SOP: Safe Handling of Hazardous Drugs (HDs)
Approved by NPC on December 21, 2017

NATIONAL INSTITUTES OF HEALTH
CLINICAL CENTER
CLINICAL CENTER NURSING DEPARTMENT

Standard of Practice/Procedure: Safe Handling of Hazardous Drugs (HDs)

SUMMARY OF SIGNIFICANT CHANGES SINCE LAST REVIEW

- Based on the 2014 ONS chemotherapy/biotherapy guidelines, we made changes to reflect the increased awareness of management of HDs in the environment.
- There are more statements that discuss environmental (surface contamination) including, but not limited to:
  - The transport and storage of HDs on nursing units
  - Separation of Intrathecal HD from other HD on nursing units
- Added statement on minimizing HD contamination when using barcode verification devices and Hazardous drugs.
- Changed Dispatch to generic term 'CC approved disinfectant product (containing bleach)'
- Revision 2/2017: Leuprolide acetate (Lupron Depot) will NOT come pre-mixed from the Pharmacy.
- Revision 12/.2017: Added intravitreal injection as a route along with article for the TOE Primary Stakeholder: Rochelle Woodard and Clinical Nurse Specialist: Ann Peterson
- Revision 12/2017: Soiled Linens Disposal Instructions
- Revision 12/2017: Disposal of unused HDs through Chemical Waste System

Clinical Nurse Specialist: Myra Woolery
Primary Stakeholder(s): Sophia Grasmeder, Therese Intrater

Deletes or Replaces - Safe Handling of Hazardous Drugs (08/17) **SOP** ♦
and Hazardous Drugs Table of Evidence (08/17)

NATIONAL INSTITUTES OF HEALTH
CLINICAL CENTER
CLINICAL CENTER NURSING DPEARTMENT

Standard of Practice: Safe Handling of Hazardous Drugs (HDs)

Essential Information:

1. "Care of the Patient Receiving Hazardous Drugs or Drugs Requiring Special Handing" competency required and annual "Safe Handling of Hazardous Drugs" Mandatory Review module is required.
2. If the HD being administered is a chemotherapy or biotherapy agent, "Chemo/Biotherapy Competency" is required, also refer to the SOP: Administration of Chemotherapy and Biotherapy.
3. Occupational Exposure to HDs
    a. Studies in cooperation with The Occupational Safety and Health Administration (OSHA) indicate potential risks for healthcare workers who handle hazardous drugs (HD) or investigational agents for which existing data support a reasonable assumption of toxicity. These potential risks of HD include: genotoxicity, carcinogenicity, teratogenicity and increased risk of fetal mortality, impaired fertility, and organ toxicity.[1-,4]
    b. Occupational exposure can occur through many routes: direct contact with skin or mucous membranes, inhalation, injection, and ingestion.[4-8]
    c. Sources of occupational exposure include materials that come into contact with hazardous drugs including but not limited to intravenous tubing, work surfaces, research participant linens, and research participant waste.[2,4,7,8]
    d. Acute symptoms associated with worker exposure may include rash, fever, shortness of breath, headache, syncope, irritation to mucous membranes of the mouth, nose, eyes, or nausea.[2,4,5,6]
    e. Any staff who are pregnant or lactating, and staff who are trying to conceive a child who have concerns about exposure to HD while caring for research participants receiving these agents, should discuss their concerns with their immediate supervisor and Occupational Medical Services (OMS).
    f. Isolation (yellow) gowns do not provide adequate protection against contamination from HDs. Only use (blue) solid-front back-closure gowns when handling HDs or disposing of body fluids contaminated with HDs.
    g. Treat all surfaces as though contaminated with trace HD. For environmental surface trace decontamination, clean surfaces with a hospital approved disinfectant. Use bleach containing wipes on IV pumps, poles, counters and surfaces in contact with hazardous drug containers. Place disposable supplies in yellow puncture resistent "sharps" container.
4. Leuprolide acetate (Lupron Depot) is hazardous drug that is administered intramuscularly and dispensed in a prefilled dual-chamber syringe. Lupron Depot will NOT come pre-mixed from Pharmacy. The administering healthcare worker must follow administration instructions found in the kit. Additional guidance for Lupron reconstitution and administration can be found in sections C. 3. c. and C. 7. b. of this procedure.

5. Intravitreal injections may involve hazardous drugs such as Avastin. The ophthalmic nurse prepares the medications using safe handling procedures. The nurse monitors and facilitates the safe handling aspects of the procedure during drug administration.
6. Resources
   a. The hazardous drug links are available via the Pharmacy website. The formulary includes one list for commercially marketed HDs labeled 'Hazardous Drug List' and a separate list labeled 'Hazardous Investigational Drug List'.
   b. NIH personnel can obtain Material Safety Data Sheet (MSDS) that describe the hazardous properties of non-exempt HD linked to the Clinical Center Pharmacy's "Formulary & Drug information" website, at http://intranet.cc.nih.gov/pharm/formulary/index.html. Material Safety Data Sheets are documents which contain information about commercially marketed hazardous drugs.
   c. Information about Hazardous Investigational Drugs can be found at the Pharmacy Department's web site (Drug Fact Sheets) or in the relevant protocol. Information about specific FDA approved drugs can be found in the Micromedex® databases linked to the Clinical Center Library's website.
   d. For information about the Clinical Center safety program related to HD, refer to the website at http://intranet.cc.nih.gov/chemsafety/

For questions about the Clinical Center's Hazard Communication Program, contact Safety Officer, Michele Evans.
For questions about the Clinical Center's Hazardous Drug List or the MSDS database, contact the Hazardous Drug Project Officer in the Pharmacy Department.

I. Assessment

A. Confirm drug has hazardous properties.
   1. All formulary Hazardous Drugs will be identified within the order in CRIS as hazardous, however, non-formulary Hazardous Drugs will not be identified as hazardous in CRIS.
   2. Hazardous Drugs prepared for administration in inpatient areas, Day Hospitals, and clinics will be identified by the Pharmacy with a prominent orange HD label.
      a. Exception: Take home HDs will not have to be labeled as hazardous.
   3. Refer to drug references, MSDS, and HD lists on the Pharmacy Dept's "Formulary & Drug Information" website at: http://intranet.cc.nih.gov/pharm/formulary/index.html

B. Determine toxicity profile for HD to be administered.
C. Gather supplies required for administration of HD and ensure that proper personal protective equipment (PPE) is available including a yellow puncture-resistant "sharps" container for packaging HD wastes.[2-9]

II. Interventions

The term hazardous describes drugs that require special handling because of health risks that may result from exposure. These risks are a result of the inherent toxicities of the drug. According to the Occupational Safety and Health Administration (OSHA), safe levels of occupational exposure cannot be determined, and no reliable method for monitoring work-related

exposure exists. Therefore, it is imperative that those who work with HDs adhere to practices designed to minimize occupational exposure.[2,4-7]

A. Use PPE to decrease or prevent the risk of occupational exposure to HD including:
    1. Wear gloves designated for hazardous drug handling when administering all HD.[1-9]
        a. Double-glove for drug preparation, drug administration, and handling of contaminated waste.
            i. Gloves must meet testing standards for protection from HD permeability set by the American Society for Testing and Materials (ASTM).[2-4]
            ii. Powder free gloves are preferred for HD handling because powder may absorb contaminants, be dispersed, and increase the possibility of surface contamination.[2-4,7]
        b. Wash hands thoroughly before gloving, and again immediately after removal of gloves.
        c. One pair of gloves should go under the gown cuff and one pair should go over the top of the gown cuff. Remove and discard gloves immediately after use; if a tear, puncture, or drug spill occurs.[1-9]
        d. Wear gloves no longer than 30 minutes. Replace both pairs of gloves after 30 minutes.[2-4]
        e. Discard used outer gloves in a yellow, puncture resistant container for packaging HD wastes and dispose of inner gloves in a Medical Pathological Waste (MPW) or “burn” box.
    2. Wear a disposable gown.[1-9]
        a. Gowns are solid front (i.e. back closure) with knit or elastic cuffs, lint free, and made of low permeability fabric.[2-4]
        b. Gowns with polyethylene or vinyl coatings provide adequate protection from splashes and penetration of tested antineoplastic agents.[2-4]
        c. Remove and discard the gown if it is visibly contaminated, before leaving handling areas (prevents contamination of other areas and reduces exposure to other staff, research participants, and visitors), and after handling HDs.[2,7,8]
        d. Do not reuse gowns. Gowns are single use and should be disposed of after use.
        e. In the event a research participant receiving an HD is on isolation, the gown for handling HDs can be used in place of the isolation gown. Isolation gowns cannot be used for handling HDs.
        f. Dispose of gowns in a MPW or “burn” box. Do not put gowns into a yellow, puncture resistant container for packaging HD wastes due to the risk of accidental needle stick. Only sharps and IV apparatus should be placed in the yellow puncture-resistant containers for packaging HD waste.

3. Wear a face shield when splashes to the face are likely to occur such as when flushing wastes or suctioning.[2-9]
4. Wear a NIOSH approved particulate respirator (N95 mask) and safety eye goggles whenever there is risk of aerosol exposure, such as when administering Ribavirin or Pentamadine.[2-4,6-9]
    a. Contact the Hospital Safety Officer if you have questions about when a respirator is required, or, in some cases, is recommended.
    b. Contact Hospital Safety on 301 496 5281 to arrange fit testing and training for particulate respirators.
    c. Staff must be medically cleared by OMS prior to fit testing and use of particulate respirators if they are part of the respiratory protection program, for the rare use of a respirator in cleaning spills, no fit testing is required.
    d. Studies have shown that surgical masks do not provide adequate protection from aerosolized HDs.[2-4,6]

B. Interventions to decrease environmental (surface) contamination from HDs:[2,5-8,10]
1. All HD preparations are transported inside of a sealed plastic bag. Neither the pneumatic tube system nor the electronic conveyor track are used to transport HDs.
2. The nurse or authorized personnel in receipt of the HD will secure it immediately and notify the nurse caring for the research participant per MAS policy M05-3 Medication Management in the Clinical Center.
3. Whenever transporting HD from one location to another, check/inspect HD containers for leakage.
4. HDs are stored in a locked medication storage area. Where possible, designate a container or storage area for HDs in the medication room that is separate from other non-hazardous medications to reduce environmental HD contamination.
5. Further, store Intrathecal HD separate from other HD.[9]
6. Handle all HDs as though the container itself has trace HD contamination. Wear gloves designated for HD handling when transporting, checking, preparing, and administering HDs.
7. Designate an area for independent double checks of calculations and labels for HDs that is away from the clinical treatment areas (i.e. in a medication room). Independent double checks may be performed at the bedside when the research participant requires continuous observation.
8. Place a plastic backed, absorbent pad under HD containers when placing them on work surfaces or patient tables.
9. When using KBMA (barcode verification devices), be mindful of preventing trace contamination to work environment.
    a. Wear gloves designated for HD handling when operating scanner, taking care not to cross-contaminate the scanner with trace HD.
    b. Consider having a ‘clean hand’ that operates scanner, and a ‘dirty hand’ to hold HD container so as to avoid contaminating scanner with HD.
    c. Place drug on top of plastic backed, absorbent pad.

C. Specific considerations for each route of HD administration
   1. Aerosolized Administration[2-9]
      a. When administering hazardous drugs by aerosolization, a National Institute for Occupational Safety and Health (NIOSH) – approved respirator must be worn.
      b. Wear goggles to protect eyes and mucous membranes from irritation.
      c. Refer to Medical Administrative Series (MAS) policy M94-4 Guidelines for Preparation and Administration of Aerosolized Ribavirin (insert hyperlink here).
   2. Intraperitoneal Administration – refer to PRO: Hazardous Drugs Intraperitoneal Instillation
   3. Intravenous (IV) Administration
      a. Use a closed system transfer device (CSTD) for all IV HD administration except for agents where the device is contraindicated, such as busulfan.[1,2,5-7,10]
         i. A CSTD is a drug transfer device that mechanically prevents the transfer of hazardous contaminants into the environment and the escape of hazardous concentrations of drug vapor from the system.
         ii. A CSTD prevents free flow of fluid prior to making connections between the closed male connector on the end of the administration set and the closed female connector on the research participant's vascular access device catheter hub. Therefore, it also prevents free flow of fluid if the connection inadvertently comes apart which will cause an IV pump to alarm for distal occlusion.
         iii. A CSTD is not considered a substitute for PPE.
         iv. A CSTD utilizes split septum technology and is not a mechanical valve.
      b. CSTD is for IV HD administration only.
         i. Pharmacy will attach a closed male connector to all IV HDs prior to dispensing to the patient care area.
         ii. The CSTD split septum adaptor may be used for sequential secondary HD infusions on the same primary tubing.
         iii. When HD infusion is complete and disconnected from a research participant, IV tubing and all HD containers are discarded.
         iv. CSTD are only compatible with Luer locking devices.
         v. Blunt cannulas or needles should not be used to access the closed female connectors.
      c. Syringes containing HDs will be no more than three quarters full to decrease the risk of accidental spills. There should be no need to expel air from the syringe; this will be performed if necessary in a Pharmacy BSC, with the exception of Leuprolide acetate (Lupron Depot). According to the administration instructions for Lupron Depot, after reconstitution, the plunger must be advanced to expel air from the syringe; for additional protection, please keep the cap in place while expeling air.

   d. Nurses should not “spike” or “un-spike” HDs to or from IV tubing at the bedside.
   e. Secure all tubing connections with luer lock (CSTD) connectors. The use of tape to secure connections is discouraged because it has been associated with bacterial contamination.[11]
   f. Refer to PRO: Hazardous Drugs IV Administration
4. Intravesical Administration (into the urinary bladder) - refer to PRO: Hazardous Drugs Intravesical Administration
5. Intravitreal Administration (into the vitreous of the eye) drug preparation is completed by the ophthalmology nurse while the ophthalmologist administers the medication.The nurse facilitates the use of safe handling of hazardous drugs practices during drug preparation and administration.
6. Oral Administration[2,7-9]
   a. Wear gloves when preparing and administering all oral HDs. In addition to gloves, PPE should include a gown and face shield if there is a potential for sprays, aerosols, or splattering of the agent, such as with liquid HDs.
   b. Do not crush tablets or open capsules. Return all oral HDs to the Pharmacy where altering product formulations will be accomplished within a biologic safety cabinet.
7. Topical Administration[2,7-9]
   a. Wear gown and gloves when applying topical HDs. Wear a face shield or a combination of mask and shield that provides splash protection whenever there is a possibility of splashing.
   b. Use a plastic backed absorbent pad if necessary to prevent soiling linens.
   c. Unless contraindicated by FDA approved product labeling or protocol specifications, cover the area where an HD has been applied with gauze or coverlet dressing to prevent contamination of surfaces.
   d. HDs should be wiped off or removed as best as possible prior to entering a shower or hydrotherapy tub. Topically applied creams and ointments create residue and build up in the tubes pumps/hoses/jets which can result in bacterial growth and pose an infection control risk. If the topical HD is cannot be adequately removed, consideration must be given for the research participant to receive treatment in a non-hydrotherapy tub.
   e. Store topical HD in medication room in designated HD storage container or area, not in the research participant’s room. Topical HD containers should be considered to have trace contamination on outer surfaces of container.[2-4,7] After administering topical HD to research participant, place container in a clean bag before returning to medication storage area.
8. Subcutaneous, Intramuscular, and Intrathecal Administration[1-4,7,9]

a. Wear gown and gloves when preparing and administering subcutaneous, intramuscular, and intrathecal HDs. Wear a face shield or a combination of mask and face shield that provides splash protection whenever there is a possibility of splashing.

b. Subcutaneous and intramuscular HDs should be drawn up within a biologic safety cabinet in the Pharmacy, with the exception of Leuprolide acetate (Lupron Depot). Intrathecal hazardous drugs are dispensed from the Pharmacy in vials. A dispensing pin should be used to draw up intrathecal HDs prior to administration.
    i. When administering Lupron Depot, the administering healthcare worker must follow administration instructions found in the kit, wearing personal protective equipment (recommended PPE includes disposable gown, double HD gloves, and face shield).
c. Wipe administration site with gauze after administration.
d. Discard gauze, all syringes and needles, and gloves in yellow puncture resistant container for packaging HD waste.

D. Research Participant Teaching
    1. Provide teaching to research participants their family and caregivers about drug interactions, side effects, universal precautions, and safe handling.[7,9]
    a. Instruct research participants and family members to wear gloves when handling oral, subcutaneous, or topical HDs.
    b. Provide research participants receiving ambulatory intravenous HD infusions with a hazardous drug spill kit and instruct them on its use in the event of a spill or leak.
    2. Research participant education materials may be found as well.

E. Disposal of bodily fluids, research participant waste, and soiled linens
1. Variable amounts of HDs and their metabolites are excreted in the urine, stool, sweat, and other body excreta of research participants receiving HDs.[4-7,9]
2. Wear gown and double gloves when handling bodily fluids, research participant waste, or soiled linens within 48 hours after the an HD was last administered to the research participant.[5-9]
3. Linens soiled with HDs should be placed in a plastic liner (located on the linen carts), sealed, and then placed in the linen bags/hampers. Soaking wet linens should be disposed of in a Medical Waste Boxes or "burn boxes. In the event a research participant's clothing becomes soiled with HDs, the clothing should be placed in a plastic bag and sent home with the research participant/family members to be washed separately from other linens/clothing.
4. Isolation gowns do not provide adequate protection from bodily fluids contaminated with HDs.

F. Transfer of research participants receiving hazardous drugs
    1. If a research participant must leave the unit while a HD is infusing, the receiving department must be notified about the HD and agree to receive the research participant with a HD infusing. A HD spill kit must accompany the research participant during transfer.

G. Accidental Exposure - Follow recommended procedures following an acute accidental HD exposure.[4,7,9] Refer to NPCS PRO: Hazardous Drugs Accidental Exposure. Staff should seek immediate assistance, and to avoid delays after hours and on weekends, contact the OMS on call LIP per steps below.

1. Skin: remove any contaminated garments; wash skin with soap and water.
2. Eye or other mucous membrane (mouth): flush eye surface with saline solution or water for at least 15 minutes; seek immediate care. Use eyewash station where available in the immediate clinical area, or use 0.9% Sodium Chloride Injection attached to IV tubing as per NPCS PRO: Hazardous Drugs Accidental Exposure.
3. Inhalation: in the unlikely event of a plume, move away from exposure area and close the door.
4. Ingestion: in the unlikely event, contact Poison Control at 1-800-222-1222 or the Clinical Center Pharmacy.
5. Employees with adverse exposures to HD should report to Occupational Medical Services (OMS) (10/6C300) or call the page operator for the LIP on call for OMS.
6. Check the MSDS for commercial HDs or the Drug Fact Sheet for investigational HD for additional information or call the Pharmacy (301-496-6551).
7. The Nurse Manager or Administrative Coordinator is to be notified when a staff member has been exposed to a HD.

H. Disposal and Spills

1. Nursing staff are responsible for packaging of items contaminated with small amounts of HD (≤ 5 mL), including clothing, linen, and drips on environmental surfaces (ex: beds or tables). Refer to PRO: Hazardous Drugs Handling Spills.
    a. A commercially available HD spill kit is to be used by staff on the Patient Care Unit. Research participants with IV HDs administered on an outpatient basis, are discharged with the home spill kit (e.g., Kendall ChemoBloc Home Health spill kit).
    b. Contaminated gloves and IV tubing can be placed in the yellow puncture resistant container for packaging HD waste.
    c. Other contaminated disposable items, such as absorbent pads, gowns, goggles, respirator masks, and any items used in the cleaning process, can be placed in the MPW box and sealed.
    d. Contaminated equipment should be cleaned in place according to normal cleaning procedures while wearing gown, gloves, and respirator mask.
2. Any spill of HD that exceeds 5 mL is managed by the NIH Fire Department (301-496-2372 or 911).
3. Staging areas for hazardous drug waste buckets and contaminated equipment, trash, and linen for additional treatment or disposal, are to be be safely secured on a Patient Care Unit and access restricted to authorized personnel.
4. Yellow puncture resistant containers for packaging HD wastes are closed and locked by nursing staff wearing double gloves when no more than three-quarters full. Remove closed containers from the treatment area.
5. IV pumps/poles should be treated as HD contaminated equipment with each infusion. For trace surface decontamination, clean the surfaces of IV pumps and poles with a Clinical Center approved disinfectant cloth containing

sodium hypochlorite (bleach) solution, after infusion and disposal of agent is complete. Don double gloves when cleaning. After wiping with disinfectant cloth, rinse/wipe down pumps with soft cloth dampened with fresh clean water followed by dry cloth, to remove residue. If known leak has occurred,follow steps in PRO: Hazardous Drugs: Handling Spills.

6. All expired, returned, or unused HDs that have been connected to the patient and containing more than 3% of their original volume shall be placed in the HD chemical waste container. If the HD has not been connected to the patient, contact pharmacy for further direction, i.e. return to pharmacy OR dispose in the chemical waste bucket. Then call the NIH Chemical Waste Service at (301) 496-4710 for pick-up and replacement.
7. Contact Administrative Coordinator on weekends and off shifts for HD Chemical Waste Container replacement. Chemical Waste must still be called during regular business hours for disposal of used bucket.

III. Documentation

A. Document drug administration in approved medical record.
B. If exposure or spill occurs, a timely report must be filed through the Occurrence Reporting System (ORS).
C. OMS will maintain employee health records. When applicable, OMS will provide supervisors with documentation of an employee's visit to OMS.

IV. References

1. American Society of Health-System Pharmacists. (2006). ASHP guidelines on handling hazardous drugs. *American Journal of Health System Pharmacy*, *63*(12), 1172-1193.
2. National Institute for Occupational Safety and Health. (2004). Preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings. Retrieved June 20, 2011, from http://www.cdc.gov/niosh/docs/2004-165.
3. National Institute for Occupational Safety and Health (2008). NIOSH Workplace Solution: personal protective equipment for health care workers who work with hazardous drugs. Cincinnati, OH: U.S. Department of Heath and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2009-106.
4. Occupational Safety and Health Administration. (1999). OSHA technical manual, section VI, chapter 2. Retrieved June 20, 2011 , from https://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.html
5. Eisenberg, S. (2009). Safe handling and administration of antineoplastic chemotherapy. *Journal of Infusion Nursing*, *32*(1), 23-32.
6. Polovich, M. (2004). Safe Handling of Hazardous Drugs. *The Online Journal of Issues in Nursing* 9, (3).
7. Polovich, M. (Ed.). (2011). *Safe handling of hazardous drugs, 2nd edition.* Pittsburgh, PA: Oncology Nursing Society.
8. Nixon, S. & Schulmeister, L. (2009). Safe handling of hazardous drugs: Are you protected? *Clinical Journal of Oncology Nursing*, 13 (4), 433-439.

9. Polovich, M., Olsen, M. & Lefebvre, K.B. (Eds). (2014). *Chemotherapy and Biotherapy Guidelines and Recommendations for Practice* (4th ed.). Pittsburgh, PA: Oncology Nursing Society
10. Sessink, P.J., Connor, T.H., Jorgenson, J.A., & Tyler, T.G. (2010). Reduction in surface contamination in 22 hospital pharmacies in the US following implementation of a closed system transfer device. *Journal of Oncology Pharmacy Practice* 17(1), 39-48.
11. Infusion Nurses Society. (2006). *Policies and procedures for infusion nursing* (3rd ed.) Norwood, MA: Author.
12. Office of Research Facilities (ORF): Chemical Waste - https://www.orf.od.nih.gov/EnvironmentalProtection/WasteDisposal/Pages/default.aspx

Approved:

_____//s//_____
Gwenyth R. Wallen, PhD, RN
Chief, Clinical Center Nursing Department

_____//s//_____
Majid Tanas, PharmD, MHA, MS
Chief, Pharmacy Department
Formulated: 6/2009
Implemented: 7/2009
Reviewed: 12/2011, 12/2014
Revised: 11/2009, 12/2011, 2/2012, 1/2014, 2/2017, 12/2017