USP 800 and Hazardous Medications

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The speaker has no actual or potential conflict of interest in relation to this presentation
Objectives

• Discuss the differences between USP 797 and 800

• Discuss safety measures and handling of the various categories of hazardous medications

• Explain differences amongst hazardous medications
Background
New England Compounding Center

Inside the New England Compounding Center

No Soliciting
United States Pharmacopeia (USP)

- USP is not an enforcement agency

- State board of pharmacy usually regulate the compounding practices within their jurisdiction

- FDA has oversight over compounding and may legally enforce USP’s compounding standards

- The Joint Commission on Accreditation Of Healthcare Organizations has standards that are congruent with <797> principles

- Anticipate Joint Commission to take a similar approach to USP<800>. 
What is USP 797 vs USP 800

**USP 797**
- Responsibilities of compound personnel
- Personnel training and facilities
- Storage and testing of finished preparations

**USP 800**
- Safe handling of hazardous drugs
- Minimize risks of exposure
- Protect healthcare personnel and environment
Sterile Compounding Preparations

- Aqueous bronchial and nasal inhalations
- Bath and soaks for live organs and tissues
- Injections
- Irrigations for wounds and body cavities
- Ophthalmic drops and ointments
- Dialysis fluids
- All have restrictions for sterility

USP 797, Chapter 35 Pharmaceutical Compounding, 2012
Prior to entering the sterile compounding room:

- Personnel must comply with cleaning and garbing procedures

- All containers must be clean with 70% isopropyl alcohol

- Compounding supplies must be placed within the hold to minimize air flow turbulence

- Discard all syringes and needles in proper sharps container

- Label all compounded products properly
USP 797 versus USP 800
Highlights from USP 800

- Internal lists
- Responsibilities of personnel
- Facilities
- Environmental quality and control
- Personal protective equipment

VETERANS HEALTH ADMINISTRATION
Storage and Unpacking of Hazardous Drugs

New in USP 800:

- HDs **MUST** be unpacked in negative pressure with at least 12 air changes per hour
- HDs **MUST** be stored separately

USP 797 → **SHOULD** but USP 800 → **MUST**

- Negative pressure
- Externally vented

Sahadeo et al, Journal of Hospital Pharm, 2015
Compounding of Hazardous Drugs

Nonsterile HDs:

- Containment primary engineering control (C-PEC or the hood) **SHOULD** be externally vented

Sterile HDs:

- C-PEC **MUST** provide a Class 5 or superior air quality and **MUST** be externally vented

  - **SHOULD** not use laminar airflow workbench (LAFW) or compounding aseptic isolator (CAI)

**Requires** C-PEC → containment secondary engineering control → ISO Class 7

Sahadeo et al, Journal of Hospital Pharm, 2015
Closed-System Transfer Device (CSTD)

USP 800:

- Protect health care workers from occupational exposure to HDs
- Not require by pharmacy during preparation

**BUT**

- Requires nurses when administering HDs to patients
USP 800:

- Mandates tracking of personnel via assessments and documentation
  - Symptom complaints
  - Physical findings
  - Laboratory values

- Health trends among exposed personnel vs unexposed personnel

- Program MUST include:
  - Identifying potential exposed workers
  - Confidentiality and maintenance of health records
  - Follow-up plans

Sahadeo et al, Journal of Hospital Pharm, 2015
Hazardous Drugs
“About 8 million U.S. healthcare workers are potentially exposed to hazardous drugs. Exposures to hazardous drugs can cause both acute and chronic health effects.” – NIOSH.org
Who is at Risk of Exposure?

- Pharmacists
- Environmental Services
- Pharmacy Technicians
- Patient Family Members
- Nurses
- Laboratory Staffs
- Physicians
- Other Hospital Staffs

### Definition of Hazardous Drugs (HDs)

<table>
<thead>
<tr>
<th><strong>American Society of Health System Pharmacists (ASHP) – 1990</strong></th>
<th><strong>National Institute of Occupational Safety and Health (NIOSH) - 2016</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity</td>
<td>Genotoxicity</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Carcinogenicity</td>
</tr>
<tr>
<td>Teratogenicity or fertility impairment</td>
<td>Teratogenicity/Developmental toxicity</td>
</tr>
<tr>
<td>Serious organ toxicity at low dose</td>
<td>Reproductive toxicity</td>
</tr>
<tr>
<td></td>
<td>Organ toxicity at low dose</td>
</tr>
<tr>
<td></td>
<td>Structure/toxicity profiles of new drugs that mimic existing HDs</td>
</tr>
</tbody>
</table>
Potential Routes of Exposures

- Inhalation
- Dermal absorption
- Ingestion
- Injection
Objective
• Assess surface contamination
• Personnel exposure to antineoplastic agents (i.e. Cyclophosphamide and Ifosfamide)

Participants
• Pharmacists
• Pharmacy technicians
• Nurses

Method
• 24-hour urine collection
• Wipe samples collected from four areas of the infusion center and pharmacy

Results
• Cyclophosphamide (+):
  • 18/48 urine sample
  • 17/17 wipe sample
• Ifosfamide (+):
  • 10/48 urine sample
  • 11/17 wipe sample
Differences Amongst Hazardous Drug Groups
Hazardous Drugs Group 1: Antineoplastic

Group 1 meets one or more of the NIOSH criteria for a hazardous drug:

- Majorities are hazardous to males or females who are:
  - Actively trying to conceive
  - Women who are pregnant or may become pregnant
  - Women who are breastfeeding

Represent an occupational hazard

Should always be handled with care
- Recommended engineering controls
- Personal protective equipment (PPE) regards of dosage form:
  - IV (intravenous)
  - SC (subcutaneous)
  - Topical
  - Tablet or capsule
Hazardous Drugs Group 1: Antineoplastics

Common Group 1 Drugs:

- Hydroxyurea
- Tamoxifen
- Carboplatin
- Flutamide
Hazardous Drugs Group 2: Non-Antineoplastic

Drugs in Table 2 meet one or more of the NIOSH criteria for a hazardous drug:

- May represent an occupational hazard:
  - Males or females who are actively trying to conceive
  - Women who are pregnant or may become pregnant
  - Women who are breastfeeding, because they may be present in breast milk.

- Unopened, intact tablets and capsules may not pose the same degree of occupational exposure risk as injectable drugs, which usually require extensive preparation.

- Cutting, crushing, or otherwise manipulating tablets and capsules will increase the risk of exposure to workers.
Hazardous Drugs Group 2

Common Group 2 Drugs:

- Risperidone
- Phenytoin
- Divalproex
- Abacavir
Hazardous Drugs Group 3: Non-Antineoplastic

Drugs in Table 3 primarily meet the NIOSH criteria for reproductive hazards:

- Represent a potential occupational hazard:
  - Males or females who are actively trying to conceive
  - Women who are pregnant or may become pregnant
  - Women who are breastfeeding, as they may be present in breast milk

- Unopened, intact tablets and capsules may not pose the same degree of occupational risk as injectable drugs that usually require extensive preparation

- Cutting, crushing, or otherwise manipulating tablets and capsules will increase the risk of exposure to workers.
References

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