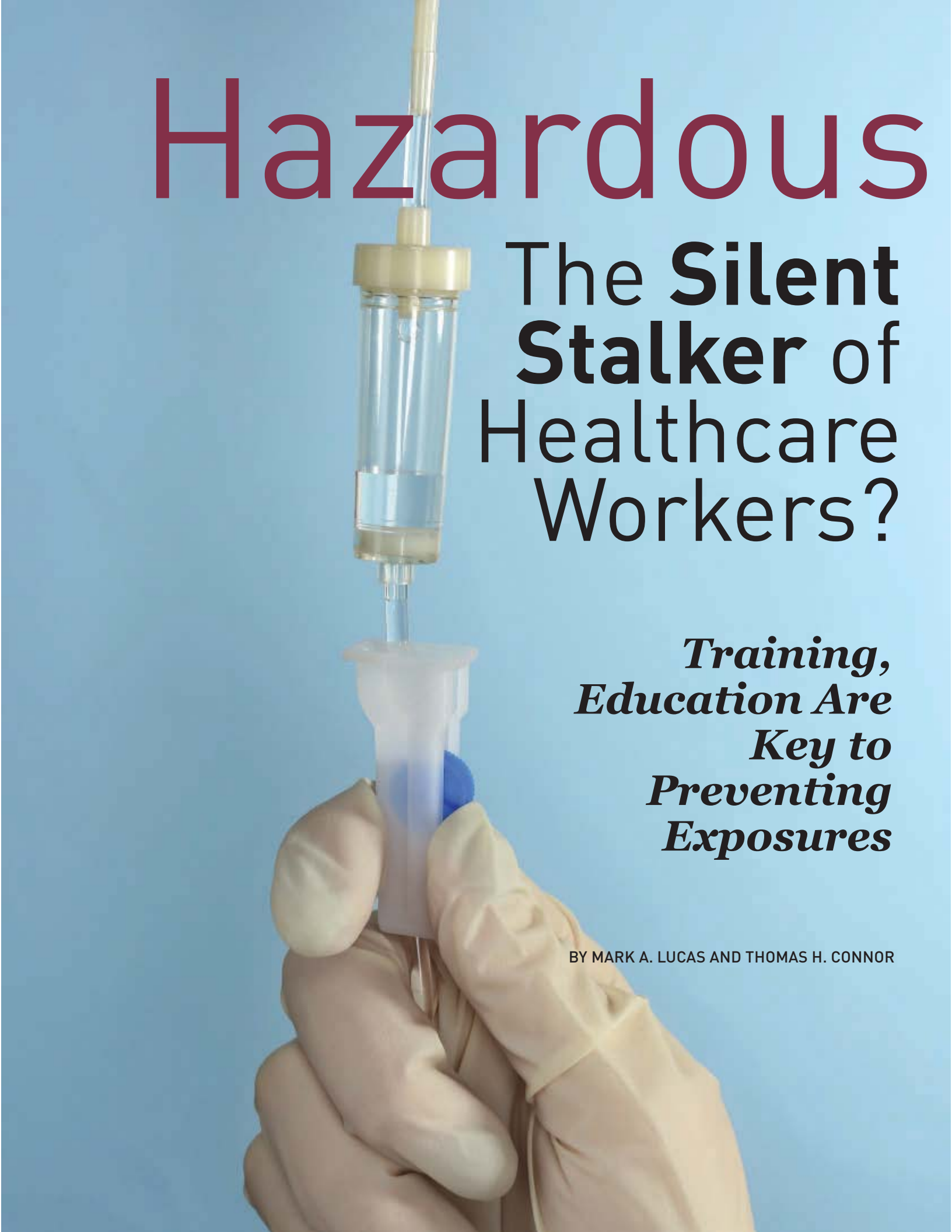

Hazardous

The **Silent Stalker** of Healthcare Workers?

Training, Education Are Key to Preventing Exposures

BY MARK A. LUCAS AND THOMAS H. CONNOR

Drugs:

NIOSH estimates that approximately 8 million healthcare workers may be exposed to hazardous drugs (HDs). Healthcare workers might not be aware that they may be harming their health when they handle HDs, which are known to cause serious side effects in patients and are capable of causing cancer, organ toxicity, fertility problems, genetic damage, and birth defects in healthcare workers.

This article is not intended as a comprehensive discussion of safe work practices for healthcare workers handling HDs. Our intent is to alert industrial hygienists about the hazards of HDs and to discuss the primary controls, which, when implemented, will minimize worker exposure: ventilation, proper work practices, use of closed system drug transfer devices (CSTDs), and personal protective equipment (PPE). Educating healthcare workers on safe work practices is also a key factor in protecting their health.

TYPES OF HAZARDOUS DRUGS

Healthcare workers handle numerous HDs on a daily basis. Drugs designated as cytotoxic (cell-killing) and antineoplastic (anti-cancer) agents are some of the most hazardous chemicals ever developed. Pharmacists, pharmacy technicians, oncology nurses, and other nursing personnel have the highest risk for HD exposure, but all healthcare workers who come into contact with HDs are at risk, including those in shipping/receiving, housekeeping, laundry, and waste disposal.

Although primarily used in the treatment of cancer, antineoplastic drugs are also used to treat noncancerous diseases such as multiple sclerosis, psoriasis, and systemic lupus erythematosus. Nearly 200 HDs are currently in use, and typically twenty to thirty new drugs are identified every year. Some are classified as carcinogens, teratogens, mutagens, target organ toxins, and reproductive toxins. In addition, information on serious side effects is reported on drugs after they are available on the market. The handling of complex-protein therapeutic drugs such as some monoclonal antibodies should also be closely controlled to reduce or eliminate inhalation and accidental oral exposure. The increased use of conjugated monoclonal antibodies, which have greater sensitivity to cancer, has raised concerns for healthcare worker safety.

Many of the same properties that make HDs effective in the treatment of cancer, HIV, or arthritis by killing cells or stopping cell replication may also affect inadequately protected healthcare workers. Treatment of patients, which typically involves high dosages, is usually well monitored. But workers who are not fully protected may be exposed to low doses of many drugs over the course of their employment. These workers handle and administer HDs multiple times during a work day. Acute symptoms of cytotoxic drug exposure are skin irritation, allergic-type reactions, and hair loss. Chronic HD exposures, particularly to antineoplastic drugs, have been shown to affect fertility and

reproductive outcomes, damage DNA, and cause cancer. (While the vast majority of healthcare workers are female, some HDs may affect reproductive outcomes in both male and female workers.)

The major sources of HD exposure for healthcare workers are through skin absorption and inhalation of HD dusts or aerosols. The physical state (tablet, capsule, ointment, or liquid) of the drug and method of compounding play a significant role in determining the potential risk for occupational exposure. Some solid pharmaceuticals are dispensed by pharmacies in automatic dispensing machines, dissolved in solutions, or crushed if patients are unable to swallow; others may be administered by inhalation therapy. All of these methods may create airborne hazards and contaminate work surfaces. During preparation of I.V. drugs, splashes and leaks may occur when HDs are transferred from one container to another (for example, from a vial to an I.V. bag). In addition, research published in the *American Journal of Health-System Pharmacy* has shown that the outside of unopened HD vials are often already contaminated with the contents of the vial.

CONTROLS

The U.S. Pharmacopeial Convention (USP) chapter <797> specifies engineering controls for compounding HDs that protect workers and maintain a sterile product for use in patient care. (Chapter < 797> is being restructured, and the section on HDs will become USP chapter <800>, which, like <797>, will be enforced by some state boards of pharmacy.) Drug compounding is typically conducted in the pharmacy where both hazardous and nonhazardous drugs are handled. However, some healthcare facilities have dedicated pharmacies for the preparation of HDs. During compounding of HDs, engineering controls include Class II biological safety cabinets or compounding aseptic containment isolators (glove box-like devices). Dedicated filtered ventilation systems and negative pressure are typically employed. These controls are designed to reduce or eliminate HD exposure to employees working in these areas, minimize the spread of HD contamination outside the restricted work area, and maintain an aseptic work environment and a sterile product.

Newly developed containment devices (CSTDs) are designed to prevent over-pressurization of the vials and to reduce leaks and spills. CSTDs should be used to minimize HD leakage when transferring liquid HDs. Other alternatives include filtered venting needles and preloaded syringes.

Skin contact is an important route of exposure to HDs. Proper use of PPE, adherence to safe work practices, and prudent personal hygiene are extremely important. The use of PPE should not be restricted to compounding and administering HDs in the pharmacy and patient treatment areas, respectively. Other places where PPE may be required include the loading dock where HDs are received, inside vehicles that transport drugs to and from the pharmacy, storage areas, oncology patient rooms, laundry services, and waste disposal areas.

NIOSH, OSHA, the American Society of Health-System Pharmacists (ASHP), and USP recommend that, at a minimum, users wear double gloves tested in accordance with the American Society for Testing and Materials standard for permeability of chemotherapy drugs (ASTM D-6978). Sterile outer gloves must be worn when compounding a sterile HD. Eye protection (for example, safety goggles) and a face shield, in some circumstances, should be worn if a potential splash hazard exists. To date, no specific consensus method exists for testing the effectiveness of material used in gowns for protection against exposure to HDs, though some gown manufacturers use the same ASTM test as used for gloves. Respirator use may be required for some healthcare workers when airborne HD hazards exist. The appropriate level of respirator protection should be determined by an occupational health and safety professional.

STANDARDS AND GUIDANCE

Though federal OSHA has not promulgated specific regulations on the safe handling of HDs, the agency published guidance on safe handling of hazardous drugs in 1995. USP published a consensus standard in 2008 in chapter <797> that outlines safe work practices and engineering controls to reduce or eliminate HD exposures to healthcare workers involved in sterile compounding of pharmaceuticals. The recommended PPE depends on which operation is being performed. The compounding process is generally considered to have the highest risk for HD exposure, so in addition to double-gloving, USP Chapter <797> also recommends the wearing of shoe

covers, head and facial hair covers, and surgical masks (for production only). Accidental HD exposure may occur with little visual evidence, so precautionary measures are important.

Currently, the only hazardous drug with a Threshold Limit Value (TLV) is cisplatin; the TLV is based solely on platinum metal toxicity, not on the chemical itself. The pharmaceutical industry has established its own internal OELs for the manufacturing process and has developed surface contamination criteria. There are presently no regulatory limits for HD surface contamination, though USP chapter <797> recommends environmental sampling (including surface sampling). The first U.S. state to enact HD workplace regulations was Washington, which adopted the NIOSH guidelines, followed by California and North Carolina. Other states are in the process of establishing their own HD workplace regulations.

PREVENTION

Detailed standard operating procedures for handling HDs must be established. Healthcare workers need to be trained on the hazards associated with each HD, effective methods for reducing or eliminating HD exposure, appropriate PPE use, decontamination and sanitation, and safe work practices. Practices such as cleaning pill dust from dispensing machines with compressed air should be prohibited. The keys to preventing HD exposure include a strong safety culture; education of workers and their supervisors, with input from industrial hygienists; and vigilant supervisory oversight to ensure compliance. No food, drinks, gum chewing, or makeup application should be allowed in pharmacies and patient treatment areas where HDs are handled. As a means of minimizing the spread of HD contamination, some facilities have separate work and street lockers for employees who handle HDs.

Decontamination, cleaning, and disinfection of work surfaces where HDs are handled or potentially contaminated is critical in reducing the spread of contamination. When feasible, chemical deactivation should also be employed. Unfortunately, no single chemical can clean, disinfect, and decontaminate surfaces contaminated with HDs. Some sources even recommend the use of sterile water rinses during the cleaning, disinfecting, and decontamination phases in certain processes. Consultation with the specific HD manufacturer for the appropriate cleaning, disinfection, and decontamination methods is highly recommended. USP chapter <797> also includes decontamination recommendations for maintaining a sterile drug work environment.

Though no current federal regulation requires implementation of a specific HD medical surveillance, NIOSH has provided guidance on this issue. Medical surveillance

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allows early detection of potential HD-related health problems and can monitor the efficiency of a safe handling program. As part of a comprehensive HD medical surveillance program, employers must be able to identify workers who are at risk of exposure based on their work tasks, and plan for follow-up after acute exposure scenarios such as spills. Annual health assessment questionnaires can determine whether workers are experiencing symptoms of HD exposure and identify laboratory results that differ from expected norms. The questionnaire should evaluate both overall and reproductive health, concentrating on target organs and systems most likely to be affected by HD exposure. A history of drug handling, as an estimate of prior and current exposure, including dates of HD duty assignment, should also be noted. Documented health changes should prompt a physical checkup and laboratory testing based on the results. Acute employee HD exposure requires prompt intervention to minimize adverse health effects.

Healthcare workers need to be educated about the hazards associated with handling HDs. HD use is on the rise as the population ages and new technology allows people a wider range of medical treatment. In addition, HD use in veterinary services is increasing. Additional toxicological studies of the potential health effects of these drugs are needed to help protect healthcare workers as new and unique drug formulations and modes of administration are developed. Occupational health and safety professionals must lead the way to educate management and workers in the use of precautionary principles to eliminate or minimize exposure to these highly toxic drugs.

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FEATURES

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