Creating a Hazardous Drug Handling Program

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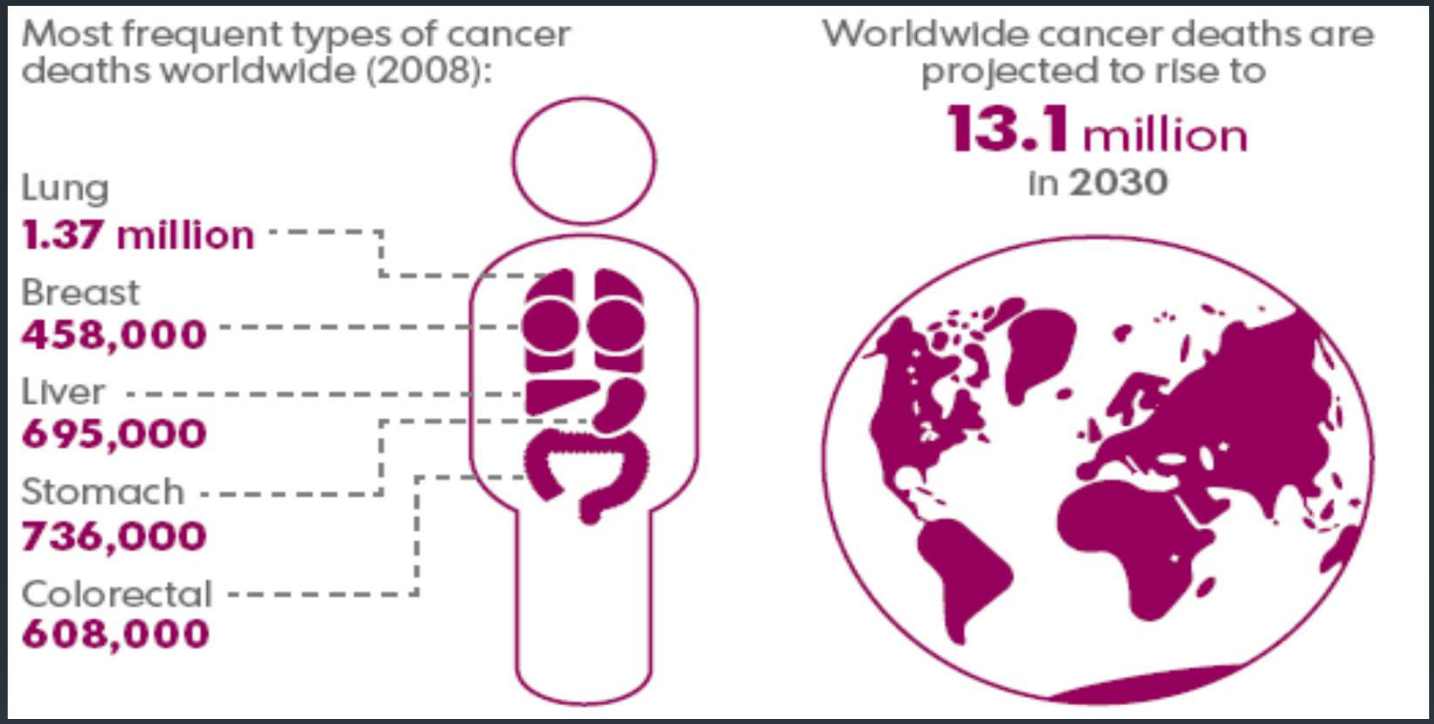
Disclosure Information

- Receives grant/research support from
  - BD
  - Equashield
  - ICU Medical
  - CareFusion
- Contributing Editor
  - Pharmacy Purchasing and Products magazine

A Notable Trend

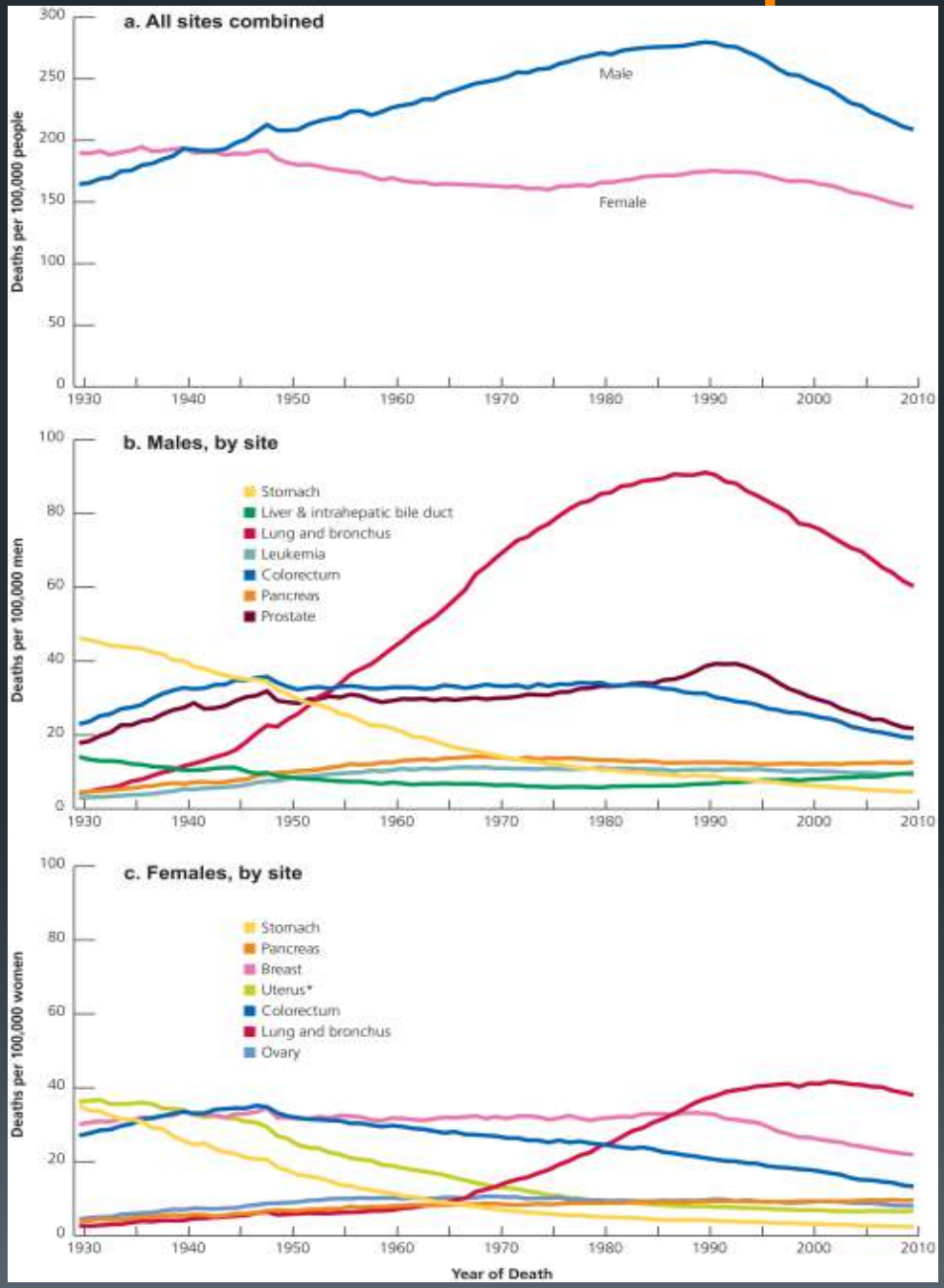


THE FACTS ABOUT CANCER

Cancer is the leading cause of death worldwide and in 2008 was responsible for 7.6 milllion deaths.

Source: WHO Globalcan 2013

Cancer Death Rates Drop in US



CA: A Cancer Journal for Clinicians
Volume 64, Issue 1, pages 9-29, 7 JAN 2014 DOI: 10.3322/caac.21208
onlinelibrary.wiley.com/doi/10.3322/caac.21208/full#caac21208-fig-0006

Who Makes These Miracles Happen?

- 5.5 million healthcare workers
  - Pharmacy & nursing staff

- Exposure is associated with adverse health outcomes:
  - Acute symptoms
  - Organ toxicity
  - Reproductive risks
  - Cancer

Source:
U.S. Census Bureau 1997; Bureau of Labor Statistics 1998, 1999; National Center for Health Statistics 1996
Harrison BR. Risks of handling cytotoxic drugs. In: Perry MC, ed. *The Chemotherapy Source Book – Third Edition.* Philadelphia: Lippincott, Williams, & Wilkins; 2001: 566-582.
Valanis BG, Vollmer WM, Labuhn KT et al. Acute symptoms associated with antineoplastic drug handling among nurses. *Cancer Nursing*. 1993; 16: 288-295.
Valanis BG, Vollmer WM, Labuhn KT et al. Association of antineoplastic drug handling with acute adverse effects in pharmacy personnel. *American Journal of Health-System Pharmacy*. 1993; 50: 455-462.
Fransman W. Occupational exposure to cytotoxic drugs. *Hospital Pharmacy Europe*. 2007; 35: 85-86.
Martin S. The adverse health effects of occupational exposure to hazardous drugs. Community Oncology. 2005; 2: 397–440.
Valanis BG, Vollmer WM, Labuhn K et al. Occupational exposure to antineoplastic agents and self-reported infertility among nurses and pharmacists. *Journal of Occupational and Environmental Medicine*. 1997; 39: 574-580.
Hansen J, Olsen JH. Cancer morbidity among Danish female pharmacy technicians. *Scandinavian Journal of Work, Environment and Health*. 1994; 20: 22-26.
Skov T, Maarup B, Olsen J et al. Leukaemia and reproductive outcome among nurses handling antineoplastic drugs. *British Journal of Industrial Medicine*. 1992; 49: 855–861.

Occupational Risks Due To Exposure to Hazardous Drugs

- *J of Occupational and Environmental Medicine*. 1999; 41(8):632-8
  - 7,094 pregnancies of 2,976 pharmacy and nursing staff studied
    - Increased risk for miscarriages by 40 - 50%
    - Increased risk for low birth weight by 17-fold
    - Increased risk for congenital malformations by 5-fold

- *Am J Obsetrics & Gyn, December 2011* (Lawson of NIOSH)
  - 7,500 nurses
  - Oncology nurses 2-fold risk of miscarriages
  - 2 out of 10 nurses lost pregnancy at week 20

Evidence of Exposure to Health Care Workers

	Days	Urine samples	Positive CP samples	Positive IF samples
Pharmacist 1	1	6	3	0
Pharmacist 2	1	10	3	9
Technician 1	1	8	8	1
Technician 2	1	6	0	0
Technician 3	1	9	0	0
Nurse 1	1	5	1	0
Nurse 2	1	4	3	0
Control		4	0	0
N(pos)=7		48	18 (N=5)	10 (N=2)

Wick et al. *Am J Health-Syst Pharm.* 2003; 60:2314-20

"There is no acceptable level of personnel exposure to HDs"

Where is Cancer Prevention?

Lifesaving cancer drugs may put workers' lives at risk

Chemo could have a hidden deadly toll on pharmacists, nurses

Profiles of exposure: Health care workers share lessons

video

Sue Crump, in her own words

by Carol Smith
InvestigateWest
updated 7/11/2010 12:44:32 PM ET

Share | Print | Font: A A + −

Sue Crump 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.

Now she hoped those same medicines would kill the tumor cells lurking in her belly. At the same time, though, she wondered whether those same drugs may have caused her cancer to begin with.

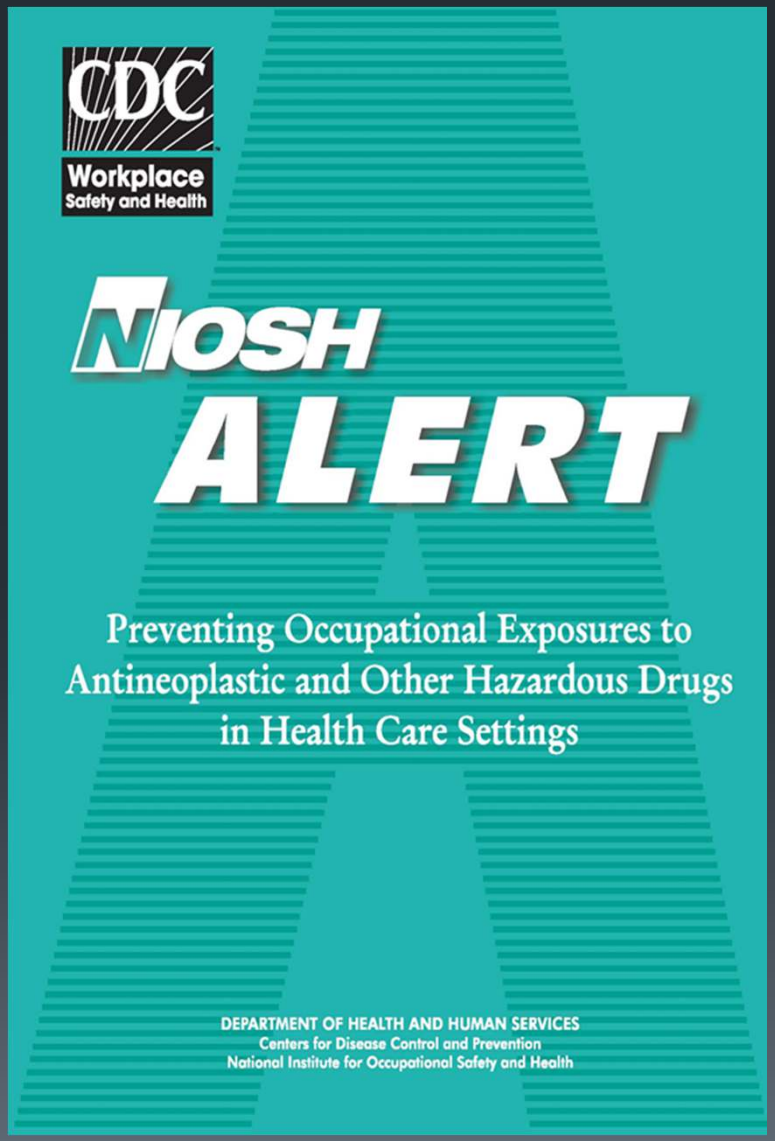
Harnessing toxic agents to save a life demands a delicate

Paul Joseph Brown / Paul Joseph Brown Photograph

Sue Crump prepares to receive chemotherapy for pancreatic cancer at Evergreen Hospital in

USP 800
A Decade Towards Safety

2004



2014

Guidelines for Hazardous Drugs

Source	Year
ASHP	1982, 1984, 1990, 2006
OSHA	1986, 1995, 1999
AMA Council on Scientific Affairs	1985
Oncology Nursing Society	1988, 2003, 2010
NIOSH Alert	2004, 2010, 2012, 2014
HOPA	2009
USP <797>	2004, 2008
USP <800>	2014 (for comment)

Globally 42 years of Safe Handling Guidelines

Journal of Occupational and Environmental Hygiene, 11: 728–740
ISSN: 1545-9624 print / 1545-9632 online
DOI: 10.1080/15459624.2014.916809

Adherence to Safe Handling Guidelines by Health Care Workers Who Administer Antineoplastic Drugs

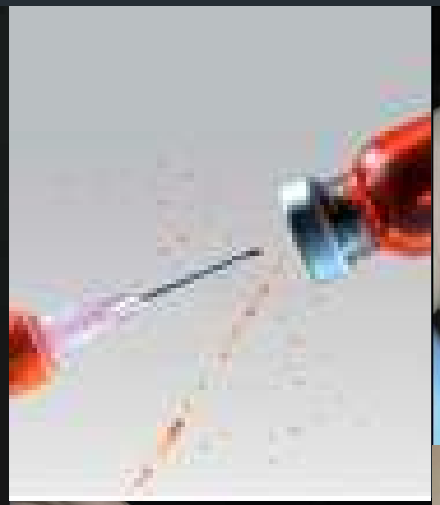
James M. Boiano, Andrea L. Steege, and Marie H. Sweeney

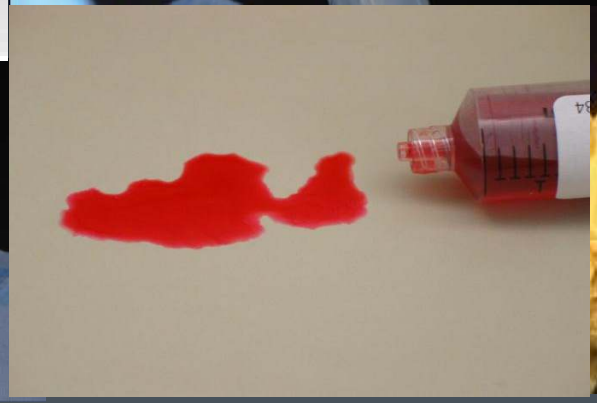
Division of Surveillance, Hazard Evaluations and Field Studies, National Institute for Occupational Safety and Health, Cincinnati, Ohio

- *Failure to wear nonabsorbent gown with closed front and tight cuffs (42%);*
- *Intravenous (I.V.) tubing primed with antineoplastic drug by respondent (6%) or by pharmacy (12%);*
- *Potentially contaminated clothing taken home (12%);*
- *Spill or leak of antineoplastic drug during administration (12%);*
- *Failure to wear chemotherapy gloves (12%);*
- *Lack of hazard awareness training (4%).*

Source: Journal of Occupational and Environmental Hygiene November 2014;11:728-40

Global Legacy & Acceptance





Legacy of Current Practices

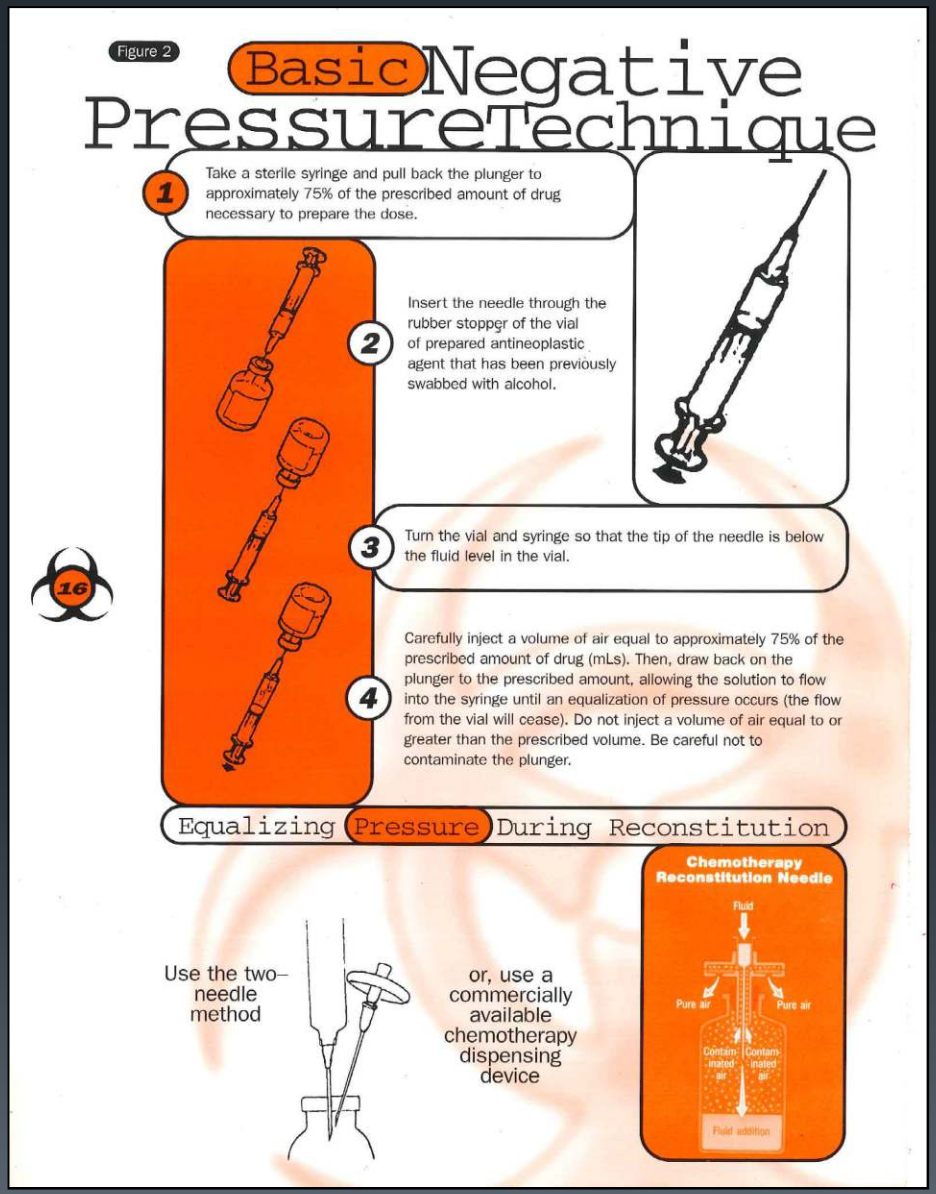
STUDY GUIDE

Safe Handling of Cytotoxic and Hazardous Drugs

American Society of Hospital Pharmacists
4630 Montgomery Avenue
Bethesda, MD 20814

American Society of Hospital Pharmacists
4630 Montgomery Avenue
Bethesda, MD 20814

Source: ASHP 1990



Source: BMS ONC CE 2001

State Health Departments

- State regulations for compounding
  - Board of Pharmacy or Health Departments
  - Most States have USP 797 specific regulations

- Specific Hazardous Drug Compounding regulations
  - Washington 2013
  - California 2013
  - North Carolina July 2014 (H644)
  - Maryland in process
    - Maryland Board of Pharmacy since 2010
      - *"Closed system vial transfer devices (CSTD) are employed when handling cytotoxic drugs COMAR 10.34.19.12(17)"*

Legal Requirements for HDs

Employee Safety

- OSHA has no standard for exposure to HD but has generated three guidelines
  - Hazard Communication Standard 29 CFR part 1910–1200
  - Controlling Occupational Exposure to Hazardous Drugs
    TED 1–0.15A, Sec VI, Chap II: 1995, 1999
  - Hazardous Waste Operations and Emergency Response: Standard (29 CFR 1910.120)

Patient Safety

- United States Pharmacopeia <797>
  - 2008 new section on Hazardous Drugs

Public Safety

- US Environmental Protection Agency
  - 1976 Resource Conservation Act (RCRA)

The Joint Commission Is Concerned

Menacing Meds

How to safely manage hazardous drugs in the health care environment

Clinicians and pharmacists aren't the only health care workers who risk exposure to toxic medications in the course of their daily tasks. Engineers, facilities personnel, and other health care staff involved in the environment of care can also come into accidental contact with hazardous drugs.

From powerful chemotherapy agents and hormones to bioengineered substances and antiviral medicines, the perils are prevalent in health care settings. Organizations can better safeguard their workers by ensuring that proper procedures to safely handle potent drugs are learned and followed.

Hazardous residue on the surfaces of contaminated drug vials can be transferred via hospital staff who receive, store, and take inventory of the substance.

Determining the dangers

To reduce the incidence of hazardous drug contamination by and exposure to workers, a health care organization should have a comprehensive safety program.

Source: TJC ECNews; March 2014:volume 7; issue3

"The objective of this chapter is to protect personnel and the environment when handling hazardous drugs (HDs)"

Sterile and non-sterile products

Source: Proposed USP <800>; 2014

USP 800
Chapter Sections

1. *Introduction*
2. *List of HDs*
3. *Types of Exposure*
4. *Responsibilities of Personnel Handling HDs*
5. *Facility Design and Engineering Controls*
6. *Personal Protective Equipment*
7. *Hazard Communication Program*
8. *Training for Compounding Personnel*
9. *Receiving*
10. *Transporting*
11. *Dispensing HD Dosage Forms Not Requiring Alteration*
12. *Compounding HD Dosage Forms*
13. *Protection When Administering HDs*
14. *Cleaning: Deactivation, Decontamination, Cleaning, and Disinfection*
15. *Spill Control*
16. *Disposal*
17. *Environmental Quality and Control*
18. *Documentation*
19. *Medical Surveillance*

Source: Proposed USP <800>; 2014

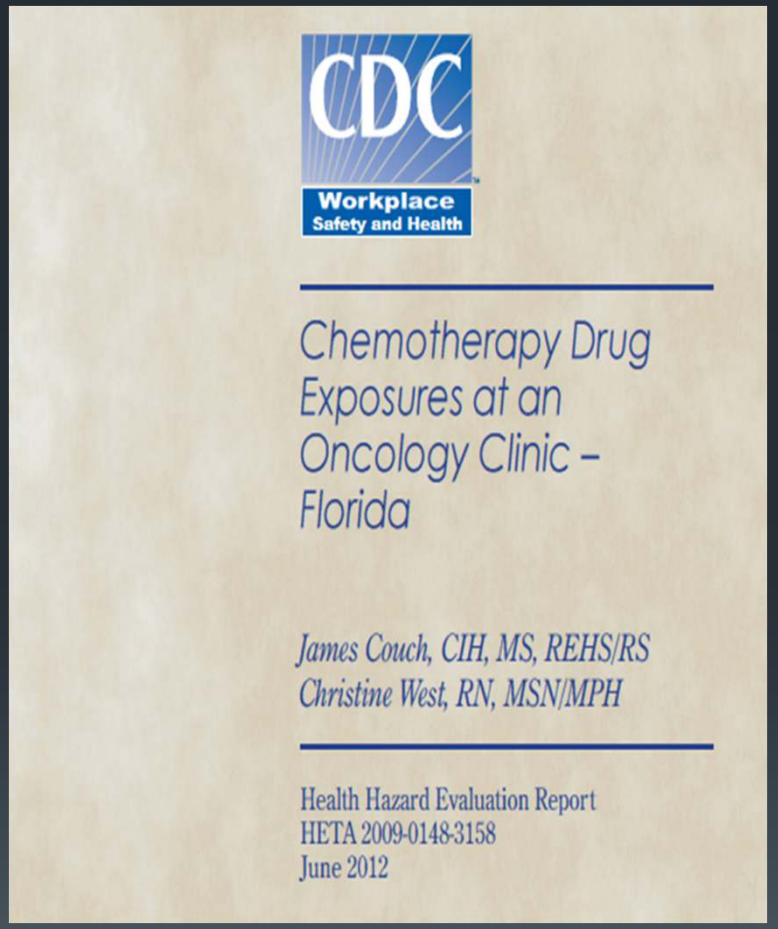
USP 800
Hazard Communication Standard

- "Right to Know Standard"
  - Standard (29 CFR part 1910 – 1200)
- A safe and healthful workplace.
- Know about hazardous chemicals.
- Complain or request hazard correction from employer.
- Hazard exposure and medical records.
- File a complaint with OSHA.
- Be free from retaliation for exercising safety and health rights.

29 CFR 1903.2 (a)(1)
Each employer shall post and keep posted……

Case Report

- CDC Case Report
- “Chemotherapy Drug Exposures of an Oncology Clinic – Florida”
- Health Hazard Evaluation Report: HETA 2009-0148-3158 June 2012
- At the request of an employee
- Site visit with follow-up visits for compliance



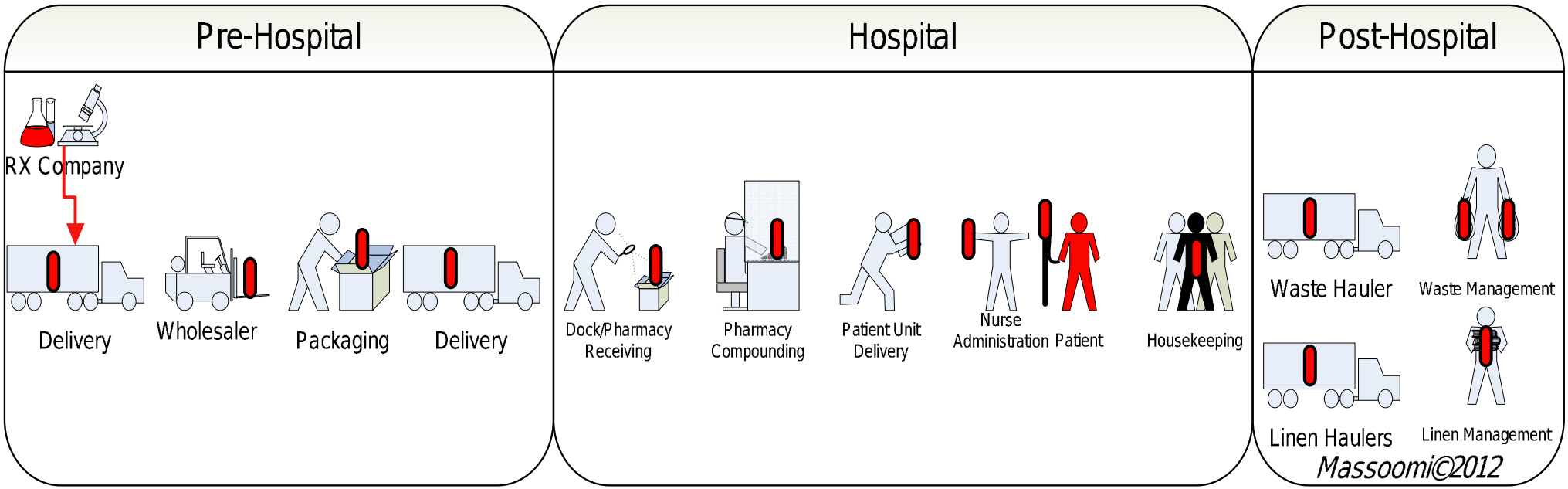
Protecting Personnel and Patient Starts with a Hazardous Drug Team

- Primary
  - Pharmacist
  - Pharmacy technicians/interns
  - Pharmacy purchasing
  - Nursing
  - Surgical Services
  - Risk management
  - Employee health
  - Environmental services
- Secondary
  - Administration
  - Safety officer
  - Physician office managers
  - Home Health managers

Primary Goal: Establish a hazardous drug safety program

Visual Hazard Mapping Tool

Hazardous Drug Process

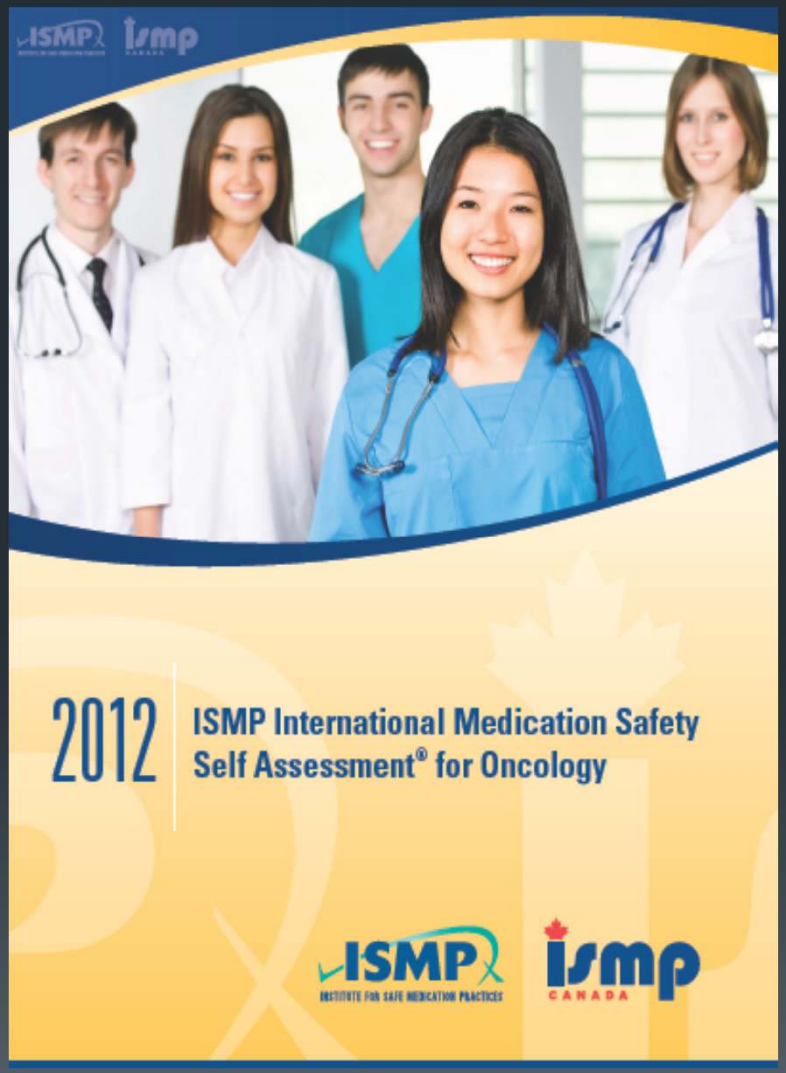


Hazardous Drugs products should always be considered contaminated on the packaging and vials until properly decontaminated.
Connor T, et al. AJHP 2005;62:475-582

Without a total hazardous drug safety program in place the drug products, the patient, the linen from patients, the pharmaceutical wastes provides multi-sourced contaminated risk to healthcare providers.
NIOSH Safety Alert 2004

Hazardous Drug
NOTE: Red Indicates Contamination points

Hazardous Drug Safety Gap Tool

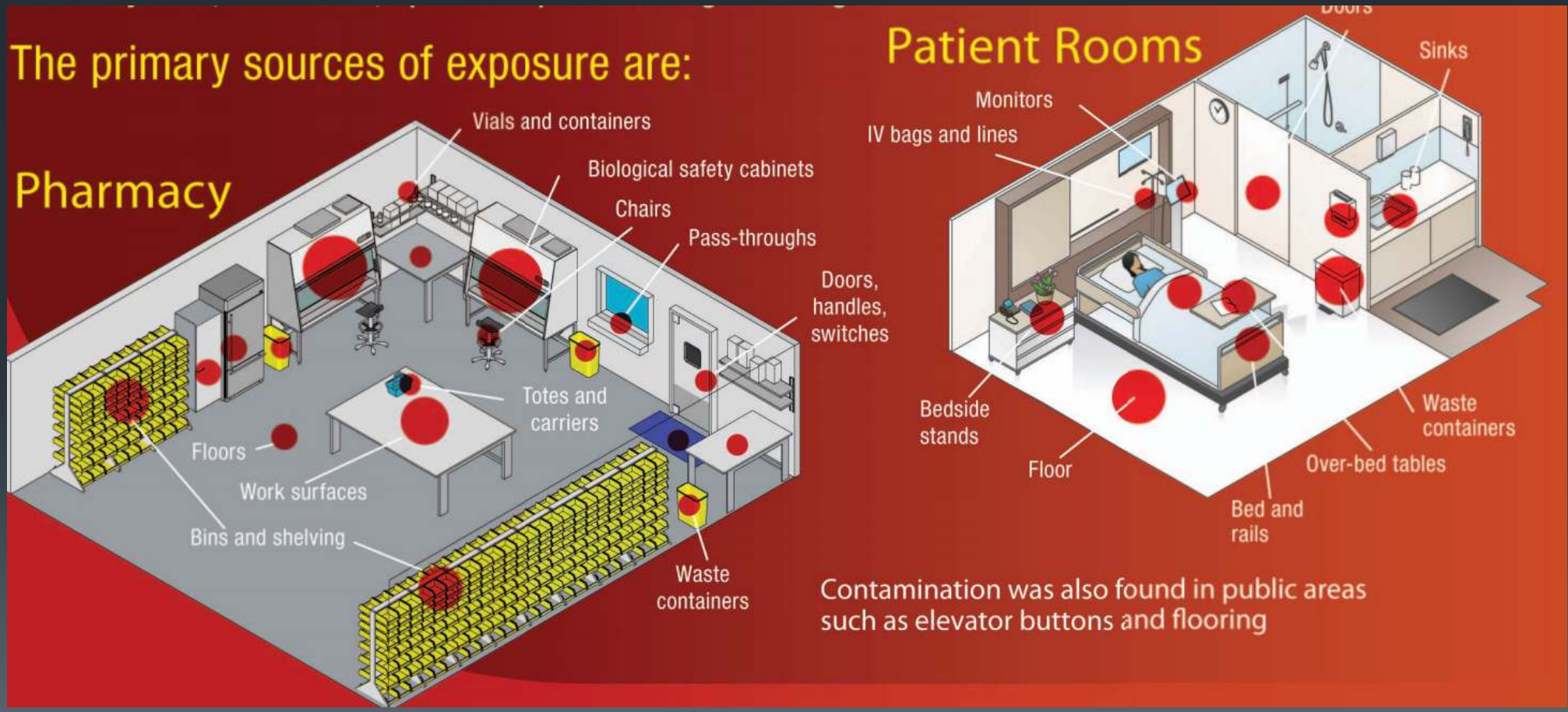


- International
- Helps define gaps
- From worker to patient
- From order to outcomes
- Great starting tool
- Free!

Source: ISMP.org

The Contaminated Environment

- More than 70 published studies
  Most surfaces that come in direct contact with hazards
  Some with in-direct contact with hazards

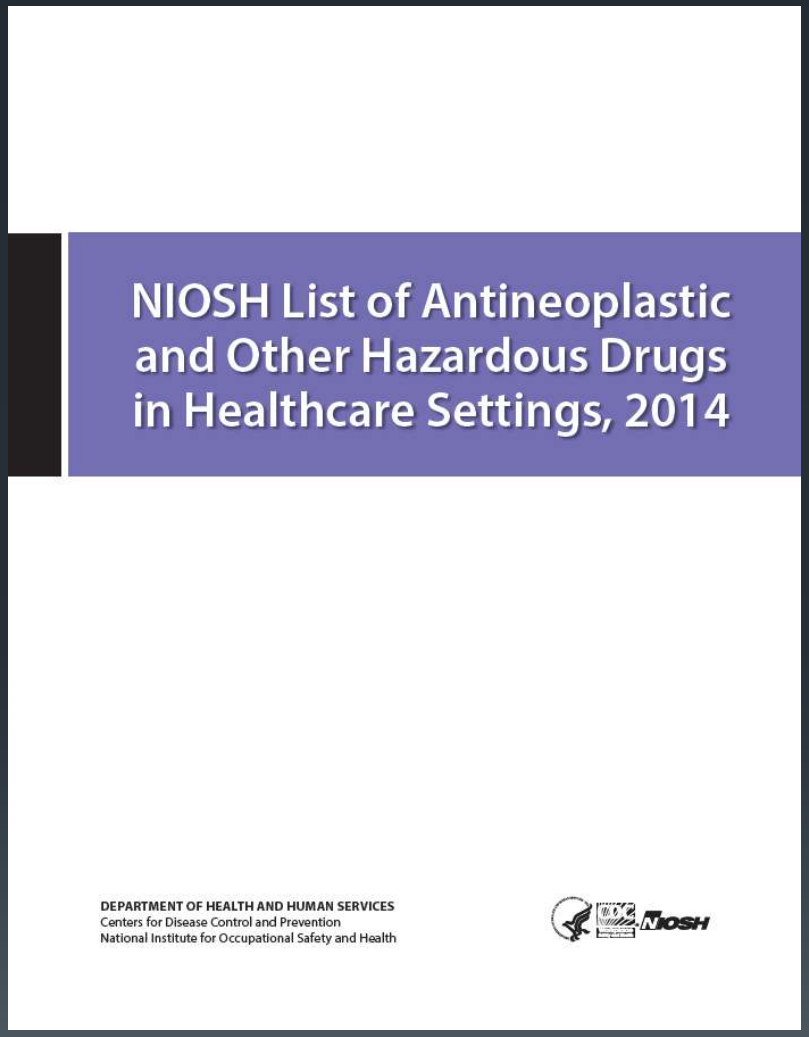


Source: B. Braun

USP 800
Environmental Quality Control

- ‘Routinely’ = every 6 months
- Approximate cost is $250 to $400 per sample

NIOSH/USP 800
NIOSH Hazardous Drug List



- September 5, 2014
- Group 1: Antineoplastic drugs
  - 97 drugs listed
- Group 2: Non-antineoplastic drugs
  - 48 drugs listed
- Group 3: Reproductive risk
  - men and women
  - 39 drugs listed
- 12 drug removed from the 2004/12 lists
- Guide to handling based on formulation

Source: NIOSH.gov DHHS (NIOSH) Publication Number 2014-138 (Supersedes 2012-150)

Formulary Assessment

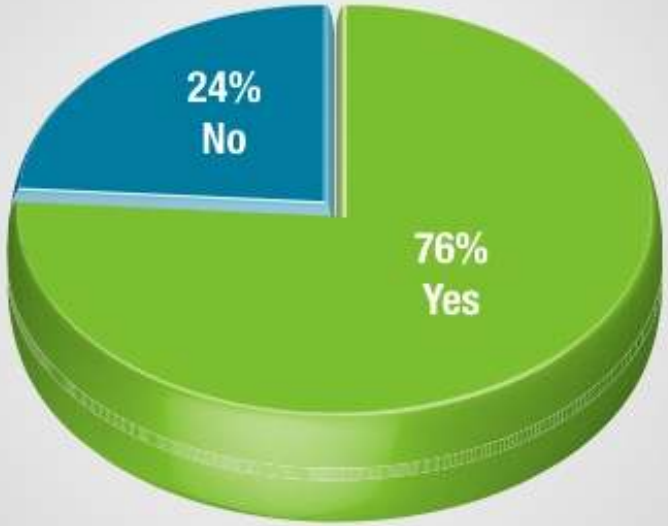
- SITE SPECIFIC Stratification of Hazards to Practice
  - **Antineoplastic** **non-Antineoplastic** **Reproductive**
- Continuously stratify

CLASS 1	Commonly includes drugs that are antineoplastic, cytotoxic, immunosuppressive and antiviral Handle with required PPE* and dispose of properly. *Do not tube or load in pyxis.*			
	Pharmacy Precautions	**Nursing Administration Precautions (Who can administer)**	**Nursing Body Fluid Precautions**	**Housekeeping and Ancillary Precautions**
IM, Subcutaneous, intradermal	BSC**, Sterile double chemo gloves, Chemo gown, Face shield	Double chemo gloves, chemo gown, Face shield (Oncology RN with required PPE)	Double chemo gloves, chemo gown. Add face shield if splashing possible.	Double chemo gloves, chemo gown. Add face shield if splashing possible.
IV Push, IVPG, IV Continuous infusion	BSC**, Sterile double chemo gloves, Chemo gown, Face shield	Double chemo gloves, chemo gown, face shield (Oncology RN with required PPE)	Double chemo gloves, chemo gown. Add face shield if splashing possible.	Double chemo gloves, chemo gown. Add face shield if splashing possible.

*PPE = Personal Protective Equipment
**BSC = Biological Safety Cabinet

Going GREEN

Hazardous Drugs List Compiled



76% of hospitals have compiled a hazardous drug list, with 72% of those reviewing drugs from all departments including radiology and nuclear medicine, while 69% included off-formulary drugs in this review.

N=343 Rx Directors

Going Green. *Pharm Purch Prod*. 2010; 12.

PHARMACY Purchasing & Products

#1 Safety Concern
The Source

- EVIDENCE: 11 Published studies
- Drug vial exteriors
- Not due to damage during shipping & handling

USP 800
Segregated Handling of Vials

Good Distribution Practices

Totes from wholesaler

Gloves to handle

Drugs left in baggies

Removed in Isolator

Shall not

- Store
- Unpack
- Compound
- Manipulate

- Not a **+** pressure area
  - Equi-pressure
  - Negative pressure

NIOSH/USP 800
Personal Protective Equipment (PPE)

Training Documentation

Hands & elbows scrubbed CDC
Hand hygiene document

www.cdc.gov/handhygiene

Proper demonstrative use

Goal

Minimize Contamination

*From product to employee

and visa versa

No Make-up or Jewels

No Fake fingernails

No iPods

No exemptions from garbing requirements

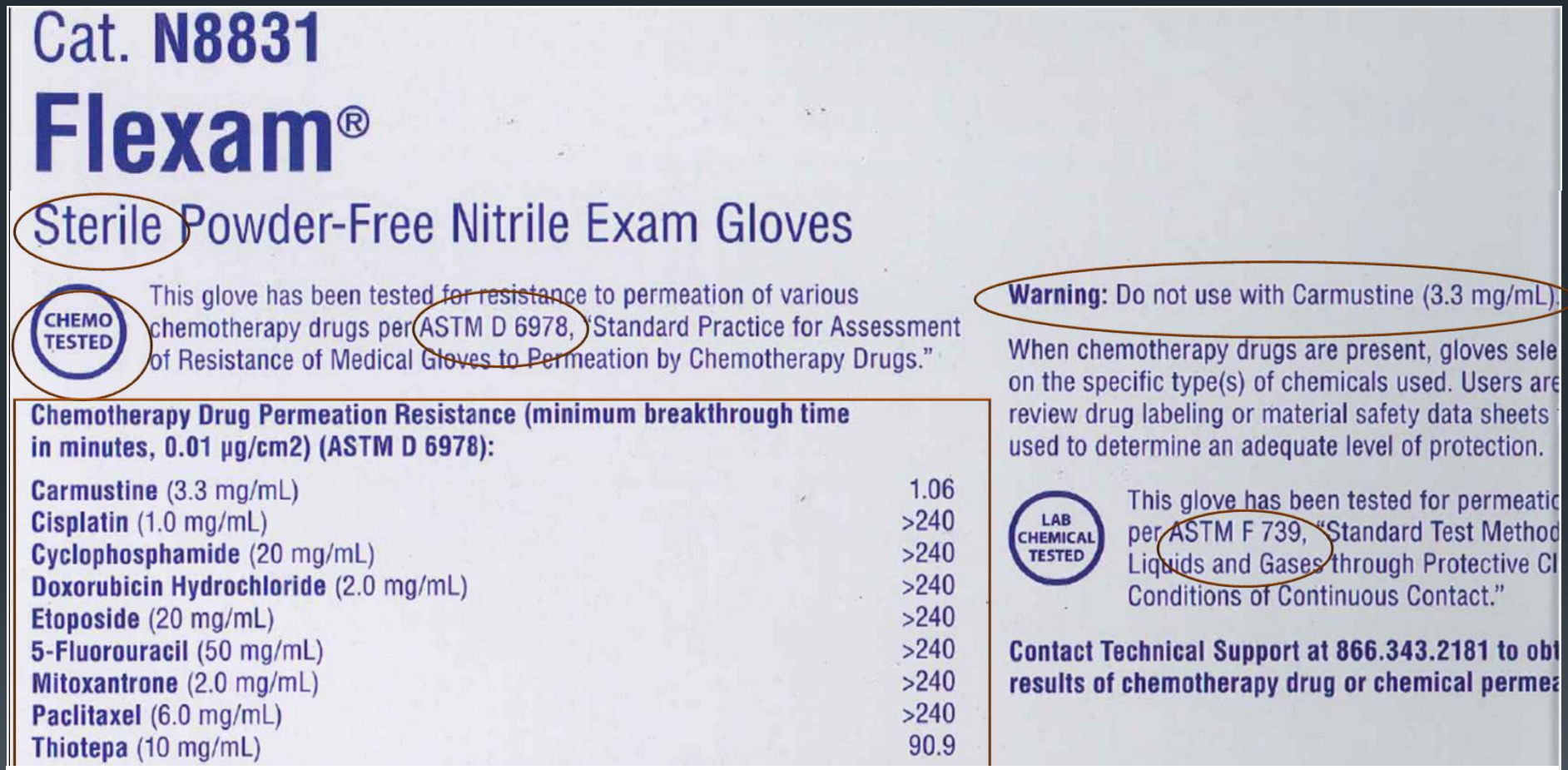
NIOSH/USP 800 Documentation of Garb Competency

Donning Sequence

Doffing Sequence

Source: Taipei Veterans Hospital; Taipei, Taiwan

NIOSH/USP 800
Choosing the Right Glove



Cat. **N8831**

Flexam®

Sterile Powder-Free Nitrile Exam Gloves

CHEMO TESTED

This glove has been tested for resistance to permeation of various chemotherapy drugs per ASTM D 6978, "Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs."

Chemotherapy Drug Permeation Resistance (minimum breakthrough time in minutes, 0.01 µg/cm2) (ASTM D 6978):

Carmustine (3.3 mg/mL)	1.06
Cisplatin (1.0 mg/mL)	>240
Cyclophosphamide (20 mg/mL)	>240
Doxorubicin Hydrochloride (2.0 mg/mL)	>240
Etoposide (20 mg/mL)	>240
5-Fluorouracil (50 mg/mL)	>240
Mitoxantrone (2.0 mg/mL)	>240
Paclitaxel (6.0 mg/mL)	>240
Thiotepa (10 mg/mL)	90.9

Warning: Do not use with Carmustine (3.3 mg/mL).

When chemotherapy drugs are present, gloves sele on the specific type(s) of chemicals used. Users are review drug labeling or material safety data sheets used to determine an adequate level of protection.

LAB CHEMICAL TESTED

This glove has been tested for permeatic per ASTM F 739, "Standard Test Method Liquids and Gases through Protective Cl Conditions of Continuous Contact."

Contact Technical Support at 866.343.2181 to obt results of chemotherapy drug or chemical permea

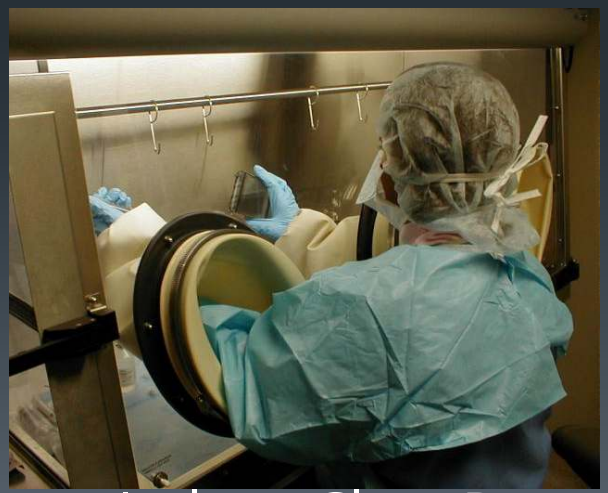
IMPORTANT: ASTM D6978 and not ASTM F739 due to permeability limits

35.2° +2 C 25° C temperature delta

NIOSH/USP 800
Primary Engineering Controls

Biological Safety Cabinet

Class II Type B2 BSC



Isolator Glove Box

Compounding Aseptic Containment Isolator (CACI)

Total Exhaust

NIOSH/USP 800
Secondary Engineering Controls

$750

$10,000

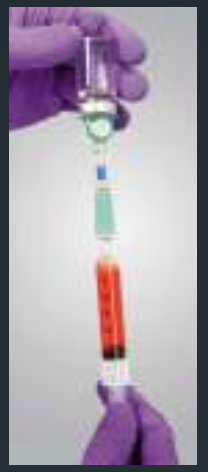
Separate Room 12 ACPH ISO 7 Negative Pressure

Closed System Transfer Devices
Supplemental Environmental Controls

- Closed System Transfer Devices (CSTDs)
- Compounding : Recommended
- Administration : Required

- Currently 7 US products
  - PhaSeal® BD
  - Smartsite ® /Texium® Cardinal
  - On-Guard® or Tevadaptor® B.Braun
  - ChemoClave® /Spiros® ICU Medical
  - Equashield®
  - Sure Connect® Baxa/Baxter
  - Q-Flo® I3 Infusion Inovations

- All Devices FDA Approved
- Three have FDA ONB Code


Smartsite/Texium


PhaSeal


Equashield

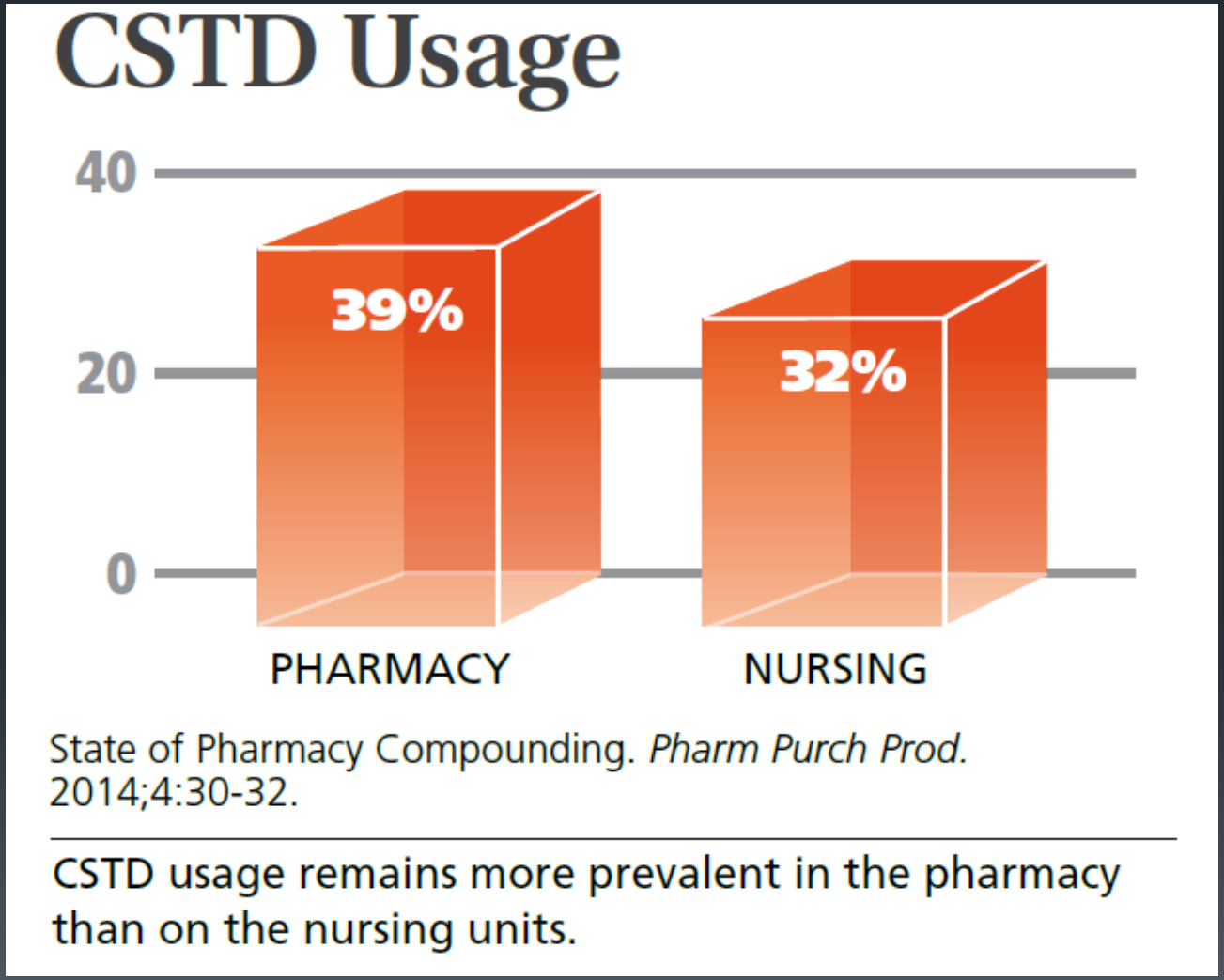

ChemoLock


On-Guard


SureConnect

Q-Flow

Uptake in CSTD Use in US



State of Pharmacy Compounding. *Pharm Purch Prod.* 2014;4:30-32.

CSTD usage remains more prevalent in the pharmacy than on the nursing units.

Source: Advisory Board: CSTD Utilization in Drug Vial Optimization and Beyond-use Dating; Pharmacy Purchasing and Products : April 2014

Time and Motion Study of CSTDs

- Compared 5 CSTDs to syringe/needle
  - PhaSeal; ChemoClave; On-guard; Equashield; Carindal Texium
- From RX to RN
  - 110 Pharmacy personnel and 120 nurses; 3 sites
- Total Time
  - Needle/Syringe: 486 sec vs. CSTD average: 477 sec

Source: D. Greisen, F Massoomi. 2012 Resident Project

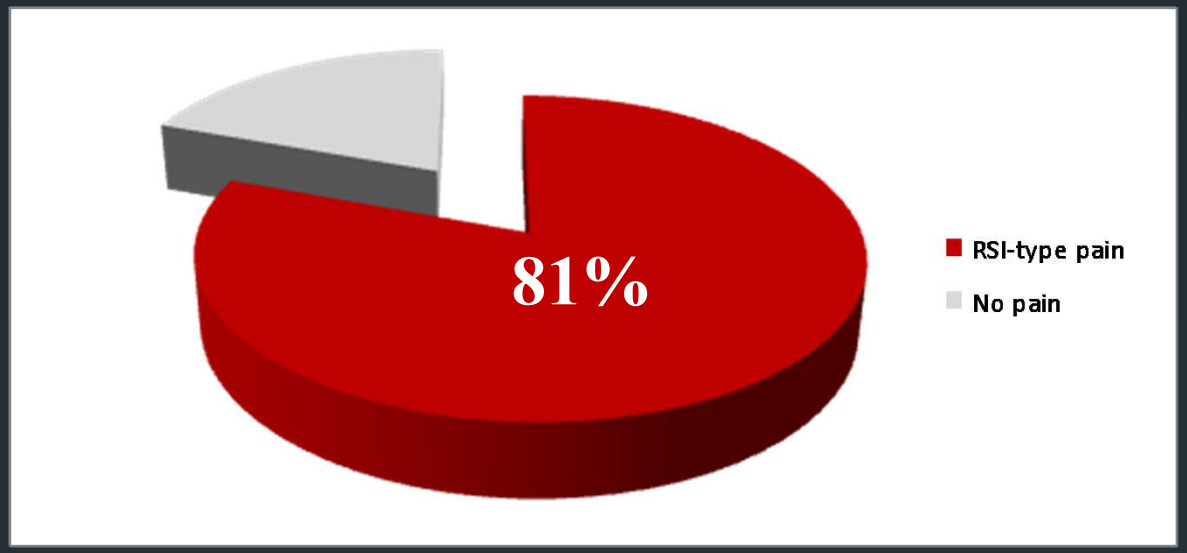
Considerations in CSTD Selection

Cost

Key CSTD Features

1. Containment
2. User interface
3. Device interface
4. Integration
5. Workflow
6. Repetitive strain reduction
7. Pre-bonded components
8. 510(k) ONB status

Repetitive Strain Injury



Source: Abbot L, Johnson T. Minimizing pain resulting from the repetitive nature of aseptic dispensing. Hospital Pharmacist, March 2002


APPROX
VOLUME 1000 ML

Known CSTD Gaps

- NO secure bag spike system
- Dose size limitations
- Ampule management
- Specialized routes of administration
  - Intrathecal
  - Irrigations
  - ophthalmic
  - topical

Cost of Protecting Pharmacy Staff

Cap $0.09

Mask $0.13

Gown $0.72

Gloves $2.00

Shoe Cover $0.23

Total Gowning per Person

$3.17

Surface Safe $2.86

ChemoMat $0.87

CSTD* $10.00

Annual Lab Test* $9.00

Total Gowning per Person

$3.17

Ancillary cost per Person

$18.73*

Total Cost

$21.90

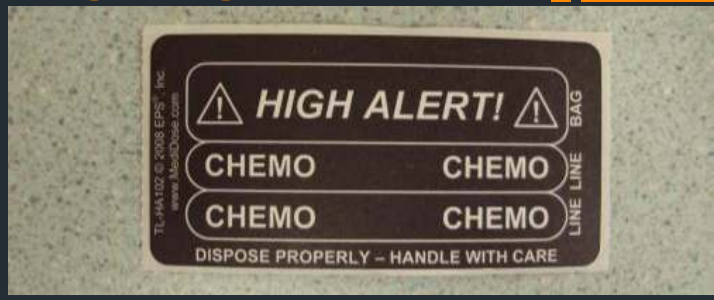
ChemoSpill Kit $30.00

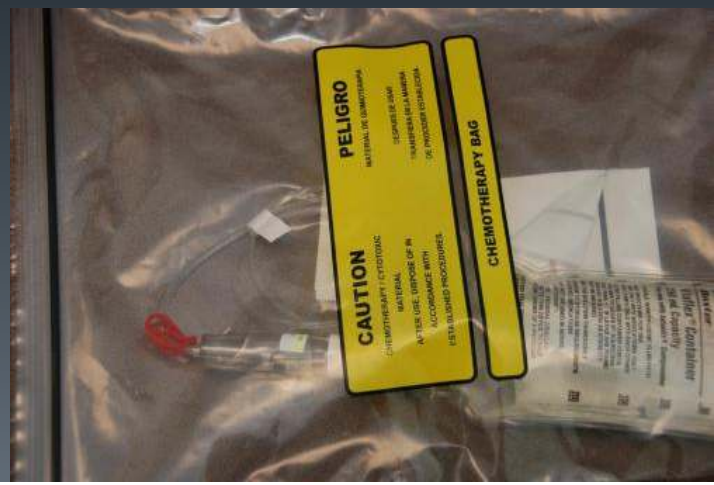
NIOSH/USP 800
Final Product Preparation

- Pre-primed bags
  - Line naïve fluid

- Proper labeling
  - Clear instructions
  - Warning labels

- Line labels $0.65
- Safety overbag $0.25





USP 800
Delivery of Hazardous Drugs

Yes to Hand Delivery

NO to Pneumatic Delivery

Compounding Competency

- **ChemoChek®** $35
  - Fluorescence test
  - Nursing certification program
    - www.Covidien.com

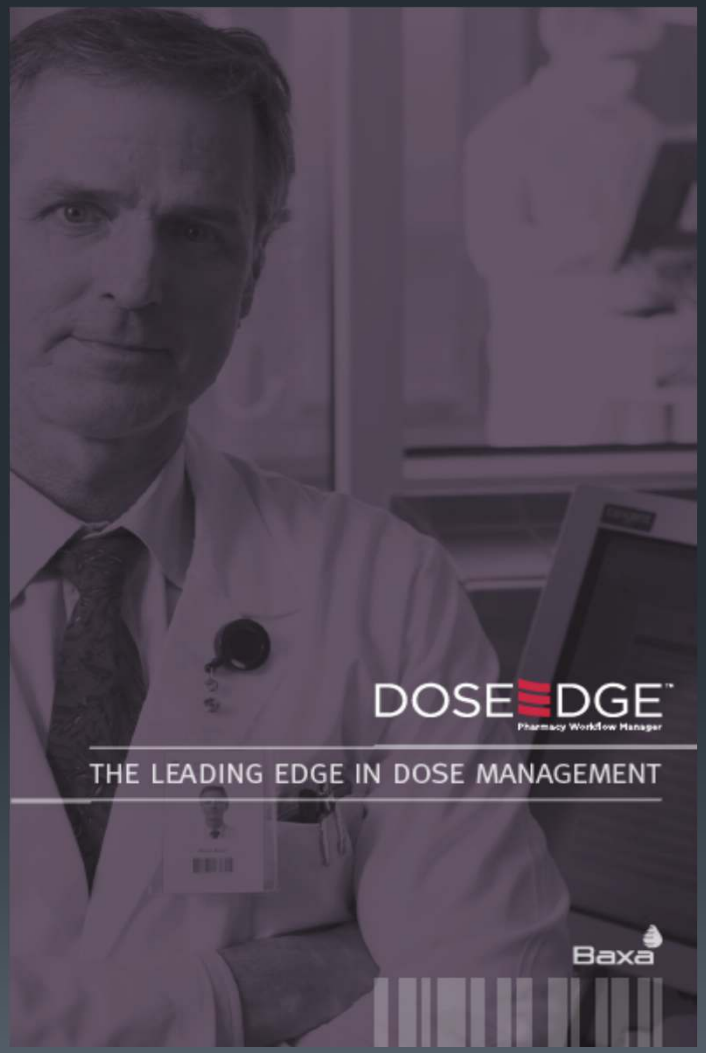
- **ChemoTEQ®**
  - Red dye and broth test
  - Videos and training materials on line
  - www.valiteq.com

Tool for Protecting Personnel Hazardous Drug Checklist

Chemo Checklist

Patient Name _____ Date _____

Two staff members are required to check this, ideally two pharmacists.	Initial #1	Initial #2
Is Medication available?		N/A
If not available, has medication been ordered?		N/A
Is order signed?		N/A
Are height, weight and BSA on order?		N/A
(if not call nursing floor for this info)		N/A
Double check BSA calculation. Does BSA match what is in computer? If not, will it affect the dose by >5% or < 5%? If it will, MD must be called to clarify.		
If regimen listed on order, does dose(s) match Tx Plan		
If regimen does not match is dosing appropriate for patient's renal fx, liver fx, etc.		
If no regimen, is dosage appropriate for what we are treating		
Verify dose calculation (dose may vary +/- 5%) If difference is <5 % or > 5% call MD to clarify		
Verify all diluents, rates and concentrations are appropriate. If MD specified a certain rate, concentration, etc. in the order and after checking 3 references and there you cannot corroborate you must then call MD to clarify or request the study, article, or protocol		
Check label to order- acknowledge all special considerations – make in glass,etc.		
Prior to making, call nursing floor to verify we are ready to go, times, etc.		N/A



NIOSH/USP 800
Hazardous Drug Spill Kits/Policy

- Develop a collaborative policy
- Define volume limits
  - Who is responsible
- Develop or purchase ‘spill kits’
  - Location of kits
  - Training on kits
  - Dating on kits
- Drill Spills

A Better Approach To Spills!

USP 800
Proper Workspace Preparation

① Deactivation
- -2% Sodium Hypochlorite solution
- -Sodium Thiosulfate

② Decontamination
- -Physical wiping of surface

③ Cleaning
- -Tri or Quadra-valent detergent
- -Peroxide

④ Disinfection
- -Sterile Isopropyl Alcohol 70%
- -UV light

NIOSH/USP 800 Medical Surveillance Program

- First Step
  - Work with Human Resources; Employee Health & Legal
- Tier-One Education and Self Surveillance
- Tier-Two Employer/Supervisor Surveillance
  - Annual reproductive questionnaire
  - Trending of sick calls
- Tier-Three Comprehensive Medical Surveillance
  - Hire and annually
  - CBC, urinanalysis, LFT's
  - Urine drug testing by exposurecontrol
- Tier-Four Post-exposure Surveillance
  - Notation in medical record with date and drug

Massoomi F. *Pharm. Purch Prod.* 2008

Baseline Employee Information

Frequency (circle one-day or week): _____times per day/week ____times per day/week ____times per day/week

Duration (minutes/hours handling each):_____ _____ _____

Personal protective equipment used: _____ _____ _____

Last training date: _____ _____ _____

REPRODUCTIVE HISTORY:

1. Have you or your partner ever had a problem conceiving a child?

   ☐Yes If yes, please specify: ☐present partner ☐previous partner

   ☐No

2. Have you or your partner consulted a physician for a fertility or other reproductive problem?

   ☐Yes If yes, please specify who consulted the physician: ☐ self ☐ partner ☐ self and partner

   If yes, please state the diagnosis that was made:_____

   ☐No

3. Have you or your partner ever conceived a child resulting in a miscarriage, stillbirth or deformity?

   ☐Yes

   ☐No

UPS 800
Oral Hazardous Drugs

- Segregate from non-hazardous
- NO C-PEC required: non-antineoplastic only
  - Simple transfers/counting
  - Unit dose formulations

- Non-Sterile characteristics
  - Tablet, capsule, liquid
  - Punch tablet or coated

- All manipulations in negative pressure room
- In a “powder box”
  - Crushing
  - Liquid Prep
  - Topical Prep

- NOT automated packaging devices

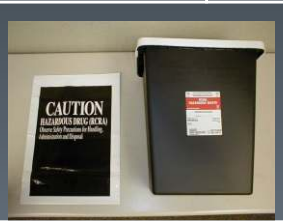
Sentry Air Ductless Fume Hood: I.E., Powder Cabinet

NIOSH/USP 800 Hazardous Waste Management

- NOTE: highest environmental concentrations

- Collaborative formulary assessment
  - State and federal regulations
  - Continuous assessment of risk and stream

DRUG - GENERIC (BRAND)	CLASS OF MEDICATION	ROUTES/ FORMS	COMPANY	PREGNANCY CATEGORY	MSDS	BSC	HAZ CLASS (1-4)	WASTE STREAM	RCRA Y/N
Aldesleukin (Proleukin)	ONC	INJ	Chrion	C	YES	YES	Class 1	YELLOW	N
Alitretinoin (Panretin)	Retinoid	TOPICAL, GEL	Ligand	D	YES	Yes, if altered	Class 1	YELLOW	N
Cychlophosphamide	ONC	INJ, ORAL	Multiple	D	YES	YES	Class 1	RCRA BLACK	Y



Proper Disposal Program

State Specific!

Biohazard Infectious (Regulated Medical)

Blood products, sharps, items contaminated with liquid blood, etc.

$0.01/pound

Hazardous & Non-Hazardous

Empty chemotherapy vials, syringes, IVs, tubing, gowns, packaging, gloves, etc.

$0.10/pound

RCRA Hazardous

Bulk chemo in vials, unused IV's, P, U, toxic & ignitable
Overtly contaminated gowns, glove, chemo spill clean up materials

$1.00/pound

RCRA Biohazardous

$1.20/pound

Proper Hazardous Drug Waste Disposal

Poster Example

Segregate the wastes of Drugs & Dispose of in appropriate containers

SHARPS *Red Container*	*BIOHAZARDOUS* *Red Container*	*Hazardous* *Yellow Container*	*RCRA HAZARDOUS* *Black Container*	*Non-Regulated Trash*
Sharps	BioHaz	CHEMO	RCRA	Trash
-Needles -Broken Glass -Ampules -Other sharps	-Non-Chemo vials -IVIG vials/bags -Albumin vials/bags -Blood factor vials -Syringes -IV Bags and Tubing	**-Empty** Chemo vials -Chemo packaging <boxes, PIs> -Chemo mats not involved with spills -Chemo Gloves -PhaSeal devices	**ALL** partial Chemo Dose vials **Drugs on EPA P & U list** 1.Chlorambucil 2.Cyclophosphamide 3.Daunomycin 4.Melphalan 5.Mitomycin C 6.Streptozotocin 7.Arsenic Trioxide 8.Idarubicin 9.Carmustin *including* **Gliadel** 10.Uracil mustard 11.Anything used 4 chemo spill	Everything Else NOT contaminated 1.Packaging 2.IV wraps 3.Syringe packaging 4.PhaSeal packaging 5.Gauzes 6.Gowns 7.Masks 8.Paper 9.Labels, etc.

Contact Service Center for questions: XXX-XXX-XXXX

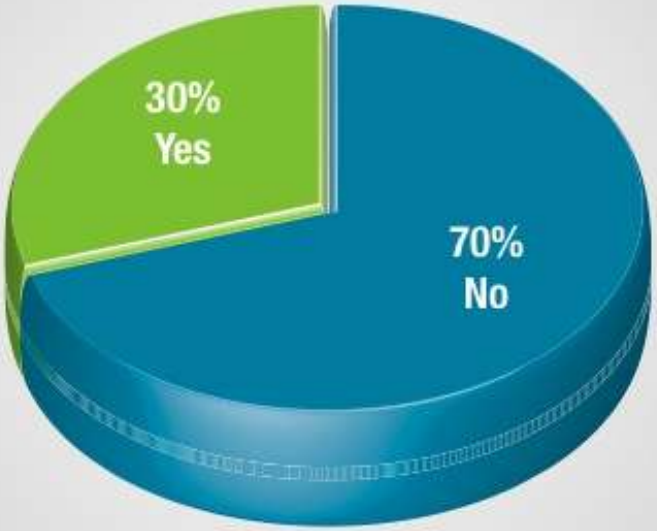
Risk Management & Liability

- Civil and criminal liability
  - Civil & Criminal: State/USEPA enforcement
- Personal liability
  - fines and/or imprisonment
- Corporate fines
  - $37,500 per violation/day

- Eastern Kansas Health Care System August 18, 2009
  - What $51,501 civil penalty & $482,069 supplemental project
  - Violations
    - No hazardous waste determinations
    - No proper hazardous waste containers
    - No documentation of inspection of hazardous waste storage
    - No documentation of personnel training
    - Unpermitted on-site incineration of hazardous waste
    - Unlawful shipping of hazardous waste

Going GREEN

Recommendations Received



Almost two thirds of hospitals have been inspected by their state boards or the EPA in the past three years with 48% questioned about RCRA compliance. Reflecting pharmacies' lack of confidence in this area, 30% of facilities received recommendations.

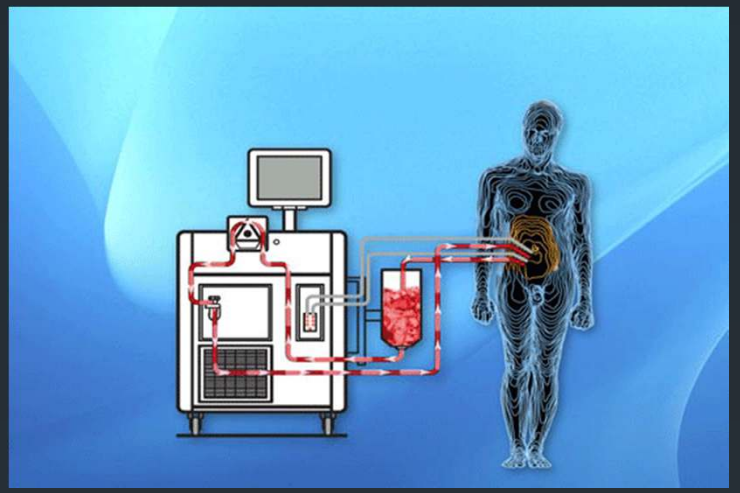
N=343 Rx Directors

Going Green. *Pharm Purch Prod*. 2010; 12.

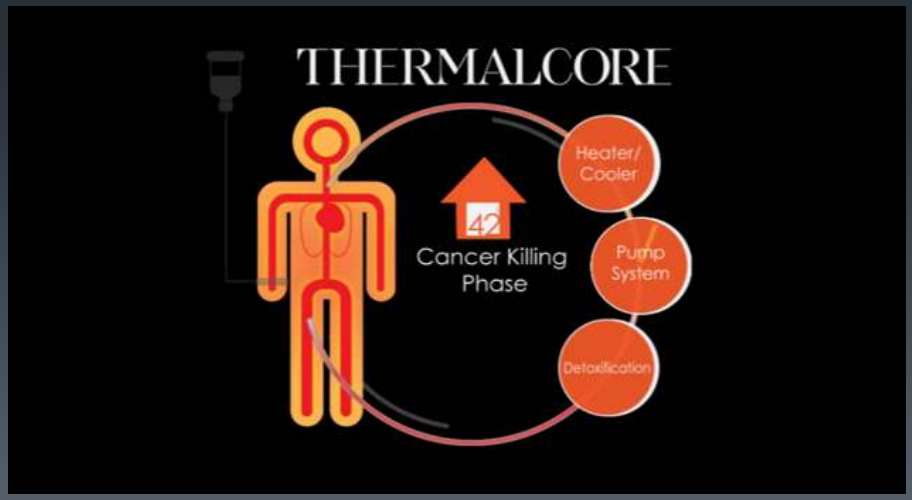
PHARMACY Purchasing & Products

Hazardous Drug Consideration
Specialized Patients and Procedures

- Surgical
  - Bladder installation
  - HOT Chemo Baths
  - Ophthalmic surgery = TOPICAL
  - Esophogeal Strictures = TOPICAL
- Obstetrics
  - Ectopic pregnancy
- Rheumatology
  - Rheumatoid arthritis
  - Lupus nephritis
- Neurology
  - Multiple sclerosis



Hyperthermic Intraperitoneal Chemotherapy



Hazardous Drug Consideration
Special Delivery Devices

Hazardous Drug Consideration
Bacille Calmette-Guerin (BCG vaccine)

- Indication: Bladder CA
- **WARNINGS**
  - Live Biological Hazard
  - BCG infections in healthcare workers have occurred
  - Case studies of deaths due to cross contamination of TPNs

Hazardous Drug Consideration
Handling Patient Excreta

- Unchanged drug and metabolites can be excreted in
  - Urine
  - Feces
  - Emesis

Drug	Detected in urine
Carmustine	≥ 4 days
Cisplatin	≥ 5 days
Etoposide	≥ 5 days
Gemcitabine	≥ 7 days
Mitoxantrone	Up to 5 days

Source: Seth Eisenberg, RN via Polovich, 2011 "Safe Handling of Hazardous Drugs," 2nd Ed.

Hazardous Drug Consideration

Monster Robots on the US market

Intellifill IV
Baxter

RIVA

CytoCare
McKesson

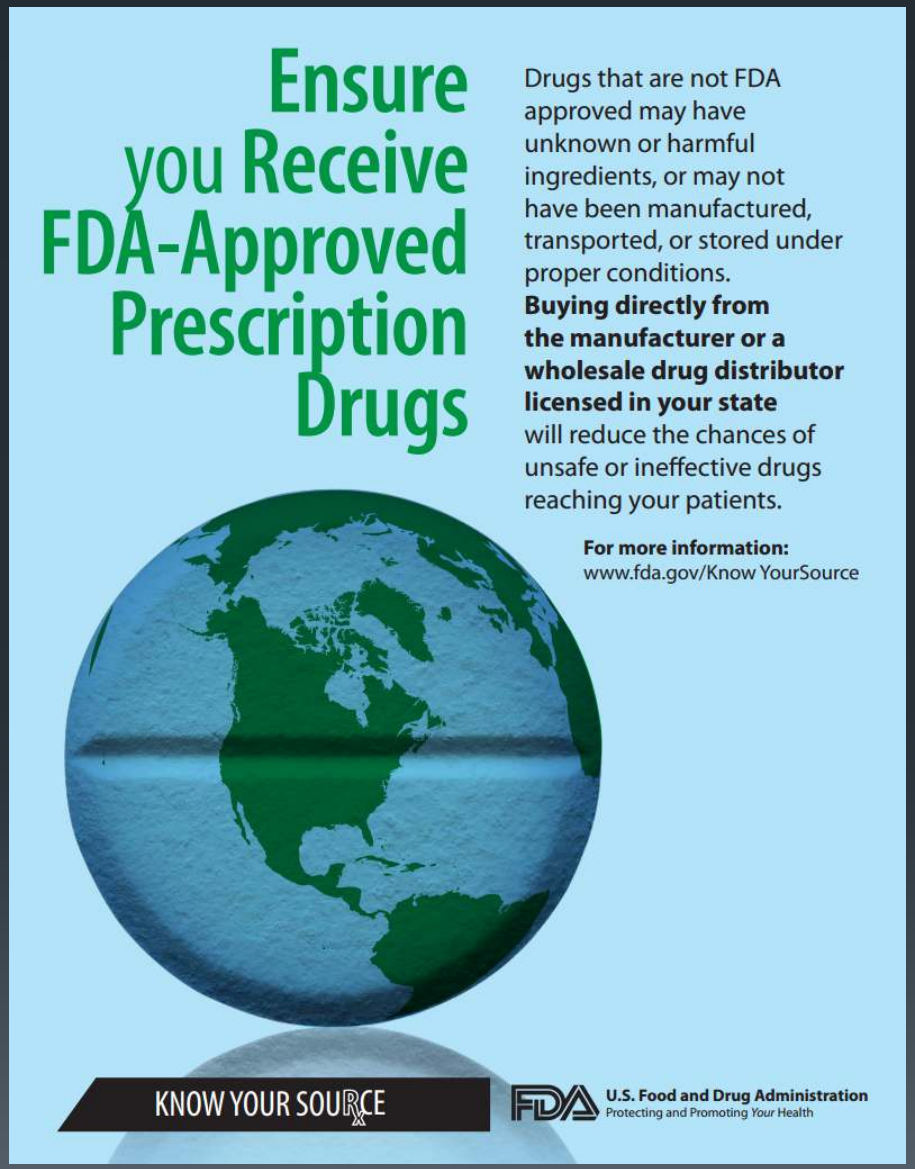
Health Robotics
IV Station

Apoteca
Loccioni

Micro-Robot on the US market

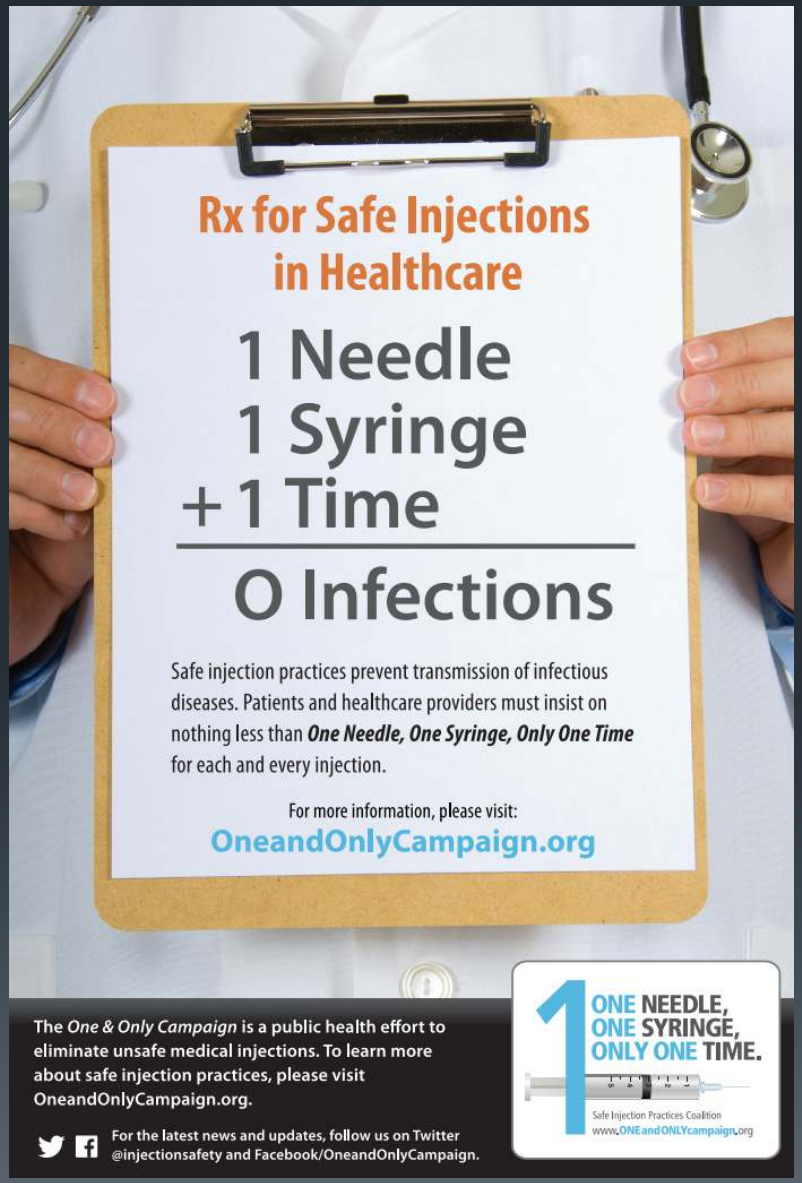
Diana
ICU Medical

Hazardous Drug Considerations
FDA's New Campaign



Source: fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm#Pacific

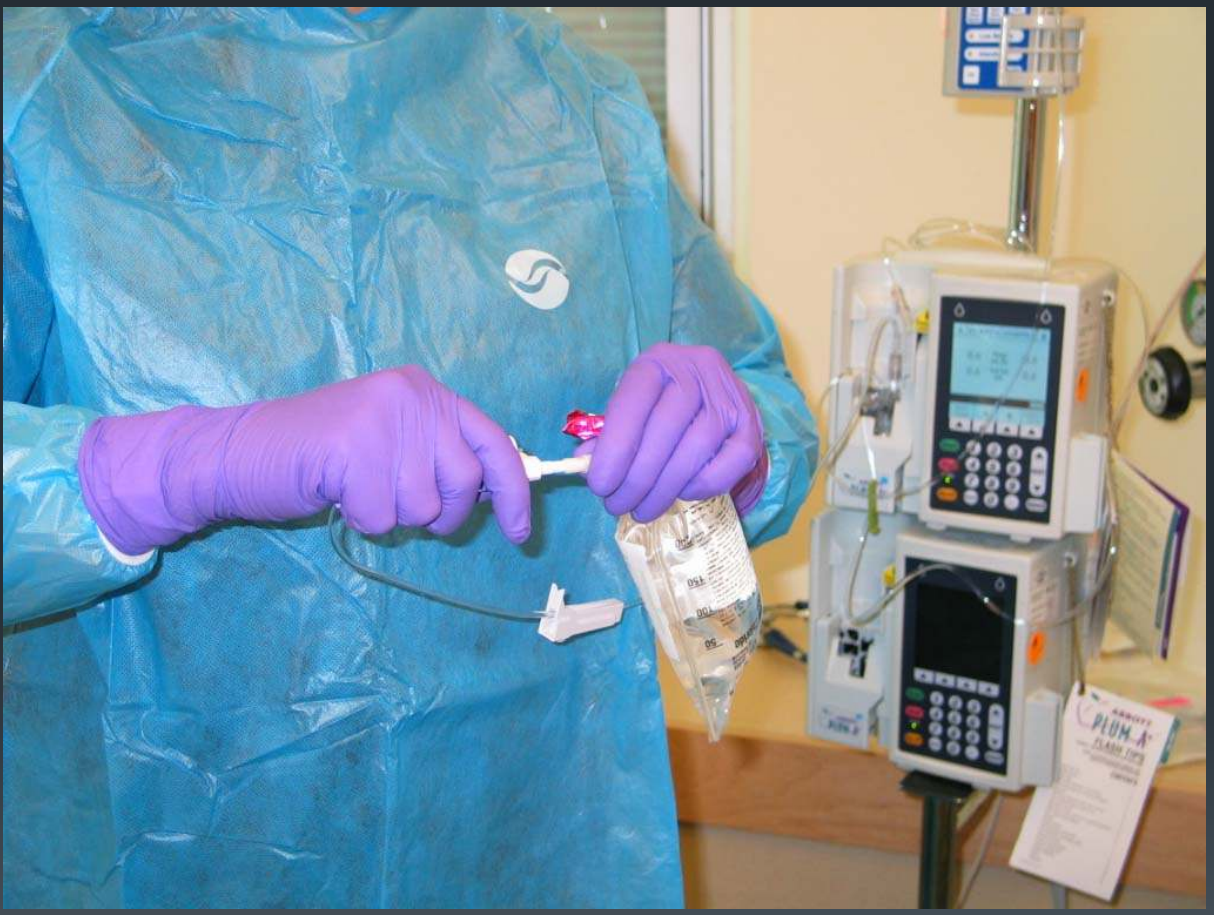
Hazardous Drug Consideration
CDC Injection Safety Campaign

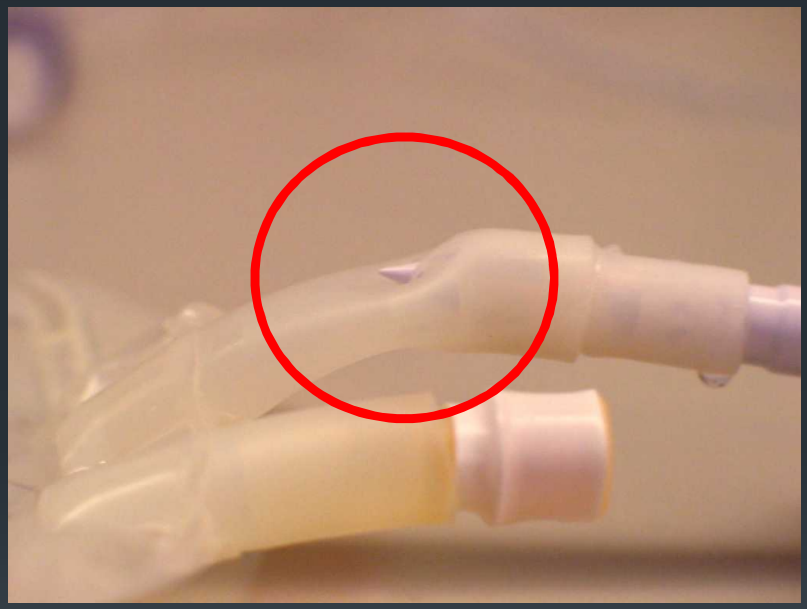


- Unsafe injection practices
  - 150,000 patients in recent years.
- From 2001 through 2011,
  - 50 outbreaks of viral hep or INFX
- Multidose vial limitations
- ALL areas

Source: oneandonlycampaign.org

NIOSH/USP 800
Spiking at the Bedside Risks





Is the pharmacy pre-priming secondary IV sets on the primary drug?

Source: Seth Eisenberg,RN

Hazardous Drug Consideration
Alternate Care Sites!

The Daily Briefing

Today's Daily Briefing | View Archives | Print Today's Daily Briefing

Grocery chain to offer chemo, other IV treatments

'It's not something you associate with a supermarket'

Topics: Oncology, Service Lines, Behavioral Health, Access to Care, Quality, Performance Improvement, Appropriateness

November 07, 2013

Schnucks—a grocery chain based in the Midwest—has opened its first ambulatory infusion center, where nurses and pharmacists provide infusion therapy for acute and chronic conditions, the *St. Louis Post-Dispatch* reports.

Source: The Advisory Board; November 07, 2013

Future Considerations

- Genotargeted drugs
- Microrobot delivery of drugs
- Nanotechnology drugs
  - “Nanopills”
  - “Nanotopicals”
  - “Nanoinjections”

“Hazardous Drug Rounds”

Preparation

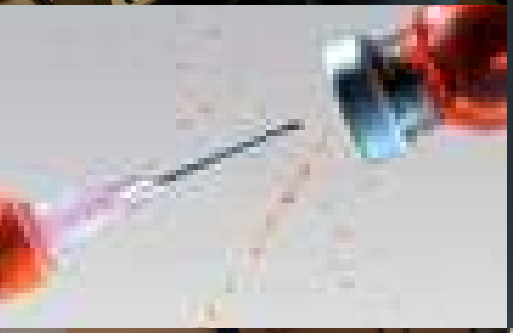
Administration

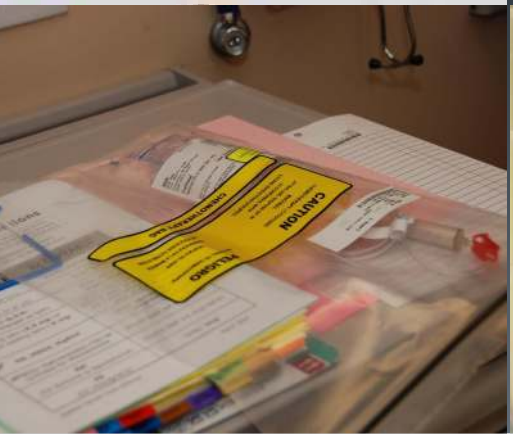
Disposal


LYOPHILIZED
CYTOXAN
(CYCLOPHOSPHAMIDE
FOR INJECTION, USP)
2 gram
IFEX
Mead Johnson


Fake Chemo
Fake Chemo


CHEMOTHERAPY




CAUTION
CAUTION