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

Andrew Szkiladz PharmD, BCPS, BCOP 1; Shawn Hegner PharmD, BCSCP 2
1 Baystate Health, Springfield, MA; 2 Riverside Health System, Newport News, VA

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

<table>
<thead>
<tr>
<th>Task Device</th>
<th>Chemolock</th>
<th>PhaSeal</th>
<th>EquaShield</th>
<th>P. Control</th>
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</thead>
<tbody>
<tr>
<td>Max Reading (ppm)</td>
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<tr>
<td>Task 1</td>
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<td>Task 2</td>
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Duration to Complete Tasks 1 and 2

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<tr>
<td>Time to Complete (min)</td>
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<tr>
<td>Task 1</td>
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<td>Task 2</td>
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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


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