

PRACTICE GUIDELINES

NIOSH Issues Hazardous Drugs Alert

In a forceful attempt to reduce exposure to hazardous drugs among healthcare workers, the National Institute for Occupational Safety and Health (NIOSH) has issued *Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Healthcare Settings*.

a member of the NIOSH Hazardous Drug Safety Working Group. "I think it will have a major impact on practice, particularly for pharmacists and nurses. Professional groups will use the document as a base for updating or revising their existing guidelines." Dr. Anderson has been a

existing guidelines set forth precautions for working with antineoplastic and other hazardous agents, including publications from the Occupational Safety and Health Administration (OSHA), the American Society of Health-System Pharmacists (ASHP) and the Oncology Nursing Society (ONS). NIOSH also first touched on the topic in 1988, when it issued a general report on worker safety issues. But research indicates that adherence is sporadic and not always effective.

"One of the big things that the alert demonstrates," said Dr. Anderson, "is that the current standard of practice or current guidelines need to go further and need to be enhanced because there's significant evidence that they don't prevent exposure to a level we all believe they should. That realization is important."

Martha Polovich, MN, RN, AOCN, another member of the NIOSH working group, called the alert long overdue. "I hope the document has a significant impact on organizations that have been slow in moving to provide protective equipment for their employees," said Ms. Polovich, an Oncology Clinical Nurse Specialist at Southern Regional Medical



The PhaSeal system in use

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—Roger W. Anderson, DrPH, RPh

The alert, the first from NIOSH to focus specifically on preparing and administering antineoplastic drugs and other hazardous pharmaceuticals, details measures for reducing the risk of exposure to the highly toxic chemicals.

"The alert is extremely important," said Roger W. Anderson, DrPH, RPh, Vice President of Pharmacy at the M.D. Anderson Cancer Center in Houston and

leading researcher of hazardous drug exposure for 25 years.

The threats posed by dangerous drugs are well documented and include skin rashes, infertility, spontaneous abortions, congenital malformations, and possibly leukemia and cancer. In addition, numerous studies have documented detectable levels of hazardous drugs in drug preparation and administration areas. A number of

Center, near Atlanta.

The alert is an important document that hospital administrators, pharmacy and nursing directors, housekeeping directors and material management people should all look at seriously, according to Joseph Defenbaugh, MPh, RPh, the ASHP's Director of Public Health and Quality. "It gives a strong message to employers that there is a real danger in the workplace that employees

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Highlights of the NIOSH Alert

According to NIOSH's new alert on the handling of antineoplastic and other hazardous drugs, employers should:

- Ensure that written policies address medical surveillance of healthcare workers and all phases of hazardous drug handling, including receipt and storage, preparation, administration, housekeeping, deactivation, and cleanup and disposal of unused drugs and contaminated spills and patient wastes.
- Formally seek input from employees who handle drugs in developing a program for preventing exposure.
- Prepare a written inventory identifying all hazardous drugs used in the workplace and establish a procedure for regular review and update of the inventory.
- Make guidance documents, Material Safety Data Sheets (MSDSs) and other information available to those who handle hazardous drugs or work in an area where hazardous drugs are handled.
- Provide training to employees on the recognition, evaluation and control of hazardous drugs.
- Ensure that horizontal laminar flow workstations that move the air from the drug towards the worker are never used for preparation of hazardous drugs.
- For hazardous drug preparation, provide and maintain ventilated cabinets designed for worker protection. Examples of these include biological safety cabinets and containment isolators that are designed to prevent hazardous drugs inside the cabinet from escaping into the surrounding environment. The exhaust from these cabinets should be HEPA-filtered and, whenever feasible, exhausted to the outdoors (away from air intake locations). Additional equipment, such as closed-system drug-transfer devices, glove bags and needle-less systems, will further protect workers from exposures when used properly.
- Establish and oversee the implementation of appropriate work practices when hazardous drugs, patient wastes and contaminated materials are handled.

- Ensure training in and the availability and use of proper personal protective equipment (PPE) to reduce exposure via inhalation, ingestion, skin absorption and injection of hazardous drugs as required based on the results of a risk assessment and the OSHA PPE Standard. PPE includes chemotherapy gloves, low-lint, low-permeability disposable gowns and sleeve covers, and eye and face protection. NIOSH-certified respiratory protection is needed when equipment such as biological safety cabinets is not adequate to protect against inhalation exposure. Surgical masks do not provide adequate respiratory protection.
 - Provide syringes and intravenous (I.V.) sets with Luer-Lok fittings for preparing and administering hazardous drugs, as well as containers for their disposal. **Closed-system, drug-transfer devices and needle-less systems should be considered to protect nursing personnel during drug administration.**
 - Complete a periodic evaluation of workplace hazardous drugs, equipment, training effectiveness, policies and procedures to reduce exposures to the greatest degree possible.
 - Comply with all relevant U.S. Environmental Protection Agency/Resource Conservation and Recovery Act regulations related to the handling, storage and transportation of hazardous waste.
- The NIOSH alert also contains several precautions that healthcare workers need to follow. According to the alert, workers should:
- Participate in standardized training on the hazards of the drugs handled and equipment and procedures used to prevent exposure.
 - Review guidance documents, MSDSs and other information resources for hazardous drugs handled.
 - Be familiar with and be able to recognize sources of exposure to hazardous drugs.
 - Prepare these agents in a dedicated area where access is restricted to authorized personnel only.
 - Prepare these agents within a ventilated cabinet designed to protect workers and adjacent personnel from exposure to provide product protec-

- tion for all drugs that require aseptic handling.
- Use two pairs of powder-free, disposable chemotherapy gloves, with the outer one covering the gown cuff whenever there is a risk of exposure to hazardous drugs.
- Avoid skin contact by using a disposable gown made of a low-lint and low-permeability fabric. The gown should have a closed front, long sleeves and elastic or knit cuffs and should not be reused.
- Wear a face shield to avoid splash contacts involving eyes, nose or mouth when adequate engineering controls are not available.
- Wash hands with soap and water immediately before using and after removing personal protective clothing, such as disposable gloves and gowns.
- Use syringes and I.V. sets with Luer-Lok fittings for preparing and administering these agents, and place drug-contaminated syringes and needles in chemotherapy sharps containers for disposal.
- **When additional protection is necessary, use closed-system, drug-transfer devices, glove bags and needle-less systems within the ventilated cabinet.**
- Handle hazardous wastes and contaminated materials separately from other trash.
- Decontaminate work areas before and after each activity with hazardous drugs and at the end of each shift.
- Clean up spills immediately while using appropriate safety precautions and PPE unless the spill is large enough to require an environmental services specialist.

To obtain the complete alert, contact NIOSH:
 Telephone: 800-356-4674
 E-mail: pubstaff@cdc.gov
 Web: www.cdc.gov/niosh/docs/2004-HazDrugAlert/
 Mail: Publications Dissemination
 4676 Columbia Parkway
 Cincinnati, OH 45226-1998.

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New Products

Steri-Tamp Tamper-Evident Seal Launched

Steri-Tamp, launched by American Pharmaceutical Partners, is a tamper-evident seal that was designed by a pharmacist with the needs of hospitals in mind. Steri-Tamp is used to cover drug product containers, such as vials, I.V. bottles, I.V. bags and syringes, whose contents are mixed in the pharmacy and then sent to the hospital floor for patient use. The patented seal technology creates an effective contamination barrier for parenteral admixtures and the contents of other, previously opened containers. Unlike alternative devices, once the Steri-Tamp is removed, it cannot be reattached, and on removal, it leaves a visible warning layer clearly indicating that the product has been opened.

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CPOE

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selected based upon negotiated prices that knocked as much as 92% off the wholesale price.

Non-formulary Medication Orders Are Prohibited

Dr. Sinnott said that many other hospitals with closed formularies cannot control drug costs in this way, because their CPOE systems still allow prescribers to order non-formulary drugs.

At Montefiore, Dr. Sinnott explained, non-formulary drugs cannot be ordered via CPOE. If the doctor attempts to order a non-formulary drug, the following message appears on the computer screen: "YOU ARE ATTEMPTING TO ORDER A NON-FORMULARY MEDICATION. You are attempting to order a medication that is non-formulary and is not stocked in the Pharmacy Department. Non-formulary medications can take 3 to 5 days [or longer] to obtain. Please consult with a pharmacist on a formulary alternative or, if applicable, the process by which the patient can use their own medication. All non-formulary usage and the justification for use is reviewed by the Pharmacy and Therapeutics Committee. If a formulary medication is not appropriate, the prescriber must contact the Pharmacy."

Dr. Sinnott said that, generally, doctors are not adamant about prescribing a formulary drug.

"Often," he said, "the physician might not be that aware of alternative medications that have become available."

Actually, he said, "we have had minimal negative feedback from all healthcare professionals." Instead, the clinicians have noted improvements in turnaround time in ordering drugs and delivering them to patients and the number of calls made from the pharmacy to the prescriber and back again. The system also prompts clinical discussions between the doctor and the pharmacist, giving the pharmacist a chance to engage in clinical decision-making.

The formulary process for "therapeutic enhancements," Dr. Sinnott said, is based on an interdisciplinary review of the drug class with decisions being made using evidence-based medicine, whenever feasible. Then, the Pharmacy and Therapeutics committee declares therapeutic equivalence and the choice of preferred agent is based on financial considerations.

While the experience at Montefiore appears to be working well, Dr. Sinnott noted that its Bronx facility is one of the few in the United States that has embraced CPOE.

"A 2002 national survey showed that approximately 30% of hospitals stated CPOE was in the early stages of implementation at their institution," Dr. Sinnott said. "Only about 3% of the hospitals stated that they have full implementation of CPOE."

—Ed Susman

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need to be protected from," he said.

Much of the alert emphasizes actions mentioned in other guidelines. But it also includes new recommendations, most notably the use of closed systems for preparing, transferring and administering drugs, and the use of containment isolators as an alternative to biological safety cabinets. Dr. Anderson said that the call for increased use of closed systems is one of the most important aspects of the NIOSH alert. "It's a big issue," he stressed. "We need to work further to close the system and contain the hazard."

The ability of closed systems to protect workers from contamination when they are handling hazardous drugs has been demonstrated in clinical trials. Researchers at the University of Texas M.D. Anderson Cancer Center in Houston, for example, evaluated the PhaSeal closed system in the preparation of various cytotoxic medications. The investigators found that the device, together with biological safety cabinets, "appeared to contain surface contamination resulting from preparation of the test drugs" (*Am J Health Syst Pharm* 2002;59:68-72).

The PhaSeal system uses dry connections and a build-in expansion chamber to prevent drug aerosol leakage into the work environment, according to Baxa Corporation, which distributes the device in the United States.

—Steve Frandzel