Preparing for USP <800>: Handling Hazardous Drugs

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Disclosure
- Patricia Kienle is an employee of Cardinal Health
- She is a member of the USP Compounding Expert Committee, but this presentation is not endorsed by or affiliated with USP

Learning Objectives
- State the document that must be used to develop an Assessment of Risk
- Explain the types of facility design allowed for compounding hazardous drugs (HDs)
- Define the use of closed system drug-transfer devices (CSTDs) when compounding and administering hazardous drugs
- List three alternative containment strategies and/or work practices that can be used to mitigate risks of HDs when permitted by <800>

Why USP <800>?
- USP is a standard-setting organization
- <800> Hazardous Drugs – Handling in Healthcare Settings protects
  - Patients
  - Personnel
  - Environment
- First enforceable standard that protects healthcare personnel from risk of hazardous drugs

Evidence: Health Effects

1970s: Secondary malignancies identified in patients following treatment
1980s: Association between exposure to antineoplastics and adverse reproductive effects
1990s: Link of cancer occurrence to healthcare workers exposed to antineoplastics


NIOSH
www.cdc.gov/niosh/topics/hazdrug/default.html
Genesis of <800>:

[Image of NIOSH Alert]

Preparation for <800>:

- **Responsible person**
  - Each facility where hazardous drugs are handled needs to assign a person to oversee the hazardous drug requirements
    - Personnel awareness, training, and monitoring
    - Facility requirements, such as hood certification and results

- **Acknowledgement of Risk**
  - OSHA: Hazard Communication Standard (HCS) is based on a simple concept: that employees have both a need and a right to know the hazards and identities of the chemicals they are exposed to when working
  - USP <800>: Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs
  - Applies to all personnel who handle HDs

What Drugs are Hazardous to Us?

- **Carcinogen**
- **Genotoxin**
- **Teratogen**
- **Reproductive Toxin**
- **Organ Toxicity at Low Doses**

New agent that mimics known HD in structure or toxicity

NIOSH List of Hazardous Drugs:

- **Table 1** – Antineoplastics
- **Table 2** – Non-antineoplastics
- **Table 3** – Reproductive-only hazards
- **Table 4** – Items removed from previous list
- **Table 5** – Recommended PPE

[Links to CDC and ASHP resources]
Ideal Situation to Handle HDs

• Handle every drug in every dosage form on the NIOSH list with all the containment strategies and work practices identified in <800>

• Is that possible?
• Is that practical?
• Is that necessary?

Your Options

- Handle all drugs and dosage forms with all containment and work practices listed in <800>
- Perform an Assessment of Risk to determine alternative containment strategies and work practices

NIOSH Approach to Risk Reduction

HD Processes

Your Hazardous Drug List

1. Review the NIOSH list of hazardous drugs
2. Identify the drugs and dosage forms you handle
3. Perform an Assessment of Risk
   • Risk of exposure
   • Packaging
   • Manipulation
4. Implement alternative containment strategies and work practices
5. Review and document the list annually

Your HD Assessment

<table>
<thead>
<tr>
<th>Require ALL containment strategies detailed in &lt;800&gt;</th>
<th>Alternative containment strategies can be considered and implemented</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Active Pharmaceutical Ingredient (API) of any HD on the list</td>
<td>• Antineoplastics you only need to count or package</td>
</tr>
<tr>
<td>• Antineoplastics that require manipulation</td>
<td>• Non-antineoplastics</td>
</tr>
<tr>
<td>• Dosage forms that don’t fit your Assessment of Risk</td>
<td>• Reproductive only hazards</td>
</tr>
</tbody>
</table>
Drugs That Must Follow All Strategies

• Active Pharmaceutical Ingredient (API) of any drug on the NIOSH list
• Antineoplastics that must be manipulated (mixed)

• **No Option** → must treat with all the containment strategies and work practices listed in <800>

Can Consider for Assessment of Risk

• Antineoplastic agents that only require counting or packaging
  ▪ Oral antineoplastics
  ▪ Patient Assistant Program antineoplastics
  ▪ Samples of antineoplastics
• Non-antineoplastics
  ▪ But some are concerning
  ▪ Reproductive-only hazards

Visible Warnings

Storing and Compounding HDs

Common Infusion Clinic Design

Containment Segregated Compounding Area
Containment Primary Engineering Control

- Two types
  - Biological Safety Cabinet (BSC)
    - Class II required
    - Type A2 preferred
  - Compounding Aseptic Containment Isolator (CACI)
- Must be placed in a room that meets the four characteristics we just discussed
- Must be certified by an independent qualified certifier every six months

Personal Protective Equipment

- Gloves
  - Must meet ASTM standard D6978
- Gowns
  - Impervious, intended for use with chemo
  - <800> standards and ONS guidance agrees
  - Two pairs of gloves when administering injectable chemo
  - Gowns when administering chemo
  - Goggles if potential of splashing
  - Respiratory protection when appropriate

Training and Competency Documentation

- Receiving and transporting
  - Competency concerning PPE
  - Spill awareness
- Competency for mixing
  - Didactic test
  - Media fill
  - Gloved fingertip test
- Competency for administering
  - Documentation

Work Practices

- Aseptic technique
- Negative pressure technique
- Use of Closed System Drug-Transfer Devices (CSTDs)
  - Required by <800> when administering injectable antineoplastics
- Decontamination and cleaning surfaces
- Handling spills

HD Compounding Technique

- Negative pressure technique
- CSTDs

Cleaning Process for HDs

1. Decontaminate with an oxidizer
2. Clean with a detergent
3. Disinfect with sterile isopropyl alcohol
Spill Management
- Have a clear policy and checklist
- Document competence
- Contain the spill
- Safe clean-up
- Review process

Hazardous Materials Waste
- Follow state and municipal requirements
- Get clear direction from waste hauler concerning type of bins and how to control them prior to pick-up
- Be aware of the difference between bulk RCRA waste and trace RCRA waste

Monitoring HDs
- Environmental monitoring
  - Requires microbial monitoring mandated by USP <797> for sterile preparations
  - Recommends wipe sampling
- Medical surveillance
  - Recommended

How All the USP Chapters Fit Together

To Do List
- Subscribe to the USP Compounding Compendium
- Perform a gap analysis
  - www.797gaptool.com
  - www.800gaptool.com
- Provide comments for proposed <797>
- Watch for final versions of <795>, <797>, and <825>
- Get ready for December 1, 2019

Resources ...
  - USP <800>
  - USP <800> FAQs
- State laws and regulations
- NIOSH, www.cdc.gov/niosh → hazardous drugs
  - Alert
  - Current HD list
  - Medical Surveillance document
... Resources ...

- ASHP, www.ashp.org
  - Compounding Resource Center
  - Guidelines on Compounded Sterile Preparations
  - Guidelines on Hazardous Drugs
  - Compounding Sterile Preparations, 3rd edition
  - The Chapter <800> Answer Book

- Critical Point, www.criticalpoint.info
  - Sterile Compounding Pearls

- Oncology Nursing Society, www.ons.org
  - Handling Hazardous Drugs, 3rd edition

- Joint Commission, www.jointcommission.org
  - Standards Interpretation FAQs

  - Improving Safe Handling Practices for Hazardous Drugs

... Resources

- Pharmacy Purchasing and Products, www.pppmag.com
  - February 2015, Evolution of the CSTDs (Massoomi)
  - March 2017, Performing an Assessment of Risk for USP <800> Compliance (Kienle and Douglass)
  - May 2018, Wipe Sampling (Kastango, Kienle, and Fortier)

- Pharmacy Practice News
  - July 2018, Kienle’s 10 Building Blocks of Compounding Safety