USP 800 Update– Safe Handling of Hazardous Drugs

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Statement of disclosure

I have no conflicts of interest.

The event programming has been approved by the Accreditation Council for Pharmacy Education through the University of New England School of Pharmacy.
University of New England School of Pharmacy is accredited by the
Accreditation Council for Pharmacy Education as a provider of Continuing Education.

Objectives

- Describe the process to construct a hazardous drug list and perform an assessment of risk
- Distinguish between the different types of hazardous drugs
- Review the types and specifications of personal protective equipment (PPE) required when handling hazardous drugs
- Summarize how to draft an action plan for USP 800 compliant practices, polices, and procedures

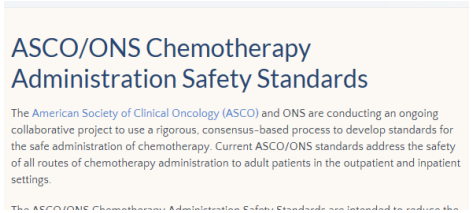
Pre-Test

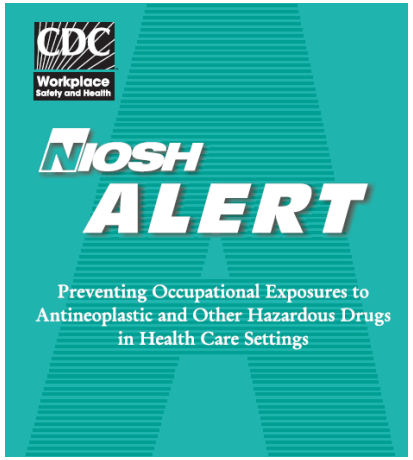
1. USP 800 Standards apply to which of the following practice settings:
    a. Hospitals/Infusion Centers
    b. Pharmacies
    c. Patient treatment clinics
    d. Veterinary offices
    e. All healthcare personnel and entities that handle hazardous drugs
2. Which of the following is not a UPS 800 requirement?
    a. Creation of an entity hazardous drug list
    b. Manipulation of all dosage forms (including tablets/capsules) must be performed in the pharmacy
    c. Personnel must be trained on spill management of hazardous drugs
    d. Sterile compounding areas for hazardous drugs must be deactivated, decontaminated, cleaned and disinfected.

Pre-Test

3. Which of the following makes a drug hazardous:
    a. Teratogenic
    b. Reproductive
    c. Organ Toxicity
    d. All of the above
4. Closed system transfer devices (CSTDs) MUST be used when compounding all hazardous drugs.
    a. True
    b. False

All personnel who handle hazardous drugs will be aware of the fundamental practices and precautions associated with hazardous drugs to prevent harm to patients, **minimize exposure to personnel**, and minimize contamination of the work and patient-care environments.





Historical Context

1985

ASHP “Technical Assistance Bulletin on Handling Cytotoxic & Hazardous Drugs”

1986

OHSA Technical Manual Controlling Occupational Exposure to HD

1996

ONS “Cancer Chemotherapy Guidelines and Recommendations”

2004

NIOSH issues alert, “Preventing Occupational Exposure to Antineoplastic and Other HD in Healthcare Settings”

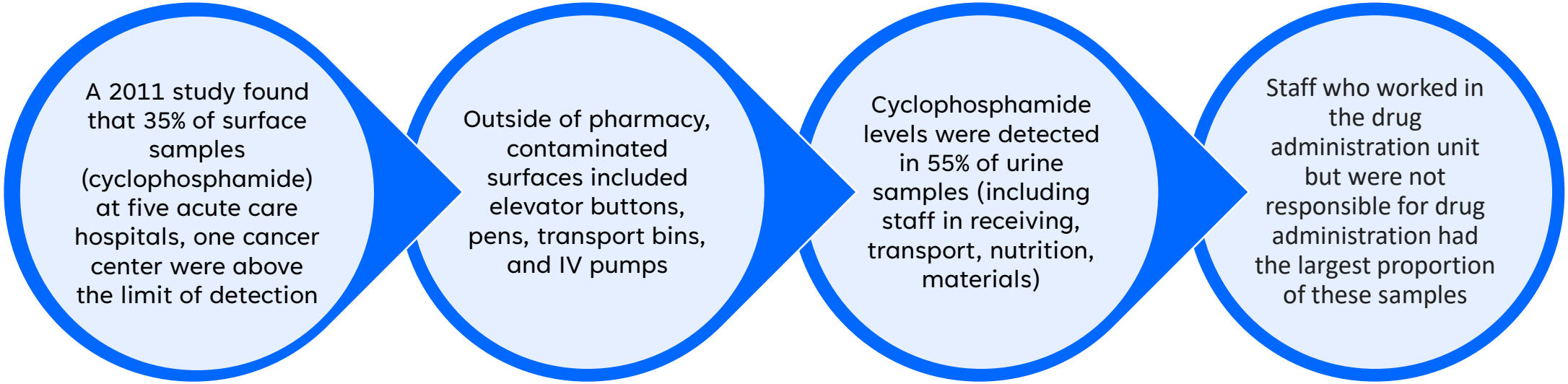
2016

USP Chapter <800> is developed

Nov 2023

USP Chapter <800> is now enforceable, along with the new revision of Chapter <797>

Why is USP <800> needed?



Part of USP 800 is for staff to acknowledge the dangers associated with handling HDs.

USP 800 is different than previous guidelines because it is a STANDARD. It is enforceable by governing regulatory bodies and many of the components are considered BEST PRACTICE.

How can exposure happen?

- Dermal and mucosal absorption
- Inhalation
- Injection
- Ingestion (contamination from surfaces, hands)

- Receiving
- Dispensing
- Compounding or other manipulation
- Administration
- Patient care activities (body fluids, linens)
- Spill management
- Transport of medications

What is the definition of a hazardous drug?

Hazardous drug definition

Any drug that exhibits at least one of the following:

Carcinogenicity

- Ability or tendency to produce cancer

Teratogenicity

- Ability to cause developmental abnormalities in a fetus

Reproductive toxicity

- Ability to interfere with human reproductive system, causing malformations

Organ toxicity

- Ability to cause serious organ damage at low doses

Genotoxicity

- Ability to damage genetic information at the cell level

NIOSH and its list

The National Institute for Occupational Safety and Health is a federal agency responsible for research and recommendations for prevention of work-related injury, illness

The NIOSH list is an aid designed to help employers identify which drugs are considered hazardous

NISOH List

Two versions: 2016 list and a ***DRAFT*** 2020 list

The 2016 version has three different categories of HDs

Group 1: Antineoplastic Drugs

Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for an HD

Group 3: Non-antineoplastic drugs that primarily pose a reproductive risk to men and women who are actively trying to conceive and women who are pregnant or breast-feeding

Creating a Hazardous Drug List

- Each entity must maintain a hazardous drug list that the entity handles
- The list must include any items on the *CURRENT* NIOSH list
- The list must be reviewed every 12 months
- New drugs should be reviewed and added to the entities list if applicable

Creating a Hazardous Drug List

Drugs that must be included on the entities HD List:

- All antineoplastics that require manipulation and are included on the NIOSH list
- All active pharmaceutical ingredients included on the NIOSH list (hormone powders, antineoplastic powders)

All other drugs on the NIOSH list can have an assessment of risk performed

Assessment of Risk

Document other containment strategies or work practices that allow for the HD to be handled outside of USP <800> requirements

Must be reviewed every 12 months

If no assessment of risk is performed then every agent on the NIOSH list must be handled according to USP <800> requirements

Best Practice Recommendations

- Develop a committee to evaluate drugs as they enter the institution to determine if they should be classified as a hazardous drug
  - New to formulary drugs, Non-formulary drugs, Investigational
- Create standardized criteria to evaluate hazardous status
- Create templates to aid in the review process
- Involve multiple reviewers from different sites (if possible)

All to create a highly reproduceable process

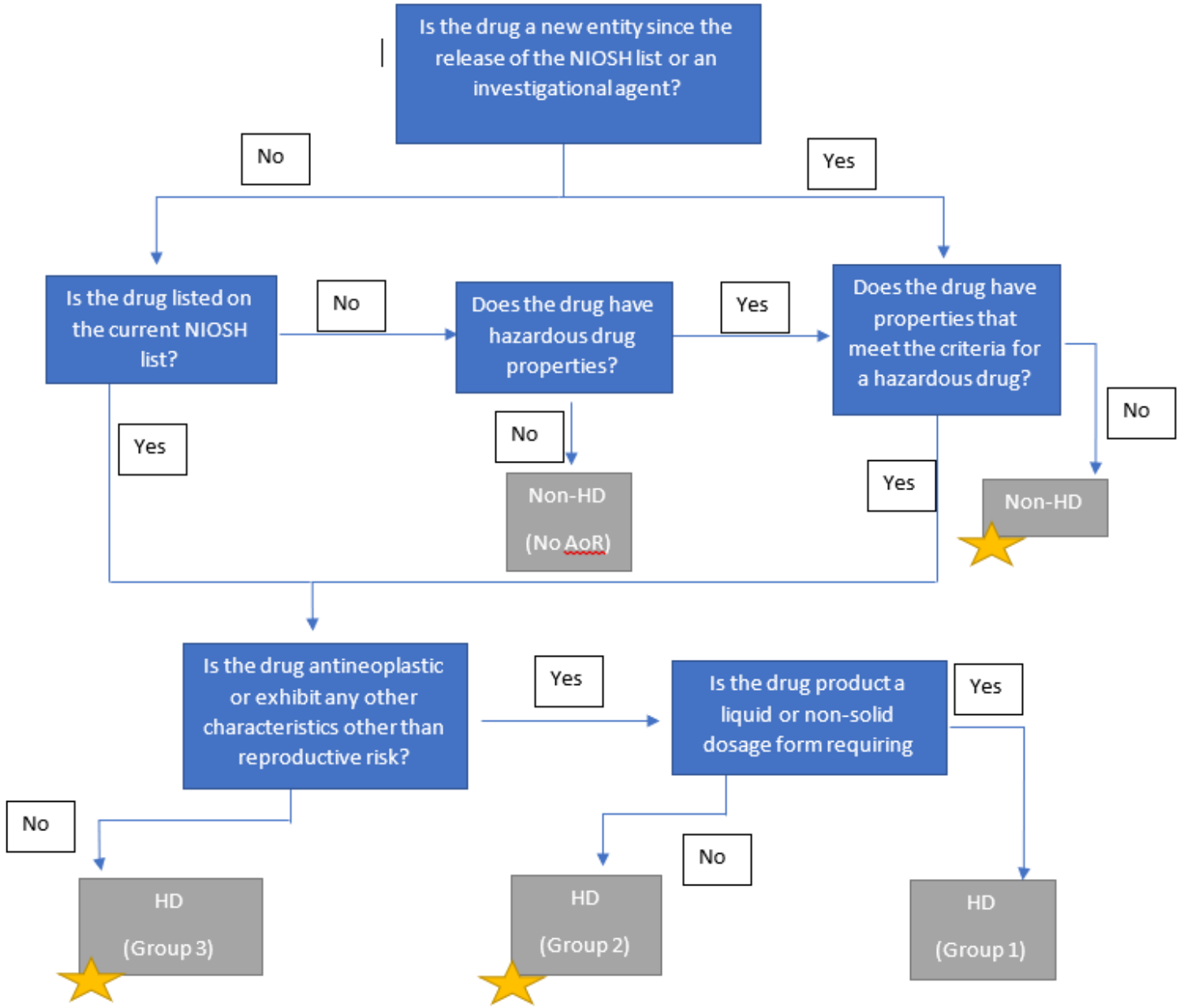
HOPA
Hematology/Oncology Pharmacy Association

Approved/Effective Date:	
Approved by:	
Annual Review by:	
Date Reviewed:	

ASSESSMENT OF RISK FORM

TO BE COMPLETED FOR ANY DRUG BEING CONSIDERED FOR CONTAINMENT STRATEGIES THAT DIFFER FROM FULL NIOSH RECOMMENDATIONS, AS DEFINED IN USP GENERAL CHAPTER <800> HAZARDOUS DRUGS-HANDLING IN HEALTHCARE SETTINGS.

Drug Name		
Dosage Form	☐ Tablet / Capsule ☐ Oral Liquid (commercial) ☐ Compounded liquid	☐ Pre-filled syringe ☐ Solution/powder for injection ☐ Other:
NIOSH Category:	☐ Table 1: Antineoplastic Drugs that only require packaging or counting ☐ Table 2: Non-antineoplastic Drugs ☐ Table 3: Reproductive Toxin Drugs	
Description of Packaging	☐ Final dosage form, ready for dispensing directly to patient (*i.e., unit dose, unit-of-use*) ☐ Bottle of [tablet/capsule/liquid] to be repackaged ☐ Other:	
Description of Required Manipulation	☐ None (product available in ready-to-dispense package) ☐ Repackaging only (e.g. counting; transfer container) ☐ Other:	
Risk of Exposure	☐ Skin contact ☐ Ingestion ☐ Inhalation ☐ Injection ☐ Other (specify):	
Alternative Containment Strategies and/or Work Practice	**[Engineering Control** *(i.e., BSC, containment isolators, CSTDs, temporary designated prep. area)*]	
	[Administrative Control *(i.e., educational materials, acknowledgement form, training)*]	
	[PPE Strategies *(i.e., gloves, gowns, booties, head cover, face shield, eye protection, respirators)*]	
Recommendation	☐ Follow all containment requirements (as per USP<800>) ☐ Follow alternative containment strategies documented above	


Is the drug a new entity since the release of the NIOSH list or an investigational agent?
No
Yes
Is the drug listed on the current NIOSH list?
No
Does the drug have hazardous drug properties?
Yes
Does the drug have properties that meet the criteria for a hazardous drug?
No
Yes
No
Non-HD (No AoR)
Yes
Non-HD
Is the drug antineoplastic or exhibit any other characteristics other than reproductive risk?
Yes
Is the drug product a liquid or non-solid dosage form requiring
Yes
No
HD (Group 3)
No
HD (Group 2)
HD (Group 1)

Personal Protective Equipment (PPE)

PPE	Sterile Compounding HD	Non-Sterile Compounding HD	Cleaning	Unpacking/ Restocking	Spill Management
Chemo Gown	X	X	X		X
Head/Hair Covers	X	X	X		X
Shoe Cover(s)	X	X	X		X
Chemo Gloves	X	X	X	X	X

Eye, Face and Respiratory protection should be considered based on type of exposure (volatile/nonvolatile drugs), risk of exposure, other containment components use (compounding hood, etc.)
USP <797> should also be followed for sterile compounding activities

“Chemo” Gloves and Gowns

Gloves

- Meet American Society for Testing and Materials (ASTM) standard D6978 (or its successor)
- When used for sterile compounding, outer most layer MUST be sterile
- Should be changed every 30 minutes, but MUST be changed if torn or contaminated
- Hands must be washed with SOAP AND WATER after gloves are removed

Gowns

- Should be permeable and shown to resist the drugs used by the entity
- No written standard in current USP <800> for chemo gowns
- ASTM recently published a new standard for chemo gowns, F3267, “Standard Specification for Protective Clothing for Use Against Liquid Chemotherapy and Other Liquid Hazardous Drugs”
  - At least one manufacturer meets these standards with (hopefully) more to come!

Best practice recommendation: all exam gloves available at your institution should be ASTM rated to ensure those administering drugs are always protected

Closed System Transfer Devices (CSTDs)

No universal performance standard for evaluation of CSTDs

CSTDs should be used when compounding as the final dosage form allows

CSTDs MUST be used when administering antineoplastic HDs when the dosage form allows

Two Types:

“Membrane to Membrane”

“Needleless”

Personal Protective Equipment (PPE)

Administration of drugs – per USP <800> - *wear appropriate PPE*

Other guidelines and societies have published recommendations

Best practice: pair with nursing to determine appropriate PPE based on final dosage form and “risk” level of activity

Low, Medium, High-Risk HDs*

Activity	Low (single pair gloves)	Medium (2 pairs of gloves, gown)	High (2 pairs of gloves, gown, HD handled in pharmacy)
Counting/Dispensing Oral HD	X		
Transporting HDs	X		
Administration of IV antineoplastics			X
Administration of HD supplied in manufacturer's syringe		X	

*Example of suggested PPE chart

Administration: Patient and Family Information

Prior to administration of HDs, ensure you inform the patient and family of additional PPE precautions that will be used during administration of the medication.

Questions from the patient and/or family may arise. Here are some examples of how to respond:

- “New guidelines are in place for healthcare workers for repeated exposure to multiple medications.”
- “This is to keep us, you, and the environment safe.”

Deactivation, Decontamination, Cleaning, Disinfection

Step	Purpose	Example Cleaning Agent
Deactivation	Render the compound inert or inactive	EPA registered oxidizers (peroxide, sodium hypochlorite)
Decontamination	Remove HD residue	Alcohol, water, peroxide, sodium hypochlorite
Cleaning	Remove organic and inorganic residue	Germicidal detergent
Disinfection	Destroy microorganisms	EPA registered disinfectant, sterile alcohol

Spill Management

- Those cleaning up spills must have the proper training to do so
- SOPs must address the size and scope of a spill
  - Best Practice Recommendation: Denote “small” and “large” spills within SOP to determine when trained staff can clean vs calling “spill response team”
- Circumstances and management of spills MUST be documented

Action Plan for USP 800 Compliant Practices

- Designated person or committee to complete the work
- Recommend completion of a Gap Analysis
- Develop entities Hazardous Drug List
- Education, education, education
- Multi-disciplinary work group – create buy-in

USP Required Policies/SOPs

- Assessment of Risk
- Deactivating, decontaminating, cleaning, disinfecting
- Facilities and Engineering controls
- HD Compounding and moving of materials
- Spill Management
- Training and Hazard Communication Program
- Labeling, packaging, and transport
- PPE
- Receiving and storage

This presentation was not inclusive of all USP <800> Requirements

Post-Test

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Questions?

References

- USP <800>. *Hazardous Drugs – Handling in Healthcare Settings*. USP Compounding Compendium
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