

Developing a hazardous drug safe-handling program

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While information about the occupational risks of chemotherapy and other hazardous drugs has been available for more than 20 years, evidence for worker exposure is still being reported. The Occupational Safety & Health Administration (OSHA) published the first national guidelines for safe handling of chemotherapy in 1986, and yet these recommendations are not universally used. This article will review the current recommendations for the safe handling of hazardous drugs and describe the components of a hazardous drug safe handling program.

Warning!

Working with or near hazardous drugs in health care settings may cause skin rashes, infertility, miscarriage, birth defects, and possibly leukemia or other cancers.¹

This warning comes from the *NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and other Hazardous Drugs in Healthcare Settings*, which was published by the National Institute for Occupational Safety and Health.¹ The purpose of the warning and the publication is to inform healthcare workers of the potential risks involved in preparing and administering chemotherapy and other similar drugs. Most drugs classified as hazardous are anti-neoplastic agents, while others are antiviral agents or drugs with similar characteristics. *Drugs should be handled as hazardous when they meet one or more of the following characteristics:*

- carcinogenicity
- teratogenicity or developmental toxicity
- reproductive toxicity
- organ toxicity at low doses
- genotoxicity
- structure or toxicity similar to drugs classified as hazardous using the above criteria.¹

Routes of exposure

Nurses and other staff members run the risk of exposure to hazardous drugs by one of the following routes:

- Inhalation—from breathing contaminated air, such as from aerosolized drugs
- Dermal contact—from touching drugs directly or touching contaminated surfaces
- Ingestion—from contaminated food or drink or other hand-to-mouth contact
- Accidental injection—from needle stick or other

contaminated sharps injury

Safe handling recommendations

Recommendations for the safe handling of hazardous drugs were first published in 1985 by the American Society of Health-System Pharmacists (ASHP). The Occupational Safety & Health Ad-

KEY POINTS

Recommendations for safe handling of hazardous drugs were first published in 1985.

Implementing a comprehensive safety program poses a number of challenges including cost, adequate staffing, and reluctance, on the part of staff, to comply.

The program requires an interdisciplinary approach.

A written plan should be put into place, with regular review and monitoring.

When consistently applied, current recommendations can reduce employee exposure and its effects.

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ministration (OSHA) guidelines for safe handling, *Controlling Occupational Exposure to Hazardous Drugs*, followed the next year.² The Oncology Nursing Society (ONS) first released guidelines and recommendations for practice related to chemotherapy in 1988. The *NIOSH Alert* reflects the most recent safe handling recommendations.¹

Safe handling recommendations focus on methods to reduce exposure to hazardous drugs in the occupational setting. The recommendations are based on the concept of the hierarchy of controls, which comes to us from industrial hygiene. Use of the term "hierarchy" is deliberate. It implies that some methods of controlling a workplace hazard are more effective, and should be applied first (Table 1).

Eliminating the hazard would be the most effective way of preventing exposure to chemotherapy in the workplace. This is not feasible with chemotherapy, since there are no substitutes.

Engineering controls are machines or equipment designed to contain a hazardous substance, thus preventing worker exposure. Ventilated cabinets, such as a biological safety cabinet (BSC) or isolator are examples of engineering controls. These devices are designed to protect workers by containing aerosols that are generated during drug preparation. A Class II BSC has an

open front and relies on airflow to move contamination away from the worker. Class III BSCs and isolators are closed during drug preparation, which takes place using gloved sleeves. All types of ventilated cabinets filter exhaust air through a high efficiency particulate air (HEPA) filter. Each can be exhausted outside or a certain amount of filtered air may be recirculated.

A closed system drug transfer device is also an engineering control. These devices are designed to prevent leaking of drug during transfer from one container to another. One component provides access to the drug vial, while others attach to IV containers, tubing, and syringes. Used together, these prevent contamination during drug preparation and administration. The system is meant to be used as an adjunct to, and not a substitute for, a ventilated cabinet.

Administrative controls include policies, procedures, scheduling practices, and other methods that limit the numbers of workers with access to hazardous drugs. Designating personnel to mix chemotherapy falls under this category of controls. Some organizations limit chemotherapy administration to certain locations as a means to minimize employee exposure.

Staff education and training are important administrative controls. Education and competency for hazardous drug handlers includes:

- Training that is role/department-specific (Table 2),
- Validating employee competency before assuming duties,
- Retraining and validation on an annual basis, and
- Documenting training.

Work-practice controls include specific ways of handling hazardous drugs that reduce worker exposure. Examples of safer work practices for individuals who prepare and/or administer chemotherapy include: using negative pressure technique when reconstituting powder drugs; using

TABLE 2

Training checklist for hazardous drug handlers

- Hazardous drug list
- Potential risks of exposure
- Exposure routes
- Drug storage
- BSC use/maintenance
- Required PPE
- Work practices
- Drug transport
- Waste disposal
- Spill management
- Record keeping
- Skill checklists/tests

locking connections on IV equipment; spiking IV containers before adding hazardous drugs; avoiding unspiking IV containers; and using needle-less systems.

Personal protective equipment (PPE) provides a barrier between the worker and chemotherapy during mixing and drug administration. PPE that has been tested with hazardous drugs protects the worker from direct contact with the drug through absorption or inhalation. For hazardous drugs, the recommended PPE includes:

- Double gloves: tested with hazardous drugs, powder-free, latex, nitrile or neoprene,
- Gowns: chemical protective, disposable, single-use, cuffs, back closure,
- Eye protection: when splashing is likely, and
- Respirator/masks: for aerosols and spill clean-up.

Hazardous medications/chemotherapy management plan

Establishing a safe-handling program requires an interdisciplinary approach. Depending on the size and complexity of the organization, the following should be included:

- Nursing,
- Pharmacy,
- Administration, and
- Employee Health

TABLE 1

Managing hazardous drug exposure, from most effective to least effective

- Eliminate the hazard—not feasible with chemotherapy
- Engineering controls—ventilated cabinets & closed systems
- Administrative controls—safe handling policies
- Work practice controls—no spiking and unspiking
- Personal protective equipment—gloves and gowns

TABLE 3

Medical surveillance plan for hazardous drug handlers

Identify employees potentially exposed
Perform baseline health appraisal
Perform periodic health appraisal
Evaluate employees following acute exposure
Investigate work-related health changes

Components of a safe handling plan

A well-designed safe-handling program includes a written plan that begins with identifying the drugs that must be handled as hazardous. Procedures should address drug preparation, drug administration, spill management, and waste management. Policies must specify that drugs are handled only by trained personnel, and education and competency requirements must be defined. In addition, there should be a policy addressing hazardous drug handling by employees who are actively trying to conceive, are pregnant, or are breast feeding. ONS recommends that employees be informed of the potential risks from hazardous drug handling before or during pregnancy, and that they be given alternative duty upon request.³

The safe-handling plan should include mechanisms for reviewing spill and acute exposure reports. The plan should also establish a system for medical surveillance of employees involved in hazardous drug handling (Table 3).

Quality monitoring can measure employee adherence to precautions, such as PPE use. The same skill checklist used for training can be used for periodic evaluation of performance during drug preparation and drug administration. All spills should

be evaluated to identify contributing factors, such as equipment and practices, as well as the effectiveness of the spill management procedures.

Implementation challenges

Implementing a comprehensive hazardous drug safe handling program is not without its challenges. One hurdle is the cost of equipment and services. Some of the costly items include:

- Containment cabinets such as BSCs,
- External venting for BSCs,
- Closed system drug transfer devices,
- Personal protective equipment, and
- Disposal of chemotherapy waste.

Staffing challenges also exist. It may be difficult to access sufficiently educated staff, particularly during the current nursing shortage. Providing alternative duty around pregnancy can be problematic, depending on the size and scope of the practice setting.

Other implementation challenges include the reluctance of staff to comply with safe handling precautions. Some frequently-cited reasons for non-adherence include:

- Discomfort with PPE, especially gowns,
- Concern for patients' reactions to protective garments, and
- Lack of concern for potential health

effects from occupational exposure.

Summary

The risks of occupational exposure to hazardous drugs are well established. Workers experience a potential threat to their health by the daily opportunity for exposure to hazardous drugs. When consistently applied, the current recommendations for safe handling can reduce employees' exposure and its effects.

An employer's responsibility for establishing a comprehensive safe handling program includes the following:

- Reviewing guidelines regularly,
- Developing policies and procedures based on guidelines,
- Training all staff according to their hazardous drug handling tasks, and
- Monitoring staff adherence to guidelines.

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