Unforeseen Dangers: Drugs That Are Hazardous to Us

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Disclosure

• Patricia Kienle is a member of the USP Compounding Expert Committee, but this talk is not endorsed by or affiliated with USP
What’s All the Fuss?
Preventing Occupational Exposure

**Warning!**

Working with or near hazardous drugs in healthcare settings may cause skin rashes, infertility, miscarriage, birth defects, and possibly leukemia or other cancers.
Purpose of USP <800>

• Approximately 8 million workers 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
Hazardous Drug Guidance

**1960s**
Reports in medical literature

**1970s**
European study found mutagenicity within urine of nurses. Beginning to evaluate occupational exposure in healthcare professionals

**1980s**
ASHP published TAB (Technical Assistance Bulletin) regarding HDs, primary focused on chemotherapy agents

**2004**
NIOSH published Alert on preventing occupational exposure to HDs

**2011-2014**
Expert panel formed, first and second versions both released for public comment

**July 1, 2018**
USP General Chapter <800> enforceable

**Feb 2016**
USP General Chapter <800> published

INS NATIONAL ACADEMY
Who Enforces USP Standards?

- FDA and other federal agencies
- States – such as boards of health
- Accreditation organizations – medication preparation standards apply throughout an organization, not just to pharmacy
But Nurses Don’t Compound

- USP compounding chapters are broad in scope, and cover any mixing of medications
- USP <797> contains information on mixing sterile preparations for immediate use
- USP <800> includes that and more
Scope of <800>

- Life Cycle of HDs
- All Healthcare Entities
- All Healthcare Personnel
What Drugs are Hazardous?

- Any drug identified by at least one of the following criteria
  - Carcinogenicity
  - Teratogenicity or other developmental toxicity
  - Reproductive toxicity
  - Organ toxicity at low doses
  - Genotoxicity
  - Structure and toxicity profile of new drug that mimics existing HD
Scope of <800>
Official Date of USP $<800>$

- Official on December 1, 2019
  - This is a recent change
- Enforceable
  - Federal agencies
  - State agencies
  - Accreditation organizations
Genesis of <800>
Elements of <800>

- Facilities
- PPE
- Hazard Communication
- Transport & Disposal
- Dispensing & Administration
- Compounding
- Cleaning
- Medical Surveillance

INS NATIONAL ACADEMY
NIOSH Approach

• USP <800> establishes the containment strategies and work practices best known to control hazardous drug contamination
  • Engineering controls
  • Protective equipment
  • Work practices

https://www.cdc.gov/niosh/topics/hierarchy
Key Elements of <800>

- Containment
- Assessment of Risk
- Work Practices
NIOSH List of Hazardous Drugs

- Hazardous to healthcare personnel
  - Different from EPA hazardous materials which are hazardous to the environment
- Use of the list is required
  - Tables 1, 2, and 3
- Use of Table 5 Personal Protective Equipment (PPE) is not required, but provides a comprehensive list for policy development

www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf
Your HD List

- Must contain all the HDs on the NIOSH list that you handle
- Must be specific to the dosage form level
NIOSH List of Hazardous Drugs

- Antineoplastic Drugs
- Non-Antineoplastic Drugs
- Reproductive-Only Hazards
## Table 2 Examples

- Azathioprine
- Cyclosporine
- Fosphenytoin

- Risperidone
- Spironolactone
- Zidovudine
Table 3 Examples

- Clonazepam
- Colchicine
- Fluconazole
- Oxytocin
- Pamidronate
- Warfarin
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
What Drugs Can BeHandled Differently?

<table>
<thead>
<tr>
<th>All &lt;800&gt; Precautions Apply</th>
<th>Can Be Included in Assessment of Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw chemical of any HD on the list</td>
<td>Antineoplastics that only need to be counted or packaged</td>
</tr>
<tr>
<td>Antineoplastics that need to be manipulated</td>
<td>Table 2 drugs</td>
</tr>
<tr>
<td>Items that don’t fit the Assessment of Risk</td>
<td>Table 3 drugs</td>
</tr>
</tbody>
</table>
Compliance with All <800> Elements

• Facilities
  – Hood: Primary Engineering Control (PEC)
  – Room: Secondary Engineering Control (SEC)

• Personal Protective Equipment

• Work Practices
  – Policies and procedures
  – Containment from receiving to administering
  – Decontamination of work surfaces
OK to Consider for Assessment of Risk

- Antineoplastics that only need to be counted or packaged
- Non-antineoplastic meds (Table 2)
- Reproductive-only hazards (Table 3)
Alternative Strategy Examples
For Assessment of Risk

- Purchase unit-dose or unit-of-use
- Store in lidded bins
- Use closed system drug-transfer devices (CSTDs)
- Handle with chemo gloves
- Designate tackle boxes for transport
“Must” vs “Should”

- Must or shall = requirement
  - PPE
  - CSTDs for administration when the dosage form allows
  - Work practices that promote containment

- Should = recommendation
  - Use of CSTDs for compounding
  - Wipe samples for environmental sampling
  - Medical surveillance
Receiving and Storage

- HDs can be received in the same area as other drugs
  - Should have a designated area
  - Can be neutral/normal or negative pressure
  - Cannot be positive pressure
- HDs (unless entity-exempt through the Assessment of Risk)
  - Must be stored with proper containment
Closed System Drug-Transfer Device

- CSTDs mechanically prohibit the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor
- Required for administration when the dosage form allows
- Recommended for use when compounding

Photo courtesy of BD
Personal Protective Equipment (PPE)

• Gloves tested to ASTM D6978
• Gowns that are impervious, close in back, knit or elastic sleeves
• In certain cases
  • Respirator
  • Eye protection

Disposable PPE cannot be re-used
Work Practices

• Policies and procedures
• Containment
  • Outside of container once compound completed
  • Waiting for administration
• PPE
• Decontamination procedures
Cleaning Process for HDs

1. Deactivate and Decontaminate
2. Clean
3. Disinfect
## Cleaning Steps

<table>
<thead>
<tr>
<th>Function</th>
<th>Agent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deactivate and decontaminate</td>
<td>Properly-diluted EPA-approved oxidizer intended for use with HDs</td>
</tr>
<tr>
<td>Clean</td>
<td>Germicidal detergent</td>
</tr>
<tr>
<td>Disinfect</td>
<td>70% isopropyl alcohol (sterile for sterile compounding)</td>
</tr>
</tbody>
</table>
Resources

- **USP <800> FAQs**

- **www.readyfor800.com**
  - One hour panel discussion (physician, nurse, pharmacist
  - Short (~5 minute) videos targeted to specific audiences
  - Ready for 800 checklist

- **Perform an Assessment of Risk to Comply with USP <800>**
  - Pharmacy Purchasing and Products ([www.pppmag.com](http://www.pppmag.com)), March 2017
References

www.ons.org

www.hazmedsafety.com

www.ashp.org