USP Chapter <800>: Handling Hazardous Drugs

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Disclosure

Denise Frank reports no actual or potential conflicts of interest associated with this presentation.

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Objectives

- Review the history and content of USP Chapter <800> and the NIOSH List of Antineoplastics and Other Hazardous Drugs in HealthCare Settings
- Describe the process to construct a hazardous drug (HD) list and perform an assessment of risk
- Define the key engineering controls required for compliance
- Review the types and specifications of the personal protective equipment (PPE) required when handling HDs
- List the elements required for training.

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What is USP Chapter <800>?

"This chapter describes practice and quality standards for handling hazardous drugs (HDs) to promote patient safety, worker safety, and environmental protection."

USP 40-NF 35 Chapter <800> Hazardous Drugs

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History

1960's and 1970's	Reports and studies performed regarding mutagenicity found in nurses' urine
1980's	ASHP publishes a Technical Assistance Bulletin (TAB) regarding hazardous drugs
2004	NIOSH publishes an Alert focusing on preventing occupational exposure to hazardous drugs
2011-2014	An expert panel develops and releases 2 versions of USP Chapter <800> for public comment
February 2016	USP Chapter <800> is published
~~July 1, 2018~~ December 1, 2019	USP Chapter <800> becomes enforceable

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USP Chapter <800> Sections

- Introduction and Scope
- List of Hazardous Drugs
- Types of Exposure
- Responsibilities of Personnel Handling Hazardous Drugs
- Facilities and Engineering Controls
- Environmental Quality and Control
- Personal Protective Equipment
- Hazard Communication Program
- Personnel Training
- Receiving

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Sections (continued)

- Labeling, Packaging, Transport and Disposal
- Dispensing Final Dosage Forms
- Compounding
- Administering
- Deactivating, Decontaminating, Cleaning and Disinfecting
- Spill Control
- Documentation and Standard Operating Procedures
- Medical Surveillance
- Glossary
- Appendices

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NIOSH List

A hazardous drug is identified by one or more of these criteria:

- Carcinogenicity
- Teratogenicity or other developmental toxicity
- Reproductive toxicity
- Organ toxicity at low doses
- Genotoxicity
- A new drug that has a structure and toxicity profile that mimics an existing hazardous drug

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NIOSH Categories of HDs

- Table 1: Antineoplastic drugs
- Table 2: Non-antineoplastic drugs
- Table 3: Non-antineoplastic drugs that primarily have adverse reproductive effects

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List of HDs

- Develop list of HDs from NIOSH list used at your pharmacy or facility
- Include any new HDs since last published
- May add AHFS classified antineoplastics
- May add other drugs based on the manufacturer safe handling guidance (MSHG)

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Identify HDs for Assessment of Risk

Using your HD list:

- All bulk powder APIs must follow USP <800>
- Table 1 Antineoplastic Drugs, when manipulation is required, must follow USP <800>
- Table 1 Antineoplastic Drugs, when no manipulation is required, may perform an assessment of risk
- Tables 2 and 3 – for Non-antineoplastic drugs and non-antineoplastic drugs with primarily adverse reproductive affects, may perform an assessment of risk

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Assessment of Risk

Includes:

- Type of HD
- Dosage form
- Risk of exposure
- Packaging
- Manipulation

Document alternative handling required

Must be performed every 12 months

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Example Assessment

Drug	Hazardous Risk	Dosage Form	Risk of Exposure	Packaging/ Manipulation	Alternative Safe Handling
Clomiphene	Reproductive (pregnancy category X)	Tablet	May occur when counting	Use only unit dose blister pack	Dispense in original blister pack, do not punch out
Megesterol	Reproductive (pregnancy category X)	Tablet	May occur when counting	Counting May split tablets	Reproductive age personnel do not handle; Separate counting tray Wear gloves

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Environment

Receipt

Storage

Counting and Pouring

Nonsterile Compounding

Sterile Compounding

Supplemental Engineering Controls

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Receipt

- Receipt in neutral or negative pressure area
- May NOT be received and unpacked in a sterile compounding or positive pressure area

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Storage

General storage with containment strategies specified in assessment

- Non-antineoplastic HDs
- Antineoplastic HDs in final dosage forms, no manipulation

Externally vented, negative pressure room with at least 12 air changes per hour

- ANY HD APIs (bulk powder HDs)
- Antineoplastic HDs requiring manipulation or compounding
- Dedicated refrigerator

Protect from breakage, store off the floor

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Counting and Pouring

- Dedicated equipment
- Decontaminating after each use
- Do not put HD tablets or capsules into automated counting or packaging machines
- Ensure appropriate PPE is used

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Nonsterile Compounding

Containment Primary Engineering Control (C-PEC)

- Externally vented or redundant HEPA filters in series
- May be a containment ventilated enclosure (CVE), Class I or II biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI)

Containment Secondary Engineering Control (C-SEC)

- Externally vented with at least 12 air changes per hour (ACPH)
- Negative pressure is maintained between 0.01 and 0.03 inches of water column relative to adjacent areas

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Sterile Compounding

Unclassified containment segregated compounding area (C-SCA)	ISO Class 7 buffer room (with an ISO Class 7 ante room)
C-PEC Externally vented Class II BSC or CACI	C-PEC Externally vented Class II BSC or CACI
C-SEC Externally vented with at least 12 ACPH Negative pressure between 0.01 and 0.03 inches of water column to adjacent areas	C-SEC Externally vented with at least 30 ACPH Negative pressure between 0.01 and 0.03 inches of water column to adjacent areas
BUD As described in USP <797> for segregated compounding areas	BUD As described in USP <797>

Supplemental Engineering Controls

Closed System Transfer Devices (CSTDs)

- May NOT be used as a substitute for C-PEC, may be used in addition when compounding
- MUST be used when administering antineoplastic HDs
- Ensure CSTD is physically and chemically compatible with the specific HD
- No universal performance standard for CSTDs, evaluate independent, peer-reviewed studies

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Personal Protective Equipment

- PPE provides protection to reduce exposure to HD aerosols and residues
- See the NIOSH list, Table 5 for guidance
- Disposable PPE must not be reused
- Sterile and nonsterile compounding requires gowns, head, hair and shoe covers, two pairs of chemotherapy gloves
- Administration of antineoplastic HDs requires two pairs of chemotherapy gloves and gowns that resist permeability.
- All other scenarios must have PPE described in SOP

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Appropriate PPE

- Receipt and storage
- Transport of HDs
- Filling, manipulation and compounding
- Administration
- All cleaning activities
- Spill control
- Waste disposal

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Gloves

- Must meet the American Society for Testing and Materials (ASTM) standard D6978
- Powder-free
- Inspect for defects
- Sterile if used for sterile compounding
- Changed every 30 minutes and must be changed if torn, punctured, or contaminated

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Gowns

- Disposable
- Resist permeability by HDs
- Close in the back, long-sleeved with closed cuffs (elastic or knit).
- Change every 2-3 hours or per manufacturer's information, and immediately after a spill or splash

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Covers and Eye/Face Protection

- Head and hair covers, including facial hair covers, shoe covers and sleeve covers
- Eye protection: Goggles
- Face protection: Full face shield

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Respiratory Protection

When to use a respirator

- Unpacking shipments of HDs not contained in plastic
- Working on HD spills larger than the spill kit can contain
- Cleaning underneath the work surface of a C-PEC
- Other known or suspected exposure to airborne particles or vapors

When use is required, include in SOPs

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Respirators

Types of respiratory protection

- N-95 respirators – for particle protection only
- Elastomeric half-mask respirators with P100 filters or targeted cartridges
- Full-facepiece chemical cartridge respirators
- Full-facepiece powered air-purifying respirator (PAPR)

Employee medical evaluation and fit testing of respirators is required

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PPE Disposal

- Trace contamination
- Appropriate waste container
- Disposal regulations – local, state, federal
- Removal before leaving the area to limit contamination of other areas

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Training Requirements

- Overview of the pharmacy's list of HDs
- Review of all HD-related policies and procedures
- Proper use of personal protective equipment
- Proper use of equipment and containment devices
- How to handle an exposure to an HD
- How to handle an HD spill
- Proper disposal of HDs
- Proper disposal of trace-contaminated materials

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Compliance

- Designate a qualified person
- Develop list of HDs and risk assessment
- Appropriate facility and engineering controls
- Ensure competent personnel
- Safe work practices and appropriate PPE
- HD waste segregation and disposal

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Recap

- Reviewed the history and content of USP Chapter <800> and the NIOSH List of Antineoplastics and Other Hazardous Drugs in Healthcare Settings
- Described the process to construct an HD list and perform HD risk assessments for your pharmacy
- Defined the key engineering controls required for compliance with USP Chapter <800>
- Reviewed the types and specifications of the personal protective equipment required when handling HDs
- Listed the elements required in your hazardous drug staff training program

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References and Resources

- NIOSH List 2016: https://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf
- Articles on USP 800 and HDs: https://www.pppmag.com/
- Comparison of Gap Analysis Tools: https://www.pppmag.com/article/2021
- Respirators: https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource.html
- Respirator Fit Testing: https://www.osha.gov/video/respiratory_protection/fittesting_transcript.html
- Medical Surveillance: https://www.cdc.gov/niosh/docs/wp-solutions/2013-103/pdfs/2013-103.pdf
- ASHP Chapter <800> Answer Book: https://www.ashp.org/products-and-meetings-aliases/chapter-800-book
- For more information, articles, and training, see also: APhA, Compounding Today, Oncological Nurses Society, CriticalPoint

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ACHC	Accreditation Commission for Health Care	CSTD	Closed-System Transfer Device
ACPH	Air Changes Per Hour	CVE	Containment Ventilated Enclosure (powder hood)
AHFS	American Hospital Formulary Service	FDA	Food and Drug Administration
APhA	American Pharmacists Association	HD	Hazardous Drug
API	Active Pharmaceutical Ingredient	HEPA	High Efficiency Particulate Air (filter)
ASHP	American Society of Health-System Pharmacists	ISO	International Standards Organization
ASTM	American Society for Testing and Materials	LAFW	Laminar Airflow Workbench
BSC	Biological Safety Cabinet	MSHG	Manufacturer Safe Handling Guidance
CACI	Compounding Aseptic Containment Isolator	NIOSH	National Institute for Occupational Safety and Health
CAI	Compounding Aseptic Isolator	PPE	Personal Protective Equipment
C-PEC	Containment Primary Engineering Control (hood)	SOP	Standard Operating Procedure
C-SCA	Containment Segregated Compounding Area	TAB	Technical Assistance Bulletin (published by ASHP)
C-SEC	Containment Secondary Engineering Control (room)	URAC	Utilization Review Accreditation Commission
CSP	Compounded Sterile Product	USP	United States Pharmacopeia

Thank You!
Any Questions?

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Closing Remarks/Discussion

- Questions, thoughts or feedback on today's content?

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  HealthEast
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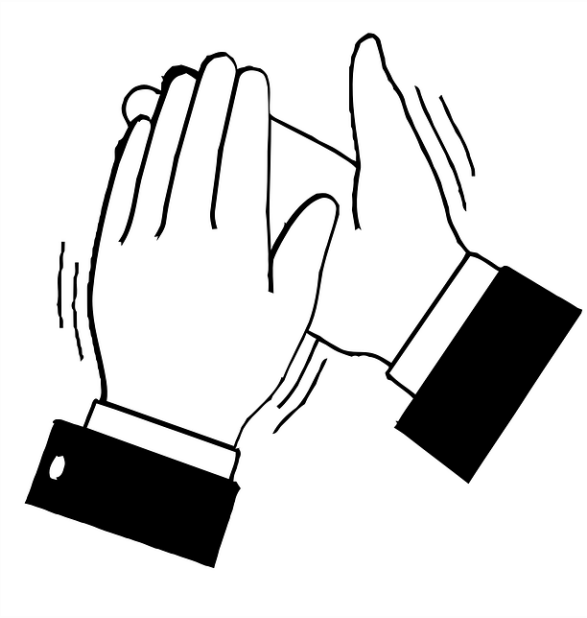
Med Rec Road Map Pilot Sites

- Riverview Health – Crookston
- Lake View Hospital – Two Harbors
- Ridgeview Medical Center – Le Sueur
- Sleepy Eye Medical Center – Sleepy Eye
- St. Luke’s Hospital – Duluth
- HealthEast – Saint Paul
- CentraCare Health -- Monticello

Hats off to facilities completing the road map

32 facilities have completed the med rec road map in the MHA Portal.



Thank you for attending today's conference and live stream event.

Minnesota Hospital Association