Medication Safety in Oncology Pharmacy
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Learning Objectives

- Recognize the various steps in the health-system process with preparation and administration of oncology drug products
- Describe the standard precautions approach to handling hazardous drugs safely
- Identify areas for improvement in the safe handling and preparation of oncology drug products and prevention of medication errors at your own institution
Overview

- Definition of Hazardous Drug
- Stages of Hazardous Drug Movement
  - Pharmacy receiving personnel
  - Pharmacists and technicians
  - Nurses and physicians
  - Patient and family members
- Personal Safety
  - Storage
  - Preparation
  - Handling
- Medication Errors in Pharmacy
- Conclusion/Questions

Hazardous Drug Definitions
ASHP Definition

- Genotoxicity
- Carcinogenicity
- Teratogenicity or fertility impairment
- Evidence of serious organ toxicity at low doses

- First defined in 1990

National Institute for Occupational Safety and Health (NIOSH)

- Refined ASHP definition in 2004
- Studies in animals or humans demonstrate:
  - Carcinogenicity – causes cancer
  - Teratogenicity – damages developing fetus
  - Reproductive toxicity – impairs fertility
  - Organ toxicity at low doses
  - Genotoxicity – damages DNA
  - Structure & toxicity profiles of new drugs that mimic those of existing drugs that are considered hazardous
Modes of Contact for Drug Exposure

- **Dermal**
  - Most common source
  - Direct Contact
  - Contaminated Surfaces

- **Ingestion**
  - Food, gum
  - Hand-to-mouth

- **Inhalation**
  - Vapors
  - Aerosols

- **Injection**
  - Sharps
  - Breakage

Hazardous Drug Handling and Personal Protective Equipment
Manufacturers & Distributors

- Clear cytotoxic labeling on exterior
- One cycle per package
- Unit-of-use when possible
- Unit dose packaging when appropriate
- Delivered separate from non-cytotoxic drugs

Receiving

- Gloves (2 pairs)
- Eye protection when opening containers
  - Assess for damage or leaks
  - Appropriate precautions
- Protective Clothing
  - nonabsorbent
  - polyethylene–coated polypropylene
- Spill kits
**Storage**

- Separated from non-hazardous drugs
- Visible warning labels
- Shelf barriers, bins, shelves
- Avoid storing “look-alike–sound-alike” drugs together

**Compounding**

- Types of compounding hoods
- Prime IV tubing and remove air from syringes within a BSC
- Wipe syringes, IV bottles, and pumps with sterile gauze to remove any drug contamination
- Compounded product stored in sealed plastic container for transport
Patient Administration

- Nurses wear same PPE
- Change gowns when leaving patient care area
- Opportunity for patient education

Patient and Family

- “Oral” does not mean safer than “IV”
- Avoid cutting/splitting oral chemo
- Double-flush toilet/close lid
- Latex gloves when handling oral agents
- Refrigerated oral chemo storage
  - Sealed plastic bag
  - Family education
Personal Protective Equipment (PPE)

- **Gloves**
  - Double pair (latex, nitrile, polyurethane)
    - Inner glove under gown cuff
    - Outer glove over gown cuff
  - Changed every 30–60 minutes
  - Wash hands before and after use
  - Powder free

PPE (cont)

- **Gowns**
  - Polyethylene coated polypropylene material
  - Change every 3 hours (ASAP if spill)
  - Do not wear outside compounding or administration area
PPE (cont)

- Shoe covers
  - Do not wear outside compounding areas
- Head/Hair covers
- Face shields vs safety goggles
- Eye wash station
- Respiratory Protection
  - Face shields vs safety goggles

Closed System Drug Transfer Devices (CSTD)

- Mechanically prohibit the transfer of environmental contaminants into the sterile system and prevents the escape of HDs or vapor concentrations outside the system
- NIOSH 1st recommends use (2004)
- U.S.P. 797 recommends use
CTSD’s

- Cost and billing challenges
- **Does not replace proper aseptic technique!**
- Lack of comparison studies between CTSD’s
- **Legislation**
  - California – requires NIOSH compliance (2013)
  - Maryland – legislation pending
  - North Carolina – legislation pending

New Technologies

- Robotic automation
  - Standardized accuracy and automation
  - Reduced occupational exposure
  - Require loading and cleaning

- Remote pharmacist verification
15% of all medication error fatalities reported to FDA from 1993–1998
- Estimated that 500 deaths annually due to oncology medication errors
- Narrow therapeutic ranges
- Varying dosages depending on indication
Source of Medication Errors

- Distractions & Excessive interruptions
- Large distance between compounding area and pharmacy/pharmacist
- Poor packaging/labeling
- Similar sounding drug names
- Unfamiliar abbreviations
- Lack of procedure/warning stickers
  - IV vs IT administration

Preventing Medication Errors

- Organized storage
  - Drug names (LASA’s)
    - cisplatin vs carboplatin
    - taxotere vs taxol
    - vincristine vs vinblastine
  - Strengths
- Reconstitution Errors
  - Vincristine IV and other formulations
  - Vincristine never stored with intrathecal meds
Preventing Medication Errors

- Tall-man Lettering
  - CARBOplatin
  - CISplatin
  - vinBLASTine
  - vinCRISTine
  - DOCEtaxel
  - PACLItaxel

Preventing Medication Errors

- Different routes of administration for drug
  - Bortezomib (Velcade®)
    - IV and SQ administration
  - Methotrexate
    - IV, IM, IT
  - Cytarabine
    - IV, IT
- Barcoding
**ISMP recommendations**

- All chemotherapy/biotherapy prepared for *one patient* at a time
- Each chemotherapy product prepared *individually*
- No chemo prepared without printed label
- When preparing batches, only one drug and one concentration prepared at a time
- Pharmacist verification *prior* to addition to base solution (do not use syringe pullback method)

**ISMP Recommendations (cont)**

- System used to deliver chemo to patient care areas is controlled by pharmacy
- Transported in sealed, leak-proof bag labeled as “chemotherapy” or “hazardous material”
- Chemotherapy/biotherapy ALWAYS *hand delivered* (never tubed)
  - Directly to chemo nurse
  - Directly to designated/segregated storage area
- Defined timeframes for ordering/preparing established AND followed
ISMP Recommendations (cont)

- Continuous Quality Improvement
  - Actual medication errors or near-misses
  - Other published errors from other facilities
  - System assessment vs personal blame
- Properly trained in specific CSTD used at your institution
- Report situations that *could lead* to an error
  - if it looks confusing to you, it may be to others also

Resources
Training and Competencies

- Orientation and routine training (annual)
- Primary educator (med safety specialist)
- Accidental Exposure to self/others
- Clinical staff in contact with oral chemo or waste from patients who received hazardous drug
  - Clerks
  - Hygiene workers
  - Sanitation workers

Medical Surveillance

- Routine monitoring for HD handlers
  - Every 2–3 years
  - Health History/assessment
    - CBC
    - Hepatic function panel
    - Urinalysis
- Recommended by:
  - Occupational Safety & Health Administration (OSHA)
  - NIOSH
  - American College of Occupational and Environmental Medicine
Professional Organizations

- National Institute for Occupational Safety and Health (NIOSH)
  - List of Antineoplastic & Other Hazardous Drugs in Healthcare Settings 2012
    - Defines categories for hazard types
    - Currently updating for 2014
- American Society of Health–System Pharmacists (ASHP)
  - Guidelines on Handling Hazardous Drugs 2006
- U.S.P. 797/800

References

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- Furlow, B. *How to Improve the safety of chemotherapy administration*. Oncology Nurse Advisor; June 2010:21–25
Questions