3.5.24 Handling of National Institute for Occupational Safety and Health (NIOSH) Hazardous Drugs

(a) Procedure Overview

Hazardous drugs specified in the National Institute for Occupational Safety and Health List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings (NIOSH List) shall be received, stored, prepared, dispensed, administered, and disposed of according to recommended practices to protect staff, patients, and the environment. Parenteral hazardous drugs shall be administered only by persons trained in the safe use of such agents. Sterile hazardous drugs shall only be compounded by pharmacies with appropriate licensure from the California State Board of Pharmacy.

(b) Purpose

To promote safety in handling of hazardous drugs, to reduce the risk of environmental or personal exposure, and to prevent exposure to hazardous drug waste.

(c) Procedure

(1) Systemwide Handling of Hazardous Drugs

(A) List of Hazardous Drugs

At least once every 12 months, California Correctional Health Care Services (CCHCS) shall review utilization within the organization and maintain a list of hazardous drugs that are used. Hazardous drugs include medications specifically identified on the NIOSH List, medications that entered the market after the most recent version of the NIOSH List and likely meet its criteria for hazardous, and investigational drugs that would also meet the same criteria for hazardous.

(B) Assessment of Risk

1. The United States Pharmacopeia (USP) General Chapter <800> standards shall be followed except where CCHCS determines that the exposure risk is minimal and a different containment strategy or work practice may be applicable. In which case, CCHCS shall complete an assessment of risk for the drug before deviating from the USP General Chapter <800> standards. The assessment of risk includes, but is not limited to, consideration of the:
   a. Type of hazardous drug (e.g., antineoplastic, non-antineoplastic, reproductive risk only)
   b. Dosage form
   c. Risk of exposure
   d. Packaging
   e. Manipulation
2. The assessment of risk includes alternative containment strategies or work practices proportional to the risk imposed on health care workers, patients, and the environment.
3. At least once every 12 months, the Systemwide Medication Management Subcommittee shall review and document the review of the assessment of risk.

(C) Hazardous Drug Handling Areas

1. The Chief Executive Officer (CEO) at each institution shall ensure that signs are prominently displayed designating the hazard before entrances to any areas that may potentially handle hazardous drugs. The pharmacist-in-charge (PIC) shall advise the CEO of areas where hazardous drugs may potentially be handled.
2. Only authorized personnel may access areas where hazardous drugs are handled.
3. Storing or consuming food, drink, chewing gum, or tobacco and applying cosmetics are prohibited in areas where hazardous drugs are prepared or administered.

(D) All individuals handling hazardous drugs are responsible for understanding the fundamental practices and precautions and for continually evaluating these procedures and the quality of final hazardous drugs to prevent harm to patients, minimize exposure to personnel, and minimize contamination of the work and patient-care environment.

(2) Training

Health care staff shall complete training on handling hazardous drugs before independently handling the hazardous drugs and annually thereafter. The breadth of the course may be limited to their job functions and shall conclude with an assessment to demonstrate and document competence.

(3) Personal Protective Equipment

(A) Health care staff shall, at minimum, don personal protective equipment (PPE) according to procedures outlined in the sections below depending on the activity. Each area supervisor shall make available chemotherapy gloves, gowns, eye/faceshields for any splash potential, and respirators for inhalation potential.

(B) Health care staff shall not reuse disposable PPEs. Reusable PPE shall be decontaminated and cleaned after use.

(C) Chemotherapy gloves shall meet American Society for Testing and Materials standard D6978 or its successor and be powder-free. Health care staff shall change gloves every 30 minutes (unless othewise recommended by the manufacturer) or when the gloves are torn, punctured, or contaminated.

(D) Gowns shall be disposable, be shown to resist permeability by hazardous drugs (e.g., polyethylene-coated polypropylene, other laminate materials), close in the back, be long-sleeved, have closed cuffs that are elastic or knit, and not have seams or closures that could allow hazardous drugs to pass through. Health care staff shall change gowns every two to three hours (unless permeation information is specified othewise by the manufacturer) or immediately after a spill or splash.

(E) Goggles and faceshields shall be worn when there is a risk for spills or splashes. Eye glasses or safety glasses with side shields alone are insufficient eye protection.

(F) A fit-tested, NIOSH-certified N95 or more protective respirator shall be used for activities that require respiratory protection. A full-facepiece, chemical cartridge-type respirator or powered air-purifying respirator shall be used when there is a high risk of respiratory exposure (e.g., cleaning up a hazardous drug spill larger than what can be contained with a spill kit).

(4) Receiving and Storing Hazardous Drugs

(A) A spill kit shall be available in areas receiving hazardous drugs.

(B) A pair of chemotherapy gloves shall be readily available for use when unpacking hazardous drugs.

(C) When receiving a shipment of hazardous drugs, the health care staff shall perform a visual examination of the shipping container for signs of damage or breakage before unpacking.

(D) If a shipping container appears damaged, seal the container without opening it, and contact the supplier.

1. If it is to be returned to the supplier, enclose the package in an impervious container and label the outer container "hazardous."
2. If it cannot be returned to the supplier, dispose of it as hazardous waste.
3. If the damaged shipping container must be opened, transport the shipping container in an impervious container to a Containment Primary Engineering Control and place it on a plastic-backed preparation mat. Then, open the package to remove undamaged items to wipe with a disposable wipe. Leave the damaged items in an impervious container, and label it "hazardous" to return to the supplier or to dispose of as hazardous waste.
4. A damaged shipping container shall be treated as a spill. See section (c)(8) for reporting procedures.

(5) Preparing and Dispensing Hazardous Drugs

(A) Manipulation of a hazardous drug or its active pharmaceutical ingredient within CCHCS for preparation purposes is prohibited. CCHCS pharmacies are not equipped for sterile and non-sterile compounding of hazardous drugs.

(B) Use of disposable/cleanable equipment (e.g., mortar, pestles, spatulas) shall be dedicated for use with hazardous drugs.

(C) When possible, the pharmacy shall procure hazardous drugs in its final dosage form and in commercially packaged unit doses.

(D) The pharmacy shall furnish all hazardous drugs of a topical, ophthalmic, or injectable dosage form in its original container to licensed units and to patients. For oral solutions and suspensions, if reasonable, the pharmacy shall furnish the full container.

(E) The pharmacy shall adhere a label ("Hazardous - Dispose of Properly") identifying any NIOSH hazardous drug that is Nurse Administered and Directly Observed Therapy, or clinic stock.

(F) Table 1 NIOSH drugs shall not be placed in automated counting or packaging machines.

(G) When necessary, pharmacy staff shall count or repackage hazardous drugs donning the following PPE:

1. For a hazardous drug on the Table 1 NIOSH List, the pharmacy staff counting or repackaging shall wear at least two pairs of chemotherapy gloves and utilize a spatula to minimize contact.

a. If counting or repackaging an uncoated tablet, the pharmacy staff shall wear a gown and respirator in addition to the two pairs of chemotherapy gloves.
b. If pouring an oral solution or suspension into a smaller container, the pharmacy staff shall wear a gown and eye/faceshield in addition to the two pairs of chemotherapy gloves.

2. For a hazardous drug on the Table 2 or Table 3 NIOSH List, the pharmacy staff shall wear at least a single pair of chemotherapy gloves and utilize a spatula to minimize contact.
a. If counting or repackaging an uncoated tablet, the pharmacy staff shall wear an additional pair of chemotherapy gloves and a gown.
b. If pouring an oral solution or suspension into a smaller container, the pharmacy staff shall wear a gown and eye/faceshield in addition to a pair of chemotherapy gloves.

(H) Any equipment that may have come into contact with the hazardous drug during the preparation or dispensing phase shall be decontaminated and cleaned after every use.

(6) Administering Hazardous Drugs

(A) When administering hazardous drugs, licensed health care staff shall minimize exposure to the medication as much as feasible, assess the patient for risk of increased exposure (e.g., potential for spitting, vomiting), and don the PPE as specified at: https://cdcr.sharepoint.com/sites/cchcs_lifeline_pharmacy/SiteAssets/SitePages/Forms---Medication-Lists/CCHCS-Hazardous-Drugs-PPE-Requirements.xlsx?web=1.

(B) Unless clinically justified, hazardous medications shall not be manipulated during the administration phase.
1. When a "crush/open and float" order is received by pharmacy, the pharmacist shall refer to both the CCHCS Statewide Pharmacy and Therapeutics Committee's Mandatory Crush/Open List and the NIOSH List before authorizing such an order.
2. Where a "crush/open and float" order is received for a drug considered hazardous, the prescriber shall be contacted to determine whether the medication can be given intact. If a "crush/open and float" instruction is considered essential, the nurse shall don additional PPE.

(7) Compounding Hazardous Drugs

(A) Drugs shall only be drawn or compounded by a pharmacist or a pharmacy technician if the pharmacy has an active sterile compounding license with the California State Board of Pharmacy and meets the requirements of USP 797 and USP 800.

(B) The PIC shall ensure that pharmacy staff engaged in the handling of parenteral hazardous drugs are properly trained and equipped to perform their duties.

(8) Accidental Contact and Spill Control

(A) Any personnel who may be required to clean up a spill of hazardous drugs shall receive proper training in spill management and the use of PPE and NIOSH-certified respirators. Spills shall be contained and cleaned immediately only by qualified personnel with appropriate PPE. Qualified personnel shall be available at all times while hazardous drugs are being handled.

(B) Spill kits and signs restricting access shall be readily available when hazardous drugs are administered. All spill materials shall be disposed of as hazardous waste.

(C) Personnel and non-pharmacy staff who are exposed during the spill or spill cleanup require immediate evaluation. A health care incident report shall be completed, including the circumstances and management of the spill. A copy of the incident report shall be forwarded to the institution's Health and Safety Committee.

(D) In the event of skin or eye contact with hazardous drugs, staff shall:
1. Wash any area of the skin that comes into contact with the medication thoroughly with soap and water.
2. Flush the eye(s) with copious amounts of water for at least 15 minutes while holding the eye lid(s) open.
3. Seek evaluation by a physician.

(9) NIOSH Hazardous Waste Disposal

Disposal of NIOSH hazardous drug waste, residual hazardous drugs, and supplies shall be consistent with waste container pursuant to HCDOM 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff.

(10) Hazardous Products Excluded from Use in the California Department of Corrections and Rehabilitation (CDCR)/CCHCS

Biohazardous medications which are biologically active and potentially infectious to patients and staff will not be purchased or administered in CDCR/CCHCS (e.g., TICE® BCG for intra-vesicular injection [urinary bladder instillation]). This exclusion does not apply to use of FDA-approved live attenuated vaccines (e.g., oral polio vaccine [OPV], varicella [chicken pox], measles, mumps and rubella [MMR combined vaccine], influenza [nasal spray], zoster [shingles], rotavirus, yellow fever [YF]).

References

- California Code of Regulations, Title 22, Division 4.5, Chapter 12, Article 3, Section 66262.34 Accumulation Time
- Medical Waste Management Act, September 2015, California Health and Safety Code, Sections 117600-118360
- California Department of Corrections and Rehabilitation, Department Operations Manual, Section 52030.4.7
- USP General Chapter <800>, Hazardous Drugs – Handling in Healthcare Settings 2017
- National Institute for Occupational Safety and Health (NIOSH) List of Antineoplastic and other Hazardous Drugs in Healthcare Settings, 2016
- UC DAVIS Health System, Policy and Procedures - Chemotherapy Agents
- Health Care Department Operations Manual, Chapter 1, Article 2, Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff
- Health Care Department Operations Manual, Chapter 3, Article 5, Section 3.5.11, Medication Inventory Management, Labeling, and Storage
- Health Care Department Operations Manual, Chapter 3, Article 5, Section 3.5.23, Repackaging and Compounding Medications
- Dorland's Medical Dictionary

Revision History

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