




Idaho Society of Health-System Pharmacists

 **CAUTION** 
Exposure to USP 800

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Disclosures

- We have no current or potential conflicts of interest associated with the content of this presentation.

Learning Objectives

- List the main difference between USP 795, USP 797, and USP 800
- Explain why USP 800 compliance is important for all healthcare staff
- List ways hazardous drug exposure can occur
- Describe ways to prepare for the implementation of USP 800

U.S. Pharmacopeia (USP) Compounding Standards

- Aims to enhance patient safety by helping healthcare professionals understand risks of compounding and establishing standards for everyday practice
- **Sterile Compounding <797>**
 - Intravenous (IV) infusions, intraocular (eye), intrathecal (spine)
- **Nonsterile Compounding <795>**
 - For formulations of medications not commercially available
- **Safe Handling of Hazardous Drugs <800>**

Compounding Standards, Rockville (MD): USP, 2018

Safe Handling of Hazardous Drugs <800>

- "Provides standards for safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients, and the environment."¹
- Describes requirements that include:
 - Responsibilities of personnel handling hazardous drugs
 - Facility and engineering controls
 - Procedures for deactivating, decontaminating and cleaning
 - Spill control
 - Documentation

Compounding Standards, Rockville (MD): USP, 2018

Hazardous Drug Exposure

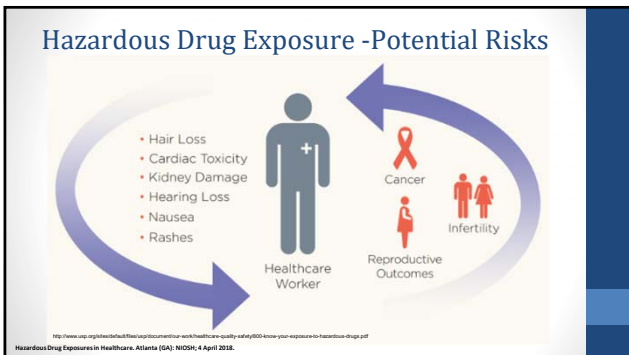
About 8 million U.S. healthcare workers are potentially exposed to hazardous drugs each year

- Healthcare workers who prepare or administer drugs used for cancer therapy, some antiviral drugs, hormone agents, and more
 - Pharmacists
 - Pharmacy technicians
 - Nurses
 - Physicians
 - Janitorial services
 - Housekeeping
 - Veterinarians
 - Shipping/receiving personnel

Hazardous Drug Exposures in Healthcare, Atlanta (GA): NIOSH, 4 April 2018.

What are examples of hazardous drug exposure?





Role of USP <800>

- Defines processes intended to minimize the exposure to hazardous drugs in healthcare settings
- Developed by the USP Compounding Expert Committee, with assistance from:
 - USP Compounding with Hazardous Drugs Expert Panel
 - U.S. Food and Drug Administration (FDA)
 - U.S. Centers for Disease Control and Prevention (CDC)
- **Official date:** December 1, 2019
 - Expected to meet the requirements of the USP <800> standard

FAQS - <800> Hazardous Drugs - Handling in Healthcare Settings, Rockville (MD) USP, 2018.

Handling Hazardous Drugs

Applies to all healthcare personnel who store, prepare, transport, or administer hazardous drugs.

NIOSH Definition of Hazardous Drug

1. Carcinogenicity
2. Teratogenicity or other developmental toxicity
3. Reproductive toxicity
4. Organ toxicity at low doses
5. Genotoxicity
6. Structure and toxicity profiles of new drugs that mimic existing drugs determined

Connor TH, et al. NIOSH 2016, 9-31

Personal Protective Equipment (PPE)

- Provides worker protection to reduce exposure to hazardous drug aerosols and residues
 - Disposable PPE must not be re-used
 - Reusable PPE must be decontaminated and cleaned after use
- Required PPE for compounding sterile & nonsterile hazardous drugs
 - Gowns
 - Head, hair, shoe covers
 - Two pairs of chemotherapy gloves
- Two pairs of chemotherapy gloves are required for administering antineoplastic hazardous drugs

Amadio, et al. Curr Oncol 2014;21:52-61.

What are some examples of hazardous drugs?

The National Institute for Occupational Safety and Health (NIOSH) Hazardous Drug List

- Antineoplastic drugs (cisplatin, doxorubicin, methotrexate, tamoxifen, etc.)
- Non-antineoplastic drugs that meet 1+ NIOSH hazardous drug criteria
 - Carbamazepine
 - Estradiol
 - Spironolactone
 - Tacrolimus
 - ...and more!
- Non-antineoplastic drugs that primarily have adverse reproductive effects
 - Clonazepam
 - Fluconazole
 - Topiramate
 - Warfarin
 - ...and more!

Connor TH, et al. NIOSH 2016, 9-31

Facility & Engineering Controls

- Hazardous drugs must be handled under conditions that promote patient safety, worker safety, and environmental safety
- Designated Areas Must be Available for
 - Receipt of Unpacking
 - Storage of hazardous drugs
 - Nonsterile hazardous drug compounding (if performed)
 - Sterile hazardous drug compounding (if performed)
- These areas must be restricted to authorized personnel, must be located away from breakrooms and from patients/visitors

Amadio, et al. Curr Oncol 2014;21:52-61.

Nonsterile & Sterile Compounding

- Primary Engineering Control (C-PEC)
 - Ventilated device designed to minimize worker/environmental exposure when working directly with hazardous drug
- Secondary Level of Control (C-SEC)
 - Room in which the C-PEC is placed
- Supplementary Level of Control
 - Adjunct controls to offer additional levels of protection
 - Ex: Closed-system drug transfer device
- Other requirements
 - Sink and eyewash station

Compounding Standards, Redville (MOS) USP, 2018

Deactivating, Decontaminating, Cleaning, and Disinfecting

- All reusable areas, equipment, and devices where hazardous drugs are handled
 - Deactivation: Inactivate compound
 - Ex: peroxide formulations, sodium hypochlorite
 - Decontamination: Remove hazardous drug residue
 - Ex: alcohol, water, peroxide, sodium hypochlorite
 - Cleaning: Remove organic and inorganic material
 - Ex: Germicidal detergent
- Sterile Compounding
 - Disinfection: destroy microorganisms
 - Ex: EPA-registered disinfectant, sterile alcohol

Amadio, et al. Curr Oncol 2014;21:52-61.

Spill Control

- Spills must be immediately contained and cleaned using a standardized procedure
- Spill Control Steps
 - Personal protective equipment with NIOSH-certified respirator
 - Spill Kits readily available
 - Signs restricting access placed
 - Personnel potentially exposed (skin or eye contact) require immediate evaluation
- All spills must be documented with circumstance and management of spill

Amadio, et al. Curr Oncol 2014;21:52-61.

Documentation

- Maintain Standards of Procedures for safe handling for all situations - reviewed every 12 months
- All training and competency assessment documented
 - Personnel who transport, compound or administer hazardous drugs
- Spill management
- Compounding logs
- Safety data sheet
- Medical Surveillance Program documentation

Amadio, et al. Curr Oncol 2014;21:52-61.

Think, Pair, Share:

- What are some things you can do to help prepare for the implementation of USP <800>?

Ways to Prepare for the Implementation of USP <800>

- Become trained based on job functions
- Have an updated NIOSH Hazardous Drug List
- Ensure pharmacy is compliant with USP 800 standards
- Stay current on updates
 - USP Website
 - Sign-up for USP Updates
 - Frequently Asked Questions
 - Education Courses
 - Download HaRx™

#1) USP 800 provides:

- A. Standards for safe handling of hazardous drugs to minimize the risk of exposure
- B. Standards to ensure quality of preparations are free from contaminants and consistent
- C. Standards for compounding process, facilities, equipment, documentation and training

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- A. Organ dysfunction
- B. Infertility in men and women
- C. Infertility in women only
- D. A and B
- E. A and C

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#3) Which healthcare worker is not at risk of a hazardous drug exposure?

- A. Pharmacist that just reconstituted amoxicillin suspension
- B. A nurse that needs to cut a patient's warfarin tablet in half
- C. Janitorial service that cleaned up a spill of methotrexate
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#4)

- **True or False:** The USP is in charge of ensuring compliance of USP <800> by applicable entities

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References

- Compounding Standards. Rockville (MD): USP; 2018. Available from: <http://www.usp.org/compounding>
- FAQs: <800> Hazardous Drugs - Handling in Healthcare Settings. Rockville (MD): USP; 2018. Available from: <http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings>
- Hazardous Drug Exposures in Healthcare. Atlanta (GA): The National Institute for Occupational Safety and Health (NIOSH); 4 April 2018. Available from: <https://www.cdc.gov/niosh/topics/hazdrug/>
- USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings. Rockville (MD): The United States Pharmacopeial Convention; 2017. Available from: <http://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/general-chapter-800.pdf>

Questions?

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