

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 (Tevadaptor® 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/ft ²)	Methotrexate (ng/ft ²)	Etoposide (ng/ft ²)	Overall (ng/ft ²)
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

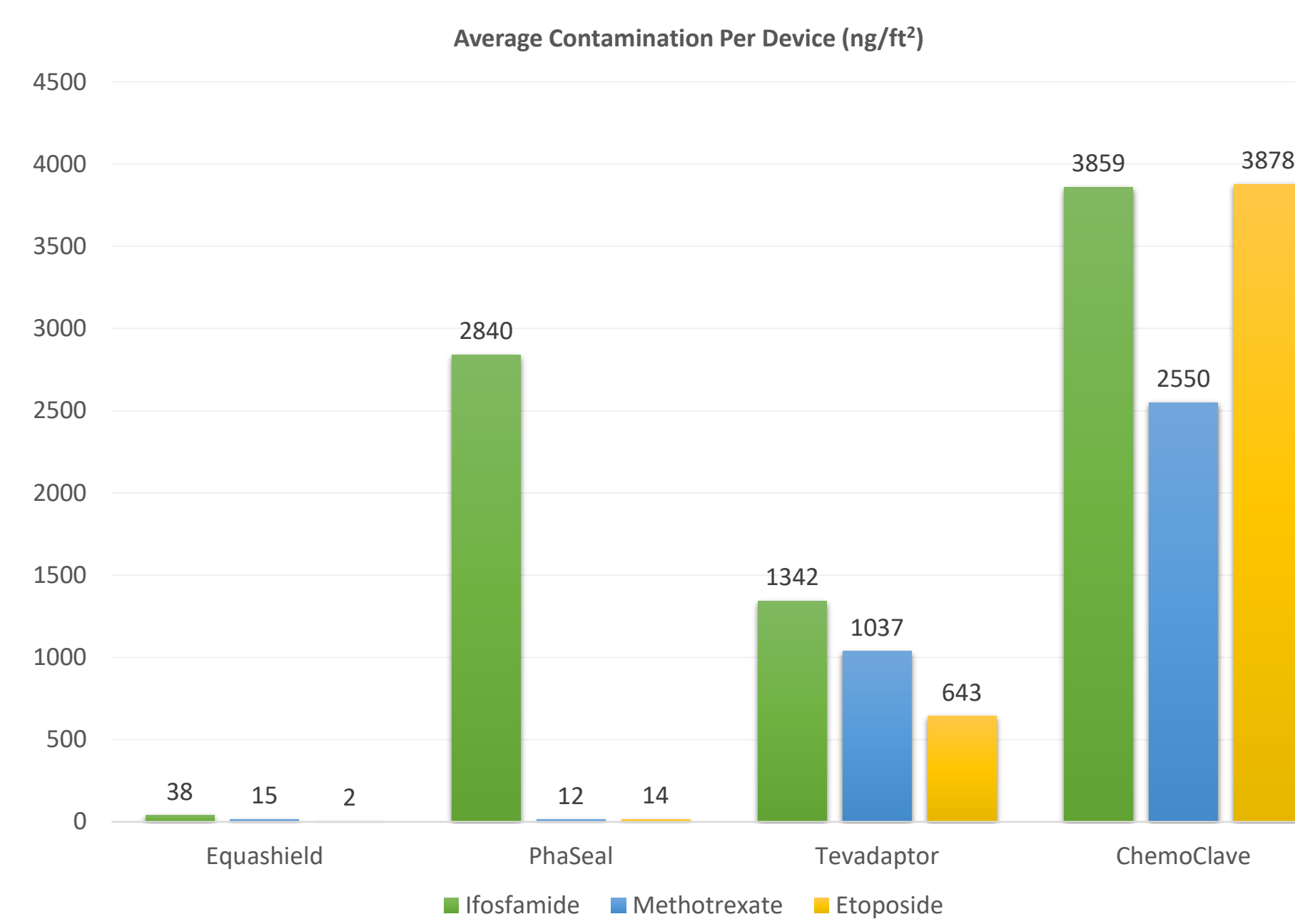


Chart 1: Average contamination stratified by device(ng/ft²)

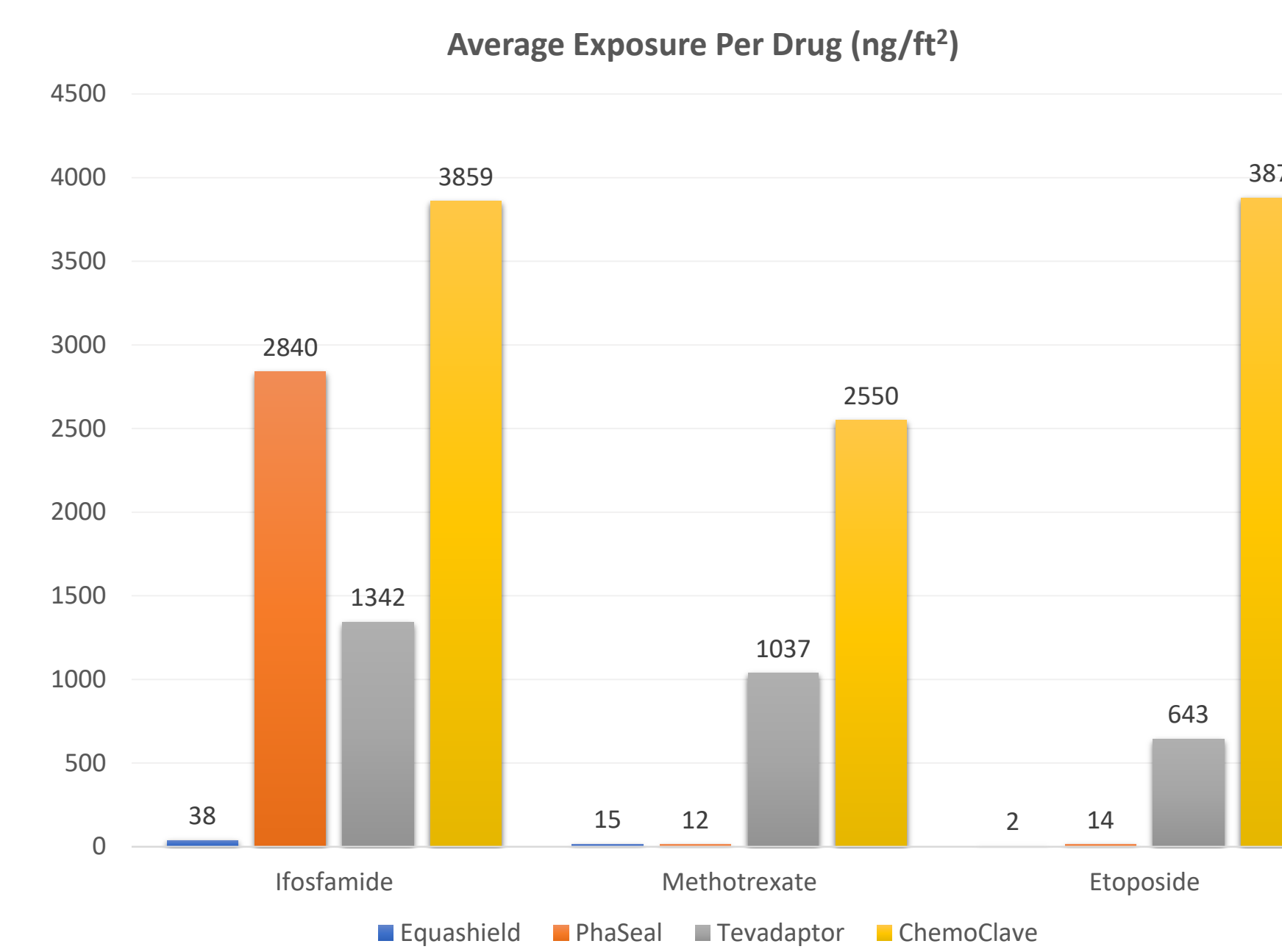


Chart 2: Average contamination stratified by HD (ng/ft²)

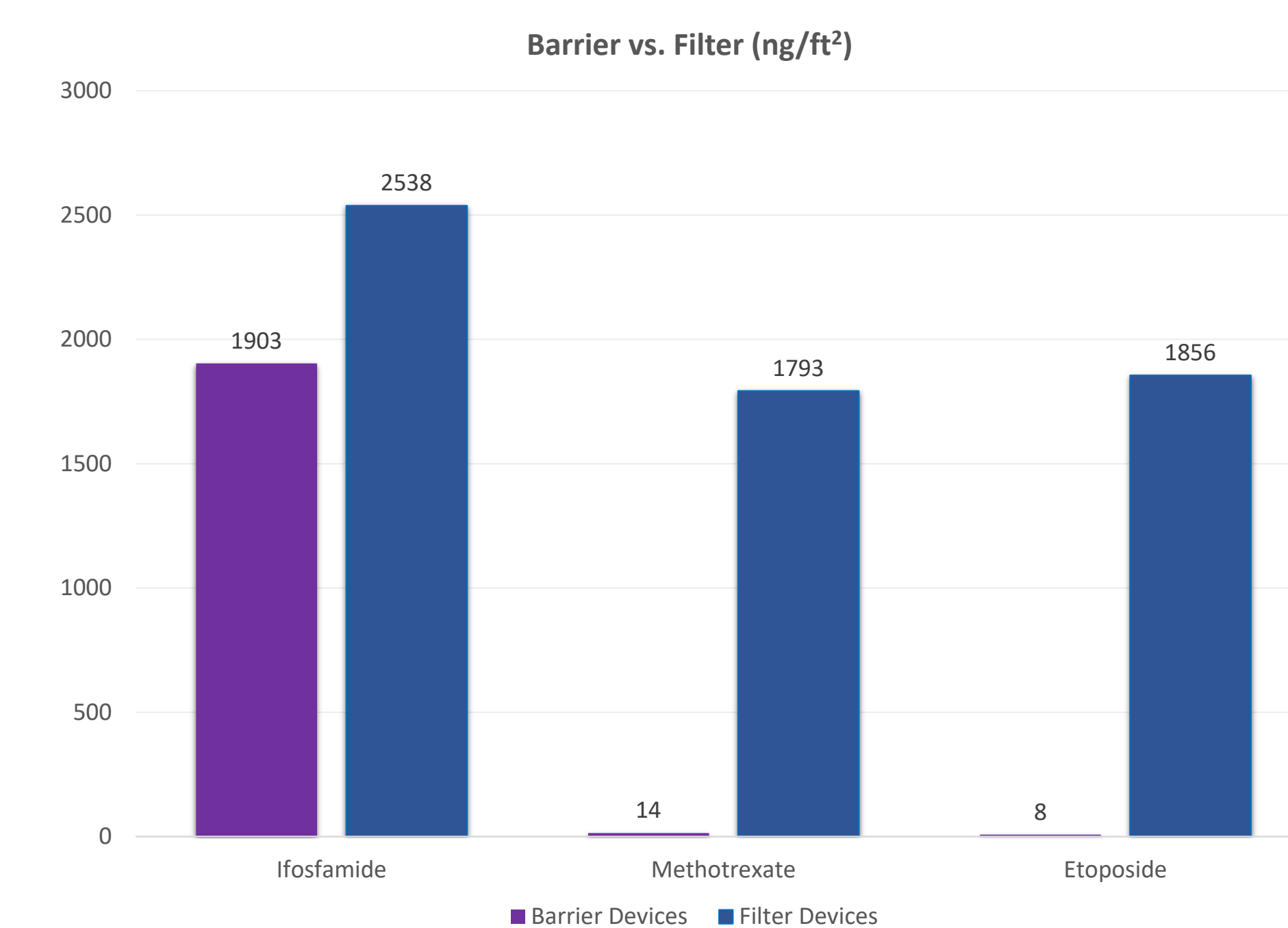


Chart 3: Comparison of exposure between barrier- and filter-based devices(ng/ft²)

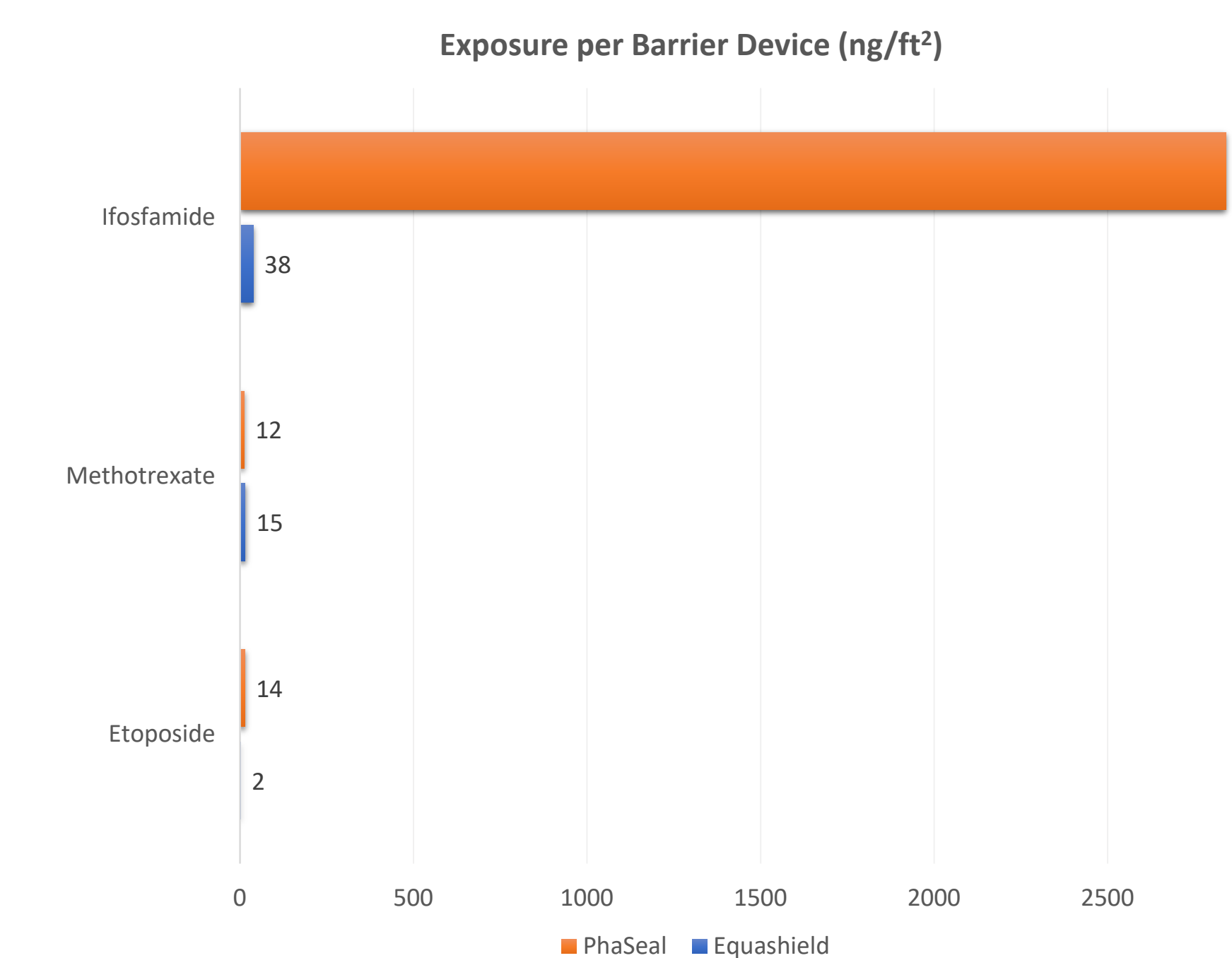


Chart 4: Comparison of exposure between barrier devices (ng/ft²)

CSTD Type		Mean Contamination Difference (ng/ft ²)	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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