Evaluation of two closed system transfer devices based on the proposed National Institute for Occupational Safety and Health performance test protocol

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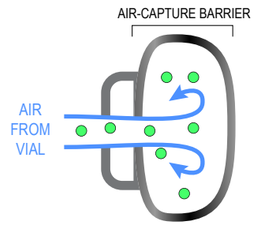
Purpose

A performance test protocol for closed system transfer devices (CSTD) is currently being developed by National Institute for Occupational Safety and Health (NIOSH) researchers along with healthcare industry representatives and individual researchers. The intent of this protocol is to test the CSTD's ability to restrict drug mass from escaping the system. While the current third iteration of the protocol is applicable to both barrier and air-cleaning types of CSTD, it should be noted that this protocol is not yet finalized and subject to change. The purpose of this study was to evaluate two different CSTD technologies based on the most recent NIOSH performance test protocol, NIOSH Docket Number 288-A, CDC-2016-0090. The two CSTD tested included a needle-free membrane-to-membrane connection with a barrier type vial adaptor or an air-cleaning vial type adaptor, and a needle-free ISO standard luer lock connection with a barrier type vial adaptor or an air-cleaning vial adaptor.

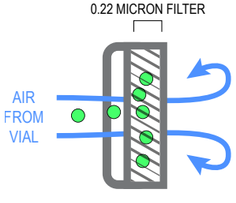
Two Vial Adapter Technologies Tested Included



Barrier Technology

Barrier Technology

Utilizes an external balloon designed to equalize pressure in the vial and limit the escape of hazardous drug particles and air.



Air-Cleaning Technology

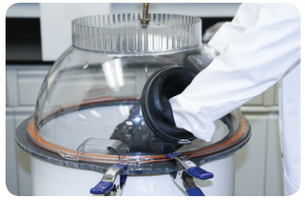
Air-cleaning Technology

Utilizes a 0.22 micron Filter designed to equalize pressure in the vial and limit the escape of hazardous drug particles while allowing air to escape.

"ICU Medical acknowledges that NIOSH's draft Performance Test Protocol referenced in the study is not an accepted test protocol to measure the effectiveness of a closed system and is yet to be finalized; therefore, any references to a "pass result" does not indicate that the draft Performance Test Protocol includes any finalized standards or criteria to be satisfied or that NIOSH endorses ICU Medical or any other manufacturer as a vendor of closed system transfer devices." NIOSH defines a closed system as a "a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of HD or vapor concentrations outside of the system.[123]"

[1] NIOSH Alert Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. Available from https://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf Accessed June 2019.
[2] USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings 2017. Available from https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare Accessed June 2019.
[3] ASHP Guidelines on Handling Hazardous Drugs. Available from https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/handling-hazardous-drugs.ashx Accessed June 2019.

Methods



The protocol as outlined by NIOSH Docket Number 288-A, CDC-2016-0090 was used for the evaluation of the two CSTD. Propylene glycol, chosen as a surrogate to represent hazardous drugs, was diluted in a 10:1 ratio in water and a ¼ inch stainless steel thermal desorption tube with Tenax TA sorbent 35/60 was used. The air pump flow rate was set to 50ml/min with a task time of 5 minutes. A needle-free membrane-to-membrane barrier and air-cleaning CSTD, a needle-free ISO standard luer lock barrier and air-cleaning CSTD, and a traditional needle and syringe were all evaluated. A positive control was also evaluated by placing one drop of the surrogate onto the chamber platform. An independent laboratory using thermal desorption-gas chromatography-mass spectrometry (TD-GC-MS) analyzed the desorption tubes.

Task 1 – Reconstitution: Simulate reconstitution using a vial adapter, CSTD syringe adapter and bag spike.

Task 2 – Administration: Simulate administration via IV push by reconstituting a drug using a vial adapter, CSTD syringe adapter and administration set with a Y-site and CSTD port.

Task 3 – Liquid Compounding: Simulate admixing an IVPB medication using a vial adapter, CSTD syringe adapter and bag spike. This task is not outlined in the NIOSH protocol, however, was added to simulate a commonly performed task in the pharmacy.

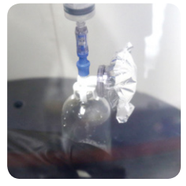
# of Trials	ChemoLock with Barrier	ChemoLock with Air-Cleaning	ChemoClave with Barrier	ChemoClave with Air-Cleaning	Needle and Syringe
Task 1 – Reconstitution	4	4	4	4	3
Task 2 – Administration	4	4	4	4	N/A
Task 3 – Liquid Compounding	4	4	4	4	N/A

ChemoLock

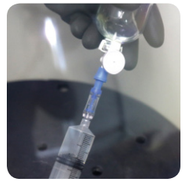
Barrier Vial Adaptor

Air-Cleaning Vial Adaptor

ChemoClave



Barrier Vial Adaptor



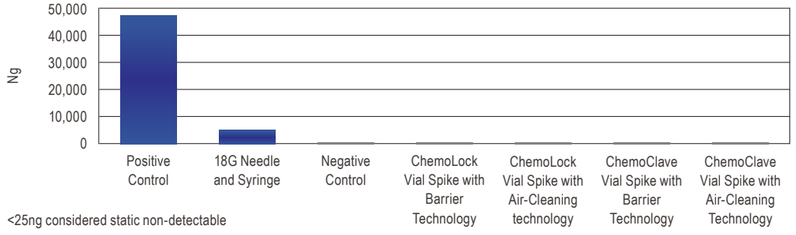
Air-Cleaning Vial Adaptor

Results

Detection of Propylene Glycol outside of a Closed System Transfer Device

	Positive Control	Needle and Syringe	Negative Control	ChemoLock with Barrier	ChemoLock with Air-Cleansing	ChemoClave with Barrier	ChemoClave with Air-Cleansing
Task 1 Reconstitution	47000ng	4817ng	Non-detectable	Non-detectable	Non-detectable	Non-detectable	Non-detectable
Task 2 Administration			Non-detectable	Non-detectable	Non-detectable	Non-detectable	Non-detectable
Task 3 Liquid Compounding			Non-detectable	Non-detectable	Non-detectable	Non-detectable	Non-detectable

Detection of Propylene Glycol outside of a Closed System Transfer Device



<25ng considered static non-detectable

Conclusions

Each CSTD evaluated yielded non-detectable results, passing the current proposed NIOSH test protocol. These results demonstrate the effectiveness of each CSTD in reducing and limiting any potential hazardous drug exposure during all tasks performed, especially when compared to a needle and syringe. However, results of this assessment should not be interpreted to represent the performance of all FDA cleared CSTDs. While the purpose of the draft NIOSH performance test protocol is to test the capability of a CSTD to perform as such, it is important to evaluate other design characteristics of the CSTD as well, such as bonding, locking mechanism, and ease of use. It should be noted that all current CSTD on the market are FDA cleared and meet the USP 800 standard. Furthermore, it is crucial to be cognizant of the fact that a CSTD only provides an additional layer of safety and does not take the place of other engineering and safety controls.

REFERENCES
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 Number 288-A

DISCLOSURES
Andrew Szkiladz: Honoraria - ICU Medical; Shawn Hegner: Honoraria - ICU Medical