Self-Advocating for Protection Against Hazardous Drugs
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The Dangers Are Not New
1979: Positive urine mutagenicity (Ames Test) in nurses and pharmacists handling chemotherapy
1985: Initial definition of hazardous drugs (HDs) by ASHP
   1. Carcinogenicity
   2. Teratogenicity or other developmental toxicity
   3. Reproductive toxicity
   4. Organ toxicity at low doses
   5. Genotoxicity
2004: Additional criteria added by NIOSH
   6. Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous
HAZARDOUS DRUG GUIDELINE TIMELINE

Recent Key Studies

  
  - 36% of samples were above level of detection for CY

  
  - 20% of the hand wipe samples were positive; highest concentration on non-nursing staff

  
  - 55% urine samples were positive; no correlation between levels and known CY contact

Recent Key Studies

  
  - 50% wipe samples were positive for Cy, including patient chairs


<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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Chromosomal Damage

“Chromosome 5 and 7 abnormalities in Oncology Personnel Handling Anticancer Drugs”

- 3 Cancer Centers; n=109 (includes 46 control)
- Abnormalities seen for chromosome 5 in exposed versus non-exposed ($p=.04$)
- Increased incidence of chromosome 5 abnormalities seen with increased drug handling
- Hazard Ratio 8.54 ($p=.01$) for alkylating agents

(Guided by AD, et al., 2010)

Guideline Limitations

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

“Although this is an important safety and health issue, OSHA has not considered a standard to specifically address hazardous drugs in the healthcare setting. Unfortunately, OSHA does not have the resources to issue standards covering every safety and health hazard facing workers.”

Jordan Barab, Deputy Assistant Secretary of Labor for OSHA (2010)

(State Laws)

- California (2013)
- North Carolina – legislation being rewritten
- Michigan legislation pending
- Maryland legislation pending
United States Pharmacopeial (USP)

- Most nurses have never heard of USP but you may have seen their name
- Who is USP?
- Why should I care?

- 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 or designated agency
- Will be tied into CMS and reimbursement

Enforcement of USP <800> begins July 1, 2018
Overview Of Current Recommendations

- Chemotherapy-resistant gown
  - “Single-use” and disposable
  - Solid front and elastic or knit cuffs
  - Shown to resist HD permeability
- Worn during:
  - Preparation
  - Administration
  - Disposal
  - Spill clean-up

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
Overview Of Current Recommendations

• Double gloving with ASTM 6978-05-tested chemotherapy gloves
• Closed System Transfer Device (CSTD) for administration
  – Required for administration
  – Recommended for compounding

Overview Of Current Recommendations

• All personnel must be trained in HD safety prior to handling
• Crushing or cutting oral HDs should be done inside of a Biologic Safety Cabinet (BSC)
• IV bags spiked with neutral solution unless CSTD is used
• Spill kit must be available

USP<800> Implications

• Spill training and appropriate respiratory protection for drugs that vaporize at room temperature
  • Carmustine
  • Etoposide
  • Cyclophosphamide
  • Thiotepa
  • Nitrogen Mustard
  • 5-FU
  • Cisplatin
  • Ifosfamide

(Connor, Shults & Fraser, 2000; Kiffmeyer et al., 2002)
Vapors And Aerosols

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

[Source: Shults & Fraser, 2000; Delaney et al., 2002]

USP<800> Implications

- A CSTD will be required for administration of chemotherapy
- Devices are designed to “restrict hazardous drug liquid or vapor from escaping into the environment.” (NIOSH 2015)

7 CSTD Systems Available

- Halo (Corvida)
- Phaseal (BD)
- Equashield (Equashield Medical)
- OnGuard (B Braun)
- ChemoLock (ICU Medical)
- ChemoClave (ICU Medical)
- Chemo Safety System (CareFusion/BD)
CSTD Effectiveness

- No standardized test for effectiveness
- NIOSH has developed a draft protocol which is currently under review
- Passed:
  - ICU ChemoLock
  - Phaseal
  - Equashield

SELF-ADVOCATING FOR PROTECTION:

CHANGING PRACTICE AT THE STATE LEVEL

Washington State

Reporter Carol Smith, who was investigating the dangers of HDs, met Chelsea Crump

Chelsea introduced Carol to her mother Sue Crump, a pharmacist who had recently developed pancreatic cancer

Sue talked about compounding HDs for 2 decades without proper safety precautions
Both Sue and Chelsea wanted to prevent more HD exposure and took the issue to state legislators.

In 2011, a bill was passed adopting NIOSH guidelines for all facilities who handle HDs.

The Department of Labor and Industries was charged with the rule-making process and enforcement of the law, effective 2012.

**Washington State**

- 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)
Challenging Road

- Delays due to ventilation control issues
- Many hospital pharmacies are in the basement or on first floor, limiting the ability to provide required ventilation
- Culture change is difficult, despite legislation

Enforcement

- 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)]

SELF-ADVOCATING FOR PROTECTION:

CHANGING PRACTICE AT THE LOCAL LEVEL
What Can YOU Do?

• Identify your areas of vulnerability
  – Gap analysis between current policies and current guidelines
  – Gap analysis between current practice and current guidelines
  – Include analysis of PPE
    • Examples:
      – Do your gloves meet the ASTM standard?
      – Do your gowns meet the USP requirements?

(Eisenberg, 2016; Walton, 2012)

What Can YOU Do?

• Identify your areas of vulnerability
  – Does your education program meet the USP requirements
    • Prior to HD handling
    • Must be documented
    • Must be performed annually
  – How are spills managed?
  – Do you have a CSTD for HD administration?
  – Are staff using the CSTD?

(Eisenberg, 2016; Walton, 2012)

What Can YOU Do?

• Identify barriers for HD safety compliance
  – Poor staffing (workload)
  – Lack of education about HD dangers
  – PPE not meeting staff needs (e.g., gowns or gloves that do not fit)
  – PPE location does not support workflow
  – Workplace culture does not support HD safety

(Callahan, 2016; Polovich & Clark, 2012)
What Can YOU Do?

• Identify your workplace culture
  – Find Hazardous Drug champions!
    • Staff nurses
    • Clinical Nurse Specialists
    • Clinical educators
    • Department manager
    • Pharmacy manager
    • Department medical director
    • Risk manager

What Can YOU Do?

• Adopt a zero-tolerance approach to preventing exposure within the workplace
• Increase nursing awareness of the risks associated with hazardous drugs through multiple mediums and methods
  – Staff meetings
  – Local ONS chapter presentations
  – Newsletters
• Work with state legislators to enact laws requiring healthcare facilities to follow the latest guidelines

(Eisenberg, 2016)
References


Polovich, M., Olsen, M. M., & LeFebvre, K. B. (2014). *Chemotherapy and biotherapy guidelines and recommendations for practice / edited by Martha Polovich, PhD, RN, AOCN, MiKaela Olsen, MS, RN, AOCNS, Kristine B. LeFebvre, MSN, RN, AOCN (Fourth edition. ed.): ONS.*
