



Empowering Nurses. Improving Safety.

Making the Case for Building Safer Systems to Reduce Exposures to Hazardous Drugs

Marty Polovich, PhD, RN AOCN®

Amber Hogan Mitchell, DrPH, MPH, CPH

Disclosures

- Dr. Amber Mitchell is a consultant to B Braun Medical Inc.
- Dr. Marty Polovich is a member of a speaker's bureau for Becton Dickinson, UK



Learning Objectives



At the conclusion of this session, attendees will be able to:

1. Discuss the risks of handling hazardous drugs
2. Describe surveillance and safety systems that are in place to prevent occupational exposures to hazardous drugs
3. Explore oncology nurses' role as an advocate on behalf of other nurses, healthcare teams, and patients.
4. Describe how USP<800> and the use of CSTD can improve HCP and patient safety
5. Identify the elements that make a case for the use of a CSTD to pharmacists and administrators.

"Workers who take care of us when we are sick or hurt should not be at such high risk for injuries — that simply is not right. Workers in hospitals, nursing homes and long-term care facilities have work injury and illness rates that are among the highest in the country, and virtually all of these injuries and illnesses are preventable," said Dr. David Michaels, assistant secretary of labor for OSHA



"OSHA has provided employers with education, training and resource materials, and it's time for hospitals and the health care industry to make the changes necessary to protect their workers."

<https://www.osha.gov/newsrelease/nat-20150625.html>



Risks Associated with Hazardous Drug Exposure

Conditions for Exposure to HDs

- Reconstituting powdered or lyophilized drugs
- Expelling air from syringes
- IV administration
- Counting, dosing, crushing oral doses, tablets
- Contacting HDs on drug vial exteriors, surfaces
- Generating aerosols
- Priming IV
- Handling body fluids or body fluid soaked items
- Handling waste, used or unused
- Decontaminating or cleaning drug prep or clinical area
- Removing, disposing of PPE after handling PPE or waste





Routes of Exposure

- Inhalation
- Skin Contact
- Skin Absorption
- Mucous Membrane Contact
- Ingestion
- Hand to mouth
- Injection
- Needlestick, Sharps Injury



Severity of Exposure Depends Upon

- HD handling circumstance
- Amount of drug prepared
- Frequency and duration of drug handling
- Potential for absorption
- Use of Engineering Controls
- Use of Ventilated Cabinets
- PPE
- Work Practices

Adverse Event & Health Outcomes



- Hazardous drugs like antineoplastic and chemotherapeutic drugs are carcinogens and genotoxins and can cause:
 - Cancer
 - Leukemia
 - Reproductive toxicity
 - Spontaneous abortion, miscarriage
 - Birth defects, congenital malformations
 - Low birth weight
 - Infertility

Hansen & Olsen, 1994; Skov, 1992, Lawson, 2012; Martin, 2005

Exposure Limits



- There are currently no general limits for HDs
 - NIOSH recommended exposure limits (RELs)
 - OSHA permissible exposure limits (PELs)
 - American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLVs®)
- There are some specific limits for the following
 - Soluble platinum salts (sensitization)
 - Inorganic arsenic compounds (arsenic trioxide)
 - Antibiotics (some like chloramphenicol)
 - Some SDS* from drug manufacturers

*SDS = Safety Data Sheet

Current Standards & Recommendations in Place



- OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030)
 - Needlesticks
 - Sharps Injuries
 - Blood and Body Fluid Splashes and Splatters
- OSHA Hazardous Chemical Standard (1910.1200, 1450)
 - Engineering Controls
 - Work Practices
 - PPE
- ONS
- American Society of Health-System Pharmacists (ASHP)
- National Institute for Occupational Safety and Health (NIOSH)
- The Joint Commission
- US Pharmacopeial Convention (USP)

ONCOLOGY NURSING SOCIETY

Safe Handling of Hazardous Drugs

SECOND EDITION

EDITED BY
MARTHA POLOVICH, PhD, RN, AOCN®



NIOSH ALERT

Preventing Occupational Exposures to
Antineoplastic and Other Hazardous Drugs
in Health Care Settings

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health





Evidence for Occupational Hazardous Drug Exposure



Summary of Published Evidence

- Contamination on external vial surfaces
(15 studies since 1992)
- Excretion of drugs and drug metabolites in
urine of health care workers
(>65 studies since 1992)
- Workplace surface contamination
(>100 studies since 1994)

Surface (Environmental) Contamination: Canada & US



1999

- 6 Cancer Treatment Centers
- 3 drugs (incl. cyclophosphamide)
- Pharmacy (preparation):
75% wipe samples > LOD
- Nursing (administration):
65% wipe samples > LOD

2010

- 3 University-based Cancer Centers
- 5 drugs
- Pharmacy:
75% wipe samples > LOD
- Nursing:
43% wipe samples > LOD
- 60% 1 drug, 32% 2+ drugs

LOD = Limit of Detection

Connor, et al., 1999; Connor, et al., 2010 *Am J Health Syst Pharm*

Nurses: Exposure Assessment Surveys



- Reported during routine handling and administration (N=2069, US):

42%	Not wearing appropriate gown
11-17%	Dermal or eye exposure (previous year)
4-11%	Skin contact (previous week)
12-24%	Taking home contaminated clothes
1.4%	Sharps injury involving chemotherapy (previous year)

- Spills and Preparation:

- 12% reported spills (previous week) (state-wide survey, Michigan)
- Multiple staff usually involved in spill clean-up
- Staff reporting spills had HDs in urine
- Staff who *DID NOT* report spills had HDs in urine
 - Staff tested positive for HD in urine; pharmacy

Connor 2010; Boiano, 2014; Boiano, 2015; Friese, 2012; 2014



USP<800> OVERVIEW

Improving Healthcare Personnel,
Patients, And Environment



- US Scientific nonprofit organization that sets standards for the identify, strength, quality and purity of medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide since 1820.
 - Drives its mission through public standards and programs
 - Created by physicians who saw a recognized need for a national lexicon of drug names and formulas
 - National Formulary



USP <800> Hazardous Drugs-Handling in Healthcare Settings



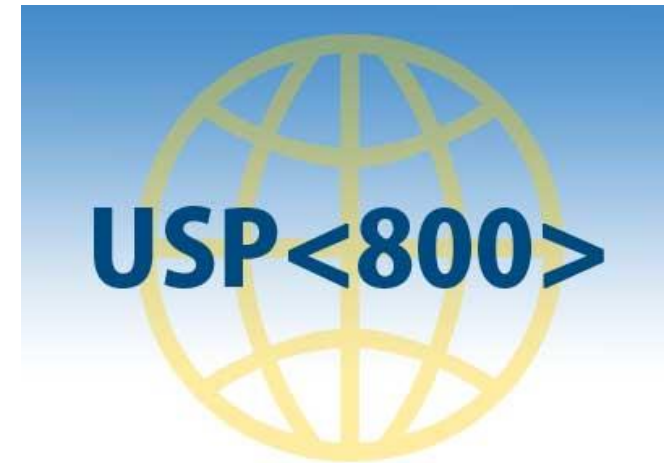
- Applies to:
 - Requirements for receipt, storage, compounding, dispensing, and administration of hazardous drugs (HDs) to protect patient, healthcare personnel, and environment
- Differs, expands from USP<797> *Pharmaceutical Compounding-Sterile Preparations* in scope
- Includes revisions, clarifications, and updates
- Implementation Date: July 2018

Link: http://www.usp.org/sites/default/files/usp_pdf/EN/m7808_pre-post.pdf

Scope



- Engineering Controls
- Competent Personnel
- Safe Work Practices
- Proper Use of PPE
- Policies for HD Waste Segregation and Disposal





Chapter Provides Specific Guidance for:

- List of Hazardous Drugs
- Containment Requirements & Labeling
- Types of Exposures
 - Dispensing, Compounding, Administration, Patient Care, Spills, Receipt, Transport
 - Counting, Crushing, Reconstituting, Transfer, Priming IV, Delivery
- Responsibilities of Personnel Handling HDs
- Facility Receipt & Storage
- Environmental Quality and Control
- PPE
- Hazard Communication Program
- Training
- Medical Surveillance



Surveillance & Safety Systems Designed to Reduce Occupational Risk



No Data. No Problem.

Without recording and measuring incidents over time, it is not possible to connect potential negative health hazards to an occupational exposure (acute or continuous).



Recording & Surveillance Systems

- Employee Health Incident Reports
- OSHA 300 Log
- Exposure Prevention Information Network (EPINet)
- Workers Compensation
- State Reporting
- Registries
- Others?

Importance of Reporting Known Exposures



- Incidents must be *reported* in order to be recorded in a surveillance system
- Direct, Acute Injury Incidents
 - Needlesticks, Sharps Injuries
 - Liquid Splash to Mucous Membrane, Skin
 - Ingestion
 - Touch
- Report to employee health, potential follow-up with workers compensation
- Ongoing exposures occurring from aeration, touch of contaminated surface are likely unknown and unreported



Similarities to Needlesticks, Sharps Safety

- Previously unknown exposures/risk become widely known; HIV/AIDS
- High profile exposures; Florida dental cases, Ryan White transfusion, nurse needlesticks
- Emergency Standards & Precautions; CalOSHA, OSHA, CDC
- National Surveillance; OSHA (300 log), CDC (former NaSH), EPINet
- Ongoing Problem Requiring Legislation; Needlestick Safety and Prevention Act
- New, Improved OSHA Bloodborne Pathogens Standard to include additional requirements for engineering controls (safer medical devices), recordkeeping (sharps injury log), frontline employee safety device evaluation



Methods of Control/Prevention

Industrial Hygiene: Hierarchy of Controls



Institutional

Departmental

Individual

- Elimination
- Substitution
- Engineering Controls
- Administrative Controls
- Work Practices
- Personal Protective Equipment

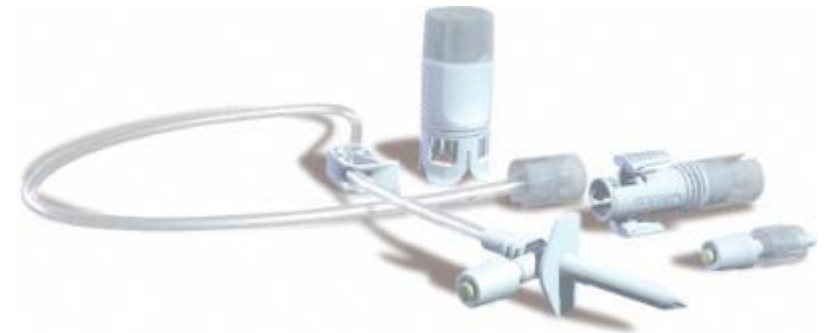
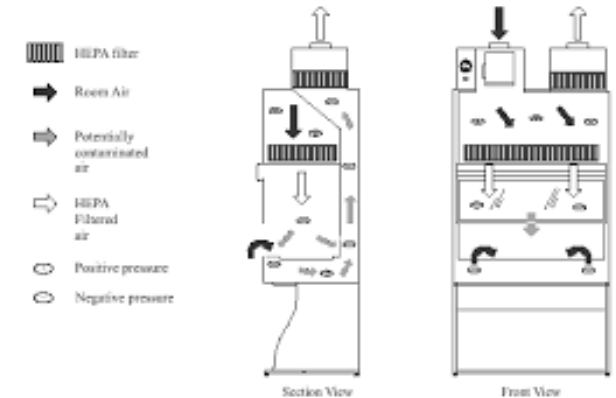
Best

Worst

Engineering Controls & Safety Systems



- Compounding:
 - Fume Hoods
 - Area Monitoring
- Administration
 - Safer Medical Devices, Sharps with Safety Features
 - Closed System Transfer Devices
 - Needless Systems
 - Locking Connections





Making the Case to Administrators

Standard = Expectation



USP<800> applies to “***all healthcare personnel*** who handle HD preparations and ***all entities*** which store, prepare, transport, or administer HDs”

- ***No exceptions based on HD volume, category of personnel, type of facility***
- ***Share the message***

Quality and Safety



- Be informed
 - “Speak” USP Chapter 800
- Quality improvement approach
 - Assess
 - Identify problem
 - Plan intervention
 - Provide intervention
 - Evaluate impact
- *Craft the message*

Past Recommendations → New Standards



- Engineering controls:
 - Negative pressure room for drug preparation
 - External venting of containment primary engineering controls
 - Closed System Transfer Devices (CSTDs) for HD administration
- Medical Surveillance of *Healthcare workers who handle HDs as a regular part of their job assignment*
- *Focus on the message*



Assess Current Status



- Perform a baseline assessment
 - Take an honest look at your practice setting
- Document areas of compliance
 - Assess the 18 sections of the chapter
 - Use a checklist for a comprehensive review

Readiness Survey



4. Responsibilities of Personnel Handling HDs				
#	Item	Present	Absent	Comments
1.	Entity designates a person to oversee compliance			
2.	Designated person is qualified and trained			
3.	Designated person monitors compliance, maintains reports of testing/ sampling			
Additional Notes:				

Readiness Survey (2)



8. Hazard Communication Program				
#	Item	Present	Absent	Comments
a.	Written plan in place			
b.	All HD containers are labeled with a hazard warning			
c.	SDS onsite for each hazardous chemical			
d.	SDSs accessible to personnel in all locations and at all times			
e.	Personnel receive initial and updated information and training			
f.	Personnel of reproductive capability confirm understanding of risks in writing			

Perform a Gap Analysis



- Process used to determine the steps needed to move from the *current* state to *future* state
- Steps
 - Review results of baseline assessment
 - List areas of non-compliance
 - ***Share the data***

Impact on Nurses



- USP<800> sets requirements for safe administration of hazardous drugs
 - Use of closed systems when the dosage form allows
 - Use of protective techniques when spiking/ priming IV tubing
 - Use of chemotherapy-tested PPE
 - Use of procedures that minimize manipulating HDs
- May involve changes in procedures / routines / equipment
- WILL require collaboration, education, and training

Definitions:



- Closed System
 - Device used to transfer a sterile drug from one container to another
 - Goals: *maintain sterility of the product*
- Closed System Transfer Device (CSTD)
 - Device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of liquid or vapor out of the system
 - Goal: *maintain sterility AND prevent escape of drug*

CSTD Selection Criteria

- Evaluate Containment
- Pharmacy and Nursing Collaboration
- Cost
- Ease of Use
- Ergonomics
- Compatibility
- Workflow





Oncology Nurse's Role as an Advocate for Safety

To Achieve Compliance with USP<800>



- Set the priority
- Establish an interdisciplinary team
- Identify barriers

Set Compliance as a Priority



- Identify a “champion” who:
 - Has the power to make change
 - Is a formal or informal leader
 - Is willing to participate in the process
- Obtain buy-in from organizational leadership
 - Educate/ inform
 - Request necessary resources

Assemble the Interdisciplinary Team



- Pharmacy
- Nursing
- Administration
- Purchasing / Products Committee
- Safety Committee
- Industrial Hygiene
- Environmental Services
- Employee Health
- Quality Department

Successful Collaboration

- Requires positive attitude across the organization
- Essential to system change
- Requires shared vision
- Requires diversity
- Based on trust



Identify the Barriers



- Things that interfere with implementing the standards
- “Unavailability, inconvenience, expense, difficulty, or time consuming nature of a particular action*”
- Examples:
 - Financial (increased cost/ “cost shift”)
 - Practical (purchasing / storing protective equipment)
 - Environmental (safety climate)
 - Situational (time constraints)
 - Psychosocial (worker / peer attitudes)

*Pender, et al., 2006, p. 53)

Safety Standards → Increased Safety



- Develop action plan
 - Specific requirement
 - Action Steps
 - Target date
 - Responsible person(s)

Action Plan



Specific Requirement	Action Steps	Target Date	Responsible Person	Resources Needed
1. Designate a person to oversee USP<800> compliance	<ul style="list-style-type: none"> • Develop position description • Request applicants • Identify training/ education needs • Identify education source 	September 2016	John Smith	XX Committee Fees: Education/ training
2. Personnel of reproductive capability confirm understanding of risk in writing	<ul style="list-style-type: none"> • Develop policy • Develop form • Develop training/ education plan • Implement policy 	December 2016	Susan Jones	Employee Health XX Committee

Conclusions



- Healthcare professionals must understand the risks of HD exposure and the safety systems that provide protection
- Practices for HD safe handling need to be consistent across the healthcare facility and in compliance with standards
- Nurses must be prepared to implement safety systems to reduce HD exposures to protect themselves, their teams, their patients, and the environment
- Oncology nurses must participate as vital stakeholders and take an active role in implementing a comprehensive HD safe handling program with support from administration



THANK YOU!

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