# Containment Testing to Assess the Efficacy of Closed System Transfer Devices

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## BACKGROUND

- Hazardous Drugs (HD) are associated with numerous toxicities; including reproductive, teratogenic, carcinogenic, and organ toxicities
- United States Pharmacopeia Chapter <800> requires nursing usage of closed system transfer devices (CSTDs) for HD administration
- Two standard classifications of CSTDs available are filter-based and barrier-based
- The initial NIOSH protocol suggests the use of the smoke-test and the tracer test, which uses 70% isopropyl alcohol as a surrogate to HDs
- Filter-based CSTDs have routinely failed simulated smoke tests and 70% isopropyl alcohol tracer tests
- 70% isopropyl alcohol fails to sufficiently mimic the chemical properties of many HDs

## OBJECTIVE

- The primary objective was to compare the contamination between barrier and filter-based closed-system transfer devices

## METHODS

- Two barrier-based (Equashield® and PhaSeal™) and two filter-based (Tevadapter® and ChemoClave®) CSTDs were used to manipulate ten samples each of ifosfamide, methotrexate, and etoposide
- Three manipulations performed at approximately 0, 4-6, and ≥24 hours for each drug-device combination
- After each manipulation, the vial/vial adapter was disconnected from the syringe/syringe-adapter and the membranes were wiped with a ChemoGLO™ wipe
- Once all three manipulations had been completed, each bag was opened and wiped using ChemoGLO™ wipes
- Before opening a new drug-device combination, the laminar flow hood was wiped using ChemoGLO™ HDClean wipes
- Completed ChemoGLO™ Wipe Kits were sent to ChemoGLO™ to be analyzed using LC-MS technology
- Student's t-test was used for two-way comparisons and two-way ANOVA for comparison of average contamination among devices

## RESULTS

| Device | Ifosfamide (ng/ft²) | Methotrexate (ng/ft²) | Etoposide (ng/ft²) | Overall (ng/ft²) |
|---|---|---|---|---|
| Equashield® | 37.7 | 15.4 | 2.2 | 18.4; 95% CI 0-328.2 |
| PhaSeal™ | 2839.5 | 12 | 14.3 | 955.2; 95% CI 708.6 - 1201.9 |
| Tevadaptor® | 1348.2 | 1036.6 | 643 | 1009.3; 95% CI 739.1 - 1279.5 |
| ChemoClave® | 3858.9 | 2550.3 | 3878 | 3429.1; 95% CI 3125.8 - 3732.3 |

**Table 1: Average contamination stratified by device and HD**

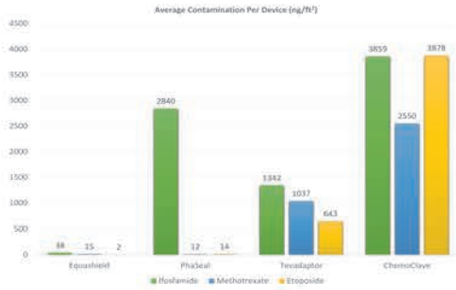


**Chart 1: Average contamination stratified by device(ng/ft²)**

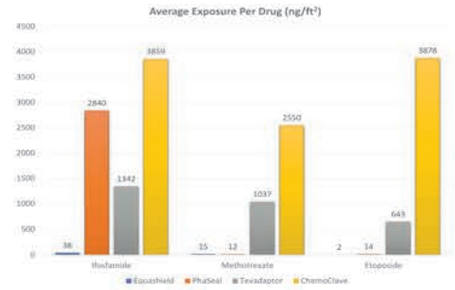


**Chart 2: Average contamination stratified by HD (ng/ft²)**

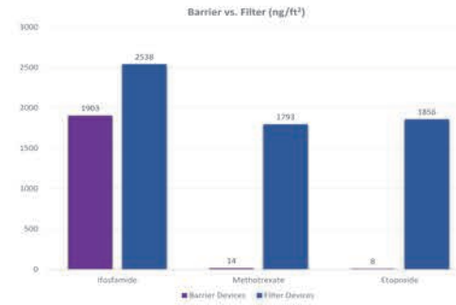


**Chart 3: Comparison of exposure between barrier- and filter-based devices(ng/ft²)**

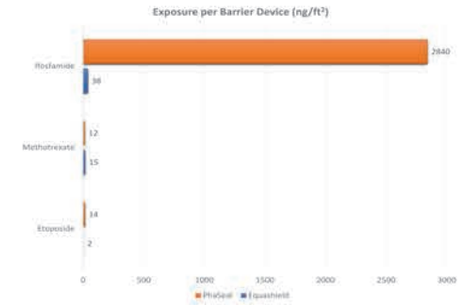


**Chart 4: Comparison of exposure between barrier devices (ng/ft²)**

| CSTD Type | | Mean Contamination Difference (ng/ft²) | P-Value |
|---|---|---|---|
| Comparator A | Comparator B | | |
| Barrier | Filtration | 1732; 95% CI 1459 - 2006 | P<0.001 |
| Equashield® | Pooled Average | 1780; 95% CI 1466 - 2093 | P<0.001 |
| Equashield® | PhaSeal™ | 936.9; 95% CI 571 - 1303 | P<0.001 |

**Table 2: Summary of primary and secondary outcome results**

## CONCLUSIONS

- Barrier-based devices are associated with significantly less HD contamination than filter-based devices
- There was significant contamination when using PhaSeal™ with ifosfamide manipulations
- Potentially, there are unstudied chemical characteristics of HDs that affect the performance of CSTDs
- Compared to all other CSTDs, Equashield® had significantly lower contamination than all other CSTDs tested
- The smoke test and 70% isopropyl alcohol vapor test do not adequately assess the effectiveness in controlling HD contamination
- Further studies are needed to fully elucidate the effects of various HDs on CSTD performance

## DISCLOSURE

**The authors of this presentation have the following disclosures concerning possible financial or personal relationships with commercial entities:**

- Joseph Arminger, BS, PharmD – No Disclosures
- Alyson Leonard, PharmD, BCPS – No Disclosures
- Adam Peele, PharmD, MHA, BCPS, BCOP – No Disclosures
- Crystal Peyton, BS, CPhT – No Disclosures

**Funding provided by Equashield, LLC**

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