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Hazardous Drugs

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Establishing a Hazardous Drug Safety Program

DRUGS ARE CLASSIFIED AS HAZARDOUS CHEMICALS WHEN they possess one of the following characteristics: carcinogenicity, teratogenicity, developmental toxicity, reproductive toxicity, genotoxicity, and/or, organ toxicity at low doses. The adverse effects of hazardous drugs are well documented in patients who have to receive them as part of their treatment.[1] Since 1979, case reports and small observational studies have shown that the adverse effects noted during treatment differ from those of accidental occupational exposures to health care workers.[2] Occupational exposures are often of the occult nature, unless an outward manifestation like a rash appears. Because of this "hidden" exposure, health care workers frequently do not receive the benefit of the countermeasures that diminish a patient's exposure to these substances. The best countermeasures for individuals who manage hazardous drugs are practice standards put in place to minimize exposure risk when handling toxic substances.

Table 1. EPA RCRA regulated pharmaceutical wastes and corresponding EPA code type

Drug	EPA Code
Arsenic Trioxide	P012
Epinephrine	P042
Nicotine	P075
Nitroglycerin	P081
Physostigmine	P204
Warfarin >0.03%	P001
Chloral Hydrate	U034
Chlorambucil	U035
Cyclophosphamide	U058
Daunomycin	U059
Diethylstilbesterol	U089
Lindane	U129
Melphalan	U150
Mitomycin C	U010
Reserpine	U200
Streptozotocin	U206
Saccharin	U202
Selenium Sulfide	U205
Uracil Mustard	U237
Warfarin <0.3%	U248

Documents such as ASHP's Guidelines on Handling Hazardous Drugs[2], OSHA's technical manual on controlling exposure to hazardous drugs[3], and the NIOSH alert entitled "Preventing occupational exposure to antineoplastic and other hazardous drugs in healthcare settings"[4] provide the evidence and the framework for establishing a hazardous drug safety program for hospitals and other practice settings that manage these drugs. In addition, unlike other standards of practice, the NIOSH alert and OSHA documents are free to download from the Internet.

At Nebraska Methodist Hospital (NMH), a 440-licensed-bed, not-for-profit facility located in Omaha, Nebraska, the primary areas of care include oncology, cardiovascular, obstetrical care, orthopedics, and neurology. In 2006, the department of pharmacy services compounded 2,107 sterile hazardous drugs for cancer therapy and dispensed greater than 32,621 doses of various oral and injectable drugs listed in Appendix A of the NIOSH alert.

A multidisciplinary sub-committee of NMH's hazardous material committee was formed in 2004 to formally address the management of hazardous drugs. The committee consisted of representatives from pharmacy, nursing, human resources, safety, radiology, performance improvement, employee health, housekeeping, and administration. The committee established the following goals:

- Address national compliance standards to daily practices to ensure patient and employee safety
- Compare practices to nationally approved labor laws and practice standards
- Conduct a gap analysis comparing OSHA and NIOSH recommendations to current practice
- Formally present findings to hospital administration
- Establish an implementation strategy for gaps

Hazardous Drugs



This article outlines the processes now in place at Nebraska Methodist Hospital for the safe handling of sterile hazardous drugs. While the multidisciplinary team in general is satisfied in having addressed all OSHA regulations and the majority of NIOSH recommendations, opportunities for improvement still exist.

Educating Staff on Risks: One of the biggest gaps identified in our analysis was staff education. Upon questioning pharmacy, nursing, and housekeeping personnel, a lack of understanding of the risk and severity of occupational exposure to hazardous drugs was strikingly evident. When presented with the definition of a hazardous drug, most employees were alarmed by the risk. A formal education plan was immediately implemented, including in-services to all pharmacy and nursing staff involved in the preparation and administration of chemotherapeutic agents. Additionally, housekeeping , laundry services, and prescribing physicians were targeted for education. The proper handling of hazardous drugs is also re-enforced in the hospital-based annual organization review test required of all employees.

Formulary Measures: One of the first steps was defining the magnitude of hazardous drugs used at NMH. Our drug formulary contained 89 of the 136 hazardous drugs listed in Appendix A of the NIOSH alert. To assist in notifying pharmacists and nurses, we electronically tagged each hazardous drug on the formulary in the hospital computer system with the following alert: "Hazardous Drug – Contact Pharmacy for Questions".

Minimizing Risks in Receiving: Personnel working in the receiving area are at risk of exposure due to vials that may have broken during shipping or those that were not properly packaged prior to shipping. Our wholesaler labels all totes that contain chemotherapy, but limits the labeling of totes to hazardous drugs that are classified as chemotherapeutics. Other non-chemotherapeutic drugs listed in the NIOSH alert's Appendix A are in totes with additional packing material to protect the drugs, and the drugs are then sealed in a zip-lock bag labeled as containing a hazardous drug. When opening these totes, purchasing personnel are required to don a mask and hazardous-drug-rated nitrile gloves.

Well-Marked Storage: Employees need to be aware of the designated areas that contain hazardous drugs. At NMH, signage has been posted in the main room where hazardous drugs are stored and compounded (See above left). Hazardous drugs are marked with tall-man lettering to minimize "look alike, sound alike" errors.

Safe Compounding Practices: All hazardous drugs are stored and compounded in an ISO Class 7 cleanroom with a negative pressure gradient of 0.02 inch water column in comparison to the surrounding environment. All sterile hazardous drugs are compounded in a Controlled Environment Testing Association (CETA) compliant, negative-pressure compounding aseptic containment isolator (CACI) from NuAire. The isolator does not recirculate the HEPA-filtered air onto the workspace and is 100% exhausted to the outside.

During the compounding process, all compounding personnel must don the required personal protective equipment (PPE) outlined in NIOSH and USP <797>, including hair bonnet, shoe booties, a polyethylene gown (Kendall's ChemoSafety), face mask, and double-gloving with hazardous-drug-rated nitrile gloves (Cardinal Health's Esteem XP, N8852XP). The use of an isolator or the PhaSeal closed-system drug transfer device does not exempt the use of PPE. Once the compounding personnel and isolator are ready, a protective compounding mat (Kendall's ChemoSafety, CT0302-1) is placed in the compounding space, and all products used for compounding are placed on the mat prior to compounding. Since 2002, NMH has utilized PhaSeal to minimize the exposure of vapors and spray that may occur during the compounding process, and establish employee consistency with compounding practices. Once the final product is checked by a pharmacist in the isolator, the product is wiped with SurfaceSafe decontaminating wipes from Hospira, prior to labeling and bagging for delivery.

Drug Delivery: Each compounded hazardous drug is placed in a 0.003-mm zip-lock bag clearly labeled as containing a hazardous drug. All hazardous drugs are hand-delivered to the nurse or physician who will administer the product. These products are prohibited from being delivered via the pneumatic tube system due to concerns over accidental spills and spill management.

Preventing Exposure During Administration: Nursing plays a critical role in preventing occupational, environmental,

and visitor exposures during sterile hazardous drug administration. All nurses who administer injectable hazardous drugs must be pre-certified by the Oncology Nursing Society. Prior to the administration of hazardous drugs, the patients are prepped with a chemo compounding mat and the nurse dons the aforementioned PPE. Utilizing the PhaSeal device, the nurse connects the drug to the patient. Once the therapy is completed, the nurse places all tubing and disposables used for administration back into the labeled zip-lock bag used for delivery. This bag is then placed in the appropriate waste stream.

Proper Waste Disposal: Hazardous drug waste may be classified as regulated waste by the EPA. Each state has different regulations for the proper disposal of hazardous waste. Some hazardous drug waste is classified as EPA-regulated hazardous waste and is further sub-classified as RCRA P-listed and U-listed waste (Table 1).[5] P-listed waste is classified as acutely hazardous and U-listed waste is more broadly defined as inherently toxic, ignitable, corrosive, flammable, or reactive. RCRA waste requires a separate waste stream from that used for chemotherapy compounding waste. A manifest must be included documenting the date and weight of the waste. NMH incorporated the use of black RCRA-approved containers from Kendall. Each time a new container is used, the date is placed on the lid.

Both nursing and pharmacy personnel were extensively educated on the different waste streams and the importance of segregating the waste at the point of use. To assist the pharmacy and nursing staffs, a poster listing RCRA-regulated waste is posted in the hazardous drug compounding area (Figure 1). Due to the number of items listed in Table 1, NMH chose to first focus on chemotherapy-based waste. In addition to the posters, to assist nursing, NMH uses yellow 0.003-mm zip lock bags for chemotherapy waste and black 0.003-mm zip-lock bags for RCRA-controlled waste. The color of the bag designates which waste stream bucket to utilize. This process works, however, it has also generated a larger quantity of black container waste than we expected. It is important to make sure the right waste stream is utilized, as black container waste is 10 times more expensive to remove from the campus than yellow container waste.

Environmental Services: Through our gap analysis, we noticed that the housekeeping staff on the units where hazardous drugs were administered were not wearing PPE beyond standard nitrile gloves. All gloves for housekeeping were replaced with hazardous-drug-rated nitrile gloves. In addition, housekeeping is now required to don masks and polyethylene gowns when performing daily cleaning of rooms where hazardous drugs are administered. NMH established an inconspicuous door placard to alert all hospital personnel of hazardous drug administration and PPE requirements.

The NIOSH alert states that body fluids (sweat, emesis) from patients receiving hazardous drugs may contaminate the patient's linen up to 48 or 72 hours post dosing. So NMH established a new yellow linen bag for linen segregate. Our laundry services vendor was educated on the recommendations and the segregation process. Laundry personnel must wear a polyethlylene gown and hazardous drug-rated nitrile gloves when handling this linen.

Future Projects

NMH still needs to formally address the following areas: medical surveillance of personnel in direct contact with hazardous drugs (pharmacy and nursing), oral hazardous drugs that are not administered on the chemotherapy units, addressing all hazardous drugs listed in NIOSH alert's Appendix I, and utilizing an automated waste segregation system such as Vestara's EcoRex to accurately manage our waste streams.

Through the gap analysis and the work of our motivated multidisciplinary team, NMH has established a safety program for managing hazardous drugs. The main investment in creating this program has been time – the time required to read and understand the OSHA regulations and the NIOSH/ASHP recommendations, to perform a gap analysis, and to effectively educate all health care staff involved with managing hazardous drugs. ■

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