Self-Advocating for Protection Against Hazardous Drugs

**Brief Timeline Of Hazardous Drug (HD) Guidelines**

1981 ASHP → 1983 ASHP → 1984 ONS

2016 USP<800> ← 2004 NIOSH Alert ← 1986 OSHA

**Recent Key Studies**

- Hon, Teschke, Chu, Demers, & Venners (2013)
  - 36% of samples above level of detection for CY
- Hon, Teschke, Demers, & Venners (2014)
  - 20% of the hand wipe samples positive; highest concentration on non-nursing staff
- Hon, Teschke, Shen, Demers, & Venners (2015)
  - 55% urine samples positive; no correlation between levels and known CY contact

**Recent Key Studies**

- Janes, Tanguay, Caron, & Bussieres (2015)
  - 50% wipe samples were positive for Cy, including patient chairs
- Boiano, Steege, & Sweeney (2014)

<table>
<thead>
<tr>
<th>Survey Item</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Touched IV pump or bed controls while wearing chemotherapy gloves</td>
<td>61</td>
</tr>
<tr>
<td>Always wear double gloves</td>
<td>20</td>
</tr>
<tr>
<td>Always wear recommended gown</td>
<td>58</td>
</tr>
<tr>
<td>Reported a spill within prior week</td>
<td>12</td>
</tr>
<tr>
<td>Spills not always cleaned up</td>
<td>10</td>
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</tbody>
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Hierarchy of Controls

Level 1
Elimination or substitution

Level 2
Engineering Controls (e.g., BSC, CSTD)

Level 3
Administrative Controls (e.g., policies)

Level 4
PPE

More effective
Less effective

Review of Current Recommendations

- Double gloving with ASTM-tested chemotherapy gloves
- Chemotherapy-resistant gown
- Worn during:
  - Preparation
  - Administration
  - Disposal
- Gowns are considered “single-use”
- Closed System Transfer Device (CSTD) for compounding and administration

Current Recommendations

- Crushing or cutting oral HDs should be done inside of a Biologic Safety Cabinet (BSC)
- IV bags spiked with neutral solution
- Spill kit must be available
- All personnel must be trained in HD handling
Enforcement Of Guidelines

- NIOSH does not have enforcement capability
- OSHA does not have the resources for enforcement

United States Pharmacopeial (USP)

- The mission of USP is to set standards “for the identity, strength, quality, and purity of medicines...”
- USP chapter 800 (USP<800>) sets standards for HD handling from delivery to disposal
- Far reaching implications for compounding and administration
- Enforceable by each state’s Board of Pharmacy
- Will be tied to CMS and reimbursement

USP<800> Implications

- Double-gloves and gown
- Spill training and appropriate respiratory protection for drugs that vaporize at room temperature
- A CSTD will be required for administration
- Eight drugs have been identified in 2 older studies
  - Carmustine
  - Etoposide
  - Cyclophosphamide
  - Thiopeta
  - Nitrogen Mustard
  - S-FU
  - Cisplatin
  - Ifosfamide

CSTDs

- Designed to “restrict hazardous drug liquid or vapor from escaping into the environment.” (NIOSH 2015)
- 6 major systems on the market:
  - Phaseal (BD)
  - Equashield (Equashield Medical)
  - OnGuard (B Braun)
  - Texium System (BD)
  - ChemoLock (ICU Medical)
  - ChemoClave (ICU Medical)

CSTD Effectiveness

- No standardized test for effectiveness
- NIOSH has developed a draft protocol:
  - “A Vapor Containment Performance Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs”

NIOSH CSTD Draft Protocol

- Uses isopropyl alcohol in a test chamber to detect vapor leakage during compounding and administration
- Does not provide “pass-fail” results
Organizational Changes

Level 1
Elimination or substitution

Level 2
Engineering Controls (e.g., BSC, CSTD)

Level 3
Administrative Controls (e.g., policies)

Level 4
PPE

Organizational Level Changes

- Join Oncology Clinical Practice Group
- Review hospital policy, compare it to NIOSH recommendations
- Educate staff (ancillary staff too)
- Educate families
- Signage
- Get support for needed supplies

Washington State Level Changes

- Lack of legislation identified by a patient’s daughter who approached two state legislators
- Bill passed in 2011 to adopt NIOSH guidelines
- Law became effective in 2012
- Rulemaking and enforcement through department of Labor and Industries
Two Washington State Laws

- **SB-5594** requires the adoption of the NIOSH guidelines
- “be consistent with and not exceed provisions adopted by the national institute for occupational safety and health’s (NIOSH)2004 alert on preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings as updated in 2010.”
- **SB 5149** directs the department of health to collect current and past employment information in the cancer registry program

Timeline To Comply With Law

- **January 1, 2015**
  - Develop hazardous drug control program
- **July 1, 2015**
  - Complete employee training
- **January 1, 2016**
  - Complete ventilation controls (BSCs)

Washington’s Challenging Road

- Ventilation control timeline delayed due to extensive lobbying
  - Physical location:
    - Some hospital pharmacies are in the basement or on first floor, limiting the ability to provide required ventilation
  - Budgeting process:
    - New BSCs (Biologic Safety Cabinets) and or improved venting is very costly
“No, this is not optional...”

- Division of Occupational Safety and Health (DOSH) Inspections staff may:
  - Take samples, photographs, videotapes, or audiotapes
  - Conduct tests or interviews
- Citations may result in $5,000 fines per violation ($70,000 max)
- May also result in violation of CMS “Conditions of Participation” (COPs) [Interpretive Guidelines §§482.23(c)(1), (c)(1)(i) and (c)(2)]

State Level Changes

- Clinical knowledge, experience and passion for keeping people safe is a good start
- Safety starts at home
- Work with others within and outside of nursing to advocate in your state
- Share personal stories
- Educate legislators
- Get involved in professional organizations
- Write Op-Eds
- Believe in the work, say yes when it’s scary and exciting! Make the change you want to see!

Lessons Learned from State Level Changes

- Enacting a state law can be led by a single voice
- Be prepared for resistance (related to associated costs and workflow changes)
- There is power in numbers- get involved with your professional organizations
- Write letters, make calls, Op-Eds, Educate!
- Be the Change
Resources For Your Journey

• Washington State Q&A
• Washington State Nursing Training Guide
Bibliography


