Important Telephone Numbers

Associate Director of Clinical Affairs, Yale Medical Group
Janine Evans, MD ................................................................. 737-2771

Director of operations, Yale Physicians Building
Lorraine F. Roseman .......................................................... 785-5144

Building Services & Operations, School of Medicine
Control Center................................................................. 785-4620
Vibha Buckingham, Associate Director Custodial Services .............. 785-5961

Office of Environmental Health and Safety
Main Office Number.......................................................... 785-3550
Emergency: Biological, Chemical or Radiation Spill............................. 785-3555
Bio-Medical Waste or Chemical Waste............................................. 785-3551
Infection Control, Environmental, Health & Safety
Maryjo Lanzillotta, MS, RBP, CBSP........................................... 737-2127
Ben Fontes, MPH, CBSP..................................................... 737-5009

Yale Employee Health
Dr. Dorothy van Rhijn.......................................................... 432-0071
Urgent Visit................................................................. 432-0123
YPB walk-in Clinic............................................................. 785-6521

Police & Fire
Yale University- On Campus.................................................. 111 or 432-4400
YNHH.............................................................................. 119
Off Campus........................................................................... 911

YNHH – Quality Improvement Support Services
Epidemiology & Infection Control.................................................. 688-4634
Dr. Louise Dembry, Director...................................................... 688-4634
YALE MEDICAL GROUP
INFECTION CONTROL POLICY

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SECTION 1 PURPOSE:

To establish guidelines which minimize the potential for transmission of microorganisms to, from, and between patients, and all other persons operating within the Yale Medical Group (YMG).

SECTION 2 DEFINITIONS:

2.1 Persons:

All clinical personnel, community physicians, students, volunteers, visitors, and/or any other individuals who receive services from the YMG.

2.2 Standard Precautions:

Standard and Transmission Based Precautions System is a method to prevent the transmission of infectious agents. It requires the use of protective apparel for all contact with blood and body substances but uses airborne, droplet and contact precautions for patients with diseases known to be transmitted in whole or in part by these routes. Standard Precautions synthesizes the major features of Universal Precautions (Blood and Body Fluid Precautions) - designed to reduce the risk of transmission of bloodborne pathogens and Body Substance Isolation (designed to reduce the risk of transmission of pathogens from moist body substances). Standard Precautions applies to all patients receiving care, regardless of their diagnosis or presumed infection status.

Health care workers should assume that all patients are potentially infectious and use handwashing, protective apparel, and special procedures to prevent exposure to blood and body substances. However, it is important to point out that the use of gloves is intended to supplement and not replace handwashing or other existing infection control measures. The effectiveness of Standard Precautions depends upon vigilant compliance by every health care worker.

2.3 Transmission Based Precautions:

Transmission Based precautions are designed for patients documented or suspected to be infected with highly transmissible or epidemiologically important pathogens for which additional precautions beyond Standard Precautions are needed to interrupt transmission of these agents. There are three type of Transmission Based Precautions: Airborne, Droplet and Contact.

Airborne Precautions are designed to reduce the risk or eliminate the airborne transmission of infectious agent; Droplet Precautions are designed to reduce the risk of droplet transmission of infectious agents and Contact Precautions are designed to reduce the risk of transmission of microorganisms by direct or indirect contact.

Each specialty will be responsible for developing a Standard Precautions protocol that is specific to that area, but complies with the Yale Medical Group.

2.4 Blood and Other Potentially Infectious Materials:

This includes all body substances and fluids which may potentially harbor contagious microorganisms and infectious agents. All secretions and excretions with the exception of sweat are considered potentially infectious for bloodborne pathogens.
2.5 Exposure Incident (Bloodborne Pathogen):
A specific eye, mouth, or other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious material.

2.6 Exposure Control Plan:
Refers to the Yale University’s plan to minimize the potential for exposure to bloodborne pathogens. Yale University’s Exposure Control Plan is available in the Medical School Library (Reference Section) or on the internet at http://www.yale.edu/oehs. Yale University Bloodborne Pathogen Training Manual for clinical and laboratory personnel is available on the internet at http://www.yale.edu/oehs.

SECTION 3 APPLICATION/SCOPE:
This policy applies to all persons who are or may be administratively responsible to the Yale Medical Group. This policy is to be used in conjunction with policies and procedures contained in the YNHH Infection Control Manual. Standard Precautions shall be applied at all times and for all patients, regardless of diagnosis.

SECTION 4 RESPONSIBILITIES:

4.1 The YMG Shall:
1) Provide appropriate types and supplies of personal protective equipment (i.e., gloves, goggles, masks, gowns, etc.)
2) Provide hypoallergenic gloves, glove liners, or other similar alternatives for those employees who are allergic to the gloves normally provided.
3) Assure that employees, all students (e.g. nursing, medical, physician assistant, etc.), and other health care personnel affiliated with the department provide evidence of education and training in the YMG’s Standard and Transmission Based Precautions and Infection Control policies and procedures that are specific to responsibilities, prior to assuming these responsibilities and annually thereafter.
4) Maintain training records for employees, and students affiliated with the department for 3 years from the date on which the training occurred.
5) Monitor and document individual compliance with the practice of Standard and Transmission Based Precautions and Infection Control policies and procedures at least annually in a fair and equitable manner.
6) Include compliance with Standard and Transmission Based Precautions and Infection Control Policies and Procedures as a part of each employee's annual performance review.
7) Provide appropriate retraining and progressive discipline, if necessary for individuals who fail to comply with department procedures for Standard and Transmission Based Precautions and Infection Control Policies and Procedures.
8) Inform visitors that they are not allowed in areas where contagion is likely, unless there is specific need and the visitor receives instruction in Standard/Transmission Based Precautions and Infection Control Policies and Procedures specific to the area/task involved.

9) Hospital employees must report the incident to their supervisor and submit a Supervisor's Report of Employee Accident/Injury (FL797) following all incidents of actual exposure to blood and body and other potentially infectious materials. The hospital employee must report to Occupational Health Services (OHS) immediately. Yale University employees must have a Department Head’s Report of Injury Form (ER15-1) documenting the route of exposure and the circumstances under which the incident occurred. Yale University employees must report the incident to their supervisor and seek medical assistance at Yale University Health Services (YUHS) Urgent Visit (open 24 hours) or Employee Health (8:30 am – 5:00pm) immediately for needlesticks, blood, body fluid, bloodborne pathogens or other infectious agent exposure. Other types of injuries call. The Yale University Employee Health satellite office is located at 800 Howard Avenue in the Yale Physician Building (2nd floor). Monday - 12:00 to 5:00 pm, Tuesday, Wednesday, Thursday - 8:30 am to 1:30 pm. The Employee Health satellite office will only see Yale employees who sustain a needlestick or human blood or body fluid exposure. If a Yale University employee cannot get to YUHS within one hour of the exposure, they can report to the hospital’s OHS (7:30am – 4:30pm) or Emergency Department (4:30pm – 7:30am) for initial visit, but all follow-up visits must be at the Yale University’s Employee Health Services at 17 Hillhouse Avenue. Hospital employees must report to the Emergency Department if the exposure incident occurs on off shifts and weekends.

10) Submit an Incident Report for all instances where an individual’s technique is not consistent with Standard/Transmission Based Precautions and Infection Control Policies and Procedures.

11) Must comply with either the hospital or Yale University’s "Exposure Control Plan".

4.2 Each Individual Shall:

1) Comply with the guidelines of the Occupational Health Service (OHS) or Yale’s Employee Health Services. These include but are not limited to:
   a) completion of pre-employment examination (Hospital)
   b) provision of proof of immunization & compliance with immunization policies
   c) not work when they have communicable diseases
   d) be cleared by the Occupational Health Service after a 3 day or longer absence date (Hospital)
   e) report the presence of diarrhea, dermatitis, boils, etc. to Occupational Health or Yale Employee Health Services, prior to working
   f) a minimum of annual TB skin testing

2) Affiliated students should have fulfilled any contractual health examinations and/or obligations negotiated between their parent school and Yale University.

3) Understand and implement the principles of Standard/Transmission Based Precautions and infection control as it applies to their specific job responsibilities.

4) Report incidents in which they have had direct contact with blood or other potentially infectious materials to their supervisor immediately and report to OHS or Yale University Health Services or Yale Employee Health Services or Yale Student Medicine if a Yale Student within one hour of the exposure. If this occurs on evenings, nights or weekends the employee should report to the Emergency Department within one hour of the exposure. This exposure includes but is not
limited to: Needle/sharps sticks, blood or body fluids splattered onto mucous membranes or non-intact skin.

5) Report individuals who do not comply with established policies and procedures regarding Standard/Transmission Based Precautions and Infection Control.

4.3 Hospital Epidemiology and Infection Control, (QISS) or Yale’s Office of Environmental Health and Safety (OEHS) Shall:

1) Provide education and assistance to the YMG staff regarding the prevention and control of infection.

2) Notify YMG staff of epidemiologically significant events that affect their specific area of practice.

3) Perform annual audits of clinical areas.

SECTION 5 HANDWASHING AND BARRIER PRECAUTIONS:

5.1 Handwashing:

Hands should be washed with soap and water for a minimum of 15 seconds, but not limited to the following situations:

   a) before and after contact with each patient
   b) after removal of gloves or other personal protective equipment
   c) following direct contact with blood or other potentially infectious materials
   d) Particular attention should be given to areas around the fingernails and between fingers.

5.2 Gloves:

Gloves should be worn when touching blood, body fluids, excretions and contaminated items. Put on clean gloves just before touching mucous membranes and non-intact skin. Change gloves between tasks and procedures on the same patient; after contact with material that may contain high concentrations of microorganisms. Remove gloves promptly after use before touching other items and environmental surfaces, and before going to another patient; wash hands immediately to avoid transfer of microorganisms to other patients and/or environments. Gloves should be discarded when torn or integrity is compromised. It is important to point out that the use of gloves is intended to supplement and not replace handwashing. Gloved hands may not be washed as an alternative to changing gloves. General-purpose utility gloves, such as household rubber gloves used for housekeeping and equipment cleaning, may be washed, disinfected, and reused. However, these gloves must be discarded if there is any evidence of peeling, cracking, punctures, tearing, discoloration or any other form of deterioration.

5.2.1 When to wear gloves

Gloves are worn to prevent the health care worker's hands from becoming contaminated with blood or body substances. Gloves should be worn for:

- Procedures involving direct contact with the blood and body substances of any patient.
- Procedures where contact with blood and body substances might be expected to occur.
- Procedures involving direct or potential contact with the mucous membranes of any patient.
• Procedures involving direct or potential contact with the non-intact skin of any patient. Non-intact skin is skin that is cut, chapped, abraded, cracked, afflicted with weeping or exudative lesions, or is otherwise broken.

• Touching or handling any instruments, equipment, or surfaces that have been, or may have been, in contact with blood or body substances.

• In addition, gloves should be worn in providing care to a patient or in managing equipment when the health care worker has cuts, scratches, or other breaks in the skin on his/her hands.

Sterile gloves should be used for all sterile procedures and for activities that involve contact with areas of the body that are normally sterile.

There should be an adequate supply of clean disposable gloves on the standard precaution stations or in other locations that are convenient to each patient's room.

Gloves used in patient's care should be worn only for contact with the patient. Once used, gloves should be discarded before leaving the patient’s room.

5.2.2 **Procedure for donning sterile gloves:**

- Remove all jewelry, including rings.
- Wash hands using an antimicrobial cleansing agent.
- Dry hands thoroughly with a paper towel. Use the towel to turn off the faucet.
- Remove the packet of gloves from the outer wrapper. Place this packet on a clean, dry, flat surface.
- Unfold the packet as if opening a book. Position the packet so that the cuffed ends of the gloves are nearest to you.
- Grasp the center flaps and open. Both gloves must have folded cuffs. Position the packaging so that it lies flat.
- Use one hand to glove the other. Grasp the edge of the right glove cuff with the fingers of the left hand, and slip the right hand into this glove. Pull it on by holding onto the cuff, but do not touch the outside of the glove.
- Adjust both gloves so they fit properly. Make sure there are no gaps between the fingertips and the ends of the gloves.
- Inspect the gloves for nicks and tears before and during the procedure. Obtain a new pair of sterile gloves if there is a break in aseptic technique or if a nick or tear occurs.

5.3 **Gowns/plastic aprons:**

Gowns, aprons, and other protective apparel are worn to prevent clothing from becoming soiled with blood and body substances. Selection of the appropriate type of protective apparel is based on the amount of blood and body substances likely to be encountered and the probability that clothing may be soiled.

Fluid repellent gowns should be worn to protect the skin and prevent gross soiling of clothing during procedures that are likely to generate splashes or sprays of blood, body fluids, secretions or excretions. Remove a soiled gown as promptly as possible and wash hands to avoid transfer of microorganisms to other patients or environments. The same gown should never be worn to care for another patient. Cloth lab coats are not acceptable substitutes for gowns.

5.3.1 **Gowns should be worn:**

- During activities that involve the management of large amounts of blood or body substances that may be difficult to contain properly.
• During procedures that may result in the splashing or splattering of blood or body substances.

5.3.2 **Gowns type:**

• Large enough to cover the clothing which is likely to be contaminated.
• Made of a moisture-resistant material that provides an effective barrier to body substances.
• Sterile gowns should be worn for procedures that require a sterile field.

5.3.3 **Gowns should be changed and discarded:**

• When torn
• After giving care to an individual patient.
• After performing any procedure involving the management of instruments, equipment, or surfaces contaminated by blood or body substances.
• Whenever gross soiling occurs.
• Discard used gowns in the patient care area or in the other areas in which they were used.

5.3.4 **Procedure for donning a clean gown:**

• Use the clean gowns intended for standard precaution purposes. The standard hospital gowns worn by patients should never be used by staff.
• Slide the gown over the hands and arms by holding arms forward and slightly above head arms forward and slightly above head.
• Fasten the gown at the back of the neck, and tie the gown securely at the waist.
• If gloves will also be worn, pull the cuffs over the sleeves of the gown.

5.3.5 **Procedure for removing a gown:**

• Untie the gown at the neck and waist.
• Remove the gown by peeling it off over the gloves.
• Hold the contaminated gown away from the uniform and discard it.
• Remove the gloves. Always wash the hands thoroughly after removing a gown and gloves.

5.4 **Masks:**

Masks shall be worn if the patient has a documented or potentially contagious infection, which is spread through the respiratory route. If Pulmonary Tuberculosis is suspected or known a properly fitted high efficiency mask must be worn (HEPA/N95) after fit testing. This is required per NIOSH recommendations and proposed OSHA Standard. Note: A surgical mask does not protect the employee from airborne disease.

5.4.1 **Standard surgical masks are to be used:**

• When splashing, splattering, or spraying of blood or body fluids is likely to prevent exposure to the mucous membranes of the nose/mouth. Additionally, eye protection is warranted in such situations as well.
• When within 3 feet of patient on Droplet Precautions
• When working in a sterile field to prevent droplets from contaminating the field.

Surgical masks do NOT provide adequate protection for those diseases spread by the airborne route (i.e., Mycobacterium tuberculosis)

5.5 **Respirators:**

Respirators are masks specifically designed to filter small particles spread by the airborne route. Current OSHA standards require that respirators used as Airborne Precautions for suspected/confirmed pulmonary tuberculosis minimally filter 95% of 0.3um sized particles. This level of
protection can be obtained from either the N95 or N100 disposable respirator. All personnel who care for a patient with suspected/confirmed pulmonary TB must wear an N95/N100 respirator upon entering the room of such a patient.

All personnel must be medically cleared to wear a respirator before one can be assigned. Additionally, personnel using a N95/N100 respirator must be fit-tested before using either respirator, to ensure that the style and size of respirator fits appropriately. Fit-testing can be arranged through YNHH Occupational Health Service (688-2462) for hospital employees. Yale University employees can arrange for fit testing through Yale’s Office of Environmental Health and Safety (785-3550).

5.6 Masks plus Eye Protection or Face Shields:
Masks plus eye protection devices (such as goggles or glasses with solid side shields) or chin length face shields should be worn whenever splashes, spray, splatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

Glasses, goggles, and face shields should be cleaned with an EPA approved disinfectant following contamination with blood or other potentially infectious material. Masks and N95 respirators used for Standard precautions should be discarded following each patient contact.

5.7 Eye Protection
- Protective eyewear is worn to prevent blood and body substances from contaminating the mucous membranes of the eyes. Protective eyewear is available for employee use and will be replaced if lost or damaged.
- Protective eyewear should be worn during procedures where blood and body substances may be expected to splash or splatter.
- Protective eyewear should be removed and cleaned after each use with soap and water and dried with a paper towel. If visibly soiled, wipe with a 70% alcohol solution.

5.8 Face Shields
Face shields are worn to prevent blood and body substances from contaminating the mucous membranes of the eyes, nose, and mouth during procedures, which may cause splashing or splattering. If blood and body substances may be expected to become aerosolized during a procedure, a mask should also be worn. Face shields should be removed and cleaned after each use with soap and water and dried with a paper towel. If visibly soiled, wipe the face shield with a 70% alcohol solution.
5.9 Examples of Appropriate Use of Personal Protective Equipment:

This following table provides examples only and should not be considered comprehensive:

<table>
<thead>
<tr>
<th>Task</th>
<th>Handwashing</th>
<th>Gloves</th>
<th>Gown or Plastic Apron</th>
<th>Mask</th>
<th>Eye Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding, Pressure Application to Control</td>
<td>Routinely</td>
<td>Routinely</td>
<td>If soiling likely</td>
<td>If splattering likely</td>
<td>If splattering likely</td>
</tr>
<tr>
<td>Blood Glucose by Finger</td>
<td>Routinely</td>
<td>Routinely</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catheterization, Urinary</td>
<td>Routinely</td>
<td>Routinely</td>
<td>If soiling likely</td>
<td>If splattering likely</td>
<td>If splattering likely</td>
</tr>
<tr>
<td>Cleaning Surfaces Contaminated by blood and/or body fluids</td>
<td>Routinely</td>
<td>Routinely</td>
<td>If soiling likely</td>
<td>If splattering likely</td>
<td>If splattering likely</td>
</tr>
<tr>
<td>CPR</td>
<td>Routinely</td>
<td>Routinely</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Direct Contact with Patient; with frequent, Forceful coughing</td>
<td>Routinely</td>
<td>Routinely</td>
<td>Routinely</td>
<td>Routinely</td>
<td></td>
</tr>
<tr>
<td>Specimen Collection</td>
<td>Routinely</td>
<td>Routinely</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Emptying Wastebaskets</td>
<td>Routinely</td>
<td>Routinely</td>
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<tr>
<td>Pelvic Exam and Pap Smear</td>
<td>Routinely</td>
<td>Routinely</td>
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<tr>
<td>IM or SCI Injection</td>
<td>Routinely</td>
<td>Routinely</td>
<td></td>
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</tr>
</tbody>
</table>

SECTION 6 HEPATITIS B VACCINATION PROGRAM:

The Yale Medical Group recognizes that even with adherence to all bloodborne pathogen practices, exposure incidents may occur. A Hepatitis B Vaccination Program is established in order to minimize the potential consequences of these exposures.

All employees whose positions have the potential for contact with bloodborne pathogens or other infectious materials are strongly encouraged to receive the Hepatitis B vaccination.

1) Hepatitis B vaccinations are provided at no cost to all employees whose positions have the potential for contact with blood, body fluids, or other potentially infectious materials in the performance of duties.

2) Hepatitis B vaccinations are available through the Occupational/Yale Employee Health Service during regular business hours for employees.

3) The HBV Vaccination Program consists of a series of three inoculations over a six-month period. This series may be modified at the discretion of the Occupational/Employee Health Physician.

4) Employees must be tested for antibody to Hepatitis B surface antigen 1 to 2 months after the completion of the series.

5) YNHH employees, who choose not to participate in the vaccination program, must sign a declination form. This form is kept in the employee’s medical record. Yale University employees must sign the Hepatitis B Vaccine Notification Form if they decline or want to be
vaccinated and this form is kept at Yale’s Office of Environmental Health and Safety. If an employee refuses to sign a declination form, a note to that effect will be placed in the employee’s personnel file, indicating that the employee’s cooperation was sought. At any time, the employee may change their mind and receive the Hepatitis B vaccinations even if a declination statement is signed.

SECTION 7  POST EXPOSURE EVALUATION AND FOLLOW-UP:

Wash area with soap and water. If area exposed is eye or mucous membrane rinse with water. Avoid use of betadine, hydrogen peroxide and other agents. There is no known benefit from using such agents and may damage healthy tissue.

Immediately report exposure to superior.

During regular business hours the supervisors should send employees promptly (within one hour) to the Occupational/Employee Health Clinic. University and Hospital employees should go to the area that is closest at the time of exposure. During the evenings, nights, weekends and holidays, the employee will be sent to the Emergency Department where the appropriateness of post exposure prophylaxis will be considered.

The YNHH supervisor will complete either the “Supervisors Report of Employee Accident/Injury (Form F1797): and send it to OHS, EHS or the Emergency Department with the employee and immediate prophylaxis will be considered. Yale University employee’s supervisor complete the “Department Head’s Report of Injury Form” and will send the completed form to Yale Workers Compensation. If it is decided that prophylaxis is not to be administered, the employee will be referred to the Occupational/Employee Health Clinic.

The supervisor will complete the report form and send it to OHS/ EHS with the employee or within 24 hours of the exposure incident

A medical evaluation and follow-up of the exposed employee is conducted in compliance with specific Occupational/ Employee Health Clinic policies.

SECTION 8  PREVENTION OF TUBERCULOSIS TRANSMISSION:

Early recognition and treatment is the single most important measure in the control of transmission of tuberculosis.

Patients with HIV or risk of HIV or at high risk of TB should be screened for TB; HIV-infected patients with history of positive reaction to PPD of Tuberculin or induration of 5mm or greater should be regarded as infected and undergo further evaluation. Note that patients with HIV infection demonstrating reactions of 5mm or greater have been regarded as infected.

Patients known or suspected of having active Pulmonary TB should:

- receive instruction on methods used to prevent the spread of TB to others
  - mask suspected patients and instruct to cover their nose and mouth when coughing, or sneezing or (applies to all patients)
  - be placed in a negative pressure room in the clinic, if available
  - transported to an area where there are negative pressure rooms
- wear an appropriate mask (without exhalation valve) prior to being transported to another area

Personnel who have contact with patients suspected or known to have TB must wear a properly fitted appropriate mask (respirator) when entering the exam room.

Visitors and family members should be encouraged to remain outside of the negative pressure room. In the event that the visitor or family member must wait with the patient they must wear an appropriate respirator. The visitor or family member should be instructed regarding the reasons for this activity.

Whenever a patient with known or suspected active TB is being transported, the patient should be evaluated to determine if it is medically feasible for the patient to wear a high filtration mask (N-95) or a molded surgical mask.

The receiving area should be notified of the impending arrival of a patient with known or suspected TB prior to the patient’s arrival.

Clinics without negative pressure rooms should provide masks (without exhalation valve) for patients with persistent coughs. This may help reduce the number of droplet nuclei in the air. These patients should be removed from common areas and be placed in a private room or cubicle and evaluated as soon as possible. Suspected or confirmed cases are to be transported to YNHH when airborne isolation techniques are used when the clinic does not have a negative pressure room.

The above isolation techniques used for a patient with suspected or confirmed TB should continue until he or she has clinical improvement, substantially decreased cough, and decreasing numbers of organisms on three sequential sputum smears. Isolation of a patient with presumptive drug-resistant organisms should continue until the sputum cultures collected on three consecutive days are free of tubercle bacilli.

SECTION 9  GENERAL GUIDELINES FOR ALL OUTPATIENT AREAS:

9.1 Storage and Consumption of Food and Drinks
   Eating, drinking, application of cosmetics or lip balm, and handling of contact lenses is prohibited in work areas where there is reasonable likelihood of occupational exposure to blood, body fluids, chemicals, radioactive materials, and all other hazardous materials.

   Food and drink should not be kept in refrigerators, freezers, cabinets, or on shelves or countertops where blood or other potentially infectious materials are present.

9.2 Material Safety Data Sheets (MSDSs)
   Material Safety Data Sheets (MSDSs) for all chemicals and disinfectants used should be maintained and readily accessible in the clinic area.

9.3 Patients with Communicable Diseases
   All patients who have or may have a disease that is transmitted by the airborne/respiratory route should be seen in a negative pressure room or a private room with the door closed. There should be the appropriate signage on the closed door. The patient with known disease requiring airborne precautions should wear mask. Staff should wear respirators and only non-immune staff should care for these patients.
Patients with known communicable (i.e., chickenpox, measles) diseases scheduled to be seen in the clinic, should be seen in a negative pressure or private room, or appointments should be deferred until the condition is resolved. In the event that this is not possible, patients should be scheduled for the end of the clinic day.

Protective pads should be placed on portions of chairs, wheelchairs, stools, and exam tables that are likely to have direct contact with a patient’s skin.

### 9.4 Cleaning, Disinfection and Sterilization

- **Stretchers and exam/treatment tables** should be covered with a clean sheet and/or disposable exam table paper before each patient use. The surface should be wiped down with an EPA approved tuberculocidal disinfectant at the end of the day and when soiled with blood or body fluids.

- **Portable equipment** (i.e., IV poles and pumps) should be cleaned with an EPA approved tuberculocidal disinfectant-detergent in accordance with the manufacturers' instructions after each patient use.

- **Blood pressure cuffs** should be cleaned with an EPA approved tuberculocidal disinfectant-detergent in accordance with manufacturer’s instructions when visibly soiled.

- **Contaminated reusable instruments** should be placed in a labeled puncture/leak-proof container before being returned to Central Sterile Supply.

- All sterile supplies shall be checked weekly for inventory rotation and rips, or moisture damage.

- Each clinic must designate an area for the storage of patient care equipment. After a piece of equipment is used, it needs to be taken to a designated “dirty area” for cleaning. After cleaning it should be transported to an area designated for clean patient care equipment. If the clinic does not have a specified clean storage area for equipment, the item must be labeled as clean with the date of cleaning. All equipment should be cleaned with an EPA approved tuberculocidal disinfectant-detergent in accordance with the manufacturer’s instructions.

- If new patient care equipment is purchased, there must be notification to OEHS or QISS prior to using the equipment in order to review the method of cleaning/disinfection/sterilization required.

- Each clinic must have a clinic specific policy regarding sterilization of reusable equipment used in the department. The policy should be reviewed annually. If all reusable equipment is sterilized by Central Sterile Supply, there should be a statement to that effect.

- If reusable equipment is sterilized within the clinic there should be a clinic specific policy on the decontamination and sterilization process, and monitoring program used.

- Clean supplies should not be stored on the floor, in the soiled utility room, or next to sinks where splashing of water or soiling is likely. There should be designated areas for clean and dirty supplies.

### 9.5 Safe Sharps Devices
Needlesticks occur in situations where needles must be manipulated or disassembled. There are devices or systems that reduce the need to use needles or decrease the danger of accidental needlesticks. These or similar devices should be utilized whenever feasible.

“Sharps with Engineered Sharps Injury Protections” include non-needle sharps or needle devices containing built-in safety features that are used for collecting fluids or administering medications or other fluids, or other procedures involving the risk of sharps injury. This description covers a broad array of devices, including:

- syringes with a sliding sheath that shields the attached needle after use;
- needles that retract into a syringe after use;
- shielded or retracting catheters
- intravenous (IV) medication delivery systems that use a catheter port with a needle housed in a protective covering.

“Needleless Systems” are devices that provide an alternative to needles for various procedures to reduce the risk of injury from contaminated sharps. Examples include:

- IV medication systems which administer medication or fluids through a catheter port using non-needle connections, and jet injection systems that deliver liquid medication beneath the skin or through a muscle.

Safe sharps devices, such as needleless systems and needles that include safety features must be strongly evaluated by the employer to prevent or minimize exposure. The employer must also evaluate whether these devices could prevent future incidents as part of its responsibility under the law in evaluating exposures that occur in the workplace. The employer must solicit input from non-managerial employees regarding the identification, evaluation and selection of effective engineering controls, including safer medical devices. The employer must document each evaluation and continue to pursue engineering controls that are designed to prevent occupational exposure. Finally, where a new engineering control is issued, suitable training on its use must be provided to the employees and documented.

Where engineering controls will reduce employee exposure either by directly removing, eliminating or isolating the hazard, they must be used. Contact Office of Environmental Health and Safety for information on needleless systems or needle protected devices or evaluation of safety devices.

Needlesticks occur in situations where needles must be manipulated or disassembled. Safe medical devices or systems reduce the need to use needles or decrease the danger of accidental needlesticks. These or similar devices should be utilized whenever feasible.

All disposable sharps should be disposed of in the designated sharps container. Contaminated needles should not be bent, or removed from the syringe by hand. Contaminated needles should not be recapped, unless absolutely necessary for the performance of the procedure. In situations where recapping may be necessary, a mechanical device or one-handed technique should be used.

### 9.5.1 Handling Sharps

The potential for transmission of bloodborne pathogens is greatest when needles, scalpels, and other sharp instruments are employed. Precautions should be taken to prevent injuries during procedures where needles and sharp instruments are required, when cleaning used instruments, and during disposal of contaminated needles. Gloves and other personal protective clothing will not prevent penetrating injuries due to accidental needle sticks or cuts from scalpels blades and other sharp instruments. To prevent injury:
Avoid rushing when handling needles and sharps.

Use extreme care when handling contaminated needles and sharp instruments. Obtain assistance when giving injections, starting intravenous lines, and for any other procedure that requires the use of needles and sharp instruments when the patient is uncooperative.

Dispose of needles and sharps in the beige sharps disposal containers located throughout the clinics in all patient care and treatment areas.

- It is everyone’s responsibility to check sharps disposal container on a daily basis.
- Upon observing a container which is 3/4 full, a designated person in clinic to carefully to close the disposable container, open the container holder using the designated key, remove the full container, and place container in the designated area for pick up.
- At this time, any contamination observable either on the outside or inside of the container holder will be wiped clean, using an approved disinfectant cleaner.
- In the event of a sharps disposal container becoming full prior to the next scheduled replacement, call OEHS at 785-3551 for pick-up.

Dispose of all needles and other sharps promptly. It is imperative that these items not be left in patient care areas, on food trays, or inadvertently deposited in trash containers.

Contaminated needles should not be recapped by hand, removed from disposable syringes by hand, or purposefully bent, broken, or otherwise manipulated by hand. In the event recapping is unavoidable, the one-handed scoop technique or a needle-recapping device should be used.

Return all non-disposable needles and sharp instruments to the Central Sterile Supply (CSS) Department for decontamination and sterilization.

- Place the needles and sharp instruments into a covered, leak-proof, puncture proof container for transportation back to Central Sterile Supply for decontamination and sterilization prior to reuse.
- Separate linen, such as towels and drapes, from the reusable needles and sharp instruments.

Do not wrap sharp objects and needles in linen or obscure them from the view of CSS personnel.

9.6 Lab Specimens

All specimens should be in a sealed leak-proof container and transported to clinical laboratories while placed in a designated leak-proof plastic bag and closed prior to storage or transportation. Laboratory requisitions should be attached to the outside of the plastic bag or in the designated pouch on the outside of the bag.

9.7 Food, Specimens and Medication Refrigerators

There must be separate refrigerators for food, specimens, and medications. Signs are affixed to each refrigerator designating its purpose. Each refrigerator is used only as designated. Each must have established cleaning schedules. Signs designating use must be affixed to each refrigerator. There should be a program to monitor temperature and cleanliness, which includes daily temperature checks, weekly and as-needed cleaning and routine inspection of contents. (See refrigerator cleaning and monitoring log in Appendix).

9.7.1 Utilization/Maintenance on Refrigerators

9.7.1.1 Food refrigerators:
Specific refrigerators are designated for employee food.

Patient food refrigerators:
- Individual patient’s food must be wrapped or placed in a leak proof storage container and labeled with the patient’s name and expiration date. Food expires after 24 hours and must be discarded.
- Bulk nourishment for patients are labeled with the date the item expires. Nourishments are discarded when expired:
  - margarine, butter or creamers are delivered to the unit with labeled expiration dates;
  - plastic jugs of juice expire 2 weeks after opening;
  - individual juices are stored first in first out and are discarded if open or seal is raised.

Breast milk refrigerators:
- breast milk refrigerators are used only for the storage of breast milk in containers labeled with the mother’s name and the date the milk was stored;
- for storage and handling of breast milk, see CMP: Breast Milk Storage and Handling.

9.7.1.2 Medication Refrigerator

Medication refrigerators are used for the storage of medication requiring refrigeration according to manufacturer’s guidelines.

9.7.1.3 Specimen refrigerators:
- All specimens must be placed in proper leakproof containers, labeled with the date and time the specimen was collected;
- Specimen refrigerators are also labeled with a biohazard sticker.

9.7.2 Temperature Regulation

The temperature of all refrigerators is checked daily to assure the appropriate temperature is maintained. The temperature registering on a thermometer inside the refrigerator and the initials of the individual performing the check are recorded on the temperature log. Logs are maintained and kept on file for a period of three months.

Temperature requirements:
- Food refrigerators are maintained between 37° and 40° F.
- Medication and specimen refrigerators are maintained between 36° and 46° F.
- Specimen refrigerators are kept 36° - 46° F.

When a refrigerator temperature is out of the appropriate range, the charge nurse is notified to determine the appropriate action to be taken. Any actions taken are documented on the temperature log.

9.8 Procedures Performed in the Clinic

All procedures involving blood or other potentially infectious materials should be performed in such a manner as to minimize splashing, spraying, or generation of droplets.

Goggles, gowns, and gloves should be available and easily accessible in all exam rooms.

Each clinic must have a clinic specific policy regarding invasive procedures performed in the clinic. This policy should be reviewed annually. There are some of these policies included in the Nursing Organization Policy Manual (NOPM) in hardcover as well as on the Clinical Workstations. All procedures performed in the clinic must have a written protocol procedure designating the infection control principles associated with the procedure.
Each clinic that performs invasive procedures should have a method in place for the surveillance of infection post procedure and report findings to the Infection Control Committee on a routine basis or inform them immediately if infections are above endemic level.

SECTION 10  PATIENT CARE ITEMS - STORAGE

10.1 Clean Supplies

Clean patient care items should not be stored on the floor, in the soiled utility room, and under or next to sinks where splashing of water or soiling is likely. There should be designated areas for clean and dirty supplies. All supplies should be stored above floor level using pallets, if necessary. No item can be stored within 18 inches from the ceiling.

10.2 Sterile items

Sterile packages must be inspected for integrity, rips, or moisture damage prior to use. If the integrity of the package has been breached, the item is discarded if single use or re-sterilized before use if re-usable.

SECTION 11  MEDICATIONS:

Multi-dose vials must be labeled with the date they were opened. Stock medications should not be left in cubicles or treatment rooms. They should be examined for precipitate matter and evidence of discoloration prior to each use.

Sterile water and saline for irrigation must be labeled with the date and time it was opened. The bottles should be discarded at the end of 24 hours.

Multi-dose bottles containing solutions such as hydrogen peroxide and betadine will be dated when opened, and discarded in one month.

For additional information on medication administration, storage and handling see section 21 in the manual or the Nursing Organization & Practice Manual (NOPM) on YNHH Clinical Workstation.

11.1 Expiration Dates for Multi-Dose Vials

In view of sterility and stability of medications in multi-dose vials and the variability of injection technique, preservatives and storage conditions for parenteral products, the following guidelines are recommended.

- Any vial that does not contain a preservative is a single-use vial and shall be used for only a single use.
- Any multi-dose vial that does contain a preservative shall be inspected prior to each use for particulate matter and discoloration.
- All open vials discard after open one month.
- Exceptions:
  - Allergenic extracts, skin test reagents, which are patient specific, can be used until the manufacturer's expiration date.
  - For all immune globulin and vaccine vials follow manufacturers specific guidelines on storage.
SECTION 12  BULK NOURISHMENTS GUIDELINES

12.1  Handling and Shelf-Life Guidelines

- All milks, orange juices, custards, and jellos are labeled for you with the expiration dates. Discard leftovers on expiration dates.
- All milks and orange juices must be dated with expiration date.
- Other items that should be dated on the Patient Division include:
  - Canned juices (once opened) - Cover & use within two (2) days
  - Margarines, Butters, and Creamers - Cover & discard when expired.
  - Individual juices - if not opened, must be used within one week.
  - Jugs of juice (Apple & Cranberry) - Once opened, they have a 2-week shelf life under refrigeration.

12.2  Tips for Handling Foods Properly

- Put bulk nourishment away as soon as they are delivered or within thirty minutes of delivery.
- Personal patient/family food items should be covered, labeled and dated with expiration date.
- Discard any items not dated or after 24 hours.
- Dispose of any opened or outdated items immediately.
- Dispose of any small (individual) juices that have "raised" lids immediately.

"WHEN IN DOUBT - THROW IT OUT"

SECTION 13  CARE AND MAINTENANCE OF TOYS:

Toys available in clinic play spaces should be limited to plastic, rubber, wood, or coated board games. Fur covered or other non-washable toys should be excluded from clinic play areas. These items may be used by staff for demonstration purposes. If they become soiled during a demonstration they must be given to the patient.

The Environmental Associate, Patient Care Associate, or other designated staff member is responsible for inspecting and cleaning toys.

The frequency of inspection and cleaning should be based on the frequency at which the toys are handled. (i.e., children handling toys daily - toys should be inspected and cleaned daily etc.). All toys should be inspected and cleaned at least weekly. Toys that are cracked, or develop openings where dirt, etc. can accumulate should be discarded. Cleaning consists of washing with a mild soap and drying, with a clean cloth or wiping all surfaces with alcohol allowing to air dry.

If a toy becomes contaminated after individual use, they should be cleaned immediately before being handled by another patient.

13.1  Washable Toys

Plastic, rubber, wood and coated board games and other washable toys should comprise the majority of the toy supply for the small children population.

The toys must be cleaned with an EPA hospital approved germicide solution followed by a thorough rinsing and drying.
If any toys become contaminated after individual use, they should be cleaned immediately before being handled by another patient.

Toys played with by children in isolation should be cleaned immediately before storage.

Toys should be stored in cabinets after cleaning.

A designated person must be assigned to cleaning the toys.

13.2 Non-Washable Toys

Only new non-washable toys should be accepted as donations.

Any non-washable toy or object (i.e. stuffed animal, blanket) that is distributed to a patient that would result in exposure to secretions and excretions must be given to that patient.

Any non-washable toy, which is used for demonstration purposes, used by the staff and will not result in exposure to secretions and excretions can be shared with other children.

SECTION 14 REGULATED MEDICAL WASTE:

14.1 Regulated Waste

Regulated wastes will be handled and disposed in accordance with established YNHH policies. Clinic personnel are responsible for identifying and placing regulated waste in the Biohazard receptacle. For details of YNHH policy, see the Regulated Medical Waste Policy in NOPM. See section 24 for YNHH Medical Waste Classification and Separation Reference Chart.

An approved outside vendor by Yale University are responsible for removing infectious waste from the clinical area. We will not use an actual volume of blood or other potentially infectious materials to determine whether or not a particular item is to be considered regulated waste. Since 10 ml of blood on a disposable sheet would appear as a spot (not regulated waste) while the same amount of blood on a cotton ball would likely cause saturation and dripping (regulated waste). Any item contaminated with blood or other potentially infectious materials which would release this substance in a liquid or semi-liquid state if compressed, items that are caked with dried blood or other potentially infectious materials and are capable of releasing (flaking-off) these material during handling.

Further information on the procedures for separating, collecting, storing, transferring, and disposing of solid wastes, including general, medical, and chemotherapy wastes, can be obtained by contacting the Environmental Services Department at 688-6688 or Yale's Office of Environmental Health and Safety at 785-3550.

14.2 Definition of Biomedical Waste

14.2.1 Human Pathological Wastes

Pathological waste consists of human tissues; organs; body parts; blood; dialysate; cerebrospinal, synovial, pleural, peritoneal, and pericardial fluids; and their respective containers.
14.2.2 Human Blood and Blood Products Waste and Their Containers Including:

- Waste human blood and blood products (e.g. blood plasma, platelets, red or white corpuscles, and other derived licensed products such as interferon, etc.)
- Items saturated or dripping with human blood or blood products.
- Items caked with dried human blood or blood products.
- Items that can release human blood, blood products or body fluids if compressed.
- Intravenous (IV) bags.

14.2.3 Intravenous bags

- Chemotherapy Intravenous bags or containers with chemotherapy liquid <3% of container volume must be placed into the red plastic medical waste containers.
- IV bags or containers containing human blood and blood products.

14.2.4 Sharps Waste

This category includes used hypodermic needles, syringes (with or without the attached needles), pasteur pipettes, disposable plastic pipettes, scalpel blades, razor blades, blood vials, test tubes, needles with attached tubing, broken plastic culture dishes, unbroken glass culture dishes, and other types of broken and unbroken glassware that was in contact with infectious material including microscope slides and coverslips.

All intravascular sharps are considered medical waste regardless of the presence of infectious material and must be discarded in beige sharps containers. Do not discard intravascular sharps in the look alike waste stream.

14.2.5 Isolation Wastes

Isolation wastes are defined as biological wastes and discarded materials contaminated with blood, excretion, exudates, or secretions from humans or animals isolated due to infection with Class 4 microbial agents.

If a human or animal is known to be infected with a Class 4 agent, contact the Biological Safety Officer (737-5009) immediately.

14.2.6 Chemotherapy Waste and Medical Waste

Items contaminated with trace amounts of a chemotherapeutic agent or empty stock bottles may be disposed of through the medical waste stream. "Empty" is defined as containing less than 3% by weight of the total capacity of the container.

Chemotherapy IV bags or containers (no needles attached) with >3% of container volume must be returned to your pharmacy for disposal. Please call OEHS at 785-3551 to schedule a pickup of this waste. Stock solutions of these chemicals and items that are heavily contaminated are disposed of through the Chemical Hazardous Waste Program. Call Yale University’s Environmental Services Section (785-3551) for guidelines concerning the disposal of chemical hazardous waste.

14.2.7 Look-Alike Waste

Look-alike waste is not considered medical waste. Look-alike waste is plastic or glass labware, lab matting and gloves that have not been in contact with human materials or other potentially
infectious material. Saline IV bags are not regulated medical waste. Place saline bags (no needles attached) into the general trash containers. Look-alike waste is disposed of through a separate waste stream and should not be placed in the medical waste stream. Items should be discarded in a manner to prevent physical injury to those people handling the waste. Glass and items that are capable of puncturing bags should be placed in a plastic lined cardboard box. Do not autoclave or chemically decontaminate look-alike waste.

14.3 Disposal Procedures

14.3.1 Sanitary Sewer

The sanitary sewer was designed for the disposal of certain liquid wastes. Use of the sanitary sewer reduces the chance for leaks or spills during transport and reduces disposal costs.

- Waste microbiological liquid stocks (Class 1, 2 and 3 agents) shall be autoclaved or chemically disinfected and poured down the drain whenever possible.
- Human blood and body fluids do not need to be disinfected before being poured down the drain.
- Remember to rinse and disinfect the sink area afterward.

14.3.2 General Trash Containers

The following items are not regulated medical waste and are discarded into the general trash container:

- Office paper, forms, packaging materials.
- All soft waste not dripping or soaked with human blood, blood products, or body fluids.
- Examples of items not visibly dripping or soaked with human blood, blood products, or body fluids are:
  - gloves, masks, gowns,
  - wrappers, foil, paper towels, tissues, cups
  - casts, cast padding and splints
  - bandages, dressings, gauze pads, table papers, table drapes
  - tape, pads, cotton
  - respiratory suction tubing, ventilator tubing
  - suction canisters liners and tubing, salem sump (NG) tubes
  - irrigation sets
  - foley bags and foley catheters, red rubber catheters
  - bed pans, emesis bassins, urinals, urinal hats, urinal filters
  - diapers, peri(OB) pads
- Any containers, saline containing IV bags and tubing not attached to needles or catheters, with no blood, body fluids, or containing chemotherapy agents.
- Urinals, bedpans, emesis basins, etc. (empty and rinsed)

14.3.3 Sharps (Needle Disposal) Wall Mounted Containers

- Discard all intravascular sharps waste
- hypodermic needles, syringes (with/without the attached needles)
- All needles such as IV, hypodermic, spinal, sutures needles
- Safety pins, spears, scrapers, scissors
- Lancets, scalpel blades
- Vacutainer holders and needles
- Deposit any other type of intravascular sharps waste into this container.
14.3.4 Red Waste Containers

Do not discard needles, syringes or other intravascular sharps into a red waste containers. It is illegal to do so.

- Discard all non-intravascular sharps waste such as: pasteur pipettes, disposable plastic pipettes, blood vials, vacutainers, glass culture dishes, microscope slides and overslips, sharp broken plasticware and other types of broken or unbroken glassware that may have been in contact with infectious material.
- Empty glass medication vials, blood transfer devices
- Discard empty treatment containers and vials,
- Discard IV containers containing blood or blood products
- Chemotherapy Intravenous bags or containers with chemotherapy liquid <3% of container volume must be placed into the red plastic medical waste containers
- Discard items saturated or dripping with human blood or blood products.
- Discard items caked with dried human blood or blood products.
- Discard items that can release human blood, blood products or body fluids if compressed. Examples of items saturated, dripping, or caked with dried human blood, blood products or body fluids:
  - sponges, pleurivacs, hemovacs, other collection bags/devices
  - hemodialysis, CVVH filters, tubing & bags
  - suction tubing and canister liners
  - specimen containers
  - vacuum bottles containing ascites or pleural fluid
- All waste from a person that has a Biosafety Level 4 disease such as hemorrhagic fever.
- Cultures and stocks of agents infectious to humans and associated biologicals including cultures from medical, clinical and laboratories, culture dishes and devices used to transfer, inoculate or mix cultures.

SECTION 15 HOUSEKEEPING & CLEANING OF BLOOD AND BODY FLUID SPILLS

Routine cleaning and cleaning of blood and body fluid spills will be done by the Custodial Services or designated personnel in accordance with established policies.

15.1 Interim Cleaning

Interim Cleaning-clinic staff performing interim cleaning services will follow the following procedure:

- put on gloves
- face protection and gown if soiling is likely
- saturate disposable cloth with the EPA approved disinfectant
- remove gross soilage (if present)
- dispose of cloth, if saturated with blood dispose into regulated waste container
- saturate second disposable cloth with disinfectant-detergent and wipe entire area
- allow area to dry according to manufacturers recommendations as listed on container

15.2 Environmental Considerations for HIV Transmission:

The AIDS virus is not stable in the external environment outside the body, and environmentally mediated HIV transmission has never been documented. Studies of the survival of HIV in the
environment have found that it is rapidly inactivated after drying and following exposure to commonly used EPA approved tuberculocidal disinfectant. Accordingly, no extraordinary procedures are required in existing sterilization, disinfection, housekeeping, laundry, or waste handling procedures.

15.3 Decontamination and Cleaning of Blood and Body Substance Spills on Environmental Surfaces:

- All spills of blood and body fluids or any other potentially infectious material should be cleaned from environmental surfaces as soon as possible.

- Personnel must wear gloves during this procedure and a gown if the spill might be expected to contaminate clothing. To clean large spills that might splash, a mask and safety glasses/face shields should also be worn.

- To wipe excess liquid that may accidentally splash, an absorbent cloth or paper towels should be used.

**NOTE:** If glass is involved, do not attempt to clean spill by hand. Tweezers, needle holder or another instrument should be used to pick up glass prior to cleaning.

Environmental surfaces should be decontaminated with a 1:10 solution of 5.25% sodium hypochlorite in water (1 part chlorine bleach to 9 parts water) or with an EPA approved tuberculocidal disinfectant and diluted according to the manufacturer's directions.

**NOTE:** These disinfectants are highly caustic unless properly diluted. In addition, disinfectant solution is intended for use on environmental surfaces only, since it can damage instruments and equipment and skin damage.

When there are large spills of cultured or concentrated infectious agents, such as in the clinical laboratory setting, the contaminated area should first be flooded with a liquid disinfectant then physically cleaned and decontaminated with a hospital approved disinfectant. Gloves, gowns, masks, and safety glasses should be worn for cleaning large spills of blood or body fluids.

15.4 Decontamination of Health Care Worker's Clothing

Health care worker's clothing that becomes contaminated by blood or body fluids/substances should be handled according to the following procedure:

- Clothing should be removed promptly while wearing gloves.

- Clothing should be placed in a plastic biohazard/leak proof bag.

- The health care worker's supervisor should be notified and arrangements should be made for health care worker's personal uniform or clothing to be decontaminated and laundered.

- The hospital health care worker should report to OHS if there is any exposure through clothing to the skin. Yale University employees report to Yale University Health Services (YUHS) Urgent Visit (open 24 hours) or Employee Health (8:30 am – 5:00pm) immediately. The Yale University Employee Health satellite office is located at 800 Howard Avenue in the Yale Physician Building (2nd floor). Monday - 12:00 to 5:00 pm, Tuesday, Wednesday, Thursday - 8:30 am to 1:30 pm.
15.5 Decontamination of Patient Clothing and Personal Belongings:

Patient clothing and personal belongings that become contaminated by blood or body substances should be handled according to the following procedures. Any items that cannot be managed in the manner below should be sealed in a plastic bag and kept at the bedside until the matter can be discussed with Hospital Epidemiology (Department of Quality Improvement Support Services) or Yale University’s Office of Environmental Health and Safety.

15.5.1 Clothing

Clothing soiled by blood or body substances should be placed in a tightly sealed plastic bag at the patient's bedside and given to the family for home laundering. The family should be instructed to wash the clothing by machine, using a laundry detergent. Hot water and chlorine bleach should also be used unless these agents will damage the items. The plastic bag used to contain the clothing during its transport should be placed in a second plastic bag, tightly sealed, and discarded in the household trash. Persons involved in the handling of contaminated clothing should be instructed to wash their hands thoroughly after handling the items.

15.5.2 Personal Belongings

- Disinfect hard surfaces by wiping the items using a 1:10 solution of 5.25% sodium hypochlorite in water (1 part chlorine bleach to 9 parts water).
- Disposable articles, such as magazines, that are contaminated by blood or body substances should be disposed of according to the hospital's regulated and non-regulated waste policy.

15.6 Linen Handling

- All clean linen must be kept covered at all times before use.
- Assigned staff from the clinical area will bag linen in impervious linen bags at the point of generation.
- The linen bag will be placed in a covered soiled linen holder.
- All used linen is considered contaminated and should remain covered at all times.
- Care should be taken to prevent linen bags from being overfilled. The bag must be able to be securely closed prior to removal from the clinic.
- Personnel removing linen from the clinic area must wear appropriate personal protective equipment.

SECTION 16 INSTRUMENTS/EQUIPMENT:

Specialized instruments should be handled according to manufacturers' recommendations. Clinics utilizing specialized instruments should have specific policies regarding processing.

Contaminated (non-sharp) instruments being returned to Central Sterile Supply (CSS) for decontamination and sterilization will be placed in an appropriately sized biohazard bag prior to transport.

Contaminated (non-sharp) instruments being cleaned and sterilized on the unit should be handled according to established clinic policy.

All reusable sharps should be placed into the impervious, leak proof container in which it came prior to transport to CSS for decontamination and sterilization.

All disposable sharps should be disposed of in the designated, impermeable sharps container.
Clean urinals and bedpans should be stored in clean storage areas. After use, they should be emptied into a commode or hopper and disposed of in the appropriate waste receptacle.

Emesis basins should be emptied into a commode or hopper. After use, it should be disposed of in the appropriate waste receptacle.

Disposable thermometers should be used whenever possible. Protective covers should be applied prior to placing tympanic thermometers into the ear canal. If mercury thermometers are used, place in a secure location to prevent breakage.

16.1 Monitoring Autoclaves

Monitoring of autoclaves should be done weekly. It takes 24 hours of incubation time to complete the procedure. (It is preferable to send items to Central Sterile Supply for sterilization.)

1) Label a biological monitor cartridge using a black marker with the following information:
   a) date of sterilization
   b) time in which cartridge was placed
   c) location of the item in the sterilizer (should be rotated)
   d) sterilizer location

2) Place the biological monitor in wrapping which is similar to the bulk of the load.

3) Begin sterilization process.

4) After the sterilization process has been completed remove the biological monitor cartridge from the bundle. Let cool for at least 10 minutes. Deliver cartridge to the Surgical Specialties Clinic for processing on the first day of the work week as outlined below:

16.2 Biological Monitor deliver to Surgical Specialties Clinic

1) Add distilled water to the incubator to a depth of approximately 1 1/2 inches. Keep the water level below the level of the bottom of the brown cap of the cartridge. Place the cover on the incubator and plug into an electrical outlet. Periodically clean incubator to remove contaminating bacteria (see general considerations).

2) Label the "control cartridge" with the date and the word "control".

3) Crush each capsule just below the cap with the brown plastic "crusher". Do not handle the cartridge more than necessary. Place capsule in incubator.

4) Record the time the incubator started on the recording form. The incubation period is 24 hours. The time of completion should also be recorded on the form.

16.3 Reading Results

1) After 24 hours remove both cartridges from the incubator.

2) The "control" cartridge should always turn yellow. This indicates that the incubation period was satisfactory as growth has occurred.

3) If the cartridge that was sterilized remains red/purple, sterilization has been achieved and the result is recorded as negative on the chart. A color change to yellow indicates the presence of
viable organisms and the result is recorded as positive on the chart. Do not discard the cartridge if positive. Hold for inspection by Hospital Epidemiology (QISS) or CSS.

4) If the positive result is reported, Surgical Specialties Clinic staff will notify the Nurse Manager or Charge Nurse of the appropriate clinic. The suspect sterilizer should be immediately taken out of service and the Nurse manager or Charge Nurse of the affected clinic should call the Engineering Department to perform operational inspection. Do not use autoclave until sterilization is verified.

OEHS or QISS should also be notified. The sterilizer should remain out of service until repeat biological monitoring is performed (using several indicators throughout the sterilizer) and results are satisfactory.

5) All items processed in the suspect load are considered unsterile. They must be retrieved, if possible, washed, repackaged, and resterilized in another sterilizer.

6) Discard all negative cartridges into a designated sharps container. Positive cartridges shall be placed in a paper bag, which shall be decontaminated in a steam sterilizer. The decontaminated cartridges shall then be discarded with waste.

16.4 General Considerations

1) The water in the incubator should be emptied after each use to minimize microbial growth.

2) Pour 1:10 bleach solution into the incubator with the rack in place. Place the cover on the incubator and start the soaking process.

3) Soak the incubator and the rack at least 20 minutes before using again.

4) Distilled water is used in the incubator to minimize rust and corrosion.

16.5 Sterilized Items

1) Packages should be checked for signs of breach in integrity. If the integrity of the package has been breached the item should be resterilized before use.

2) The date of sterilization shall be placed on the sterilized item.

3) With event related sterility, it is essential to inspect all packages prior to use and to use the instruments with the older sterilization date first.
SECTION 17 SCREENING OF OUTPATIENTS FOR POTENTIAL COMMUNICABLE DISEASES

Yale Medical Group Clinic

In a waiting area, many types of patients may congregate, including: young, elderly, pregnant, immunocompromised, post-operative patients; any of whom may have active or incubating communicable/infectious diseases.

Each waiting area should have a plan in place where patients are observed upon arrival into the ambulatory setting and assessed for signs and symptoms of potentially communicable diseases. When a potentially communicable disease is suspected, the patient should be taken out of the waiting area immediately and placed into specified holding area until additional triage can be undertaken.

________________________________________ Clinic

Upon arrival, the patient will be seen by _______________________________. At that time, the patient will be observed for signs and symptoms of a potentially communicable disease: coughing, sweating, itching, rash, lesions, etc.

If any of these or additional signs are present, the patient will be given a mask and escorted to ____________ where a more thorough evaluation for communicable infectious disease may take place.

If a communicable infectious disease is suspected, and inpatient treatment is sought, the inpatient unit must be notified prior to the patient's arrival to arrange for appropriate isolation to include a negative pressure room if Airborne Precautions are required. If a communicable/infectious disease is suspected and the patient is sent back into the community, education shall be provided to patient and significant others regarding the method of transmission of the disease and the State and Local Public Health Departments must be notified if it's a Reportable Disease.

If there are any exposures to staff and patients, the following procedure must be carried out:

QISS/ Epidemiology should be notified of the exposure to include the names of all staff and volunteers in the clinic as well as the names of the patients and their attending physicians.

All YNHH employees will be referred to Occupational Health Services and Yale University Employees will be referred to the Yale University Employee Health Services where they will also receive the appropriate follow up if needed.
SECTION 18 REPORTABLE DISEASES:

The Commissioner of the Department of Public Health (DPH) declares a list of reportable diseases annually. It is the responsibility of the Physician, Clinical Service Manager, or designee to report a reportable disease upon its recognition or strong suspicion.

Forms for reporting may be obtained from:
Department of Public Health, Epidemiology Section
410 Capitol Avenue
MS# 11LOC
PO Box 340308
Hartford, CT 06134-0308
Telephone: (860) 509-7660

There are several standard forms for reporting. These include:

1. The Communicable Diseases Report (PD-23)
2. The Acquired Immunodeficiency Syndrome (AIDS) Case Report
3. The Sexually Transmitted Disease Confidential Case Report (STD-23)
4. The Tuberculosis Case Report (TB-86)

Clinic patients who have “significant laboratory findings” indicative of reporting, the Microbiology Laboratory will attach a Communicable Disease Report (PD-23) to the culture report.

The Nurse Manager, responsible physician or designee is responsible for completing the form.

Copies of multi-copy forms should be promptly mailed to the Preventable Diseases Division, Hartford and to the local health department of the patient’s place of residence. The remaining copy should be filed in the department of origin in a secured location.

For further information on reportable diseases, consult the Reportable Disease Section of the YNHH Infection Control Manual on the Clinical Workstation.

18.1 List of Reportable Diseases – 2003

The Commissioner of the Department of Public Health (DPH) is required to declare an annual list of reportable diseases. Changes for 2003 are marked in bold with an asterisk (*). Each report (by mail or telephone) should minimally include: the full name and address of the person reporting and the attending physician, the disease being reported, and the full name, address, race/ethnicity, sex and occupation of the person affected. The reports should be sent in envelopes marked “CONFIDENTIAL.”.

Category 1: Reportable immediately by telephone on the day of recognition or strong suspicion of disease. On weekdays, reports are made to the DPH and local health departments. In the evening and on weekends to the DPH. A Confidential Disease Report (PD-23) or more disease-specific report form should be mailed to both the DPH and local health departments within 12 hours.

Chickenpox*
- Admission to hospital, any age
- Adults >18 years, any clinical setting
Cholera
Diphtheria
Measles
Meningococcal disease
Outbreaks:
  Foodborne outbreaks (involving ≥ 2 persons)
  Institutional outbreaks
  Unusual disease or illness (1)

Pertussis
Poliomyelitis
Rabies (human and animal)
Rubella (including congenital)
Severe Acute Respiratory Syndrome (3)
Staphylococcus aureus disease, reduced or resistant susceptibility to vancomycin (2)
Tuberculosis
Yellow Fever

Diseases which are possible indicators of bioterrorism:
  Anthrax
  Botulism
  Brucellosis
  Gram positive rod septicemia or meningitis, growth within 72 hours of inoculation in laboratory*
  Outbreaks of unusual disease or illness (1)
  Plague
  Q fever
  Ricin poisoning
  Smallpox
  Staphylococcal enterotoxin B pulmonary poisoning
  Tularemia
  Venezuelan equine encephalitis

Category 2: Reportable by mail within 12 hours of recognition or strong suspicion to both the DPH and local health departments.

  Acquired immunodeficiency syndrome (2,3)
  Babesiosis
  Campylobacteriosis
  Carbon monoxide poisoning (4)
  Chancroid
  Chlamydia (C. trachomatis) (all sites)
  Chickenpox
  Chickenpox-related death
  Creutzfeldt-Jacob disease (< 55 years of age)
  Cryptosporidiosis
  Cyclosporiasis
  Ehrlichiosis
  Encephalitis
  Escherichia Coli O157:H7 gastroenteritis
  Gonorrhea
  Group A streptococcal disease, invasive (5)
  Group B streptococcal disease, invasive (5)
  Haemophilus influenzae disease, invasive, all serotypes (5)
Hansen's disease (Leprosy)
Hemolytic-uremic syndrome
Hepatitis A, C, Delta, Non-A/non-B
Hepatitis B
  • Acute Infection
  • HBsAg positive pregnant woman
HIV exposure in infant born 1/1/2001 or later (2,6)
HIV infection in: (2)
  • persons with active tuberculosis disease
  • persons with latent tuberculosis infection (history or current tuberculin skin test \( \geq 5 \)mm by Mantoux technique)
  • child < 13 years of age
  • person \( \geq 13 \) years of age not included above (7)
Lead Toxicity (blood lead \( \geq 20 \) ug/dl
Legionellosis
Listeriosis
Lyme disease
Malaria
Mercury poisoning
Mumps
Neonatal herpes (<1 month of age)
Occupational asthma
Pneumococcal disease, invasive (5)
Reye syndrome
Rheumatic fever
Rocky Mountain spotted fever
Salmonellosis
Shiga toxin-related disease (gastroenteritis)
Shigellosis
Silicosis
Staphylococcus aureus methicillin-resistant disease, invasive, community acquired (5, 8)
Staphylococcus epidermidis disease, reduced or resistant susceptibility to vancomycin (2)
Syphilis
Tetanus
Toxoplasmosis
Trichinosis
Typhoid fever
Typhus
Vaccinia disease*
  • persons not vaccinated
  • persons vaccinated with the following manifestations; autoinoculation, generalized vaccinia, eczema vaccinatum, progressive vaccinia, or post-vaccination encephalitis
Vibrio parahaemolyticus infection
Vibrio vulnificus infection

1. Individual cases of “significant unusual illness” are also reportable.
2. Report only to the State.
3. CDC case definition.
4. Includes persons being treated in hyperbaric chambers for suspect CO poisoning.
5. Invasive disease: confirmed by isolation from blood, CSF, pericardial fluid, pleural fluid, peritoneal fluid, joint fluid, bone, and intraoperative swab from a normally sterile site or normally sterile tissue obtained during surgery.
6. “Exposure” includes infant born to known HIV-infected mother.
7. Persons with HIV infection and active tuberculosis or latent tuberculosis infection (history of tuberculin skin test + 5 mm induration by Mantoux technique), or children (<13 years of age) should be reported using full name and street address. Person +13 years of age, should be reported by full name and street address or by state-specified unique identifier (UI). To make the UI, the first 3 letters of the patient’s last name, date of birth, gender and race need to be reported.
8. Community-acquired: infection present on admission to hospital and person has no previous hospitalizations or regular contact with the health care setting.

18.1.1 How to report:

The PD-23 is the general disease reporting form and should be used if other specialized forms are not available. Specialized reporting forms from the following programs are available: HIV/AIDS Surveillance (860-509-7900), Sexually Transmitted Disease Program (860-509-7920), the Pulmonary Diseases Program (860-509-7722), or the Occupational Health Surveillance Program (860-509-7744). Forms may be obtained by writing the Department of Public Health, Epidemiology Program, 410 Capitol Ave., MS#11EPI, P.O. Box 340308, Hartford, CT 06134-0308 (860-509-7994); or by calling the individual program.

Telephone reports of Category 1 disease should be made to the local director of health for the town in which the patient resides and to the Epidemiology Program (860-509-7994). Tuberculosis cases should be directly reported to the Pulmonary Diseases Program (860-509-7722). For the name, address, or telephone number of the local Director of Health for a specific town contact the Office of Local Health Administration (860-509-7660). For public health emergencies, an epidemiologist can be reached nights and weekends through the DPH emergency number (860-509-8000).

18.2 Laboratory Reportable Significant Finding – 2003

The director of any clinical laboratory must report any laboratory evidence suggestive of reportable diseases. A standard form, known as the Laboratory Report of Significant Findings (OL-15C) is available for reporting these laboratory findings. These forms are available from the Connecticut Department of Public Health, Epidemiology Program, 410 Capitol Ave., MS#11EPI, P.O. Box 340308, Hartford, CT 06134-0308; telephone: (860 509-7994). The laboratory reports are not substitutes for physician reports; they are supplements to physician reports which allow verification of diagnosis. A special listing of diseases indicative of possible bioterrorism is highlighted at the end of this list. Changes for 2003 are noted in bold and with an asterisk (*).

- AIDS (report only to the State)
  - CD4+ T-lymphocyte counts <200 cells/uL: _____cells/uL
  - CD4+ count < 14% of total lymphocytes: _____%
- Babesiosis: □IFA IgM (titer) _____ IgG (titer): _____
- □Blood smear (1)* □PCR □Other: ______
- Campylobacteriosis (species) ____________________________
- Carboxyhemoglobin ≥9%: ____________% COHb
- Chancroid
- Chickenpox, acute: □IgM □Culture □PCR
  □DFA □Other: ______
- Chlamydia (C. trachomatis) (test type: ________)
- Creutzfeldt-Jakob disease, age < 55 years (biopsy)
Cryptosporidiosis (method of ID) ____________
Cryptosporiasis (method of ID) __________
Diphtheria (1)
Ehrlichiosis (2): ☐HGE ☐HME ☐Unspecified
☐IFA ☐Blood smear ☐PCR ☐Other: _________
Encephalitis:
California group virus (species) ________________
Eastern equine encephalitis virus
St Louis encephalitis virus
West Nile virus infection - human or animal
Other arbovirus (specify):
____________________________________
Enterococcal infection, vancomycin-resistant (2, 3)___________
*Escherichia coli O157* infection (1)
Food poisoning (2): __________
Giardiasis
Gonorrhea (test type: _________________)
Group A streptococcal disease, invasive (1,3)
Group B streptococcal disease, invasive (3)
*Haemophilus influenzae* disease, invasive, all serotypes (1,3)
Hansen's disease (Leprosy)
Hepatitis A ☐IgM anti-HAV
Hepatitis B ☐HBsAg ☐IgM anti-HBe
Hepatitis C (anti-HCV)
Hepatitis delta ☐HDAg, ☐IgM anti-HD
HIV Infection (report only to the State)
• HIV-1 infection in children < 13 years of age (4)
• HIV-1 infection in persons > 13 years of age (5)
Influenza: ☐A ☐B :
Lead Poisoning (blood lead ≥ 10μg/dL)
 ☐Finger Stick: _______ μg/dL ☐Venous: _________μg/dL
Legionellosis ☐Culture ☐DFA ☐Ag positive
☐Four-fold serologic change (titer): ________________
Listeriosis (1)
Lyme disease (check all that apply)
EIA ☐IgM_________IgG_________Polyvalent_________
W. blot IgM_________IgG_________Polyvalent_________
Malaria/blood parasites (1,2): ______________________________________
Measles (Rubeola) (titer): ___________________________________________
Meningococcal disease, invasive (1,3)
Mercury poisoning
☐urine ≥35 μg/g creatinine _________________μg/L
☐blood ≥1.5 μg/dL _________________μg/L
Mumps (titer): ________
Pertussis (titer): ______________
☐DFA Smear: ☐Positive ☐Negative
☐Culture: ☐Positive ☐Negative
Pneumococcal disease, invasive (1,3)
Oxacillin disk zone size: _______mm
MIC to penicillin: _______μg/mL
Poliomyelitis
Rabies
Rocky Mountain spotted fever
Rubella (titer): __________
Salmonellosis (1,2) (serogroup/serotype): __________
Shiga-toxin related disease (1)
Shigellosis (1,2) (serogroup/species): __________
Staphylococcus aureus disease, invasive (3) methicillin-resistant Date pt. Admitted ___/___/___
Staphylococcus epidermidis infection with MIC to vancomycin ≥4 ug/mL (1)
    MIC to vancomycin: __________ ug/mL
Syphilis RPR (titer): __________ FTA (titer): __________
    VDRL (titer): __________ MHA (titer): __________
Toxoplasmosis (7) IgM (titer) _____ IgG (titer) _____ PCR
Trichinosis
Tuberculosis (1)
    Specimen type: ________________________________
    AFB Smear: ☐ Positive ☐ Negative
    If positive: ☐ Rare ☐ Few ☐ Numerous
    Culture:
        ☐ Mycobacterium tuberculosis only
        ☐ Other mycobacterium (specify: M.__________________)
Typhus
Vibrio infection (6) (species) __________________________
Yersiniosis (species) __________________________

Bioterrorism: possible disease indicators
Anthrax (1)
Botulism
Brucellosis (1)
    Gram positive rod septicemia or meningitis, growth within 72 hours of inoculation in laboratory*
    Plague
    Q fever
    Ricin poisoning
    Smallpox
    Staphylococcal enterotoxin B pulmonary poisoning
    Tularemia
    Venezuelan equine encephalitis
    Viral hemorrhagic fever

1. Send isolate, culture or slide to the State Laboratory for confirmation. For Shiga-toxin, send broth culture from which positive Shiga-toxin test was made.
2. Specify etiologic agent.
3. Invasive disease: confirmed by isolation from blood, CSF, pericardial fluid, pleural fluid, peritoneal fluid, joint fluid, bone, and intra-operative swab from a normally sterile site or normally sterile tissue obtained during surgery.
4. Report any tests indicative of HIV infection including antibody, antigen, PCR-based and viral load tests with name and street address.
5. Report only confirmed HIV antibody tests or positive HIV antigen tests without names or street addresses. Viral load and PCR-based test results not reportable for this age group.
6. Send V. cholerae, V. parahaemolyticus, and V. vulnificus isolates to the State Laboratory for confirmation.
7. Report only IgG titers that are considered signofocant by the laboratory performing the test.
The other disease-specific report forms may be obtained by calling or writing the following programs at the same address:

1. The Epidemiology Unit/AIDS Section (860) 509-7900
2. The Sexually Transmitted Diseases Program (860) 509-7920
3. The Pulmonary Diseases Program (860) 509-7722
4. The Occupational Disease Program (860) 509-7744

Telephone reports of Category 1 diseases should be made to the local Department of Health of the town in which the patient resides and to the State Epidemiology Program (860) 509-7994.

Tuberculosis cases should be directly reported to the State Pulmonary Program (860) 509-7722.

For public health emergencies an epidemiologist can be reached nights and weekends through the department's emergency number (860) 509-8000.

**Laboratory Reportable Significant Findings**

The director of any clinical laboratory must report laboratory evidence suggestive of reportable diseases. A standard form, known as the Laboratory Report of Significant Findings (OL-15C), is available for reporting these laboratory findings. These forms are available from:

State of Connecticut Department of Public Health
Epidemiology Program
410 Capitol Avenue, MS#EPI, P.O. Box 340308
Hartford, CT 06134-0308
Telephone (860) 509-7994

**Instructions for Laboratories**

A. CD4+ T-Lymphocyte Counts <200/ul or CD4+ percent <14

The director of a laboratory that receives a primary specimen or sample for absolute CD4+ T-lymphocyte determination shall be responsible for reporting all results with an absolute CD4+ lymphocyte count less than 200/ul or a CD4+ count less than 14% of total lymphocytes within forty-eight (48) hours to the AIDS Section of the Department of Health Services. The report shall at a minimum include the name and address of the attending physician, hospital, clinic or other person from whom the specimen was obtained, (or if not available, the unique identifier), age or date of birth, sex, race/ethnicity of the person tested, date and result(s) of test(s) performed, laboratory (specimen) number, name and address of submitting laboratory.

The reporting laboratory may submit either a legible copy of the laboratory report itself or the standard OL-15C (Laboratory Report of Significant Findings) used to report other laboratory findings as long as the required data elements are present.

The report should be sent in an envelope marked "CONFIDENTIAL" to:

Connecticut Department of Health Services
AIDS Section Surveillance Unit
150 Washington Street
Hartford, CT 06106
These reports should not be sent to local Directors of Health.

B. Lead Poisoning

The director of a laboratory that receives a primary blood specimen for lead determination shall be responsible for reporting all results with a lead level $\geq 10$up/dl within forty-eight (48) hours to the Connecticut Department of Health Services and the local Director of Health of the town in which the affected person normally resides. The standard OL-15C shall be used for this purpose.

Instructions for AIDS Case Reporting

Effective January 1, 1993, the Centers for Disease Control implemented on expanded AIDS surveillance definition. This was published in the Morbidity and Mortality Weekly Report (MMWR) in December 1992. This expansion retains the 23 clinical conditions in the AIDS surveillance case definitions published in 1987 (Attachment 1). The expanded AIDS surveillance case definition includes the following four conditions:

a) HIV infection with an absolute CD4+ T-lymphocyte count less than 200 cells per microliter or a CD4+ count less than 14 percent of total lymphocytes.

b) HIV infection with active pulmonary tuberculosis.

c) HIV Infection with recurrent bacterial or unspecified pneumonia within a one-year period (2 or more episodes).

d) Invasive cervical carcinoma in an HIV-infected woman.

e) This expanded definition requires laboratory evidence for HIV infection in persons with less than 200 CD4+ T-lymphocytes or with one of the added clinical conditions.

The objectives of these changes are to simplify the classification of HIV infection and the AIDS case reporting process, to be consistent with standards of medical care for HIV-infected persons, to better categorize HIV-related morbidity, and to more accurately reflect the number of persons with HIV-related immunosuppression who are at highest risk for severe HIV-related morbidity and most in need of close medical follow-up. The addition of the three clinical conditions reflects their documented or potential importance in the HIV epidemic.

To report cases of AIDS, use the FHV Confidential Case Report (copy enclosed). Please be certain to complete the top section of both front and back with both patient and provider identifying information. As indicated on the form, identifier information will not be sent to CDC.

The form should be sent in an envelope marked "CONFIDENTIAL" to:

Connecticut Department of Health Services
AIDS Section/Surveillance Unit
150 Washington Street
Hartford, CT 06106

These reports should NOT be sent to local Directors of Health.

C. 1993 AIDS Surveillance Case Definition

List of Conditions Qualifying as AIDS in the Presence of HIV Infection
CD4+ T-lymphocyte count <200 cells per uL or a CD4+ percent <14 of total lymphocytes*
Candidiasis of bronchi, trachea, or lungs
Candidiasis, esophageal
Cervical cancer, invasive*
Coccidioidomycosis, disseminated or extrapulmonary
Cryptococcosis, extrapulmonary
Cryptosporidiosis, chronic intestinal (>1 month duration)
Cytomegalovirus disease (other than liver, spleen, or nodes)
Cytomegalovirus retinitis (with loss of vision)
HIV encephalopathy
Herpes simplex: chronic ulcer(s) (>1 month duration); or bronchitis, pneumomtis, or esophagitis
Histoplasmosis, disseminated or extrapulmonary
Isosporiasis, chronic intestinal (>1 month duration)
Kaposi's sarcoma
Lymphoma, Burkitt's (or equivalent term)
Lymphoma, primary in brain
Mycobacterium avium complex or M. Kansasi, disseminated or extrapulmonary
Mycobacterium tuberculosis, any site (pulmonary* or extrapulmonary)
Mycobacterium, other species of unidentified species, disseminated or extrapulmonary
Pneumocystis carinii pneumonia
Pneumonia, recurrent*
Progressive multifocal leukoencephalopathy
Salmonella septicemia, recurrent
Toxoplasmosis of brain
Wasting syndrome due to HIV

* = Added in 1993 expansion of the AIDS surveillance case definition

D. Reporting Requirements

1. In-patient Units

- Physicians, nurses, and other individuals who are aware of a known or suspected case of a reportable communicable disease should notify the Department of Epidemiology and Infection Control by telephone (8-4634) of all newly diagnosed cases. Be certain to include:

  1. The patient's full name, address, age, race/ethnicity, sex, occupation, unit location and attending physician.
  2. The name of the diagnosed or suspected disease.
  3. The date of disease onset.

The Department of Epidemiology and Infection Control will investigate the circumstances and file the Communicable Disease Report (PD-23), the Sexually Transmitted Disease Confidential Case Report (STD-23), or the Tuberculosis Case Report (TB-86) with the appropriate State and local health agencies.

- Newly diagnosed cases of Acquired Immunodeficiency Syndrome (AIDS) are reported to the State Department of Health Services by the Yale-New Haven Hospital AIDS Care Program or by Hospital Epidemiology and Infection Control. Cases should be reported to the AIDS Care Program (5-5303) so that patients can be entered into the program and the Acquired Immunodeficiency Syndrome (AIDS) Case Report can be filed.
2. Ambulatory Clinics

The completion and filing of all official reporting forms for ambulatory patients with newly diagnosed cases of a reportable disease are the responsibility of each individual department. Reporting may be done by the physician, the head nurse, or a designated representative. There are several standard forms for reporting. These include:

1. The Communicable Diseases Report form (PD-23)
2. The Sexually Transmitted Disease Confidential Case Report (STD-23)
3. The Tuberculosis Case Report (TB-86)

Communicable Diseases Report forms may be obtained from the:

State Department of Health Services
Epidemiology Section
150 Washington Street
Hartford, CT 06106
Telephone (860) 509-7994

The other disease-specific report forms may be obtained by calling or writing to the following programs at the same address:

1. The Epidemiology Unit/AIDS Section (860) 509-7900
2. The Sexually Transmitted Diseases Program (860) 509-7920
3. The Pulmonary Diseases Program (860) 509-7722
4. The Occupational Disease Program (860) 509-7744

Copies of disease reporting forms should be placed on file with the Yale-New Haven Hospital Department of Epidemiology and Infection Control in the Grace Building, third floor, Room 326. All forms should include the following information:

- The full name and address of Yale-New Haven Hospital, the name of the person filing the report, and the name of the attending physician.
- The name of the diagnosed or suspected disease.
- The date of onset, treatment if any.
- The patient's full name, address, age, race/ethnicity, sex and occupation.
- Any other pertinent information required by the reporting form.

Telephone reports of Category I diseases should be made to the local Department of Health of the town in which the patient resides and to the State Epidemiology Program (860)509-7994. Tuberculosis cases should be directly reported to the State Pulmonary Program (860)509-7722. For public health emergencies, a state epidemiologist can be reached nights and weekends by calling (860)509-8000.

Written reports are sent to the Connecticut Department of Health Services (Preventable Diseases Division) and to the patient's local director of health in envelopes marked, "CONFIDENTIAL."

4. Time Requirements for Reporting

Category I (diseases of high priority due to the need for timely public health action): Report immediately by telephone on the day of recognition or suspicion of disease. On weekdays reports
are made to the local and state health departments, and on weekends to the State Department of Health Services. A Communicable Disease Report form should be mailed to both the local and state health departments within 12 hours.

**Category II** (diseases of significant public health importance requiring public health action): Report by mail within 12 hours of the confirmed or suspected diagnosis to both local and state health departments.

**Considerations and Responsibilities**

The State of Connecticut requires the reporting of specific communicable infections, disease outbreaks, laboratory findings, and other conditions of public health significance (such as non-communicable diseases that are due to a common source exposure, e.g., lead poisoning). Reports are made to the Connecticut Department of Health Services and to the local Director of Health in the patient's place of residence. The attending or other treating physician is officially responsible for filing these reports, but at Yale-New Haven Hospital, the Department of Epidemiology and Infection Control assists in the coordination of these reporting efforts among inpatient units, the Emergency Department, Ambulatory Services, and the Clinics.

**Procedure for Follow-up of Hospital Employees, Family Members, and Other Contacts**

1. Upon notification of a suspected or confirmed reportable disease, the Department of Epidemiology and Infection Control will investigate the circumstances and, if necessary, develop a list of all susceptible hospital personnel, patient roommates, visitors, and others who were exposed to the communicable disease when appropriate universal precautions or respiratory isolation techniques were not in use.

2. After the initial investigation, the Department of Epidemiology and Infection Control will take the following actions:
   - Inform Personnel Health Services (PHS) so that the department can identify susceptible hospital personnel for follow-up.
   - Contact the physicians of any patients who were exposed to communicable diseases for follow-up care.
   - Notify the Health Department concerning other contacts not included in follow-up procedures described in Parts (a) and (b) above.

3. The attending physician of the patient diagnosed with or suspected of having a communicable disease is responsible for the follow-up and care of the family members and visitors who were exposed and susceptible to the disease.
SECTION 19  YNHH POLICY FOR HEALTHCARE WORKERS INFECTED WITH
BLOODBORNE PATHOGENS

Definition: For the purposes of this policy, Bloodborne Pathogens include:

Human Immunodeficiency Virus (HIV)
Hepatitis B Virus (HBV)
Hepatitis C Virus (HCV)

Background Statement: The transmission of Bloodborne Pathogens has been documented to occur between Patients and Healthcare Workers. For each of these agents, transmission from Patients to Healthcare Workers has far exceeded the risk of transmission from Healthcare Workers to Patients.

HIV - the transmission from Healthcare Workers to Patients is extremely rare and despite the documented follow up of tens of thousands of potential exposures, HIV transmission appears to have been documented from only two individuals to a total of 5 patients since the beginning of the HIV epidemic in the mid-1980's. While improvements in the therapy and prophylaxis for HIV have been reported recently, no vaccine or curative treatment is available.

Hepatitis B Virus is highly infectious, and transmission from Healthcare Workers to Patients has been well documented in multiple epidemics. The most significant risk factors for these transmissions have been oral surgical and deep surgical procedures with an increased potential for injury to the hands of the operating team and the presence of circulating HBV "e" antigen in the transmitting team member. However, HBV transmission recently has been documented with a genetic variant of the virus that does not portray "e" antigen characteristics on testing. Routine immunization of Healthcare Workers with HBV vaccine protects Healthcare Workers from infection with HBV and together with the routine immunization of children, should lead to decreasing numbers of infections, fewer chronic infections and reduced numbers of transmissions in the Healthcare Workers of the future. However, HBV immunization has not been completed in all Healthcare Workers and unprotected Workers and many individuals infected before the availability of HBV vaccine remain as a potential pool of chronic transmitting carriers to their patients, especially during high risk procedures. Prophylaxis with Hepatitis B immune globulin is available and successful if transmission is recognized within one week of exposure and successfully immunized individuals are highly protected from infection and disease.

Hepatitis C Virus transmission has been documented from Patients to Healthcare Workers and the reverse. This virus appears to be intermediate in transmissibility between Hepatitis B Virus and HIV. Currently, testing for HCV is difficult and no vaccine or treatment is available to prevent infection and disease. Disease is associated with high rates of chronic infection, liver failure and cancer.

National Guidelines, Recommendations, and Statutes

In July1991, the Centers for Disease Control and Prevention (CDC) developed and published the Virus Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B to Patients during Exposure-Prone Invasive Procedures. Hepatitis C Virus was not addressed since information on the agent was limited at that time. These guidelines recommended that Healthcare Workers at risk for infection with HIV, HBV or HCV through occupational exposure or lifestyle events, should periodically have themselves tested for evidence of infection with these viruses. This testing should be voluntary and confidential. If such testing is positive, it is recommended that the Healthcare Worker should confidentially share this information with an expert committee to assist the Healthcare Worker in determining the advisability of continuing or modifying their Healthcare practices. These discussions should be based on the information available in the scientific literature concerning the risk of transmission, the potential for prevention, and the progression of disease in the Healthcare Worker.
In October 1991, the Congress of the United States passed and the President signed legislation, as part of the Treasury, Postal Service and General Government Appropriations Act 1992, Public Law 102-141 (H.R. 2622), which mandated acceptance by each State of the provisions of the CDC Recommendations for HIV in the Healthcare Worker. The CDC was mandated to monitor each State's compliance with the provisions of the act. States not deemed by the CDC to be in compliance with the act would lose Federal Public Health funding. In January, 1992, the Commissioner of Public Health of the State of Connecticut published a program which provides a State level committee to assist individuals in the review of their HIV infections and which allows individual institutions within the State to develop committees to assist their Healthcare Workers in review of their ability to continue practice.

19.1 YNHH Policies for Healthcare Workers Infected with Bloodborne Pathogens:

1. Yale-New Haven Hospital has established an Expert Committee to assist the Bloodborne Pathogen Infected Healthcare Worker to review the appropriateness and safety of his/her continuing to provide health care and at what level. All Committee discussions are confidential. The Committee meets the National and State of Connecticut statutes and recommendations for the review of Bloodborne Pathogen infections in Healthcare Workers.

2. The presence of a positive test for a Bloodborne Pathogen (HIV, HBV, HCV) does not in and of itself prevent any Healthcare Worker at Yale-New Haven Hospital from continuing his/her current practice of clinical care.

3. All administrative rules for reviewing the practice of potentially disabled Healthcare Workers at Yale-New Haven Hospital apply for workers disabled by disease associated with infections with Bloodborne Pathogens.

4. Healthcare Workers exposed to Bloodborne Pathogens in the course of their health care practices or through lifestyle events should periodically and confidentially have themselves tested for evidence of infection with Bloodborne Pathogens.

5. Healthcare Workers who find they are positive on testing for infection with a Bloodborne Pathogen should report this fact to the Yale-New Haven Hospital Bloodborne Pathogen Review Committee through its Chairman, the Chief of Staff, or one of the Committee Members. Alternatively, Healthcare Workers may consult the State of Connecticut Review Panel for Evaluating Infected Healthcare Workers.

6. The Committee will, in confidence, review the clinical status of the Healthcare Worker with the individual and their personal physician. An off-site meeting location may be chosen. Current Committee members have expertise on Infectious Disease, HIV/AIDS, Infection Control, Occupational Health and Liability. Based on this confidential review, the Committee will advise the Healthcare Worker and their personal physician of their opinion on the appropriateness of their continuing to provide health care at Yale-New Haven Hospital and any recommendations for modification of the Healthcare Worker's practice(s). Final decisions on continuation or modification of practice will be governed under Yale-New Haven Hospital's policies and procedures for the evaluation of issues relating to disability and fitness to practice.

7. The Committee will ask the Healthcare Worker and his/her private physician to advise the Committee or its representative of any changes in disease status that might impact on the Healthcare Worker's ability to continue safe patient care practice at Yale-New Haven Hospital. All communications and records will be held in confidence to the extent permitted by law.

8. Questions concerning this Policy may be directed to the Chief of Staff of Yale-New Haven Hospital or other members of the Committee for Review of Bloodborne Pathogens in Healthcare Workers.*

19.2 Steps to take

When exposed to blood or body fluids, i.e.: needlestick, splash to mucous membranes or non-intact skin take the following steps:
• Remain calm
• Clean the wound with soap and water
• Notify your supervisor to initiate accident report
• Report immediately (within 1 hour) to Occupational Health Services (Monday - Friday 7:30am-4:00pm)
• If Occupational Health Services is closed, report immediately to the Emergency Department (within 1 hour)
• Bring accident report with you

Other Potentially Infectious Materials

ALL BODY FLUIDS ARE CONSIDERED POTENTIALLY INFECTIOUS EXCEPT FOR SWEAT

<table>
<thead>
<tr>
<th>Amniotic Fluid</th>
<th>Nasal Secretions</th>
<th>Pleural Fluid</th>
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<tr>
<td>Body Tissues</td>
<td>Non-Intact Skin</td>
<td>Saliva</td>
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<tr>
<td>Breast Milk</td>
<td>Pericardial Fluid</td>
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<tr>
<td>Cerebral Spinal Fluid</td>
<td>Peritoneal Fluid</td>
<td>Sputum</td>
<td>Vomitus</td>
</tr>
<tr>
<td>Feces</td>
<td>Perspiration</td>
<td>Synovial Fluid</td>
<td>Wound Drainage</td>
</tr>
</tbody>
</table>

19.3 Steps To Take When Exposed To Tuberculosis

If unprotected exposure (i.e. no mask, patient not on Airborne Precautions) to a patient with pulmonary (or laryngeal) tuberculosis occurs, the employee must report to Occupational Health Services as soon as possible after notifying his/her supervisor.

Evaluation for baseline tuberculin skin testing (i.e. PPD), if indicated, will be performed. A follow up PPD at 12 weeks post exposure will be required if the employee's baseline PPD was negative.

19.4 Steps To Take When Exposed To Chickenpox (Varicella zoster virus)

If an employee who has never had chickenpox is exposed to chickenpox, disseminated Herpes zoster or localized Herpes zoster in an immunocompromised patient, the employee should notify his/her supervisor and report to Occupational Health Services as soon as possible. An exposure determination will be made at that time and the employee may need to have a blood test drawn to determine immunity to the Varicella zoster virus.

If the employee has previously received the varicella vaccine, he/she still must report to OHS for evaluation.

If the employee that has a negative blood test for varicella antibody, he/she may have his/her work schedule adjusted.

19.5 Steps To Take When Exposed To Other Respiratory Pathogens

• B 19 (Human Parvovirus) Infection, Chronic
• Chickenpox, Disseminated Herpes Zoster (or localized in Immunocompromised Patient)
• Measles (Rubeola)
• Meningococcal Diseases (Meningitis, Pneumonia, Bacteremia)
• Mumps (Infectious Parotitis)
• Pertussis (Whooping Cough)
• Rubella (German Measles)

For all other infectious diseases not listed here, please call Quality Improvement Support Services at
(203) 688-4634 for further instruction.

Evaluation of Bloodborne Pathogen Exposures

"Six Important Steps"

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<td>2. Counseling</td>
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- Introduction
- Information Sheet for Post-Exposure Prophylaxis Against HIV - Increased Risk
- Information Sheet for Post-Exposure Prophylaxis Against HIV - Highest Risk
- Known Anti-HIV Effects in Pregnancy

Introduction

The CDC has published a recommendation calling for anti-retroviral prophylaxis following exposure to potentially HIV-infected blood or body fluids. Because it is preferable to begin such prophylaxis as soon as possible (i.e. within 1-2 hours) after exposure, healthcare workers will be instructed following such incidents to report to the YNHH Emergency Department when the episode occurs outside of Occupational Health Service or Yale Health Plan clinical operating hours (7:30 AM - 4:30 PM, Monday - Friday).

This set of documents has been prepared to instruct Emergency Department attending physicians in the initial evaluation of health care workers who may have had exposure to HIV-infected blood, and to provide guidelines for the dispensing of anti-retroviral prophylaxis. Because a healthcare worker also may have been exposed to hepatitis B or C at the same time, proper triage of these exposures will be addressed as well.

In short, six steps must be carried out:

1. When possible, determine whether the source patient is documented to be infected with HIV, hepatitis B, or hepatitis C; and if he or she has risk factors for these infections. Assess the severity of exposure, i.e., deep or shallow stick, hollow-bore needle vs. suture needle etc. Base decision whether to provide anti-retroviral prophylaxis according to the attached CDC table (Table 1).
2. Provide counseling to the exposed health care worker regarding risk of seroconversion, symptoms of disease, precautions to prevent secondary spread, and possible side effects of anti-viral prophylaxis.
3. Draw baseline blood tests for HIV antibody (by ELISA), Hepatitis B screen (HBSAg, HBSAb, HBCAb), and Hepatitis C antibody. Additional baseline blood tests should be drawn for those prescribed anti-retroviral therapy (see below).
4. When indicated, provide exposed health care worker with the first dose of anti-retroviral prophylaxis plus a 96-hour prescription to continue the medications.
5. When appropriate, provide Hepatitis B immune globulin.
6. Instruct the exposed health care worker to follow-up at the appropriate site (see below) the next business day.

The following outline provides supplementary information pertinent to each of the above six steps:

1. Risk characterization of source patient and the exposure event.

The CDC recommends that the prescription of anti-retroviral therapy be based on the risk level of the exposure as per the attached chart. "Recommend" implies to communicate that Anti-retroviral therapy
may have benefit and should be taken. "Offer" means anti-retroviral therapy should be discussed and offered, but that it is not necessarily recommended. "Not offer" means anti-retroviral therapy is not recommended because the exposure is not considered significant.

"Highest Risk" implies an increased volume of blood (e.g. injury with hollow needle) and blood containing a high titer of HIV (e.g. source with acute retroviral illness or end stage AIDS). "Increased Risk" implies either an exposure increased volume of blood or blood with high titer of HIV. "No increased Risk" applies when there is neither exposure to increased volume of blood nor blood with a high titer of HIV (e.g. solid suture needle injury from source with asymptomatic HIV infection).

Relevant history regarding the source patient's clinical status should be obtained from the exposed employee.

If the employee was exposed in the Emergency Department and the source patient is still present, efforts should be made to draw an HIV test, as well as Hepatitis B and C from that patient, assuming his or her serological status is not known.

If the employee was exposed on the Hospital ward, the charge nurse on that ward should be able to provide you with the serological status of the source patient if testing has already been carried out and is in the medical record. If the employee was exposed to a source patient whose serological status is not known, the employee should be instructed to request that the source patient's physician order HIV and Hepatitis B, C testing. The Occupational Health Service is available the next business day to assist with this process.

When serological information regarding the source patient is not known and cannot immediately be determined, (as will often be the case) the decision whether or not to prescribe anti-retroviral prophylaxis should be based on any known HIV risk factors in the source patient and the attached CDC table (Table 1).

When E.M.S. personnel are evaluated for an exposure, which occurred in the field, and no information is available on the source-patient, it should generally be assumed that the source-patient was high-risk.

2. Counseling the exposed worker

Risk of seroconversion:

The average risk of IRV infection due to all types of reported percutaneous exposures to HIV-infected blood is 0.3%. Risk is increased when exposure involves (1) a deep injury, (2) visible blood on the device causing the injury, (3) a device previously placed in the source patient's vein or artery (e.g., a needle used for phlebotomy), or (4) the source patient has end-stage AIDS. Risk may exceed 0.3% when a percutaneous exposure involves an increased volume of blood and/or a high titer of IRV in the blood. If post-exposure anti-retroviral therapy is not used, the risk of infection due to percutaneous exposure to HIV-infected blood with none of the above four risk factors may be 0.04%, or 1 in 2500. With three or four risk factors, the risk may exceed 5%. Risks after mucous membrane and skin exposure to IRV-infected blood is estimated to be 0.1% and less than 0.1% respectively.

Symptoms of disease:

Some individuals infected with IRV experience a viral syndrome within a few weeks of exposure. Fever is frequent and symptoms may include headache, nausea, decreased appetite, and sore throat. Enlarged lymph nodes may accompany the symptoms. The individual who experiences a viral syndrome within weeks of exposure should be counseled that similar clinical presentations are commonly due to other
agents, and that he or she should not panic. Still, all exposed persons should follow the precautions below to prevent possible secondary transmission.

**Precautions or prevent secondary spread:**

Individuals who have had a possibly significant exposure to blood or body fluids infected with IRV, Hepatitis B, or Hepatitis C, should use a condom when engaging in sexual intercourse and should refrain from open-mouth kissing until testing at 6 months post-exposure confirms lack of seroconversion. Sharing of shaving instruments should be avoided. Individuals also should refrain from any type of blood, tissue or organ donation. Breastfeeding or becoming pregnant should be avoided.

**Side effects of anti-viral prophylaxis:**

The three primary medications used for IRV prophylaxis at YNHH are zidovudine, lamivudine, and indinavir.

Information sheets regarding the side effects of the two-drug and three-drug post-exposure prophylactic medication regimens are attached. The appropriate information sheet should be provided to an exposed individual receiving prophylactic therapy.

Side effects of zidovudine include dose-related gastrointestinal symptoms, fatigue, and headache. Nausea may be decreased by taking zidovudine with food. Tylenol, aspirin, or ibuprofen may be taken for headache. Zidovudine can also cause anemia and low white blood cell counts.

Lamivudine may cause gastrointestinal symptoms and, rarely, pancreatitis. Headache, rash, and agitation/insomnia may also occur. Lamivudine may be taken with food.

Indinavir toxicity has included mild hyperbilirubinemia (10%) and kidney stones (2 - 3%); the latter can be limited by drinking at least 1.5 liters (48 oz.) of fluid per 24-hour period. The concurrent use of indinavir and certain other drugs, including some antihistamines, is contraindicated. Indinavir should be taken on an empty stomach (one hour before or two hours after a meal). Absorption of the drug is decreased if taken with food. If an individual taking the medication needs to eat at the time of an indinavir dose, a light low-fat snack should be suggested.

The exposed worker should be made aware that with the exception of zidovudine, there is little information on the toxicity of antiretroviral drugs in persons not infected with HIV. Zidovudine is usually well tolerated by healthcare workers as post-exposure prophylaxis.

**Use during pregnancy:**

Few data are available on the safety of zidovudine use during the first trimester of pregnancy. No data are available on other agents used prophylactically during pregnancy. You may refer to the attached chart of known effects for anti-HIV medications during pregnancy or to the product inserts. Antiretroviral medications should be used during pregnancy only if the potential benefits outweigh the risks.

**3. Baseline blood tests for the exposed worker**

Blood tests for HIV antibody (by ELISA), Hepatitis B screen (HBSAg, HBASb, HBCAb), and Hepatitis C antibody should be drawn in the Emergency Department. In the exposed worker who is prescribed anti-retroviral prophylaxis, a baseline complete blood count, serum electrolytes, and liver enzymes also should be drawn. For individuals exposed at Yale-New Haven Hospital (regardless of whether they are Hospital employees or University employees), use the tab slips and coded labels provided by the YNHH
Occupational Health Service. For E.M.S. personnel, use the lab slips contained in the box marked "E.M.S. lab slips for bloodborne pathogen exposures".

Clinical follow-up for YNHH employees, hospital-sponsored trainees, and community (non-University employed) attending physicians will be carried out at the YNHH Occupational Health Service. Clinical follow-up for Yale students and other students, as well as University-employed faculty will be carried out at the Yale Health Plan, but the YNHH Occupational Health Service can coordinate this for you if the log sheet is filled out.

Very important. For each individual evaluated in the Emergency Department following a potential bloodborne pathogen exposure, fill out the log sheet provided by the Yale-New Haven Hospital Occupational Health Service. This will help assure that the exposed individual receives appropriate clinical follow-up. Remember to use the lab slips provided by the Yale-New Haven Hospital Occupational Health Service. Leave a voice mail at 8-2462 indicating the name and department of the exposed individual.

4. 96-hour retroviral prophylaxis prescription

Refer to the attached CDC table (Table 1) for guidance in prescribing the appropriate prophylactic regimen. If the decision is made to treat with anti-retroviral therapy, one of two 96-hour prophylactic regimens should be prescribed by the Emergency Department attending physician. Instruct the exposed individual to have the 96-hour prescription filled at the YNHH in-patient pharmacy window located in the East Pavilion basement across from the “A” Elevators.

The standard 96-hour prescription should consist of a 96-hour supply of zidovudine 200 mg tid (#12) and a 96-hour supply of lamivudine 150 mg bid (#98).

Indinavir (800 mg q 8 hours, (#12) should be added to this regimen only for the highest risk percutaneous exposures due to its potential toxicity.

Prescription prophylactic medication for persons exposed at Yale-New Haven Hospital beyond 96-hours will be carried out either at the YNHH Occupational Health Service of the Yale Health Plan.

Attached to this protocol are information sheets on medication side effects, which may be Xeroxed and given to the exposed individual.

The exposed individual should be advised to return to the Emergency Department if medication-related side effects occur before either the YNHH Occupational Health Service or the Yale Health Plan has opened. (This is likely to transpire only if the exposed individual begins the medication over a weekend.) In most cases, zidovudine will be the cause of side effects. If side effects are judged to be due to zidovudine, it should be replaced in the regimen with stavudine 40 mg bid (decrease for body weight < 13.0 lbs). Consult the infectious disease fellow on call for guidance.

5. Hepatitis B immune globulin

The individual exposed to known Hepatitis BsAg positive blood should receive hepatitis B immune globulin if he/she has not had the hepatitis B vaccine series or is a known vaccine non-responder.

Individuals who have not had the hepatitis B vaccine series and are exposed to blood at high risk of hepatitis B Sag positively should be offered hepatitis B immune globulin. Hepatitis B immune globulin generally should be administered within 72 hours of the exposure event, enough time for baseline testing of the source patient to be completed if the exposure event occurs on a weekend. (Serum samples for
HIV and hepatitis B, C sent to the lab over a weekend will be run by 1:00 PM on Monday). Hence, for exposures where the source patient’s hepatitis serology is not known, administration of hepatitis B vaccine boosting or hepatitis B immune globulin can be administered as appropriate by the clinic carrying out the exposed individual’s follow-up treatment.

To expedite source-patient testing, the exposed individual should inform the source patient’s physician of the exposure and request that the patient’s physician order HIV, hepatitis B screen, and Hepatitis C testing.

6. Clinical follow-up and Billing

Billing for individuals exposed at Yale-New Haven Hospital is carried out through the YNHH Occupational Health Service. Billing for E.M.S. Occupational cannot be carried out through the YNHH Personnel Health Service, because E.M.S. personnel have their own worker’s compensation insurance policies. Those policies must be billed directly by the Emergency Department.

E.M.S. personnel should be informed to report to their provider of occupational medicine services the next business day. Most of these services are provided through the occupational medicine clinic of the Hospital of St. Raphael. If the E.M.S. employee does not know who provides his or her occupational health services, consult the list of occupational health providers for E.M.S. personnel.

Information Sheet for Post-Exposure Prophylaxis Against HIV – Increased Risk

The drugs in this packet are offered to you because you have had an exposure to blood or other material, which may contain Human Immunodeficiency Virus (HIV), the virus, which causes AIDS. It is believed that the risk of your becoming infected with HIV as a result of this exposure, which is already less than 1%, can be reduced even more by taking these drugs. The following guidelines will help you take these drugs in the most effective manner and to recognize side effects that may occur. The drugs which you're being given are zidovudine (AZT) and lamivudine (3TC).

1. Begin taking these drugs immediately. If possible the first dose should be taken within one hour of the exposure. If there has been a delay, you may still benefit from this medication and should begin as soon as possible.

2. Continue taking both drugs for four weeks. This initial supply is enough to last until you can receive a regular prescription from your occupational health provider.

3. Take these drugs according to the following schedule:

Zidovudine:
Two capsules (100 mg each) three times a day (a total of six capsules a day). Side effects may be decreased if you take AZT with food.

Lamivudine:
Take one capsule (150 mg) twice a day. May be taken with food or with other medication.

4. The following is a list of most common side effects. If you experience any of these, contact your doctor or occupational health provider. In some cases you can keep taking the drugs. If more serious side effects occur, another regimen may be substituted.

Zidovudine: Most people have no side effects, but nausea, headache and malaise are fairly common, especially during the first week or two. Nausea may be decreased by taking zidovudine with food. You may take Tylenol or aspirin or ibuprofen for headache. These symptoms usually subside with time.
Zidovudine can also cause anemia and low white blood cell counts - mild. You should have a blood test done to check on these after about two weeks of taking zidovudine.

Lamivudine:
Side effects are rare with lamivudine but have included headache, rash, and agitation/insomnia.

**Information Sheet for Post-Exposure Prophylaxis Against HIV - Highest Risk**

*The drugs in this packet are recommended for you because you have had an exposure to blood or other material, which may contain Human Immunodeficiency Virus (HIV), the virus, which causes AIDS. It is believed that the risk of your becoming infected with HIV as a result of this exposure, which is already less than 1%, can be reduced even more by taking these drugs. The following guidelines will help you to take these drugs in the most effective manner and to recognize side effects that may occur. The drugs, which you are being given, are zidovudine (AZT), lamivudine (3 TC) and indinavir (Crixivan).*

1. Begin taking these drugs immediately. If possible the first dose should be taken within one hour of the exposure. If there has been a delay, you may still benefit from this medication and should begin as soon as possible.
2. Continue taking all three drugs for four weeks. This initial supply is enough to last until you can, receive a regular prescription from your occupational health provider.
3. Take these drugs according to the following schedule.

**Zidovudine:**

Two capsules (100 mg each) three times a day (a total of six capsules a day). Side effects may be decreased if you take AZT with food.

**Lamivudine:**

Take one capsule (150 mg) twice a day. May be taken with food or with other medication.

**Indinavir:**

Take 2 capsules (800 mg) every eight hours on an empty stomach (one hour before or two hours after a meal). Try to arrange a schedule that is as close to every eight hours as possible without having to wake up to take a dose. Absorption of the drug is decreased if taken with food, but if you need to eat something, a light low-fat snack is OK. Do the best you can, but don't skip doses and don't skip meals.

4. The following is a list of most common side effects. If you experience any of these, contact your doctor or occupational health provider. In some cases you can keep taking the drugs. If more serious side effects occur, another regimen may be substituted.

**Zidovudine:**

Most people have no side effects, but nausea, headache and malaise are fairly common, especially during the first week or two. Nausea may be decreased by taking zidovudine with food. You may take Tylenol or aspirin or ibuprofen for headache. These symptoms usually subside with time. Zidovudine can also cause anemia and low white blood cell counts - mild. You should have a blood test done to check on these after about two weeks of taking zidovudine.

**Lamivudine:**
Side effects are rare with lamivudine, both have included headache, rash, and agitation/insomnia.

Indinavir:

Indinavir may cause kidney stones. To decrease the chances of this, you should drink at least two quarts of water a day. The symptoms of kidney stones are pain - usually in the lower back, flank, or lower abdomen - and sometimes blood in the urine. If you develop these symptoms, stop taking Indinavir and see your doctor. Indinavir can also cause jaundice (yellow color in the eyes, skin, urine). When this happens it is usually very mild. A blood test should be done after about two weeks to look for increases in bilirubin.
SECTION 20  MANAGEMENT OF PREGNANT PERSONNEL

Under the Standard Precautions system, factors that are generally associated with the transmission of communicable diseases from patients to personnel are:

- Delays in the diagnosis and isolation of infectious diseases that are transmitted in whole or in part by the airborne route.
- Failure to use appropriate barrier protection (gloves, gowns, masks, etc.) for procedures involving contact with blood and body substances.
- Lack of immunity to a specific infectious agent.

Pregnant health care workers are not known to be at greater risk of acquiring infectious diseases as a consequence of caring for patients than other personnel who are not pregnant. However, certain infections acquired during pregnancy can pose a significant risk to the fetus due to perinatal transmission of infectious agents. Therefore, pregnant health care workers, like other health care workers, should be:

- Familiar with, and strictly adhere to, Standard Precautions and Contact, Airborne/ Droplet isolation techniques. (Frequent handwashing at prescribed intervals and the appropriate use of barrier protection are effective in limiting the transmission of infections from the patient to personnel.). Even if the pregnant health care worker is immune to a patient's specifically diagnosed disease, the use of standard precautions and Airborne/Droplet Precautions will protect the employee from infections which may not have been diagnosed and provides for consistency in work practices.
- Aware of their own history of immunity to specific communicable diseases. Females of childbearing potential should take advantage of vaccines which will limit their susceptibility to specific infections. Pregnant HCW's who are immune to infections associated with congenital or perinatal transmission can effectively prevent the spread of disease to the unborn baby.

The following table lists the general guidelines for the pregnant employee and others in caring for patients with communicable infections that are associated with congenital or perinatal transmission.

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<tr>
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<th>INTERVENTION FOR PREGNANT HEALTH CARE WORKERS</th>
<th>COMMENTS</th>
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</thead>
<tbody>
<tr>
<td>Acquired Immune Deficiency Syndrome (AIDS)</td>
<td>Standard Precautions - Handwashing. Care in handling contaminated needles, sharps, and other used items. Employ barrier protection as needed. <strong>No work restriction is necessary.</strong></td>
<td>Transmission occurs via sexual, parenteral, and mucous membrane contact with infected blood and body substances. If the mother is HIV positive, the fetus may also become infected as a result of perinatal transmission</td>
</tr>
<tr>
<td>Cytornegalovirus (CMV)</td>
<td>Standard Precautions - Handwashing. Use barrier protection as needed. <strong>No work restriction is necessary.</strong></td>
<td>Transmission occurs via sexual, parenteral, and direct contact with infected body substances (urine). Risk of perinatal transmission is greatest with primary maternal infection. Significant congenital abnormalities may occur. Most CMV infections are transmitted to susceptible individuals in the community and not in the hospital setting. Children who are susceptible to CMV are often exposed in day care settings</td>
</tr>
<tr>
<td>INFECTIOUS DISEASE PROCESS</td>
<td>INTERVENTION FOR PREGNANT HEALTH CARE WORKERS</td>
<td>COMMENTS</td>
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<tr>
<td>Rubella (German Measles)</td>
<td>Healthcare workers should not care for patients with rubella unless the employees' immunity is proven by serology or documentation of vaccination. Susceptible employees are required to receive the rubella vaccine prior to patient contact. No vaccine if pregnant or planning pregnancy within 3 months.</td>
<td>Transmission occurs by droplet spread and contact with infected body substances (nasopharyngeal secretions, blood, urine). Risk of congenital transmission is greatest during the first trimester. Significant congenital abnormalities may occur.</td>
</tr>
<tr>
<td>Measles (Rubeola)</td>
<td>Healthcare workers should not care for patients with measles unless the employee's immunity is proven by serology or documentation of vaccination. Susceptible employees are required to receive 2 doses of the measles vaccine prior to patient contact. Measles vaccine should not be given to healthcare workers when they are pregnant.</td>
<td>Transmission occurs via the airborne route. There is a low risk of perinatal transmission, that may result in prematurity, spontaneous abortion, or congenital abnormalities.</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>All employees who are exposed or who may be potentially exposed to blood and body substances should receive the Hepatitis B vaccine</td>
<td>Transmission occurs via sexual and parenteral contact. Moderate risk of perinatal transmission if the mother has acute hepatitis and is HbsAg positive. High risk of perinatal transmission from an asymptomatic mother to the fetus if the mother is HbsAg positive (a chronic carrier of HbsAg).</td>
</tr>
<tr>
<td>Herpes Simplex</td>
<td>Handwashing - Standard Precautions. Use barrier protection as needed. <strong>No work restriction is necessary</strong></td>
<td>Transmission occurs via contact with infected skin lesions and body fluids (saliva). Perinatal transmission may occur in the antepartum, intrapartum, or postpartum periods. May result in spontaneous abortion, stillbirth, congenital abnormalities or severe disease.</td>
</tr>
<tr>
<td>Syphilis</td>
<td>Standard Precautions - Handwashings. Care in handling contaminated needles, sharps, and other used items. <strong>No work restriction is necessary</strong></td>
<td>Transmission occurs via sexual and parenteral contact. Perinatal transmission may result in spontaneous abortion, stillbirth, or systemic infection of the newborn if the mother is not treated.</td>
</tr>
<tr>
<td>Toxoplasmosis (Toxoplasma gondii)</td>
<td><strong>No work restriction is necessary</strong></td>
<td>Transmission does not occur person-to-person, except in-utero. The disease is acquired from eating raw/undercooked infected meats or by direct contact with contaminated feline feces. Perinatal transmission may result in spontaneous abortion, stillbirth, or severe congenital disease.</td>
</tr>
<tr>
<td>INFECTIOUS DISEASE PROCESS</td>
<td>INTERVENTION FOR PREGNANT HEALTH CARE WORKERS</td>
<td>COMMENTS</td>
</tr>
<tr>
<td>---------------------------</td>
<td>---------------------------------------------</td>
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</tr>
<tr>
<td>Tuberculosis</td>
<td>Standard Precautions – Handwashing Airborne Precautions. Proper use of personal respiratory protection (N95/HEPA mask) is required. <strong>No work restriction is necessary</strong></td>
<td>Transmission occurs via the airborne route. Perinatal transmission is rare but may result in an increased risk of spontaneous abortion or stillbirth. Active tuberculosis at the time of delivery can result in the death of the newborn</td>
</tr>
<tr>
<td>Varicella (chickenpox)</td>
<td>Health care workers who have not had chickenpox (or who are unsure) should not care for patients with chickenpox, disseminated Herpes zoster, or localized Herpes zoster in immunocompromised patients. A susceptible, pregnant health care worker who is exposed to varicella should inform her physician. Varicella immunoglobulin (VZIG) may be given at term to help prevent disease in the newborn. Susceptible health care workers should receive the Varicella vaccine. Pregnant workers cannot receive the Varicella vaccine</td>
<td>Transmission occurs via the airborne and contact routes. Maternal infection results in a low risk of congenital abnormalities, prematurity, or spontaneous abortion. The risk of neonatal chickenpox is high when the mother manifests the rash within seven days prior to delivery</td>
</tr>
<tr>
<td>Poliovirus</td>
<td>Susceptible employees are urged to receive the polio vaccine. (Past history of immunization is evidence of immunity). Pregnant health care workers should not receive the oral polio vaccine but may be given the injectable polio vaccine instead</td>
<td>Transmission occurs via the fecal-oral route and by droplet spread. Low risk of perinatal transmission: in early pregnancy may result in prematurity, low birth weight, stillbirth, or spontaneous abortion; at the time of delivery may result in severe neonatal infection</td>
</tr>
<tr>
<td>Coxsackievirus</td>
<td>Standard Precautions - Handwashing <strong>No work restriction is necessary</strong></td>
<td>Transmission occurs via the fecal-oral route and droplet spread. Low risk of perinatal transmission: a few strains are associated with prematurity, congenital abnormalities, and spontaneous abortion. Maternal infection at the time of delivery may result in severe neonatal infection</td>
</tr>
<tr>
<td>Parvovirus B 19</td>
<td>Standard Precautions - Handwashing. Use barrier protection as needed. <strong>No work restriction is necessary</strong>. (Droplet Precautions in immunosuppressed patients with chronic infection and sickle cell patients with red cell aplasia/aplastic crisis.)</td>
<td>Generally, B 19 infection during pregnancy has not been found to cause adverse effects, but in some cases the infection has been associated with fetal death. NOTE: Immunocompetent patients with Erythema Infectiosum (Fifth Disease) are past the period of infection and do not pose a risk of further transmission. However, immunosuppressed patients with chronic infection or sickle cell patients with asplastic crisis require Droplet Precautions as noted in the Disease List</td>
</tr>
</tbody>
</table>
SECTION 21  YNHH NOPM MEDICATION ADMINISTRATION, STORAGE, AND HANDLING

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• Medication Administration, Storage, and Handling

• Effective: 9/02
• Original: 6/87
• Reviewed: 1/01; 9/02
• Revised: 9/02

Purpose: This policy provides guidelines for the administration of medications by nursing personnel. See the Master Index for Volume II of this manual for additional information, which may be contained in clinical standards (e.g. administration of specific drugs and administration via specific routes or methods).

Contents:
I. Medication Prescriptions
   A. Written Medication Prescriptions
   B. Verbal Medication Prescriptions
   C. Nursing Responsibilities
   D. Prescription Cancellation, Renewal, and "Holding"
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    A. Administration of Medication of Registered Nurses (RN and Licensed Practical Nurses (LPN)
    B. Safety Precautions Observed During Medication Administration
III. Medication Documentation
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    B. Mobile Drug Storage Supplies
    C. General Guidelines: Storage and Handling
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X. Analgesia and the Pain Service
    A. Patient Controlled Analgesia (PCA)
    B. Single Dose Epidural or Spinal Injection
XI. Investigational Drugs
XII. Antineoplastic (Chemotherapeutic) Agents
XIII. Vaccines
I. Medication Prescriptions

A. Written Medication Prescriptions:
   1. may be written/entered by authorized physicians, dentists, physician assistants, nurse midwives, and advanced practice registered nurses with prescriptive authority (i.e. APRN license);
   2. include the patient's name, full name of drug, dose form, strength, route of administration, frequency/rate of administration, and other necessary administration parameters;
   3. conclude with the signature of the prescriber; and
   4. must not be presigned (i.e. blank prescriptions).

B. Verbal Medication Prescriptions
   1. As warranted in an urgent or emergency situation, a verbal medication prescription may be dictated by an authorized physician, dentist, nurse midwife, physician's assistant, or advanced practice registered nurse (APRN) to a registered nurse (RN), pharmacist, dietician, or respiratory therapist.
   2. Each verbal prescription is written/entered as soon as possible by the individual who received it. Medication orders and Diagnostic Imaging orders for contrast media or IV agents (along with diet, DNR, restraint, intravenous solution, physical therapy/occupational therapy, and AMA orders) must be signed by the prescriber within 24 hours.

C. Nursing Responsibilities
   The nurse:
   1. evaluates the appropriateness of the medication prescription and discusses questions with the prescriber.
   2. verifies that the patient has no documented allergy to the prescribed medication;
   3. assesses each patient request for a PRN medication and acts accordingly;
   4. knows the following before administering a medication: usual dosage range, route(s) of administration, actions, desired effects, risks, side effects and adverse drug reactions;
      a. physical and pharmacological compatibilities;
      b. how to use and access necessary equipment; and
      c. nursing interventions to be taken if side effects or adverse drug reactions occur.
   5. consults the Guidelines for the Administration of Parenteral Medications, YNHH Formulary Catalog, pharmaceutical references, and/or the Drug Information Service as necessary;
   6. ensures accurate transcription of medication prescriptions as necessary (not necessary with CCSS);
   7. ensures medication prescriptions are forwarded to Pharmacy (not necessary with CCSS); and
   8. documents all medications administered to the patient.

D. Prescription Cancellation, Renewal, and "Holding"
   1. A current set of medication prescriptions is written, activated, or restarted when a patient is admitted or readmitted to a patient care area from the Emergency Department, operating room, post anesthesia care unit (PACU), or intensive care unit or when a patient is transferred from one service to another. Prescriptions entered via CCSS are reviewed for accuracy. Refer to CCSS manual for specific steps to take regarding prescriptions and transfers.
   2. Unless renewed, prescriptions are automatically canceled as follows: (Note: A list of DEA scheduled drugs is in the YNHH Formulary Catalog.)
      a. schedule II, III, IV or V controlled substance prescriptions - 7 days after the original prescription is written/entered;
      b. prophylactic antibiotic prescriptions - 24 hours after the original prescription is written/entered, unless otherwise specified on the or antibiotic medication schedule (CCSS);
c. *empiric Vancomycin Therapy* 72 hours (continuation beyond 72 hours must meet one of the culture documented/treatment vancomycin criteria outlined in CCSS;  
d. *other inpatient medication prescriptions* - after 30 days if no stop date is noted on the original prescription.

3. When a patient goes home on pass, the nurse places prescribed medications on hold and documents that the patient is "out on pass." The nurse restarts the held medications when the patient returns.

II. Medication Administration

A. Administration of Medications by Registered Nurses (RN) and Licensed Practical Nurses (LPN)  
1. RNs may not administer medications by the following routes:  
   a. epidural (single dose[s]);  
   b. intrapleural;  
   c. intra-articular; or  
   d. intrathecal.  
2. LPNs may administer medications by the following routes:  
   a. intradermal;  
   b. intramuscular;  
   c. intraperitoneal;  
   d. intravenous;  
   e. oral;  
   f. rectal;  
   g. subcutaneous; and  
   h. topical.  
4. Routine exceptions to the Guidelines for the Administration of Parenteral Medications:  
   a. Any patient care area/nursing department whose patient population warrants routine deviation from the Guidelines or policy should incorporate the practice change into its structure standards with the approval of the Administrative Director who consults, as appropriate, the Department of Pharmacy Services, the Medical Director/Chief of Service for the patient care area, and the Pharmacy and Therapeutics Committee. The Patient Service Manager (or Administrative Director if the entire department is affected) also notifies the chair of the Clinical Practice Council of the practice change after approval is obtained.  
   b. IN AN URGENT OR EMERGENCY SITUATION, AN RN MAY PUSH ANY APPROPRIATE INTRAVENOUS MEDICATION PRESCRIBED BY THE PHYSICIAN.

B. Safety Precautions Observed During Medication Administration  
1. The nurse safely administers prescribed medications by checking the following before administering each drug:  
   a. medication prescription (including appropriateness of drug and dose);  
   b. label on the medication;  
   c. patient's identification wrist band or patient’s identification label;
d. patient's medication allergy history via:
   1) allergy bracelet,
   2) medical record; and

  e. pertinent laboratory values or vital signs.

2. Most scheduled medications are given within the half-hour before or after their scheduled administration time. However, depending on dosing frequency and half-life, some medications require stricter adherence to scheduled administration times (e.g. regular-release procainamide); and greater latitude may be appropriate with other medications (e.g. once-a-day digoxin).

3. The nurse ensures that oral medications are taken by the patient as prescribed.

4. The nurse monitors the patient's response to all medications.

5. Cancer chemotherapy orders require that:
   a. Two cancer chemotherapy registered nurses:
      1. verify and sign each cancer chemotherapy order,
      2. schedule all chemotherapeutic agents and related medications and sign that schedule is accurate.

   b. Two cancer chemotherapy certified registered nurses or a chemotherapy certified registered nurse and a pharmacist check each prepared bag or syringe of cancer chemotherapy with the patient's order and check the name and unit number on the prepared bag/syringe with the name and unit number on the patient's wrist band/ID label immediately prior to administration.

   c. The cancer chemotherapy certified registered nurse, who is administering the cancer chemotherapy, and a second employee check the name and unit number on the prepared bag/syringe with the name and unit number on the patient's wrist band/ID label immediately prior to administration.

   (NOTE: In any location within this policy there is reference to A cancer chemotherapy registered nurse, it is defined as a registered nurse who has successfully completed either the YNHH Cancer Chemotherapy Course or the Oncology Nursing Society Cancer Chemotherapy/Biotherapy Course AND the YNHH competency based clinical practicum.)

III. Medication Documentation

A. The nurse documents (electronically or manually as appropriate):  
   1. the drug name, dose, dosage form, date, time and route of administration (and site of administration as prompted by CCSS), and signature with title for all medications administered by the nurse or self-administered by the patient;

2. for continuous medication infusions (e.g. intravenous, epidural), the time the infusion is initiated and the initial dose "hung"; the cumulative amount (usually in milligrams) that the patient receives every eight hours (or less if the infusion is discontinued); and the time at which the infusion is stopped;

3. any short term or long term adverse drug effect of medication on the patient's physical or mental status and action taken;

4. the effect of PRN medications on the patient's physical or mental status; and

5. the rationale for not administering a scheduled medication.

B. Medications are documented as soon as possible, but no later than one hour after administration.

IV. Medication Storage and Handling

A. Medication Rooms
   1. Medication Unit Dose Cart/Room doors are locked when not in use. Approval to keep medication room doors closed, but unlocked in an ICU may be granted by the Administrative Director, as long as access is readily restricted to authorized personnel.
2. Medication Unit Dose Cart/Room doors are locked when not in use. Approval to keep medication room doors closed, but unlocked in an ICU may be granted by the Administrative Director, as long as access is readily restricted to authorized personnel.

3. Medications, syringes, and needles are kept in locked storage areas; work surfaces are kept clear except when medications are being prepared for administration.

**B. Mobile drug storage supplies (tackle boxes, treatment trays, etc.) are kept in secure areas.**

**C. General Storage and Handling Guidelines:**

1. Multidose medication vials must be inspected prior to each use for particulate matter and discoloration. These vials will be discarded monthly by the pharmacy during the unit’s inspection. These vials do not require dating upon opening.

2. Single-dose vials of medications are used once, for one patient only and discard.

3. The Department of Pharmacy inspects each patient care unit monthly. Removing expired medications and discarding all multiple dose medication containers are a component of this inspection.

4. Pharmacy technicians will remove open single dose, injectable medication containers on a daily basis. Technicians will check the refrigerators in the medication room and the supply cabinets while on the patient care units during refilling of Pyxis machines and IV syringes.

5. Medications are administered only to the patient for whom they were sent.

6. Medications from the patient's personal supply may be administered by the nurse only after they have been relabeled by Pharmacy and prescribed by the physician.

7. Drug samples used in the Ambulatory setting are stored in a locked area.

**V. Self-Administration of Medications** (see NO & PM Vol. II CMP: Medication, Self Administration of) Upon the order of a physician, patients may self-administer specified medications under the supervision of a nurse. Self-Administration of Medications are labeled and dispensed by the Department of Pharmacy and are stored in a secured location. Such medications are packaged in child resistant containers unless the patient requests otherwise. Patients must request their medications from the nurse who facilitates and observes administration by the patient. All observations of doses self-administered are documented in CCSS.

**VI. Medication Dispensation to Ambulatory Services Patients**

A. Medications dispensed to outpatients are prescribed by authorized personnel and dispensed in containers labeled with the full name of the patient, prescriber's full name, YNHH's name and address, the date of dispensing, name and strength of the medication, instructions for use, and any cautionary statements which may be required by law. Such medications are packaged in child resistant containers approved by the Federal Consumer Products Safety Commission.

B. Samples of prescription and over-the-counter drugs may be distributed by Pharmacy to outpatient clinic areas only, and criteria regarding ordering, distributing, labeling, and storage which are defined in the Yale-New Haven Hospital Formulary Catalog must be fulfilled.

**VII. Medication Use Variance (MUV)**

A. A medication use variance is the occurrence of any error or misadventure in prescribing, transcribing, dispensing, administering or monitoring of drugs. Examples include (but are not limited to):

1. wrong drug;
2. wrong dose;
3. extra dose;
4. wrong patient;
5. dose omitted (except as noted in IV.A.5)
6. wrong rate;
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7. wrong time;
8. wrong route of administration;
9. wrong formulation (e.g., sustained release versus immediate release);
10. drug administered in the presence of a documented allergy to drug.

B. The term “Medication Use Variance” includes circumstances or events that have the capacity to cause error and those events that are detected before they reach the patient. Each medication use variance is rated according to the following severity rating scale: Circumstances or events that have the capacity to cause a medication use variance.

1. Variance occurred but was detected before it reached the patient.
2. Variance occurred, reached the patient, but caused no harm or is unlikely to cause harm.
3. Variance will require additional patient monitoring but is unlikely to result in a change in vital signs or patient harm.
4. Variance requires intervention and caused or is likely to cause temporary patient harm.
5. Variance caused or is likely to cause temporary patient harm and prolonged hospitalization.
6. Variance caused or is likely to cause permanent patient harm.
7. Variance resulted in a near death event (e.g., anaphylaxis, cardiac arrest).
8. Variance resulted in or contributed to patient death.

C. All events that reach the patient, that is severity rating 2 or higher, must be reported to the patient’s physician and appropriate action taken to ensure patient well-being.

D. The Medication Use Variance Report (F.877), located on each unit’s Pyxis Medstation, is used to document all medication use variances. Completed reports are forwarded to the Department of Pharmacy Services, Drug Information Service, for analysis and follow-up. Reports can be anonymous, though reporter identification is encouraged to enhance follow-up.

VIII. Adverse Drug Reactions (ADR; Drug Related Morbidity)
Adverse drug reactions to medications are immediately reported to the physician. The nurse documents the reaction including signs and symptoms noted, actions taken, and outcome/plan in the medical record. An alert is sent to the Department of Pharmacy Services via the DRM Infogram in CCSS. A pharmacist will then investigate and complete the Adverse Drug Reaction Reporting Form (F2573). A report may be forwarded to the FDA based on its severity, rarity, or for newly marketed drugs.

IX. Controlled Substances Policy for Non-Pyxis Areas
Note: 1) A list of controlled substances and their schedules can be found in the YNHH Formulary Catalog prepared by Pharmacy Services.
2) If the patient care area's controlled substances are stored in a Pyxis system, see policy 9: Q-2 (Pyxis) regarding their storage, record keeping and distribution.

A. Storage of Controlled Substances

1. Controlled substances are stored in a secured, locked cabinet, which is housed in a second, fixed, locked cabinet. The cabinets are opened only when medications are being withdrawn for a patient and for inventories and replenishment. Narcotics that need refrigeration are kept in a locked, fixed container; the refrigerator does not need to be locked.

2. Two keys are required to obtain access to the controlled substance cabinet. One key opens the outer door and the second key opens the controlled substance cabinet itself. The key to the outer cabinet door is kept on one cord and the key to the inner controlled substance cabinet door and refrigerator container are kept on a second, separate, cord.

3. At the beginning of each shift, one registered nurse (Scheduled Drug Control Nurse) assumes responsibility for the controlled substance stock in the patient care area. The Scheduled Drug Control Nurse keeps the controlled substance cabinet keys during that shift except when they are being used by another nurse to obtain a dose of a controlled substance. Nurses are responsible for returning keys to the Scheduled Drug Control Nurse after use.
4. Nurses in patient care areas not open around the clock return narcotic cabinet keys to a Security Officer when the area closes or the OR charge nurse assumes responsibility by taking keys off site. The nurse obtains the keys from Security when the area reopens.
5. If narcotic keys are lost/misplaced consider the need to change the lock on the narcotic cabinet. Security personnel can assist with the decision.

B. Inventory Management of Controlled Substances

1. Each time a nurse removes a dose of a controlled substance, the nurse verifies the accuracy of the drug's inventory and "Record of Controlled Substances Disposition", (i.e. "Proof of Use Sheet, F-3357) and reports any discrepancy.
2. Oncoming and off-going Scheduled Drug Control Nurses inventory ("count") the controlled substances together at the change of each nursing shift (i.e. every eight to twelve hours). The oncoming nurse examines inventory and the off-going nurse examines documentation.
3. In areas that are open for one shift or opened "on-call", inventory is counted at the beginning and end of the shift; one nurse may complete the inventory, if only one nurse works in the area. Rotating responsibility for counting inventory in such areas is desirable.
4. Both nurses sign the inventory record (F 821-1) in the space corresponding to the time the inventory was taken. The pharmacist who audits the patient care area each month collects completed inventory records.
5. If there is a discrepancy between the actual quantity of controlled substances and the amount remaining per the Proof-of-Use Sheet for any controlled substance, the procedure outlined below in section X.G is followed.
6. The Patient Service Manager receives a list of Proof-of-Use Sheets for controlled substances outstanding for 45 days or longer to verify that the Proof-of-Use Sheets and the controlled substances are in the patient care area. If either are missing, the Patient Service Manager contacts the Director of Pharmacy as soon as possible.

C. Distribution of Controlled Substances

11. Ordering Controlled Substances
   a. When controlled substances are needed in Ambulatory care areas or at times other than the daily delivery on inpatient care areas, an RN or LPN with hospital identification obtains the controlled substance(s) and Proof-of-Use Sheet(s) from the Pharmacy. A Controlled Substance Clerk verifies the presence of the controlled substance and Proof-of-Use Sheet the following day. Within 48 hours, the Patient Service Manager receives written notification that controlled substances were picked up during off-hours.
21. Delivering Controlled Substances in Inpatient Areas:
   a. The Controlled Substance Clerk delivers controlled substances Monday through Saturday.
   b. A nurse may call in additional orders for drugs needed.
31. Receiving Controlled Substances in Inpatient Areas
   a. Upon receiving controlled substances, the Scheduled Drug Control Nurse verifies that the quantity and identification number of each item matches that on the accompanying Proof-of-Use Sheet.
41. Returning Controlled Substances
   a. When controlled substances are to be returned to Pharmacy, the Scheduled Drug Control Nurse gives them directly to the Controlled Substance Clerk.
51. Returning Proof-of-Use Sheets
D. Documenting Controlled Substance Use

61. Each dose of a controlled substance administered is documented on the Proof-of-Use Sheet assigned to that drug and includes the following:
   a. first and last name of the patient receiving the drug;
   b. date (including year);
   c. time (including AM/PM);
   d. name of the patient's physician;
   e. amount administered;
   f. amount wasted (as appropriate);
   g. amount remaining in the inventory;
   h. full signature (first and last name) and title of the nurse administering (or wasting);
   i. full signature (first and last name) and title of the witness (RN, LPN, MD) present for wasted dose (partial or complete); and
   j. reason for wasted dose of the controlled substance (as appropriate).

2. In addition, the administering nurse and the witness sign the Proof-of-Use Sheet in the following instances:
   a. the destruction and discard of a controlled substance transdermal patch (e.g. Fentanyl) removed from a patient;
   b. the discard of any controlled substance remaining in a multi-dose vial after preparing an infusion of a controlled substance; and
   c. the discard of any controlled substance solution remaining after an infusion is discontinued or the solution container is changed.

E. Controlled Substance Prescriptions: Controlled substance prescription pads are re-ordered, and are delivered in shrink-wrap, in the morning, with the controlled substances. When controlled substance pads are needed in Ambulatory care areas, an RN or LPN with hospital identification obtains them from the Pharmacy. The nurse returns the Controlled Substance Prescription Blank Audit (F-1889), the used prescription pad containing copies of the prescriptions.

F. Continuous Narcotic Transfer Notice (F-3618) is to be used whenever a patient who is receiving continuous narcotics (e.g. PCA, infusions, patches) is transferred from one patient care area to another.

G. Controlled Substance Inventory Discrepancy

71. The Scheduled Drug Control Nurse verifies that a discrepancy exists by checking:
   1) the tally accuracy on the Proof-of-Use Sheet;
   2) the narcotic box for misplaced drugs;
   3) whether a controlled substance was administered without documenting the administration on the Proof-of-Use Sheet (see the medical record of patients who may have received the controlled substance);
   4) with each nurse (by telephone, if necessary) who had access to the controlled substance cabinet since the last controlled substance audit to check whether a controlled substance was administered without documenting the administration on the Proof-of-Use Sheet, or to solicit other pertinent information;

b. notifies the following if the discrepancy is verified:
   1) Security Services;
   2) Director of Pharmacy (on off shifts and weekends notify the Charge Pharmacist); and
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3) Patient Service Manager (on off shifts and weekends notify the Clinical Advisor);
   c. initiates the "Report of Controlled Substance Loss" (F.2707);
   d. assures that all nurses still present from the shift during which the discrepancy was discovered
      remain at the scene until dismissed by the investigator;
   e. maintains possession of the keys to the controlled substance cabinet at all times during the
      investigation; if it is necessary to open the controlled substance cabinet during the investigation, the
      nurse remains present during the time that the controlled substance cabinet is open; and
   f. completes the "Report of Controlled Substance Loss" (F.2707) and gives it to the investigating
      officer.
2. Security Services:
   a. dispatches an officer immediately to conduct an investigation of the reported controlled substance
      discrepancy;
   b. initiates and completes an investigation of the controlled substance discrepancy:
      1) consults with all nursing staff present regarding the actions implemented to resolve the
         controlled substance discrepancy; and
      2) signs the "Report of Controlled Substance Loss" (F-2707);
   c. completes the "Case Incident Narrative Report" of the controlled substance discrepancy; and
   d. distributes copies of the "Report of Controlled Substance Loss" (F-2707) within 24 hours to:
      1) Pharmacy Services;
      2) Administrative Director for Nursing Services; and
      3) Security Services.
      (Note: When a controlled substance inventory discrepancy is found on an off-shift or weekend,
      the Clinical Advisor informs the appropriate Administrative Director/designee of the incident on
      the Administrative Director's first working day after the discrepancy is discovered.) The
      Administrative Director sends a photocopy of the "Report of Controlled Substance Loss"
      (F.2707) to the Patient Service Manager.

X. Analgesia and the Pain Service
A. Patient Controlled Analgesia (PCA)
   1. PCA therapy is administered by a PCA infusion device that is locked at all times. The infusion
      device key is kept with the controlled substance key, which opens the outer door of the controlled
      substance cabinet in the patient care area. The Acute Pain Service Resident also carries a key.
   2. The clinical management protocol in NO&PM, Vol. II - Patient Controlled Analgesia –contains
      guidelines for the management of patients receiving pain management via PCA.
      Documentation guidelines are included.
B. Single Dose Epidural or Spinal Injections: The clinical management protocol in NO&PM, Vol. II-
Single Dose Epidural or Spinal Injection of Narcotic - contains guidelines (including requirements
for documentation) for the management of patients receiving such treatment.
C. Questions regarding medications administered under the direction of the Acute Pain Services which
   cannot be answered by the physician can be directed to the Clinical Nurse Coordinator, Acute Pain
   Service and the Patient Service Manager, Pain Management Center, respectively.

XI. Investigational Drugs
A. Nurses administer investigational drugs only:
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1. when the investigational drug is being used under protocol approved by the Yale University School of Medicine the Human Investigation Committee (HIC) or it is an emergency use, which fits the following definition:
   a. Emergency use is defined as the use of an investigational drug or biologic product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB (HIC) approval. This emergency use provision is the only exemption from prior review and approval by HIC, and all stated conditions must be met. Life threatening includes the scope of life-threatening and severely debilitating. The investigator must notify the HIC within 5 working days of this emergency use.
2. under the direct supervision of the principal investigator or an authorized investigator for the protocol who is a member of the medical or dental staff;
3. after the investigational drug has been prepared and/or labeled by the Pharmacy;
4. if the consent form is signed by the patient, or as appropriate, by the patient's parent or guardian or person otherwise responsible for that patient. This is not required:
   a. when the protocol has been approved by HIC to use verbal consent;
   b. in rare cases of emergency when informed consent may not be possible. (NOTE: Emergency use as defined above does not necessarily involve waiver of written consent.) Emergency use should include an informed consent process with the subject or appropriate family member. Only when the following conditions apply may the requirement for written consent be waived:
      1) both the investigator and another physician who is not otherwise participating in the clinical investigation must certify in writing that the subject is confronted by a life-threatening situation necessitating use of the test article and informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from the subject and time is not sufficient to obtain consent from the subject's legal representative and no alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.
5. according to the dosage, route of administration and duration as defined in the investigational drug protocol and as approved by the HIC.

B. An investigational drug fact sheet (if available), a copy of the approved protocol, and signed consent form are inserted in the patient's medical record before administering the drug. Even in an emergency use situation, some protocol must exist from the sponsor of the investigational product, and this may be used for the chart copy. Likewise, a sponsor's consent form may be used in this one situation.

C. Study protocols include the doses of the investigational drug, the route and duration of its administration, the known risks to date, and the clinical and laboratory examinations to be performed.

XII. Antineoplastic (Chemotherapeutic) Agents

A. Antineoplastic agents are administered to patients via the oral, subcutaneous, intramuscular, intravenous, intraperitoneal, and intra-arterial routes by cancer chemotherapy certified registered nurses.

B. Cancer chemotherapy orders require that:
   1. Two cancer chemotherapy registered nurses:
      a) verify and sign each cancer chemotherapy order,
      b) schedule all chemotherapeutic agents and related medications and sign that schedule is accurate.
   2. Two cancer chemotherapy certified registered nurses or a chemotherapy certified registered nurse and a pharmacist check each prepared bag or syringe of cancer chemotherapy with the patient's order and check the name and unit number on the prepared bag/syringe with the name and unit number on the patient's wrist band/ID label immediately prior to administration.
3. The cancer chemotherapy certified registered nurse, who is administering the cancer chemotherapy, and a second employee check the name and unit number on the prepared bag/syringe with the name and unit number on the patient's wrist band/ID label immediately prior to administration.

4. a registered nurse who is not cancer chemotherapy certified may administer continuous infusion of non-vesicant agents under the following conditions:
   a. the patient is an adult.
   b. at initiation, the entire order set and schedule is verified by two, cancer chemotherapy certified registered nurses.
   c. consultation is obtained from a certified cancer chemotherapy registered nurse regarding side effects, monitoring parameters, and safe handling.

5. a registered nurse who is NOT cancer chemotherapy certified but who attends an educational session regarding the safe administration of a particular agent or agents in her specialty area may administer the agent or agents if:
   a. the practice/specialty area has a unit specific standard
   b. the registered nurse successfully completes a clinical practicum.

C. All caregivers who may be assigned to care for patients receiving parenteral antineoplastic agent therapy have ready access to information regarding:
   1. the risks associated with the drug therapy; and
   2. the proper safety precautions that are used when caring for patients receiving this drug therapy.

D. Antineoplastic agents are prepared in designated areas equipped with vertical flow, biological safety cabinets only.

E. Direct Contact with an Antineoplastic Agent: Procedure
   1. Wear gloves when handling antineoplastic agents.
   2. Change gloves if they come in contact with an antineoplastic agent.
   3. If skin contact occurs wash area immediately with copious amounts of soap and water.
   4. If eye contact occurs flood affected eye(s) immediately with copious amounts of isotonic eye wash solution and obtain an evaluation for the need of an Ophthalmology Consult from PHS and/or the Emergency Department.
   5. If mucosal contact occurs irrigate affected area with water.
   6. If clothing becomes contaminated, remove immediately.
   7. Report all contact incidents to PHS and complete an "Employee First Injury Report" (F-1797).

F. All patient care areas in which antineoplastic agents are administered have a "chemo spill kit" readily available on the unit, and all antineoplastic agent spills are reported by completing a "Report of Incident" (F-877).

G. Disposal of Chemotherapy Waste on Inpatient Units
   1. Dispose of trace chemotherapy waste (defined as 3% or less of the ultimate volume) in the normal medical waste containers (either red plastic bags or wall needle boxes). This includes "empty" syringes, "empty" intravenous bags and tubing, needles, and gloves.
   2. Dispose of bulk chemotherapy waste (defined as greater than 3% of the ultimate volume) as follows:
      a. return unused syringes and intravenous bags to Pharmacy; and
      b. place partly filled syringes and intravenous bags and bottles with tubing in a sharp's container and Pharmacy is called to collect the container. Keep the container covered, in an upright position, and labeled "chemotherapy waste".
   3. Fluid drainage from the peritoneal cavity following intraperitoneal chemotherapy is considered medical waste. While wearing splash goggles and a mask, the nurse empties the bag containing the post-chemotherapy fluid into the toilet and flushes twice, taking care not to cause splashing.
H. Disposal of Chemotherapy Waste on Outpatients Units (Yale University)
   1. Cytotoxic waste is defined as the cytotoxic agent and all materials which could potentially come in contact with the drug such as: drug receptacles, alcohol swabs, vials, syringes, gloves, etc. Four waste containers shall be used in the medical oncology clinic pharmacy.
   2. The first container is a standard paper waste container in which only paper items shall be discarded. (Exam paper, forms, packaging material)
   3. The second container is a red medical waste container which shall be used for all glass vials that contain a trace amount (i.e., < 3% of the total fluid volume of the container) of all cytotoxic and non-cytotoxic agents. This container shall also be used for the disposal of IV bags that contain a trace amount of cytotoxic and non-cytotoxic agents. All contaminated equipment used in preparing chemotherapy (excluding needles and syringes) should be disposed of in the red container. Also blood products and supplies saturated with bodily fluids.
   4. The third container shall be for the disposal of “regulated” and bulk non-regulated cytotoxic waste in volumes greater than 3% of the contents of the vials. This container is a cardboard chemotherapy box with an inner plastic bag lining. Currently, this container is housed in the main pharmacy IV prep room and waste is transported there for disposal.
   5. The fourth container is the wall mounted needle box for sharps, syringes, applicator sticks, scalpel blades and scissors.

XIII. Vaccines
   A. Registered nurses and licensed practical nurses may administer vaccines.
   B. Vaccine administration is documented including lot number and site of administration in the medical record and as required by state and federal regulations (e.g. The National Childhood Vaccine Injury Act). Literature is also distributed to patients, parents, or guardians as per state and federal regulations.
   C. The physician administers antisera and antitoxins.
SECTION 22  GENERAL GUIDELINES FOR CLEANING, DISINFECTION AND
STERILIZATION OF PATIENT CARE EQUIPMENT

22.1 Introduction
For disinfection and sterilization purposes, reusable patient care equipment will be classified and processed according to recommendations of the Centers for Disease Control and the Association for Practitioners in Infection Control Guidelines on the Selection and Use of Disinfectants.

Disinfectant agents and chemical sterilants used for reprocessing medical instruments and devices must be approved by the Infection Control Committee, the Safety Committee, and the Equipment and Product Standards Committee. These guidelines have been developed to standardize practices used in the cleaning, disinfection, and sterilization of patient care equipment. In addition, because certain chemical sterilants may be potentially hazardous, strict attention will be given to the enforcement of appropriate technique and to the use of personal protective equipment, engineering, and work practice controls as required by OSHA.

The following guidelines have been developed to assist health care professionals in cleaning, disinfecting and sterilizing patient care equipment.

22.2 Equipment Classification Procedure:
A. Determine the appropriate category under which the article to be cleaned, disinfected, or sterilized is classified:

1. CLASS I - CRITICAL
   Equipment in this category includes any instrument which will be introduced into the patient's bloodstream, through the patient's skin, or into other normally sterile areas. Examples include surgical instruments, implanted devices, cardiac catheters, pacemakers, and so forth. Sterility is required for these instruments.

2. CLASS II - SEMI-CRITICAL
   Equipment in this category includes any instrument that will come into contact with intact mucous membranes and does not penetrate body surfaces. Such instruments include non-invasive endoscopes, endotracheal tubes, MacGill forceps, oropharyngeal airways, endotracheal tube stylets, anesthesia masks, Ambu bag masks, thermometers, laryngoscope blades, and so forth. Sterility is not essential. However, at a minimum, a high-level disinfection procedure that can be expected to destroy vegetative microorganisms, most fungal spores, tubercle bacilli, and small non-lipid viruses is recommended.

   Meticulous physical cleansing followed by an appropriate high-level disinfection treatment gives a reasonable degree of assurance that the items are free of pathogens.

3. CLASS III – NON-CRITICAL
   Equipment in this category comes in contact with patients and their intact skin and rarely, if ever, is implicated in the transmission of disease. Items in this category include crutches, bed boards, blood pressure cuffs, stethoscopes, and so forth.
Routine cleansing with soap and water and an EPA-approved disinfectant is sufficient to reduce the number of microorganisms on the surface of this equipment. Alcohol may also be used to clean the surface of these items if they are not visibly soiled.

B. Determine the level of disinfection which is indicated:

### 22.3 Examples of Instruments, Levels of Disinfection, and Procedures

<table>
<thead>
<tr>
<th>INSTRUMENTS</th>
<th>LEVEL OF DISINFECTION/ STERILIZATION PROCEDURE</th>
<th>PROCEDURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLASS I – CRITICAL Includes all instruments (i.e., surgical instruments, IV catheters, implanted devices, etc.)</td>
<td>Sterility required</td>
<td>Moist heat, dry heat, or ethylene oxide.</td>
</tr>
<tr>
<td>CLASS II – SEMI-CRITICAL All instruments which contact mucous membranes (i.e., endotracheal tubes and stylets, endoscopes, airways, amnesia masks, etc., or skin that is not intact.</td>
<td>High level disinfection required between patients.</td>
<td>Moist heat, 100°C for 30 min.; aqueous 2% glutaraldehyde for 20-30 minutes; 1:10 dilution of bleach for 20 minutes. A sterile water rinse after disinfection is required to prevent contamination with tap water.</td>
</tr>
<tr>
<td>CLASS III – NON-CRITICAL</td>
<td>Low level required</td>
<td>Chemical disinfectants include ethyl or isopropyl alcohol (70-90%), phenolic disinfectant solutions, iodophors for intermediate level. An exposure (contact) time of at least 10 minutes is required. For low level, ethyl or isopropyl alcohol (70-90%)– bleach (1:10 dilution), phenolics, IODOPHORS, quaternary ammonium compounds.</td>
</tr>
</tbody>
</table>

C. Prior to disinfection a thorough mechanical cleansing with enzymatic cleanser is required.

D. Following the disinfection process the item must be thoroughly rinsed with sterile water and dried aseptically.

E. When using a disinfectant agent for reprocessing of medical devices/instruments, the manufacturer's instructions for dilution, activation, contact time, and appropriate use must be strictly followed.

### 22.4 Standards for Infection Control and Reprocessing of Flexible Gastrointestinal Endoscopes

#### 22.4.1 Preparing the Endoscope for Cleaning:

The initial steps in the reprocessing protocol begin in the patient room immediately after removal of the insertion tube from the patient and before removing the endoscope from the power source.

Have the following available:

- Personal protective equipment (gloves, eye protection, face protection and impervious gown).
• Container with enzymatic detergent solution.
• Sponge or soft, lint-free cloth.
• Air and water channel cleaning adapters per manufacturer's instructions.
• Protective video caps.

Immediately after removing the endoscope from the patient, wipe the insertion tube with the wet cloth or sponge soaked in the freshly prepared enzymatic detergent solution.

• Dispose of the cloth or sponge between cases.

Place the distal end of the endoscope into the enzymatic detergent solution. Suction the solution through the biopsy/suction channel until the solution is visibly clean. Alternate suctioning detergent solution and air several times. Finish by suctioning air.

• Alternate suctioning of fluid and air is more effective than suctioning fluid alone in the removal of debris from internal lumens.
• Immediate flushing of the biopsy/suction and air/water channels precludes drying of organic and inorganic debris on lumen surfaces and may remove large numbers or microorganisms.

Flush of blow out air and water channels in accordance with the endoscope manufacturer's instructions.

• Detach the endoscope from the light source and suction pump.
• Attach protective video cap.

Transport the endoscope to the reprocessing area in an enclosed container.

• Containers, sink, and basins should be large enough that the endoscope will not be damaged by being coiled too tightly.
• A container will prevent contamination during transport.
• Reprocessing should occur in a room separate from the procedure room.

22.4.2 Cleaning the Endoscope in the Reprocessing Area:

Have the following available:

• Personal protective equipment (gloves, eye protection, impervious gown).
• Leakage tester equipment.
• Channel cleaning adapters (per manufacturer's instructions).
• Large basin of enzymatic detergent solution prepared according to the manufacturer's instructions.
• Channel cleaning brushes and lint-free cleaning swabs.
• Sponge and/or lint-free cloth.

22.4.3 Leak Testing:

• Leak test the endoscope following manufacturer's instructions.
• Attach the leak tester and pressurize the scope before submerging it in water.
• Remove the detachable parts of the endoscope.
• With the pressurized endoscope completely submerged, flex the distal portion of the scope in all directions. Observe the insertion tube, distal bending section, and the universal cord for bubbles coming from the interior of the scope.
• The leak test will detect damage to the interior or exterior of the endoscope. The leak test is done before immersion of the endoscope in reprocessing solutions to minimize damage to parts of the endoscope not designed for fluid exposure.
• Follow the manufacturer's instructions if a leak is detected or the endoscope appears damaged.

22.4.4 Cleaning:
Mechanical cleaning is the first and most important step in removing the microbial burden from an endoscope. Retained debris may inactivate or interfere with the capability of the active ingredient of the liquid-chemical germicide to effectively kill and/or inactivate microorganisms. Cleaning gastrointestinal endoscopes is necessary before automated or manual disinfection.

Fill a sink or basin with freshly made solution of water and a low-sudsing enzymatic detergent compatible with the endoscope.

Dilute according to the detergent manufacturer's instructions.

• Depending on the detergent formulation used, water temperature may be essential to activate the detergent solution.
• Use fresh detergent solution for each endoscope to prevent cross contamination.
• Low-sudsing detergents are recommended so that the device can be clearly visualized during the cleaning process to preclude personnel injury and to allow for complete cleaning of lumen surfaces. Excessive sudsing can inhibit good fluid contact with the device surfaces.

Immerse the endoscope.

Wash all debris from the exterior of the endoscope by brushing and wiping the instrument while submerged in the detergent solution. Whenever practical, leave the endoscope submerged in the detergent solution when performing all subsequent cleaning steps.

• The instrument should be left under water during the cleaning process to prevent splashing of contaminated fluid.

Detach the suction and air/water valves, the biopsy channel cover, the distal end hood, if present, and all other removable parts. Discard those parts that are designated as disposable.

• The endoscope must be completely disassembled so that all surfaces may be reached for thorough cleaning.

Use a small, soft brush and/or lint-free cleaning swab to clean all removable parts including inside and under the suction valve, air/water valve, and biopsy port cover and openings.

• Use of nonabrasive and lint-free cleaning tools will prevent damage to the endoscope.

Brush all accessible endoscope channels including the body, insertion tube, and the umbilicus of the endoscope. Use a brush size compatible with each channel.

After each passage, rinse the brush, removing any visible debris in the detergent solution before retracting and reinserting it.
Continue brushing until there is no debris visible on the brush.

Discard single-use channel cleaning brushes. Clean and high-level disinfect reusable brushes between cases.

- Reusable brushes should be inspected between uses and replaced when worn, frayed, bent, or otherwise damaged. Worn bristles are ineffective in cleaning, and damaged brushes may damage endoscope channels.

Attach all cleaning adapters for suction, biopsy, air and water channels.

Attach cleaning adapters for special endoscope channels (i.e. elevator channel, forward water jet, double-channel scopes).

- To achieve adequate flow through all lumens, various adapters or channel restrictors may be required. Refer to the manufacturer's instructions.
- Because the elevator channels of these scopes have small lumens, force greater than can be generated by an automated reprocessor is needed to force fluid through them. This channel requires manual reprocessing (all steps) using a 2- to 5-milliliter syringe. Although the elevator channels of these scopes have channel adapters that may be made to fit reprocessors, this channel must be manually reprocessed.

Flush all channels with the detergent solution to remove debris. Prolonged soaking of the channels in the detergent solution may be beneficial if there has been a delay in beginning the cleaning process.

22.5 Glutaraldehyde

Glutaraldehyde, (i.e., Metricide, Cidex, VHA Plus) is an effective chemical used for high level disinfection. However, there is a growing concern over the potential adverse effects of exposure to glutaraldehyde liquid and vapors.

One should avoid glutaraldehyde if high level disinfection is not required. If high level disinfection is necessary, the equipment may be sent to a central processing location such as Central Sterile Supply. One should look into whether other, less hazardous, high level liquid disinfectants that may be utilized as well.

If it is absolutely necessary to use glutaraldehyde for high level disinfect equipment in a clinical area, the following must be carried out:

Notification

The Department of Hospital Epidemiology (QISS) and Yale University Office of Environmental Health and Safety (785-3550) needs to be notified of any clinical area utilizing glutaraldehyde for any purpose.

Environmental Considerations

The dirty utility area should be separate from patient and employee areas. Proper ventilation is required and the room should have a minimum of 10 air exchanges per hour. In addition, there should be a local exhaust ventilation system at the point of discharge of the vapors, i.e., contained station or exhaust hood.

Monitor Exposure Levels

Measurement of glutaraldehyde exposure levels must be conducted in any area using glutaraldehyde. The current exposure limit is a ceiling value of 0.05 ppm, which should not be exceeded at any time. This monitoring should be conducted at least once in every area where glutaraldehyde is used. It should also
be conducted whenever there is a change in the operation or equipment that may result in a change of exposure. The Yale Office of Environmental Health and Safety will conduct this monitoring and evaluate the results.

**Hazard Communication Training**

All employees who work with hazardous chemicals are required to attend chemical safety training. This training includes information on the hazards of the chemicals they work with, personal protective equipment, safe work practices, spill clean up procedures, Material Safety Data Sheets (MSDSs), labeling, and engineering controls and other methods to reduce exposures.

**Appropriate Barrier Protection**

Employees using glutaraldehyde must wear appropriate personal protective equipment (PPE) to protect skin, face, and clothing. At a minimum, anyone working with gluteraldehyde should wear chemical goggles, nitrile gloves, and an impervious gown or apron.

**Administrative and Work Practice Controls**

Limit employee access and centralize glutaraldehyde usage as much as possible. Install appropriate eyewash stations within the area of all glutaraldehyde usage locations.

Glutaraldehyde vapors increase during agitation of the solution. Pouring, dumping, and moving of glutaraldehyde should be minimized.

**Activating and Testing of the Solution**

Record the date of activation and expiration of the glutaraldehyde solution. Monitor the solution at least daily with dialdehyde concentration indicators. Document this information on a log sheet. All glutaraldehyde solutions should be stored in closed, covered and correctly labeled containers. The cover of the soaking container should be kept on at all times except when items are deposited or removed.

**Accidental Exposure**

Employees exposed to glutaraldehyde should immediately remove contaminated clothing and thoroughly wash the skin with water. In case of eye contact, eyes should be flushed with copious amounts of water for at least 15 minutes and contact lenses should be removed. The hospital employee should then report immediately to Occupational Health Services. Yale University employees should report immediately to YUHS Urgent Visit (open 24 hours) or Employee Health (8:30 am – 5:00pm).

### 22.6 Methods of Sterilization

<table>
<thead>
<tr>
<th>METHOD OF STERILIZATION</th>
<th>CONCENTRATION OR TEMPERATURE</th>
<th>ACTIVITY LEVEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heat</td>
<td>&gt;250 F. (121 C) pre vac. Cycle</td>
<td>Sterility</td>
</tr>
<tr>
<td>Moist Heat</td>
<td>271 F (132 C) **</td>
<td></td>
</tr>
<tr>
<td>Dry Heat</td>
<td>171 C x 1 hr.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>160 C x 2 hr.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>121 C x &gt; 16 hr.</td>
<td></td>
</tr>
<tr>
<td>Gas</td>
<td>450-500 mg/liter at</td>
<td></td>
</tr>
<tr>
<td>Ethylene Oxide (ET07)</td>
<td>**Time variable. Follow sterilizer manufacturer's recommendations for specific exposure and aeration times.</td>
<td></td>
</tr>
</tbody>
</table>
SECTION 23 • APPENDIX A YNHH MEDICAL WASTE CLASSIFICATION AND SEPARATION REFERENCE CHART

The following items are REGULATED MEDICAL WASTE (RMW):

1. **SHARPS:** to be deposited into the designated needle disposal containers. •
   - BLADES, GLASS SLIDES, GLASS TUBES
   - ALL NEEDLES – e.g.; IV, HYPODERMIC, SPINAL, SUTURE
   - LANCETS, PROBES, SAFETY-PINS, SPEARS, SCRAPERS, SCISSORS
   - VACUTAINER HOLDERS & NEEDLES, BLOOD TRANSFER DVICES
   - GLASS MEDICATION VIALS, SYRINGES WITH OR WITHOUT NEEDLE

2. **VISIBLY DRIPPING WASTE BLOOD:** contain the fluids when possible and deposit any items saturated with visibly dripping blood in RMW container.

3. **INFECTIOUS WASTE:** Empty fluids whenever possible and deposit containers. Includes, BLOOD, CEREBROSPINAL, PLEURAL & PERIONEAL FLUIDS (EXCLUDES DIALYATES). Items that may contain the above fluids:
   - SPONGES (OR)
   - PLEUREVACS, HEMOVACS, OTHER COLLECTION BAGS/DEVICES
   - HEMODIALYSIS, CVVH – FILTERS, TUBING & BAGS
   - BLOOD PRODUCTS – FILTERS, TUBING & BAGS
   - OPERATING ROOM SUCTION TUBING & CANISTER LINERS
   - SPECIMEN CONTAINERS (MOSTLY FROM LABS)
   - GLASS VACUUM BOTTLES CONTAINING ASCITES OR PLEURAL FLUID

4. **ALL WASTE FOR BIOSAFETY LEVEL 4 AGENTS:** All waste from a person that has a Biosafety Level 4 Disease such as hemorrhagic fever, etc.

5. **CULTURES AND STOCKS:** of agents infectious to humans associated biologicals including cultures from medical, clinical and hospital laboratories; culture dishes and devices used to transfer, inoculate, or mix cultures.

6. **RESEARCH ANIMAL WASTE:** which includes contaminated animal carcasses, animal bedding or animals that were intentionally exposed to infectious agents during research.

7. **PATHOLOGICAL WASTE:** means any human tissue, organ or body part removed during surgery, autopsy or other medical procedure. Waste to be segregated in corrugated boxes.

8. **CHEMOTHERAPY WASTE:** IV bags containing <3% of anti-neoplastic agents (bag is empty) can be deposited directly into RMW containers. IV bags containing >3% unused anti-neoplastic agents must be returned to Pharmacy for disposal as “hazardous” waste.

   The following items are NOT REGULATED MEDICAL WASTE unless visibly dripping with blood:

   - Empty container of fluids in sanitary sewer system, rinse and place in ordinary waste container.

   - **BEDS PANS**

   - **SPECIMEN CONTAINERS** of non-regulated waste

   If NOT visibly dripping waste blood, deposit the following in regular waste containers.

   - DRESSINGS, GAUZE PADS
   - MASKS, GLOVES, GOWNS
   - TAPE, PADS, COTTON
   - VENTILATOR TUBING
   - FOLEY BAGS & FOLEY CATHETERS
   - RED RUBBER CATHETERS
   - BED PANS, EMESIS BASINS
   - DIAPERS, URINALS, URINE HATS & URINE FILTERS
   - PERI (OB) PADS
   - SALEM SUMP (NG) TUBES
   - SUCTION CANISTERS LINERS & TUBING
   - IRRIGATION SETS, BULB SYRINGES
   - PAPER TOWELS, TISSUES, CUPS
   - PACKAGING MATERIAL
   - CASTS, CAST PADDING & SPLINTS
   - PLASTIC MEDICATION VIALS

   Remove all needles from tubing, and if the tubing is NOT visibly dripping waste blood, deposit tubing in ordinary waste container.

   - Empty fluid from all used/unused I.V. containers then lace into ordinary waste container.

   - **ALL PLASTIC IV BAGS**

   Empty fluid from glass IV bottle; then discard into GLASS-ONLY containers.

   If you need a Glass-Only Container contact Environmental Services.

Call Infection Control (8-4634) regarding questions about medical waste classification or separation.
Call Environmental Services (8-6688) concerning questions about medical waste containers or pick-up schedule.

Yale Medical Group
Revised August 5, 2003
### SECTION 24 REFRIGERATOR MONITORING LOG

#### MEDICATION/SPECIMEN MONITORING LOG

| Temp/Range | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|------------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| 50°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 49°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 48°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 47°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 46°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 45°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 44°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 43°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 42°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 41°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 40°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 39°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 38°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 37°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 36°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 35°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 34°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 33°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| ≤33°F      |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |

- **Unit:**
- **Month:**
- **Temp/Range:**
- **Actions Taken:** Date and initials

#### FOOD MONITORING LOG

| Temp/Range | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|------------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| 44°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 43°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 42°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 41°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 40°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 39°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 38°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 37°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 36°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 35°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 34°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 33°F       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| ≤33°F      |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |

- **Unit:**
- **Month:**
- **Temp/Range:**
- **Actions Taken:** Date and initials

* Cleaned every week (Wkly)
* Discard untagged or expired food
* Charge Nurse authorizes
* Engineering notification