Disclosure Information

- Receives grant/research support from
  - BD
  - Equashield
  - ICU Medical
  - CareFusion

- Contributing Editor
  - Pharmacy Purchasing and Products magazine
A Notable Trend

Most frequent types of cancer deaths worldwide (2008):

- Lung: 1.37 million
- Breast: 458,000
- Liver: 695,000
- Stomach: 736,000
- Colorectal: 608,000

Worldwide cancer deaths are projected to rise to 13.1 million in 2030.

THE FACTS ABOUT CANCER

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

Source: WHO Global_can 2013
Cancer Death Rates Drop in US
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:
Fransman W. Occupational exposure to cytotoxic drugs. Hospital Pharmacy Europe. 2007; 35: 85-86.
Occupational Risks Due To Exposure to Hazardous Drugs

  - 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

<table>
<thead>
<tr>
<th></th>
<th>Days</th>
<th>Urine samples</th>
<th>Positive CP samples</th>
<th>Positive IF samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist 1</td>
<td>1</td>
<td>6</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Pharmacist 2</td>
<td>1</td>
<td>10</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>Technician 1</td>
<td>1</td>
<td>8</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Technician 2</td>
<td>1</td>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Technician 3</td>
<td>1</td>
<td>9</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nurse 1</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Nurse 2</td>
<td>1</td>
<td>4</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Control</td>
<td></td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>N(pos)=7</td>
<td>1</td>
<td>48</td>
<td>18 (N=5)</td>
<td>10 (N=2)</td>
</tr>
</tbody>
</table>


“There is no acceptable level of personnel exposure to HDs”
Lifesaving cancer drugs may put workers' lives at risk
Chemo could have a hidden deadly toll on pharmacists, nurses

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

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 25 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
## Guidelines for Hazardous Drugs

<table>
<thead>
<tr>
<th>Source</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA</td>
<td>1986, 1995, 1999</td>
</tr>
<tr>
<td>AMA Council on Scientific Affairs</td>
<td>1985</td>
</tr>
<tr>
<td>Oncology Nursing Society</td>
<td>1988, 2003, 2010</td>
</tr>
<tr>
<td>HOPA</td>
<td>2009</td>
</tr>
<tr>
<td>USP &lt;797&gt;</td>
<td>2004, 2008</td>
</tr>
<tr>
<td>USP &lt;800&gt;</td>
<td>2014 (for comment)</td>
</tr>
</tbody>
</table>

Globally 42 years of Safe Handling Guidelines
How Are We Doing?

- 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
Legacy of Current Practices

Safe Handling of Cytotoxic and Hazardous Drugs

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

- OSHA has no standard for exposure to HD but has generated three guidelines
  - Controlling Occupational Exposure to Hazardous Drugs
    TED 1–0.15A, Sec VI, Chap II: 1995, 1999

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

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

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
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”


- 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
Hazardous Drugs products should always be considered contaminated on the packaging and vials until properly decontaminated.


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 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

<table>
<thead>
<tr>
<th>CLASS 1</th>
<th>Pharmacy Precautions</th>
<th>Nursing Administration Precautions (Who can administer)</th>
<th>Nursing Body Fluid Precautions</th>
<th>Housekeeping and Ancillary Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>IM, Subcutaneous, intradermal</td>
<td>BSC**, Sterile double chemo gloves, Chemo gown, Face shield</td>
<td>Double chemo gloves, chemo gown, Face shield (Oncology RN with required PPE)</td>
<td>Double chemo gloves, chemo gown. Add face shield if splashing possible.</td>
<td>Double chemo gloves, chemo gown. Add face shield if splashing possible.</td>
</tr>
<tr>
<td>IV Push, IVPG, IV Continuous infusion</td>
<td>BSC**, Sterile double chemo gloves, Chemo gown, Face shield</td>
<td>Double chemo gloves, chemo gown, face shield (Oncology RN with required PPE)</td>
<td>Double chemo gloves, chemo gown. Add face shield if splashing possible.</td>
<td>Double chemo gloves, chemo gown. Add face shield if splashing possible.</td>
</tr>
</tbody>
</table>

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

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.*
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
#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
Choosing the Right Glove

**Cat. N8831 Flexam®**
Sterile Powder-Free Nitrile Exam Gloves

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."

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

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

<table>
<thead>
<tr>
<th>Chemotherapy Drug Permeation Resistance (minimum breakthrough time in minutes, 0.01 µg/cm²) (ASTM D 6978):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carmustine (3.3 mg/mL)</td>
</tr>
<tr>
<td>Cisplatin (1.0 mg/mL)</td>
</tr>
<tr>
<td>Cyclophosphamide (20 mg/mL)</td>
</tr>
<tr>
<td>Doxorubicin Hydrochloride (2.0 mg/mL)</td>
</tr>
<tr>
<td>Etoposide (20 mg/mL)</td>
</tr>
<tr>
<td>5-Fluorouracil (50 mg/mL)</td>
</tr>
<tr>
<td>Mitoxantrone (2.0 mg/mL)</td>
</tr>
<tr>
<td>Paclitaxel (6.0 mg/mL)</td>
</tr>
<tr>
<td>Thiotepa (10 mg/mL)</td>
</tr>
</tbody>
</table>

**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

Separate Room 12 ACPH ISO 7 Negative Pressure

$750 $10,000

Hazardous Drugs are Stored & Compounded in this Area
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 Innovations

- All Devices FDA Approved
- Three have FDA ONB Code
Uptake in CSTD Use in US

CSTD Usage


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

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

Cost
Repetitive Strain Injury

81%

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

- Surface Safe: $2.86
- ChemoMat: $0.87
- CSTD*: $10.00
- Annual Lab Test*: $9.00
- ChemoSpill Kit: $30.00

Total Gowning per Person: $3.17
Ancillary cost per Person: $18.73*

Total Cost: $21.90

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

- **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.

<table>
<thead>
<tr>
<th>Initial #1</th>
<th>Initial #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is Medication available?</td>
<td>N/A</td>
</tr>
<tr>
<td>(if not available, has medication been ordered?)</td>
<td>N/A</td>
</tr>
<tr>
<td>Is order signed?</td>
<td>N/A</td>
</tr>
<tr>
<td>Are height, weight and BSA on order?</td>
<td>N/A</td>
</tr>
<tr>
<td>(if not call nursing floor for this info)</td>
<td>N/A</td>
</tr>
<tr>
<td>Double check BSA calculation. Does BSA match what is in computer? If not, will it affect the dose by &gt;5% or &lt; 5%? If it will, MD must be called to clarify.</td>
<td></td>
</tr>
<tr>
<td>If regimen listed on order, does dose(s) match Tx Plan</td>
<td></td>
</tr>
<tr>
<td>If regimen does not match is dosing appropriate for patient's renal fx, liver fx, etc.</td>
<td></td>
</tr>
<tr>
<td>If no regimen, is dosage appropriate for what we are treating</td>
<td></td>
</tr>
<tr>
<td>Verify dose calculation (dose may vary +/- 5%) If difference is &lt;5% or &gt;5% call MD to clarify</td>
<td></td>
</tr>
<tr>
<td>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</td>
<td></td>
</tr>
<tr>
<td>Check label to order- acknowledge all special considerations – make in glass, etc.</td>
<td></td>
</tr>
<tr>
<td>Prior to making, call nursing floor to verify we are ready to go, times, etc.</td>
<td>N/A</td>
</tr>
</tbody>
</table>
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 www.exposurecontrol.nl

- Tier-Four Post-exposure Surveillance
  - Notation in medical record with date and drug

Massoomi F. Pharm. Purch Prod. 2008
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
   - No

2. Have you or your partner consulted a physician for a fertility or other reproductive problem?
   - Yes
   - No
   - If yes, please specify who consulted the physician: □ self  □ partner  □ self and partner
   - If yes, please state the diagnosis that was made: ______________________________

3. Have you or your partner ever conceived a child resulting in a miscarriage, stillbirth or deformity?
   - Yes
   - No
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

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

### State Specific!

<table>
<thead>
<tr>
<th>Category</th>
<th>Items</th>
<th>Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Biohazard Infectious (Regulated Medical)</strong></td>
<td>Blood products, sharps, items contaminated with liquid blood, etc.</td>
<td>$0.01/pound</td>
</tr>
<tr>
<td><strong>Hazardous &amp; Non-Hazardous</strong></td>
<td>Empty chemotherapy vials, syringes, IVs, tubing, gowns, packaging, gloves, etc.</td>
<td>$0.10/pound</td>
</tr>
<tr>
<td><strong>RCRA Hazardous</strong></td>
<td>Bulk chemo in vials, unused IV’s, P, U, toxic &amp; ignitable</td>
<td>$1.00/pound</td>
</tr>
<tr>
<td><strong>RCRA Biohazardous</strong></td>
<td>Overtly contaminated gowns, glove, chemo spill clean up materials</td>
<td>$1.20/pound</td>
</tr>
</tbody>
</table>
Proper Hazardous Drug Waste Disposal

Poster Example

Segregate the wastes of Drugs & Dispose of in appropriate containers

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

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
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
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
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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Detected in urine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carmustine</td>
<td>≥ 4 days</td>
</tr>
<tr>
<td>Cisplatin</td>
<td>≥ 5 days</td>
</tr>
<tr>
<td>Etoposide</td>
<td>≥ 5 days</td>
</tr>
<tr>
<td>Gemcitabine</td>
<td>≥ 7 days</td>
</tr>
<tr>
<td>Mitoxantrone</td>
<td>Up to 5 days</td>
</tr>
</tbody>
</table>

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

Ensure you Receive FDA-Approved Prescription Drugs

Drugs that are not FDA approved may have unknown or harmful ingredients, or may not have been manufactured, transported, or stored under proper conditions. Buying directly from the manufacturer or a wholesale drug distributor licensed in your state will reduce the chances of unsafe or ineffective drugs reaching your patients.

For more information: www.fda.gov/KnowYourSource

Aggressive marketing tactics and deep discounts on prescription drugs may indicate that the products are stolen, counterfeit, substandard, or unapproved.

For more information: www.fda.gov/KnowYourSource

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!

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