


Preventing Occupational Exposure to Hazardous Drugs

September 16, 2016

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MHCSA: Who we are

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The mission of the **Michigan Health Care Safety Association (MHCSA)** is to promote and maintain safety as a primary function in the delivery of quality health care services. As a statewide organization of professionals, MHCSA will provide resources, leadership and educational opportunities to its membership and the health care industry.


www.mhcsa.org



2016 MHCSA Quarterly Meetings

- Friday, March 1, 2016
- Thursday, June 16, 2016
- Friday, September 16, 2016
- Friday, November 4, 2016 - Conference

\$25 Annual Membership
To apply, see website at www.mhcsa.org.



Mark your calendar



MHCSA Fall Conference

November 4, 2016
8:30 am – 3:25 pm

Registration
\$60 fee. Each participant completes the attached form to register. Payment includes light morning snack, lunch, and 2017 membership.

Conference features
National speakers. Hot topics. Networking. MHCSA Membership.

For more information
Contact: Janice Monette | jmonette@mhcsa.org | 517.886.7972



Safe Patient Mobilization

Revitalize Your Slip Trip and Fall Program

Ventilation and the Joint Commission

Essential Elements of a Workplace Violence Prevention Program

Revitalize Your Sharps Injury Prevention Program

Location:
St. Mary Mercy Livonia
34425 Ford Walk Road
Livonia, MI 48154

South entrance
Room 2000, 2nd level
www.stmarymercy.org



Our Speaker

Janelle Thelen

Senior Industrial Hygienist

MIOSHA

Consultation, Education, and Training Division

thelenj10@michigan.gov

313-580-9803



PREVENTING OCCUPATIONAL EXPOSURE TO HAZARDOUS DRUGS

Module 1

Consultation Education & Training Division
Michigan Occupational Safety & Health Administration
www.michigan.gov/miosha
517-284-7720



MODULE 1 TRAINING OVERVIEW

- Hazardous drug categories
- Specific hazards of drugs
- Employees at risk
- Applicable MIOsha standards
- Resources

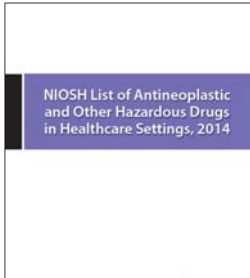


HAZARDOUS DRUGS

- Anti-neoplastic medications
- Anti-viral drugs
- Hormones
- Bioengineered drugs




LIST OF HAZARDOUS DRUGS




- Carcinogenicity
- Teratogenicity or other developmental toxicity
- Reproductive toxicity
- Organ toxicity at low doses
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria
- Proposed 2016 revision

www.cdc.gov/niosh/docs/2014-138



NIOSH LIST OF HAZARDOUS DRUG

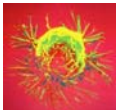

- **Table 1:** Antineoplastic drugs
- **Table 2:** Non-antineoplastic that meet one or more of the NIOSH criteria for a hazardous drug
- **Table 3:** Drugs that primarily pose a reproductive risk to men and women who are actively trying to conceive and women who are pregnant or breastfeeding



WHAT ARE THE HAZARDS OF EXPOSURE?

Hazardous drugs may cause the following:

- Cancer
- Developmental or reproductive toxicity
- Genotoxicity: Chromosome 5 or 7 changes
- Harm to organs:
 - Liver
 - Kidney
- Nausea
- Rashes
- Hair loss
- Hearing loss





HAZARDOUS DRUGS THAT ARE CARCINOGENS

<u>Known Carcinogens</u>	<u>Probable Carcinogens</u>	<u>Possible Carcinogens</u>
Arsenic trioxide	Tamoxifen	Azacitidine
Azothiaprine	Thiotepa	Carmustine
Busulfan	Treosulfan	Cisplatin
Chlorambucil	MOPP*	Doxorubicin
Cyclophosphamide	ECB*	Lomustine
Etoposide		Nitrogen Mustard
Melphalan		Procarbazine
Semustine		Teniposide
		Amsacrine
		Bleomycin
		Dacarbazine
		Daunorubicin
		Mitomycin
		Mitoxantrone
		Streptozocin

*Combination regimens

International Agency for Research on Cancer (IARC) <http://www.iarc.fr/>



WHO IS AT RISK?

- Pharmacy staff
- Nursing staff
- Physicians
- Medical assistants
- Operating room staff
- Veterinary care workers
- Research staff in laboratories
- Environmental service workers
- Shipping and receiving personnel
- Others



POTENTIAL ROUTES OF EXPOSURE

- Dermal absorption:
 - Direct drug contact
 - Contact with contaminated surfaces*
 - Contact contaminated body fluids
- Injection:
 - Sharps
 - Breakage
- Ingestion via contaminated:
 - Food, gum
 - Hand-to-mouth transfer
- Inhalation:
 - Aerosols
 - Vapors

ASHP, 2006; NIOSH, 2014; Polovich, et. al. (ONS), 2014; Polovich, 2011



EXPOSURE OPPORTUNITIES: DRUG PREPARATION

- Unpacking / stocking hazardous drugs
- Handling drug vials
- Breaking open ampoules
- Reconstituting / mixing drugs
- Pressure build-up in vials
- Transferring drugs from one container to another
- Needle sticks
- Crushing oral forms



EXPOSURE OPPORTUNITIES: DRUG ADMINISTRATION

- Injected drugs
 - Aerosols from purging air
 - Needle-sticks
- Intracavitary drugs
 - Poor fitting connections
 - Splashing
- Intravenous infusions
 - Spiking into a drug-filled bag
 - Leaks from prime tubing
 - Loose connections
 - Needle-sticks
 - "Un-spiking"
- Oral drugs
 - Broken tablets / capsules
 - Crushing tablets / opening capsules
 - Spilling liquid forms



EXPOSURE OPPORTUNITIES: DRUG DISPOSAL

- Handling contaminated materials
 - Used IV equipment
 - Residual drug
 - Used personal protective equipment
- Carrying drug waste from administration site to disposal site
- Reaching into waste containers
- Using wrong containers
- Over-full containers



EXPOSURE OPPORTUNITIES: CONTAMINATED EXCRETIONS

- Variable HD excretion: hours to days (48 hours average)
- Handling body fluids of patients who have received HDs
 - Urinals / urine
 - Bedpans / stool
 - Emesis basins / emesis
 - Sweat (?)
 - Flushing toilets
 - Linen contaminated with bodily fluids



APPLICABLE MIOSHA REGULATIONS

- Hazard Communication - MIOSHA Part 92/430
- Personal Protective Equipment - MIOSHA Part 33/433
- Respiratory Protection - MIOSHA Part 451
- Bloodborne Infectious Diseases - MIOSHA Part 554
- Housekeeping – MIOSHA Part 1
- Sanitation – MIOSHA Part 474
- Recordkeeping – MIOSHA Part 11



MIOSHA PART 92/430 HAZARD COMMUNICATION (HAZ COM)

Requires manufactures and employers to provide chemical safety and health information to employees:

- Written Program
 - Chemical Inventory (list of chemicals)*
 - Multi-employer worksites
 - Non-routine Tasks
- Labeling
- Safety Data Sheets (SDSs)
- Training*



* List of Hazardous Drugs reviewed annually and annual documented effective training competency is required by U.S. Pharmacopeial Convention (USP) <800>



SAFETY DATA SHEETS (SDSs)

Maintain SDSs for all hazardous chemicals

○ Examples:

- Hazardous drugs (liquid or powdered)
- Disinfectants
- Oxygen

○ Consumer products exemptions:

- Personal use items (i.e. hairspray, aspirin)
- Other household products used for purpose and quantity intended in the home.

○ Contact manufacturer/distributor/supplier when required SDS not received



SAFETY DATA SHEETS (SDSs)

NEW 16-SECTION STANDARDIZED SDS FORMAT REQUIRED (ANSI Z400.1)

Section 1 – Identification

Section 2 – Hazard(s) identification

Section 3 – Composition/Ingredients

Section 4 – First-aid Measures

Section 5 – Fire-fighting Measures

Section 6 – Accidental Release Measures

Section 7 – Handling and Storage

Section 8 – Exposure Controls / PPE

Section 9 – Physical and Chemical

Properties

Section 10 – Stability and Reactivity

Section 11 – Toxicological Information

Section 12 – Ecological Information*

Section 13 – Disposal Consideration*

Section 14 – Transport Information*

Section 15 – Regulatory Information*

Section 16 – Other information including date of preparation of last revision

*Sections outside of MIOSHA jurisdiction but inclusion of these sections is necessary for a GHS compliant SDS



MIOSHA PART 33/433

PERSONAL PROTECTIVE EQUIPMENT (PPE)

MIOSHA Parts 33 and 433:

- Perform a Job Hazard Assessment (JHA)
- Certification of hazard assessment
- Employee training
- Clean and sanitize multi-user PPE





PPE HAZARD ASSESSMENT

An employer shall:

- Assess the workplace to determine hazards present
- Select PPE needed and required to perform the job
- Communicate selection decision to employees
- Written certification of PPE assessment including
 - Workplace evaluated
 - Person who certified assessment
 - Date of hazard assessment completion



MIOSHA PART 451 RESPIRATORY PROTECTION





MIOSHA PART 451 RESPIRATORY PROTECTION

Employer must evaluate exposure and determine:
If respiratory protection is required

Examples:


- Aerosolization of hazardous drugs – ribavirin, pentamidine, others
- Preparing outside a biological safety cabinet- fluorouracil, cyclophosphamide, crushing tablets/dust
- Spill response



SELECTING THE APPROPRIATE RESPIRATOR

All must be NIOSH Certified. The type selected depends on the task and form of the drug.



- Surgical mask: Not appropriate; not a respirator
- N-95: for particles but not for vapors or splash
- Surgical N-95: for particles and splash but not for vapors
- Half-mask with a multi-gas cartridge and P100-filter: unpacking HDs that are not contained in plastic (USP 800 requirement)
- Full-face piece chemical cartridge-type respirator: for large spills or while compounding where vapor protection is needed
- Powered air purifying respirator: for large spills or while compounding



MIOSHA PART 451 RESPIRATORY PROTECTION EMPLOYER RESPONSIBILITIES


For required use of a respirator, the employer must:

- Supply required respirators at no cost to the employees
- Maintain a written program by a program administrator
- Provide training:
 - Use
 - Limitations
 - Proper care, maintenance and disposal
- Medical Evaluation
- Fit testing – complete initial then annually





TYPES OF RESPIRATORS



Surgical N-95 w/fluid protection



Full Face Air purifying w/HEPA filter




Powered air purifying respirator (PAPR)





EVALUATION OF RESPIRATORY PROTECTION

Is this a respirator?
Is this proper use?




1.



2.




MIOSHA PART 554 BLOODBORNE INFECTIOUS DISEASES



MIOSHA PART 554 BLOODBORNE INFECTIOUS DISEASES

- Applies where reasonable anticipation of occupational exposure to blood or other potentially infectious materials
- Needle stick with needle contaminated only with hazardous drugs are not covered by Bloodborne Standard
- Bloodborne Standard engineering and work practices controls could be implemented to reduce exposure to hazardous drugs



BLOODBORNE EXPOSURE CONTROL PLAN RELATED PROVISIONS

- Exposure determination
- Summary of the training program.
- Procedures for evaluating exposure incidents
- Task-specific SOP's to include:
 - Employee recognition of exposure
 - Personal Protective Equipment (PPE) selection, use, maintenance, and disposal
 - Contingency Plans
- Task-specific SOPs for management of inadvertent exposures such as needlesticks



WASTE DISPOSAL

Containers or bags that are:

- Closable
- Leak-proof
- Color-coded or labeled

For contaminated sharps all the above plus puncture-resistant



(Image used with permission)



MIOSHA PART 1 GENERAL PROVISIONS AND PART 474 SANITATION

General Provisions – Housekeeping:

- Materials shall be placed in a container in a manner that does not create a hazard to an employee
- All places of employment, aisles, passageways, storerooms, and service rooms shall be kept clean and orderly

Sanitation - Food and beverages:

- No employee shall be allowed to consume food or beverages in any area exposed to a toxic material
- Food or beverages shall not be stored in an area exposed to a toxic material



MIOSHA Part 11 Recording and Reporting Occupational Injuries and Illnesses



WHO MUST KEEP MIOSHA RECORDS?

- Employers with more than 10 employees during the previous calendar year.
- Employers selected to participate in the mandatory Bureau of Labor Statistics (BLS) annual survey.
- Partially Exempt employers:
 - Employer with ≤ 10 employees during the previous calendar year.
 - Employers in designated North American Industry Classification System (NAICS) codes.



PARTIALLY EXEMPT HEALTHCARE INDUSTRIAL CODES

- 6211 Offices of Physicians
- 6212 Offices of Dentists
- 6213 Offices of Other Health Practitioners
- 6214 Outpatient Care Centers
- 6215 Medical and Diagnostic Laboratories



“PARTIALLY EXEMPT” MUST REPORT WHEN:

- When requested to record/report by the Bureau of Labor Statistics (BLS)
- Any workplace incident that results in:
 - fatality
 - in-patient hospitalization
 - amputation
 - loss of an eye



EXPANDED REPORTING REQUIREMENTS

Began **September 1, 2015**, all covered employers **must report** the following:

- Within 8 hours: any work-related fatality (No change from previous requirement)
- Within 24 hours:
 - work-related in-patient hospitalizations of one or more employees
 - work-related amputations
 - work-related losses of an eye



OCCUPATIONAL DISEASE REPORTING

- Employee information
- Employer information
- Illness and comments information
- Report submitted to the State (see MIOSHA website)

Michigan Department of Licensing and Regulatory Affairs Management and Technical Services Division
Known or Suspected Occupational Disease Report
(Information will be held confidential as prescribed in Act.)

EMPLOYEE AFFECTED					
Name (Last, First, Middle)	Age	Sex M F	Race: <input type="radio"/> White <input type="radio"/> Black <input type="radio"/> Hispanic <input type="radio"/> Other		
Street	City	State	Zip		
Home Phone Number	Last Four Digits of Social Security Number (Optional)				
CURRENT EMPLOYER					
Current Employer Name	Worksite County				
Worksite Address	City	State	Zip		



MIOSHA RESOURCES: STANDARDS AND COMPLIANCE

- Compliance Instruction (coming soon)
- [Part 92 and 430 Hazard Communication](#)
- [Part 431 Hazardous Work in Laboratories](#)
- [Part 33](#) and [Part 433](#) Personal Protective Equipment
- [Part 451 Respiratory Protection](#)
- [Part 474 Sanitation](#)
- [Part 554 Bloodborne Infectious Diseases](#)
- [Recording & Reporting of Occupational Injuries & Illnesses](#)



MIOSHA RESOURCES: CONSULTATION AND TRAINING

- [Preventing Exposure to Hazardous Drugs Training Module 1 – Overview](#)
- Preventing Exposure to Hazardous Drugs Training Module 2 – Staff (coming soon)
- [Fact Sheet: Preventing Exposure to Hazardous Drugs](#) (doc)
- [Hazard Communication Sample Plan](#) (doc)
- [Personal Protective Equipment Guide](#) (doc)
- [Respiratory Protection Program](#) (doc)
- [Bloodborne Sample Exposure Control Plan](#) (doc)



FEDERAL RESOURCES

Centers for Disease Control and Prevention:
[NIOSH Hazardous Drugs webpage](#)

OSHA:

- [Hazardous Drugs Website](#)
- [Hazardous Drugs eTool](#)
- Technical Manual Section VI: Chapter 2:
[Controlling Occupational Exposure To Hazardous Drugs](#)

