EHSSENTIALS 2017

Environmental, Health & Safety Symposium for Healthcare

APRIL 28, 2017

The University of Texas MD Anderson Cancer Center

Houston, Texas

PRESENTED BY

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

UTHealth The University of Texas Health Science Center at Houston School of Public Health

Texas Children's Hospital

bsi.

CHI St. Luke's Health

Hazardous Drug (HD) Management

The Good, the Bad, and the Ugly of HD Exposure Management

Doug Rush, MSc, CIH,CSP,CHMM
Principal Consultant
BSI EHS Services and Solutions
832-544-8245

EHSSENTIALS 2017
Environmental, Health & Safety Symposium for Healthcare

Objectives of Presentation

- How to identify Hazardous Drugs (HDs)
- Basic understanding of USP 795/797/800
- USP 800 compliance timeline
- Where HDs encountered
- Control of HD exposure
- Steps to compliance

Who is USP?

- The U.S. Pharmacopeia Convention (USP) is a scientific nonprofit organization that sets standards
- USP's drug standards are enforceable in the US by the FDA
- Since its founding in 1820, USP has helped secure the quality of the American drug supply

How We Got Here…Why USP 795/797/800?

- 12.5 Million Healthcare Workers in the US (1 Million in Texas)
- Studies indicate workplace exposure to HD is a problem
- Safe levels of exposure to HDs difficult due to absorption and mixed exposures
- Air samples may show low concentrations (robust sampling questionable)
- Wipe samples frequently find widespread contamination
- Toxic exposure possible via handling of unopened vials & new packaging
- Aerosol treatments
- Highly toxic chemicals designed to kill or change cells

Case Studies

- Case I: Oncology Nurse-Spilled infusion bottle on leg and arm
  - Convulsions (Acute exposure)
- Case II: Oncology Ward Nurse-Handling of antineoplastic drugs
  - Allergic Asthma (Chronic Exposure)
- Case III: Patient-care assistant-Cleaning commode of urine (aerosolized)
  - Allergic Skin Rash (Acute Exposure)

Hazardous Drugs & USP

- USP 795: Pharmaceutical Compounding
  - Nonsterile Preparations
- USP 797: Pharmaceutical Compounding
  - Sterile Preparations
- USP 800: Hazardous Drugs
  - Handling in Healthcare Settings

Progression to USP 800

Scope & Application of USP 800

- USP 800 Hazardous Drugs — Handling of HDs in Healthcare Settings
- Prescribes appropriate facilities, worker training, and practices to protect patients, workers, and the environment Includes:
  - Receipt
  - Storage
  - Compounding
  - Dispensing
  - Administration
  - Disposal

Scope & Application of USP 800

- Healthcare entities who handle HDs including:
  - pharmacies
  - hospitals
  - other healthcare institutions
  - patient treatment clinics
  - physicians' practice facilities
  - veterinarians' offices
- Personnel potentially exposed to HDs including:
  - pharmacist and technicians
  - nurses
  - physicians and assistants
  - home healthcare workers
  - veterinarians and technicians

Scope & Application of USP 800

- Entities who handle HDs must incorporate USP 800 into their Occupational Safety Plan to include:
  - List of HDs
  - Facility Engineering Controls
  - Competent Personnel
  - Safe Work Practices
  - Proper Use of Personal Protective Equipment (PPE)
  - Policies for Hazardous Waste Segregation and Disposal

Identification of Hazardous Drugs

- Generally, HDs belong to one of three groups of drugs:
  - Group 1: Antineoplastic drugs
  - Group 2: Non-antineoplastic drugs that meet one or more of the criteria for a hazardous drug
  - Group 3: Drugs that primarily pose a reproductive risk to men and women who are actively trying to conceive and women who are pregnant or breast feeding

Identification of Hazardous Drugs

- National Institute of Occupational Safety and Health (NIOSH) defines HDs to include drugs that exhibit 1 (one) of the following 6 (six) characteristics in humans or animals*:
  - Carcinogenicity
  - Teratogenicity or other developmental toxicity
  - Reproductive toxicity
  - Organ toxicity at low doses
  - Genotoxicity
  - Structure and toxicity profile of new drugs that mimic existing drugs determined to be hazardous by the above criteria

* NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016

Identification of Hazardous Drugs

- Exempted drugs include*:
  - Final compounded dosage preparations and manufactured HDs that do not require any further manipulation other than counting or repackaging
  - Dosage forms of HDs that do not pose a significant risk of direct occupational exposure (e.g., tablets or capsules—solid, intact medication that are administered to patients without modifying for formulation)

*Exemption only applies if an Assessment of Risk (AOR) is performed to determine alternative containment and/or work practices will control the risk

Assessment of Risk (AOR)

- Assessment of Risk (AOR) includes at a minimum
  - Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only)
  - Dosage form
  - Risk of exposure
  - Packaging
  - Manipulation
  - AOR is required Annually for each HD
  - AOR Tools: JSA, NIOSH Alert Tables, Drug Insert

AOR Tool

www.pppmag.com

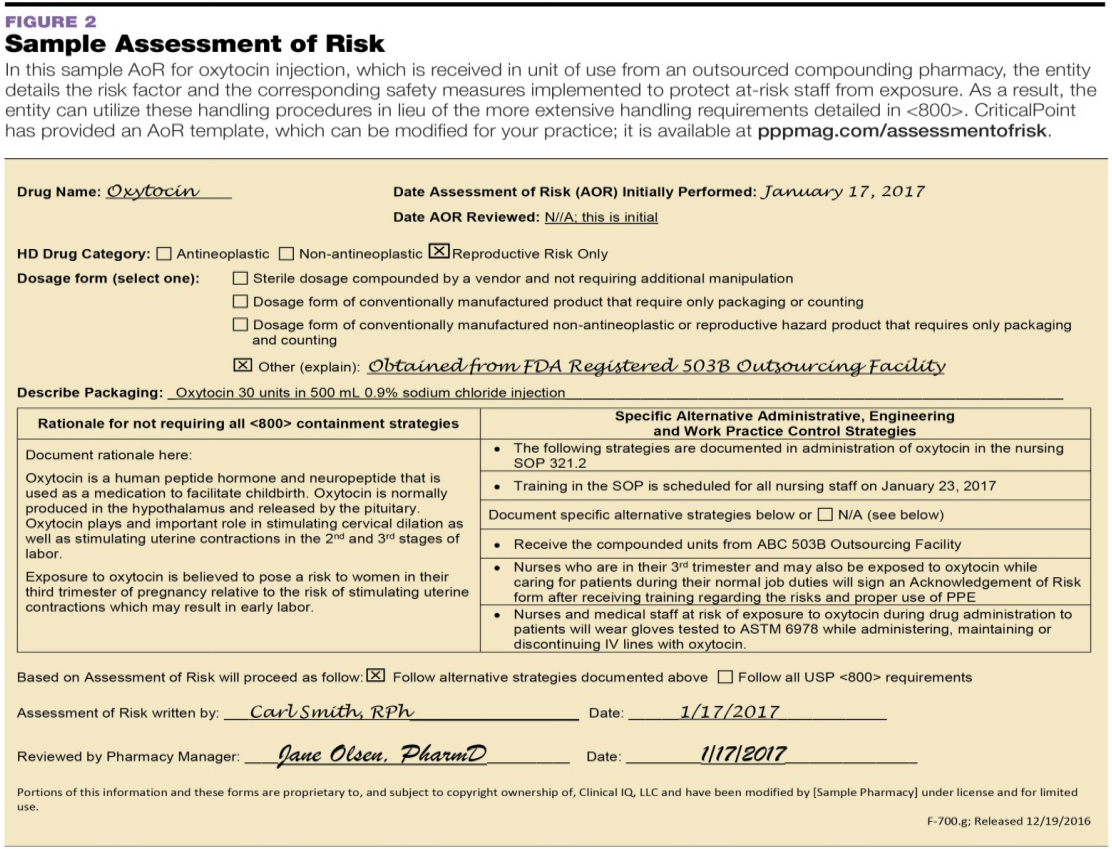

FIGURE 2

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

HD Drug Category: ☐ Antineoplastic ☐ Non-antineoplastic ☒ Reproductive Risk Only

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	Specific Alternative Administrative, Engineering and Work Practice Control Strategies
Document rationale here: Oxytocin is a human peptide hormone and neuropeptide that is used as a medication to facilitate childbirth. Oxytocin is normally produced in the hypothalamus and released by the pituitary. Oxytocin plays and important role in stimulating cervical dilation as well as stimulating uterine contractions in the 2nd and 3rd stages of labor. Exposure to oxytocin is believed to pose a risk to women in their third trimester of pregnancy relative to the risk of stimulating uterine contractions which may result in early labor.	• 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 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

Portions of this information and these forms are proprietary to, and subject to copyright ownership of, Clinical IQ, LLC and have been modified by [Sample Pharmacy] under license and for limited use.

F-700.g; Released 12/19/2016

Routes of Exposure

- Primary routes of unintended entry of HD into the body include:
  - Dermal and Mucosal Absorption
  - Inhalation
  - Injection
  - Ingestion

Potential Opportunities of Exposure Activities

- Receipt
- Dispensing
- Compounding and other manipulations
- Administration
- Patient-care Activities
- Spills
- Transport
- Waste

Responsibilities

- Entities “Must” have a Designated Person
  - Qualified and trained to develop and implement procedures
  - Ensuring competency
  - Understanding of risk-prevention policies
  - Taking Action
- HDs handlers are responsible for:
  - Understanding fundamental practices and precautions
  - Prevention of harm to patients
  - Minimizing exposure to personnel
  - Minimizing contamination of work and patient-care environment

Environmental Quality and Control

- Environmental surface wipe sampling*
  - Benchmark and every 6 months
- Locations
  - Inside PEC
  - Pass-through chambers
  - Surface in staging or work areas near PEC
  - Areas adjacent to PEC
  - Areas outside buffer room or the SCA
  - Patient administration areas

*Need sample plan with objective, locations, sampling & analytical parameters, sampling methods and acceptable limits

Personal Protective Equipment

- Gloves (ASTM D6978)
- Gowns (polyethylene-coated polypropylene or other Laminate materials)
- Hair covers
- Shoe covers
- Eye & Face protection
- Respirators
- Disposal
- Costs & Behavioral Issues

Hazard Communication Program

- Establish polices and procedures to ensure worker safety:
  - Written plan
  - Training
  - Labeling
  - Accessible
  - Transport, storage, disposal
  - SDSs
  - Drug inserts
  - Persons of reproductive capability must confirm that they understand risks

Personnel Training

- Training based on job function (receipt, storage compounding, administration…)
- Before independent handling of HDs
- Effectiveness demonstrated
- Reassessed every 12 months
- New equipment or significant changes

Receiving

- Ensure HDs received in impervious plastic
- Ensure HDs are received with labels
- Establish SOPs
- Provide
  - Chemo Gloves
  - Spill Kit

Minimum Standard Operating Procedures

- Hazard Communication Program
- Occupational Safety Program
- Description of HD areas
- Receipt
- Storage
- Compounding
- Use and maintenance of engineering controls (C-PECs, C-SECs, and CSTDs)
- Hand hygiene and PPE
- Deactivation, decontamination, cleaning, and disinfection
- Dispensing
- Transport
- Administering
- Environmental monitoring
- Disposal
- Spill control
- Medical surveillance

Medical Surveillance

- ID workers exposed
- Protect confidentiality
- Baseline assessment including medical history
- Tests may include CBC and Differential or chemical specific indicators
- Maintain records according to OSHA regulation
- Periodic monitoring
- Identifies data trends or markers
- Follow-Up on workers who show health changes
- Include exit exams

Next Steps-Change Management

I. Obtain Top Management Support
II. Assess Expertise to Lead Change (Person/Firm Must Know USP 800!)
III. Appoint a Change Manager
IV. Gap Analysis: Identify where you are to where you need to be
V. Build a Change Management Team (Include Stakeholders)
VI. Develop the Change Management Plan
VII. Implement the Change Management Plan
VIII. Follow-up (Measure Progress)

Major Takeaways

- USP 800 Compliance Required by July 1, 2018
- Covers HD exposure across the healthcare organization
- Requires Top Management support
- Gap assessment and change management plan
- **Start now, set realistic deadlines & take them seriously**

Discussion Questions

- Must vs. Should Language?
- PPE Costs?
- Environmental Sampling?
- Behavioral Changes?
- Training Challenges?

Hazardous Drug (HD) Management

Presented by:
Doug Rush, MSc, CIH, CSP, CHMM
Principal Consultant

Contact Information:
Email: doug.rush@bsigroup.com
Direct: 832-544-8245

Summary of Experience

Mr. Doug Rush is a results driven professional services leader with exceptional business, communication, organizational, interpersonal and technical skills. He possesses greater than 25 years of leadership in senior HSE operations and management roles including founder and owner of 3 full service HSE consulting firms with a staff of up to 33 professionals. His experience has been focused in healthcare, engineering consulting entities and Fortune 500 Companies positioned locally and internationally.

He is a Certified Industrial Hygienist (CIH), Certified Safety Professional (CSP), and Certified Hazardous Materials Manager (CHMM) providing forensic, HSE, and expert testimony in the occupational workplace. His priorities are founded in the 3 P's: People, Property, and Profit. He is a Passionate HSE Mountain Builder and a Dedicated HSE Mountain Climber.