Evaluation of three barrier-type closed system transfer devices using the 2015 NIOSH vapor containment performance draft protocol

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Introduction

- Healthcare worker exposure to hazardous drug (HD) vapor may result in serious side effects.
- To verify that a Closed System Transfer Device (CSTD) can mechanically restrict the release of HDs, NIOSH has provided guidance for the evaluation of barrier-type CSTDs.
- To evaluate a CSTD's performance in preventing the escape of drug vapors, NIOSH developed a 2015 draft testing protocol incorporating two compounding tasks utilizing 70% isopropyl alcohol (IPA) as a hazardous drug surrogate.

Objectives

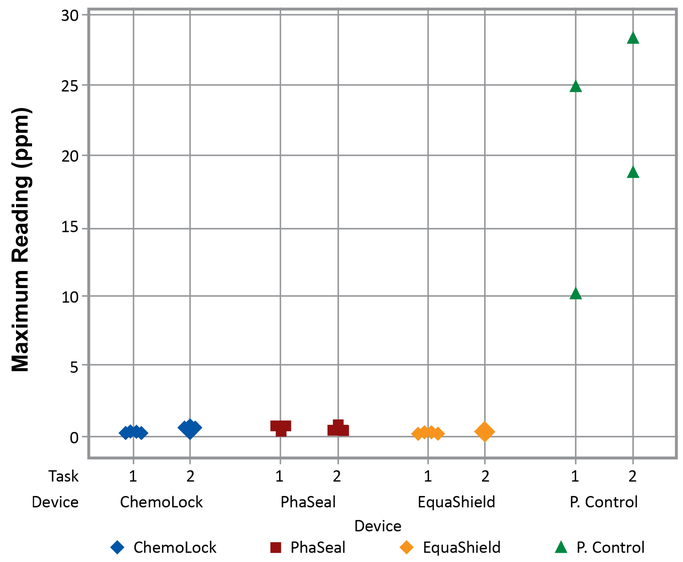
- To evaluate the performance of three barrier-type CSTDs in minimizing the transfer of 70% IPA vapor into the surrounding environment during simulated compounding and administration tasks.
- Efficiency and ease of use during simulated compounding and administration tasks were assessed as secondary outcomes.

Methods

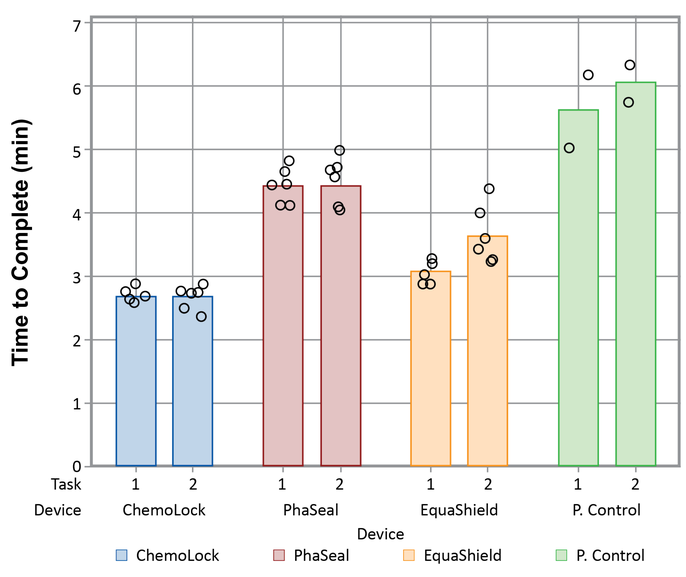
- Three different CSTDs were evaluated by repeating each simulated compounding and administration tasks six times
- Task 1 involved compounding of a lyophilized drug and IV bag preparation
- Task 2 involved compounding of lyophilized drug and bolus administration
- Tasks were performed inside a Secador Technidome 360 Vacuum Desiccator with IPA escaping vapor collected and analyzed using a Miran SapphIRe Infrared Analyzer
- Modifications were made to the protocol to allow the CSTDs to be used in accordance with manufacturer's instruction for use and to represent clinical practice
- Time to complete tasks was recorded for each CSTD

Results

Maximum Readings of 70% IPA Vapor During Tasks 1 and 2



Duration to Complete Tasks 1 and 2



Conclusion

- Measurements from the three CSTDs were determined to have statistically equivalent IPA vapor release below the IPA 1.0 ppm limit of detection.
- In comparison, the positive control (needle and syringe), demonstrated significantly higher vapor release and increased time commitment to perform the simulated tasks.
- Max duration to complete each task was shortest with Chemolock, followed by Equashield and PhaSeal
- Given that barrier type CSTDs are effective in vapor containment, healthcare workers should consider other factors (ease of use, workflow, time savings), when choosing a CSTD.
- Healthcare workers should remain cognizant that CSTDs only provide an additional layer of safety and does not take the place of other engineering and safety controls and practices

References

[1] National Institute for Occupational Safety and Health (NIOSH): A Performance Test Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs. NIOSH Docket # 288-A

Contact and Disclosures

- Andrew Szkiladz — andrew.szkiladz@baystatehealth.org
- Shawn Hegner – dr.hegner@gmail.com
- Andrew Szkiladz and Shawn Hegner have received honorarium from ICU Medical for previous speaker roles

Secador Technidome 360 Vacuum Desiccator