

## PRACTICE PEARLS

# Hazardous Drugs

*Maintaining standards of safe pharmacy practice*

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Handling hazardous drugs is complicated, and meeting current standards and requirements outlined in the latest revision of United States Pharmacopeia (USP) Chapter <797> can be challenging. However, hospitals are legally obligated to ensure that these specific provisions are in place to prevent unsafe practices and protect workers from unnecessary exposure. Pharmacists play a fundamental role in assessing, planning, and implementing these specifications into pharmacy operations. Their involvement is crucial to the success of maintaining these standards of practice. The purpose of this article is to provide pharmacists and hospital staff with a framework to better identify hazardous drugs in the workplace, recognize their possible dangers, assess the risk for exposure, and understand the necessary measures involved in handling these potentially harmful agents.

### Defining Hazardous Drugs

Any drug or substance that has the potential to cause harm to a person's health upon exposure can be said to be hazardous. The National Institute for Occupational Safety and Health (NIOSH) modified an earlier definition by the American Society of Health-System Pharmacists (ASHP) to define a *hazardous drug* as any drug having one or more of the following characteristics in humans or animals.<sup>1</sup> These characteristics can be broadly classified as:

- Genotoxicity
- Carcinogenicity
- Teratogenicity or other developmental toxicity

- Organ toxicity at low doses
- Reproductive toxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs that have been determined to be hazardous by the above criteria.

Therapeutic agents, including antineoplastic, biological, immunosuppressive, antiviral, and cytotoxic agents can be classified as hazardous drugs. Accidental skin contact, inhalation, ingestion, or injection is possible during preparation and/or administration of these drugs.<sup>2</sup> Exposures may result in skin rashes, infertility, congenital defects, cancers, and acute harm.<sup>3</sup> The frequent use of these agents in critical and life-threatening conditions presents multiple opportunities for exposure and unintended harm to various health care workers.<sup>2</sup> Pharmacists, in particular, have a high chance of exposure because they are involved in preparing, handling, and storing these drugs. To standardize the practice of handling hazardous drugs and improve safety for pharmacists and other health care workers, government and professional health care organizations have published pharmacy practice guidelines during the past 3 decades, such as ASHP's "Quality Assurance for Pharmacy-Prepared Sterile Products."<sup>4</sup>

### Addressing an Ongoing Problem

Despite these efforts, NIOSH estimated hazardous drug exposures among health care workers to have increased from approximately 5.5 million to 8 million between 2004 and 2007.<sup>1,3</sup> Furthermore, exposed personnel unknowingly can spread hazardous agents in the hospital and to their homes, making it a concern for public safety. In a study conducted by Massachusetts General Hospital, drug residues were found



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on surfaces throughout the hospital, including computer keyboards, elevator buttons and pumps sent home with patients, even on some items that were located several hundred feet away from preparation and administration areas.<sup>5</sup>

In an attempt to address this issue, the USP published Chapter <797> on Pharmaceutical Compounding—Sterile Preparations in 2004 and revised it in 2008.<sup>6,7</sup> Pharmacists are in a prime position to ensure that health care facilities and staff members comply with USP Chapter <797> provisions as well as guidelines from the Occupational Safety and Health Administration (OSHA), NIOSH, and ASHP regarding environmental and work practice controls, personnel training, and personal protective equipment (PPE).<sup>2</sup>

### Environmental and Work Practice Controls

The revised standards of USP Chapter <797> include a separate category for handling hazardous agents.<sup>6,7</sup> Pharmacists must play an active role in adhering to and enforcing these safeguards when compounding drugs to help prevent injury and illness from exposures and to ensure personnel safety. They must ensure that the compounding environment and procedures maintain a standard of quality that prevents microbial contamination of sterile products. This includes constant air changes, ventilation using HEPA filters, routine environmental testing, and appropri-

ate allocation for disposal of hazardous drugs.<sup>6</sup> The environmental and work practice controls set by USP Chapter <797> and NIOSH are listed in the Table.<sup>1,2,4,6-10</sup>

### Training on Handling Hazardous Drugs

Pharmacists can ensure that all pharmacy personnel are adequately educated on all standards and regulations regarding the preparation and handling of hazardous drugs. Continuing education programs are essential to ensure that all staff members are up to date on protocols, regulations, and safe practices regarding these hazardous agents. The various guidelines also provide specific details regarding the personnel training required for handling and preparing hazardous drugs (Table).<sup>1,2,4,6-10</sup> Given their knowledge and expertise on drugs, pharmacists should be involved in the development and implementation of these training programs. These programs should be ongoing and provide trainees with material safety data sheets (MSDS) and didactic review of hazardous drugs and their properties.<sup>6,8</sup>

### Using Personal Protective Equipment

The OSHA requires that PPE, including gloves, gowns, respiratory protection, eye and face protection, and sleeve, hair, and shoe coverings be used to reduce hazardous drug exposures among employees.<sup>9</sup> It is the responsibility of the health care facility to ensure that all staff members understand the uses and limitations of PPE to reduce potential contamination by these agents in the workplace. Pharmacists should be actively involved in the ordering of and training on PPE to ensure that it is used adequately and appropriately. General practice guidelines for using PPE are provided in the Table.<sup>1,2,4,6-10</sup>

### Medical Surveillance

Although measures are taken to protect health care workers from dangerous drug exposures, contact with these substances is still possible in the



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workplace. For this reason, a medical surveillance program should be instituted to monitor staff members who work with hazardous agents. Medical surveillance collects data, interprets information, and detects health status changes among workers who are potentially exposed to hazardous drugs. Such programs are used to establish the initial baseline health of the employees and to monitor their health for future complications resulting from potential exposures to hazardous agents. Basic medical surveillance components include routine collection of reproductive and general health information, laboratory tests, physical examinations, and adequate follow-up of exposed employees. Pharmacists must be part of overseeing the medical surveillance program to ensure that all personnel actively report hazardous drug exposures as they occur. Pharmacists also can provide guidance on improving and expanding the program. Health care facilities can use the data collected via medical surveillance to determine the effectiveness of their environmental and work practice controls, training, and PPE, and can develop action plans to prevent future worker exposure.<sup>2</sup>

## The Bottom Line For Pharmacists

Pharmacists play a key role in developing, initiating, and expanding medical surveillance programs that monitor the health of workers who potentially may be exposed to hazardous drugs. Their skills in pharmacotherapy help to ensure safer handling of these agents. By using pharmacists in both medical surveillance and enforcement of USP Chapter <797>, NIOSH, ASHP, and OSHA standards and requirements, health care facilities can address proactively this public health safety issue in the workplace to ensure a safe environment for all staff members who handle, compound, and administer hazardous drugs to patients. These safe practices also will reduce unintended exposures of patients as a public health initiative.

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2. Power LA, Polovich M. Safe handling of hazardous drugs: reviewing standards for worker protection. *Pharmacy Practice News*. 2010;37(3):1-8.
3. National Institute for Occupational Safety and Health. Medical surveillance for health care

## Table. Checklist for Hazardous Drug Controls, Handling, Training, and Medical Surveillance

<b>Environmental Controls</b>	<p>Written inventory, update, and review of all hazardous drugs in the workplace</p> <p>Storage and preparation of hazardous drugs within a negative pressure ISO Class 7 (&lt;352,000 particles/m<sup>3</sup>) buffer area that is physically separate from other areas</p> <p>Preparation phase requiring ISO Class 5 (&lt;3,520 particles/m<sup>3</sup>) BSC or CACI that vents to the outside air using HEPA filtration</p> <p>Adjacent ante-areas that are ISO 7 or better</p> <p>12 ACPH in the compounding area</p> <p>Acceptable 2-tier containment protocols for preparations in facilities that prepare low volumes of hazardous drugs and do not require a buffer area</p> <p>Routine environmental testing, such as surface or gloved fingertip sampling and viable air sampling</p> <p>Pressure differential monitoring at least every work shift or by a continuous recording device</p> <p>Maintenance and review of all certification records by supervising employees to ensure that controlled environment complies with proper air cleanliness, room pressures, and ACPH</p>
<b>Work Practice Controls</b>	<p>Removal of all personal outer garments, cosmetics, and jewelry, and use of appropriate PPE</p> <p>Antiseptic hand cleaning prior to entering buffer area or segregated compounding area</p> <p>Disposal of hazardous drug-contaminated syringes and needles in chemotherapy sharps container</p> <p>Separation of hazardous waste and contaminants from other trash</p> <p>Cleaning and disinfecting work areas in contact with hazardous drugs before and after each activity, and at the end of each work shift</p> <p>Immediately cleaning hazardous drug spills using proper safety protocols, PPE, and EMS assistance</p>
<b>Personnel Training/Evaluation</b>	<p>Provide instructional audio-visual sources, professional publications, and didactic review on:</p> <ul style="list-style-type: none"> <li>- Hazardous drugs and their properties</li> <li>- Packaging, handling, transporting, and storing hazardous drugs</li> <li>- Proper garbing and gloving</li> <li>- Adequate cleaning and disinfecting of compounding area</li> <li>- Aseptic manipulation</li> <li>- Maintaining ISO Class 5 environmental conditions</li> <li>- Proper compounding techniques within an ISO Class 5 BSC or CACI</li> <li>- CSTDs</li> <li>- Hazardous drug exposure procedures and reporting</li> <li>- State and local regulations on hazardous drug cleanup and disposal</li> <li>- CSP labeling requirements</li> </ul> <p>Require all compounding personnel to pass written competence assessment and media-fill test annually for low- and medium-risk level compounding, and semiannually for high-risk level compounding</p>
<b>PPE Use</b>	<p>Use 2 pairs of sterile powder-free chemotherapy gloves—1 covering the cuff of the gown—when there is a risk for hazardous drug exposure</p> <p>Use a lint-free, nonabsorbent, disposable gown that has a closed front and long sleeves with closed cuffs</p> <p>Use appropriate full-face respirator to protect against airborne particulates</p> <p>Use a face shield and/or goggles to protect from splashes to the eyes, nose, and mouth</p> <p>Use coated sleeve, hair and shoe coverings that reduce contamination</p> <p>Ensure that all PPE is correctly fitted</p>
<b>Medical Surveillance Program</b>	<p>Set up a comprehensive and ongoing medical surveillance program by a designated team that provides:</p> <ul style="list-style-type: none"> <li>- Initial and continuous health monitoring</li> <li>- Routine collection of reproductive and general health information</li> <li>- Physical examinations</li> <li>- Laboratory workup (ie, complete blood count, comprehensive metabolic panel liver enzymes, urinalysis)</li> <li>- Screening tests</li> <li>- Exposure assessment and documentation</li> <li>- Analysis and notification of test results</li> <li>- Exposure control plan</li> <li>- Occupational health follow-up and consultation</li> </ul>

Based on references 1, 2, 4, and 6-10.

**ACPH**, air changes per hour; **BSC**, biological safety cabinet; **CACI**, compounding aseptic containment isolator; **CSP**, compounding sterile preparation; **CSTD**, closed system transfer device; **EMS**, environmental management service; **HEPA**, high efficiency particulate air; **PPE**, personal protective equipment

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