed equivalent course work or training. No need to complete course work or training exists when health professionals are in settings where they do not provide direct patient care, do not have responsibility for supervising staff who provide direct patient care or reprocess used patient care equipment, or do not perform services to which these standards would be expected to
apply, or when the professional does not practice in New York State. A physician, a P.A. or S.A. who has been granted an exemption shall notify the department in writing of any change in the nature of his or her practice within 30 days of the occurrence of such change. The physician, P.A. or S.A. shall then obtain necessary course work or training within 90 days of the change in practice.

92-1. 10 Equivalencies. Equivalent training or course work shall be that training or course work, which covers the concepts of disease transmission, scientifically accepted principles and practices for infection control, and engineering and work practice control as detailed in the syllabus. Equivalent course work or training must emphasize the bidirectional aspect of disease transmission.

NEW YORK STATE DEPARTMENT OF HEALTH

MEDICAL CONDUCT IN THE AREAS OF ACCEPTABLE BARRIER PRECAUTIONS AND INFECTION CONTROL PRACTICES

(Statutory authority: Public Health Law, section 230-a)

Part 92 of Subchapter N of Chapter ii or Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York

PHYSICIANS, REGISTERED PHYSICIAN ASSISTANTS AND SPECIALIST ASSISTANTS REQUIRED USE OF INFECTION CONTROL. PRACTICES.

Section 92.2 For physicians, registered physicians assistants, and specialist assistants, the definition of unprofessional conduct shall include the failure to use scientifically accepted infection control practices to prevent transmission of disease pathogens from patient to patient, physician to patient, registered physician (assistant) or specialist assistant to patient, employee to patient, and patient to employee, as appropriate to physicians, registered physician assistants and specialist assistants. Such practices include:

(a) adherence to scientifically accepted standards for: handwashing; aseptic technique; use of gloves and other barriers for preventing bidirectional contact with blood and body fluids; thorough cleaning following sterilization or disinfection of medical devices; disposal of non-reusable materials and equipment; and cleaning between patients of objects that - are visibly contaminated or subject to touch contamination with blood or body fluids;

(b) use of scientifically accepted injury prevention techniques or engineering controls to reduce the opportunity for patient and employee exposure; and

(c) performance monitoring of all personnel, licensed or unlicensed, for whom the licensee is responsible regarding infection control techniques.

New York State Department of Health Policy Statement and Guidelines To Prevent Transmission of HIV and Hepatitis B Through Medical/Dental Procedures

Background

All medical and scientific data confirm that the risk of transmission of human immunodeficiency virus (HIV) and hepatitis B (HBV) through medical/dental procedures is remote and largely preventable through strict adherence to barrier precautions and infection control practices decrease the opportunity of blood-to-blood exposure for both health care personnel and patients.

After more than 10 years of experience and millions of procedures, there is still only one documented case in which a health care worker with HIV transmitted the virus to patients. Ongoing and completed studies involving more than 15,000 patients of health care personnel infected with HIV, including surgeons and dentists, have revealed no infection *of* patients through medical procedures. Evaluation of AIDS cases that have no identified *risk* also has not implicated an infected health care worker in transmission

The risk of hepatitis B vines (HBV) transmission through medical/dental procedures is several times greater than HIV. Twenty clusters of hepatitis B transmission to patients have been reported and investigated over the past 20 years. These cases commonly involved a breakdown in infection control during procedures where the health care worker's hands were within a body cavity and injury to the worker caused bleeding into the patient. Most reported clusters of hepatitis B in the U.S. occurred prior to 1985. The decrease in such reports in recent years may reflect the adoption of universal precautions and increased use of hepatitis B vaccine among health care workers.

Since the advent of the AIDS epidemic, both the Centers for Disease Control (CDC) and the New York State Department of Health have issued recommendations to health care workers and health care facilities emphasizing importance of strict adherence to infection control standards and universal barrier precautions to minimize exposure to bloodborne pathogens in medical/dental settings.

In January 1991, the Department of Health issued a policy statement and guidelines concerning HIV-infected medical personnel. This policy emphasizes voluntary testing of health care workers and case-by-case evaluation of HIV-infected personnel who perform invasive procedures to determine if they pose a significant risk to patients. The policy states that HIV infection alone is not sufficient justification to limit the professional duties of health care professionals unless specific factors compromise a worker's ability to meet infection control standards or to provide quality patient care.

In July 1991, the CDC issued "Recommendations for Preventing the Transmission of HIV and Hepatitis B to Patients During Exposure-prone Invasive Procedures." in September, Congress passed a law directing all states to adopt the CDC recommendations or equivalent standards.

These actions prompted the New York State Department of Health to again review all scientific and medical data bearing on the risk of HIV transmission through medical/ dental procedures. In conducting this evaluation, the department consulted widely with infection control experts and with representatives of medical, dental and hospital associations, and consumer groups.

On October 8, 1991, the department issued for public comment a proposed 'Policy Statement and Action Flan to Prevent Transmission of HIV through Medical/Dental Procedures." The document reaffirmed the state's existing HIV-prevention/protection policies. It also outlined proposed state initiatives to strengthen infection control training and practice for health care practitioners. A total of 36 interested groups or individuals representing a broad range of interests provided written comment or testified at a public hearing held on November 4, 1991. The overwhelming majority of those providing comment endorsed the state's policy and action plan; some also provided specific suggestions for modifications or adjustments.

On August 11, 1992, Governor Cuomo signed legislation that formally codifies New York's policies and guidelines to protect all citizens from exposure to HIV, HBV and other bloodborne pathogens during medical/dental procedures, and to safeguard the rights of infected workers.

Policy Statement

Based on evaluation of all available medical and scientific data, the Department of Health believes the following HIV and BV-related policies best safeguard New York's citizens and protect the viability of our health care system.

1. The most effective means of preventing HIV and HBV transmission in health care settings is through strict adherence to universal barrier precautions and established infection control practices which decrease the opportunity of direct exposure to blood and body fluids for both workers and patients.

2. Voluntary testing without fear of disclosure or discrimination is the best means of encouraging people at risk for HIV or HBV to seek counseling and testing.

3. All patients and health care personnel who have been potentially exposed to HIV or HBV through personal risk behavior, blood products or occupational accidents should be strongly counseled to seek testing so they may benefit from medical management.

4. Mandatory HIV screening of New York health care workers would cost millions of dollars and would not produce any appreciable gain in public safety. A negative antibody test does not rule out the presence of infection since it can take some time for measurable antibodies to appear.

5. HIV or HBV infection alone does not justify limiting a health care worker's professional duties. Limitations, if any, should be determined on a case-by-case basis after consideration of the factors that influence transmission risk, including inability or unwillingness to comply with infection control standards or functional impairment which interferes with job performance.

6. Requiring health care workers to inform patients or employers that they are HIV or HBV positive would only serve as a deterrent to workers seeking voluntary testing and medical evaluation. It also would endanger the professional careers of competent and needed health personnel who pose no risk to patients.

Guidelines

In its ongoing evaluation of the risk associated with potential exposure to HIV and HBV in health care settings, the Department of Health has identified measures the state can take to enhance public safety and to guard against discrimination for HIV- or HBV-infected health care personnel.

1. Mandatory Infection Control Training for Health Care Personnel

New York State has been in the forefront of promoting infection control training and practice to prevent bloodborne disease exposure to health care workers or patients. All hospitals are required by regulation to train their staffs in infection control techniques, to provide appropriate equipment and to enforce use of universal barrier precautions in situations involving potential exposure to blood or other body fluids. The department also has provided detailed infection control guidelines to all physicians and dentists practicing in New York State.

To increase public safety, New York State has passed legislation to require licensed health care professionals (including physicians, physicians' assistants, specialists' assistants, registered nurses, licensed practical nurses, dentists, dental hygienists, podiatrists, optometrists) to complete a course in infection control and barrier precautions on or before July 1, 1994, and every four years thereafter. Required courses, tailored to the infection control training needs of specific medical and dental specialties, include work practices and engineering controls, disinfections and sterilization procedures. Course content must be approved by the State Department of Health and/or Education.

Proof of completion of required infection control training must be submitted by health professionals to either the State Department of Health or the Education Department. physicians with hospital privileges will present the necessary training documentation to the hospital (in lieu of the Department of Health) during the process of renewing hospital privileges. A waiver of this training requirement may be granted by the Department *of* Health to health professionals who demonstrate that such training is not needed due to the nature of their work, or that they have met criteria for equivalency.

2. Enforcement of Infection Control Standards

All licensed health care facilities are responsible under existing regulations for monitoring and enforcing proper use of infection control practices and universal precautions by health care personnel functioning under their jurisdiction. Failure to comply with this requirement will result in Department of Health citation, potential fines and other disciplinary action against the institution.

Any licensed health care professional who fails to use appropriate infection control techniques to protect patients or fails to ensure that health care workers under his/her supervision do so may be subject to charges of professional misconduct and disciplinary action.

Any patient or employee complaint regarding lax infection control practices in a private medical or dental office will prompt an investigation by the departments *of* Health and/or Education. Substantiated *lapses* in infection control in a private practice setting may result in charges of professional misconduct against any licensed professional in the practice

was directly involved, was aware of the violation or who has responsibility for ensuring that office staff are adequately trained and follow patient protection me measures.

The state departments of Health and Education will promulgate regulations and/or statutory amendments to implement these more stringent enforcement provisions.

3. Protecting Health Care Workers from Infection

Each health care facility should take the following steps to protect workers from occupational exposure to HIV, HBV and other bloodborne pathogens.

1. All health care workers should receive appropriate training for their job titles in infection control techniques, including engineering and work practice controls, universal precautions and work practices that help prevent needle sticks or other injuries and splashes of blood and body fluids.

2. All health care personnel should be provided a safe work environment, including protective equipment, clothing and devices to reduce the risk of occupational exposure to blood and body fluids.

3. All health rare workers whose job responsibilities involve contact with blood or sharp objects likely to be contaminated with blood should be offered and encouraged to receive the hepatitis B vaccine.

4. All health care personnel should receive information about the risks associated with HIV and HBV transmission the merits of knowing their status if they have personal or occupational risks so they may benefit from medical management.

5. All health care workers should be informed that if they have an impaired immune system due to HIV infection or other medical condition, they are at risk of acquiring potentially life-threatening infections, including TB, from patients.

6. Information on the availability of voluntary, confidential or anonymous counseling and testing far HIV and HBV should be made available to health care workers.

4. Process for Evaluating Infected Health Care Workers

To ensure that public protection is a primary consideration and that health care personnel are afforded appropriate and equitable treatment, the Department of Health will establish a uniform process and criteria for evaluating HIV/HBV-infected health care workers to determine if practice limitations are warranted

Evaluation Criteria

The evaluation of a health care worker should be based on the premise that HIV or HBV infection alone is not sufficient justification to limit a health care worker's professional duties. The determination of whether an individual health care worker poses a significant risk to patients which warrants job modification, limitation or restriction requires a case-by-case evaluation which considers the multiple factors that can influence *risk.* Periodic re-evaluation of an HIV-infected health care worker may be appropriate if physical or mental functioning changes due to disease progression.

Factors that may have a bearing on the ability of health care workers, including those with bloodbome infections, to provide quality health care include:

• physical or mental condition that may interfere with the workers ability to perform assigned tasks or regular duties;

• lack of compliance with established guidelines to prevent transmission of disease and/or documentation or evidence of previous transmission of bloodborne pathogens;

• the appropriateness of techniques as related to performance of procedures;

• any health condition that would pose a significant risk to others.

Institutional Review Process

Under State Health Department regulations, all licensed health care institutions are responsible for ensuring that their employees, medical staff and volunteers do not have physical or mental impairments related to HIV or HBV infection o r any other condition that would interfere with the performance of their duties or pose a risk to patients.

Consistent with this regulation, health care facilities are responsible far establishing a mechanism for evaluating health care workers with HIV or HBV infection. This requirement should not be misconstrued to foster or condone involuntary screening of employees for HIV or HBV by health care institutions.

New York State law prohibits HIV testing of any citizen without written, informed consent. All health care workers should be counseled about the importance of learning their HIV and HBV status if they have been potentially infected through personal behavior or occupational exposure.

Institutional evaluations of individual workers known to be infected with HIV or HBV shall be based on the Department of Health criteria, and shall involve consultation with experts who can provide a balanced perspective. Such experts include an infectious disease physician and/or hospital epidemiologist with an understanding of HIV and HBV, a representative from the infected health care worker's practice area and the personal physician of the infected worker. All matters related to such evaluations must be handled confidentially.

Any modification of work practice must seek to impose he least restrictive alternative in accordance with federal disability laws. Any worker who believes that his/her employment has been restricted or terminated without just cause may ask for a second opinion from a Department of Health review parcel and/or file a complaint with the State Human Rights Commission.

State-Appointed Review Panels

The State Health Department will establish and oversee a voluntary evaluation process to provide guidance to HIV/HBV-infected health care workers who seek consultation. Access to state-appointed panel review will be available to infected health care workers who perform procedures that might increase the risk of worker-to-patient blood exposure. State panels will function as a primary evaluation resource for practitioners who are not affiliated with institutions, or as asecond opinion *for* workers affiliated with health facilities who have been evaluated by their institutions.

Each panel will include a public health official, an infectious disease expert, an expert in infection control/ epidemiology. In addition, an individual from the infected practitioner's area of practice and the individual's private physician may be asked to serve as members of the panel.

The purpose of such panels is to provide timely advice and consultation on an individual's risk of bloodborne disease transmission through his/her professional practice, and to recommend practice limitations, modifications or restrictions where the evidence suggests there is a significant risk to patients.

The evaluation process will be confidential except for the following circumstances:

• To adequately evaluate workers who are institutionally based, the panel --- directly or through its designees - may need to request information about the worker's practice from the facility.

• If practice restrictions are recommended, the individual involved shall assure - and verify to the panel - that all health facilities where he/she practices are informed. If assurance is not forthcoming, the panel will inform such facilities. Within all facilities, the normal rules of confidentiality apply.

DOH Consultation

Staff of the Department of Health will be available to any individual, institution or organization to discuss concerns about the management of employees with HfV or HBV. In addition, the department will provide information, confidentially or anonymously, on the process for accessing the state review panels described above.

Enforcement of Practice Restrictions

Health care institutions will be responsible for ensuring that any practice limitations recommended by institutional panels are followed in the facility by health care workers who are in their employ or who provide patient care from their facilities. If practice limitations are recommended for a community-based physician or dentist, periodic monitoring to ensure compliance will be performed by the State Department of Health or Education with the professional's consent. if a health care professional does not follow the practice restrictions or if compliance is uncertain, the appropriate state licensing/certification/permit board will be notified. The professional may be charged with professional misconduct for negligent practice in violation of the State Education Law.

Confidentiality of A Health Care Worker's HIV Status

HIV-infected health care workers are entitled to protections under the New York State HIV Confidentiality Law as are all citizens. Such workers are not required to disclose their HIV status to patients or employers. Health care facilities am under no obligation under New York Law to disclose to patients the status of *an* infected health care worker in their employ, such disclosure, without the consent of the worker, would likely violate New York's HIV Confidentiality law.

Notification of patients that they were exposed to the blood of a health care worker should be based on documentation of an injury to a worker that could have resulted in the worker's blood coming into direct contact with a patient's bloodstream or mucous membranes. In such circumstances, the patient should be advised to receive testing for potential HIV or HBV exposure. The Department of Health will be available to assist hospitals in determining if a significant risk of exposure to bloodborne pathogens warrants notification to patients.

5. Quality Assurance Protections

Hospital quality assurance programs and, under their umbrella, infection control policies and procedures are key mechanisms for preventing disease transmission within healthcare settings. To further reduce the low risk of HIV or HBV transmission through medical procedures, hospitals should take the following actions:

1. Assure that infection control policies and procedures for the prevention of bloodborne infections are in place and being monitored for compliance.

2. Review existing policies and procedures to assure that mechanisms are in place for reporting and managing circumstances where an employee is exposed to a patient's blood or there has been mutual blood exposure between a patient and employee (i.e., during a procedure where injury to a worker insulted in both parties having contact with the other person's blood).

3. Form cooperative work groups to review surgical techniques to identify changes in practice or other alternatives to reduce any risk of potential injury to a health care worker that could result in blood exposure to patients.