

Ensuring Readiness for USP Chapter <800> on Handling Hazardous Drugs: Assessment, Planning, and Implementation

Presented as a Midday Symposium and Live Webinar at the
51st ASHP Midyear Clinical Meeting and Exhibition

Tuesday, December 6, 2016
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www.ashpadvantage.com/go/800

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**Ensuring Readiness for USP Chapter <800> on Handling Hazardous Drugs:
Assessment, Planning, and Implementation**

Agenda

11:30 a.m. – 11:35 a.m.

Welcome and Introductions

Ryan A. Forrey, Pharm.D., M.S., FASHP

11:35 a.m. – 11:45 a.m.

Overview of USP Chapter <800>

Martha Polovich, Ph.D., RN, AOCN

11:45 a.m. – 12:40 p.m.

Panel Discussion: 4 Key Topics from USP Chapter <800>

All Faculty

12:40 p.m. – 1:00 p.m.

Faculty Discussion and Audience Questions

All Faculty

Faculty

Thomas H. Connor, Ph.D., *Activity Chair*

Research Biologist

Division of Applied Research and Technology

National Institute for Occupational Safety and Health

Centers for Disease Control and Prevention

Cincinnati, Ohio

Ryan A. Forrey, Pharm.D., M.S., FASHP

Director of Pharmaceutical Services

Emory University Hospital Midtown

Atlanta, Georgia

Jeannell M. Mansur, Pharm.D., FASHP, FSMSO, CJCP

Principal Consultant, Medication Management and Safety

Joint Commission Resources

Joint Commission International

Oak Brook, Illinois

Martha Polovich, Ph.D., RN, AOCN

Director, Ph.D. Program

Byrdine F. Lewis School of Nursing and Health Professions

Georgia State University

Atlanta, Georgia

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- Dr. Forrey is a member of the United States Pharmacopeia (USP) Compounding Expert Committee, but is not speaking as a representative of USP.
- Thomas Connor participated in the development of the content for this activity. Although Dr. Connor is an employee of National Institute for Occupational Safety and Health (NIOSH), his contributions do not necessarily represent the views of NIOSH. Mention of any company or product does not constitute endorsement by NIOSH. In addition, citations to Web sites external to NIOSH do not constitute NIOSH endorsement of the sponsoring organizations or their programs or products. Furthermore, NIOSH is not responsible for the content of these Web sites. All Web addresses referenced in this document were accessible as of the publication date.
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Activity Overview

The countdown is on to July 1, 2018, which marks the official implementation date for USP General Chapter <800> titled, “Hazardous Drugs---Handling in Healthcare Settings.” In this activity, faculty will review key engineering controls required for compliance with the standards, noting that those controls vary for the three categories of hazardous drugs on the NIOSH hazardous drug list. In addition, resources to guide a healthcare facility’s self assessment of readiness to meet Chapter <800> standards will be described. Firsthand experience from a site that has already implemented many of the standards will be shared. Implementation of the standards from the perspective of the inter-professional team will be included.

Learning Objectives

At the conclusion of this application-based educational activity, participants should be able to

- Describe key engineering controls required for compliance with USP General Chapter <800> on handling hazardous drugs in healthcare settings.
- Define the three categories of hazardous drugs on the NIOSH hazardous drug list.
- Describe the process of performing an assessment of risk for drugs used in your practice setting
- List at least two resources to guide a healthcare facility’s assessment of its readiness to meet Chapter <800> standards.
- Describe an interdisciplinary plan for assessing a healthcare facility’s compliance with USP General Chapter <800> standards and identifying solutions for areas needing change.

Additional Educational Opportunities about USP Chapter <800> Coming in 2017

- **Web-based activity** - Based on today’s live symposium (1.5 hours of CE, *please note that individuals who claim CE credit for the live symposium or webinar are ineligible to claim credit for the web-based activity*)

For more information and to sign up to receive e-mail updates visit

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Continuing Education Accreditation



The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

This activity provides 1.5 hours (0.15 CEUs – no partial credit) of continuing pharmacy education credit.

Live Activity ACPE #: 0204-0000-16-475-L03-P

On-Demand Activity ACPE #: 0204-0000-16-475-H03-P



Complete instructions for processing continuing education credit online are listed on the last page.

Webinar Information

Visit www.ashpadvantage/go/800 to find:

- Webinar registration link
- Group viewing information and technical requirements

**Ensuring Readiness for USP Chapter <800> on Handling Hazardous Drugs:
Assessment, Planning, and Implementation**

Faculty

Thomas H. Connor, Ph.D., *Activity Chair*

Research Biologist

Division of Applied Research and Technology

National Institute for Occupational Safety and Health

Centers for Disease Control and Prevention

Cincinnati, Ohio

Thomas H. Connor, Ph.D, is currently Research Biologist in the Division of Applied Research and Technology at NIOSH. He received his doctoral degree from the University of Texas Medical Branch and was a member of the faculty of the University of Texas, School of Public Health in Houston for 20 years.

Dr. Connor was a primary contributor to the NIOSH Alert on Hazardous Drugs and is responsible for updating the Alert and periodic updates to the list of hazardous drugs in the Alert. Dr. Connor was a member of the USP 800 Expert Panel. He was awarded the 2008 ASHP Board of Directors' Award honoring non-pharmacists for their contribution to the practice of pharmacy. In 2010 he received the International Society of Oncology Pharmacy Practitioners' Achievement Award for developing the ISOPP Standards of Practice for Safe Handling of Hazardous Drugs. His research has focused on occupational exposure to hazardous drugs in healthcare settings. Dr. Connor has published and lectured extensively on hazardous drug exposure topics.

**Ensuring Readiness for USP Chapter <800> on Handling Hazardous Drugs:
Assessment, Planning, and Implementation**

Ryan A. Forrey, Pharm.D., M.S., FASHP

Director of Pharmaceutical Services
Emory University Hospital Midtown
Atlanta, Georgia

Ryan A. Forrey, Pharm.D., M.S., FASHP, is Director of Pharmaceutical Services, at Emory University Hospital Midtown in Atlanta, Georgia, and Clinical Assistant Professor at The Ohio State University (OSU) College of Pharmacy, Columbus, Ohio.

Dr. Forrey has published articles in the field of medication errors and prevention, operational efficiency and productivity measurement, and hazardous drug safe handling. He has presented on numerous topics, USP Chapter <797>, USP Chapter <800>, hazardous medication handling and preparation, and pharmaceutical waste management. In his role at Emory, he leads and directs the Department of Pharmacy for Emory University Hospital Midtown, which includes the outpatient infusion pharmacy areas for the Emory Winship Cancer Institute.

Dr. Forrey currently serves on the United States Pharmacopeial Convention (USP) Compounding Expert Committee for 2015-2020. He is also an active member of the Hematology/Oncology Pharmacists Association (HOPA), ASHP, and the International Pharmaceutical Federation (FIP). He currently represents HOPA on the Oncology Nursing Society (ONS) Safe-Handling Taskforce.

Ensuring Readiness for USP Chapter <800> on Handling Hazardous Drugs: Assessment, Planning, and Implementation

Jeannell Mansur, Pharm.D., FASHP, FSMSO, CJCP

Principal Consultant, Medication Management and Safety
Joint Commission Resources
Joint Commission International
Oak Brook, Illinois

Jeannell Mansur, Pharm.D, FASHP, FSMSO, CJCP, is Principal Consultant for Medication Management and Safety for Joint Commission Resources (JCR) and Joint Commission International. In this role, she provides direction to hospital leaders on medication safety design, medication system optimization and technology implementation to support patient safety and effectiveness. Organizations have sought her expertise in Lean Six Sigma and change acceleration performance improvement methods and tools to implement effective and sustainable improvement to challenging issues. Also in her role as Principal Consultant, Dr. Mansur provides expertise to the Joint Commission enterprise on medication system themes.

Dr. Mansur completed training with the Institute for Healthcare Improvement in medication safety under the direction of Drs. Donald Berwick and Lucian Leape. As a result of this training Dr. Mansur was able to craft a systems-based approach to medication safety that is in line with Dr. Mansur's philosophies.

Dr. Mansur has extensive experience in all aspects of medication system design and implementation as well as hospital pharmacy, which includes clinical, operational and management responsibilities. Dr. Mansur was Director of Pharmaceutical Services at the University of Chicago Medical Center for 12 years before she became Executive Director for Pharmacy Informatics. As the Executive Director for Pharmacy Informatics she was involved in the planning, building and implementation of the organization's electronic medical record.

Dr. Mansur received her Bachelor of Science degree in Pharmacy from the University of Michigan and her Doctor of Pharmacy degree from Wayne State University.

Dr. Mansur has consulted throughout the United States, and internationally in Europe, Asia, Africa, Central and South America, the Far East and the Middle East. Dr. Mansur has published and presented extensively in the areas of medication safety and pharmacy operations improvement. She authored a chapter on Medication Safety in "*Pediatric Safety in the Emergency Department*," a textbook published jointly by Joint Commission Resources and the American Academy of Pediatrics. In 2016 she authored an article entitled "Medication Systems and the Important Role of Pharmacists" in *Drugs & Aging* and a chapter entitled "Immediate-Use Compounding" in *Compounding Sterile Preparations, Fourth Edition*, published by the American Society of Health-system Pharmacists.

Dr. Mansur has been recognized for her distinguished work by the designation of Fellow with the American Society of Health-System Pharmacists and the American Society for Medication Safety Officers. She is a voting member of the United States Pharmacopeial (USP) Convention.

Ensuring Readiness for USP Chapter <800> on Handling Hazardous Drugs: Assessment, Planning, and Implementation

Martha Polovich, Ph.D., RN, AOCN

Assistant Professor
Director, Ph.D. Program
Byrdine F. Lewis School of Nursing and Health Professions
Georgia State University
Atlanta, Georgia

Martha Polovich, Ph.D., RN, AOCN, is Assistant Professor and Director of the Nursing Ph.D. program for Byrdine F. Lewis School of Nursing and Health Professions at Georgia State University in Atlanta, Georgia. Dr. Polovich graduated from Mount Sinai Hospital School of Nursing in Chicago, Illinois. She received her Bachelor of Science and Master of Science degrees in nursing from Louisiana State University in New Orleans, Louisiana, and received her Doctor of Philosophy degree in Nursing from Georgia State University.

Prior to teaching at Georgia State University, she was Director of Clinical Practice, Nursing Research and Education at the Duke Oncology Network (now Duke Cancer Network) in Durham, North Carolina. From 1987-2012, Dr. Polovich cared for oncology patients in inpatient, outpatient, and home hospice settings, and provided education for oncology nurses and evaluated nurses' competency related to chemotherapy administration.

Dr. Polovich's research interests include occupational hazardous drug exposure of nurses and other healthcare workers. Dr. Polovich has published extensively on this topic. Dr. Polovich was lead author of "Chemotherapy and Biotherapy Guidelines and Recommendations for Practice, 4th Edition, which was published by the Oncology Nursing Society in 2014, and was editor of the "Safe Handling of Hazardous Drugs, 2nd edition," which was published by the Oncology Nursing Society (ONS) in 2011.

Dr. Polovich has served in the past as a member on the Expert Panel on Hazardous Drugs for the United States Pharmacopeial Convention, and as a member of the Technical Expert Panel for the Outpatient Chemotherapy Standards for the Centers for Medicaid and Medicare Services. She is member of the American Society of Clinical Oncology (ASCO) /ONS Chemotherapy Safety Standards Steering Committee and the NIOSH Hazardous Drug Review Panel.

ENSURING READINESS FOR USP CHAPTER <800> ON HANDLING HAZARDOUS DRUGS



ASSESSMENT, PLANNING AND IMPLEMENTATION

A MIDDAY SYMPOSIUM AND LIVE WEBINAR CONDUCTED AT

THE 51ST ASHP MIDYEAR CLINICAL MEETING AND EXHIBITION

Tuesday, December 6, 2016 | 11:30 a.m. – 1:00 p.m. PT

Islander Ballroom F, Mandalay Bay Hotel
North Convention Center | Las Vegas, Nevada

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FACULTY

<p>Thomas H. Connor, Ph.D., Activity Chair Research Biologist Division of Applied Research and Technology National Institute for Occupational Safety and Health Centers for Disease Control and Prevention Cincinnati, Ohio</p>	<p>Ryan A. Forrey, Pharm.D., M.S., FASHP Director of Pharmaceutical Services Emory University Hospital Midtown Atlanta, Georgia</p>
<p>Jeannell Mansur, Pharm.D., FASHP, FSMSO, CJCP Principal Consultant, Medication Management and Safety Joint Commission Resources Joint Commission International Oak Brook, Illinois</p>	<p>Martha Polovich, Ph.D., RN, AOCN Assistant Professor Director, Ph.D. Program Byrdine F. Lewis School of Nursing and Health Professions Georgia State University Atlanta, Georgia</p>

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- Describe key engineering controls required for compliance with USP General Chapter <800> on handling hazardous drugs in healthcare settings.
- Define the three categories of hazardous drugs on the NIOSH hazardous drug list.
- Describe the process of performing an assessment of risk for hazardous drugs used in your practice setting.
- List at least two resources to guide a healthcare facility's assessment of its readiness to meet Chapter <800> standards.
- Describe an interdisciplinary plan for assessing a healthcare facility's compliance with USP General Chapter <800> standards and identifying solutions for areas needing change.

Overview of USP Chapter <800>

Martha Polovich, Ph.D., RN, AOCN

Assistant Professor
Director, Ph.D. Program
Byrdine F. Lewis School of Nursing and
Health Professions
Georgia State University
Atlanta, Georgia

How compliant is your organization with the USP Chapter <800> standards?



- A. My organization is fully compliant
- B. My organization is about 75 % compliant
- C. My organization is about 50% compliant
- D. My organization is about 25% compliant
- E. We are in trouble!

Guidelines vs. Standards

Guidelines

- Recommended practice
- Based on evidence
- From a reliable source
- What “should” be
- Example:
 - ASHP Guidelines

Standards

- Expectations for practice
- Based on strong evidence
- From a reliable source or regulatory agency
- What “must” be
- Example:
 - The Joint Commission Standards

Guidelines for Hazardous Drug Safety

- **ASHP** – *Technical Assistance Bulletin / Guidelines on Handling Cytotoxic & Hazardous Drugs* (1985, 1990, 2006)
- **Occupational Safety and Health Administration** – *Controlling Occupational Exposure to Hazardous Drugs* (1986, 1995, 1999, 2016)
- **Oncology Nursing Society (ONS)** – *Chemotherapy & Biotherapy Guidelines and Recommendations for Practice* (1984, 1988, 1996, 1999, 2001, 2005, 2009, 2014)
- **National Institute for Occupational Safety & Health** – *Preventing Occupational Exposures to Antineoplastic & Other Hazardous Drugs in Healthcare Settings* (2004, 2010, 2012, 2014, 2016*)

Standards for Hazardous Drug Safety

- U.S. Pharmacopeial Convention
 - Quality standards for medicines sold in U.S.
- Applicable standards:
 - USP <795> Non-sterile Compounding
 - USP <797> Sterile Compounding
 - USP <800> Hazardous Drugs Handling in Healthcare Settings
- Enforceable by:
 - Food Drug Administration
 - State Boards of Pharmacy
 - The Joint Commission

The Facts

- **General Chapter <800> published:**
 - February 1, 2016
- **Delayed official implementation:**
 - July 1, 2018
- **Practice & Quality Standards to promote:**
 - Patient safety
 - Worker safety
 - Environmental protection

<http://www.usp.org/usp-nf/notices/general-chapter-hazardous-drugs-handling-healthcare-settings-published-usp-39-nf-34-first-supplement>

USP Chapter <800> Applies To

“...All healthcare personnel who handle hazardous drug (HD) preparations and all entities which store, prepare, transport, or administer HDs”

No exceptions based on HD volume, category of personnel, or type of facility

USP. 39-NF 34. 2016; (1 suppl):7721-7739.

Specific Guidance

- List of Hazardous Drugs
- Types of exposures
- Personnel responsibilities
- Facilities and engineering controls
- Environmental quality and control
- Personal protective equipment
- Hazard communication
- Personnel training
- Receiving
- Labeling, packaging, transport, and disposal
- Dispensing final dosage forms
- Compounding
- Administering
- Deactivating, decontaminating, cleaning, disinfecting
- Spill control
- Standard operating procedures
- Medical Surveillance

All Standards → All Hazardous Drugs

- Step 1: Develop facility-specific list of hazardous drugs
 - Determines applicability of standards
- Step 2: Establish multidisciplinary team
 - Organization-wide endeavor

Assessment of Risk

Ryan A. Forrey, Pharm.D., M.S., FASHP
Director of Pharmacy
Emory University Hospital Midtown
Atlanta, Georgia

Has your institution conducted an assessment of risk for handling hazardous drugs?



- A. Yes, we have started
- B. Yes, we have completed
- C. No
- D. I'm not sure

Risk Assessment vs. Assessment of Risk

- Quite different processes
- Should understand the difference between the two

Risk Assessment

- Human health risk assessment
- Qualitative or quantitative
- Multi-step process
 - Hazard identification
 - Dose-response assessment
 - Exposure assessment
 - Risk characterization

Risk Assessment

- Is not practical for healthcare settings
 - Difficult to quantify exposure
 - Potential exposure to dozens of drugs

Assessment of Risk

- Hazard identification
 - Drugs listed by NIOSH as potential occupational hazards
- Compare your formulary to NIOSH list
- Determine use of drug in your facility
 - Formulation, frequency, where/how used
- Risk varies from very low (single intact tablet) to very high (i.v. chemotherapy drug)

Assessment of Risk

- Must be a multi-disciplinary process
- Cannot be just pharmacy
- All affected job titles need to be involved
 - Pharmacy, nursing, receiving, transportation, housekeeping, waste disposal

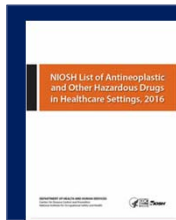
Assessment of Risk

- Examples:
 - Pharmacy dispenses cyclophosphamide tablets
 - Nurse crushes tablets and places in applesauce
 - Patient vomits after receiving drug
 - Disposal of a wet diaper from pediatric patient

Risk changes with each activity

NIOSH List of Hazardous Drugs

- Original list (2004) compilation of several lists
- Updated every other year since 2010
- In 2014, all drugs re-evaluated and list divided into three groups
- All drugs considered hazardous
- Current update September 2016



NIOSH list of Hazardous Drugs 2014

- Group 1 – Antineoplastic Drugs (AHFS 10:00)
 - All are reproductive hazards
- Group 2 – Non-antineoplastic hazardous drugs
 - Reproductive hazards are identified by font color
- Group 3 – Drugs with reproductive risk only
 - All are reproductive hazards

Table 5. Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
All types of hazardous drugs	Receiving, unpacking, and placing in storage	no (single glove can be used)	yes, when spills and leaks occur	no	yes, when spills and leaks occur	no
Intact tablet or capsule	Administration from unit-dose package	no (single glove can be used)	no	no	no	N/A
Tablets or capsules	Cutting, crushing, or manipulating tablets or capsules; handling uncoated tablets	yes	yes	no	yes, if not done in a control device	yes ¹
	Administration	no (single glove can be used)	no	yes, if vomit or potential to spit up ¹	no	N/A

http://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf

Example Assessment of Risk

Generic Name	HD	Trace	HD# No	Block	Prog	Act	Supplemental Information	Drugs Form(s)	HD Storage	HD Compounding	Administration	Special Precautions for Disposal (if RCRA HD)	
Abiraterone	Y		81818-20	Y	C	antitumor	pregnant women observed on trade and brand name HD and HD# are contraindicated to use reproductive toxic.	Oral tablet	N	N		Single glove	Non-HD
Abiraterone			3030	X		OPV3 inhibitor	pregnant women who given or do not handle	Oral tablet	N	Y	Double Glove	RCRA HD	
Abiraterone			8034	Y	X	retardant	black box warning on adverse reproductive effects	Oral capsule	N	N	Single glove	Non-HD	
Abiraterone			3030	Y	S	antitumor	Special warning on contraindication to breast-feeding	Oral capsule	N	Y	Double Glove	RCRA HD	
Abiraterone			3030	Y	S	antitumor	Special warning on contraindication to breast-feeding	Oral capsule	N	Y	Double Glove	RCRA HD	
Abiraterone			8032	Y	S	antitumor/antipain	Accidental increased frequency of emphysema/ hyperinflated lungs (patients)	Or	N	Y	Single glove	Non-HD	
Abiraterone			8032	Y	S	retardant		Oral capsule	N	N	Single glove	Non-HD	
Abiraterone			3030	Y	S	antineoplastic		Oral capsule	N	Y	Double Glove	RCRA HD	

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See page 30 for enlarged view

Example Assessment of Risk

HD#	Dosage Form(s)	HD Storage	HD Compounding	Administration	Special Precautions for Disposal (if RCRA HD)
6	Oral tablet	N	N	Single glove	Non-HD
	Oral tablet	N	Y	Double Gloves	RCRA HD
	Oral capsule	N	N	Single glove	Non-HD
	IV	Y	Y	Full PPE	Trace Chemo
7	Oral tablet	N	Y	Double Gloves	RCRA HD
	IV	N	Y	Single glove	Non-HD
	Oral capsule	N	N	Single glove	Non-HD
	Oral capsule	N	Y	Double Gloves	RCRA HD


Used with Permission: Ryan Forrey, Emory University Hospital Midtown

See page 31 for enlarged view

**Panel Discussion:
Assessment of Risk**

Engineering Controls

Ryan A. Forrey, Pharm.D., M.S., FASHP
Director of Pharmacy
Emory University Hospital Midtown
Atlanta, Georgia

Which of the following primary engineering controls are acceptable for sterile hazardous drug compounding? 

A. Containment ventilated enclosure (CVE)
B. Class II Type A2 biological safety cabinet
C. Class II Type B2 biological safety cabinet
D. B and C
E. All of the above

Types of Engineering Controls

Nonhazardous Drug Compounding

- Primary engineering control (PEC)
- Secondary engineering control (SEC)

Hazardous Drug (HD) Compounding

- Containment primary engineering control (C-PEC)
- Containment secondary engineering control (C-SEC)
- Supplemental engineering control

Primary Engineering Control (PEC)

- A device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs
 - Examples include:
 - Laminar Airflow Workbench (LAFW)
 - aka “horizontal hood”
 - Biological Safety Cabinet (BSC)
 - aka “vertical hood”
 - Compounding Aseptic Isolator
 - aka “glove box”

Secondary Engineering Control (SEC)

- The room in which the PEC is placed
- Buffer room
 - ISO Class 7
 - 30 air changes per hour (ACPH)
- Segregated Compounding Area (SCA)
 - Not classified
 - No unsealed windows or doors to the outside
 - Beyond Use Date (BUD) limited to 12 hours or less

Containment Primary Engineering Control (C-PEC)

- A ventilated device designed to minimize worker and environmental HD exposure when directly handling HDs
 - Compounding Aseptic Containment Isolator (CACI)
 - Biological Safety Cabinet (BSC)
 - Class II Type A2
 - Class II Type B2



Photo used with Permission: Ryan Forrey, Emory University Hospital Midtown

Containment Secondary Engineering Control (C-SEC)

- This is the room in which the C-PEC is placed
 - Buffer room
 - Pressure -0.01 to -0.03 inches water column
 - ISO Class 7
 - 30 ACPH
 - Externally vented



Photo used with Permission: Ryan Forrey, Emory University Hospital Midtown

Containment Secondary Engineering Control (C-SEC)

- Containment Segregated Compounding Area (C-SCA)
 - 12 ACPH
 - Pressure -0.01 to -0.03 inches water column
 - Externally vented



Photo used with Permission: Ryan Forrey, Emory University Hospital Midtown

Supplemental Engineering Controls

- Adjunct engineering controls to offer additional levels of protection
 - Closed system drug transfer devices (CSTDs)
- Supplemental when other engineering controls are required (i.e., C-PECs and C-SEC)
- Required when no other engineering control are required (e.g., administration of HDs)

Panel Discussion: Engineering Controls

Training and Competency

Martha Polovich, Ph.D., RN, AOCN
Assistant Professor
Director, Ph.D. Program
Byrdine F. Lewis School of Nursing and
Health Professions
Georgia State University
Atlanta, Georgia

Which of the following statements would indicate that a pharmacy technician is competent in the use of personal protective equipment for handling HDs?



- a. "If I am mixing a HD infusion, I can just wear a pair of chemotherapy gloves"
- b. "Wearing personal protective equipment is recommended, but is really a personal choice."
- c. "Chemotherapy agents are hazardous, require special handling, and pose a potential health risk"
- d. "Personal protective equipment is only required for preparing i.v. doses of HDs."

Training and Competency

- Training: What HD handlers need to *know*:
 - Job-specific
 - Provided before workers handle HDs independently
- Competency: What HD handlers *actually do*:
 - Job-specific
 - Demonstrated by each employee
 - Reassessed at least every 12 months

USP, 2016

Essential Components of Education

- List of HDs
- Risks of exposure
- Policies and procedures for HD handling
- Proper use of PPE
- Proper use of safety equipment
- What to do for exposure
- Managing spills
- Disposal



**Resources for HD Education,
Training, Competency**

- NIOSH: Recommended PPE and Safety Equipment
 - <http://www.cdc.gov/niosh/topics/antineoplastic/nioshpubs.html>
- OSHA: Training and Information Dissemination
 - https://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.html
- ONS: Personal Protective Equipment Guide
 - <https://www.ons.org/practice-resources/standards-reports/chemotherapy>

**Panel Discussion:
Training and Competency**

Organizing for Success

Jeannell Mansur, Pharm.D., FASHP, FSMSO, CJCP
Principal Consultant, Medication Management and Safety
Joint Commission Resources
Joint Commission International
Oak Brook, Illinois

Do you feel you have sufficient internal resources within your organization to help prepare an individual appointed to oversee USP <800> compliance?



- A. Yes
- B. No
- C. I'm not sure

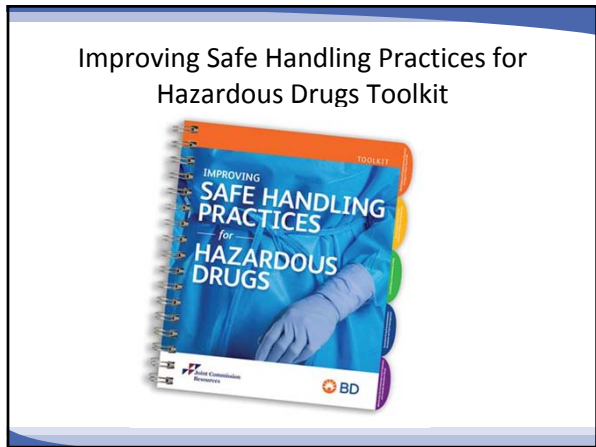
Organizing for Success

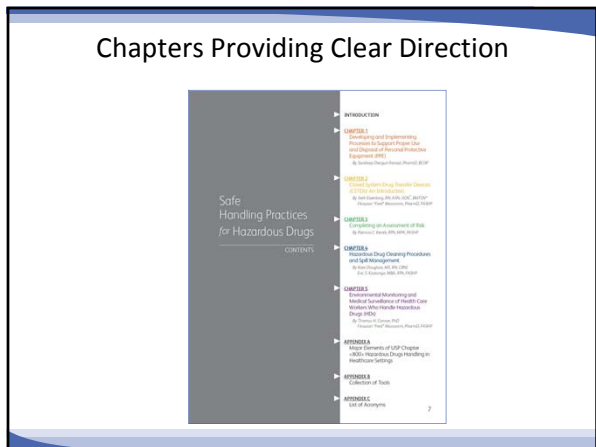
- Demonstrated expertise within the organization
 - Appointing an individual to oversee compliance
- Required documents
 - List of hazardous drugs used in the organization
 - Standard operating procedures for handling of hazardous drugs in all settings
 - Hazard communication plan
 - Occupational safety program

Organizing for Success

- Training of employees
- Confirmation of competency
- Assessment of risk, as per organization decision







Monitoring for Compliance

- Yearly review and update of written procedures
- Ensuring employee training and competency
- Using a tracer approach
 - Staff knowledge
 - Staff performance
 - Environmental monitoring
- Employee surveillance

**Panel Discussion:
Organizing for Success**

Take Away Points

- Assessment of Risk
 - The assessment of risk must be completed by a multi-disciplinary team, with each discipline providing input based on their handling of HDs
- Engineering Controls
 - All HD compounding must be done in a negative pressure C-SEC, but the C-SEC can either be a classified space or an unclassified C-SCA
 - The C-PEC for HD sterile compounding must be exhausted externally

Take Away Points

- Training and Competency
 - Personnel training is required for anyone and everyone with HD handling responsibilities.
- Organizing for Success
 - Prepare to organize your hospital for compliance now by identifying the person who will provide oversight, build expertise and perform a gap analysis of needs

Example Assessment of Risk

2016 NIOSH HAZARDOUS DRUGS LIST												
Generic Name	SHG	Table No	AHFS No	Black Box	Preg Cat	Activity	Supplemental Information	Dosage Form(s)	HD Storage	HD Compounding	Administration	Disposal (empty containers if IV, full/partial doses if oral) (Non-empty Trace Chemo containers must always be disposed of as RCRA HD)
abacavir		2	8:18:08:20	Y	C	antiviral	malignant tumors observed in male and female mice and rats; genotoxic in in vivo micronucleus test	Oral tablet	N	N	Single glove	Non-HD
abiraterone		1	10:00		X	CYP17 inhibitor	pregnant women wear gloves or do not handle	Oral tablet	N	Y	Double Gloves	RCRA HD
acitretin		3	88:04	Y	X	retinoid	black box warning on adverse reproductive effects	Oral capsule	N	N	Single glove	Non-HD
ado-trastuzumab emtansine	Y	1	10:00	Y	D	antineoplastic		IV	Y	Y	Full PPE	Trace Chemo
afatanib		1	10:00		D	antineoplastic	special warnings on contraception for females while taking and 2 weeks post-treatment	Oral tablet	N	Y	Double Gloves	RCRA HD
alefacept		2	84:92		B	immunosuppressant	discontinued; increased frequency of malignancies observed in treated patients	IV	N	Y	Single glove	Non-HD
alitretinoin		3	84:92	Y	D	retinoid		Oral capsule	N	N	Single glove	Non-HD
altretamine	Y	1	10:00	Y	D	antineoplastic		Oral capsule	N	Y	Double Gloves	RCRA HD

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Example Assessment of Risk

	Dosage Form(s)	HD Storage	HD Compounding	Administration	Disposal (empty containers if IV, full/partial doses if oral) (Non-empty Trace Chemo containers must always be disposed of as RCRA HD)
e	Oral tablet	N	N	Single glove	Non-HD
	Oral tablet	N	Y	Double Gloves	RCRA HD
	Oral capsule	N	N	Single glove	Non-HD
	IV	Y	Y	Full PPE	Trace Chemo
a	Oral tablet	N	Y	Double Gloves	RCRA HD
	IV	N	Y	Single glove	Non-HD
	Oral capsule	N	N	Single glove	Non-HD
	Oral capsule	N	Y	Double Gloves	RCRA HD

Used with Permission: Ryan Forrey, Emory University Hospital Midtown

Self-assessment Questions

1. Which of the following must be considered when determining the content of education for healthcare workers responsible for hazardous drug handling?
 - a. The expected frequency of hazardous drug handling.
 - b. The job-specific functions for which they are responsible.
 - c. The likelihood of spills in their work area.
 - d. The number of employees who require training.

2. Which of the following statements accurately reflects the USP Chapter <800> recommendations for the frequency of education, training and competency validation for hazardous drug handlers?
 - a. Frequency of training can be determined by facility policies and procedures.
 - b. Training must occur during orientation and after known exposure to hazardous drugs.
 - c. Training must occur prior to handling, at least every 12 months, and with new HDs or procedures.
 - d. Training is required prior to handling; reassessment frequency is not specified.

3. Competency of hazardous drug handlers refers to:
 - a. The results of knowledge assessment (e.g., passing a test).
 - b. The familiarity with policies or standard operating procedures for HD handling.
 - c. The demonstration of safe handling precautions during HD handling.
 - d. The documentation of HD handling education.

4. Which of the following are components of an Assessment of Risk?
 - a. Comparison of institutional formulary to the NIOSH HD list.
 - b. Determination of formulations, frequency and locations of use of HDs.
 - c. Multidisciplinary review of HD list.
 - d. A and B.
 - e. A, B and C.

5. As described in the 2016 NIOSH HD list, which of the groups of HDs represents those with reproductive risk only?
 - a. Group 1.
 - b. Group 2.
 - c. Group 3.
 - d. A and B.
 - e. A, B and C

**Ensuring Readiness for USP Chapter <800> on Handling Hazardous Drugs:
Assessment, Planning, and Implementation**

6. Which of the following are requirements for a containment segregated compounding area (C-SCA)?
 - a. A minimum of 12 air changes per hour (ACPH).
 - b. Negative pressure of 0.01 to 0.03 inches of water column pressure.
 - c. ISO class 7 air.
 - d. A and B.
 - e. A, B and C.

7. What type of containment primary engineering control (C-PEC) is appropriate for sterile HD compounding?
 - a. Class II Type A2 BSC.
 - b. Class II Type A2 BSC with external exhaust.
 - c. Containment ventilated enclosure (CVE) with double HEPA filtration.
 - d. A and B.
 - e. A, B, and C.

8. Which of the following would be good topics to include in the training of staff on safe handling of Hazardous drugs:
 - a. Sterile compounding techniques.
 - b. USP chapter <797> dating limits for sterile compounding.
 - c. Proper use of closed system transfer devices.
 - d. All of the above.

9. Competency assessment to determine acquisition of skills and incorporation of correct practices with handling of hazardous drugs could include all of the following except:
 - a. Demonstration of correct use of personal protective equipment (PPE).
 - b. Successful passing of a written exam on hazardous drugs handling procedures.
 - c. Observation of correct use of a vapor respirator.
 - d. Gloved fingertip testing.

Answers

1. b
2. c
3. c
4. e
5. c
6. d
7. b
8. d
9. d

**Ensuring Readiness for USP Chapter <800> on Handling Hazardous Drugs:
Assessment, Planning, and Implementation**

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