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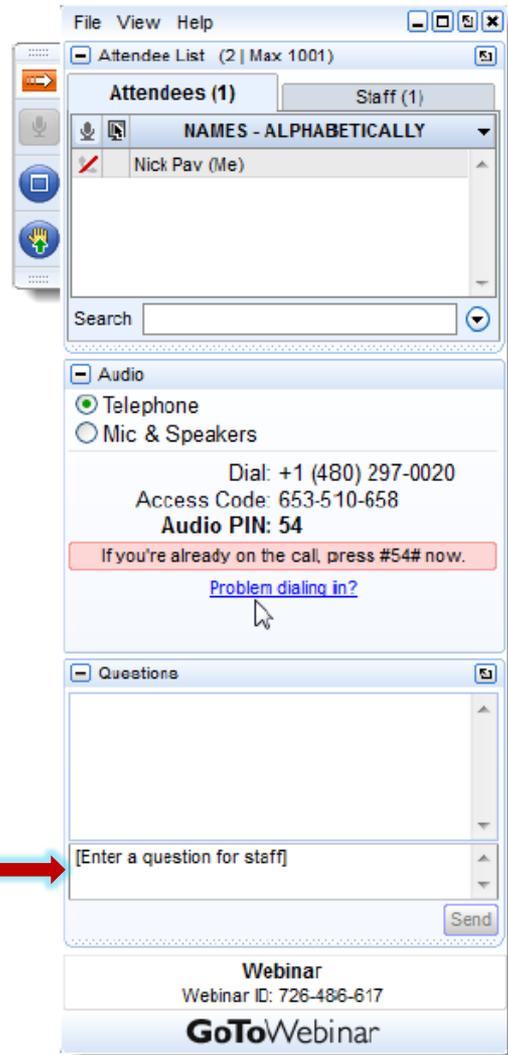
WEB021-2017



USP 800

What Is It and How Will It Affect Your Occupational Health Practice?

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Step 1 →

← Step 2

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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

Safety Culture vs. Safety Climate

- **Culture**
 - Values, attitudes and behaviors

- **Climate**
 - *Perception* about an organization's commitment to safety

Why Nurses Don't Protect Themselves

- Time
- Workload
- PPE
 - Not convenient
 - Discomfort when wearing
- Cost
- Modeling by leaders/co-workers



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

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
- All procedures/work practices
- Environment
 - Receiving
 - Docks, pharmacies
 - Storage areas
 - Separate from other drugs, safe
 - Compounding/manipulation areas
 - Transporting within facility
 - Administration areas
 - Waste disposal areas



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, finasteride (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
- American Society of Health System Pharmacists (ASHP) Guidelines on Handling Hazardous Drugs: *Am J of Health-System Pharm.* 2006
- Polovich M, Belcher C, Glynn-Tucker EM et al. Safe Handling of Hazardous Drugs. Oncology Nursing Society 2003

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







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