Chemotherapy Safe Handling: What You Need to Know

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Objectives

- Describe the requirements of USP <800> Hazardous Drugs – Handling in Healthcare Settings
- Discuss the updates to the QOPI standards related to chemotherapy administration safety
- Identify resources for compliance with USP and QOPI standards

Defining Hazardous Drugs

- Carcinogens
- Genotoxins
- Teratogens
- Reproductive toxins
- Organ toxicity at low doses
- Structure or toxicity similar to drugs classified as hazardous

(ASHP, 2006; NIOSH, 2014)

Why USP<800>?

- Occupational hazardous drug exposure results in adverse outcomes
- Occupational hazardous drug exposure continues
- Organizations vary in implementing hazardous drug safe handling precautions

Genotoxic Biomarkers in Exposed Workers

- Chromosomal aberrations: *5 studies since 2006*
  - Chromosome 5 or 7 abnormalities in pharmacists & nurses (McDiarmid, 2010)
- Sister chromatid exchange (SCE): *2 studies since 2006*
- Micronuclei (MN): *4 studies since 2007*
- Comet Assay: *7 studies since 2006*
- HPRT Mutation test: *2 studies since 2005*

Summarized in: Suspiro, A., & Prista, J. (2011)

Cancer Occurrence

- Increased occurrence of cancer [pharmacy technicians]
  (*RR* = 1.1-3.6)
- Increase in acute leukemia [nurses]
  (*RR* = 10.65)
- Overall increased occurrence of cancer [nurses]
  (*OR* = 3.27, p = .03)

RR = Relative Risk; OR = Odds Ratio

Hansen & Olsen, 1994; Martin, 2003; Skov et al., 1992

Adverse Reproductive Outcomes

- Infertility (*OR* = 1.42-1.5)
- Spontaneous abortion/ miscarriage (2 - 3.5 X risk)
- Premature labor (*OR* = 2.98)
- Pre-term birth (*OR* = 5.56)
- Learning disabilities in offspring (*OR* = 2.56)

OR = Odds Ratio

Fransman, 2007; Hansen & Olsen, 1994; Lawson, 2012; Martin, 2003; Skov, 1992

Published Evidence: Exposure Opportunities

- Contamination on external vial surfaces
  (15 studies since 1992)
- Workplace surface contamination
  (>100 studies since 1994)
- Excretion of drugs and drug metabolites in urine of health care workers
  (>55 studies *since 1992)*

http://www.cdc.gov/niosh/topics/antineoplastic/pubs.html

Pharmacists & Nurses: Exposure

- Reported during routine handling:
  - 11-17% - dermal or eye exposure (previous year)
  - 4-11% - skin contact (previous 7 days)
  - 12-24% - taking home potentially contaminated clothes
  - 1.4% - sharps injury involving chemotherapy (previous year)

- Nurses & Spills:
  - 12% reported spills (previous 7 days)
  - Multiple staff usually involved in spill clean-up
  - Staff reporting spills had HDs in urine
  - Staff who *DID NOT* report spills had HDs in urine

Boiano, 2014; Boiano, 2015; Friese, 2012; 2014

Practice Setting Impacts HD Safety

- Most common reason for failure to wear gowns:
  - *Gowns not provided by employer*
- Most common reason for failure to use chemo-tested gloves:
  - *Gloves not provided by employer*
- Use of Closed System Transfer Devices (CSTDs):
  - *25% of nurses; 47% of pharmacists*

Boiano, 2015; Polovich & Clark, 2012

What is USP<800>?

U.S. Pharmacopeial Convention

- Quality standards for medicines sold in U.S.
- Applicable standards:
  - USP <797> Sterile Compounding
  - USP <800> Hazardous Drugs Handling in Healthcare Settings
- Enforceable by:
  - FDA
  - North Carolina State Board of Pharmacy

Who/ What Facilities will be Impacted?

USP<800> applies to "***all healthcare personnel*** who handle HD preparations and ***all entities*** which store, prepare, transport, or administer HDs"

- *No exceptions based on HD volume, category of personnel, or type of facility*

USP <800>
Overview of Provisions

- Maintain list of all HDs in facility (NIOSH, 2014)
- Designate person to oversee compliance
- Facilities & engineering controls
  - Separate storage for HDs
  - Containment primary engineering controls
  - Negative pressure
  - External venting
  - Closed System Transfer Devices for administration

USP <800> Provisions (cont'd)

- Environmental Quality Control
- Hazard Communication Program
- Labeling, Packaging, Transport, Disposal
- Personnel Training
- Spill control plan
- Decontamination protocols
- Personal Protective Equipment
- Medical Surveillance of personnel

Impact on Nurses

- USP<800> sets requirements for safe administration of hazardous drugs
  - Use of closed systems when the dosage form allows
  - Use of protective techniques when spiking/ priming IV tubing
  - Use of chemotherapy-tested PPE
  - Use of procedures that minimize manipulating HDs
- May involve changes in procedures / routines / equipment
- *WILL* require collaboration & education

Closed System Transfer Device (CSTD)

"A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor outside the system"

- Five products currently available in U.S.
- New testing standard developed by NIOSH (2016)

NIOSH , 2004

Literature and CSTDs

- Many studies show that CSTDs decrease HD contamination in compounding and administration
- CSTDs do not address all HD contamination (e.g. vials, spills, waste)
- No study determined the cost/benefit of CSTDs

Personal Protective Equipment (PPE)

- **Gloves**:
  - *two pair, tested with hazardous drugs*
  - powder-free
  - latex, nitrile, neoprene
- **Gowns**:
  - *tested with hazardous drugs*
  - disposable, single-use
  - cuffs
  - back closure

ASHP, NIOSH, OSHA, ONS

Double Gloves

- To protect against permeation of some drugs
  - Carmustine
  - Thiotepa
- To prevent transfer of contamination from outer gloves to hands and other surfaces
  - ALWAYS consider gloves contaminated after chemotherapy handling *(5 studies since 1992)*

Task-Dependent PPE

- **Eye protection**
  - when splashing is possible
- **Respirator/mask**
  - aerosols & spills

Medical Surveillance

- What it is:
  - Collecting and interpreting health data
- Purpose:
  - Identifying the earliest reversible biologic effects of exposure
  - Detecting changes in health status
  - Correcting prevention failures
  - Preventing adverse outcomes in other workers

NIOSH, 2012; USP, 2015

Medical Surveillance Program

- Organized approach to identify potentially exposed workers
- Surveillance appropriate to the exposure
- Pre-placement health assessment
- Periodic and routine health appraisal
- Exposure tracking (routine and acute)
- Monitoring of the data
- Follow up plan for workers w/ health changes
- Exit examination

NIOSH, 2012; USP, 2015

Follow-up For Acute Exposure

- Based on type of exposure
- Assessment of extent of exposure
- Physical examination
- Treatment / labs guided by protocols
- Verify / document controls in use
- Action plan to prevent additional exposure
- Evaluation of effectiveness of plan

USP, 2015

ASCO/ ONS Chemotherapy Safety Standards

AND QOPI CERTIFICATION

Establishing Criteria for Standards

- Applicable to diverse practice settings
- Understandable and clinically intuitive
- Realistic to achieve
- Valid and evidence-based
- Reliable
- Measurable
- Actionable

What's New: 2015-2016 Revisions

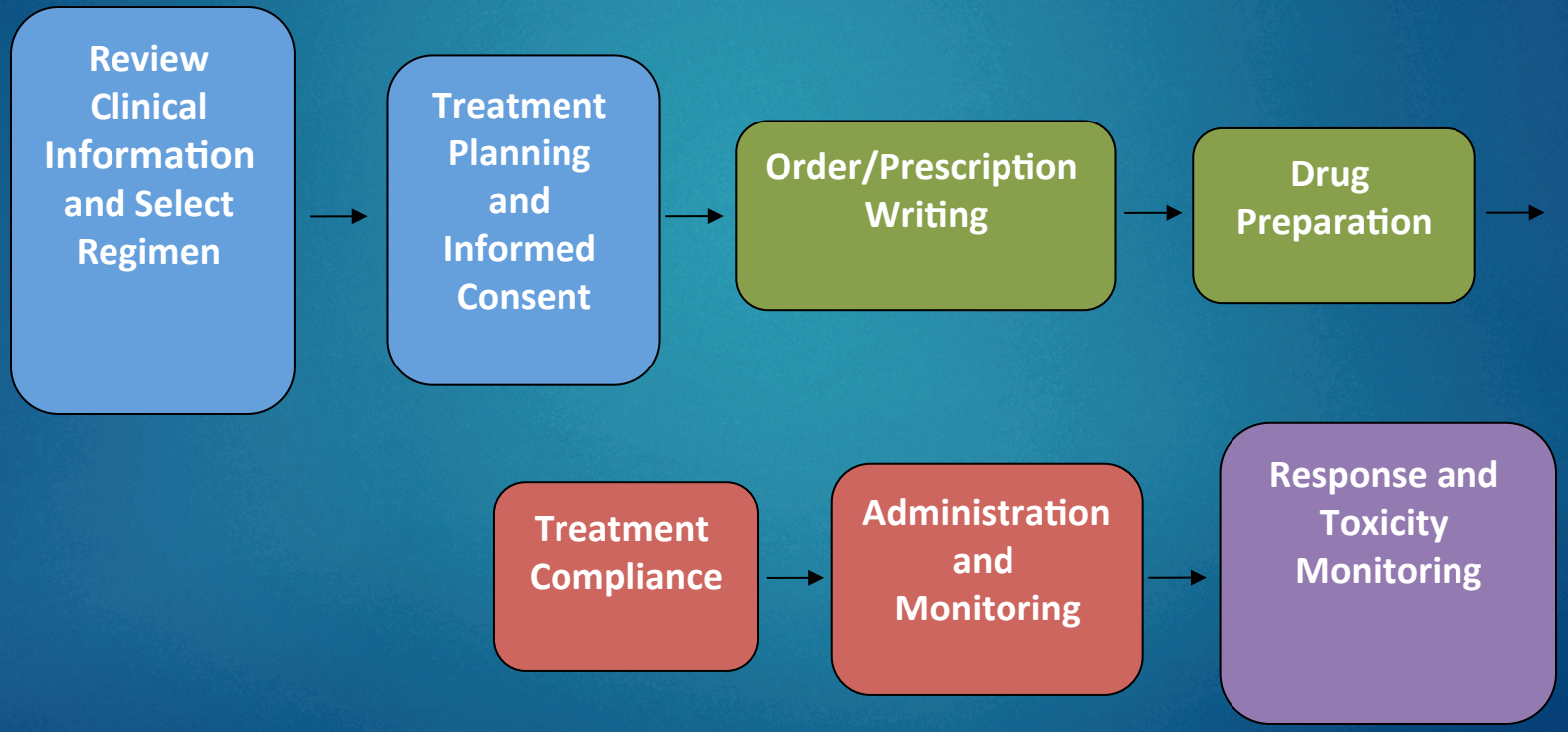
- All health care settings where chemotherapy is administered
- Addressing use of chemotherapy in pediatric patients
- Expanded glossary
- Re-organization of standards

Draft standards open for public comment until January 13, 2016

http://research.zarca.com/survey.aspx?k=RQsTUTRsRPSTsPsPsP&lang=0&data=

https://www.ons.org/sites/default/files/0192_ASCO%20ONS%20chemotherapy%20administration%20Standards%20Draft_2015.pdf

Domains in Initial Standards



Jacobson, et al., 2009; 2012

Domains in Update

1. Creating a Safe Environment: Staffing and general policy
2. Treatment Planning, patient consent and education
3. Ordering, preparing, dispensing and administering chemotherapy
4. Monitoring after chemotherapy is given, including adherence, toxicity, complications

Chemotherapy Consent

- 2.2 Informed consent or assent for chemotherapy treatment, as appropriate to the treatment population, is documented prior to initiation of a chemotherapy regimen.

Safety with Oral Chemotherapy Agents

- 3.5.2 New orders or changes to orders, including changes to oral chemotherapy regimens (e.g., dose adjustments communicated directly to patients), are documented in the medical record.

Prescriptions for Oral Chemotherapy

- 3.6.1 The patient's name
- 3.6.2 A second patient identifier
- 3.6.3 Full generic drug name
- 3.6.4 Date of order
- 3.6.5 Drug dose (standard abbreviations)
- 3.6.6 Includes calculation methodology
- 3.6.7 Route of administration, special instructions (if applicable)
- 3.6.8 Drug quantity to be dispensed
- 3.6.9 Schedule of administration
- 3.6.10 Duration of therapy (e.g. time limitation, such as number of cycles)
- 3.6.11 Number of refills, with **zero** being the acceptable default value

Labels for Oral Chemotherapy (dispensed by setting):

- 3.11.1 Patient's name
- 3.11.2 A second patient identifier
- 3.11.3 Date of preparation and expiration
- 3.11.4 Full generic drug name
- 3.11.5 **Dosage** form and strength
- 3.11.6 Quantity dispensed within each container
- 3.11.7 Number of pills per dose when the container holds more than one dose
- 3.11.8. Administration schedule, times/day, days on and off treatment when applicable
- 3.11.9 Administration instructions related to food ingestion and other medications
- 3.11.10 A warning or precaution statement as applicable to storage and handling
- 3.11.11 Caution statement (e.g. "caution: chemotherapy" or HAZARDOUS DRUG)
- 3.11.12 Storage conditions
- 3.11.13 Prescriber name

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