USP 800: Hazardous Drugs-Handling in Healthcare Settings

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Disclosure

- I have no actual or potential conflict of interest in relation to this program/presentation.

Pharmacist Learning Objectives

- Review the background of USP 800 and how it impacts pharmacist compliance.
- Discuss the process of determining your hazardous drug list and performing an assessment of risk.
- Summarize practice changes of USP 800 as they relate to pharmacist workflow compliance.

Technician Learning Objectives

- Discuss USP 800 and how it impacts pharmacy technician workflow.
- Review the differences in hazardous agents, which can impact their handling.
- Summarize practice changes that technicians can introduce into their workflow in the handling of hazardous medications.

Historical Foundation of USP 800

- Most of the content in USP 800 have been recommendations from the last 30 years
  - ONS-1982 Chemotherapy
  - ASHP-1983, 1985 Cytotoxic Drugs
  - OSHA-1986 Cytotoxic (Antineoplastic) Drugs
  - ASHP-1990 Cytotoxic and Hazardous Drugs
  - NIH-1992, 2002 Cytotoxic Drugs
  - OSHA-1995 Hazardous Drugs
  - NIOSH-2004 Antineoplastic and Other Hazardous Drugs
  - ASHP-2006 Hazardous Drugs
  - USP-2008 Sterile (Hazardous) Drugs
  - ONS-2011Hazardous Drugs
  - NIOSH-2016 [2] Antineoplastic and Other Hazardous Drugs

Topics Covered in USP 800

- 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

Definition of a Hazardous Agent

- Any drug identified by at least one of the following criteria:
  - Carcinogenicity, teratogenicity or developmental toxicity
  - Reproductive toxicity in humans
  - Organ toxicity at low doses in humans or animals
  - Genotoxicity or new drugs that mimic existing hazardous drugs in structure or toxicity

NIOSH Lists 3 Hazardous Drug Tables of Hazardous Medications

- Table 1 are typically what we consider chemotherapy, high risk hazardous medications
  - cyclophosphamide, doxorubicin
- Tables 2 and 3 are non-antineoplastic drugs meeting one or more criteria of a hazardous drug and those having adverse reproductive effects respectively
  - fosphenytoin, paroxetine

Hazardous Drug List

- Current proposed draft procedure for our hospital delineates two categories based on the NIOSH tables.
  - High Risk Hazardous Drugs-Table 1
  - Low Risk Hazardous Drugs-Tables 2 and 3

Assessment of Risk

- May be performed for some dosage forms to allow for alternative handling.
- If not performed all requirements of the chapter must be followed.
- Assessment must include Type of HD, Dosage Form, Risk of Exposure, Packaging, Manipulation.
- Assessment of Risk requires an annual review that is documented.

Is There a Risk?

- We have evidence that shows some workers exposed to certain chemotherapies have chromosomal abnormalities in chromosomes 5 and 7.[3]
- We have evidence that shows that patients treated with chemotherapy that develop secondary malignancies have similar chromosomal abnormalities in 5 and 7.[4]
- No definitive study connecting exposure while handling to the development of cancer.

By handling hazardous medications will you develop cancer?

A. Yes

B. No

C. We aren't sure, but regardless drugs listed as hazardous still meet at least one NIOSH criteria of a hazardous drug so handle with care.

Focused on Patient Safety

- Besides the safety of our patients we need to focus on:
  - Worker Safety
  - Environmental Protection

Potential Routes of Exposure

Activity	
Receipt	• Contacting HD residues present on drug containers, individual dosage units, outer containers, work surfaces, or floors.
Dispensing	• Counting or repackaging tablets or capsules
Compounding and other manipulations	• Crushing or splitting tablets or opening capsules • Pouring oral or topical liquids from one container to another • Weighing or mixing components • Constituting or reconstituting powdered or lyophilized HDs • Withdrawing or diluting injectable HDs from parenteral containers • Expelling air or HDs from syringes • Contacting HD residue present on PPE or other garments • Deactivating, decontaminating, cleaning, and disinfecting areas contaminated with or suspected to be contaminated with HDs • Maintenance activities for potentially contaminated equipment and devices
Administration	• Generating aerosols during administration of HDs by various routes • Performing certain specialized procedures • Priming an IV administration set
Patient-care activities	• Handling body fluids or body-fluid contaminated clothing, dressings, linens and other materials
Spills	• Spill generation, management, and disposal
Transport	• Moving HDs within a healthcare setting
Waste	• Collection and disposal of hazardous waste and trace contaminated waste

Personnel Responsibilities

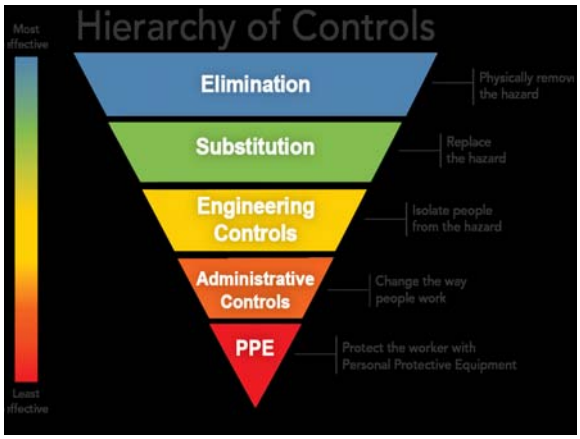
- Point person for compliance with USP 800, responsible for:
  - Procedure development
  - Entity Compliance
  - Personnel Competency Assurances
  - Understanding of Risks

Facility and Engineering Controls

- Designated areas must be available for:
  - Receipt and Unpacking
  - Storage of HDs
  - Nonsterile HD Compounding
  - Sterile HD Compounding

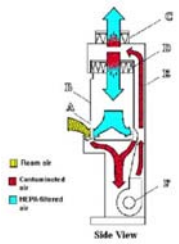
Receipt and Storage

- Specific controls on receiving area
  - Neutral/negative pressure, spill kit in vicinity
  - PPE
  - Inspect prior to opening
  - Handle breakage as spill
  - Drugs delivered from receiving to storage in plastic
- Storage
  - High risk hazardous and API under negative pressure
  - Final dosage units and low risk can be with regular inventory



Primary Engineering Control

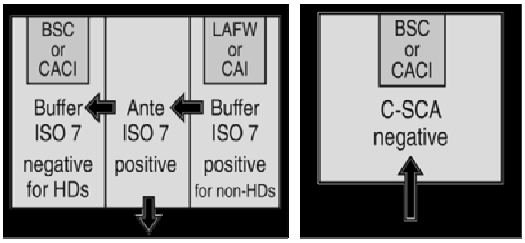
- AKA a chemo hood, Biological Safety Cabinet
- Required for antineoplastic agents
- Plan is for us to prepare everything from the 2016 NIOSH Table 1 in a Biological Safety Cabinet



Secondary Engineering Control

- This is the buffer room where the primary engineering control is located
  - Hazardous buffer rooms meet negative pressure differential, Air Changes per Hour, etc.
  - Containment Segregated Compounding Areas now allowed for hazardous preps, with finished products having a 12 hour Beyond Use Date.

Secondary Engineering Control



Supplemental Engineering Controls

- These are Closed System Transfer Devices
  - Required for the administration of Table 1 hazardous agents.
  - UNM Hospitals currently provides these for both the preparation and administration of these agents.

Environmental Quality and Control

- Wipe studies of work areas should be performed routinely.
  - For example, initially and every 6 months
  - Standardized sampling of common areas such as interior of C-PEC, surfaces near the C-PEC, areas immediately outside of the C-SEC, and hazardous drug administration areas.

Personal Protective Equipment (PPE)

- Gloves must be chemo rated, outer pair must be sterile
- Booties, two pairs required
  - Two lines of demarcation, don first pair of booties upon entry of the anteroom, second pair of booties upon entry to the hazardous buffer room.
- Chemo gown required for high risk hazardous prep, only good for 3 hours, cannot be reused once removed.

Personal Protective Equipment (PPE)

- Respiratory protection with a cartridge half mask should be considered:
  - When breaking down a Biological Safety Cabinet for full cleaning
  - Unpacking hazardous shipments not in plastic

Based on Hierarchy of Controls, a Biological Safety Cabinet

A. Provides a higher level of employee protection than wearing a second pair of chemo gloves.

B. Allows us to eliminate and substitute the hazard.

C. When combined with supplemental engineering controls, proper PPE, and staff training helps ensure that our work environment is safe.

D. Both A and C

PPE is User Dependent

- So if we really want to ensure the safety of ourselves and our coworkers we need to ensure that we are doing what needs to be done.
- Proper PPE usage can be improved by considering all alternatives
  - Employee comfort
  - Variation in color allowing surveillance

Hazard Communication Program

- OSHA mandated compliance provides a solid structure to build upon
- Proper identification of hazardous chemicals
- Safety Data Sheets
  - For each hazardous chemical used
  - Readily available to employees
- Employees trained prior to using HDs, including confirmation in writing of understanding of risk

Personnel Training

- Overview of entity's HD List and their risks
- Review of SOPs related to handling HDs
- Proper use of PPE
- Proper use of equipment and devices
- Response to known or suspected HD exposure
- Spill management
- Proper disposal of HDs and trace-contaminated materials

Labeling, Packaging, Transport and Disposal

- HDs requiring special handling should be properly labeled at all times and labeling must not introduce contamination in non-HD handling areas
- Proper packaging material must be used to protect product and the healthcare worker
- HDs must be transported in containers that minimize the risk of breakage or leakage
- All federal, state, and local regs must be followed for transport and waste disposal

Dispensing Final Dosage Forms

- HDs not requiring further manipulation, other than counting or repackaging of final dosage forms, may be prepared for dispensing without any further requirements for containment unless required by manufacturer or if visual indicators of risk of exposure present (dust, leakage)
  - Counting or repackaging must be done carefully
    - Clean equipment used
    - Equipment should be decontaminated after use
    - Do not use automated counting or packaging machines

Administering

- Use protective medical devices
  - Closed systems
- Use protective techniques
  - Spiking and priming of IV tubing with diluent prior to addition of HD
  - Crushing tablets in a plastic pouch
- Use proper PPE
- Partner with nursing

For a Table 1 NIOSH hazardous drug administered IV

A. Nursing can decide to not use a closed system transfer device when administering if pharmacy primes the line with NS.

B. Pharmacy should prepare the dose using a closed system transfer device, while nursing must use a CSTD to administer.

C. If an assessment of risk is performed that allows for the administration without a CSTD then nursing can administer without a CSTD.

Deactivating, Decontaminating, Cleaning, and Disinfecting

- Deactivating–render compound inert or inactive
- Decontaminating–remove HD residue
- Cleaning–remove organic and inorganic material
- Disinfecting–destroy microorganisms

Does proper cleaning negate the need to do wipe studies?

A. Yes, provided the decontamination step occurs immediately after the deactivation step.

B. No, because residue from cleaning will provide a false positive on the wipe study.

C. Yes, if things are clean no residue will show up with the wipe study.

D. No, results from wipe studies might demonstrate the need for improved cleaning.

Spill Control

- All personnel who may be required to clean up a spill of HDs must receive proper training in spill management and the use of PPE and NIOSH-certified respirators
- Spill kits must be available in all areas where HDs are handled
- Spill materials must be handled as hazardous waste

Documentation and Standard Operating Procedures

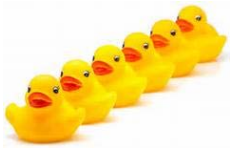
- SOPs must be reviewed at least every 12 months by the designated person and the review documented.
- Changes in forms or records must be made as needed and communicated to all personnel handling HDs.

Medical Surveillance

- Per USP 800, Healthcare workers who handle hazardous drugs as a regular part of their job assignment should be enrolled in a medical surveillance program.

Get your Ducks in a Row, Now

- Enforceable by:
  - Food Drug Administration
  - State Boards of Pharmacy
  - The Joint Commission



- Beginning of Enforcement:
  - July 2018

Contact info

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References

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[4] Casorelli I, Bossa C, Bignami M. DNA damage and repair in human cancer: molecular mechanisms and contribution to therapy-related leukemias. Int J Environ Res Public Health. 2012;9(8):2636-2657.


THANK YOU