Self-Advocating for Protection Against Hazardous Drugs

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Disclosures:

- ICU Medical
- BD/CareFusion
- B Braun
- Takeda
- Genentech
- Mobius Therapeutics

Disclaimer: The views expressed in this presentation are solely those of the author.

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

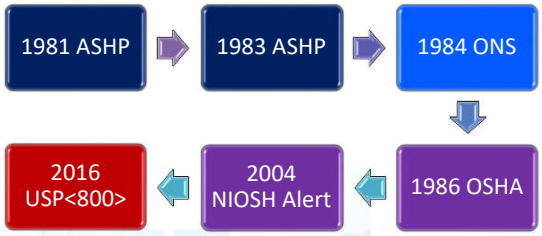
1. Carcinogenicity
2. Teratogenicity or other developmental toxicity
3. Reproductive toxicity
4. Organ toxicity at low doses
5. Genotoxicity

2004: Additional criteria added by NIOSH

6. Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous

(Falck, 1979)

HAZARDOUS DRUG GUIDELINE TIMELINE



Wipe Testing

- 6 hospitals
- Wipe testing for cyclophosphamide (Cy)
- 438 surfaces in pharmacy and administration areas
- **36% of samples were above level of detection and included:**

(Hon C., et al., 2013)

Wipe Testing

- IV hook (N = 6)
- IV pump (N = 22)
- Calculator (N = 6)
- Cart (N = 7)
- Chair (N = 4)
- Computer mouse (N = 2)
- Countertop (N = 29)
- Pen (N = 13)
- Printer (N = 2)
- Patient bedside table (N = 11)
- Elevator button (N = 2)

Hand Contamination

- N = 110; 225 wipe samples collected
- Sample included nurses, oncologists, dietitians, ward clerks, volunteers, housekeeping
- **20% of the samples were positive**
  - Highest level of contamination on non-nurses
  - Hand-washing did not prevent positive results

(Hon C., et al., 2014)

Urine Excretion

- N = 103 staff
- 201 (24hr) samples collected
- **55% were positive for Cy**
  - Highest concentration in unit clerks and other departments that did not prepare or administer
  - No correlation between levels and known contact with CY

(Hon C., et al., 2015)

Multi-Hospital Wipe Testing

- Performed at 51 Canadian hospitals
- 584 samples obtained
- **50% were positive for Cy**
  - Contamination found in pharmacy and patient care areas including infusion chairs and on the counter

(Janes A., et al., 2015)

NIOSH Survey

- N = 1954 nurses

Survey Item	%
Primed tubing with hazardous drug	6
Crushed tables or opened capsules (n=494)	13
Touched IV pump or bed controls while wearing chemotherapy gloves	**61**
Used pens or pencils while wearing chemotherapy gloves	26
Touched doorknobs or cabinets while wearing chemotherapy gloves	20
Never used a Closed System Transfer Device (CSTD)	47
Always wear double gloves	**20**
Always wear recommended gown	**58**
Reported a spill within prior week	**12**
Spills not always cleaned up	**10**

(Boiano, Steege & Sweeney, 2014)

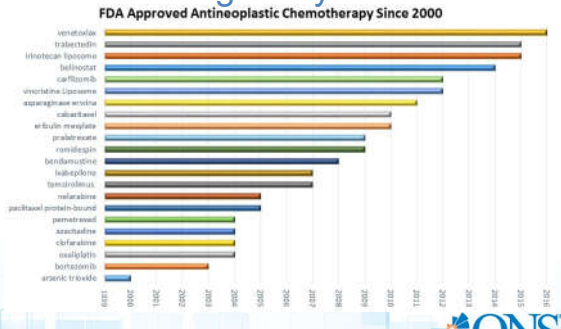
Chromosomal Damage

"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 abnormalities with increased drug handling**
- **Hazard Ratio 8.54 (*p*=.01) for alkylating agents**

(McDiarmid M., et al., 2010)

It's Not Going Away



Based on information from Wilkes & Barton-Burke, 2015; http://www.accessdata.fda.gov/scripts/cder/drugsatfda/ Retrieved June, 2016. Copyright 2016 S. Eisenberg

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 ASHA (2010)

(Smith, 2010)

State Laws

- Washington State (2012)
- California (2013) (antineoplastic agents only)
- North Carolina – legislation being rewritten
- Michigan legislation – legislation pending
- Maryland legislation – legislation pending
- New Jersey – legislation pending

United States Pharmacopeial (USP)

- Most nurses have never heard of USP although their logo is on a lot of products
- Who is USP?
- Why should we care?

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 or designated agency
- Will be tied into CMS and reimbursement

(CMS Standard §482.25(a))

Photos courtesy of Seth Eisenberg

United States Pharmacopeial (USP)

Enforcement of USP <800> begins July 1, 2018 in all states except for California*

*January 1, 2017 in California, but limited to antineoplastic agents only

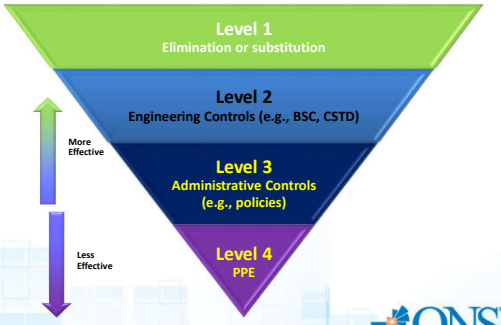
California

- "…at CPhA's insistence, the BOP included a process for pharmacies to apply for a waiver … when compliance requires physical construction or alteration and the pharmacy needs additional time … to complete the upgrades."

California Pharmacists Association, September 2016
http://www.cpha.com/Compounding-Regulations

REVIEW OF CURRENT RECOMMENDATIONS

Hierarchy of Controls



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

Overview Of Current Recommendations

- Two pairs of **ASTM 6978-05-tested** chemotherapy gloves

Photo courtesy of Seth Eisenberg

Overview Of Current Recommendations

- Closed System Transfer Device (CSTD) **Required** for administration
  - Recommended for compounding
- 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

Overview Of Current Recommendations

- All employees must have access to and understand the organization's HD list
- All personnel must be trained in HD safety
  - prior to handling
  - for management of spills
- Spill kit must be available

USP<800> Implications

- Appropriate respiratory protection during spill management 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., window cleaner)
- N95 or N100 are for aerosols and particles
- Vapors require a cartridge respirator or PAPR (Powered Air Purifying Respirator)

Vapors And Aerosols

Cartridge Respirator

PAPR (Powered Air Purifying Respirator)

Note: All respirators and PAPRs require annual training

Photos courtesy of Seth Eisenberg

USP<800> Implications

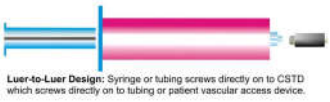
- A CSTD will be required for administration of chemotherapy
- Designed to "restrict hazardous drug liquid or vapor from escaping into the environment."

(NIOSH 2015)

7 CSTD Systems Available

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

CSTD Designs



Luer-to-Luer Design: Syringe or tubing screws directly on to CSTD which screws directly on to tubing or patient vascular access device.

Membrane-to-Membrane design: Drug passes from A to B via needle after both membranes have been compressed. Needle mechanism is removed only after both membranes have separated.

Note: ICU ChemoLock is a needleless Membrane-to-Membrane design

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 Compounding Components

Phaseal

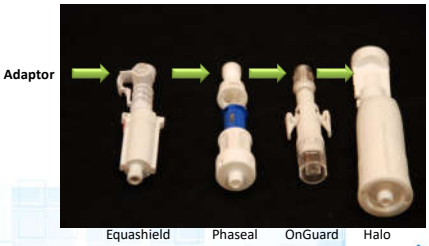
Equashield II

ChemoLock

On Guard

Photos courtesy of Seth Eisenberg

Membrane To Membrane Devices & Adaptors



Membrane To Membrane Devices & Adaptors

Adaptor

ICU Medical ChemoLock

CSTD Effectiveness

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

CSTD Trial

- Assemble a multi-disciplinary workgroup
  - Nursing
  - Pharmacy
  - Purchasing
  - Educators
  - Purchasing

CSTD Trial

- Select 1-2 devices based on organizational criteria
  - Determine compatibility with existing equipment
    - IV pumps
    - IV tubing
- Perform gap analysis to anticipate requisite changes in workflow
- Obtain estimate of annual cost based on projected usage

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 without proper safety precautions

Washington State

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 that handle HDs

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

Timeline To Comply With Law

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 may:
  - Take samples, photographs, video, or audio recordings
  - 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
    - 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
    - Occurs prior to HD handling
    - Documented
    - Performed annually

(Eisenberg, 2016; Walton, 2012)

What Can YOU Do?

- Identify your areas of vulnerability
  - How are spills managed?
    - Do you have the requisite respiratory protection?
  - 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

(Eisenberg, 2016)

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

(Eisenberg, 2016)