USP 800
What Is It and How Will It Affect Your Occupational Health Practice?
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Is Your Health Care Organization Ready?

• Have you heard of USP 800?

• Is there planning happening in your organization?

• Who is at the table?

• Who owns your hazardous drug policy?

• What is your responsibility as an occupational health nurse?
USP — What Is It?

• USP — United States Pharmacopeial Convention

• United States Pharmacopeia — National Formulary
  – Health care quality standards
  – Pharmacies have to comply with
  – Enforcement — citations, fines, close pharmacy
  – Can be enforced by Joint Commission, CMS and state boards of pharmacy
  – USP no regulatory authority — rely on government agencies to adopt standards and enforce
USP 800 — What Is It?

- New general chapter
  - Hazardous Drugs — Handling in Healthcare Settings

- New standard
  - Protect personnel and patients, reduce risk of exposure, environmental protection

- Applies to all health care personnel and health care facilities where hazardous drugs are handled or manipulated, from receipt to disposal

- Adds to USP 797 (2004)

- Implementation date: July 1, 2018
Background

• Developed by USP Compounding Expert Committee with input from experts

• Builds upon previous publications
  – Alert - Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings (NIOSH)
  – Medical Surveillance for Healthcare Workers Exposed to Hazardous Drugs (NIOSH)
  – Controlling Occupational Exposure to Hazardous Drugs (OSHA)
  – ASHP Guidelines on Handling Hazardous Drugs
  – Safe Handling of Hazardous Drugs (ONS)

• OSHA recommending since 1995, poor compliance

• No standard practice
USP 800 Coverage Groups

- Pharmacists
- Pharmacy technicians
- Transporters/couriers
- Nurses, technicians
- Material management/supply
- Environmental services
- Physicians
- Physician assistants
- Home health personnel
- Veterinarians
- Veterinary technicians
- Others?
Locations Covered

- Pharmacies
  - Inpatient
  - Outpatient
- Hospitals
- Treatment clinics
- Physician practices
- Veterinary practices
- Operating rooms
- Emergency department
- Obstetrics
- Home care
- Others?
Why is USP 800 So Important?

- Health care exposure protection
- Exposure risks are great
- Safety climate of organization
- Human nature, perception of risk
Health Care Exposure

• 8 million U.S. health care workers potentially exposed each year

• Often unaware of risk and risk reduction measures

• Many different employee groups affected, not just pharmacy
Exposure Risk Causation

• Not wearing personal protective equipment
  – Choice or not available

• Limited use of closed system drug transfer devices

• Policy and procedure adherence

• Knowledge
  – Perceived risk: Not serious or low-risk
  – Their susceptibility
  – Short- and long-term consequences
  – Surface contamination
  – Respiratory protection

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Safety Culture vs. Safety Climate

• **Culture**
  – Values, attitudes and behaviors

• **Climate**
  – *Perception* about an organization’s commitment to safety

Polovich, M. Joint Commission Resources Webinar 2016. USP Chapter <800> What Nurses Need to Know
Why Nurses Don’t Protect Themselves

• Time

• Workload

• PPE
  – Not convenient
  – Discomfort when wearing

• Cost

• Modeling by leaders/co-workers

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Exposure Routes

• **Absorption** (skin, mucous membrane)
  - Spill clean-up, work surfaces and floors, contaminated containers on receipt, handling contaminated wastes, linens, body fluids, during preparation and administration

• **Inhalation**
  - Priming IV sets, generating aerosols (ribavirin), during preparation and administration, clean-up

• **Injection**
  - Sharps injuries

• **Ingestion**
  - Contaminated foodstuffs, hand-to-mouth contaminants
Adverse Outcomes of Exposure

• Acute
  – Nausea, dizziness, nasal sores

• Chromosome changes

• Cancer
  – Leukemia and lymphoma

• Reproductive effects
  – Spontaneous abortion
  – Infertility
  – Premature labor
  – Premature birth
  – Fetal abnormalities
  – Learning disabilities

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USP 800 Components

- Facilities
- Risk assessment
- Hazardous drug list
- Work practices
- Education and training
- Personal protective equipment
- Environmental monitoring
- Medical surveillance
Safety 101 Review: Hierarchy of Controls

- Eliminate
- Substitute
- Engineering controls
- Administrative controls
- Personal protective equipment
Facilities — Engineering Controls

- Room signage
- Controlled access
- Specified rooms for compounding, location
- Buffer rooms
- Ventilation
  - Air exchanges, negative pressure
- Biological safety cabinets
- Closed system for drug transfer devices (recommended)

- Sinks
- Eyewashes
- Spill kits
- Wipe sampling (recommended)
- Drug labeling
- Waste container labeling
Risk Assessment

• Drugs
  – Type and dosage form
  – Risk of exposure
  – Packaging
  – Manipulation

• Environment
  – Receiving
    • Docks, pharmacies
  – Storage areas
    • Separate from other drugs, safe
  – Compounding/manipulation areas
  – Transporting within facility
  – Administration areas
  – Waste disposal areas

• All procedures/work practices
NIOSH Hazardous Drugs List

• Spells out what makes a drug hazardous
  – 2016 latest revision

• Three categories:
  – Antineoplastic: cisplatin
  – Non-antineoplastic: phenytoin, estrogens
  – Reproductive hazards: oxytocin, finastaride (Proscar, Propecia)

• Some antivirals, hormones, bioengineered, experimental

• Develop list for each hospital/site

• Review/update annually and with new drugs/dosage forms
NIOSH Working Group on Hazardous Drugs Definition

- Those that exhibit at least one of the following characteristics:
  - Carcinogenicity
  - Teratogenicity
  - Other developmental toxicity
  - Reproductive toxicity in humans
  - Organ toxicity at low doses in humans or animals
  - Genotoxicity
  - New drugs that mimic existing hazardous drugs in structure or toxicity
Work Practices

• Designated person for oversight - hazardous drug officer

• Policies and procedures for:
  – Receiving damaged containers
  – Compounding/manipulation
  – Cleaning preparation areas (deactivate and decontamination)
  – Spill clean-up, respirators
  – Personal protective equipment
  – Administering-closed system transfer devices, PPE
  – Handling body fluids, contaminated clothing and linens, dressings
  – No contaminated clothing goes home
  – Waste disposal (EPA)

• Regular observance of work practices
Education and Training

- Prior to handling
- Competency every 12 months
- Hazard communication (OSHA)
- Safety data sheets
- Training right groups for their role? Documenting?
Education and Training, cont’d

• Patient/family education (semi-private rooms)

• New hazardous drug notification

• Pregnant, breast-feeding, trying to conceive employees, male employees (partner pregnancy risk)
  – Prenatal Reference Guide
  – Temporary re-assignment
  – OH counseling
Personal Protective Equipment

- Chemotherapy-approved gloves (double) and change per manufacturer’s recommendations; hand washing
- Non-permeable gowns (back opening, cuffs, no seams) and change per manufacturer’s recommendation
- Hair, head and shoe covers
- Sleeve covers
- Goggles, face shields
- Respirators
  - N95, surgical N95s, half-face with appropriate cartridge/filter, full-face, PAPR
- Fit testing annually
Environmental Monitoring

• Wipe sampling
  – Screening tool - evaluate work practices, engineering controls and PPE needs
  – No U.S. standard for allowable surface contamination
  – No U.S. regulation on surface contamination
  – Cannot be used as indicator of work exposure - no correlation with uptake of drugs in health care workers
  – Many variables and limitations
Medical Surveillance

• Analysis of health information to look for trends that require targeted prevention. Detect and eliminate underlying causes such as hazards or exposures of any discovered trends.
  – OSHA - *should* conduct (recommendation, not a requirement)

• Minimize adverse health effects - hazard control

• Early detection of changes in health, deviations from expected norms
Medical Surveillance, cont’d

• Comparison over time in individuals
  – Baseline and monitor future health

• Trend populations of workers
  – Compare with unexposed workers

• Evaluate effectiveness of engineering controls, safe work practices, PPE, education
NIOSH - Elements of a Medical Surveillance Program

• NIOSH recommends surveillance, not a regulation

• Reproductive and general health questionnaires at hire and periodically

• History of hazardous drug handling

• Baseline clinical evaluation - medical history, physical examination (least helpful), laboratory testing

• Follow-up plan for workers showing health changes or acute exposure

• Examination of aggregate data for trends
USP 800 Medical Surveillance Elements

- Identify workers potentially exposed based on job duties

- Surveillance program
  - Maintain records confidentially

- Pre-placement baseline health status and medical, work and reproductive history, physical exam, laboratory values

- Periodic surveillance

- Monitoring of data

- Follow-up plan for employees with acute exposures or health changes

- Exit exam
Post-Exposure Follow-Up Plan

- Post-exposure exam
  - Type and amount of exposure, treatment and labs as indicated

- Environmental sampling

- Engineering controls operating correctly

- Following policies and procedures

- Action plan to prevent additional exposure

- Confidential communication with employee

- Alternative duty or temporary re-assignment

- On-going medical surveillance
Our History

• 1997: No scientific basis found to support blood work
• Post-exposure evaluation only, very few exposures reported

• 2009-2010: Hazardous drug policy team creation for policy review and revision
  – Pharmacy, occupational health, safety
• Benchmarked against local health care organizations and others with established programs
• Varied widely from nothing in place to questionnaire, physician exam, EKG, labs, mandatory annual training
• Reviewed resources
Resources

- National Institute of Occupational Safety and Health (NIOSH) Alert: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2004

- Occupational Safety and Health Administration (OSHA) Controlling Occupational Exposures to Hazardous Drugs, OSHA Technical manual 1999


Decisions

• Develop hazardous drug questionnaire and administer to:
  – New hire employees w/previous employment in environments where hazardous drugs were handled, triggered by “yes” to previous work-related exposure
  – New hire employees assigned to departments where hazardous drugs are handled
  – Current employees transferring to departments where hazardous drugs are handled
  – Every two years by employees in departments identified as high risk for hazardous drug exposures
  – Post unprotected exposure to hazardous drugs
  – Employees leaving departments where hazardous drugs are handled (offered, but not required)
Questionnaire Components/Review

• Initial/periodic/post-exposure
  – Medical history - targeted questions for any changes to health, target organs (skin, mucous membranes, lymphatic system, liver, CNS, urologic, hematopoietic, pulmonary)
  – Reproductive health
  – Work history - hazardous drug handling experience and personal protective equipment utilized
  – Review by occupational health/physician referral
  – Testing as determined by physician
    • CBC with differential (indicator of bone marrow reserve), liver function, BUN. Cr, urine dip for blood
Potential HD Exposure Evaluation/Information Sheet

• Initial response and reporting
  – Remove contaminated clothing
  – Decontamination - flush skin/eyes
  – Reported to supervisor/occupational health/safety
  – Policy provided

• Initial assessment and treatment
  – Documentation of exposure (drug name, route, dose, concentration, duration)
  – SDS consulted
  – Questionnaire completed
  – OHN review
  – Referral to physician
Potential HD Exposure Evaluation/Information Sheet cont’d

- Employee can request physician evaluation
- Reproductive toxicity information provided
- Physician evaluation complete
- Labs ordered
- Follow-up plan
Considerations with USP 800

• Revise core hazardous drug safety and health plan policy

• Do we add routine labs?

• Do we add routine physician exams?

• Do we find a better way to capture and monitor data for individuals and groups?
  – Electronic questionnaires for individuals
  – Way to track entire employee group electronically for epidemiologic review (exposure-health outcome linkage)
  – Exposure tracking
Laboratory Testing Questions

- No recommended safe exposure levels for hazardous drugs

- CBC, liver function, reticulocyte count, urine dip - abnormalities attributed to HD exposure only?, impractical, useful?

- Biological testing - measures specific drug or metabolite
  - Feasibility questionable - workers handle multiple hazardous drugs
  - Difficult to interpret results
  - Only specified labs can conduct testing
  - Used in research - not meant to evaluate exposure in individuals
Surveillance Program Plan

• Form team to identify those employee groups who will be in the surveillance group

• Determine what elements you will include in your medical surveillance
  – Questionnaire - what to include?
  – Physician exam?
  – Labs?

• Determine frequency
  – Baseline on hire – document pre-existing conditions i.e., asthma triggered by question on health assessment all new hires complete
  – Prior to placement for transfers
  – Annually-bi-annually-signal poor work practices?
  – Post exposure
  – Exit
Surveillance Program Plan, cont’d

- How will you maintain list of employees in surveillance?
- How will you get questionnaires completed? How stored?
- Who reviews questionnaires and determines further evaluation?
- Who will you send the employees to for further evaluation?
- How will you monitor data for individuals and groups?
- How/who will analyze aggregate questionnaire data for trends?
- If you have a trend, how do you address/manage?
- Get involved with your USP 800 committee
- Reach out to other health care organizations
- Research expert resources
The bottom line for a robust program

• Our mission:
  – Protect our health care workers
  – Be proactive to lower risk of exposure
  – Take excellent care if exposure occurs
Questions?
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