Managing Hazardous Drugs – are we doing enough?

2018 Asia Pacific Oncology Pharmacy Congress

8th September 2018

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Thank you, Singapore and PSP!

Disclosure Information

Eric S. Kastango, BS Pharm, MBA, FASHP

- I have the following financial relationships to disclose:
  - Grant/Research support from: Equashield, Contec, BD Medical, and Braun (past client)
  - Principal of: Clinical IQ, and CriticalPoint, LLC

- I will not discuss off label use and/or investigational use in my presentation.

- List References here

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The views and opinions presented are entirely their own.

They do not necessarily reflect the views of any other organization they may be associated with, nor should they be construed as an “official” explanation or interpretation of any USP chapter or any State Board of Pharmacy rule/law.

Acknowledgements

Thanks to Fred Massoomi, Luci Power, Kate Douglass, and Patti Kienle for the use of slides/information presented in this slide deck!

What's all the fuss?

Preventing Occupational Exposure

Warning!

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

Source: NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings, 2004

Who is at Risk of Occupational Exposure?

- 8 million US healthcare workers at risk
  - **Pharmacy personnel,**
  - **Nursing personnel**,
  - Physicians
  - Operating room personnel,
  - Veterinary personnel,
  - Shipping and receiving personnel,
  - Laundry workers,
  - Waste handlers,
  - Maintenance workers

Source: NIOSH [2008]. NIOSH Workplace Solution: Personal Protective Equipment for Health Care Workers Who Work with Hazardous Drugs. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2009–106.

What is a “Hazardous Drug”?

- All drugs are hazardous to some degree
- NIOSH defines a hazardous drug as:
  - Any drug identified by at least one of the following six characteristics:
    - Carcinogenicity
    - Teratogenicity or developmental toxicity
    - Reproductive toxicity in humans
    - Organ toxicity at low doses in humans (<10 mg/day) or animals (<1mg/kg/day)
    - Genotoxicity
    - New drugs that mimic existing hazardous drugs in structure or toxicity

(NIOSH, 2004)

Evidence: Health Effects

1970s Secondary malignancies identified in patients following treatment[1]

1980s Association between exposure to antineoplastics and adverse reproductive effects: miscarriages, congenital malformations, low birth weight and infertility

1990s Link of cancer occurrence to healthcare workers exposure to antineoplastics

[1]Roussel C. et al. Meta-analysis of chromosomal aberrations as a biomarker of exposure in healthcare workers occupationally exposed to antineoplastic drugs. Mutation Research/Reviews in Mutation Research. (2017). Retrieved -2/22/2018.

Evidence: Exposure

- Biological Markers
- Studies demonstrate antineoplastics in urine
- Present in workers who did not handle HDs

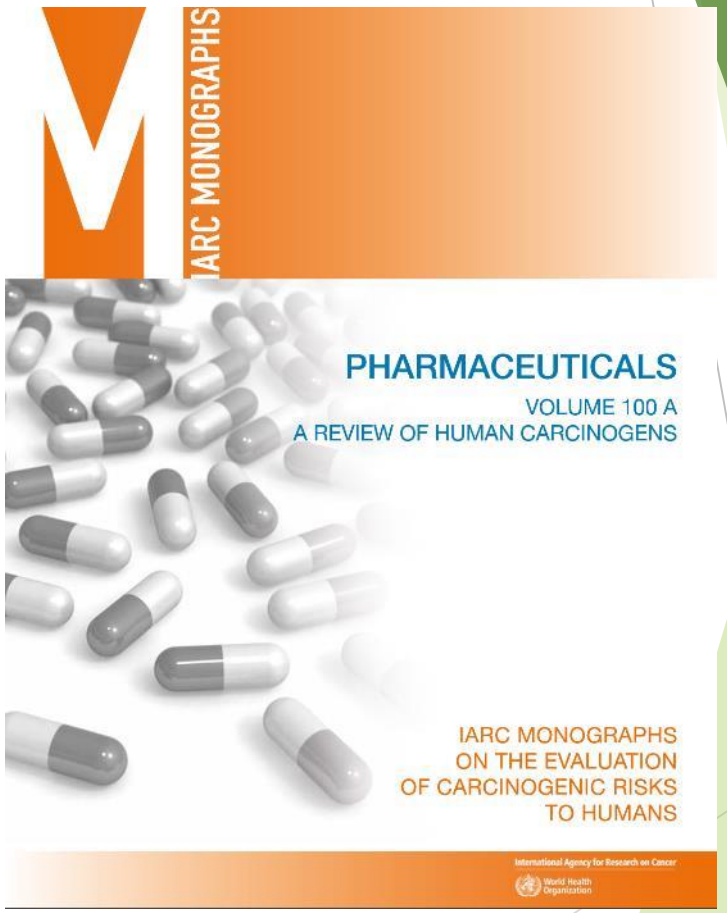
Safe Handling of HDs

Early 1970s	Europe
1981	Australia
1983	USA

30+ years of pharmacy awareness in US alone

IARC (continued)

- A Review of Human Carcinogens – Pharmaceuticals
  - Group 1 Human carcinogens
  - Group 2A Probably carcinogenic in humans
  - Group 2B Possibly carcinogenic in humans
  - Group 3 Not classifiable as to carcinogenicity in humans
  - Group 4 Probably not carcinogenic humans



Occupational Hazard Characteristics of HDs

- Genotoxicity (mutagenicity)
- Carcinogenicity in animal models
- Teratogenicity or fertility impairment
- Evidence of serious organ or other toxicity at low doses

Source: ASHP TAB on Handling Cytotoxic and Hazardous Drugs, 1990

Evidence-based Brutal Facts

What should we know and accept as self-evident!

- A number of health risks associated with healthcare workers' exposure to antineoplastic drugs have been established since the 1970s [1].
- Occupational exposure to these agents have led to a range of health outcomes reported in healthcare workers including acute effects [2], cardiotoxicity [3], reproductive toxic effects [4-6], and chromosomal damage - a precursor to cancer development [7,8].

Should we be concerned and why?

Yes and for several reasons

- The use of antineoplastic drugs is growing because of the increasing incidence of cancer [9].
- Existing safe drug handling practices may not effectively eliminate the risk potential as drug contamination of surfaces is prevalent in multiple departments within a hospital [10,11].
- The number and variety of healthcare workers potentially exposed to antineoplastic drugs has increased because the use of these agents for treating nonmalignant diseases has expanded [1].

Why should we be concerned?

Yes and for several reasons

- After 40 years, NO occupational exposure limits have been established for these drugs by any of the recognized agencies that produce such exposure thresholds
  - American Conference of Governmental Industrial Hygienists threshold limit values,
  - German maximum workplace concentration.

Contamination Levels

Reference Values for Environmental Contamination with Cyclophosphamide (CP) in the Netherlands

NIOSH has yet to define how to use surface sampling or how often to conduct testing. In the interim, Paul Sessink, PhD, who pioneered hazardous drug environmental sampling, has provided a guide of sampling frequency based on concentrations of cyclophosphamide.[8] Guidance is also provided on when to examine processes for handling hazardous drugs and when to repeat sampling. At this time, this is the only published recommendation detailing a suggested sampling frequency.

	Strive Risk Level			Prohibitory Risk Level
Contamination CP (ng/cm)	< 0.1	0.1 - 1	1 - 10	>10
Actions	Monitoring once a year Evaluate after 4 years	Risk Estimate Monitoring within 3 - 6 months Eventually followed by measures		Take measures Check by monitoring

Table modified with permission from Paul JM Sessink, PhD.

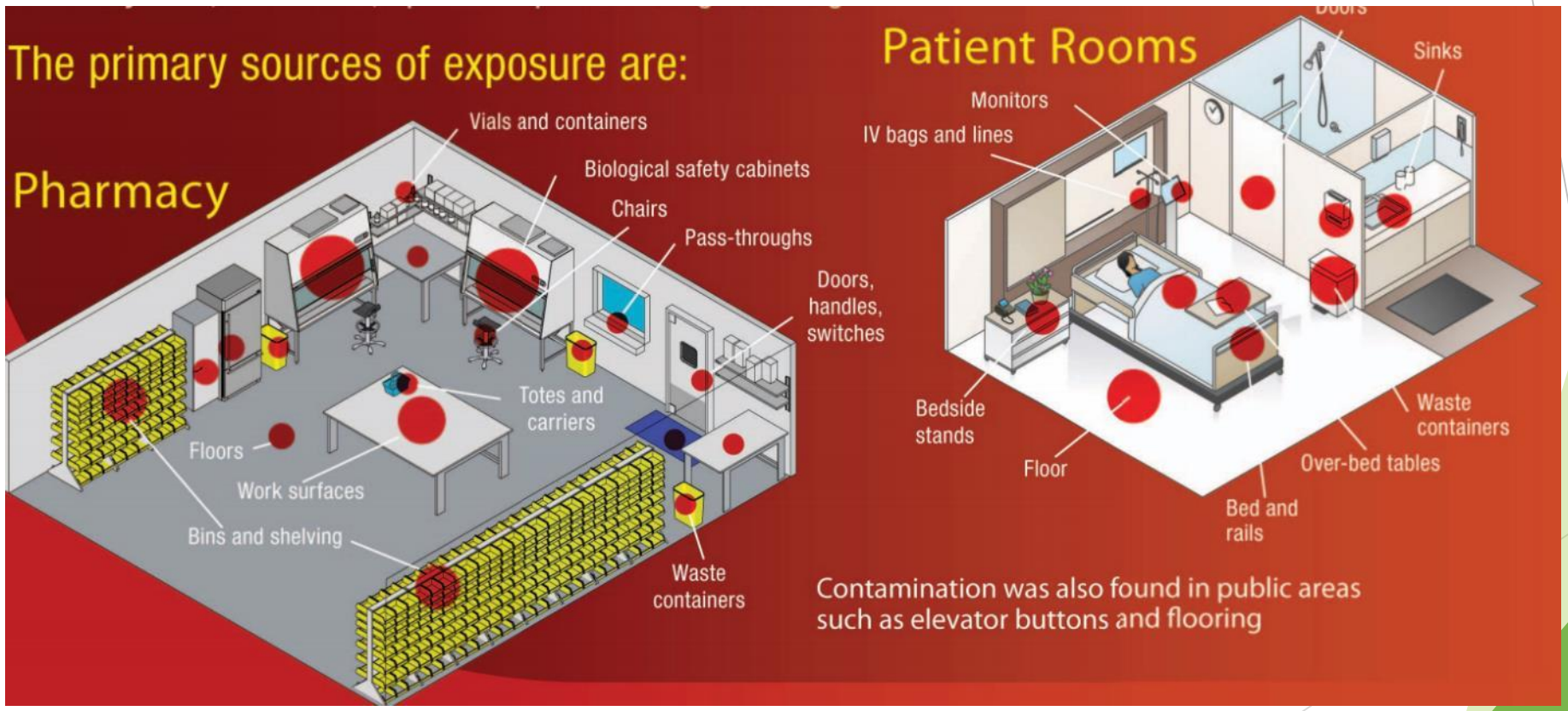
Why should we be concerned?

- No other industry comes close to healthcare regarding the number of hazardous agents handled by a variety of different professionals
  - Known or suspected human and/or animal carcinogens, teratogens, mutagens
  - Known or suspected human and/or animal reproductive toxicants
  - Known or suspected drugs with effects on fertility
  - Known human acute and/or chronic toxicants

Source: Connor TH-HD presentation to ASCO, December 2014

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

HD Residue

1999 Study	2010 Study
3 drugs measured in 6 hospitals: • 75% of the pharmacy wipes and • 65% of the nursing wipes were contaminated	5 drugs measured in 3 hospitals: • 75% of the pharmacy wipes and • 43% of the nursing wipes were contaminated

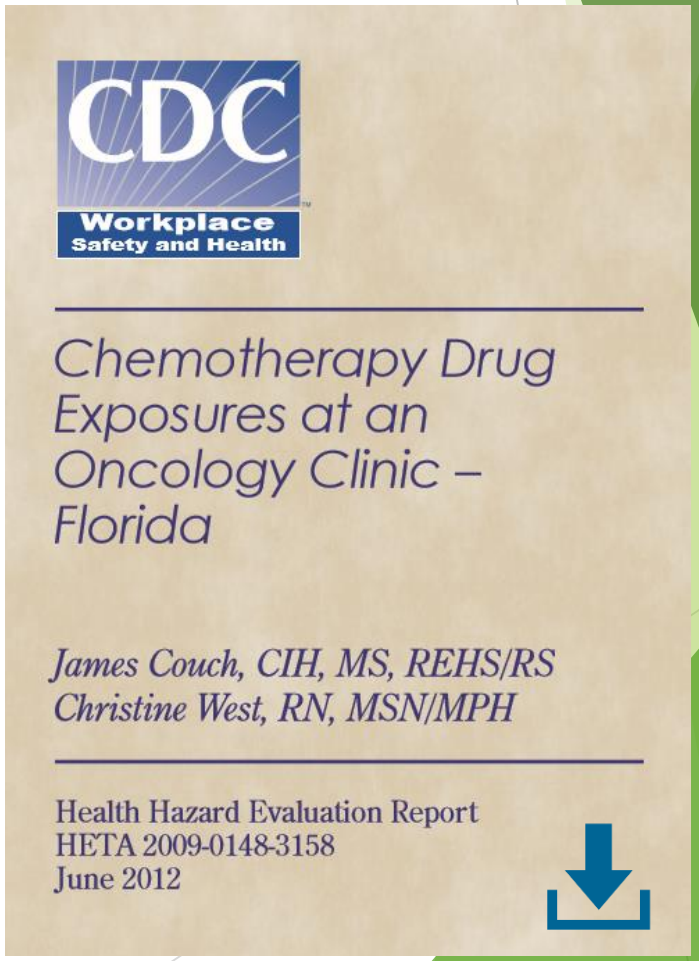
Connor TH. AJHP 7/1999; Connor TH. JOEM 10/2010

NIOSH Review of Exposure at an Oncology Clinic

- On May 1, 2009, NIOSH received a confidential employee request for an Health Hazard Evaluation at an oncology clinic in Florida. The request concerned potential exposures to chemotherapy drugs and adverse health effects such as upper respiratory symptoms, rash, diarrhea, migraine, and headache.
- Evaluation included
  - Surface and hand wipe samples
  - Health interviews
  - Biological Safety Cabinet evaluation
  - Review of housekeeping practices

NIOSH Review of Exposure at an Oncology Clinic

- Findings
  - Platinum in several of surface wipe samples, demonstrating that employees may be exposed to platinum-containing chemotherapy drugs, including cisplatin
  - Detected cyclophosphamide in the clinic pharmacy (on the floor in front of the BSC and the prepared drugs), the left treatment room (under the IV stand next to the first chair), and the checkout (desk surface on the right)
  - Cyclophosphamide was detected in every surface wipe sample collected in the checkout area
- Recommendations (see download link ➡)



Hazards in Health Care Settings

(What's wrong with this picture?)

No. 56,786 MONDAY, FEBRUARY 23, 2015 $2.50

Slump, kdown nezuela

es the U.S. ic Chaos

OIL PIPELINE VETO EXPECTED TO BE FIRST IN A WAVE

'NEW PERIOD' FOR OBAMA

Strategy Aims to Protec Legacy in the Face of G.O.P. Opposition

By MICHAEL D. SHEAR and CORAL DAVENPORT

Tabitha Waugh, left, preparing to administer a chemo treatment at St. Mary's Medical Center in Huntington, W.Va., last October.

In Pre-Primary Pivot to Right, Walker Shifts Tone on Abortion

By TRIP GABRIEL

As Market Evolves, Health Care Opens Paths, Often for Women

NY Times: February 23, 2015

What's Wrong with this Picture?

- Opaque bag cover suggests a chemotherapy drug
- No protective gown
- No double gloves
- No gloves at all
- Working well above eye level

No. 56,786 MONDAY, FEBRUARY 23, 2015 $2.50

Slump, ...down ...nezuela

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WASHINGTON — ...

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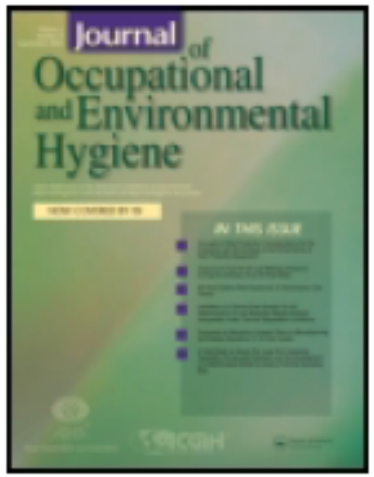
As Market Evolves, Health Care Opens Paths, Often for Women

This article is by Dionne Sear... Eduardo Porter and Robert ... was paying off.

NY Times: February 23, 2015

HD Work Practice Survey



Journal of Occupational and Environmental Hygiene

Publication details, including instructions for authors and subscription information:
http://www.tandfonline.com/loi/uoeh20

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

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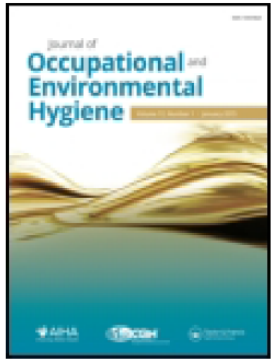
Accepted author version posted online: 25 Apr 2014.Published online: 25 Sep 2014.

Conclusions:

- Our results suggest that knowledge regarding risks associated with antineoplastic drugs can be improved, especially amongst job categories that are not tasked with drug preparation or drug administration.
- There is also a gap between knowledge and compliance with glove usage and hand hygiene.
- Training is also recommended to improve healthcare workers' perceptions of the risks associated with antineoplastic drugs.

HD Work Practice Survey



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Journal of Occupational and Environmental Hygiene

ISSN: 1545-9624 (Print) 1545-9632 (Online) Journal homepage: http://www.tandfonline.com/loi/uoeh20

Adherence to Precautionary Guidelines for Compounding Antineoplastic Drugs: A Survey of Nurses and Pharmacy Practitioners

Boiano JM, Steege & Sweeney MH. (2015) Adherence to Precautionary Guidelines for Compounding Antineoplastic Drugs: A Survey of Nurses and Pharmacy Practitioners, Journal of Occupational and Environmental Hygiene, 12:9, 588-602,

HD Work Practice Survey

Behavior	Nurses n=241	Pharmacy practitioners n=183
Not always wearing two pairs of chemo-therapy gloves	85%	47%,
Not always even a single pair of chemo-therapy gloves	8%	10%
Not always using closed system drug-transfer devices	75%	53%
Not always wearing recommended gown	38%,	20%
I.V. lines sometimes/always primed with antineoplastic drug	19%	30%
Always using either a biological safety cabinet or isolator	9%	15%
They also reported lack of:		
Hazard awareness training	9%,	13%
Safe handling procedures	20%	11%
Medical surveillance programs	61%	45%

Boiano JM, Steege & Sweeney MH. (2015) Adherence to Precautionary Guidelines for Compounding Antineoplastic Drugs: A Survey of Nurses and Pharmacy Practitioners, Journal of Occupational and Environmental Hygiene, 12:9, 588-602,

Nurse Attitude towards Safe Handling

- Most oncology nurses accept the fact that HDs are harmful, and that exposure should be avoided.
- Yet, what some clinicians fail to recognize is that they are potentially exposed when performing routine handling activities or that they might be personally vulnerable to the adverse effects of exposure. Recent studies indicate nurses' HD exposure is frequent enough to warrant concern

Frequency	Type of Exposure	Time Frame
11%– 17%	Dermal or eye exposure	Previous year
12%– 26%	HD spills	Previous week – 6 months
12%–24%	Took home potentially contaminated clothes	No time frame
6%–8%	Sharps injury involving HDs	Previous year

https://www.oncnursingnews.com/publications/oncology-nurse/2017/march-2017/attitude-shift-making-safe-handling-of-hazardous-drugs-a-priority-

Skin contact

- Workers from 6 Canadian hospitals sampled
- Wiped front and back of hands
- Analyzed for cyclophosphamide
- 44/225 (20%) had levels above the limit of detection
- A number of workers from various job categories had contaminated hands
  - Volunteer, oncologist, aide and dietician
  - Pharmacist, pharmacy technician, pharmacy receiver, nurse, transporter

Hon CY, Teschke K, Demers PA and Venners S. Antineoplastic drug contamination on the hands of employees working throughout the hospital medication system. Ann Occup Hyg. 2014; 58:761-770.

Letter from OSHA, NIOSH and The Joint Commission

April 4, 2011

Dear Colleague:

Every day in healthcare settings across America, workers are exposed to hundreds of powerful drugs used for cancer chemotherapy, antiviral treatments, hormone regimens and other therapies. While these drugs are used to relieve and heal patients, many of them present serious hazards to the health and safety of your workers. Some of these drugs have been known to cause cancer, reproductive and developmental problems, allergic reactions, and other adverse effects that can be irreversible even after low-level exposures.

Joint Statement: ASCO, ONS and HOPA

It is the position of the Oncology Nursing Society, the American Society of Clinical Oncology, and the Hematology/Oncology Pharmacy Association that

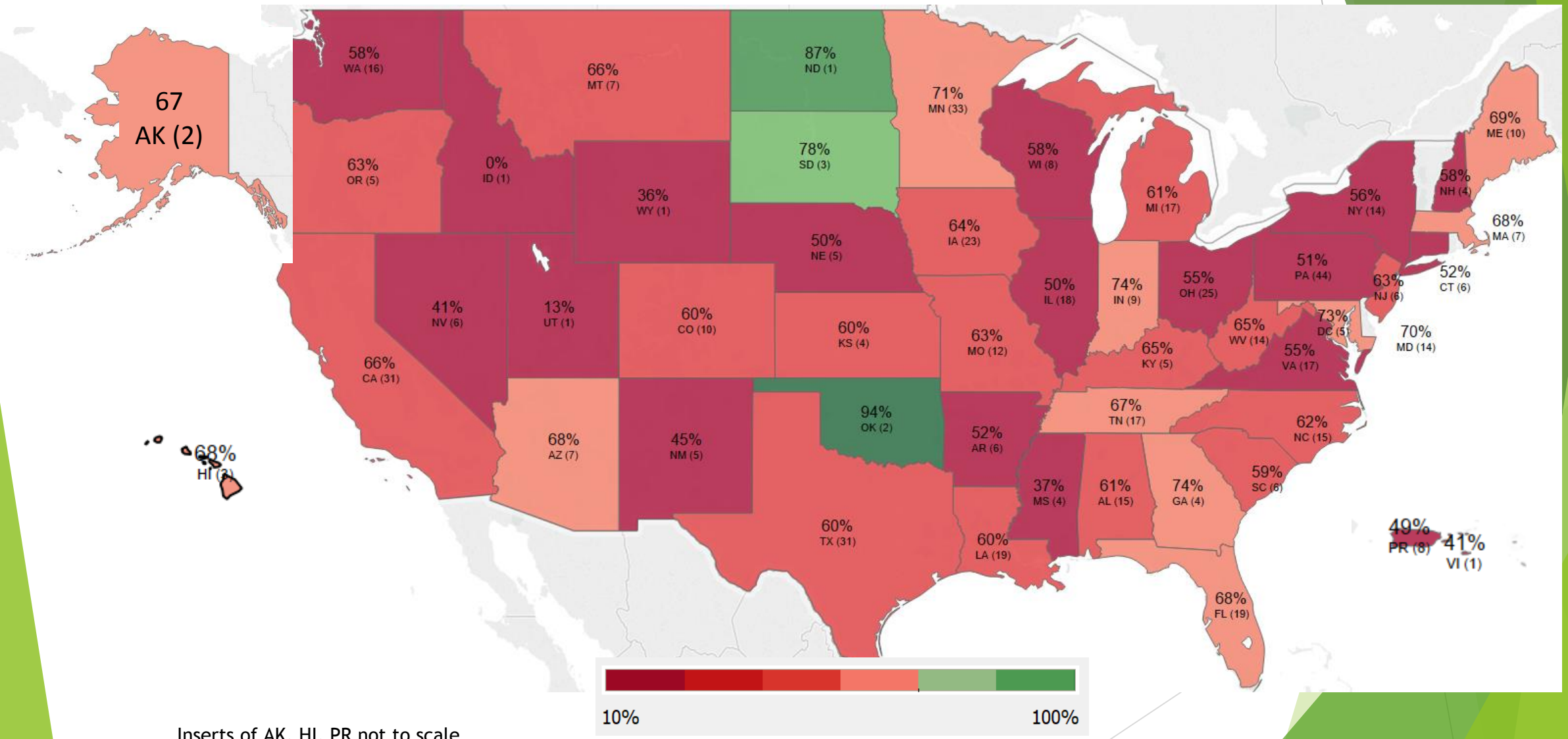
- Organizations in which HDs are present will establish evidence-based policies and procedures for safe handling that comply with regulatory requirements.
- Organizations in which HDs are prepared and administered will provide and maintain primary engineering controls and evaluate the utility of supplemental engineering controls such as closed-system transfer devices to reduce worker exposure.
- Organizations in which HDs are present will ensure that appropriate personal protective equipment is available to all staff to minimize exposure.
- Organizations in which HDs are present will provide education and training specific to each worker's role for staff who are potentially exposed. Education and training will include the risks of exposure, including the reproductive and developmental effects, the recommended precautions for specific handling activities, safe handling of contaminated patient excreta, proper disposal of contaminated waste, and how to handle acute exposure.
- Organizations in which HDs are present will protect the right of staff who are trying to conceive, pregnant, or breast feeding to engage in alternative duty that does not require HD handling.
- Organizations in which HDs are present will ensure that patients who receive these drugs and their caregivers receive education about safe handling to minimize unintended exposure.
- Organizations will ensure that HD waste is disposed of according to regulatory guidelines and in a manner that protects staff and the environment.
- Our professional societies will continue to explore evidence-based strategies for mitigation of risk associated with handling HDs and share recommendations with our respective members.

Alarming Studies

- 2017
  - Meta-analysis of 39 published studies "…confirmed a significant association between occupational exposure during the course of a normal workday and increases in chromosomal aberration in healthcare workers"

Roussel C et al. *Mutat Res Rev Mutat Res*. In press, online 24 Aug 2017. http://dx.doi.org/10.1016/j.mrrev.2017.08.002

USP <800> Overall Self-Reported Compliance by State
(all provider types)



Inserts of AK, HI, PR not to scale
No applicable data if state is greyed out

2017 Overall USP <800> Self-Reported Compliance by Domain

	Hospital	Non-Hospital	Grand Total
USP 800: Administration	62%	69%	63%
USP 800: Compounding	64%	74%	66%
USP 800: Decontamination, Cleaning and Disinfection	73%	72%	73%
USP 800: Dispensing Final Dosage Forms	96%	88%	95%
USP 800: Documentation and SOPs	44%	45%	45%
USP 800: Facilities and Engineering Controls	62%	65%	63%
USP 800: Hazard Communication Program	45%	50%	46%
USP 800: Hazardous Drug List	54%	49%	53%
USP 800: Labeling, Packaging, Transport and Disposal	58%	57%	58%
USP 800: Personal Protective Equipment	63%	62%	63%
USP 800: Personnel Training	45%	52%	46%
USP 800: Receiving	55%	61%	56%
USP 800: Responsibilities of Personnel	58%	58%	58%
USP 800: Spill Control	46%	57%	48%
Grand Total	61%	62%	61%

No
Tin

Chapter <800> Domain	All Providers		Hospitals Only	
	2016	2017	2016	2017
Administration	67	63	66	62
Compounding	72	66	69	64
Decontamination, Cleaning and Disinfection	77	73	75	73
Dispensing Final Dosage Forms	97	95	97	96
Documentation and SOPs	50	45	47	44
Facilities and Engineering Controls	64	63	64	62
Hazard Communication Program	56	46	52	45
Hazardous Drug List	52	53	50	54
Labeling, Packaging, Transport and Disposal	64	58	62	58
Personal Protective Equipment	65	63	64	63
Personnel Training	53	46	49	45
Receiving	58	56	56	55
Responsibilities of Personnel	64	58	61	58
Spill Control	55	48	54	46
Overall Compliance	***64***	***61***	***63***	***61***

USP <800> Self-Reported Compliance by Practice Setting

	Alt. Site Provider	Central Fill/ Outsource	Clinic	Community Pharm	FDA Registered	Hospital	MD Office	Other	Grand Total
USP 800: Administration	73%	60%	71%	40%	100%	62%	50%	71%	63%
USP 800: Compounding	86%	100%	74%	69%	50%	64%	57%	46%	66%
USP 800: Decontamination, Cleaning and Disinfection	78%	82%	82%	64%	42%	73%	48%	54%	73%
USP 800: Dispensing Final Dosage Forms	96%	100%	93%	80%	100%	96%	100%	67%	95%
USP 800: Documentation and SOPs	51%	33%	45%	44%	33%	44%	33%	37%	45%
USP 800: Facilities and Engineering Controls	72%	72%	67%	61%	53%	62%	37%	54%	63%
USP 800: Hazard Communication Program	55%	50%	50%	72%	50%	45%	50%	29%	46%
USP 800: Hazardous Drug List	52%	50%	42%	74%	0%	54%	17%	46%	53%
USP 800: Labeling, Packaging, Transport and Disposal	72%	40%	57%	49%	0%	58%	20%	42%	58%
USP 800: Personal Protective Equipment	71%	87%	60%	63%	63%	63%	33%	47%	63%
USP 800: Personnel Training	56%	50%	57%	63%	33%	45%	25%	40%	46%
USP 800: Receiving	70%	69%	66%	53%	29%	55%	36%	42%	56%
USP 800: Responsibilities of Personnel	69%	0%	52%	67%	50%	58%	38%	45%	58%
USP 800: Spill Control	64%	50%	71%	44%	0%	46%	25%	42%	48%
Grand Total	70%	68%	64%	61%	44%	61%	36%	47%	61%

USP <800> Self-Reported Compliance by Negative Findings (all providers)

	Negative Findings	No Negative Findings	Grand Total
USP 800: Administration	63%	63%	63%
USP 800: Compounding	64%	68%	66%
USP 800: Decontamination, Cleaning and Disi..	71%	74%	73%
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Grand Total	59%	62%	61%

Practitioner Knowledge

Who knows this?

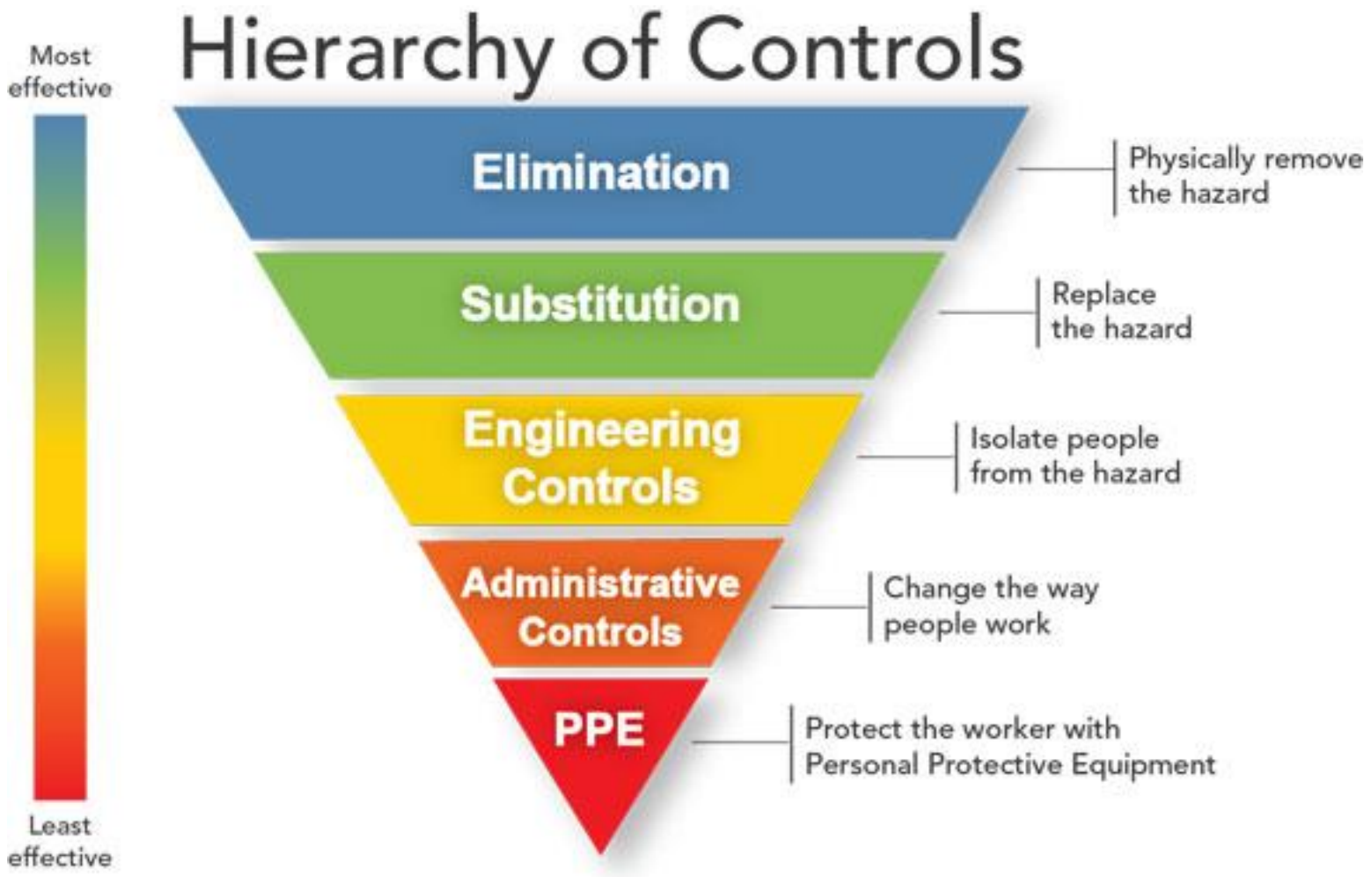
Who has been left out of the loop?

DAN BEGAN TO SUSPECT HE'D BEEN LEFT OUT OF THE LOOP AGAIN.

Show Me the Science

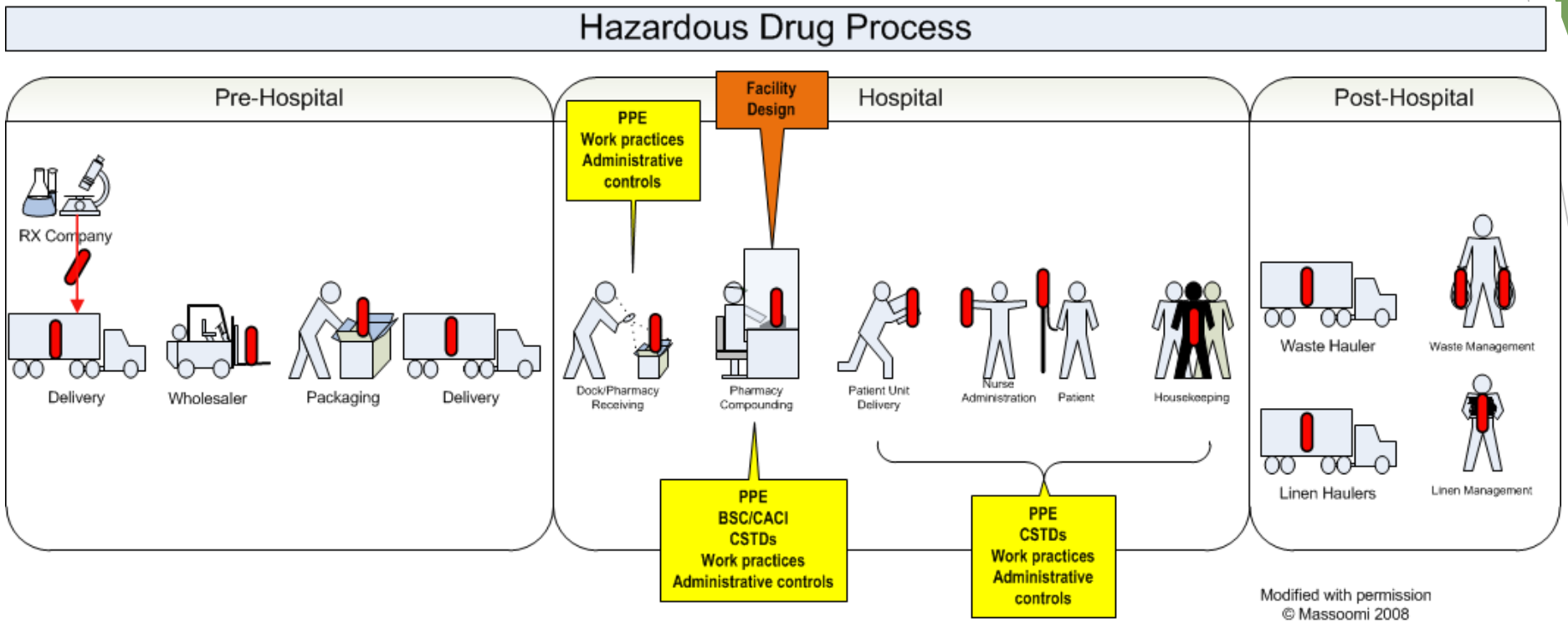
www.cdc.gov/niosh/topics/hazdrug/

NIOSH Hierarchy of Controls



https://www.cdc.gov/niosh/topics/hierarchy/default.html

Occupational Exposure Strategies



Denotes Hazardous Drug (HD) Product and Exposure Potentials

Denotes Occupational Exposure Prevention Strategies

Denotes Containment Prevention Strategies

Cost to Protect From Radiation

- Personal Protective Equipment
  - Lead Apron costs range from $300 - $700
    - Must Fluoro test annually
  - Lead glasses $150
  - Lead gloves $250

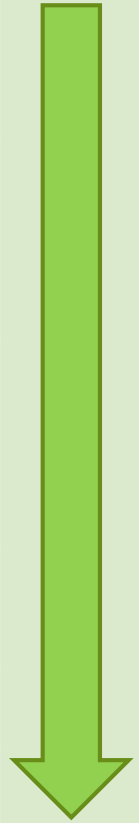
- Personal Dosimeters
  - high energy, low energy; body badge, ring badge
  - 1,086 badges, $26,340/year

- Upcharge for delivery of Isotopes

NIOSH Hierarchy of Controls

- USP <800> establishes the containment strategies and work practices best known to control occupational hazards based on NIOSH documents
  - Engineering controls
  - Protective equipment
  - Work practices

Factors Affecting Workplace Contamination

	Increase	Decrease	
	More hazardous drugs in use	Better awareness	
	More patients receiving hazardous drugs	Improved engineering controls	
	New procedures/ applications for hazardous drugs	New and updated guidelines	
		Closed system transfer devices	
		Robotics	
		Legislation	

Key Items to Consider

- This is not new information
  - There have been guidance documents in the pharmacy literature for over 30 years
- You need a proper facility
  - All compounding of hazardous drugs must be done in a negative pressure room
- There are things you can work on to improve personnel safety
  - HD list, policies and procedures, personnel training and monitoring, proper PPE, use of CSTD, decontamination and cleaning can be implemented at every site now

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Resources

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