Hazardous Drugs

HAWAIʻI PACIFIC HEALTH

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Course Objectives

After completion of this module, the learner will be able to:

- State the definition of a hazardous drug.
- Identify the different groups of hazardous drugs, and appropriate handling precautions for each category.
- State how you will know if your patient is receiving a hazardous drug.
- Know where to find specific PPE recommendations.
- Describe principles of storage, transport, administration, post-administration and disposal of hazardous drugs and waste.
- Describe how to manage spills, exposures and injuries related to hazardous drugs.
- Know where to find policies and procedures related to hazardous drugs, chemotherapy / biotherapy administration, hazardous waste, and spill management for more information.

Hazardous Drug – Definition

- A drug that possesses any one of the following six characteristics in humans or animals:
  - 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

National Institute for Occupational Safety and Health
NIOSH

Hazardous Drug Categories

Hazardous drugs are categorized into 3 groups:

- Antineoplastic Hazardous Drugs
- Non-Antineoplastic Hazardous Drugs
- Reproductive Risk Hazardous Drugs

Antineoplastic Hazardous Drugs

- Cytotoxic drugs that represent the highest risk for occupational hazard

- Example drugs
  - Chemotherapy
  - BCG (Bacillus Calmette-Guerin)

Non-Antineoplastic Hazardous Drugs

- Drugs that are not classified as antineoplastics (preventing growth and spread of tumors) but do meet characteristics of a hazardous drug
- Example drugs
  - Immunosuppressants: Cyclosporine, Cellcept
  - Estrogen products
  - Gancyclovir, Valgancyclovir

Reproductive Risk Hazardous Drugs

- Drugs that represent a potential occupational hazard to males and females actively trying to conceive, and pregnant and breastfeeding women
- Example drugs
  - Carbamazepine, Oxcarbazepine
  - Fosphenytoin, Phenytoin
  - Clonazepam
  - Fluconazole
  - Spironolactone

How do I know if my Patient is Receiving a Hazardous Drug?

- All hazardous medications will be labeled by pharmacy
  - Antineoplastic Hazardous Drug

  - Non-Antineoplastic Hazardous Drug

  - Reproductive Risk Hazardous Drug

- EPIC notation of hazardous drugs are found in the administration instructions field of the MAR and the EPIC medication label (if one is provided)
- Pyxis notation of non-cytotoxic hazardous drugs or reproductive risk hazardous drugs is found on the removal screen for those that are loaded in Pyxis (if they are loaded)
- A complete list of hazardous drugs may be found in the *Hazardous Drugs, Preparation and Handling* Policy and Procedure

Requirements

- OSHA requires every hospital to develop and implement policies and procedures addressing protective measures for handling hazardous drugs. The intention is to protect the employee, the patient, and the environment.

- The *Hazardous Drugs, Preparation and Handling* policy and procedure can be found on the Intranet in the Policy and Procedure database

Employee Screening

- Employees with high risk for hazardous drug exposure will be offered a health assessment at the following intervals:
  - Before job placement
  - Periodically during employment
  - Following acute exposures
  - Upon job exit
- See *HPH Cytotoxic Drug Handlers Medical Surveillance Policy and Procedure* on the Intranet for more details

Main Routes of Possible Exposure

- Inhalation
- Absorption
- Ingestion
- Injection through Accidental Needle Stick
- Drug Vaporization

- Exposure occurs when safe handling measures fail or when they are not used
- The safest possible amount of exposure is NO exposure

Personal Protective Equipment (PPE)

- Studies have shown that the use of PPE reduces the risk of exposure to hazardous drugs. Together with other safe handling precautions, PPE reduces the incidence of adverse health effects from exposure to hazardous drugs.
- Recommendations for PPE are dependent on the hazardous drug category, drug formulation and activity being performed.
- Required PPE by hazardous drug category

Hazardous Drug Category	PPE Required?
Antineoplastic Hazardous Drugs	Yes – All Employees
Non-Antineoplastic Hazardous Drugs	
Reproductive Risk Hazardous Drugs	Only for men and women actively trying to conceive, and women who are pregnant or breastfeeding

Recommended PPE

Formulation	Activity	Gloves	Gown	Eye Protection	Respiratory Protection
IV solution	Administration	Double glove	Yes	Yes, if liquid could splash	Yes, if inhalation potential
IV solution	Compounding	Double glove	Yes	Yes, if not done in a control device	Yes, if not done in a control device
Intact tablet or capsule	Administration	Single glove	No	No	No
Tablet or capsule	Cutting, crushing or otherwise manipulating	Double glove	Yes	No	Yes, if not done in a control device
Oral liquid	Administration	Double glove	Yes	No, unless pt may resist or administered by feeding tube	No, unless pt may resist or administered by feeding tube

A complete list of PPE recommendations may be found in the *Hazardous Drug, Preparation & Handling* Policy and Procedure on the Intranet

Gown

- Lint-free, low permeability material
- Solid front (open at back), long sleeves, tight-fitting cuffs
- Cuffs should be worn over inner gloves and tucked under outer gloves – no skin should be exposed
- Shall only be used once, then removed and disposed of as trace-contaminated hazardous waste
- Promptly change following any hazardous drug spills or exposure

Gloves

- Use chemotherapy gloves made of nitrile, neoprene or polyurethane
- Wash hands prior to donning and after removing gloves
- Pharmacy: With each new set of gloves, wipe gloves with 70% sterile IPA before you start working in the hood
- When to change gloves:
  - Every 30 minutes of continuous preparation
  - Whenever leaving the work area
  - Immediately if they are torn, punctured or contaminated with a hazardous drug

- If double gloves are required, outer gloves should be removed first, then the gown, followed by inner gloves last
- Dispose of used gloves as trace-contaminated hazardous waste

Additional PPE

- Respiratory Protection
  - A NIOSH-approved respirator must be used if a biological safety cabinet (chemo or IV hood) is not available
  - Surgical masks are not appropriate

- Eyes and Face Protection
  - Must be used whenever the potential for splashes, sprays, and aerosols of hazardous drugs exist

- Shoe Covers
  - Must be worn in hazardous drug compounding areas to reduce possibility of contamination
  - Do not wear shoe covers outside the hazardous drug compounding area to avoid spreading drug contamination

Activities that Put the Health Care Worker at Risk for Exposure

- Preparation
- Transport
- Administration
- Disposal
- Handling of body fluids
- Cleaning up spills

Storage

- Storage in Pharmacy
  - Segregate hazardous drugs from non-hazardous drugs, unless the hazardous drug already exists in its final unit dose or unit-of-use packaging
  - Apply warning labels to all hazardous drugs, storage shelves, and general areas where these drugs are stored
  - Store hazardous drugs at or below eye level, in containers that minimize the risk of breakage and leakage, and never on the floor
- Storage in Pyxis

Hazardous Drug Category	Storage in Pyxis
Antineoplastic Hazardous Drugs	Never
Non-Antineoplastic Hazardous Drugs	Only intact unit dose oral formulations OK (i.e. intact tablet or capsule)
Reproductive Risk Hazardous Drugs	All formulations OK

Transport

- Delivery via pneumatic tube

Hazardous Drug Category	Transport via Pneumatic Tube
Antineoplastic Hazardous Drugs	Never
Non-Antineoplastic Hazardous Drugs	Only intact unit dose oral formulations OK (i.e. intact tablet or capsule)
Reproductive Risk Hazardous Drugs	All formulations OK

- Volunteers may not handle or transport hazardous drugs
- A spill kit is required for all transports
- A clean, leak-proof, breakage-resistant container must be used for transport
- Hazardous drugs will not be transported in the stairways

Intrathecal Chemotherapy

- Will be labeled as ‘INTRATHECAL’
- Will generally be prepared, dispensed and administered before any other chemo agent is prepared for that same patient
- Will never be sent in a container with other medications
  - Exception: Only vinka alkaloids that are prepared in a mini-bag – not possible to give intrathecally - may be dispensed with an intrathecal chemotherapy agent

‘FATAL if given intrathecally’

- Vinka alkaloids (vincristine, vinblastine) will be labeled ‘FATAL if given intrathecally’

FATAL if given intrathecally

(vin*cris*tine sulfate injection, USP)
PRESERVATIVE FREE SOLUTION
2 mg/2 mL
FATAL IF GIVEN INTRATHECALLY
FOR INTRAVENOUS USE ONLY

Administration

- Utilize PPE in all activities related to hazardous drug administration
- Place a disposable, absorbent plastic-backed pad under the connection to catch possible droplets and avoid exposing the patient's skin to the drug
- Change gloves every 30 minutes or immediately when torn, punctured or contaminated. Remove outer gloves first, then the gown, then the inner gloves last.
- All PPE worn for hazardous drug administration may only be used once, then removed and disposed of as hazardous waste.
- Wash hands before and after handling the drug, avoid touching the drug, and always wear gloves when handling the container of a hazardous drug.
- Wash surfaces that come into contact with the drug with soap and water, and dispose of toweling as hazardous waste.

Administration Cont'd

- Always place a plastic-backed protective pad under the container of chemotherapy (antineoplastic hazardous drugs).
- Never disconnect tubing from a bag of a hazardous drug.
- Pharmacy will prime all IV tubing with a non-hazardous solution unless otherwise indicated. Return the drug to pharmacy for correction if you identify an issue.
- Never express excess medication or air contained within a syringe into the air.
- Never crush, break or otherwise manipulate a hazardous drug. If the patient is unable to swallow pills, return the drug to pharmacy to prepare a suspension in the biological safety cabinet (chemo or IV hood). The family is never instructed to crush pills at home.

After Administration – Body Fluids

- Use universal precautions when handling blood, emesis or excretions of patients who have received a hazardous drug until 48 hours after the last dose. Wear a gown and eyes and face protection if splashing could occur.
- Provide a urinal with a tight fitting lid for male patients
- For patients using diapers, apply a protective barrier ointment to the diaper area to avoid painful chemical burns. Change diapers frequently and clean the skin well with each diaper change.
- Instruct family members to wear gloves when changing diapers or assisting the patient with toileting. Recommend that female family members who may be pregnant or breastfeeding refrain from handling excretions as much as possible.

After Administration - Linen

- Use universal precautions when handling linen soiled with blood or body fluids.
- Discard diapers and heavily soiled pads as hazardous waste for 48 hours following the last dose of a hazardous drug.
- After use, discard gloves and gown in the appropriate hazardous waste container.

Hazardous Drug Waste Disposal

- Waste containers
  - Should be available where hazardous drugs are prepared and administered
  - Must be puncture-proof with secure lid, and clearly labeled as hazardous waste
  - Any container 75% full should be sealed and disposed of in accordance with policies and procedures
- All materials and waste used in compounding and administering hazardous drugs should be considered contaminated and disposed of as hazardous waste
- All liquid should be contained in a closed system
- Only those Environmental Services personnel who have successfully completed an appropriate competency in safe handling procedures shall handle hazardous drug waste containers.

RCRA (PUD) Drugs

- The EPA's Resource Conservation and Recovery Act (RCRA) specifies 3 pharmaceutical categories of hazardous waste
  - P-listed drugs: Acutely hazardous
  - U-listed drugs: Chemical pharmaceuticals considered toxic
  - D-listed drugs: Ignitable, Toxic, Corrosive, and / or Reactive
- Discard P-, U-, and D-listed drugs (including the syringe, vial and tubing) in designated black boxes
- Refer to your facility's policy and procedure for more information on RCRA and PUD drugs

HPH Hospital Waste Disposal

Regular Waste: Clear Bag	Biohazardous Waste: Red Bag	Sharps: Sharps Disposal Containers	Yellow Chemotherapy Boxes	Special Waste	Hazardous Waste
❑ Trash ❑ Paper, Wrappers ❑ Dressings ❑ Chux ❑ Diapers ❑ Gloves ❑ Empty Foley Bags and Other Drainage Bags ❑ Disposable Patient Items ❑ Sanitary Napkins	❑ Blood and all **OPIM** (**O**ther **P**otentially **I**nfectious **M**aterial) ❑ Blood Tubing/ Bags/Hemovacs/ Pleurovacs ❑ **Soaked/ Dripping Bloody** Dressings. ❑ Intact Glass or Plastic Bottles with Bloody Fluid or OPIM ❑ Suction Liners with Bloody Fluid or OPIM ❑ All Disposable Items **Soaked or Dripping** with Blood or OPIM	❑ **All sharps** Example: needles, blades, scalpels, razors, pins, clips, staples ❑ All **empty** syringes, tubex, carpujects ❑ Trocars, introducers, guidewires, sharps from procedures, specimen devices in endoscopy etc.	**Trace Chemo:** ❑ All supplies used to make and administer chemotherapy medication ❑ Bulk Chemo (concentration greater than 3% of volume) Example: tubing, empty bags/ bottles/ vials, syringes, gloves, pads, masks, gowns, wipes etc. **Return all unused Chemotherapy to Pharmacy**	**Special Handling** Batteries ❑ Throw in the regular waste: • Alkaline batteries, unless you have > 100 ❑ Call Plant Ops for disposal: • Nickel cadmium, lead or lithium batteries	**Hazardous Pharmaceuticals** Federal **R**esource **C**onservation and **R**ecovery **A**ct (RCRA) All RCRA medications will be labeled by pharmacy with a black HW label HW

Management of Spills

- Any spillage should be managed in accordance with department and Environment of Care policies
- Spill kits, clearly labeled, should be kept in or near preparation and administration areas and during transport
- If the spill is manageable by the department, then it should be cleaned by staff in the immediate area
- Follow the instructions included with the spill kit
- Consult the Safety Data Sheet (SDS) for recommendations specific to the spilled drug or chemical

Safety Data Sheet (SDS)

- In case of chemical exposures or spills:
  - Call SDS Fax-on-Demand Program: **1-800-451-8346**
  - Provide the product name & manufacturer, and nearest fax machine number
  - The SDS will be faxed to you
- Access 3E's Healthcare SDS Database at:
  - www.3eonline.com
  - To login: enter Username **HPACHLTH** and password **MSDS**
  - Search by Product Name, Manufacturer, Chemical Name, CAS# (Chemical Abstract Services #)

Management of Spills Cont'd

- If the spill is deemed unmanageable by the department, a Code Orange should be called to the area of the spill
- If the patient received a partial dose prior to the spill, estimate amount of drug delivered and lost, and contact the ordering prescriber to determine plans for a replacement dose

Exposure & Injuries

- Immediately removed the contaminated PPE and dispose of in appropriate hazardous waste
- Immediately wash affected area with soap and water
- For eye exposure: immediately flood the affected eye with water for at least 15 minutes
- Obtain medical attention as soon as possible
  - Exposed employees – report to Employee Health or the Emergency Department if Employee Health is unavailable
  - Exposed family members – report to the Emergency Department

Exposure and Injuries Cont'd

- Call the HPH Work Injury Line (535-7200) as soon as possible to file an event report
- Immediately report all spills, exposures, injuries and unsafe conditions to the appropriate supervisor(s)

References

- Kam, Kristina: (Fall 2005) Quality Management Research: Staff's Adherence to Chemotherapy Protocols.
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- Power & Polovich: *Safe Handling of Hazardous Drugs.* Clinical Oncology News. March/April 2009
- Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. NIOSH. Department of Health and Human Services. September 2004
- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2014. Available at: http://www.cdc.gov/niosh/docs/2014-138/pdfs/2014-138_v3.pdf.

To access any of Hawai'i Pacific Health's policies regarding hazardous drugs, chemotherapy / biotherapy administration, hazardous waste, and spill management go to the Intranet and click **Policies and Procedures** in the left column.