

**Building a successful US business
a personal experience**

Building a successful US business a personal experience

The mindset

The customer

The product

The message

The people

The mindset

The Mindset

- Top management involvement critical
- Firsthand understanding essential
- Presence a must
- Accept differences but maintain leadership
- Reiterate strategy and direction until it becomes a mantra

The Customer

- Make sure the customer is properly identified
- Make sure YOU understand the customers and their needs and sometimes more importantly their fears

The Product

Technology and clinical benefits must be cutting edge

Financial parameters may supersede clinical benefits

The Message

Clearcut message
Clearcut to everyone
Clearcut need to everyone
Make them experience it
Make it visual – never to forget
Make it matter above the clutter

**UTAH Protocol
MDA/UTAH Study**

Movie time

Article

How to protect environment and employees against cytotoxic agents, the UZ Ghent experience

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Objective. To compare two different systems for the reconstitution and preparation of cytotoxic drug-containing infusion bags. The Classical System (open) uses Luer lock syringes and needles, and the PhaSeal® system (closed) uses special devices.
Methods. Both wipe samples of the Biological Safety Cabinet (BSC) plus surroundings and urine analysis of technicians and pharmacists involved in the preparatory activities were used. Analyses were performed using gas chromatography in tandem with mass spectrometry.

Results. An important difference has been found in the surface contamination rate and in the number, periods and values of contaminated urine samples in favour of the closed PhaSeal® system.
J Oncol Pharm Practice (2001) 6, 146–152.

Key Words: Cytotoxic drugs; contamination; cyclophosphamide; pharmacy; toxicity; health risk; environmental; wipe samples; urine samples; cytotoxic contamination; monitoring; safe handling.

INTRODUCTION

Since 1999, there has been a significant increase in international interest on the safety aspects of handling cytotoxic agents. This has been accompanied by a change of attitude towards the risks of handling these products, similar to the change in attitude 20 years ago regarding the risks of radiation. Also, the publication of several studies about the health risk associated with occupational exposure to cytotoxic agents^{1–5} and the chemical/physical properties of cytotoxic drugs^{6,7} has raised awareness on these issues.

In 1995, the Ghent University Hospital started a multidisciplinary Quality Assurance Programme: "Handling cytotoxics in hospital environment." In 1997, this project became an official quality project supported by the government, the Ministry of Social Security, Health, and Environment. Part of this project

involved the monitoring of people and the environment during preparatory activities of cytotoxic drugs in the pharmacy unit oncology.

THE MONITORING PROGRAM: AIM OF THE STUDY

The aim of the study is to determine if there is a difference in contamination risk between two systems for the reconstitution and preparation of cytotoxic drug-containing infusion bags.

Classical System (CS)

The CS uses Luer lock syringes and needles and is therefore classified as "open" system as droplets can be liberated during the activities. The people involved in this part of the study are well-trained pharmacy technicians with a broad experience in preparing sterile and cytotoxic preparations. The procedures followed are in accordance with our internal "safety handbook for cytotoxics."

PhaSeal® System (PS)

The PhaSeal consists of three different parts to be connected on the vial (injector, Fig. 1), syringe (injector, Fig. 2), and injection port of the infusion bag (connector, Fig. 3). The combination of the different

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FEATURED ARTICLE

Workplace Contamination with Antineoplastic Agents in a New Cancer Hospital Using a Closed-System Drug Transfer Device

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Abstract

Objective: To determine levels of environmental chemotherapy contamination in a new cancer hospital that has exclusively used a closed-system drug transfer device (PhaSeal) for preparing and administering all compatible antineoplastics.

Methods: After 6 months of operation, surface samples were collected from pharmacy and nursing areas to determine levels of contamination with cyclophosphamide and ifosfamide. In addition, urine samples were collected from pharmacists, pharmacy technicians, and nurses to determine employee exposure to these agents. All samples were analyzed using liquid chromatography/tandem mass spectrometry.

Results: Twenty-one percent (7/34) of surface samples collected tested positive for cyclophosphamide contamination. Twelve percent (4/34) of surface samples tested positive for ifosfamide. To place this into perspective, historical data collected at our outpatient oncology infusion clinic 6 months after converting to PhaSeal from conventional methods of antineoplastic preparation showed 33% (7/21) and 71% (15/21) of samples tested positive for cyclophosphamide and ifosfamide, respectively. The level of ifosfamide contamination found in samples that tested positive at our new hospital also appeared to be lower than in positive samples at the outpatient infusion clinic. In the current study, the urine of one participant (1/11), a pharmacy technician, tested positive for low levels of cyclophosphamide and ifosfamide. To compare, 71% and 0% of participants tested at the outpatient infusion clinic had positive urine samples prior to and 6 months after implementation of PhaSeal, respectively.

Conclusion: Compared with historical levels of contamination in our outpatient oncology infusion clinic, levels of chemotherapy contamination appeared lower. However, some contamination was still present in our new cancer hospital where PhaSeal had been used exclusively.

Keywords: environmental contamination; antineoplastic drugs; containment device; closed system; cyclophosphamide; ifosfamide; PhaSeal; closed-system drug transfer device

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Health care workers who prepare and administer antineoplastic agents risk exposure to these drugs. Although the long-term effects of exposure to relatively low levels of antineoplastic agents over long periods of time is unknown, some literature

reports suggest that hazards may include rash, infertility, birth defects, miscarriages, and a possible increased risk of cancer.^{1,2} Much of these data regarding the potential adverse effects of occupational exposure predate current standards for hazardous drug

preparation and administration, which include negative pressure cleanrooms, vented class II or III biological safety cabinets or compounding aseptic barrier isolators, appropriate personal protective devices, including gowns, gloves, masks, and caps, and policies to guide storage of contaminated waste. However, no safe level of exposure to antineoplastic agents has been set in the US.

Despite current safety measures, studies continue to find

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Evaluation of Vial Transfer Devices for Containment of Hazardous Drug Vapors

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BACKGROUND

Medical personnel have been examining the issues of exposure to hazardous medications and prevention. Malformations, spontaneous abortions, and stillbirths have been associated with exposures to cytostatic agents. Closed-system drug-transfer devices are recommended by the National Institute for Occupational Safety and Health (NIOSH) for the containment of hazardous drugs. The purpose of this study is to examine several available products utilized for drug-transfer to determine which device prevents the escape of vapor meeting the NIOSH definition of a closed-system.

METHODS

Five drug-transfer devices were tested:
 ♦Tevadaptor™ Vial Adaptor System (Teva Medical Ltd.)
 ♦Chemo Mini-Spike Plus™ Dispensing Pin (B. Braun Medical Inc.)
 ♦Alaris® Smart Site® (Cardinal Health)
 ♦Chemoprotect Spike® (Codan US Corporation)
 ♦PhaSeal® Protector 50 & Injector Luer Lock (Carmel Pharma)

Titanium tetrachloride (TiCl₄) was used to simulate gas-containing active drug. Titanium tetrachloride generates very visible smoke when it comes into contact with moisture in the air. It was placed into glass vials attached to the above closed-system devices to determine which system prevents the escape of vapor.

RESULTS/CONCLUSIONS

Only the PhaSeal® system prevented the release of titanium smoke out of the closed-system drug-transfer device.

Only the PhaSeal® system met the definition of a closed-system drug-transfer device.

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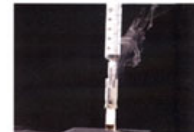
PhaSeal®
(Carmel Pharma)



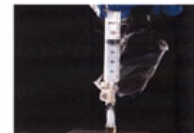
Chemo Mini-Spike Plus™ Dispensing Pin
(B. Braun Medical Inc.)



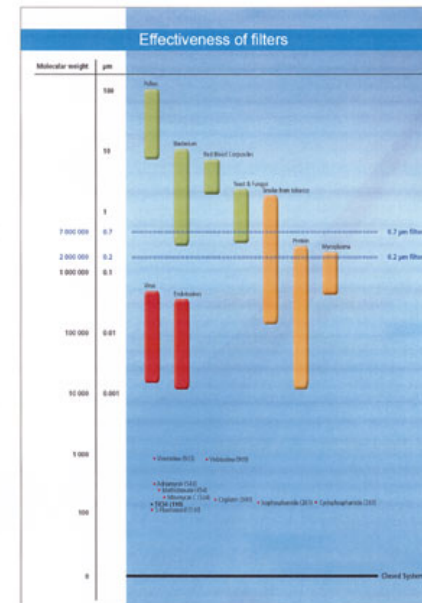
Alaris® Smart Site®
(Cardinal Health)



Tevadaptor™
(Teva Medical Ltd)



Chemoprotect Spike®
(Codan US Corporation)

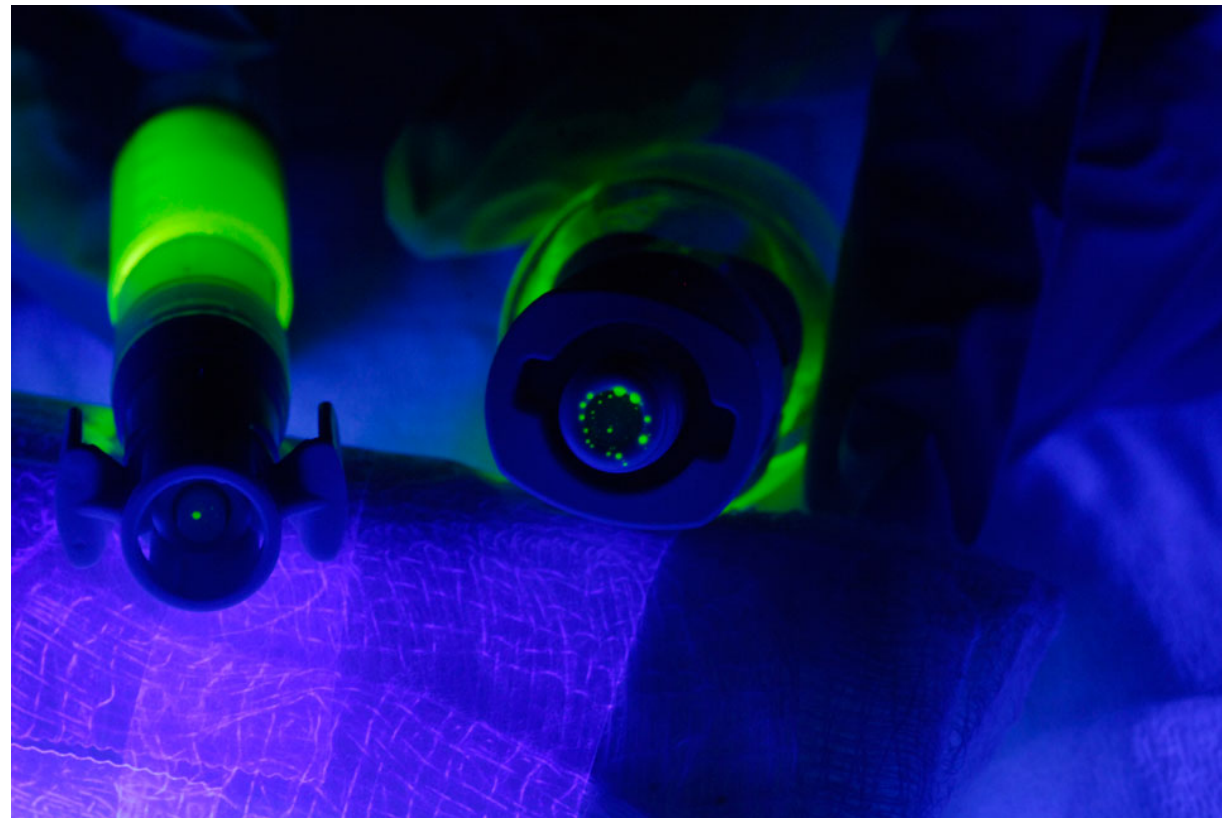


**MD Anderson Cancer Center Houston
and University of Utah**

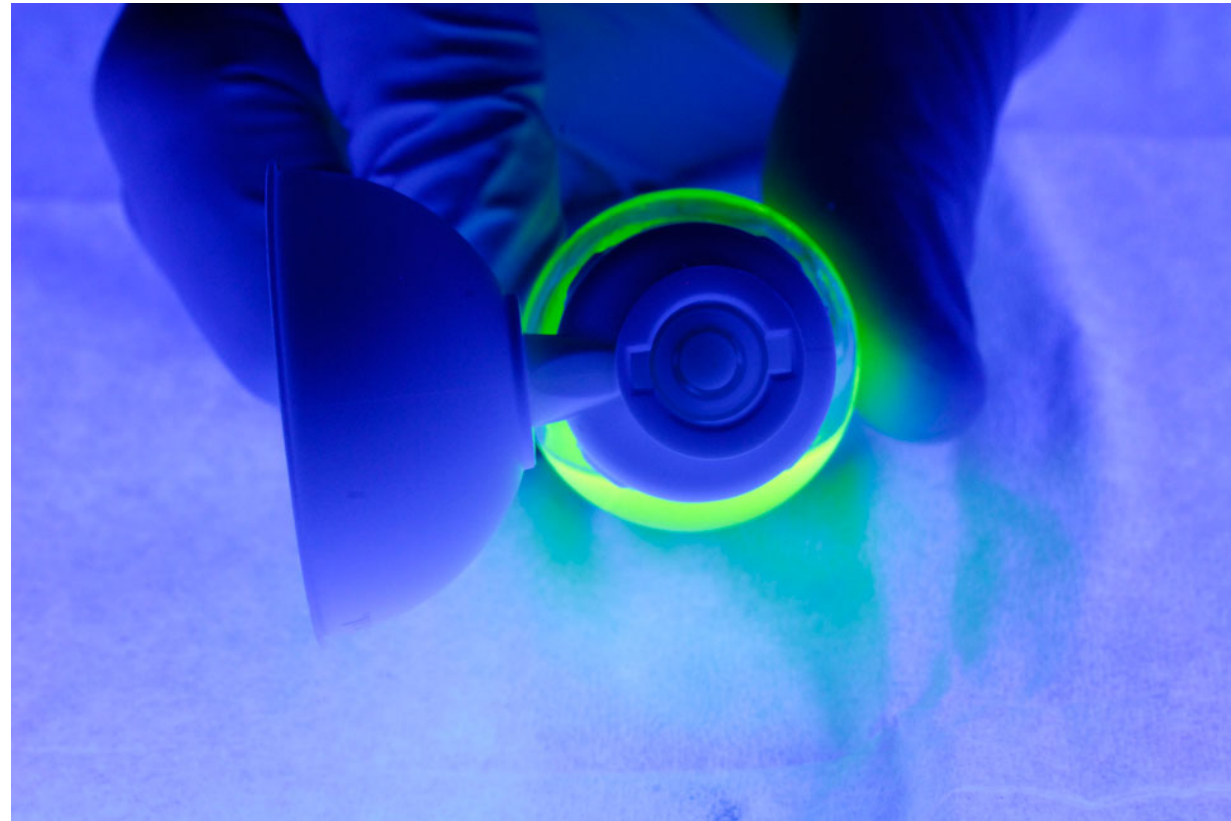
Contamination Comparison of Transfer Devices
Intended for Handling Hazardous Drugs

At ONS May 2007 Las Vegas

Tevadaptor by Teva Medical



PhaSeal Protector by Carmel Pharma



The People

Personality
Religion
Flak jacket
Everpresence