

Evaluation of surface contamination with cyclophosphamide following simulated hazardous drug preparation activities using two closed-system products

Zock M, Soefje S, Rickabaugh K, J Oncology Pharm Practice. 2010; Aug 10

PURPOSE

This study evaluated the effectiveness of two closed-system drug transfer products, the ChemoClave™ Oncology Preparation and Delivery System by ICU Medical, Inc., and the PhaSeal® Preparation and Delivery system by BD (Becton, Dickinson and Company), in preventing contamination in a typical pharmacy workplace.

MATERIALS AND METHODS

The ChemoClave system, and the PhaSeal system were evaluated in a two-day comparative study simulating hazardous drug preparation in a controlled laboratory setting. Cyclophosphamide (CP) was the hazardous drug marker. Samples were collected from gloves, workbench, airfoil, and floor before and after each trial. Forty vials of lyophilized cyclophosphamide were divided into two groups of 20 vials each. Wipe samples were collected before each trial and after cleaning with SurfaceSafe®.

RESULTS

ChemoClave system: CP was detected on the exterior of some of the vials. None was found on the BSC airfoil/grille or on the floor; however CP was detected on the workbench and gloves. Researchers noted it was possible that the chemical contamination on the vials “contributed to the low level detected on the BSC workbench” and was spread from the vials to the technician’s gloves, and ultimately to the workbench.

PhaSeal system: No CP was detected on the exterior of the vials. CP was detected on the BSC workbench. Because no CP was detected on the exterior of vials or gloves, surface transfer is unlikely to have occurred. On two occasions the Luer Lock protective needle caps failed to retract when withdrawn from the vial, exposing the needles. In addition to creating a needlestick hazard, droplets that would have ordinarily been contained could have contaminated the workbench.

Table 2. Summary of pre-trial sample results

Surface description	Surface area (cm ²)	Prior to ChemoClave™ trial		Prior to PhaSeal® trial	
		Cyclophosphamide (ng)	Cyclophosphamide concentration (ng/cm ²)	Cyclophosphamide (ng)	Cyclophosphamide concentration (ng/cm ²)
Floor	4400	nd ^a	<0.004	nd	<0.004
Airfoil/grill	2000	nd	<0.008	nd	<0.008
Workbench	4400	nd	<0.004	nd	<0.004

^and = not detected (cyclophosphamide < 15.7 ng).

Table 3. Summary of post-trial sample results

Surface description	Surface area (cm ²)	Following ChemoClave™ trial		Following PhaSeal® trial	
		Cyclophosphamide (ng)	Cyclophosphamide concentration (ng/cm ²)	Cyclophosphamide (ng)	Cyclophosphamide concentration (ng/cm ²)
Floor	4400	nd ^a	<0.004	nd	<0.004
Airfoil/grill	2000	nd	<0.008	nd	<0.008
Workbench	4400	468	0	622	0
Gloves	2 gloves	377	na ^b	nd	na

^and = not detected (cyclophosphamide < 15.7 ng).

^bna = not applicable

CONCLUSION

The ChemoClave and PhaSeal systems, when operated properly, are similarly effective. Vial contamination may have contributed to the low level of CS observed on the BSC workbench following the ChemoClave trial. Work practices and procedures regarding product operation may have contributed to the low level of CS observed on the BSC workbench following the PhaSeal trial. Work practices and procedures regarding product operation appeared to be an important factor in hazardous drug containment and needle safety when using PhaSeal, but not when using ChemoClave, which requires fewer steps and it is needlefree.