What to wear? Hospital evaluation and operations for hazardous drug handling

Bridget Gegorski, PharmD
Medication Safety Officer

Indrani Kar, PharmD
Drug Formulary/Policy Specialist
Disclosure

• Nothing to disclose
Objectives

1. Formulate an institution-specific comprehensive hazardous drug list

2. Identify methods to provide hazardous drug handling guidance to front line staff for operations

3. Illustrate the need for multidisciplinary engagement in creating policy
USP 800 Overview

• Requirements for hazardous drug (HD) handling
• Enforceable July 2018
• Requirements:
  • Healthcare entities maintain a list of hazardous drugs
  • List reviewed yearly/when new drugs come to market
• Considerations
  • NIOSH maintains a list of antineoplastic and other hazardous drugs
  • Hospitals may use entire NIOSH list or complete an assessment of risk (AoR) on each medication
Risk Assessment requirements

• At minimum must address the following elements:
  – Type of HD (i.e. antineoplastic, non-antineoplastic, reproductive risk only)
  – Dosage form
  – Risk of exposure
  – Packaging
  – Manipulation
  – Specific alternative containment strategies and/or work practices that will be employed to reduce the risk of exposure

• Who conducts a risk assessment?
# Risk assessment example

**FIGURE 2**

**Sample Assessment of Risk**

In this sample AoR for oxytocin injection, which is received in unit of use from an outsourced compounding pharmacy, the entity details the risk factor and the corresponding safety measures implemented to protect at-risk staff from exposure. As a result, the entity can utilize these handling procedures in lieu of the more extensive handling requirements detailed in <800>. CriticalPoint has provided an AoR template, which can be modified for your practice; it is available at pppmag.com/assessmentofrisk.


**Drug Name:** Oxytocin

**Date Assessment of Risk (AOR) Initially Performed:** January 17, 2017

**Date AOR Reviewed:** N/A; this is initial

<table>
<thead>
<tr>
<th>HD Drug Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Antineoplastic</td>
<td>☑ Reproductive Risk Only</td>
</tr>
<tr>
<td>☑ Non-antineoplastic</td>
<td></td>
</tr>
</tbody>
</table>

**Dosage form (select one):**

- ☐ Sterile dosage compounded by a vendor and not requiring additional manipulation
- ☐ Dosage form of conventionally manufactured product that require only packaging or counting
- ☑ Dosage form of conventionally manufactured non-antineoplastic or reproductive hazard product that requires only packaging and counting
- ☑ Other (explain): Obtained from FDA Registered 503B Outsourcing Facility

**Describe Packaging:** Oxytocin 30 units in 500 mL 0.9% sodium chloride injection

**Rationale for not requiring all <800> containment strategies**

- The following strategies are documented in administration of oxytocin in the nursing SOP 321.2
- Training in the SOP is scheduled for all nursing staff on January 23, 2017

**Specific Alternative Administrative, Engineering and Work Practice Control Strategies**

- Document specific alternative strategies below or ☑ N/A (see below)
- Receive the compounded units from ABC 503B Outsourcing Facility
- Nurses who are in their 3rd trimester and may also be exposed to oxytocin while caring for patients during their normal job duties will sign an Acknowledgement of Risk form after receiving training regarding the risks and proper use of PPE
- Nurses and medical staff at risk of exposure to oxytocin during drug administration to patients will wear gloves tested to ASTM 6978 while administering, maintaining or discontinuing IV lines with oxytocin.

**Based on Assessment of Risk will proceed as follow: ☑ Follow alternative strategies documented above ☑ Follow all USP <800> requirements**

**Assessment of Risk written by:** Carl Smith, RPh  **Date:** 1/17/2017

**Reviewed by Pharmacy Manager:** Jane Olsen, PharmD  **Date:** 1/17/2017

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Joint Commission MM 01.01.03

• The hospital must complete the following:
  – Identify in writing its hazardous medications
    • TJC recommends use of NIOSH to formulate list
  – Have a process for managing HDs
    • EC 02.02.01 EP 8 and MM 03.01.01 EP 9
  – Implement hospital’s process for managing HDs
    • EC 02.02.01 EPs 1 and 8

• SAFER Matrix


Key Stakeholders

- Pharmacy
- Nursing
- Physicians
- Waste Management
- Environmental Services
- Chemical Safety
USP 800 Personal Protective Equipment (PPE) requirements

• Appropriate PPE must be worn when handling HDs
  – Receipt & Storage
  – Transport
  – Compounding (sterile and nonsterile)
  – Administration
  – Deactivation/decontamination, cleaning, disinfecting
  – Spill Control & Waste disposal
• NIOSH Table 5
  – Dictates when PPE should be worn
  – Based on dosage form
NIOSH Table 5 PPE Requirements Flowsheet

**Preparation**
- Single chemotherapy glove
- All tablet, liquid, and topical compounding completed in BSC or CACI type hood.
  - Clean/sterilize hood before subsequent sterile IV preparations.
- Preparation in BSC or CACI type hood with CSTD (if dosage form allows)
- Preparation in BSC or CACI type hood

**Formulation Type**
- Intact capsules and tablets
- Tablets or capsules that:
  - Pharmacy has/will cut, crush, or otherwise manipulate
  - Uncoated tablets
- Oral liquids
  - Commercially available
  - Pharmacy compounded
- Topicals
  - Commercially available
  - Pharmacy compounded
- Manufacturer-prepared syringe
- SQ/IM vial
- IV/IM
- Solutions for irrigation and powders/solutions for inhalation or aerosolization

**Administration**
- Single chemotherapy glove
- Double chemotherapy glove
  - Protective gown
  - Optional: Eye/face protection, if splash/vomit suspected
  - Optional: N95 mask if inhalation expected
  - Use CSTD if dosage form allows
  - Double chemotherapy glove
  - Protective gown
  - Optional: Eye/face protection, if splash/vomit suspected
  - Optional: N95 mask if inhalation expected

**Disposal/Cleaning**
- Double chemotherapy glove and protective gown
- Use face splash shield if there is splash/vomit potential
- Use N95 mask if aerosol potential

**Receipt/Storage**
- Chemotherapy is transported in a sealed bag labeled "Chemotherapy"
- Hazardous drugs not including chemotherapy is transported in a sealed bag labeled "hazardous"
- Carry spill kit for transport

Gloves

• American Society of Testing and Materials (ASTM) requirements
  – D6978 (or its successor)
  – “Chemotherapy gloves”
  – Powder free
  – Outer layer must be sterile when used for compounding
  – Gloves should be changed every 30 minutes
    • Or when torn punctured or contaminated
    • Permeability issues with some chemotherapy drugs
      – Thiotepa, Carmustine

• Gloves must be worn for handling all HDs
  – Antineoplastic
  – Non-antineoplastic
  – Reproductive risk only
Gowns

• Disposable
• Resist permeability by HDs
  – Gowns coated with polyethylene coated polypropylene offer better protection than uncoated
• Close in the back
• Long sleeve with elastic or knit cuffs

Head, Hair, Shoe, and Sleeve Covers

- Head and hair covers (including beard and mustache) are worn when compounding.
- Double shoe covers are worn when compounding HDs
  - Remove outer booty when exiting the HD buffer room
  - Prevents spreading of contamination to ante room
- Disposable sleeve covers may be used to protect arms that may come in contacted with HDs
  - Should be made of impenetrable material
Eye and Face Protection

• Protection must be worn when there is a risk for spills or splashes
  – Administration in the surgical suite
  – Working at or above eye level
  – Cleaning a spill

Types

• Full face respirator
  – Provides eye and face protection

• Goggles
  – Must be used when eye protection is needed

• Face shields
  – Do not provide full eye and face protection
Respiratory Protection

• A full-face chemical cartridge type respirator or powered air-purifying respirator (PAPR) should be worn when there is risk for respiratory exposure
  – HD spills that are larger than what can be contained by a spill kit
  – Cleaning under the work surface of a C-PEC
  – Known or suspected airborne exposure to powders or vapors

• A properly fit tested respirator should be in the pharmacy spill kit

• N-95 respirator
  – Protects against particles but NOT against gases and vapors
Spill Kit

Contents

- Various sizes
  - Chemo gloves
  - Chemo gown
- Face/eye protection
- Full respirator
- Absorbent pads
- Scraper and dustpan for powder spills
- Decontaminate/deactivation agent

Spill Drills
Operationalization of PPE requirements

- Policies and Standard operating procedures
  - PPE workflow sheet
  - Describes HD list and assessment of risks
  - Include management/implementation process
- EMR
  - Add medication directive for nurses to describe what PPE to don when looking a medication administration record (MAR)
  - Medication directive should print on medication label
- Automatic dispensing cabinets (ADC)
  - Add PPE directive to HDs stored in ADC
- Extra yellow bins (waste)
  - All PPE for HD handling is considered trace
Barriers

- Personnel
- Change control
- Interpretation of USP 800
- EMR capabilities
- Resources
Key Takeaways

• HD list and management process are a Joint Commission and USP 800 requirement

• PPE requirements differ by formulation type and are needed at all points of contact with HDs

• Smooth operations and policy development require engagement from several stakeholders
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Contact Information:
Bridget.Gegorski@UHhospitals.org or Indrani.Kar@UHhospitals.org