

PEER-REVIEWED ARTICLE

Evaluation of the *PhaSeal* Hazardous Drug Containment System

Paul J. M. Sessink, PhD,* Mary-Ann E. Rolf, RN,** and N. Stefan Rydén, MD, PhD†

Abstract — *PhaSeal is a containment system designed to ensure the safe preparation and administration of cytostatic drugs and thus reduce environmental contamination to work areas and to medical and support staff. The PhaSeal system was tested in an outpatient setting in Sweden for 1 year during the preparation and administration of cyclophosphamide, fluorouracil, and similar cytostatic drugs. The study was designed to determine the effectiveness of PhaSeal in preventing the leakage of cytostatic drugs frequently reported in a number of studies. Cytostatic drugs were prepared and administered using standard safety procedures, except that a biological safety cabinet was not used. At the conclusion of the study period, environmental contamination was determined from wiping samples of objects and surfaces in the drug preparation room. Neither cyclophosphamide nor fluorouracil was found in any of these samples. Results show that use of the PhaSeal system alone is sufficient to prevent environmental contamination during the preparation of cytostatic drugs.*

Key Words — *cytostatic drugs; environmental contamination; cyclophosphamide; fluorouracil; closed system; containment device*

Hosp Pharm — 1999;34:1311-1317

Cytostatic drugs are widely used in the treatment of cancer and certain non-neoplastic diseases.¹⁻³ This

class of drugs exhibits a high degree of biological activity and acts primarily by interfering with the synthesis of DNA during the replication of

tumor cells, resulting in a marked decrease in the replication of malignant cells.

Cytostatic drugs are highly non-selective in their activity, however, resulting in extensive damage to normal (nontumor) cells during normal replication. Health care workers are routinely exposed to low levels of these drugs in the workplace, potentially on a daily basis.

TOXIC SIDE EFFECTS

Patients treated with cytostatic drugs commonly exhibit acute and dose-limiting side effects, including irritation of the skin, eyes, and mucous membranes; alopecia; nausea; vomiting; and diarrhea. More toxic side effects have been documented in bone marrow, liver, bladder, kidney, and lung tissue.^{1,2,4,5}

The long-term toxic side effects of cytostatic drugs include mutagenic, carcinogenic, and reproductive changes.³ The International Agency for Research on Cancer (IARC) has determined that a sufficient body of data exists to support the human car-

*Chemist/Toxicologist, Exposure Control, Wijchen, The Netherlands; **Oncology Nurse Specialist, Oncology Outpatient Clinic, Ängelholm Hospital, Ängelholm, Sweden; †Associate Professor, Department of Surgery, Ängelholm Hospital, Ängelholm, Sweden

Address correspondence to Paul J. M. Sessink, Exposure Control, P.O. Box 467, 6600 AL Wijchen, The Netherlands. Tel: (31) 24 645 27 45; Fax: (31) 24 645 27 46; E-mail: exposure.control@wxs.nl

Portions of this study were presented by Dr. Sessink at the M.D. Anderson Cancer Center's 19th Annual Pharmacy Symposium on Cancer Chemotherapy, October 5-7, 1997, in Houston, TX.

Financial support for this study was provided by Carmel Pharma ab, P.O. Box 5352, S-40228 Göteborg, Sweden. Tel (46) 31 703 04 00; Fax (46) 31 703 04 04. *PhaSeal* is manufactured and marketed by Carmel Pharma ab, P.O. Box 5352, SE-40228, Göteborg, Sweden. Tel: (46) 31 703 0400; Fax: (46) 31 703 0404. In the United States, *PhaSeal* is marketed by Carmel Pharma Inc., One Reservoir Corporate Center, Suite 206, Research Drive, Shelton, CT 06484. Tel: 203-925-8821; Fax: 203-925-8890; E-mail: christdgc@carmelusa.com