# Application of vapor containment protocol for closed system transfer devices to assess efficacy during pharmacy compounding and administration of hazardous drugs

The NIOSH Vapor testing performing by UNC in 2016 using Isopropyl Alcohol(IPA) as a surrogate has finally **published in JOPP**. As a primer, below are some details about this study:

- Study Evaluates Equashield, Phaseal, ChemoLock, ChemoClave, Tevadaptor/OnGuard and CareFusion VialShield
- The study used NIOSH Original Protocol with testing with IPA as a surrogate
- Of the six devices tested with two tasks (one task for preparation and another task for administration), only two passed the NIOSH suggested threshold of <1PPM (parts per million) detection of alcohol vapors.

  Two 'truly' closed systems that can contain alcohol vapors (and therefore any drug vapors, as IPA is deemed as the worst case) include Equashield and PhaSeal

Please feel free to share with your customers/potential customers, but please keep in mind the following:

1. NIOSH is still in the process of defining the right surrogate for testing CSTDs for their ability to contain vapor
2. NIOSH was pushed by industry (filter based system manufacturer) to abandon a protocol that took five years in the making for a more 'universal' protocol
3. Currently, there is no 'official' NIOSH Protocol. However, the IPA protocol is the most defined and tested protocol in the market
4. Our stance is, if a CSTD can contain IPA vapors, it can contain any other weaker surrogate and therefore any Hazardous Drug Vapors
5. Ultimately, Equashield and PhaSeal are the only two true CSTDs on the market that can contain IPA. All others tested, seem to fail in containing vapors.
6. In addition to vapors, a decision maker still needs to consider liquid leakage as a second measure of CSTDs ability to contain the hazardous drug.

Please find attached the initial UNC Poster and the newly published Peer-Reviewed Study.

# Application of vapor containment protocol for closed system transfer devices to assess efficacy during pharmacy compounding and administration of hazardous drugs

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## BACKGROUND

- Recent United States Pharmacopeia 800 guidelines require the use of closed system transfer devices (CSTDs) for hazardous drug administration.
- The National Institute for Occupational Safety and Health (NIOSH) released a proposed protocol to compare CSTDs for their ability to contain vapors.[1]
- To date, limited data exists for a comprehensive evaluation of various CSTDs against this protocol.

## PURPOSE

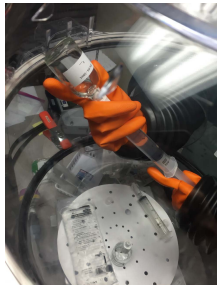
- To compare the ability of 6 different marketed and available CSTD products to adequately contain hazardous drug vapors during IV compounding and administration following the NIOSH vapor containment protocol.

## METHODS

- Each CSTD product underwent a testing process which evaluated the system during both compounding (Task 1) and administration (Task 2). The process in each task was repeated for a total of 4 manipulations per device.
- Task 1: The technician added 90 mL of isopropyl alcohol, using two 45 mL transfers from two 60 mL syringes and two 50 mL vials, to a 500 mL normal saline IV bag. The CSTD components evaluated under this task included one bag adapter, two vial adapters, and two syringe adapters.
- Task 2: The technician prepared a 45 mL dose of isopropyl alcohol in each of two 60 mL syringes and injected each syringe into the Y-site of the IV tubing, simulating an IV push. The CSTD components evaluated under this task included two vial adapters, two syringe adapters, one bag adapter, and one IV port adapter.
- Vapor release was detected by the Miran Analyzer. Data points were recorded in real time after the following steps: capping of 2 vials with CSTDs, withdrawal of 45 mL from the first vial, injection of 45 mL into a bag, withdrawal of 45 mL from the second vial, and injection into a bag (Task 1) or an IV administration tubing (Task 2).

FIGURE 1. Environmental test chamber with sample hose.

FIGURE 2. Manipulation of withdrawal from isopropyl alcohol vial inside test chamber.



## RESULTS

### TASK 1

TABLE 1. Summary of the mean maximum concentrations of isopropyl alcohol observed for each CSTD product throughout Task 1.

| Product (n=4) | Mean of BG-$0_{max}$ Concentration (ppm)+ | 95% Confidence Interval (ppm)# |
|---|---|---|
| Equashield® | 0.35 | 0.25 - 0.45 |
| PhaSeal™ | 0.48 | 0.13 - 0.82 |
| ChemoLock™ | 0.93 | 0.59 - 1.26 |
| ChemoClave® | 2.68* | 2.05 - 3.30 |
| Vial Shield | 4.88 | 4.09 - 5.66 |
| OnGuard™ w/ Tevadaptor® | 10.7* | 8.21 - 13.34 |

Data points were background-corrected and zero-adjusted for the detection limit of the equipment (0.3 ppm). The point of interest for each sample was the maximum value observed, and those values were averaged to give the Mean of BG-$0_{max}$ concentration values for each CSTD.

### TASK 2

TABLE 2. Summary of the mean maximum concentrations of isopropyl alcohol observed for each CSTD product throughout Task 2.

| Product (n=4) | Mean of BG-$0_{max}$ Concentration (ppm)+ | 95% Confidence Interval (ppm)# |
|---|---|---|
| PhaSeal™ | 0.30 | 0.30 - 0.30 |
| Equashield® | 0.60 | 0.34 - 0.81 |
| ChemoLock™ | 0.60 | 0.39 - 0.81 |
| ChemoClave® | 2.60* | 1.29 - 3.91 |
| Vial Shield | 5.40 | 4.01 - 6.71 |
| OnGuard™ w/ Tevadaptor® | 14.85* | 12.76 - 16.94 |

+ Average values less than 1.0 ppm indicated successful containment of isopropyl alcohol vapor.

# A CSTD failed to effectively contain vapor if the 95 percent confidence interval contained greater than or equal to 1.0 ppm.

*Testing stopped early in manipulation process due to high levels of isopropyl alcohol vapor leakage.

## CONCLUSION

- For Task 1, 2 CSTDs successfully contained isopropyl alcohol vapor; for Task 2, 3 CSTDs successfully contained the isopropyl alcohol vapor per NIOSH protocol.
- Based on these results, only 2 CSTDs completely eliminated the vapor release during both compounding and administration of hazardous drugs.
- To improve patient outcomes and employee safety in chemotherapy preparation, CSTDs that demonstrate no leakage should be the preferred choices.
- Limitations: Testing was stopped early for some samples if a concentration significantly over 1.0 ppm had been detected. This data can determine if the CSTD device passes or failed the vapor test, but cannot be used to rank the CSTDs.
- Next steps: Because isopropyl alcohol has different chemical properties than hazardous drugs for therapeutic use, further testing using a more representative compound is recommended. Because of this limitation, NIOSH currently has this protocol under review.

## REFERENCES

1. Hirst, D, Mead K. A Vapor Containment Performance Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs: Draft. National Institute for Occupational Safety and Health. August 2015.

## DISCLOSURE

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:

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