





USP <800> HANDLING & ADMINISTRATION OF HAZARDOUS DRUGS FREQUENTLY ASKED QUESTIONS

OVERVIEW

- What is a hazardous drug (HD)?
 - A HD is any drug identified as hazardous or potentially hazardous by the National Institute for Occupational Safety and Health (NIOSH) on the basis of at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, and new drugs that mimic existing HDs in structure or toxicity.
- Is there a list of medications that are classified as hazardous?
 - Yes. The list changes as new drugs enter the market. Each drug considered hazardous will arrive with appropriate labelling and precautions stated. Our current hazardous drug list will be located at go-live in Lexicomp.

PERSONNEL

- What are health implications for staff who have administered and handled HDs until now?
 - The majority of studies related to health outcomes from occupational exposure are primarily aimed at chemotherapy drugs. Long-term health implications are not explained in detail for all hazardous drugs. More research is needed to quantify the degree of risk of exposure using administrative and engineering controls. Following USP <800> guidelines at UCM and Ingalls with full integration of PPE, including implementation of environmental and administrative controls, are critical steps to minimize risk and adverse outcomes to healthcare workers.
- What is the recommendation if staff are pregnant?
 - If a pregnant staff member's role involves handling of HDs, they can request alternative duty. This is at the discretion of the employee. Pregnant staff are encouraged to have a conversation with their direct supervisor regarding this. If a pregnant staff member wishes not to take alternate duty, the same safety measures for handling of HDs are taken as those that are not pregnant to minimize risk of exposure.
- Are there other categories for people that might be at higher risk other than pregnancy that may consider requesting alternate duty?
 - Anyone trying to conceive, both male and female
 - o Immunosuppressed
 - Breastfeeding parents
 - Staff within these categories are encouraged to have a conversation with their direct supervisor regarding this. If a staff member wishes not to take alternate duty, the same safety measures for handling of HDs are taken as those that are not within these categories to minimize risk of exposure.







ADMINISTRATION AND SAFE HANDLING

- How do we administer HDs when there is no closed system transfer device (CSTD) at the end of the primary line already in place?
 - Administer IV HD and add CSTD at the end of the line when next line change is due if ongoing doses of the IV HD will be given. This is to avoid frequent tubing disconnections, which could increase the risk of bloodstream infections.
- What is the priming volume of the Spiros CSTD?
 - The priming volume of the Spiros CSTD is 0.1mL



- Staff members may use face shields for extended periods of time so long as the face shield is not removed. Once a face shield is removed, it must be disposed of. Eye protection can be reused if cleaned with bleach then soap and water. However, it is preferred to dispose of eye protection after each use. Always immediately dispose of face shields and eye protection if worn during a hazardous drug spill or if the product is damaged.
- What precautions should be followed when administering ophthalmologic hazardous drugs?
 - Per <u>Managing Hazardous Drug Exposures: Information for Healthcare Settings (cdc.gov)</u> (pg. 38), ophthalmologic applications require double HD gloves and a HD gown. Add eye and face protection if administering a liquid that is likely to splash. In addition, closed system transfer devices (CSTDs) should be used if the dosage form allows.
 - Many of these preparations are very low volume (less than 1mL). Best practice in this case is to not utilize a CSTD but wear HD PPE to decrease occupational exposure, such as double HD gloves and HD gown. Don additional PPE for eye and face protection when the risk of splash is likely (e.g., HD eye drops).

PATIENT/FAMILY (Information will be included in Patient Education handouts)

- How do we explain these changes to patients/families? Example: Staff are now wearing PPE for medications in front of patient/families when this PPE was not being worn in the past.
 - National guidelines on safe handling of hazardous drugs have been updated and we are following these guidelines. The purpose of PPE is to decrease occupational exposure, since our healthcare workers handle these drugs for multiple patients throughout their careers. Educational forms are available and will be updated for go-live. See patient/family section below regarding FAQs related to safe handling of hazardous drugs in the home.
- Is it safe for my family members to have contact with me when I am receiving hazardous drugs?
 - Yes. Eating together, enjoying favorite activities together, hugging and kissing are all safe.









- Is it safe for my family to use the same toilet as I do when I am receiving hazardous drugs?
 - If possible, use of separate bathrooms during hazardous drug treatment is preferred. For homes with one bathroom, clean the toilet seat with sanitation wipes after each use. This wiping action helps to remove remaining drug from the surface while sanitizing the seat.
 - Precautions should be followed during treatment and 48 hours after treatment is done. Once precautions are over, washing toilet and bathroom floor around toilet is best. Wash hands with soap and water after using and cleaning the restroom.
- What if I use a bedpan, urinal, or commode?
 - Your caregiver should wear a double pair of gloves when emptying body wastes. Reusable items should be handled with a double pair of gloves and washed with soap and water.
- What if I vomit?
 - Your caregiver should wear a double pair of gloves when emptying the basin. The container should be washed with soap and water.
- What should I do if I do not have control of my bladder or bowels?
 - Use disposable, plastic-backed pad, diaper or sheet to soak up urine or bowel movements.
 Change immediately when soiled, wash skin with soap & water.
 - For ostomies, patient or caregivers should wear a double pair of gloves when emptying or changing bags. Dispose ostomy supplies into a double plastic bag for disposal along with gloves once removed. Wash hands with soap and water.
- Is it safe to be sexually active when receiving hazardous drugs?
 - Ask your healthcare provider this question. Traces of hazardous drugs may be present in semen and vaginal fluid for up to 48 hours after your treatment. Special precautions may be necessary.
- How should I store hazardous drugs at home?
 - You should store hazardous drugs and equipment in a safe place that is out of reach of children and pets. Avoid storing hazardous drugs in the bathroom because high levels of humidity can damage the drugs. Keep labels on medicine as they will also list if they need to be refrigerated or stored away from light. Review all directions with patient's specific medications and follow those as well. Speak with your pharmacist with additional questions.
- Is it safe to dispose of hazardous drugs in the trash?
 - No. If you have left over drugs there are special ways to dispose of these safely. Some pharmacies have bins that allow for unused drugs to be disposed. In addition, if you are receiving a hazardous drug infusion at home, you should receive a kit to dispose of hazardous waste. Follow disposal instructions from your healthcare team for hazardous drug infusions.
- Can I travel with my hazardous drugs?
 - Yes. Traveling is usually not a problem. Some hazardous drugs may require special storage requirements, such as refrigeration. If this is the case, you might need to make special arrangements. Check with your healthcare provider and pharmacy for specific instructions. When traveling, always seal your hazardous drugs in a plastic bag.







- What should I do if I spill hazardous drugs at home?
 - You will receive a spill kit with instructions on how to handle spills if you are receiving hazardous drug infusions at home from the company supplying you with the infusion pump and/or hazardous drug.

PPE SUPPLY

- Will there be an increase of PAR in the supply rooms for PPE?
 - Supply chain is working with leaders to ensure rooms are stocked for go-live needs. Additional PPE will be available to ensure protection. Reach out to your direct supervisor if you have identified a need for additional PPE supplies.

STUDENTS AND HAZARDOUS DRUGS

- Are nursing students allowed to administer hazardous drugs?
 - At this time, nursing students are not allowed to administer hazardous drugs since this is a new process within our facility. Information will be communicated if this changes in the future.

RESOURCES

Phone Numbers and Pagers

- UCM Environmental Health and Safety (EHS) 5-SAFE, pager 8382
- UCM Patent Safety Hotline 2-5544
- Ingalls Environmental Services (EVS) 6010, pager 1244
- Ingalls Risk Manager On-Call, pager 1241

UCM Policies

- PC146 Safe Handling and Administration of Designated Hazardous Drugs
- S04-11 Hazardous Material Spill Response
- S01-03 Hazardous Materials and Waste Management Plan.
- A06-01 Work Related Injury, Illness & Exposure Reporting
- S04-10-01 Pharmaceutical Waste Management Program

Ingalls Policies

- PH01-024 Hazardous Medications Disposal Spillage Contamination
- PH01-025 Hazardous Medications Receiving Preparation and Recordkeeping in Pharmacy







EXTERNAL RESOURCES

- The National Institute of Occupational Safety and Health (NIOSH)- Hazardous Drug Exposures in Healthcare https://www.cdc.gov/niosh/topics/hazdrug/default.html
- Centers for Disease Control and Prevention (CDC) and NIOSH- Managing Drug Exposures: Information for Healthcare Settings <u>Managing Hazardous Drug Exposures: Information for Healthcare Settings</u> (cdc.gov)
- U.S. Pharmacopeia (USP)- USP General Chapter <800> <u>https://www.usp.org/compounding/general-</u> <u>chapter-hazardous-drugs-handling-healthcare</u>

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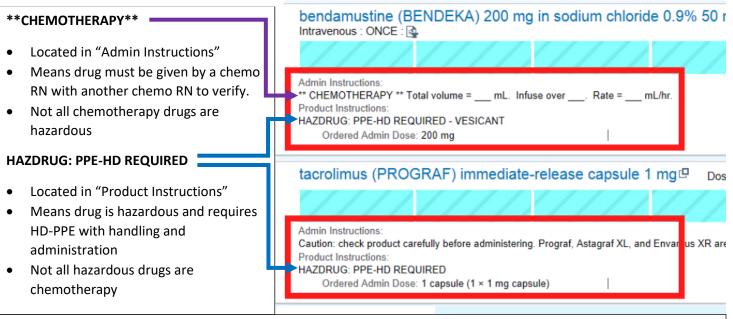
TIP SHEET: Nursing Management of Hazardous Drugs (HDs)

Effective October 17, 2023 UChicago Medicine will implement the United States Pharmacopeia (USP) Chapter <800> on standards for safe handling of HDs. Based on these standards, the list of HDs has expanded. As such, repeated exposure to HDs may result in acute and/or chronic health effects in healthcare workers. The purpose of this tip sheet is to provide a quick guide on how best to identify these drugs and protect yourself from exposure when handling them.

#1 Tip: Identification of HDs

• A warning statement "HAZDRUG: PPE HD REQUIRED" can be seen on the medication labels, electronic medication administration record, and Omnicell screen.

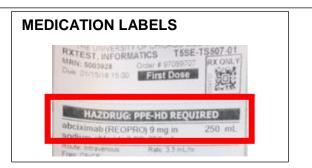
MAR NOTIFICATIONS



HANDLING PRECAUTIONS

- Listed in "Admin Instructions"
- Does not mean the drug is hazardous. This may indicate other needs (e.g., light sensitivity, do not tube).









#2 Tip: Transport of HDs

- Hand delivered by pharmacy or Moxi in a yellow HD bag.
- HDs are <u>not</u> to be sent via pneumatic tube system.
- Carry drug in yellow HD bag to patient room to prevent spills.

#3 Tip: Room Signage

- Metabolites of HDs are excreted in body fluids of patients up to 48 hours of last dose.
- Signage must be placed on the door of patient rooms that are receiving HDs.
- Complete the dates and times of when precautions begin and end.
- This sign allows visitors and anyone coming in the room that might come into contact with body fluids what PPE to wear.
- If a patient is continuously on a hazardous drug (e.g., daily dosing), then it is acceptable to leave the end date blank.
- Place signage on the patient's door.
- Click <u>here</u> for a copy of door signage.







#4 Tip: Wearing PPE-HD

• This guide provides PPE-HD standards when administering hazardous drugs.

Drug Formulation	HD Gloves	HD Gown	Eye & Face Protection	Respiratory Protection	Closed System Transfer Device
Intact Tablet or Capsule	Single Pair	No	No	No	N/A
Oral Liquid	Double	Yes	Yes	No	N/A
Topical Drug	Double	Yes	Yes, if there is a risk of direct contact during administration	Yes, if there is a risk of inhalation	N/A
Injection (SQ, IM, or IV)	Double	Yes	Yes	No	Yes
Solution for irrigation (bladder, intraperitoneal, limb perfusion, etc.)	Double	Yes	Yes	Yes, if there is a risk of inhalation	N/A
Powder, solution for inhalation, aerosol	Double	Yes	Yes	Yes	If applicable







#5 Tip: Helpful Quick HD Administration Videos (2-3 minutes each)

 Priming Primary Line with non-HD Fluid PPE to wear: Clean gloves 	
 Examples of Antineoplastic HDs as IVPB PPE to wear: Double HD gloves, HD gown, eye protection AND face shield 	
 Non-Antineoplastic HD IVPB with Dry Spike PPE to wear: Double HD gloves, HD gown, eye protection AND face shield 	
 Administration of Non-Antineoplastic HD IVPB- In Omnicell PPE to wear: Double HD gloves, HD gown, eye protection AND face shield 	
 HD Vial Spike Adapter- 20mm and 13mm PPE to wear: Double HD gloves, HD gown, eye protection AND face shield 	
 Administration of IVP HD PPE to wear: Double HD gloves, HD gown, eye protection AND face shield 	
 Administration of HD via Syringe Pump (Pediatric) PPE to wear: Double HD gloves, HD gown, eye protection AND face shield 	
 Dilution of Vial-drawn HD into Syringe (Pediatric) PPE to wear: Double HD gloves, HD gown, eye protection AND face shield 	
 Enteral HD Administration: If HD is to be crushed, pharmacy will send to unit in a solution, using a CSTD, if available, to contain medication. If drug is to be administered via enteric tube, pharmacy will prepare HD and send to nursing unit using an EnFit adapter attached, if available. Use plastic backed absorbent pad to protect environment beneath connection of enteric tube to syringe during administration in case of leak or splash. 	 PPE to wear: Double HD gloves HD gown Eye protection Face shield







6 Tip: Disposal of HD Waste

- Waste must be placed in the appropriate container based on the amount of HD to be disposed.
- New empty yellow 18 gallon and black 8 gallon bins can be found in clean supply rooms.
- Extra yellow HD bags can also be found in clean supply rooms.

Transporting HD Waste	Yellow Container (Trace Waste)	Black Container (Bulk Waste)
 Transport waste in yellow HD bag from patient room to bin in soiled utility room 	 Less than or equal to 3% of total HD dose Examples: PPE, empty HD syringe or HD IV bag 	 Greater than 3% of total HD dose Examples: Partial HD dose, intact HD tablets, HD spill debris

References:

- UCM Policies: PC 146 Safe Handling of Designated Hazardous Drugs, S04-11 Hazardous Material Spill
- NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. 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. 2016-161 (Supersedes 2014-138).
- NIOSH [2023]. Managing hazardous drug exposures: information for healthcare settings. By Hodson L, Ovesen J, Couch J, Hirst D, Lawson C, Lentz TJ, MacKenzie B, Mead K. 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. 2023-130, https://doi.org/10.26616/NIOSHPUB2023130
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- Polovich, M. & Olsen, M. M. (2018). Safe handling of hazardous drugs. Pittsburgh, PA: Oncology Nursing Society.
- Connor, T. H., Douglass, K., Eisenberg, S., Kastango, E. S., Kienle, P. C., Massoomi, F., & Parsad, S. D. (n.d.). *Improving Safe Handling Practices for Hazardous Drugs*. Joint Commission Resources. American Society of Health-System Pharmacists. (2006). ASHP Guidelines on Handling Hazardous Drugs. *American Journal of Health-System Pharmacy, 63*, 1172-1193.







USP800 PPE and HD Administration Table

PPE and HD Administration								
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Topical Drug	Double	Yes	Yes, if there is a risk of direct contact during administration	Yes, if there is a risk of inhalation	N/A			
Injection (SQ, IM, or IV)	Double	Yes	Yes	No	Yes			
Solution for irrigation (bladder, intraperitoneal, limb perfusion, etc.)	Double	Yes	Yes	Yes, if there is a risk of inhalation	N/A			
Powder, solution for inhalation, aerosol	Double	Yes	Yes	Yes	If applicable			

PPE and HD Administration







HAZARDOUS DRUG SPILL TIP SHEET: COVIDIEN SPILL KIT

The purpose of this is tip sheet is to guide staff on how to minimize or prevent occupational exposure to hazardous drugs (HDs) in the event of an unexpected HD spill.

Incidental Spill (a few drops)

- 1. After the initial response, keep persons out of spill area and explain situation to affected patient as needed.
- 2. Don two (2) pairs of HD gloves, a HD gown and splash goggles.
- 3. Rinse area with water and clean with detergent.
- 4. Rinse area with plain water several more times.
- Dispose of PPE and waste materials in <u>YELLOW</u> waste container. The yellow containers are for trace or slightly contaminated items.
- 6. Wash hands with soap and water.

Minor Spill (up to the amount absorbed by the spill kit)

Note: The Covidien ChemoPlus[™] Spill Kit will absorb up to 4 cups (32 oz or just under 1 liter) per pillow and each kit has 2 pillows. If spill is more than 8 cups (64 oz, or around 2 liters), page Environmental Health Services (EHS) at pager 8382.

Click here or scan the QR code to watch the HD Spill Cleanup video: https://bcove.video/44UWII8

- 1. Stop leakage if necessary or possible, using HD PPE.
- 2. Keep persons out of spill area and explain situation to affected patient as needed.
- 3. Call for help to obtain supplies for cleaning spill: HD Spill Kit, 2 step wipes, additional PPE (e.g., N95 mask, PPE for helper).
- 4. Staff participating in spill cleanup need to don PPE appropriate for HD spill cleaning. Don PPE from the kit outside of the spill room to decrease exposure to HD, obtaining additional PPE as necessary.
 - a. Wash hands with soap and water.
 - b. Don eye/face protection (e.g., goggles, face shield, respirator)
 - i. Use a NIOSH-approved filtering face piece respirator, such as a fit-tested N95. Do not use the N95 in the kit.
 - c. Don shoe covers
 - d. Wash hands with soap & water
 - e. Don first pair of HD gloves
 - f. Don HD gown, placing gown cuffs over first pair of gloves
 - g. Don outer gloves, placing wrist of glove over gown cuff
- 5. Place spill pillows in a V pattern to prevent spread.





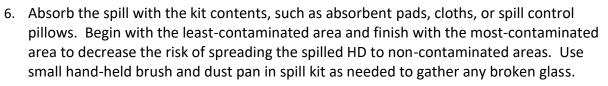












7. Rinse area with water.



8. Next, use 2-step wipe package. First wipe is to clean and second wipe is to deactivate.





- 9. Rinse the area with plain water several more times to dilute any HD residue and ensure it is transferred to the wipes.
- 10. Discard all material used in cleanup, including any unused bulk medication, in the HD bag contained within the spill kit. Seal the waste bag and place it into a **BLACK** bin for bulk HD waste.



- 11. Remove PPE in the following order to decrease risk of exposure to and contamination of HDs:
 - a. Doff and discard outer gloves, removing one at a time, turning inside out
 - b. Doff and discard HD gown, pull gown AWAY from body, turn inside out & fold tightly
 - c. Doff and discard shoe covers
 - d. Doff and discard inner gloves, removing one at a time, turning inside out
 - e. Wash hands with soap and water
 - f. Don new HD gloves
 - g. Doff and discard eye/face protection (e.g., goggles, face shield, respirator), avoiding contact with front of eye/face protection
 - h. Doff and discard gloves, removing one at a time, turning inside out.



12. Dispose PPE into the second waste bag within the spill kit, placing it into **YELLOW** bin for trace HD waste



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- 13. Wash hands with soap and water.
- 14. Communicate to the following departments:
 - a. Notify Environmental Services (EVS) for final cleanup. Indicate the spill has been cleaned up.
 - b. Fill out an online Patient Event Report. Call the Patient Safety Hotline 2-5544 if there is potential for an adverse patient event.
 - c. Contact Supply Chain to replace spill kit (or Kanban).
 - d. If HD was spilled during administration to the patient, inform the healthcare provider, contact pharmacy and document a note in the medical record.
 - e. If the spill is larger than your spill kit or you are not trained and cannot find anyone who is trained:

UCM: Contact Environmental Health and Safety (EHS) at pager 8382 Ingalls: Contact Environmental Services at extension 6010 Off-Sites: Follow local process, contact direct leader for more information.

Contaminated Linen

- 1. Do not place HD contaminated linen in the soiled linen bag.
- Potentially contaminated clothing from hazardous drugs should not be taken home by staff and instead be disposed of in <u>YELLOW</u> or <u>BLACK</u> bins, depending on the volume of HD contamination. Hospital scrubs or alternative clothing should be worn home.
 - i. UCM: Contact Linen at Pager 1500 or HOA during off-hours
 - ii. Ingalls: Contact Linen at extension 5512
 - iii. **Off-Sites**: Follow local process, contact direct leader for more information.
- 3. Wearing HD PPE, remove any linen grossly contaminated with HD, double bag the linen for proper disposal.

UCM: Label bag as Hazardous Waste with name of drug and add "dispose by EHS 5-SAFE." Call EHS at 5-SAFE for pickup and place in waste room. Add "dispose by EHS 5-SAFE" on bag.

Ingalls: Call EVS at 6010 to pick up yellow container. It will be taken to the dock and provide the proper label.

Off-sites: Follow local processes, contact direct leader for more information.

Note: The linen contractor will refuse any linen contaminated with large amount of hazardous medications from a spill. Linen contaminated with body fluids can be disposed in the yellow container.

References:

- UCM Policies: PC 146 Safe Handling of Designated Hazardous Drugs, S04-11 Hazardous Material Spill
- NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. 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. 2016-161 (Supersedes 2014-138).
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