



Implementing a Personnel Surveillance Program for Hazardous Drug Safety

Occupational exposure to hazardous drugs (HDs) during the compounding and administration process is a real and unpredictable risk. The results from a 1979 study identified the potential risks to health care providers who handle hazardous drugs or chemicals while providing care to patients.¹



Photo courtesy of Carmel Pharma

The use of a closed-system drug transfer device can reduce employee exposure to hazardous agents.

Guidelines & Recommendations

The Centers for Disease Control, through the National Institute of Safety and Health (NIOSH), issued an alert entitled "Preventing Occupational Exposure to Antineoplastics and Other Hazardous Drugs in Healthcare Settings" in March 2004.² The alert was published as an update to the United States Department of Labor's Occupational Safety and Health Agency (OSHA) technical manual for employers, in order to minimize the risk to employees responsible for the handling of hazardous drugs.³ The NIOSH alert provides alarming evidence of the risk associated with handling hazardous drugs, and expands the risk beyond the individuals who compound and administer these products to all individuals (i.e., shipping/receiving, housekeeping, laundry staff, etc.) who may come into contact with these chemicals. In 2007, NIOSH published an update to the 2004 recommendations, emphasizing a formal medical surveillance program for personnel who handle HDs.⁴

Designating Drugs as Hazardous

To date, the FDA has not mandated that drugs bear a symbol to designate them as hazardous. Each institution should individually assess new drugs

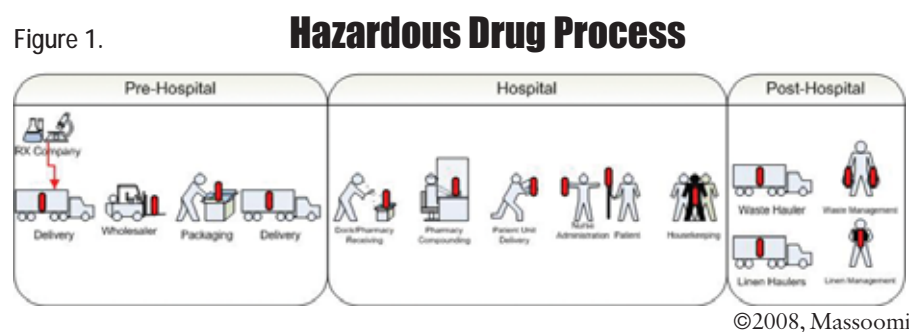
based upon the hazardous drug criteria contained within the NIOSH document. Once they are identified, it is up to the institution to educate their personnel on the hazards involved with managing these agents. Based on the potential long-term risks associated with these agents, it is incumbent on the FDA to require a universal symbol on hazardous drugs to aid individuals in identifying them.

Setting

Nebraska Methodist Hospital (NMH) is a community-based, not-for-profit hospital located in Omaha, Nebraska. It is licensed for 440 beds with an average daily census of 300. The centers of excellence at NMH include oncology, obstetrics, orthopedics, and cardiovascular services. During the 2007 calendar year, the pharmacy department aseptically compounded 2,372 oncology-related hazardous drugs. Additionally, 33,779 doses of hazardous drugs, as defined by NMH with the assistance of Appendix A of the NIOSH alert, were dispensed for administration. In 2004, NMH's hazardous materials committee formed a subcommittee, consisting of representation from pharmacy, nursing, human resources, safety, radiology, performance improvement, employee health, housekeeping, and administration, to formally address the safety of hazardous drugs and develop policies and procedures that could ensure the safety of NMH's employees.

Identifying "At Risk" Employees

The NMH committee's analysis identified an important gap: a knowledge deficit of hospital administration, pharmacy, and nursing personnel regarding the risk and severity of occupational exposure to HDs. Additionally, the spectrum of the



problem was not fully understood. To better understand the magnitude of the risk, a "cradle to grave" concept for HD management was used when defining "at risk" employees. (See Figure 1.)

Each person who handles an HD is at risk for an occupational exposure. Your safety program for managing these agents should take into account all aspects of



HD management. A less-known point of exposure is the patient. NIOSH clearly states that body fluids (i.e., sweat, emesis, etc.) from patients receiving HDs may contaminate the linen associated with the care of the patient for up to seven days post-dosing. The hospital's linen and waste management service providers should be notified that the end products they receive from the hospital may be contaminated with hazardous materials. Hospitals may have to assist their service providers with understanding the risks and provide guidance on how to formally address HD management.

During our assessment, NMH identified individuals who are at high risk and low risk of exposure. High-risk individuals are those whose position puts them at risk of coming into direct contact with concentrated forms of HDs. These employees include shipping/receiving personnel, compounding personnel (pharmacists, interns, and technicians), nurses, and physicians. Low-risk individuals, such as housekeeping personnel, linen handlers, and waste haulers, are those who have the potential of exposure due to a casual relationship to HDs. Actually, any person who crosses the path of the HD (visitors, chaplains, food-service personnel, contractors, etc.), as outlined in Figure 1, is at low risk of exposure. However, we limited the definition to those individuals whose job requires them to be involved with HDs or the ensuing waste. Using these criteria, NMH identified 48 high-risk individuals and 136 low-risk individuals on its staff.

Surveillance of Personnel

The NIOSH and OSHA documents emphasize the responsibility of employers to educate their employees on the risks associated with handling hazardous drugs and to implement steps to minimize exposure risk to employees. Both of these documents mention the inclusion of a medical surveillance program for at-risk employees. The concept of a medical surveillance program is only a recommendation and is not mandated. Building upon the NIOSH recommendations, NMH developed a four-tier surveillance program. (See Table 1.)

A comprehensive safety program should incorporate all four tiers. Currently, debate exists on the value of annualized laboratory tests. Hospital administration and employee health departments may be turned off by the additional expense of a tier-three surveillance program, which is due to the costs of obtaining lab results and the subsequent ramifications if an abnormal test result arises. That said, individuals who frequently work with HDs find value in knowing their employer has provided them with every possible recommendation to detect issues and assure their safety.

Products to Prevent Worker Exposure to Hazardous Drugs
Nebraska Methodist Hospital uses a variety of products to prevent worker exposure to hazardous drug agents, including the following:

Product Name	Reader Service Number
Carmel Pharma's PhaSeal Closed-System Drug Transfer Device	1
Cardinal Health's Esteem XP chemotherapy-rated nitrile gloves	2
Hospira's SurfaceSafe decontaminating wipes	3
Kendall's ChemoSafety polyethylene gowns and protective compounding mats	4
NuAire's PharmGard negative pressure compounding aseptic containment isolator	5

For more information on the products above,
circle their corresponding numbers on PP&P's free reader service card (see page 1).

Table 1. Formal Surveillance Program for Hazardous Drugs

Tier-One: *Self Surveillance*

- Education by employer to employee on hazardous drugs used and safety measures required
- Education on side effects associated with an acute exposure (i.e., nausea, vomiting, rashes)
- Notification to employee's primary care physician of occupational hazards
- Notification to supervisor and primary care physician of any health changes from norm
- Immediate notification to supervisor of reproductive changes

Tier-Two: *Employer/Supervisor Surveillance*

- All tier-one activities
- Annual basic physical exam
- Annual questionnaire on reproductive changes
- Trending of sick call types for high-risk employees (i.e., nausea after heavy chemo day)
- If trend is noted, consultation with employee health physician

Tier-Three: *Comprehensive Medical Surveillance*

- All tier-one and tier-two activities
- Comprehensive physical examination directed toward hazardous drug exposure
- Complete blood count with differential upon hire and annually thereafter
- Complete urinalysis with dipstick upon hire and annually thereafter
- Liver function and transaminase tests upon hire and annually thereafter

Tier-Four: *Post-Exposure Surveillance (exposure known or suspected)*

- Comprehensive physical examination directed toward hazardous drug exposure
- Complete blood count with differential
- Complete urinalysis with dipstick
- Liver function and transaminase tests
- Notation in employee's medical record of exposure to include date, drug name (if known), and short-term and long-term side effects
- Continuous (defined by the institution) self-monitoring and employer monitoring

Estimated Costs

To implement NIOSH's current recommendations for laboratory-based medical surveillance, you need to consider the time required to educate at-risk personnel and the cost associated with laboratory testing equipment and activities. The following guidelines, based on 2007 pricing, can be used to estimate the cost of laboratory tests for your facility:

- Complete blood count with differential (CPT4 #85025) = \$3.00 to \$6.00 per test
- Complete urinalysis with dipstick (CPT4 #81001) = \$1.50 to \$3.00 per test

At NMH, we estimated the cost of laboratory tests for a tier-three surveillance program for 48 high-risk staff to be \$144 to \$288 for the complete blood count and

For more information, circle #72 on the Reader Service Card

\$72 to \$144 for urinalysis, resulting in a total cost of \$216 to \$432 per year.

Conclusions

The implementation of a HD safety program involves incremental costs. It is important to note that the costs associated with protecting health care workers from exposure to hazardous chemicals is incalculable, in terms of the long-term mortality and morbidity of health care personnel. We do not fully understand the magnitude and long-term effects of hospital personnel's continuous exposure to HDs, but because we are aware of the potential for risk, it is our obligation to prevent harm to our employees. ■

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4. National Institute for Occupational Safety and Health. NIOSH Publication No. 2007-117: Medical Surveillance for Health Care Workers Exposed to Hazardous Drugs. Available at: <http://www.cdc.gov/niosh/docs/wp-solutions/2007-117/>. Accessed February 1, 2008.



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