Chemotherapy Safety

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Objectives

- Define hazardous drugs and negative health effects associated with exposure
- Identify work practices that present a risk to exposure to hazardous drugs
- Outline workplace strategies and practices to reduce exposure
- Describe technological advances that include CSTD and what the practical considerations are when selecting a device

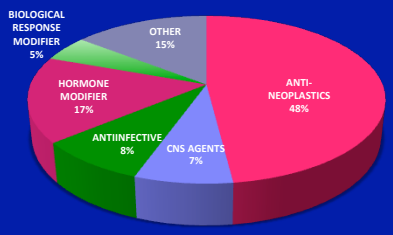
Safe Handling

- **Hazardous** – drugs that require special handling because of health risk that may result from exposure
  - There is no such thing as a "safe level"
  - No reliable way to monitor work related exposure

People who work with hazardous drugs must adhere to practices designed to minimize exposure!

ASHP, 2006; NIOSH, 2004;
Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2010



Antineoplastices – per ASHP therapeutic classification (AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS) American Hospital Formulary Service

Other Hazardous Drugs in Healthcare Settings 2010

- Antiinfective agents (17) – i.e. ganciclovir, cidofovir, micafungin, pentamidine
- Bilogical Response Modifiers (10) – i.e. thalidomide, interferon alpha 2a/b, infliximab
- CNS agents (15) – i.e. divalproex, paroxetine, risperidone, valproic acid
- Hormone Modifiers (33) – i.e. estradiol/estrogen, medroxyprogesterone, testosterone, leuprolide, tamoxifen
- Others (29) – i.e. anticholinergic agent, antigout agent, cardiovascular drug, dermatological agent, GI agents, immunosuppressant, etc.

Antineoplastices – per ASHP therapeutic classification (AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS) American Hospital Formulary Service

Characteristics of Hazardous Drugs

- Carcinogenicity
- Teratogenicity
- Reproductive toxicity
- Organ toxicity at low doses
- Genotoxicity
- Drugs similar in structure or toxicity

ASHP. 2006; NIOSH, 2004;
Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

What about Biotherapy?

- Limited data is available
- Most agents do not affect DNA and do not cause genetic changes
- INF and Antiangiogenic agents have reproductive and fertility toxicity
- Targeted agents
  - The -nibs and vorinostat meet the criteria for hazardous drugs and should be handled as such
- Conjugated MoAbs

ASHP, 2006; NIOSH, 2004;
Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Potential Health Risks

- Adverse outcomes of exposure
  - Acute symptoms
    - GI, Skin, allergic, infectious, general
  - Chronic Changes
- Reproductive outcomes
  - Menstrual dysfunction
  - Spontaneous abortions / miscarriages
  - Fetal abnormalities
  - Infertility / longer time to conception
  - Low birth weights / Premature labor
  - Learning disabilities in offspring

ASHP, 2006; NIOSH, 2004;
Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Potential Health Risks

- Biological changes
  - Mutagenic changes
  - DNA damage
  - Chromosomal aberration
- Cancer related to exposure
  - Leukemia in nurses and physicians
  - Lymphoma and skin cancer in pharmacist
  - Overall increased occurrence of cancer
  - Cyclophosphamide calculated risk assessment is 1.4 – 10 cancers per year per one million workers

ASHP, 2006; NIOSH, 2004;
Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Occupational exposures among nurses and risk of spontaneous abortion

- The rate of spontaneous abortion in nurses who handle chemotherapy drugs is twice that of nurses who did not handle the drugs
- 8,461 participants in the Nurses' Health Study 2. Participants reported 6,707 live births and 775 (10%) spontaneous abortions (less than 20 weeks)
- The rates varied by spe-cialty area
  - Lowest rates
    - medical/surgical (8.4%)
    - critical care (8.8%)
  - Highest rates
    - home health/community (13.1%)
    - oncology (13.1%)

Lawson CC, Rocheleau CM, Whelan EA, et al. Occupational exposures among nurses and risk of spontaneous abortion. Am J Obstet Gynecol 2012;206:327.e1-8.

Limitations of Study

- Asked nurses how many hours they spent working with potentially toxic exposures
  - Not about incidents where a nurse knew they had skin exposure
- Did not collect information on measures to control exposure such as use of:
  - gloves
  - respirators
  - lead aprons
  - ventilation or scavenging system.

Lawson CC, Rocheleau CM, Whelan EA, et al. Occupational exposures among nurses and risk of spontaneous abortion. Am J Obstet Gynecol 2012;206:327.e1-8.

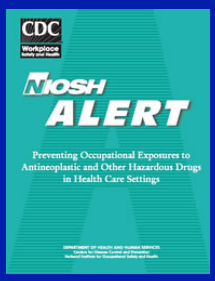
Nurses' Use of Hazardous Drug-Handling Precautions and Awareness of National Safety Guidelines

- 330 Nurses at 2006 ONS Congress were surveyed about HD handling practice
- Research shows that nurses are not always careful when handling chemotherapy drugs.
  - Foregoing gowns or gloves
  - Using non- chemotherapy tested/ resistant supplies
- Respondents were well educated
  - 57% had a bachelor's degree
  - Experienced and certified
  - 47% of respondents were aware of the NIOSH Alert
- 35% of all participants reported preparing chemotherapy
- 95%-100% Glove use
  - Higher than that reported in earlier studies
- Gown Use
  - 65% for drug preparation
  - 50% drug administration
- **23% used PPE when handling excretions**
- **Double-gloving was rare** (11%-18%).

Polovich.M., & Martin, S. (2011) Nurses' Use of Hazardous Drug-Handling Precautions and Awareness of National Safety Guidelines. Oncology Nursing Forum, 2011;38, 718-726.

Nursing Responsibility

- Safe Handling Recommendations were first made in 1985
  - Nurses must know about the risks of HD exposure and ways to reduce exposure.
  - Employers must provide appropriate PPE and encourage its use
  - Alternative methods of disseminating safety recommendations are needed.



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Who does what?

- **The Ocupational Safety and Health Act of 1970** created both NIOSH and the Occupational Safety and Health Administration (OSHA).
- **OSHA** is responsible for developing and **enforcing** workplace safety and health reguations
- **NIOSH** is in the Department of Health and Human Services and is established to help assure safe and healthful working conditions and provide **research, information**, education and training in the field of occuaptional safety and health.
- **NIOSH** recommends guidelines for the benefit of healthcare clinicians. They expect that products reach their standards.

Regulatory Oversight

- "All employers with hazardous chemicals in their workplaces are required to have a hazard communication program, including container labels, safety data sheets, and employee training."
  - » **OSHA Hazard Communication - 71:53617-53627** . Federal Registers - Table of Contents • **Publication Date:** 09/12/2006• **Publication Type:**Proposed Rules• **Fed Register #:**71:53617-53627• **Standard Number:**1910; 1915; 1917; 1918; 1926• **Title:**Hazard Communication

U.S. Department of Labor Hierarchy of Control

1. Elimination
2. Substitution
3. Engineering Controls
4. Administrative Controls
5. Personal Protective Equipment

U.S. Department of Labor 1998

Routes of Exposure

- Direct or Indirect drug contact
  - Dermal absorption – skin or mucous membranes
  - Injection
  - Ingestion
  - Inhalation
- Environment
  - Drug preparation areas
  - Drug administration areas
  - Patient Care areas
- Contamination of the outside of drug vials directly from the manufacturers

ASHP, 2006; NIOSH, 2004;
Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Has this happened to you?

- Damaged PPE? (torn glove?)
- Purging air from system or priming IV with drug?
- IV tubing spike through bag
- Leaking connections
- What else?

Personal Protective Equipment (PPE)

- Gloves
- Gown
- Respirators
- Eye and Face Protection

ASHP, 2006; NIOSH, 2004;
Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

When to wear PPE

- Introducing or withdrawing needles from vials
- Transferring drugs from vials to containers
- Administering HDs by any route
- Spiking IV bags containing HDs or changing IV tubing
- Priming IV tubing
- Handling leakage from tubing, syringe and connection site
- Disposing of HDs and items contaminated with HDs
- Handling the body fluids of a patient who received HDs in the past 48 hours.

Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Gloves

- Must be powder free and tested with hazardous drugs
  - FDA requires permeation testing before gloves are designated to be used for chemotherapy
  - American Society for Testing and Materials (ASMT) developed standards.
    - Must be tested on Carmustine, cyclophosphamide, doxorubicin, etoposide, flurouracil, paclitaxel, thiotepa
    - Tested for 4 hours of continuous contact with agent for defect and breakthrough
- Change after every 30 minutes of wear or if a puncture, tear or spill occurs

ASHP, 2006; NIOSH, 2004; ASTM, 2005
Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Gown

- Disposable and lint free
- Low-permeability fabric
- Solid front, tight cuffs and long sleeves with a back closure
- Inner glove cuff is under the gown cuff and outer glove cuff is over the gown cuff
- Gowns are meant for single use

ASHP, 2006; NIOSH, 2004;
Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Respirators and Face Protection

- Respirators – non-powdered, air-purifying particulate-filter respirator when there is a risk of
  - Aerosolized HDs
  - Cleaning a Spill
- Eye and Face Shields
  - Risk for splashing
  - Intravesical chemotherapy administration

ASHP, 2006; NIOSH, 2004;
Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Storage And Labeling

- Store chemo in a location that limits exposure
- Distinct Label
- Have access to instructions (MSDS)
- Check containers before taking them from one area to another to detect any leakage or breakage

ASHP, 2006; NIOSH, 2004;
Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Compounding Requirements

- The environment where sterile hazardous drugs are prepared must meet standards for ventilation; exchanges per hour, negative pressure and particle counts
  - Vertical laminar airflow, HEPA filter, continuously operating fan, with a negative pressure buffer area
  - Personnel must be trained, machine must be serviced and recertified
- Prepare cytotoxic drugs in a primary engineering control (PEC)
  - Biological Safety Cabinet
  - Aseptic containment isolator

U.S. Pharmacopeial Convention (2008); OSHA 1999; National Sanitation Foundation, 2007; Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Compounding

- May interfere with airflow in PEC
  - Sterile, plastic backed absorbent pad
  - Too many items
- Avoid pressure build-up in vials
- Use a closed system device
- Use Luer Lock fittings
- Spike IV and prime tubing before adding cytotoxic drug
- Wipe the outside of the container with a moist gauze and label
- Don't forget hand washing!

ASHP. 2006; NIOSH, 2004; Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Transporting

- Transport in a sealed container!
  - Luer lock end of syringe should be capped
  - Ensure that transporter knows how to use a spill kit
  - What about patients leaving the floor?

ASHP. 2006; NIOSH, 2004; Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Drug Administration

- ALWAYS WEAR PPE!
- Know where the spill kit is and how to use it
- Use a closed system device
- Use a disposable, absorbent plastic backed drape
- Luer lock connections
- Remove entire IV set at completion
- Discard of contaminated material and PPE in hazardous waste containers

ASHP, 2006; NIOSH, 2004;
Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Closed Systems

- Recommended in updated ONS Chemo and Biotherapy Guidelines and ASHP 2006 guidelines
- Provide additional protection during drug preparation and administration
- Containment of droplet and aerosolized particles
- Two basic components
  - Vial adaptor used during drug preparation
  - Closed valve used on tubing and syringes before, during and after chemotherapy administration to prevent leakage

ASHP, 2006; NIOSH, 2004;
Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Straight out of NIOSH

- Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Heath Care Settings (2004)

BD's PhaSeal®

- On the market since 1999
- Several published studies demonstrating efficacy
- Uses multiple components
  - Injector uses internal needle
  - Requires adaptor for luer lock devices

External chamber traps vapors, requires injecting air

www.carmelpharma.com/phaseal.html

ICU Medical's Chemo Clave System ™

- Includes Genie and Spiros
- Closed male Luer using Clave components
- No additional adaptors required
- Compatible with all standard Luer connections
- Creates vacuum at disconnect

Internal balloon traps vapors, does not require injecting air into vial

/www.icumed.com/Oncology.asp

B Braun's OnGuard™

- Teva Components
- Valve has internal needle
- Requires adaptor for use with Luer devices

Traps vapors and particles Using special dual layer micro-filter

www.hit.bbraunusa.com/onguard.html

CareFusion Texium System ®

- Closed male Luer using SmartSite ® components
- Designed to be compatible with Alaris ® tubing
- 0.2 micron vented filter

http://www.carefusion.com/pdf/Infusion/Closed_System_Solution_Brochure.pdf

Codan Cyto®

- Reliable aerosol retention
- Needle-free luer lock access
- 0.2 Micron Air Filter
- Swan lock Spike adapters

http://www.codanuscorp.com/brochures/CODAN_CYTO_Product_Line.pdf
http://www.tmml.com/Catalogue/SellSheets/C98_INFO_Codan%20CYTO%20Flyer.pdf

How do you choose?

- Evidence Based Practice
  - "a total process beginning with knowing what clinical questions to ask, how to find the best practice, and how to critically appraise the evidence for validity and applicability to the particular care situation.
- The Evidence Source Equation: Clinician Experience + Patient Preferences + Scientific Findings = Evidence-Based Guidelines

DePalma, J. (2000). Evidence-based clinical practice guidelines.
http://onsopcontent.ons.org/toolkits/evidence/practice.shtml

Body Fluids

- Standard precautions kicked up a notch
- Incontinent patients
- Flushing – hospital barriers?

Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Interesting Facts

- Some drugs that are excreted unchanged in the urine in the first 24 hours after administration:

Don't forget to communicate with care partners and helpful family members!

Etoposide	67% unchanged
Dacarbazine	40% unchanged
Ifosfamide	61% unchanged
Cytarabine	<10% unchanged
Methotrexate	80-90% unchanged

Micromedex

Linens

- Try to avoid contamination and use disposable items
- Refer to hospital policy
- Linens are treated as hazardous, contained and infections by laundry personnel

Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Disposal of Hazardous Materials

- Bin most be sealable, leakproof and labeled
  - Trace or Bulk
- Use puncture proof containers for sharps (not red bins)

ASHP, 2006; NIOSH, 2004;
Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Oh no, I spilled!

- Use detergent or bleach (bleach will need to be neutralized) followed by clean water
  - Repeat again
- Surface Safe
- If spill occurs on carpet
  - Use absorbent powder
  - Use vacuum reserved for hazardous drug clean-up

Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Oh no, I spilled on Myself and My patient!

- Skin exposure – remove contaminated garments and wash skin with soap and water
- Eye exposure – wash eyes for 15 minutes with saline solution or water

Look at the MSDS!

\Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Where does it all go?

- California Medical Waste Act
  - Requires trace chemotherapy be sent for incineration at a medical waste incineration facility
  - Bulk chemotherapy waste must be sent to RCRA facility to be incinerated

Flush the Chemo out of the IV line with compatible solution

Requirements for Policies around Hazardous Medications

- Safe storage, transport, compounding (BSC), administration and disposal
- Up to date listing of Hazardous drugs in the facility
- Employees wear PPE and no eating or drinking where drugs are used or prepared
- Mandatory training
- MSDS and spill procedures
- Address handling around pregnancy
- Quality improvement programs

ASHP, 2006; NIOSH, 2004;
Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. (2009) ONS.

Compliance

- Knowledge deficit?
- Reasons for non-compliance?
- Reasons for compliance?
- What do you see in your practice?
- How can you improve chemotherapy safety for you and your colleagues?

HOT TOPICS

- Chemo/Biotherapy administration for Non-Oncology diagnosis
- Employee monitoring programs in healthcare settings

ASCO/ONS Standards for Safe Chemotherapy Administration

- Develop consensus for standards focused on adult patients in the INPATIENT and outpatient setting
  - Chemotherapy drugs are labeled immediately upon preparation
  - Two individuals independently verify each order
  - Practice site maintains a policy for how chemotherapy informed consent is obtained and documented
  - The practice site does not allow verbal orders for chemotherapy

ASCO/ONS Standards for Safe Chemotherapy Administration

- "The practice/institution has a comprehensive educational program for new staff administering chemotherapy, including a competency assessment, *or* the practice/institution uses an off-site educational program regarding chemotherapy administration that ends in competency assessment. Chemotherapy administration education must include all routes of administration used in the practice/institution site (e.g., parenteral, oral, intrathecal, intraperitoneal, intravesicular)."

Resources

- The Oncology Nursing Society
- NIOSH
- ASHP
- www.chemoregimen.com