

US Public Policy Position
Advancing the Safe Handling of Hazardous Drugs
to Protect Healthcare Personnel

ISSUE: Exposure to Hazardous Drugs Can Have Harmful Effects on Healthcare Personnel

Healthcare personnel who transport, prepare, administer and dispose of hazardous drugs can be exposed to these toxic agents in the air or on work surfaces, clothing, medical equipment and other surfaces. As a result, both clinical and nonclinical workers are at risk for exposure when they create aerosols, mix liquids, generate dust, or touch contaminated surfaces if safe handling precautions are not followed. Frequent exposures to even very small concentrations of powerful drugs used for cancer chemotherapy, antiviral treatments, hormone regimens and other therapies have serious health consequences for workers who come in contact with them.¹

National guidelines have been established for handling hazardous drugs, but compliance with these guidelines is not required and adherence has been reported to be sporadic.^{2 3 4 5} In 2004, the National Institute for Occupational Safety and Health (NIOSH) warned the public that working with or near hazardous drugs in healthcare settings may cause cancer, reproductive and developmental problems, allergic reactions and other adverse effects that can be irreversible even after low-level exposures.⁶ The lack of adherence to existing voluntary guidelines is a safety risk for healthcare personnel and comprehensive standards must be developed and enforced to ensure the safe handling of hazardous drugs.

POSITION: In accordance with the NIOSH 2004 alert, BD supports the development of comprehensive standards that require facilities that handle hazardous drugs to take the following actions to protect healthcare personnel:

1. Evaluate workplace to identify and assess hazards

All healthcare settings, veterinary medicine, research laboratories, retail pharmacies and home healthcare agencies must catalog the types of drugs, volume, frequency of shipment and form of drugs being handled at their facility. In addition, facilities should complete a work environment inventory that includes a catalogue of equipment designed to reduce exposure to hazardous drugs as well as the physical layout of work areas.

2. Establish management policies and training programs for handling hazardous drugs

Facilities that handle hazardous drugs must establish administrative controls to address preparing, administering and disposing of these agents. Policies and training programs should be instituted to address: presence of hazardous drugs, labeling, storage, spill control, personnel issues (exposure of pregnant workers) and detailed procedures for preparing, administering, testing for surface contamination and disposing of hazardous drugs.

3. Require comprehensive use of equipment designed to reduce exposure to hazardous drugs

To help prevent occupational exposure to hazardous drugs, the use of personal protective equipment (PPE), ventilated cabinets (Class II or III biological safety cabinets (BSC) or a compounding aseptic containment isolators (CACI) that meet the USP 797 requirements) and engineering controls that are clinically proven such as closed-system transfer devices (CSTDs) – are recommended by NIOSH, International Society of Oncology Pharmacy Practitioners (ISOPP), American Society of Health-System Pharmacists (ASHP), Oncology Nursing Society (ONS) and U.S. Pharmacopeia 797 (USP 797)^{7 8 9 10 11} and should be required.

4. Increase and standardize efforts to survey and report exposures to hazardous drugs

All incidences in healthcare settings related to hazardous drug exposure, spills and splash should be reported to management. Survey and report data should capture the worker's past exposure, medical history and ongoing monitoring of blood and urine tests to help determine linkage to exposure and facilitate long-term epidemiological review. State cancer registries must capture the occupation of cancer patients to assist in efforts to identify the cause of the cancer nationally.

BACKGROUND: Exposure to Hazardous Drugs Can Have Serious Consequences for Healthcare Personnel

Drugs of Concern

Drugs that are classified hazardous are defined by their carcinogenic, teratogenic, reproductive toxicity, organ toxicity at low doses, genotoxic, structure and toxicity.¹² These hazardous drugs include antineoplastics, which are drugs used to treat cancer. Antineoplastic agents, also known as chemotherapy, were developed from chemical agents introduced originally as nitrogen mustard during World War I. These agents caused bone marrow and lymph tissue regression. The same mechanisms that kill cancer cells are damaging to healthy cells.

However, hazardous drugs are not limited to just antineoplastics, they also include antiviral drugs, hormones, and bioengineered drugs.¹³ NIOSH revised the ASHP definition of hazardous drugs and identified approximately 150 drugs as hazardous, including 30 International Agency for Research on Cancer (IARC) carcinogens.^{14, 15, 16}

Effects of Exposure to Hazardous Drugs

Results show that coming into contact with hazardous agents can cause numerous problems. Exposed healthcare workers experienced higher rates of spontaneous abortions and potential fetal malformations. Lawson et al recently reported a statistically significant, nearly two-fold increase in risk for spontaneous abortions among nurses exposed to antineoplastic agents during the first trimester.¹⁷ Workers reported that they were experiencing side effects similar to those of a chemotherapy patient (hair loss, vomiting, mouth sores, and skin rashes).^{18 19} Additionally, the incidence of cancer in these workers was higher, especially for leukemia and bladder cancer.^{20 21}

The Kaiser Permanente Center for Health Research published a study showing that exposure of pregnant women handling antineoplastic agents during pregnancy was associated with an increased risk for spontaneous abortions and stillbirth. In 2005, a survey of 7500 members of the Oncology Nursing Society found a significant increased risk for infertility and miscarriage among nurses under 25 years of age working with chemotherapy.²²

In 2009, a Danish study using cancer registries of 92,000 female nurses found a correlation of elevated risks for breast cancer, thyroid, nervous system and brain cancer among female nurses.²³ Furthermore, a study using data from three US university hospital-based cancer centers discovered chromosome 5 and 7 changes among healthcare workers handling hazardous drugs.²⁴ Chromosome 5 and 7 abnormalities are often associated with secondary malignancies such as myelodysplastic syndrome (disease of blood or bone marrow) or acute myeloid leukemia following chemotherapy treatment.

Increasing Risks for Exposure to Hazardous Drugs

There is increasing evidence of the risks posed by exposure to hazardous drugs. In the US alone, approximately 8 million healthcare personnel are involved in nursing, pharmacy, transport and cleanup of chemotherapy waste.²⁵ Many of these workers are not properly trained to handle exposures to hazardous drugs. In addition, some healthcare personnel experience barriers to accessing proper engineering controls and protective equipment while other healthcare workers think they are immune from exposure. The demand on this workforce will only increase overtime. In fact, the World Health Organization predicts a 50% increase of cancer case over the next 20 years as the population ages.²⁶

In the US, an estimated 23 million adult visits occur annually for chemotherapy treatment, and of these visits 84% are administered in ambulatory settings by nurses.²⁷ The increasing number of cancer cases will also require more potent chemotherapy drugs and will elevate the risk for exposure on healthcare workers. In many circumstances, investigational and experimental drugs are considered hazardous until proven otherwise. In addition, chemotherapy drugs and other hazardous drugs are reportedly used to treat non-malignant diseases like arthritis and multiple sclerosis. Uses for them have also expanded into the veterinary field. In 2010, NIOSH issued an updated document providing guidelines for safe handling of hazardous drugs for veterinarian workers.²⁸

A study conducted by the University of Michigan on ambulatory oncology nurses discovered that the overall rate of exposure to the skin or eyes over a year period among 1339 nurses surveyed was 16.9%.²⁹ A study conducted by NIOSH demonstrated the surfaces in healthcare facilities are typically contaminated with antineoplastic drugs and that contamination may lead to worker exposure.³⁰ This is consistent with studies published in the US and many other countries around the world.

In response to this information, The Joint Commission, OSHA and NIOSH issued a joint letter to healthcare facilities in the US urging them to re-evaluate their safe handling practices related to hazardous drugs and alerting them to the updated NIOSH hazardous drug list (2010). However, adherence to national guidelines remains sporadic and comprehensive standards are required to adequately protect healthcare personnel from hazardous drugs.

¹ National Institute for Occupational Safety and Health. NIOSH alert: preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings. 2004; 1-4.

² Valinis B, McNeil V, Driscoll K. Staff members' compliance with their facility's antineoplastic drug handling policy. *Onc Nurs Forum*. 1991 ; 18 (3): 571-576. Nieweg et al. 1994.

³ Valinis B, Vollmer WM, Labuhn K, Glass A, Corelle C. Antineoplastic drug handling protection after OSHA guidelines : comparison by profession, handling activity, and work site. *J Occup Med*. 1992; 34: 149-155.

⁴ Mahon SM, Casperson DS, Yackzan S, Goodner S, Hasses B, Hawkins J, Parham J, Rimkus C, Schlomer M, Witcher V. Safe handling practices of cytotoxic drugs: the results of a chapter survey. *Oncol Nurs Forum*, 1994; 21 (7): 1157-1165.

⁵ Newberg RMB, de Boer M, Dubbleman RC, Gall HE, Hesselman GM, Lenssen PCHP, Van Maanen LWGM, Majoor PWFM, Ouwerkerk J, Slegt JH. Safe Handling of Antineoplastic drugs. *Cancer Nurs*, 1994; 17:501-511.

⁶ National Institute for Occupational Safety and Health. NIOSH alert: preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings. 2004; 1

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- ⁷ National Institute for Occupational Safety and Health. NIOSH alert: preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings. 2004; 14-15.
- ⁸ International Society of Oncology Pharmacy Practitioners. ISOPP Standards of Practice. *Journal of Oncology Pharmacy Practice*. 2007; 13 Suppl: 1-81.
- ⁹ American Society of Health-System Pharmacists. ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm*. 2006; 63:1172-93.
- ¹⁰ Polovich M. Safe Handling of Hazardous Drugs, Second Edition. Oncology Nursing Society; 2011.
- ¹¹ USP <797> Guidebook to Pharmaceutical Compounding – Sterile Preparations. United States Pharmacopeial Convention; 2008: 37-38.
- ¹² National Institute for Occupational Safety and Health. NIOSH alert: preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings. 2004; 32.
- ¹³ National Institute for Occupational Safety and Health. NIOSH alert: preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings. 2004; 31.
- ¹⁴ Center for Disease Control. NIOSH List of antineoplastics and other hazardous drugs in healthcare settings 2010. <http://www.cdc.gov/niosh/docs/2010-167/pdfs/2010-167.pdf> (assessed 2012 May 3).
- ¹⁵ American Society of Health-System Pharmacists. ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm*. 2006; 63:1172-93.
- ¹⁶ International Agency for Cancer Research. IARC Monographs on the evaluation of carcinogenic risks to humans <http://monographs.iarc.fr/ENG/Classification/index.php> (assessed 10 May 2012).
- ¹⁷ Lawson, C.C., Rocheleau, C.M., Whelan, E.A., Hilbert, E.N.L., Grajewski, B., Spiegelman, D. and Rich-Edwards, J.W. Occupational exposures among nurses and risk of spontaneous abortion. *American Journal of Obstetrics and Gynecology*; 2012;206: E-pub ahead of print. doi.org/10.1016/j.ajog.2011.12.030
- ¹⁸ Valanis BG, Herzberg V, Shortridge L. Antineoplastic drugs: handle with care. *AAOHN J*. 1987; 35:487-92.
- ¹⁹ Valanis BG, Vollmer WM, Labuhn KT et al. Association of antineoplastic drug handling with acute adverse effects in Pharmacy personnel. *Am J Hosp Pharm*. 1993; 39: 141-7.
- ²⁰ National Institute for Occupational Safety and Health. NIOSH alert: preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings. 2004; 6.
- ²¹ Washburn, DJ. Intravesical Antineoplastic Therapy Following Transurethral Resection of Bladder Tumors: Nursing Implications from Operating Room to Discharge. *Clinical Journal of Oncology Nursing* 11 (4). 2007.
- ²² Martin, S, RN, DNSc, AOCN, Chemotherapy Handling and Effects Among Nurses and Their Offspring. Oncology Nursing Consultant, 2005. (assessed 2012 May 3).
- ²³ Scand J Work Environ Health. 2009 Dec; 35(6):446-53. Epub 2009 Oct 1.
- ²⁴ McDiarmid MA, Oliver MS, Roth TS, Rogers B. and Escalante CP. Chromosome 5 and 7 abnormalities in oncology personnel handling anticancer drugs. *J Occup Environ Med*. 2010; 52:1028-1034.
- ²⁵ Center for Disease Control. Hazardous Drug Exposures in Health Care <http://www.cdc.gov/niosh/topics/hazdrug/#a> (accessed 2012 October 5).
- ²⁶ World Health Organization, Genetics in Prevention Treatment of Cancer. www.who.int/genomics/about/Cancer.pdf (assessed 2012 April 28).
- ²⁷ Friese, CR, Himes-Ferris L, Frasier Mn, et al. *BMJ Qual Saf* (2011). Doi:10.1136/bmjqs-2011-000178.
- ²⁸ Center for Disease Control, National Institute for Occupational Safety and Health, Workplace Solutions: Safe Handling of Hazardous Drugs for Veterinary Healthcare Workers DHHS (NIOSH) Publication No. 2010-150 (June 2010)
- ²⁹ Friese, CR, Himes-Ferris L, Frasier Mn, et al. *BMJ Qual Saf* (2011). Doi:10.1136/bmjqs-2011-000178.
- ³⁰ Connor TH, DeBord DG, Pretty JR, Oliver MS, Roth TS, Lees PSJ, Krieg EF Jr., Rogers B, Escalante CP, Toennis CA, Clark JC, Johnson BC, McDiarmid MA .2010. Evaluation of antineoplastic drug exposure of health care workers at three university-based US cancer centers. *J Occup Environ Med* 52(10):1019–1027.