

A significant body of science and research is available on the subjects of environmental contamination and the health issues related to the handling of hazardous drugs. Below is a summary of six key studies on this topic. For a comprehensive list of references regarding environmental contamination and hazardous drug handling, please see NIOSH Publication No. 2004-165 from September 2004: *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings* (<http://www.cdc.gov/niosh/docs/2004-165/2004-165c.html#n>).

Connor TH, Anderson RW, Sessink PJ et al. *Surface contamination with antineoplastic agents in six cancer treatment centers in Canada and the United States. AJHP 1999; 56: 1427-1432.*

Significant surface contamination of cyclophosphamide, ifosfamide and 5-fluorouracil were found outside biological safety cabinets on floors and cabinets both in preparation and administration areas at six cancer treatment centers in the United States and Canada. All sites had been using practices that were thought to adequately contain these drugs, such as biological safety cabinets (BSCs). Measurable amounts of antineoplastic drugs were detected in 75% of the pharmacy samples and 65% of the administration area samples.

Study concludes that "reliance on BSCs to provide total protection from exposure to antineoplastic agents may be misguided and may provide a false sense of security." It is suggested that a thorough review of current procedures be undertaken to ensure that health care workers are adequately protected from the handling of dangerous agents.

Valanis B, Vollmer WM, Steele P. *Occupational exposure to antineoplastic agents: self-reported miscarriages and stillbirths among nurses and pharmacists. J Occup Environ Med 1999; 41: 632-638.*

Data suggests that there is a statistically significant increase of risk of miscarriage for women handling cytotoxic agents just prior to, or during pregnancy. The authors indicate that "... there is sufficient evidence of possible harm such that women of childbearing age and men planning to have children should use all available protection when handling these drugs."

Connor TH, Anderson RW, Sessink PJ et al. *Effectiveness of a closed-system device in containing surface contamination with cyclophosphamide and ifosfamide in an IV admixture area. AJHP 2002; 59: 68-72.*

The closed-system drug transfer device was tested at the MD Anderson Cancer Center in Houston in conjunction with biological safety cabinets. Surface contamination resulting from the preparation of cyclophosphamide and ifosfamide was contained in periods measuring up to 168 days in a high-volume IV admixture area.

Sessink PJM, Rolf, ME, Ryden NS. *Evaluation of the PhaSeal® hazardous drug containment system. Hosp Pharm. 1999; 34: 1311-1317.*

Study demonstrates that there were "no detectable levels" of environmental contamination from cyclophosphamide or fluorouracil in an outpatient oncology clinic following one year of use of the PhaSeal® system for preparation and administration of these drugs. Study was completed outside of a biological safety cabinet to confirm that the PhaSeal System alone could contain the drugs.

The authors also concluded that "there is no need to invest in and maintain a cleanroom facility with a ventilation system and a biological safety cabinet when PhaSeal® is used." It was noted that using fewer personal protective measures have lowered costs.

Spivey SM, Connor TH. *Determining Sources of Workplace Contamination with Antineoplastic Drugs and Comparing Conventional IV Preparation with a Closed System. Hospital Pharmacy. 2003; 38: 135-139.*

Standard needle and syringe techniques were used to manipulate fluorescein solutions in five steps, ranging from drug reconstitution to IV administration. Using UV light, the result of the manipulations demonstrated solution release to the environment in every one of the five phases.

When the same process was then repeated with the closed system in 75 separate manipulations, there was no release to the environment in any situation.

Wick C, Slawson MH, Jorgenson JA, Tyler LS. *Using a closed-system protective device to reduce personnel exposure to antineoplastic agents. AJHP 2003; 60: 2314-2320.*

This comprehensive study (University of Utah) includes an excellent summary of the progression of procedures recommended during the last 20 years to protect US healthcare workers from the dangers of handling antineoplastic drugs. The authors conclude that the problem is not yet solved.

Study indicates wipe studies in multiple pharmacy and infusion center areas showed significant cyclophosphamide and ifosfamide contamination despite using all customary procedures such as class II biological safety cabinets. Wipe studies conducted in the same areas after 6 months of using PhaSeal[®] showed dramatic reductions in environmental contamination levels.

Prior to implementing the closed-system drug transfer device (CSDTD), urine samples were taken from a total of eight pharmacists, IV technicians and nurses with 32 of 94 samples testing positive for the two drugs studied. After six months of CSDTD use, subsequent urine samples tested negative for both drugs.