Hazardous Drugs – Handling in Healthcare Settings

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Purpose of <800>

- Approximately 8 million healthcare workers in the United States are potentially exposed to hazardous drugs (HDs) each year.

- <800> was developed to promote patient safety, worker safety, and environmental protection.
  - Defines practice and quality standards for handling HDs
  - Builds on existing science, guidelines, and expertise
1960s
Reports in medical literature

1970s
European study found mutagenicity within urine of nurses

1980s
ASHP published TAB regarding HDs, primary focused on chemotherapy agents

2004
NIOSH published Alert on preventing occupational exposure to HDs

2011-2014
Expert panel formed, 1st and 2nd versions both published for public comment

Jul 2018
USP General Chapter <800> enforceable

Feb 2016
USP General Chapter <800> published
• Published in USP-NF and Compounding Compendium
  February 1, 2016

• Official Date
  July 1, 2018
Scope

Entire Life Cycle of HD

• Receiving
• Storing
• Compounding
• Dispensing
• Administering
• Disposal

All Entities

• Hospitals
• Pharmacies
• Veterinary offices

• Physician offices
• Skilled Nursing Facilities
• Outpatient clinics

All Healthcare Personnel

• Pharmacists
• Technician
• Nurses
• Physicians

• Veterinary personnel
• Environmental Services
What is a Hazardous Drug (HD)?

- Any drug identified by $\geq 1$ of the following criteria:
  - Carcinogenicity
  - Teratogenicity or other developmental toxicity
  - Reproductive toxicity
  - Organ toxicity at low doses
  - Genotoxicity
  - Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria
Hazardous Drugs vs. Hazardous Materials

NIOSH List of Hazardous drugs

EPA list of hazardous materials

HDs that are hazardous to personnel

Materials that are hazardous to the environment
NIOSH publishes List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings

First published

2004
2010
2012
2014
2016

Last updated

List of HDs

Table 1 • Antineoplastic drugs

Table 2 • Non-antineoplastic drugs

Table 3 • Non-antineoplastic drugs with adverse reproductive effects
HDs that must follow **all** the requirements:

- Any HD API
- Any antineoplastic requiring manipulation

HDs eligible for an **assessment of risk** include:

- Final dosage forms of antineoplastics that do not require any further manipulation
- Dosage forms of other HDs
Overview

Risks of Exposures

Facilities

PPE

Transport & Disposal

Dispensing & Administration

Cleaning

Medical Surveillance
Types of Unintentional Exposures

- Dermal and mucosal absorption
- Inhalation
- Injection
- Ingestion
- Containers of HDs have been shown to be contaminated upon receipt

Facilities

• Tenets of Safety
  – Containment
    • Contain hazard
  – Dilution
    • Remove hazard
Engineering Controls protect the preparation from cross-contamination (and microbial contamination for sterile preparations)

Containment Primary Engineering Control (C-PEC)
- Ventilated device ("hood") designed to minimize worker and environmental HD exposure when directly handling HDs

Secondary Engineering Control (C-SEC)
- Room in which the C-PEC is placed

Supplemental Engineering Control
- Adjunct control that offer additional levels of protection
<800> Facilities

Containment Primary Engineering Control (C-PEC)

- Containment Ventilated Enclosure
- Biological Safety Cabinet
- Compounding Aseptic Containment Isolator
Secondary Engineering Control (C-SEC)

Contains hazard:
- Separate room with fixed walls
- Negative pressure of 0.01 to 0.03" to adjacent space

Removes hazard:
- Vented outside the building
- At least 12 air changes per hour
<800> Facilities

Nonsterile Compounding
- CVE or BSC
- Negative Pressure
- 12 ACPH

Sterile Compounding
- BSC or CACI
- Buffer
- ISO 7
- Ante
- ISO 7
- Negative for HDs
- Positive
Personal Protective Equipment (PPE)

- PPE provides worker protection to reduce exposure to HD aerosols and residues
  - Chemotherapy Gloves
    - ASTM D6978 standards
  - Protective Gowns
    - Polyethylene-coated polypropylene or other laminate material
  - Head, Hair, Shoe, and Sleeve Covers
  - Eye and Face Protection
  - Respiratory Protection
Transport & Disposal

- Transport in containers that minimize the risk of breakage or leakage
- Pneumatic tubes must not be used for liquid or antineoplastic HDs
- Consult transport information on the Safety Data Sheet
- Labels and accessory labeling include
  - Storage instructions
  - Disposal instructions
  - HD category information
Dispensing Final Dosage Forms
- Dedicated clean equipment
- Antineoplastic HDs must not be placed in automated counting or packaging machines

Administration
- Use protective medical devices and techniques
  - Needleless systems
  - Closed-system drug-transfer devices
# Cleaning

<table>
<thead>
<tr>
<th>Cleaning Step</th>
<th>Purpose</th>
<th>Example Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deactivation</td>
<td>Render compound inert or inactive</td>
<td>EPA-registered oxidizers</td>
</tr>
<tr>
<td>Decontamination</td>
<td>Remove HD residue</td>
<td>Alcohol, water, peroxide, or sodium hypochlorite</td>
</tr>
<tr>
<td>Cleaning</td>
<td>Remove organic and inorganic material</td>
<td>Germicidal detergent</td>
</tr>
<tr>
<td>Disinfection (for sterile manipulations)</td>
<td>Destroy microorganisms</td>
<td>Sterile isopropyl alcohol</td>
</tr>
</tbody>
</table>
Medical Surveillance

- Healthcare workers who handle HDs should be enrolled in a medical surveillance program
  - Designed to minimize adverse health effects
  - Assessment and documentation
    - Symptom complaints
    - Physical findings
    - Laboratory values
Thank You

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