

Safety in Hazardous Drugs, Including Chemotherapy

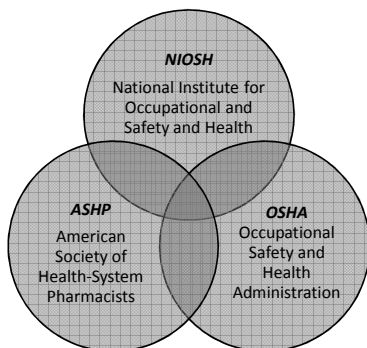
Michael L. Brandt, B.S., PharmD, FASHP
Pharmacy Clinical Supervisor
Kootenai Health
Coeur d'Alene, Idaho



Objectives

- ❖ Define Hazardous Drugs
- ❖ Outline safety procedures in mixing chemotherapy agents
- ❖ Understand safety measures in administration of chemotherapy
- ❖ Become aware of some special handling for new or seldom-used agents

The Regulators



What is a Hazardous Drug?

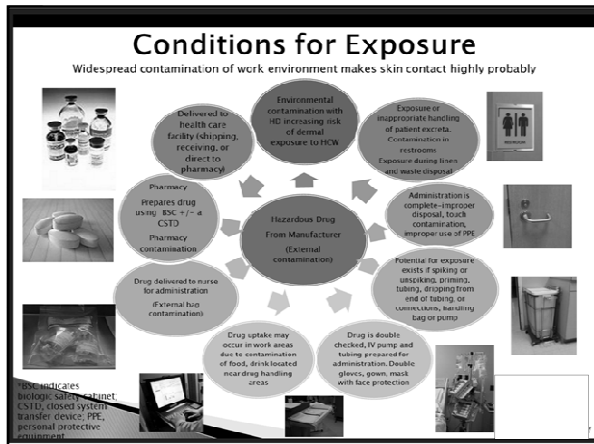
- ❖ Chemotherapy
- ❖ Antiviral Drugs
- ❖ Hormones
- ❖ Some Bioengineered Drugs
Avastin, Rituxan (?), Erbitux

“Although potential therapeutic benefits of hazardous drugs outweigh the side effects for ill patients, exposed health care workers risk these same effects without the therapeutic benefits.”

NIOSH

The National Institute for Occupational Safety and Health
www.cdc.gov/NIOSH

Working with or near hazardous drugs in health care settings may cause skin rashes, infertility, miscarriage, birth defects and possibly leukemia or other cancers



No single biologic marker has been found to be a good indicator of exposure or a good predictor of adverse effects

Exposure to Hazardous Drugs

In nurses, pharmacists, and technicians routinely exposed to hazardous drugs in the workplace, two controlled studies have reported significant increases in the number of certain symptoms.

Some symptoms of exposure

- ❖ Sore throat
- ❖ Chronic cough
- ❖ Infections
- ❖ Dizziness
- ❖ Eye irritation
- ❖ Headaches

What is your risk?

AIRBORNE SAMPLING

- ❖ Studies have attempted to measure airborne concentrations of antineoplastic drugs.
- ❖ Most studies have found that the percentage of air samples containing hazardous drugs is low.
- ❖ Of those that did contain measurable amounts, the concentration was very low.
- ❖ However, this may possibly be attributed to inefficiency in sampling and analyzing.

What is your risk?

SURFACE SAMPLING

Wipe samples used in most investigations find measurable detectable concentrations of hazardous materials.

SURFACE SAMPLING

- *Biological Safety Cabinets (BSC)*
- *Floors*
- *Storage Areas*
- *Tables and chairs in patient treatment areas*
- *Locations adjacent to drug handling areas*

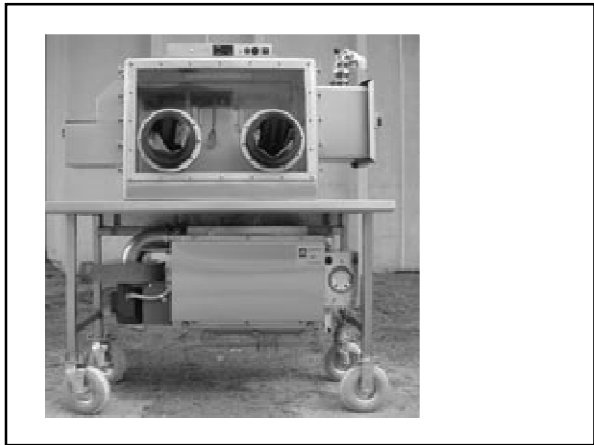
Exposure Control

- ❖ *Biologic Safety Cabinet (BSC)*
- ❖ *Closed System Transfer Devices (CSTD)*
- ❖ *PPE*
 - *Gloves* *Respirator*
 - *Gowns* *Eye/face shield*
- ❖ *Surface Decontamination*
- ❖ *Work Practices*

Biologic Safety Cabinets and Isolators

- *NIOSH Recommended Procedures.*
- *Provide and maintain ventilated cabinets designed to protect workers and others from exposure to hazardous drugs and to protect all drugs that require sterile handling. Examples of ventilated cabinets include biological safety cabinets (BSCs) and containment isolators designed to prevent hazardous drugs from escaping into the work environment.*





Exposure

- ❖ Several studies have found measurable concentrations of hazardous drugs on the outside of drug vials.
- ❖ This has been found in the absence of breakage.

Exposure

- ❖ It can be presumed that contamination occurs when vials are incompletely washed after filling, or are handled by workers wearing contaminated gloves.
- ❖ This includes **boxes** and **package inserts!**

Closed-System Transfer Devices (CSTDs)

- ❖ These devices prevent the transfer of environmental contaminants in the system and the escape of drug or vapor out of the system.
- ❖ Some examples of CSTD are
- ❖ ADD-vantage, Spiros (ICU), OnGuard (aka Tevadaptor,) and PhaSeal Systems.

Closed-System Transfer Devices

Several studies have shown a reduction in environmental contamination during both compounding and administration of hazardous drugs compared to standard techniques.

Contamination Comparison of Transfer Devices Intended for Handling Hazardous Drugs. Jorgenson JA et. al. Hosp Pharm 43 (9), 723-727, 2008

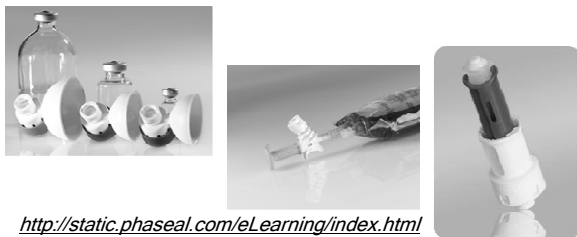
Advantages of PhaSeal

The Double Membrane:

- Provides **dry connections**, thus eliminating exposure when connecting and disconnecting from vials, syringes, IV bags and patient IV lines.

Disadvantages of PhaSeal

- ❖ Cost (is it reimbursed?)
- ❖ Difficulty in physically manipulating – it's a learning curve.



Spiros (ICU Medical)

❖ Advantages:

- Provides a dry connection
- Easy to use

❖ Disadvantages

- Still an expense that may or may not get reimbursed
- Can create exposure if not used correctly

OnGuard (Tevadaptor)

http://www.youtube.com/watch?v=YjL1dD3XE&feature=player_detailpage



Personal Protective Equipment

Gloves	<ul style="list-style-type: none"> • Wear double gloves for all handling activities (eg, preparation, administration, handling of contaminated waste) • Disposable, powder-free gloves, tested for use with HDs • Inspect gloves for visible defects prior to use • Change gloves every 30 minutes or immediately if damaged or contaminated; DO NOT reuse gloves • Wash hands with soap and water after removing gloves
Eye and Face Protection	<ul style="list-style-type: none"> • Combination of mask and face shield when possibility of splashing exists
Gowns	<ul style="list-style-type: none"> • Disposable, lint-free, low-permeability fabric • Solid front with back closure, long sleeves, tight cuffs • Cloth fabrics, including lab coats, should not be used • Inner glove under gown, outer glove over gown • Discard if visibly contaminated, after handling drug, and before leaving area where drug is handled • Gowns are for single use only – DO NOT reapply

Polovich M. (Ed.) Safe Handling of Hazardous Drugs (2nd Ed). Pittsburgh, PA: Oncology Nursing Society, 2011. Polovich M, Whitford JM, and Olsen M (eds.) Chemotherapy and Biotechnology Guidelines and Recommendations for Practice (3rd Ed.) Pittsburgh, PA: Oncology Nursing Society, 2009.

Situations requiring PPE

- ❖ Whenever there's a risk of hazardous drugs being released into the environment
- ❖ Examples:
 - Introducing or withdrawing needles from vials
 - Transferring drugs using needles or syringes
 - Opening ampules

Situations requiring PPE

- ❖ Expelling air from a drug-filled syringe
- ❖ Administering hazardous drugs by any route
- ❖ Spiking IV bags and changing IV tubing
- ❖ Priming IV tubing
- ❖ Handling leakage from, well, anywhere
- ❖ Disposing of hazardous drugs and items contaminated by hazardous drugs

Situations requiring PPE

- ❖ Handling the body fluids of a patient who received hazardous agents in the past 48 hours.
- ❖ Cleaning hazardous drug spills

- ❖ Speaking of which.....

Hazardous drug spills

- Use a Cytotoxic Spill Kit containing:
 - Gloves, gowns, shoe covers
 - Safety glasses or goggles
 - Respirator mask
 - Spill pads, towels, scoop
 - Containment vessels: bags, sharps container

Hazardous drug spills

- Post a sign to warn others if it can't be addressed immediately
- Put on gloves, gown, face mask, shield
- Use the items in the spill kit
- Use appropriate measures for glass, liquids vs powders, and hard surface vs carpet.

Disposal

- ❖ ASHP and OSHA have provided rules and regulations for safe disposal of materials related to the preparation and administration of cytotoxic agents
- ❖ All items used with cytotoxic agents should be treated as hazardous chemical waste
- ❖ Place contaminated materials in a leak proof, puncture-proof container
 - Container must be labeled as "BioHazard"
 - Do Not clip needles or syringes

Disposal

- ❖ Cytotoxic waste containers may be stored in a designated area until collected for disposal
- ❖ Sealed containers are disposed of as hazardous chemical waste by licensed waste disposal company
 - May be incinerated in an Environmental Protection Agency (EPA) permitted hazardous waste incinerator
 - May be buried at an EPA permitted site

Gloves – what can you say?

- ❖ Gloves are **essential**.
- ❖ They must be worn at **all times** when:
 - Handling drug packaging
 - Handling cartons
 - Handling vials
- ❖ Gloves should be Chemotherapy Approved
 - Labeled as ASTM Approved

- ❖ All glove materials have been shown to be permeable to some hazardous drugs.



- ❖ Great variation has been observed in glove permeability even within the **same glove lots**.

DOUBLE GLOVE

- ❖ The risk that two pair of gloves will be permeated is small.
- ❖ Double gloving will also reduce the risk of contamination when the gloves are removed.

- ❖ ALWAYS remove the outer gloves first.
- ❖ Then remove the gown.
- ❖ Then remove the inner gloves.
- ❖ ALWAYS wash hands with soap and water not only before gloving, but after removing gloves as well.

❖ GLOVE PERMEABILITY INCREASES WITH TIME!

- ❖ Change gloves every 30 minutes.
- ❖ Replace gloves immediately if torn, punctured, or contaminated by a spill.

A vesicant is defined as an agent that has the potential to cause

- a. Blistering, severe tissue injury, or tissue necrosis.
- b. A palpable cord along a vein.
- c. Immediate streaking along a vein.
- d. Aching and tightness along a vein.

Which of the following is the best site for administering a vesicant via a peripheral IV catheter?

- a. Antecubital fossa
- b. Ventral wrist area
- c. Dorsum of the hand
- d. Lower to mid forearm

When a vesicant is administered via IV bolus (push), how often should a blood return be verified?

- a. Once, prior to vesicant administration
- b. Before and after vesicant administration
- c. Every 2–5 ml during vesicant administration
- d. Every 10 ml during vesicant administration

What happens if you don't.....



Prevention of extravasation

- ❖ ONS Guidelines: "When administering a vesicant drug by short infusion using a peripheral vein, avoid using an IV pump in order to decrease pressure on the veins; monitor the site for signs of extravasation every 5-10 minutes for infusions less than 30 minutes."
- ❖ "Use a central venous access catheter or implanted access device to administer any vesicant infusing for longer than 30-60 minutes. If IVP: when administering a vesicant, verify blood return every 2 to 5 ml."

Are you pregnant?
Breast-feeding?



Trying to conceive?



If you are pregnant, breast-feeding, or trying to conceive

ONS Guidelines:

Allow employees who are pregnant, actively trying to conceive, or breast-feeding or who have other medical reasons for not being exposed to hazardous drugs to refrain from preparing or administering those agents or caring for patients during their treatment with them upon request. (No information is available regarding the reproductive risks of workers who use currently recommended precautions [OSHA, 1995; Welch & Silveira, 1997]).
