

Recommendations for the Safe Use of Handling of Cytotoxic Drugs



Introduction

Cytotoxic drugs are toxic compounds and are known to have carcinogenic, mutagenic and/or teratogenic potential. With direct contact they may cause irritation to the skin, eyes, and mucous membranes, and ulceration and necrosis of tissue. The toxicity of cytotoxic drugs dictates that the exposure of health-care personnel to these drugs should be minimized. At the same time, the requirement for maintenance of aseptic conditions must be satisfied.

Potential Routes of Exposure

This brochure reviews the routes through which exposure may occur and presents recommendations for the safe handling of parenteral cytotoxic drugs by pharmacists, nurses, physicians and other personnel who participate in the preparation and administration of these drugs to patients. These guidelines apply in any setting where cytotoxic drugs are prepared - including pharmacies, nursing units, clinics, physicians' offices and the home health care environment. The primary routes of exposure during the preparation and administration phases are through the inhalation of aerosolized drug or by direct skin contact.

During drug preparation, a variety of manipulations are performed which may result in aerosol generation, spraying, and splattering. Examples of these manipulations include: the withdrawal of needles from drug vials; the use of syringes and needles or filter straws for drug transfer; the opening of ampules; and the expulsion of air from the syringe when measuring the precise volume of a drug. Pharmaceutical practice calls for the use of aseptic techniques and a sterile environment. Many pharmacies provide this sterile environment by using a horizontal laminar flow work bench. However, while this type of unit provides product protection, it may expose the operator and the other room occupants to aerosols generated during drug preparation procedures. Therefore, a Class 11 laminar flow (vertical) biological safety cabinet that provides both product and operator protection is needed for the preparation of cytotoxic drugs. This is accomplished by filtering incoming and exhaust air through a high-efficiency particulate air (HEPA) filter. It should be noted that the filters are not effective for volatile materials because they do not capture vapors and gases. Personnel

should be familiar with the capabilities, limitations and proper utilization of the biological safety cabinet selected.

During administration, clearing air from a syringe or infusion line and leakage at tubing, syringe, or stopcock connections should be avoided to prevent opportunities for accidental skin contact and aerosol generation. Dispose of syringes and unclipped needles into a leakproof and puncture-resistant container.

The disposal of cytotoxic drugs and trace contaminated materials (e.g., gloves, gowns, needles, syringes, vials) presents a possible source of exposure to pharmacists, nurses and physicians as well as to ancillary personnel, especially the housekeeping staff. Excreta from patients receiving cytotoxic drug therapy may contain high concentrations of the drug. All personnel should be aware of this source of potential exposure and should take appropriate precautions as established by your hospital or clinic to avoid accidental contact.

The potential risks to pharmacists, nurses and physicians from repeated contact with parenteral cytotoxic drugs can be effectively controlled by using a combination of specific containment equipment and certain work techniques which are described in the recommendations sections. For the most part, the techniques are merely an extension of good work practices by health-care and ancillary personnel, and similar in principle and practice to Universal Precautions (*Centers for Disease Control. 1988.Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings. Morbidity and Mortality Weekly Report, 37(24): 377-382, 387-388.*). These may be supplemented as deemed appropriate for the work being performed. By using these precautions, personnel are better able to minimize possible exposure to cytotoxic drugs.

Recommended Practices for Personnel PREPARING Cytotoxic Drugs

Professionally accepted standards concerning the aseptic preparation of parenteral products should be followed. Only properly trained personnel should handle cytotoxic drugs. Training sessions should be offered to new professionals as well as to technical and housekeeping personnel who may come in contact with these drugs. Safe handling should be the focus of such training. To speed loading time, the information regarding safe preparation has been divided into 3 sections:

Steps A, B, C

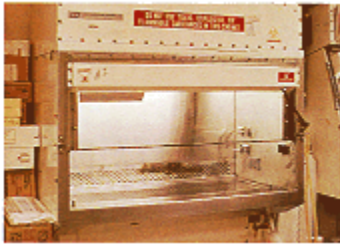
Steps D, E, F, G

Steps H, I, J, K, L

Safe Preparation of Cytotoxic Drugs- Steps A, B, C

A. Part I All procedures involved in the preparation of cytotoxic drugs should be performed in a Class 11, Type A or Type B laminar flow biological safety cabinet. The cabinet exhaust should be discharged to the outdoors in order to eliminate the exposure of personnel to drugs that may volatilize after retention on filters of the cabinet. The cabinet of choice is a Class 11, Type B which discharges exhaust to the outdoors and can be

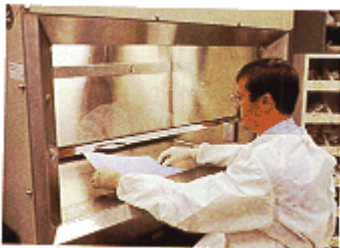
obtained with a bag-in/bag-out filter to protect the personnel servicing the cabinet and to facilitate disposal.



Part 2 Alternatively, a Class II, Type A cabinet can be equipped with a canopy or thimble unit which exhausts to the outdoors. For detailed information about the design, capabilities and limitations of various types of biological safety cabinets, refer to the National Sanitation Foundation Standard 49 *National Science Foundation. Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry.*



B. The work surface of the safety cabinet should be covered with plastic-backed absorbent paper. This will reduce the potential for dispersion of droplets and spills and facilitate cleanup. This paper should be changed after any overt spill and at the end of each work shift.



C. Personnel preparing the drugs should wear unpowdered latex surgical gloves and a disposable gown with elastic or knit cuffs. Gloves should be changed regularly and immediately if torn or punctured. Protective clothing should not be worn outside of the drug preparation area. Overtly contaminated gowns require immediate removal and replacement. In case of skin contact with any cytotoxic drug, thoroughly wash the affected area with soap and water. However, do not abrade the skin by using a scrub brush. Flush the affected eye(s), while holding back the eyelid(s), with copious amounts of water for at least 15 minutes. Then seek medical evaluation by a physician.



Safe Preparation of Cytotoxic Drugs- Steps D, E, F, G

D. Vials containing drugs requiring reconstitution should be vented to reduce the internal pressure with a venting device using a 0.22 micron hydrophobic filter or other appropriate means such as a chemotherapy dispensing pin. This reduces the probability of spraying and spillage.



E. If a chemotherapy dispensing pin is not used, a sterile alcohol pad should be carefully placed around the needle and vial top during withdrawal from the septum.



F. The external surfaces contaminated with a drug should be wiped clean with an alcohol pad prior to transfer or transport.



G. When opening the glass ampule, wrap it and then snap it at the break point using an alcohol pad to reduce the possibility of injury and to contain the aerosol produced. Use a 5 micron filter needle or straw when removing the drug solution.



Safe Preparation of Cytotoxic Drugs- Steps H, I, J, K and L

H. Syringes and I.V. bottles containing cytotoxic drugs should be labeled and dated. Before these items leave the preparation area, an additional label reading, "*Caution-chemotherapy, Dispose of Properly*" is recommended.



1. After completing the drug preparation process, wipe down the interior of the safety cabinet with water (for injection or irrigation) followed by 70% alcohol using disposable towels. All wastes are considered contaminated and should be disposed of properly.



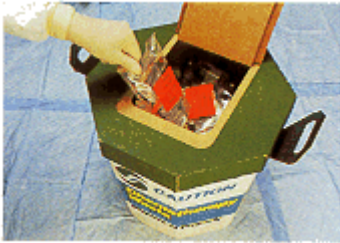
J. Contaminated needles and syringes, I.V. tubing, butterfly clips, etc., should be disposed of intact to prevent aerosol generation and injury. *Do not recap needles*. Place these items in a puncture resistant container along with any contaminated bottles, vials, gloves, absorbent paper, disposable gowns, gauze and other waste. The container should then be placed in a box labeled, "*Cytotoxic waste only,*" sealed and disposed of according to Federal, state and local requirements. Linen contaminated with drugs, patient excreta or body fluids should be handled separately.



K. Hands should be washed between glove changes and after glove removal.



L. Cytotoxic drugs are categorized as regulated wastes and therefore, should be disposed of according to Federal, state and local requirements.



Recommended Practices for Personnel Administering Parenteral Cytotoxic Drugs

A. A protective outer garment such as a closed-front surgical-type gown with knit cuffs should be worn. Gowns may be of the disposable or washable variety.



B. Disposable latex surgical gloves should be worn during those procedures where exposure to the drugs may result and when handling patient body fluids or excreta. When bubbles are removed from syringes or I.V. tubing, an alcohol pad should be placed carefully over the tip of such items in order to collect any of the cytotoxic drugs which may be inadvertently discharged. Discard gloves after each use and wash hands.



C. Contaminated needles and syringes and I.V. apparatus should be disposed of intact into a labeled, puncture-resistant container in order to minimize aerosol generation and risk of injury. *Do not recap needles.* The container, as well as other contaminated materials should be placed in a box labeled, "*Cytotoxic waste only.*" Linen overtly contaminated with any cytotoxic agent or excreta from a patient within 48 hours following drug administration, may be safely handled by using the procedures prescribed for isolation cases. For example, place the contaminated articles in a "yellow" cloth bag lined with a water-soluble plastic bag and then place into the washing machine. Linen without overt contamination can be handled by routine laundering procedures.



D. In case of skin contact with any cytotoxic drug, thoroughly wash the affected area with soap and water. However, do not abrade the skin by using a scrub brush. Flush the affected eye(s), while holding back the eyelid(s), with copious amounts of water for at least 15 minutes. Then seek medical evaluation by a physician. Always wash hands after removing gloves.

