Personal Protection Against Chemotherapy and Other Hazardous Hospital Chemical Agents

Background

Chemical agents used to treat cancer are referred to as cytotoxic agents, chemotherapy agents, or antineoplastic agents. These agents are toxic to all living cells, but are especially selective against rapidly growing cancer cells. The chemical composition of these chemical agents varies extensively as well as to the degree and type of toxicity exhibited on living cells. These chemicals are classified as acute and chronic toxics and may cause cancer (carcinogenic), mutations (mutagenic), birth defects (teratogenic), or cause reproductive effects in parts per million exposures.

Healthcare professionals preparing or administering chemotherapy agents must be protected against exposure when handling any amount at any concentration of these drugs. Although primary exposure would come through the hands during preparation or administration, full body protection (i.e., torso and arms) is also mandatory by OSHA to ensure exposures are minimized or prevented (1).

Chemotherapy drugs are handled in two areas of the hospital where exposures could occur: Pharmacy and Oncology Nursing. The Pharmacy is the primary site where the drugs are prepared for patient use. These drugs are prepared within the confines of a laminar flow safety cabinet which protects both the product (e.g., the drug) and the person preparing the drug. The pharmacist or technician is further protected through the use of a gloves and a gown to minimize or prevent direct exposure to the hands and to the body. Gown coverage should be to the full torso, arms, and legs to prevent exposure in the event of a spill or splash.

Oncology Nursing is the site where drugs are administered to the patient. Although the primary function of Oncology Nursing is to administer the drugs, in some instances drugs may also be prepared at this site. Patient drug administration requires the same personal protective wear as used by Pharmacy in the event of a spill or other unplanned release. Most drugs are given to the patient through an IV drip, but some drugs are “pushed” via syringe. In either case, drug administration poses a risk to the nurse from a spill or release from the IV bag or through a pressured release during the drug “push”.

In both the Pharmacy and Oncology Nursing, gowns are also required for clean-up in the event of a spill or release of the drug or from patient vomiting or excreta Gowns, once worn, are disposed of immediately if known to be contaminated or, if not overtly contaminated, may be allowed for re-use until the end of the day with discard at shift’s end.

To protect individuals handling chemotherapy agents requires that the personal protective wear prohibit agents from reaching the skin or clothes. Migration of chemical agents can occur via chemical permeation through the material or through material adulteration due to chemical reaction of the agent with the protective material. For years it had been assumed that vinyl or latex gloves were equally protective against chemotherapy agents. Testing revealed, however, that for the majority of gloves either vinyl or latex provided adequate protection but not interchangeably. And with some drugs, neither material provided any protection.

Unfortunately, methodologies to evaluate the ability of personal protective gowns to prevent skin contact from chemotherapy drugs have not been standardized. However in the few studies that have been conducted, both total barrier protection and chemical resistance to material adulteration have been found necessary to prohibit chemotherapy drug penetration from the wide spectrum of chemical agents used to combat cancer.

Chemotherapy drugs represent a variety of chemical classes, molecular sizes, and solubility properties that must be taken into account in material selection. These drugs represent nitrosourea compounds, nitrogen-mustard related compounds, inorganic planar molecules, and complex multi-ringed compounds. Although most are water soluble, some drugs are available only in an organic solvent base. This broad spectrum of properties requires a gown material to be universal in its application since selecting specific gowns for individual drug application would be difficult if not impossible to achieve.

With the extreme toxicity exhibited by chemotherapy agents, the gown must be able to prevent drug penetration to provide the protection required for the healthcare professional handling or administering chemotherapy drugs. Both parameters of barrier protection and material resistance to chemical-physical interaction must be satisfied to provide the assurance that no chemotherapy agent will come in contact with clothes or skin.

Breathable Versus Total Barrier Protection

Although chemotherapy drug exposure is more likely to be through hand contact, gowns provide essential protection to the body and arms in the event of a spill or a splash. However, little attention by healthcare or safety professionals has been given to the effectiveness of the gown in providing protection from slash protection or chemical permeation. As such, gowns specifically marketed for chemotherapy protection have been and continue to be sold that have a pronounced permeability to chemotherapy agents as demonstrated in independent studies (3,4).

Selecting the appropriate gown for a specific application requires a cursory knowledge of the spectrum of gown materials currently used and the limitations and attributes each has in providing the protection required of the application. To generalize, gown material can be initially classified as (1) “breathable” or as (2) “barrier” by its physical properties. Materials such as Tyvek or spunbond are classified as “breathable”, having micro-porosity characteristics to allow the transfer of air to and/or from the body to provide comfort to the wearer over extended periods of time. This attribute, however, allows direct physical permeation of chemotherapy drugs in either a gaseous or liquid phase through the material to the wearer.

To counter drug penetration through these materials, a coating (e.g., polyethylene) or lamination (e.g., Saranex, a co-extruded thermoplastic film of Saran between layers of polyethylene) to the outer layer of the base material (e.g., Tyvek or spunbonded) has been applied with mixed success. Independent tests have shown that polyethylene-coated spunbond and Tyvek have varying results in drug permeability dependent on the drug tested and variance between lot number and manufacturer (2, 3). It is speculated that imperfections in the polyethylene coating cause microscopic holes that can directly lead to permeation. Only Saranex-laminated Tyvek, a multi-layered laminate, was found to be impermeable to all drugs tested at four hours contact. This garment is an industrial gown that is heavy, uncomfortable and unsuited for hospital or clinic use. It should be further noted that with the addition of the polyethylene coating or Sananex lamination, these materials are no longer breathable.

Lightweight protective gowns have been introduced to the market to provide both a barrier to drug penetration but also retain a “breathable” quality. These gowns are made of a material known as SMS (spunbonded/meltblown/spunbonded), a three-layer polypropylene, cross-weave non-woven. The material is constructed of a middle high-density layer (i.e., meltblown) sandwiched between two layers of spunbonded to provide “torturous interference” for chemicals attempting to migrate through the material. These gowns have also been subjected to permeation testing and with the exception of an experimental material, all experienced minimal penetration with one or more of the tested drugs (4).

To virtually exclude any chemotherapy drug penetration requires that the gown be constructed of a material that will provide a solid total barrier to drug penetration. Use of this material would preclude any “breathable” characteristics found in Tyvek or the spunbond non-wovens, but hospital procedures for preparing, administering, or spill cleanup of chemotherapy drugs usually do not require lengthy wear times. The material should be chemically resistant to a broad spectrum of chemicals to meet the challenges of varying chemical classes, molecular sizes, and solubility properties found with chemotherapy drugs. To maximize the barrier’s intactness, the material should be multi-layered to prevent drug penetration through microscopic holes that may form during fabrication processes. The more layers, the less likelihood of microscopic hole overlap and thus providing a resultant minimization of penetration.

VR™ by PolyConversions, Inc.

To meet challenges imposed by chemotherapy drugs, PolyConversions, Inc. has developed a gown that meets the criteria of universal chemotherapy drug resistance. This gown is light-weight and offers chemical resistance to a wide range of chemicals including strong acids and bases, long and short chain alcohols, and formaldehyde. This material is marketed under the name, VR™.

In tests similar to those conducted against Tyvek, spundbond, and SMS materials, a two-layered construction of the material was tested at 1.5 and 2.25 mil thickness against four commonly used chemotherapy drugs (i.e., Cyclophosphamide, Carmustine, Cisplatin, and

Doxorubicin Hydrochloride) representing the broad range of chemical and physical properties found within the chemotherapy drug spectrum. Of all four drugs tested against the material at two and four hours exposure, only the 1.5 mil thickness at four hours had any detectable drug penetration (e.g., Carmustine which has been shown previously to be the most penetrable of all drugs tested against all gown materials). It should be emphasized that at the 2.25 thickness at four hours, no penetration was detected in these studies for any of the drugs tested. It should also be noted that the current marketed VR™ gown is a 5-layered material having a 4 mil thickness to provide additional assurance against chemotherapy drug penetration.

As such, the VR™ protective gown provides universal protection against even the most penetrable of chemotherapy drugs under extreme time-of-contact conditions (i.e., four hours). The ability of the VR™ barrier protective gown to provide exposure protection is attributable to its:

- Five-layer co-extruded, cross orientation, polyolefin-based construction;
- 4 mil thickness; and
- Chemical resistance properties to aqueous-based chemicals and strong acids and bases.

Other Uses for Protective Wear in the Hospital Setting

The hospital as an institution is composed of many departments that use chemicals requiring personal protective wear during handling or spill cleanup. Listed in Appendix I are those departments and their representative chemicals that are most typically found in most hospitals.

References

(1) OSHA Technical Manual, Section VI, Chapter 2 "Controlling Occupational Exposure to Hazardous Drugs. January, 1999).

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(3) Harrison B.R. and Kloos M.D. Penetration and splash protection of six disposable gown materials against fifteen antineoplastic drugs. *J Oncol Pharm Practice*. 1999; 5: 61-66.

(4) Connor, T.H. An evaluation of the permeability of disposable polypropylene-based protective gowns to a battery of cancer chemotherapy drugs. *Applied Occupational and Environmental Hygiene*, 8:785-789 (1993).

(5) Connor, T.H. Final Report: Permeability Testing of PolyConversions, Inc. Duplex Barrier Gown Based on DRG-Tower Material. 1994.

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APPENDIX I

HOSPITAL HAZARDOUS CHEMICALS BY DEPARTMENTAL LOCATION

Location	Hazard
Central supply	Soaps, detergents Mercury
Dialysis units	Formaldehyde
Respiratory	Glutaraldehyde
Food service	Soaps, detergents Disinfectants Ammonia Chlorine Solvents Drain cleaners Oven cleaners Caustic solutions Pesticides
Housekeeping	Soaps, detergents Cleaners Solvents Disinfectants Glutaraldehyde Wastes (chemical, radioactive infectious)
Laboratory	Acids/Bases Benzene Formaldehyde Solvents Flammable and explosive agents Carcinogens Teratogens Mutagens Wastes (chemical, radioactive, infectious)
Laundry	Detergents, soaps Bleaches Solvents Wastes (chemical and radioactive)

Maintenance and engineering	Flammable liquids Solvents Mercury Pesticides Cleaners Ammonia Paints, adhesives Water treatment chemicals Muratic Acid
Operating rooms	Methyl methacrylate
Pathology	Formaldehyde Glutaraldehyde Flammable substances Solvents Phenols
Patient care	Chemotherapeutic agents
Pharmacy	Pharmaceuticals Antineoplastic agents Mercury
Print shops	Inks Solvents