





Public Perception

July 11, 2010

The Seattle Times

By Carol Smith
Investigative reporter

Lifesaving drugs may be killing health workers

Sue Cratty braced as the chemo drugs dripped into her body. She knew treatment would be rough. She had seen its signature countless times in the ravaged bodies and hopeful faces of cancer patients in hospitals where she had spent 23 years mixing chemo as a pharmacist.

At the same time, though, she wondered whether those same drugs *she* experienced as a form of "secondhand chemo," while she mixed the drugs as a pharmacist at Swedish Medical Center and elsewhere *she* may have caused her once-to-beautiful self to begin ugly.

http://health.newsvine.com/_news/2010/07/09/4648928-lifesaving-cancer-drugs-may-put-workers-lives-at-risk

Washington Senate Bill

Senate passes two health-care worker safety bills prompted by InvestigateWest reporting

MAR. 2, 2011

Two bills sparked by InvestigateWest's reporting on hazardous drug handling practices passed unanimously through the Washington State Senate this week.

SB 5594 requires the state to establish a workplace standard regulating the handling of chemotherapy and other hazardous drugs. The standards would create safety rules to protect workers who come in contact with hazardous drugs, including chemotherapy agents. Sen. Jeannie Kohl-Welles introduced the bill, which if signed into law could set precedents for other states.

Washington Senate Bill

- SB 5594 requires the state to establish a workplace standard regulating the handling of chemotherapy and other hazardous drugs. The standards would create safety rules to protect workers who come in contact with hazardous drugs, including chemotherapy agents.

Subject to Interpretation

- “minimum requirements”
- “reasonably anticipated exposure”
- “in case of conflict, the most protective requirement will take precedent”

Implementation Date

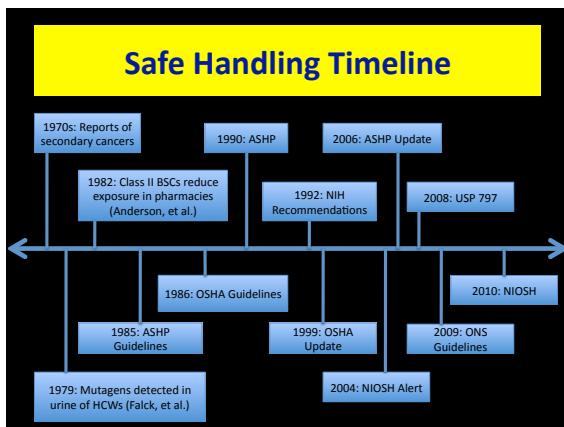
- January 1, 2014- written hazardous drug control program
- July 1, 2014- employee training
- January 1, 2015- installation of appropriate ventilated cabinets

Washington Senate Bill

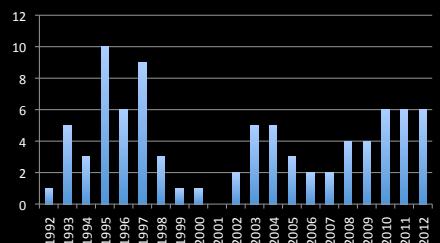
- SB 5149 would require that a cancer patient's occupation be reported to the registry, and that if the patient is retired, the patient's primary occupation before retirement be reported.

Where do you belong?

Personality Type	Emoji
The Oblivious	?
The Indifferent	:(
The Suspicious	:(
The Confident	:(
The Paranoid	:(



Publications



Risk to Healthcare Workers

- Acute toxicities
 - Dermal reactions
 - Allergic reactions
 - Hair loss
 - Headache
 - Cognitive dysfunction*

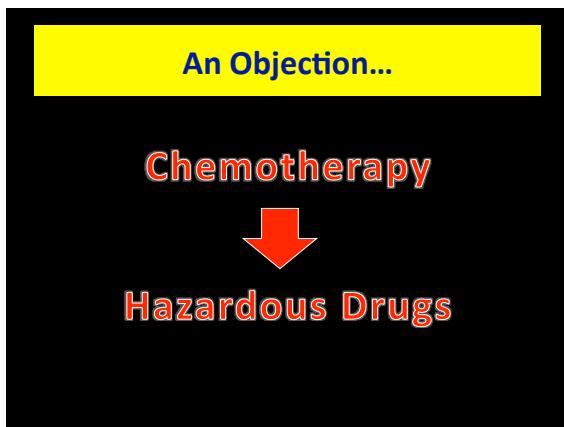
* Anecdotal

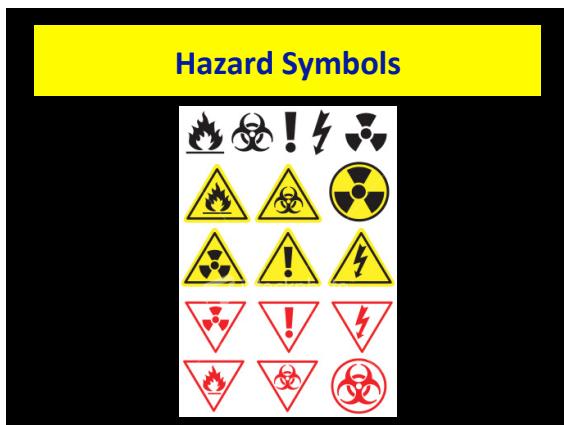
Risk to Patients

- Organ / system toxicities
- Secondary cancers









Hazardous Drugs

Drugs are considered hazardous if they meet one or more of the following criteria:

- Carcinogenicity
- Teratogenicity or developmental toxicity
- Reproductive toxicity
- Organ toxicity at low doses (<10mg/day)
- Genotoxicity
- New drugs that are similar in structure or toxicity to HD

National Institute for Occupational Safety and Health. (2004).

Carcinogenic to Humans

- Azathioprine
- Busulfan
- Chlorambucil
- Cyclophosphamide
- Melphalan
- Tamoxifen
- Thiotepa
- MOPP and other agents containing alkylating agents

International Agency for Research on Cancer (from Martin, 2005. Community Oncology Vol. 2 No. 5, 397-400)

Probable Carcinogens

- Azacitidine
- Carmustine
- Cisplatin
- Doxorubicin
- Etoposide
- Lomustine
- Mechlorethamine
- Procarbazine
- Teniposide

International Agency for Research on Cancer (from Martin, 2005. Community Oncology Vol. 2 No. 5, 397-400)

Possible Carcinogens

- Bleomycin
- Dacarbazine
- Daunorubicin
- Mitomycin
- Mitoxantrone
- Streptozocin

International Agency for Research on Cancer (from Martin, 2005. Community Oncology Vol. 2 No. 5, 397-400)

Identification of Hazardous Drugs

- Review all new FDA drug approvals
- Review all new warnings (Black Box) on existing drugs
- Eliminate warnings that do not apply
- Review drug package inserts
- Evaluate based on criteria in HD definition
- Stratify according to criteria
- Utilize external review

NIOSH Hazardous Drug List

- Antineoplastic agents: 89
- Hormonal agents: 21
- Biological agents: 8
- Antiviral agents: 7
- Immunosuppressants: 5
- Antibiotics: 1
- Vaccines: 1

Hazardous Drug Research

- Evidence for environmental contamination is mounting
 - Typically, a battery of common drugs is used to measure surface contamination
- Cyclophosphamide/
Ifosfamide
 - 5-Fluorouracil
 - Methotrexate
 - Doxorubicin
 - Etoposide
 - Paclitaxel
 - Platinum agents

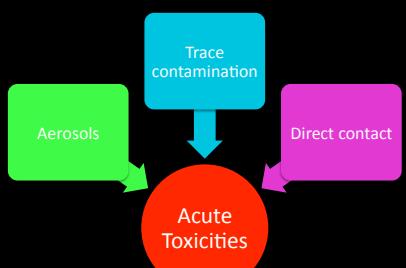
What are the study end-points?

- Chemical reactions
- Surface contamination
- Drug concentration in urine
- Adverse effects

What are the secondary end-points?

- Utilization
- Satisfaction
- Cost

Causal Relationship

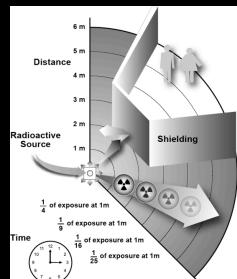
Causal Relationship

Measurement

- Not possible (or very difficult) to measure all drugs in use
 - Dose-Response effect
 - Time (e.g. alcohol)
 - Drug properties

Arble. (2004). Toxicology primer: understanding workplace hazards and protecting worker health. AAOHN J: 52(6):254-61

Radiation Safety



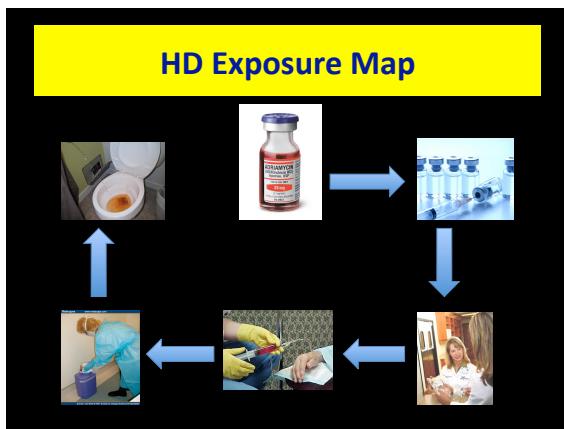
Levels of Exposure

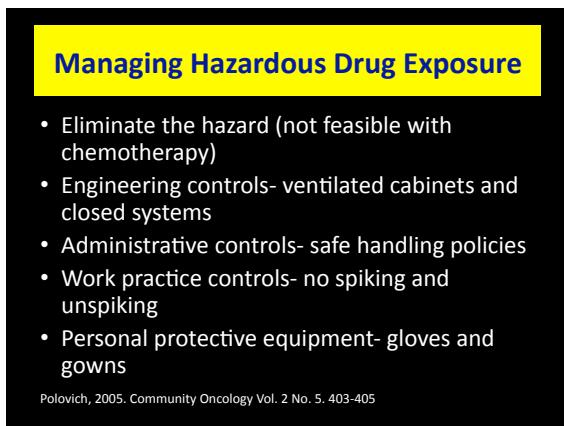
Drug preparation

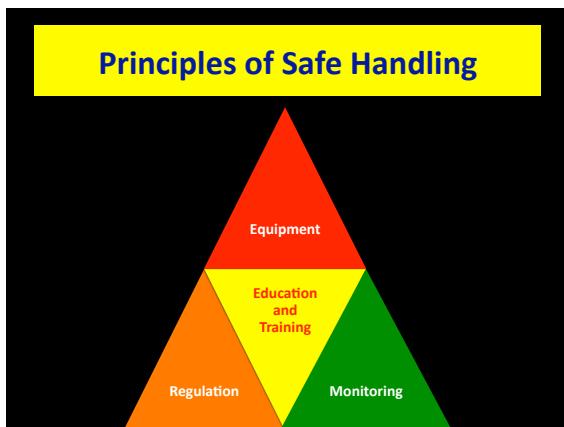
Drug administration

Handling excreta

EXPOSURE RISK



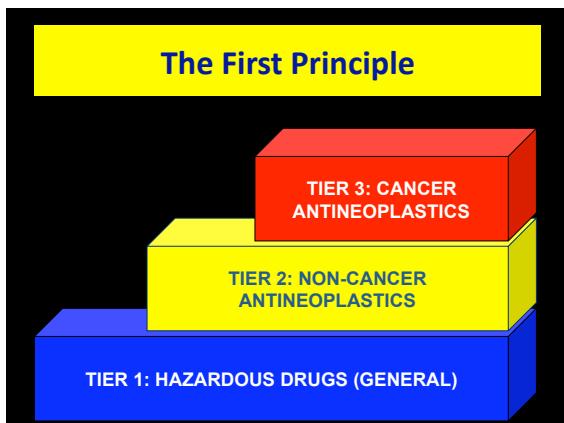
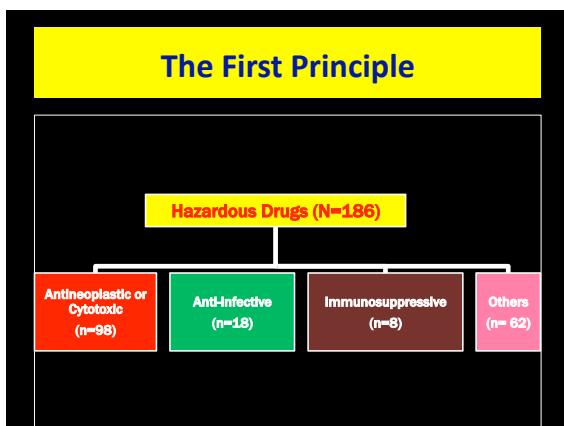




Principles of Safe Handling

The First Principle: EDUCATION and TRAINING

- All personnel handling hazardous drugs shall be trained
 - Training shall be according to their involvement with and exposure risk to hazardous drugs
 - Minimum requirements
 - Recognize the hazardous drugs they are handling
 - Be aware of the appropriate properties and hazards
 - Know the action to take in the event of an emergency



The First Principle				
TIER	STRUCTURE	PROCESS	OUTCOMES	
TIER 1: Hazardous drugs	<ul style="list-style-type: none"> ✓ Availability of e-learning module ✓ Hazardous drug list up-to-date and current 	<ul style="list-style-type: none"> ✓ Include content in annual regulatory requirement for nursing ✓ Annual pharmacy review of list 	<ul style="list-style-type: none"> ✓ 90% of current staff will complete course within 60 days ✓ 100% of new employees will get content from new employee orientation 	
TIER 2: Non-cancer antineoplastics	<ul style="list-style-type: none"> ✓ Availability of e-learning module ✓ Availability of drug-specific fact sheets ✓ Mechanism to identify drugs 	<ul style="list-style-type: none"> ✓ Same as TIER 1 plus: <ul style="list-style-type: none"> ✓ Unit-specific drug information for specialty nurses ✓ PYXIS and e-MAK pop-ups for group 2 and 3 immunosuppressants ✓ Labels for compounded medications compounded in pharmacy 	<ul style="list-style-type: none"> ✓ Same as TIER 1 plus: <ul style="list-style-type: none"> ✓ 100% of specialty nurses will complete unit-specific drug modules ✓ 100% of drugs in group 2 and 3 will be clearly marked or identified as hazardous 	
TIER 3: Cancer antineoplastics	<ul style="list-style-type: none"> ✓ ONS Chemotherapy and Biotherapy Course ✓ Availability of preceptor for preclinical 	<ul style="list-style-type: none"> ✓ Mandatory completion of ONS Chemotherapy and Biotherapy Provider Course with preceptor for oncology nurses ✓ Drug updates on new FDA-approvals 	<ul style="list-style-type: none"> ✓ 90% of staff in oncology areas will complete ONS chemotherapy course ✓ New grads will have 1 year to complete course ✓ 100% of ONS providers will complete new drug update as they are made available 	

Training Checklist

- ✓ Hazardous drug list
- ✓ Potential risks of exposure
- ✓ Exposure routes
- ✓ Drug storage
- ✓ BSC use/maintenance
- ✓ Required PPE
- ✓ Work practices
- ✓ Drug transport
- ✓ Waste disposal
- ✓ Spill management
- ✓ Record keeping
- ✓ Skill checklists/tests

Principles of Safe Handling

The Second Principle

Principles of Safe Handling

The Third Principle

Medical Surveillance for Health Care Workers Exposed to Hazardous Drugs - Workplace Solutions - NIOSH 7/31/2007 (10:7 PM)

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CDC **NIOSH** National Institute for Occupational Safety and Health

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NIOSH Number: 2007-157

Medical Surveillance for Health Care Workers Exposed to Hazardous Drugs

[English](#) [Español](#)

Summary

Health care workers who handle, prepare, or administer hazardous drugs may face risks to their own health such as skin rashes, cancer, and reproductive disorders. NIOSH recommends that employers evaluate a medical surveillance program to protect workers who handle hazardous drugs in the workplace.

Description of Exposure

Drugs are considered hazardous if studies in animals or humans show that exposures to them have a potential for causing cancer, reproductive toxicity, birth defects, or acute health harm. In the United States, about 5 million health care workers are potentially exposed to hazardous drugs in the workplace.

These workers include pharmacists, nurses, physicians, technicians, laboratory workers, pharmacists, operating room personnel, shipping and receiving personnel, waste handlers, custodians, nurses, and emergency room practice. Workers may be exposed to hazardous drugs when they create aerosols or dusts from handling, mixing, or touching contaminated surfaces when preparing, dispensing, or administering hazardous drugs.

Figure 1
A photograph showing a pharmacist wearing a respirator mask and gloves while working at a counter.

NIOSH PUBLICATIONS

[Protecting National Security and Health](#)

NIOSH Publications for Health Care Workers Exposed to Hazardous Drugs

On This Page:

[Description of Exposure](#)
[Medical Surveillance](#)
[Elements of a Program](#)
[Success Stories](#)
[Acknowledgments](#)
[References](#)
[For More Information](#)

Employee Medical Surveillance

- Medical surveillance form
 - Urine and blood testing

Who to test?

How much does testing cost?

- \$400 for labs
 - \$100 for physician appointment

Reeves, J. (2012). Creating an Employee Medical Surveillance Program. Pharmacy Purchasing & Products Vol 9 No 7.

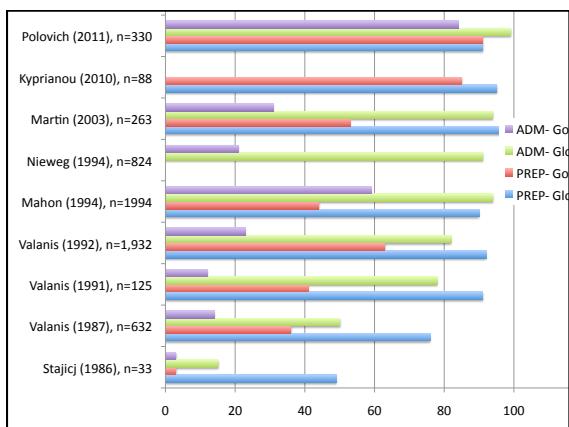
Principles of Safe Handling

The Fourth Principle: Equipment

- Personnel handling hazardous drugs should be provided with appropriate safety equipment

PPE

- Chemotherapy-resistant gown
 - Chemotherapy-resistant gloves
 - Eye protection
(if risk of splashing)
 - NIOSH-approved respirator during spill cleanup



Chemotherapy Gowns

- Low-permeability fabric such as polyethylene or vinyl
- Solid front with long sleeves and tight cuffs
- Single-use: not reapplied after removal

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Chemotherapy and Biotherapy Guidelines and Recommendations for Practice, 2009.

Gloves

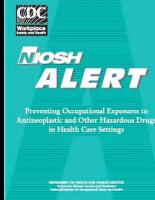
- Effectiveness influenced by material, thickness and wear-time
 - Nitrile (latex-free rubber)
 - Latex
 - Polyurethane
 - Neoprene
- Long cuffs and powder-free
- 30 minute wear time
- Gloves marketed for chemotherapy have been tested against a number of hazardous drugs
- Conform to ASTM D6978 - 05 Standard

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Connor, 1999; Klein, 2003; Wallemacq, 2006; American Society for Testing and Materials

Double-Gloving

NIOSH, ASHP and ONS recommendation

<http://www.cdc.gov/niosh/docs/2004-165>

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Gloves

- Wash hands thoroughly with soap and water after removal
- Alcohol gel is not effective for removing chemotherapy



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Eye Protection

- Goggles or face shields should be readily available
- Used in situations where splashing could occur (e.g., bladder instillation)




Chemotherapy and Biotherapy Guidelines and Recommendations for Practice, 2009.

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Respirators & Masks

- Use if risk of aerosol exposure
- Paper surgical masks are not effective
- NIOSH-approved cartridge respirators are recommended but require fit-testing




Chemotherapy and Biotherapy Guidelines and Recommendations for Practice, 2009.
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NIOSH Respirators

Three Kinds of Air-purifying Respirators		
		
Particulate Respirators	Combination Respirators	Gas & Vapor Respirators
<ul style="list-style-type: none"> • capture particles in the air, such as dusts, mists, and fumes • do not protect against gases or vapors • generally become more effective as particles increase in size after and plug spaces between particles • filters should be replaced when user finds it difficult to breath through them (see Selection Criteria for Particulate Filters) 	<ul style="list-style-type: none"> • are normally used in atmosphere that contains hazards of both particulates and gases/vapors • have both particulate filters and gas/vapor filters • may be heavier 	<ul style="list-style-type: none"> • are normally used when there are only hazardous gases and vapors in the air • use cartridges or canisters to remove dangerous gases or vapors • do not protect against airborne particles • are made to protect against specific gases or vapors • may protect longer than as long as the filter's absorbing capacity is not depleted • the service life of filters depends on many factors and can be estimated in various ways

56 <http://www.cdc.gov/niosh/review/public/105-A/>

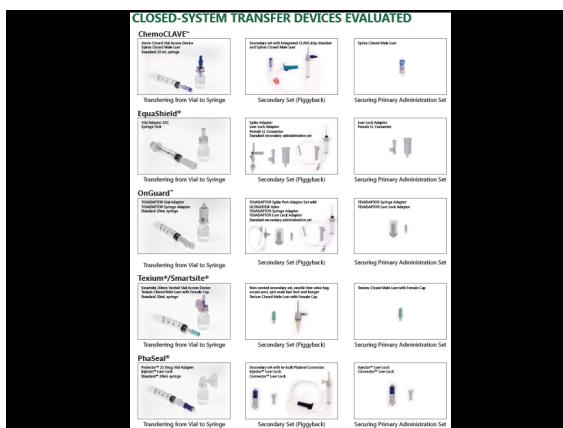
Closed-System Transfer Devices

- Provide additional protection during drug preparation and administration
- Containment of aerosolized and droplet particles
- Recommended in 2006 ASHP Guidelines and USP <797> 2008 update
- is NOT a substitute for PPE and BSC

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Closed system basics

- Two essential components:
 - A vial adaptor used during drug preparation to prevent leakage and vapor release
 - A closed valve used on tubing and syringes to prevent leakage before, during and after administration



ChemoClaveTM System

- Vial adaptor: Genie has internal balloon traps vapors
 - Spiros® closed male luer using ChemoClave® components
 - 2 versions (1 removable, one permanently locks on syringe or tubing)
 - Creates vacuum at disconnect



ChemoCLAVE™

- Compatible with all standard luer connections
- No adaptors required



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Passive (Fail-Safe) Technology

ChemoCLAVE™ System have a passive (fail-safe) closing technology where they automatically return to the closed position when there is a disconnect; accidental or intentional

Back-flushing

- When used with closed system syringe adaptors, CSTDs provide the potential for back-flushing chemotherapy on primary tubing sets

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Closed Systems: Other Considerations

- No standardized efficacy tests
- Lack of published, unbiased comparisons

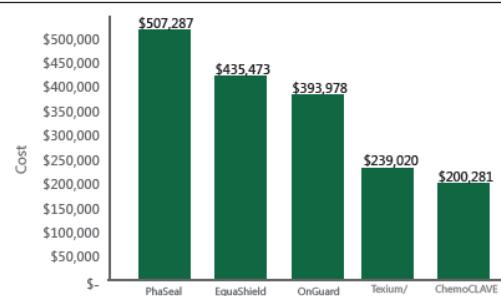
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Closed Systems: Other Considerations

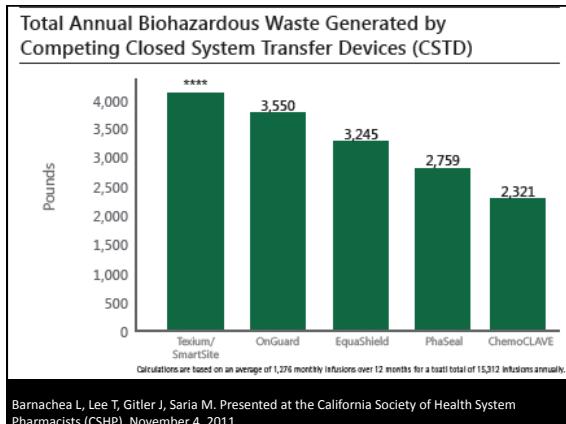
- Difficult to conduct a comparison trial
- Pharmacy and nursing education required in order to use effectively
- Additional cost

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Total Annual Costs Associated with Implementing Competing Closed System Transfer Devices (CSTD)



Barnachea L, Lee T, Gitler J, Saria M. Presented at the California Society of Health System Pharmacists (CSHP). November 4, 2011.



Bodily Fluids

- Use PPE when handling bodily fluids for a minimum of 48 hours
- Place soiled linen in leak-proof bag
- Encourage use of toilet instead of bedpan or urinal
- Close lid (if present) before flushing toilet
- Consider covering with pad (e.g. Chux™) if no lid

Chemotherapy and Biotherapy Guidelines and Recommendations for Practice, 2009.
68

Double Flushing

- There is **no** evidence to support double-flushing in hospitals.
- However, it may be of some use with low volume toilets

Chemotherapy and Biotherapy Guidelines and Recommendations for Practice, 2009.
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Double Flushing



The image shows the Hoover Dam in Nevada, with Lake Mead visible behind it. The dam is a large concrete structure spanning a narrow canyon. The water is a deep blue-green color. In the foreground, there's some rocky terrain and a small area of sand.

Excretion trivia

- Excreted **unchanged** in urine within first 24 hours:

Etoposide	55%
Cyclophosphamide	25%
Fludarabine	40%
Dacarbazine	40%



71 Source: MicroMedex

Administration

- Tubing setup will depend on administration method and brand of pump.
- Avoid
 - Priming or spiking into bag at bedside
 - Disconnecting tubing unless CSTD is in use
- Remove gloves before touching pump

Chemotherapy and Biotherapy Guidelines and Recommendations for Practice, 2009; ASHP 2006.
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Chemotherapy Disposal

- Waste should be placed in special Ziploc® bags or sealable chemotherapy containers
 - Hard-sided containers can also accept sharps and bottles



Spills

- Kits can be pre-made or custom-made



Basic spill kit contents

- Absorbent pads
 - Multiple sizes



24 x 24 inches



8 x 8 inches

Chemotherapy and Biotherapy Guidelines and Recommendations for Practice, 2009; ASHP 2006.

Basic spill kit contents

- Chemotherapy bags
- Booties



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Basic spill kit contents

- Goggles
- Caution Sign
- Dustpan and brush if working with bottles
- NIOSH approved respirator
- Appropriate institutional documentation



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Neutralizing

- Bleach (5.25%) effective in laboratory tests for most drugs
- Difficult to use in clinical settings due to toxic vapors and corrosive properties
- Requires neutralization
- ONS Guidelines recommend detergent



Dorr, R., and Alberts, D. (1992). Benvenuto, et al. (1993). Castegnaro, M., et al (1997). Hansel, S., et al. (1997). Gullatte, M. (ed) (2007). Clinical Guide to Antineoplastic Therapy: A chemotherapy Handbook.

Inactivated by Sodium Hypochlorite

- Cyclophosphamide
- Cytarabine
- Dacarbazine
- Doxorubicin
- Epirubicin
- Fluorouracil
- Ifosfamide
- Melphalan
- Methotrexate
- Vinblastine

Hansel, S. (1997); Wren, A. (1993)

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Neutralizing

- Surface Safe®
- Two-chemical packets:
 - Sodium hypochlorite (bleach)
 - Sodium thiosulfate (neutralizer, and binds platinum agents)
- Not completely effective with Mitoxantrone, Carmustine or Paclitaxel



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General Spill Procedure

- Assess the size of the spill
- Put on PPE (use double-gloves)
- Use pads to soak up spill
- Put pads into chemotherapy disposal bag or container
- Document per policy

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Body contamination

- Wash skin exposure immediately with soap and water
- Change clothing and put into chemotherapy bag
- Launder separately in detergent
- Complete appropriate documentation

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