Personal Protective Equipment and Closed System Transfer Devices

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Disclosure

• Seth Eisenberg has consulting agreements with:
  – BD
  – ICU Medical
  – Medtronic
  – B Braun
Personal Protective Equipment

- Must be worn during:
  - Receipt and storage
  - Transport
  - Compounding (sterile and nonsterile)
  - Administration
  - Deactivation/decontamination, cleaning, and disinfecting
  - Spills
  - Waste disposal
  - Handling excreta

- Must be disposed of in designated HD waste container
Personal Protective Equipment

• Different PPE is required for different activities

• **Compounding**
  – Gowns
  – Head covers
  – Hair covers
  – Shoe covers
  – Two pairs of chemotherapy gloves
Personal Protective Equipment

• Different PPE is required for different activities

• Administration
  – Gowns
  – Two pairs of chemotherapy gloves
  – Facial protection for high risk of splashing
    • Examples: surgery, working above eye level
Personal Protective Equipment

• Different PPE is required for different activities

• **Spills**
  – Gowns
  – Two pairs of chemotherapy gloves
  – Facial protection
  – Respiratory protection for drugs that vaporize
Personal Protective Equipment

- Different PPE is required for different activities

- **Excreta**
  - Gowns
  - Two pairs of chemotherapy gloves
  - Facial protection if risk of splashing
Gloves

- Two pairs of ASTM D6978 tested gloves
- Do not use the older ASTM F739 standard
- Cuffs must be long enough to allow the inner glove remain under the cuff of the gown and the outer glove to sufficiently cover the gown

Photo courtesy of S. Eisenberg
Gloves

- Do not need to be the same brand or thickness
- Consider trying several brands over/under to determine which combination works best

Photos courtesy of S. Eisenberg
Gloves

• Worn for all HDs (antineoplastic, non-antineoplastic, and reproductive risk HDs)
• Powder free
• Gloves used for compounding must be sterile
• Maximum wear time of 30 minutes
  – Note that not all gloves resist all HDs for the same length of time
<table>
<thead>
<tr>
<th>Drug</th>
<th>Minimum breakthrough time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cardinal Cool Blue</td>
</tr>
<tr>
<td>Carmustine (BCNU)</td>
<td>7.28</td>
</tr>
<tr>
<td>Cisplatin</td>
<td>&gt;240</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>&gt;240</td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>&gt;240</td>
</tr>
<tr>
<td>Etoposide</td>
<td>&gt;240</td>
</tr>
<tr>
<td>5FU</td>
<td>&gt;240</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>&gt;24</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>&gt;40</td>
</tr>
<tr>
<td>Thiotepa</td>
<td>2.67</td>
</tr>
</tbody>
</table>

[https://www.accessdata.fda.gov/cdrh_docs/pdf12/K122696.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf12/K122696.pdf)
• Be sure to know your product!

*Warning*: Do not use with Carmustine (BCNU) (3.3 mg/ml) and Thiotepa (10 mg/ml).
# USP <800> vs NIOSH

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Activity</th>
<th>Double chemo-therapy gloves</th>
<th>Protective gown</th>
<th>Eye/face protection</th>
<th>Respiratory protection</th>
<th>Ventilated engineering control</th>
</tr>
</thead>
<tbody>
<tr>
<td>All types of hazardous drugs</td>
<td>Receiving, unpacking, and placing in storage</td>
<td>no (single glove can be used, unless spills occur)</td>
<td>yes, when spills and leaks occur</td>
<td>no</td>
<td>yes, when spills and leaks occur</td>
<td>no</td>
</tr>
<tr>
<td>Intact tablet or capsule</td>
<td>Administration from unit-dose package</td>
<td>no (single glove can be used)</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>N/A</td>
</tr>
<tr>
<td>Tablets or capsules</td>
<td>Cutting, crushing, or manipulating tablets or capsules; handling uncoated tablets</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
<td>yes, if not done in a control device</td>
<td>yes†</td>
</tr>
<tr>
<td>Administration</td>
<td>Administration</td>
<td>no (single glove can be used)</td>
<td>yes, if vomit or potential to spit up‡</td>
<td>no</td>
<td>no</td>
<td>N/A</td>
</tr>
</tbody>
</table>

NIOSH 2016 Table 5. p32.
Gowns

• Disposable, single-use
• Cannot be worn outside of HD handling area
• Shown to resist HD
  – Ask manufacturer to provide documentation
  – ASTM is currently working on a gown standard
• Must close in the back
• No seams or openings in front
• Long sleeves with elastic or knit cuffs
Respiratory Protection

• Required for spills of drugs that vaporize at room temperature

• Carmustine
• Etoposide
• Cyclophosphamide
• Thiotepa

• Nitrogen Mustard
• 5-FU
• Cisplatin
• Ifosfamide

60 second chemistry review
Vapors and Aerosols

- **Vapors**: small particles (e.g. perfume)
- **Aerosols**: larger particles (e.g., Windex™)
- N95 or N100 are for aerosols and particulates
- Vapors require a canister respirator or PAPR (Powered Air Purifying Respirator) with organic vapor cartridge

DHHS (NIOSH) Publication No. 2009–106; USP<800> 2016
Vapor Protection

Full Face Respirator with OV canister

PAPR (Powered Air Purifying Respirator) with OV cartridge

Photos courtesy of Seth Eisenberg
Closed System Transfer Devices

• A Closed System Transfer Device (CSTD) will be **required** for administration of antineoplastic HDs

• Designed to “restrict hazardous drug liquid or vapor from escaping into the environment.”

• CSTDs are **recommended** for compounding
Closed System Transfer Devices

There are 2 components to CSTDs:

1. A vial adaptor designed to prevent the escape of aerosols, vapors and droplets

2. A connector used to transfer drug into IV bags and on IV tubing and syringes to prevent droplets

Photo Credit: S. Eisenberg
Closed System Transfer Devices

• Although not “required” for compounding, facilities without a CSTD will likely adopt one for both departments
  – Requires collaboration between departments
• The CSTD that works best in pharmacy may not work best for nursing
  – Not all CSTDs are compatible with needless caps/tubing
• Hybrid systems, or 2 different brands have been successfully used in facilities
7 CSTD Systems Available

- Phaseal (BD)
- Chemo Safety System [Texium] (CareFusion/BD)
- OnGuard (B Braun)
- Halo (Corvida)
- Equashield (Equashield Medical)
- ChemoClave (ICU Medical)
- ChemoLock (ICU Medical)
CSTDs For Administration

- Should be used wherever connection or disconnection occurs on secondary and primary tubing

Eisenberg, S. PPPmag, 2014, February
Drips Happen!
CSTDs

• For administering drugs in a syringe

• On chemotherapy bags if attaching at bedside or disconnecting bag from tubing

Photo Credit: S. Eisenberg
CSTD Designs

- ICU Spiros
- CareFusion Texium

- B Braun On Guard
- BD Phaseal
- Corvida Halo
- Equashield
- ICU ChemoLock (needless)
## CSTD Comparison

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Device</th>
<th>Luer / Membrane</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD</td>
<td>Phaseal</td>
<td>Membrane</td>
<td>First to market (1999)</td>
</tr>
<tr>
<td>BD</td>
<td>ChemoSafety [Texium]</td>
<td>Luer</td>
<td>Designed to work with CareFusion Smartsite™ valve</td>
</tr>
<tr>
<td>B Braun</td>
<td>OnGuard</td>
<td>Membrane</td>
<td>Dual layer microfilters on vial adapter</td>
</tr>
<tr>
<td>Corvida</td>
<td>Halo</td>
<td>Membrane</td>
<td>New; limited availability</td>
</tr>
<tr>
<td>Equashield</td>
<td>Equashield II</td>
<td>Membrane</td>
<td>Dual-chamber syringes</td>
</tr>
<tr>
<td>ICU Medical</td>
<td>ChemoClave</td>
<td>Luer</td>
<td>Universal luer compatibility</td>
</tr>
<tr>
<td>ICU Medical</td>
<td>ChemoLock</td>
<td>Membrane</td>
<td>Needless</td>
</tr>
</tbody>
</table>
Membrane Devices & Adapters

Equashield  Phaseal  OnGuard  Halo  Chemolock

All membrane devices require a luer adapter

Photo Credit: S. Eisenberg
CSTD Size Comparison

Does not include luer adapters
CSTD Direct Spikes

- Allows for **connecting** tubing at the bedside
- Eliminates the need to prime tubing in pharmacy
  - Reduces opportunity for tubing contamination in the BSC
  - Saves pharmacy time and space
- Available from all CSTD manufacturers
CSTD Direct Spike Examples

Photo Credit: S. Eisenberg
Direct Spike Example

Bag arrives with CSTD Direct Spike

Photo Credit: S. Eisenberg
CSTD Dry Spike

- Similar to Direct Spike, but designed to use **existing** primary tubing.
- Allows for spiking of tubing at the bedside **without** risk of puncturing the IV bag.
- Eliminates the need to prime tubing in pharmacy, and reduces opportunity for tubing contamination in the BSC.
- Available from all CSTD manufacturers.
CSTD Dry Spike Examples

ICU ChemoLock

BD Phaseal

Photo Credit: S. Eisenberg
CSTD Circle Priming

Photo Credit: S. Eisenberg
CSTD Effectiveness

- No standardized test for effectiveness
- NIOSH developed a test protocol in 2016, although a number of issues were identified by manufacturers
- Products that passed:
  - Phaseal
  - OnGuard
  - Equashield
  - ChemoLock
CSTD Effectiveness

- NIOSH is currently working with manufacturers on a second testing protocol
- NIOSH will not be performing independent tests
- Manufacturers will use test to measure effectiveness
- Regardless of results, ANY CSTD is better than NO CSTD
Summary

• Proper PPE will be required for the administration of HDs
  – Double ASTM 6978 gloves
  – Chemotherapy tested gown

• CSTDs will be required for the administration of antineoplastic HDs
  – 7 brands available
  – Each device has its strengths and weaknesses