Protecting workers from hazardous drug exposure:

Key elements of USP 800

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Introduction

While chemotherapy agents can be lifesaving for patients, they pose serious risks for health care workers who deliver or compound these drugs. Exposure can cause health effects that may accumulate over time. Unfortunately, these exposures often go unrecognized without routine environmental and medical monitoring. This is why organizations like the United States Pharmacopeia (USP) publish standards like USP 800. Even though these standards can be challenging to implement in the workplace, examination of the dangers of hazardous drug (HD) exposure and how HDs enter the body shows how key elements of USP 800 offer important protection for health care workers.

What makes a hazardous drug hazardous?

The National Institute of Occupational Safety and Health (NIOSH) classifies a drug as hazardous if it:

- Causes cancer
- Causes developmental abnormalities
- Impacts fertility or developing fetus
- Has organ toxicity at low doses
- Has similar structure and toxicity profile as an existing hazardous drug

NIOSH publishes a list of hazardous drugs on its website that is updated every two years (bit.ly/3J1EBG0). Safety data sheets also provide important health hazard information.

Some examples of commonly used hazardous drugs

- Cyclophosphamide
- 5-Fluorouracil
- Methotrexate
- Cisplatin
- Doxorubicin

How does exposure occur?

Exposure can occur via dermal and mucosal absorption, inhalation, injection, and ingestion. Here are some examples:

Contact with contaminated surfaces: This is the most common route, followed by accidental hand-to-mouth ingestion and inhalation. Touching contaminated surfaces, improper use of personal protective equipment (PPE), or wearing contaminated clothing can all result in skin absorption of a hazardous drug.

- Some examples of commonly contaminated surfaces include:
  - Computer workstations
  - IV pumps
  - Floors
  - Door and cabinet handles

Breathing in aerosols: Some hazardous drugs, like cisplatin, cyclophosphamide, and 5-fluorouracil have the potential to vaporize at room temperature.

Compounding: Preparing solutions can generate dusts, vapors, and aerosols.

Administration: There are a variety of administration methods for chemotherapy, such as injection, irrigation, inhalation, or topical application. Even if a worker is not exposed during the administration process itself, events before and after administration also contribute to exposure. For example, in the case of injection administration, accidental needlesticks or unexpected spills from air being expelled from a syringe before administration can pose an exposure risk. Other methods, like irrigation or inhalation, create aerosols that health care workers might inadvertently breathe in.

Patient care: It can take up to 48 hours after administration for hazardous drugs to pass through a patient's body. Activities such as handling patient body fluids or contaminated clothing during patient care activities can expose workers, even if that worker did not administer the drugs. It's also important to note that shared restrooms are another source of exposure.

Spills: Spills can cause exposure and surface contamination.

Who is at risk?

Anyone who handles hazardous drugs or works near someone who does is at risk of exposure. This includes not only nurses and oncologists but also housekeepers, transporters, veterinarians, and others. Everyday work activities such as transportation, compounding, administration, and patient care activities can contaminate PPE and shared work surfaces.

Exposure prevention strategies

Key elements of USP 800

Engineering controls

- Facility ventilation
  - Maintaining proper airflow and differences in relative pressures with the HVAC system control spread of contamination in air.
- Primary containment control devices (C-PECs)
  - C-PECs capture aerosols and vapors at the source. Some examples of C-PECs include:
    - Containment ventilated enclosures (CVE)
    - Powder hoods
    - Biological safety cabinets (BSCs, Class II Type A2)
    - Compounding aseptic containment isolators (CACI).
- Secondary containment control devices (C-SECs)
  - C-SECs are secondary controls that back up C-PECs (primary controls). This can include the physical room in which compounding occurs, anterooms, and buffer rooms. They are designed with negative and positive air flow areas to control hazardous drug contamination.
- Closed system drug transfer devices (CSDTs)

  - Used during compounding and administration (when compatible)
  - Prevent release of aerosols and vapors into the environment
  - Prevent environmental contamination from entering the system.
- Other supplemental engineering controls
  - Other devices and accessories that reduce leaks, spills, and accidental needlesticks are:
    - Needleless delivery systems and small-bore connectors
    - Syringe caps, capping of container ports
    - Sealed impervious plastic bags
    - Impact-resistant and/or watertight containers.

Medical surveillance

- Medical surveillance provides a proactive approach to detecting and mitigating occupational exposures to hazardous drugs. Routine monitoring allows for early identification of adverse health effects, which is when intervention is most effective.
- Some core components of a medical surveillance program include:
  - **Baseline health assessment**
    - History of hazardous drug handling to help estimate previous exposures
      - Approximate number of hazardous drugs handled
      - Total years in roles related to hazardous drugs handling
    - Physical health examination
      - Example: Complete blood count (CBC)
      - Evaluate target organs affected by hazardous drugs that your facility handles
  - **Post-exposure assessment**
    - Post-exposure evaluations are recommended and should be tailored to the type of exposure and hazard.
  - **Exit evaluations**
    - If possible, conduct medical exams upon completion of employment. These assessments establish a worker's health at time of exit, which may help in future health claims or investigations.
- Some best practices for follow-up include, but are not limited to:
  - Biologic monitoring: Analyze urine or blood to verify exposure levels.
  - Re-evaluation of controls: Review engineering controls and cleaning practices.
  - Environmental monitoring: Test for hazardous drug surface contamination.

Environmental monitoring

- **Validate your handling methods -** Environmental monitoring by surface wipe sampling can provide a valuable assessment of cleaning and decontamination practices. This can help you ensure that the exposure prevention measures you have in place are working as expected.
- **Validate your cleaning methods -** This is true for regular daily decontamination and cleaning procedures as well as for spill response.

- **Reduce contamination of shared areas -** This can also help you make sure that cleaning and decontamination are preventing residues from being spread to spaces like restrooms and breakrooms.
- **Develop your own sampling strategy -** Wipe sampling can serve a variety of purposes. SAIF industrial hygiene can help you develop your sampling strategy as part of your overall program.

Spill/acute exposure response

- Have a training program that outlines spill kit locations, spill kit contents, and required PPE depending on the size of the spill to streamline spill response and help responders stay safe.
- Organizations such as the Oncology Nursing Society (ONS) provide example spill response guides (bit.ly/45BowiS).
- After a potential exposure event, such as accidental needlestick or spill, it is important to document the agents and approximate quantities that each worker was exposed to.
- Conduct practice drills.

Personal protective equipment (PPE)

- Different tasks and different hazardous drugs have different PPE requirements. Your workplace should have a policy or procedure detailing the PPE requirements for each task. NIOSH provides guidance on selecting the right PPE for health care workers handling hazardous drugs (bit.ly/3J7TPZX).
- Make sure that PPE equipment is readily accessible.
- Even when PPE is worn properly, removing contaminated PPE improperly can result in exposure. Make sure that workers are trained to put on and take off PPE correctly to reduce exposure.
- Be mindful that touching shared work surfaces while wearing contaminated PPE spreads drug residues. This includes computer keyboards, IV pumps, and door/cabinet handles.
- Contaminants can also be tracked into other areas on shoes or booties.

Special considerations: chemical exposures to cleaning agents

Deactivating chemotherapy agents on surfaces involves either chemically degrading the drug (deactivation) or physically removing it (decontamination). Common methods include the use of oxidizing agents such as hydrogen peroxide or sodium hypochlorite, or cleaning with detergents and surfactants. While complete elimination of all traces is difficult, consistent and effective cleaning protocols can substantially reduce surface contamination and worker exposure risk.

The cleaning agents themselves, however, can pose health hazards, too. Oxidizing chemicals used for deactivation may irritate the eyes, skin, or respiratory tract and can contribute to chemical exposures in the workplace. Always review safety data sheets (SDS) for deactivation and cleaning products and ensure that workers performing cleaning tasks are trained and provided with the appropriate PPE. This may include some type of respiratory protection, depending on the cleaning product being used.

Some helpful considerations for cleaning product use:

- Minimize the amount of time that the cleaning product is sitting on surfaces.
- If using a respirator, ensure that the cartridge is rated for the chemicals in the cleaning agent. Some chemicals, like hydrogen peroxide, need specific cartridges that are rated to remove that contaminant.

**** In all exposure scenarios, it is important to take a layered approach to controls, such as utilizing engineering controls in conjunction with personal protective equipment and administrative controls.***

Resources

NIOSH PPE for Hazardous Drug Handling (bit.ly/3J7TPZX)

ONS Safe Handling Toolkit (bit.ly/45BowiS)

NIOSH List of Hazardous Drugs (bit.ly/3J1EBG0)

ONS Drug Reference Sheets (bit.ly/4fty2rQ)