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A Survey of the Status of Hazardous Drug Awareness and Control in a Sample Massachusetts Nursing Population

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Case Study

A Survey of the Status of Hazardous Drug Awareness and Control in a Sample Massachusetts Nursing Population

BACKGROUND AND INTRODUCTION

As early as 1970, researchers and practitioners were hypothesizing about the potential occupational exposures to hazardous drugs in health care. Over the next three decades, numerous research projects and publications identified a variety of chemicals to which health care providers and nurses were exposed.⁽¹⁾ The projects described the means to perform occupational monitoring of respiratory or dermal exposures. They covered a variety of drugs and identified workers who had been exposed as indicated by either environmental exposure assessment or, in some cases, by biological exposure indicators through medical surveillance.^(2,3) In other studies there were indications that workers also suffered symptoms and deleterious health effects as the result of some of their exposures.^(4–6)

During the 1980s and 1990s, in association with the results of the published findings, other papers were written that described and promoted additional methods to monitor and document exposures and to protect workers.⁽¹⁾ Engineering controls were recommended, administrative programs for control and training were proposed, and the use of effective personal protective equipment (PPE) was encouraged.^(7,8)

In September 2004, the Department of Health and Human Services Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) issued “NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings.”⁽⁹⁾ The purpose was to increase awareness among health care workers and their employers about the health risks posed by working with hazardous drugs and to provide them with measures for protection.

Although NIOSH reported that approximately 5.5 million workers a year were exposed to hazardous drugs in the workplace, the number of workers that have the potential for a truly significant exposure is probably significantly less.⁽⁹⁾ The NIOSH population included pharmacists, nurses, physicians, operating room personnel, environmental service staff, researchers, veterinary workers, and materials distribution staff. However, the number also includes dietary staff, administrators, information specialists, and clerical staff, which accounts for a significant number of any hospital employee total. There are 2.4 million registered nurses who also work in locations with potential for routine exposure to hazardous drugs.⁽¹⁰⁾ In Massachusetts, specifically, there are nearly 110,000 registered nurses with potential exposures to hazardous drugs.

As the number of exposed workers increases due to expanded cancer therapy and treatment, worker exposures to hazardous drugs also increases due to increasing numbers of patients with cancer and other chronic illnesses, the use of higher treatment doses, noncancer use of antineoplastic drugs, and the development of other potent drugs, such as antiviral agents.⁽¹¹⁾ Oftentimes, new drugs are in developmental

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research phases, and little is known about either the side effects to patients or the potential effects on exposed workers. The goal of drugs is to be more effective, but they could also be more potent, not only to the patient but to the workers handling the medications or treatments. Often, two drugs are used together, and little is known about the potential synergistic effects of chemicals in exposed workers. Moreover, the methods of treatment and distribution to the patient are changing to include novel methods, such as the increase use of nebulizers and the respiratory pathway. The use of nanotechnology and associated treatment methods introduces another new means of worker exposure for which there are many unknown variables.

In addition to the increases in uses and potencies of hazardous drugs, the Food and Drug Administration (FDA) continues to expand the number of approved drugs and molecules. In the first 40 years that the FDA kept records of chemotherapeutic drug approvals, they approved 74 new drugs from 1950 to 1990. Since 1990, however, they have approved 202 new chemotherapy agents.⁽¹²⁾ In addition to the chemotherapeutic agents, the FDA Center for Drug Evaluation and Research has approved more than 175 new drugs in the years 2005 and 2006.⁽¹³⁾

Since the NIOSH Alert in 2004, there have been relatively few research projects and published papers in the area of worker exposure to hazardous drugs when compared with preceding decades. With published warnings and information, it seems there has been a renewed confidence that we are aware of the problem and it is being addressed. However, even though there has been a marked downturn in the published measurement of hazardous drugs in the workplace and studies of worker exposures and worker symptoms or health effects, those few that have been published generally indicate that worker exposures are continuing.^(11,14) Occupational monitoring methods and analytical techniques are yet to be developed for all but a few drugs used in health care.

Although the NIOSH Alert provided numerous recommendations for further workplace evaluations, development of hazardous drug programs, increased use of engineering controls, calls for worker training, and greater use of PPE, it does not appear that hospitals have expanded their hazardous drug programs.^(15,16) Anecdotal reports from nurses indicate that they continue to handle drugs in the same way as had been done in the 1990s, and the nurses generally are not aware of any significantly different or expanded controls that have been implemented. Also, in many cases, nurses were not aware that the drugs they handle are even considered hazardous as listed in the NIOSH report

Lastly, numerous drugs enter the market and health care settings on a regular basis, and it can be assumed that the NIOSH list is no longer comprehensive. Further, full consideration of hazards and appropriate controls has not yet been given to all the new chemicals that have entered the health care workplace in the past few years.

The Occupational Safety and Health Administration (OSHA) originally published guidelines for antineoplastic drugs in 1986.⁽¹⁷⁾ Additional OSHA standards and guidelines

that address hazardous drug exposure include the hazard communication standard (29CFR1910.1200), the occupational exposure to hazardous chemicals in laboratories standard (29CFR1450), and Chapter 2 of the *OSHA Technical Manual*, "Controlling Occupational Exposure to Hazardous Drugs."⁽¹⁸⁾ Similar to the recommendations of the NIOSH Alert, the *OSHA Technical Manual* also calls for written hazardous drug safety and health plans, specific engineering and administrative controls, and designated types of PPE.

The United States Pharmaceutical Convention (USP) is presently drafting a new guideline entitled "Pharmaceutical Compounding—Sterile Preparations—797."⁽¹⁹⁾ This document sets new industry standards for product protection, worker safety, and infection control, along with other criteria for facility design and worker training. The guideline recognizes the concerns of the NIOSH Alert and stipulates such workplace controls as improved ventilation systems and employee monitoring.

One of the recommendations in the 2004 NIOSH Alert was for health care organizations to establish hazardous drug programs and procedures to ensure safe handling and to minimize occupational exposures. This survey was developed by the Massachusetts Nurses Association Congress on Health and Safety to identify the extent to which nurses are exposed to hazardous drugs in the workplace and to begin determining the extent that concerns identified in the NIOSH Alert have been addressed. The project was designed to attempt to answer the following questions:

1. Are nurses aware whether their organizations have developed and instituted hazardous drug programs?
2. Are nurses aware whether their organizations have evaluated worker exposures to hazardous drugs at their facilities?
3. Are nurses using engineering, administrative, and personal protective equipment (PPE) to control exposures to hazardous drugs?
4. Have nurses incurred health effects that might be linked to their work with hazardous drugs?
5. Are there differences in nurses' knowledge/awareness of hazardous drug programs, exposure assessment, and control, and the health outcomes in the nurses at the three different hospitals included in the study?

METHODS

A questionnaire entitled "Hazardous Drug Information Form" was distributed to 2000 Massachusetts Nurses Association (MNA) nurses located at three Massachusetts hospitals. The hospitals included one large metropolitan teaching hospital, one smaller rural hospital, and one suburban midsized hospital. These hospitals were selected based on their representativeness to the broad range of the 22,000 MNA member base across the state. It was also intended to provide additional information about the differences between the types

of hospitals. All MNA nurses at each hospital received the questionnaire and were asked to complete and return it within 1 month.

The questionnaire comprised 32 major question headings. Many of the questions had multiple subquestions. For most answers, the participants either circled the responses that applied to them or answered Yes or No. In some questions they were asked to answer with a number or a description.

The data from completed surveys were entered into an Access database and later transferred into SAS. All the analyses were conducted in SAS using the frequency and means procedures. The data analyses and interpretation are limited to descriptive statistics of the responders because sampling was not random but, rather, stratified clusters of samples obtained from three hospitals representing different sizes and locations (rural vs. urban). Because the estimate of the effect, as well as the confidence intervals, from a nonrandom sample can be biased and can produce smaller confidence intervals, they are not calculated here. Complex survey design requires that poststratification weights be assigned to obtain appropriate estimates of the effect and its variance and, hence, confidence intervals. Adequate information about the population of MNA nurses was unavailable to generate these weights. The following information about the population of MNA nurses would be necessary to generate these weights: distribution by age, gender, ethnicity, certification status, type/location of hospitals.

RESULTS

There were nearly 400 completed responses returned, or about a 20% response rate. The response rates were about the same for each of the three types of hospitals.

The means and frequencies of responses are reported in Figures 1–4. The results should be interpreted with caution because the effects of the nonresponder bias could not be assessed accurately. Some basic demographic data about the nurses' population from which the sample was drawn were not available, so the degree of representativeness of the sample of responders could not be determined. However, if it was found that the MNA population parameters are similar to the sample in terms of ethnic composition, age, gender, and certification status, then weighting would not be necessary and inferences could be made about the general MNA population. Despite these limitations, the survey results provide useful descriptive information about the responding nurses' knowledge and practices in handling hazardous drugs at the three hospitals.

Hazardous Drug Programs

Even though one of the major recommendations of the NIOSH Alert was the implementation and annual review of programs for safely handling hazardous drugs and associated training, only 54% of nurses surveyed were aware of such programs at their hospitals. Beyond that, only 30% of the nurses had read their hospitals programs. Figure 1 shows various responses to related survey questions.

Of the nurses surveyed, 87% stated they handled or administered hazardous drugs in the workplace. However, only 12% reported receiving classroom training on the hazards and controls associated with the drugs. Even fewer, only 6% of the workers, reported receiving hands-on training in the workplace. The duration of both hands-on and classroom training was usually 1 hour.

Hazardous drug exposure assessment was a key recommendation in the 2004 NIOSH Alert. It recommended a comprehensive workplace evaluation of equipment, layout, drugs, volumes, frequency, decontamination, waste handling, and the equipment used to control exposures. None of the 400 nurses who responded to the survey indicated they were aware of such exposure assessments in their workplaces.

Engineering Controls

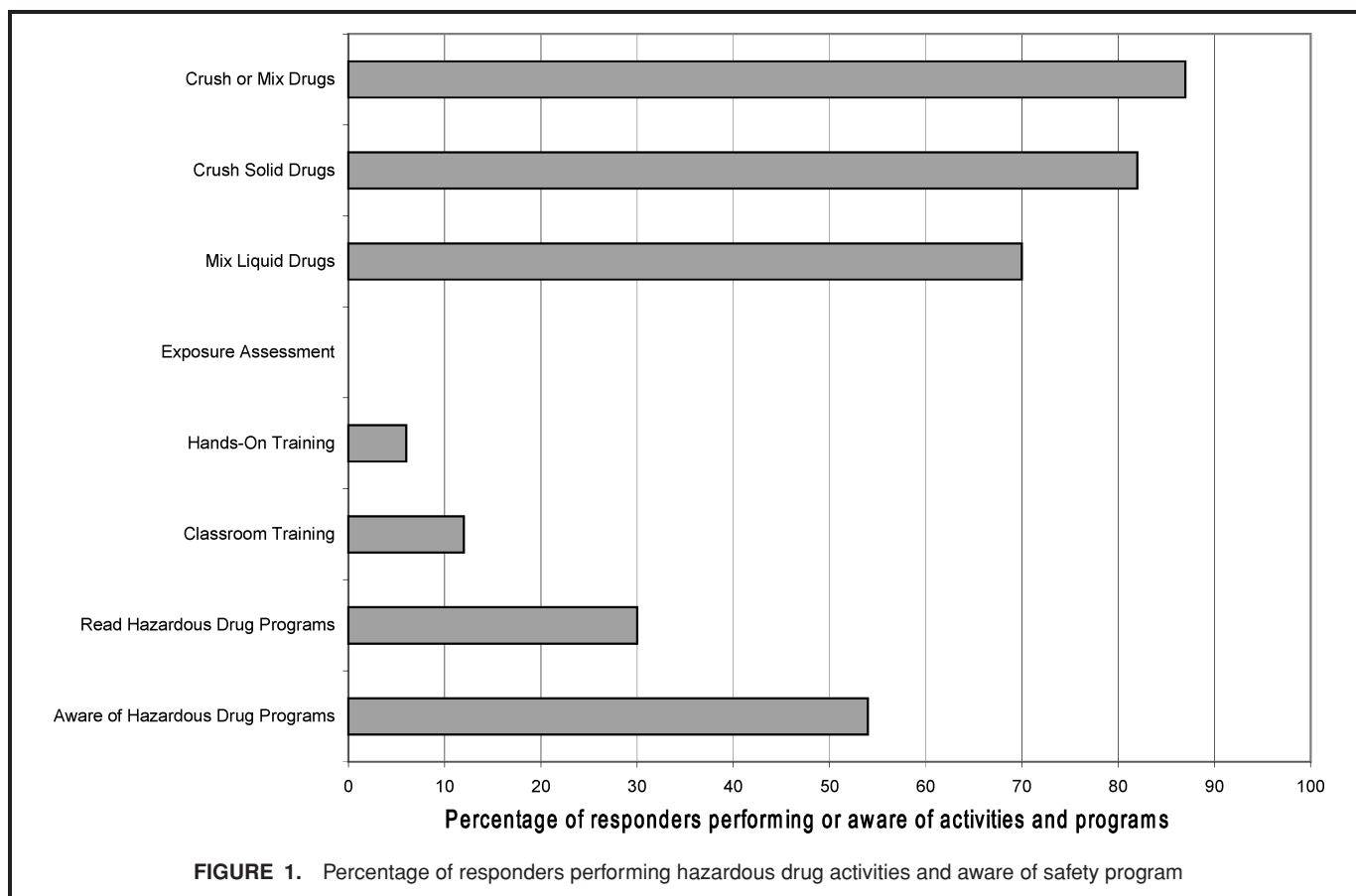
A variety of engineering controls for the safe use and handling of hazardous drugs have been recommended by the NIOSH Alert and numerous other publications. These include the use of such devices as closed and exhausted mixing systems, laminar flow benches, bench top ductless hoods, general room ventilation, and local exhaust ventilation systems. The use of various engineering controls used by nurses is shown in Figure 2.

About half the nurses were aware of at least one engineering control method in place at their hospital for control of hazardous drug exposure. Most of the responses indicated awareness of general ventilation or filtration systems and the use of closed containers. Control of hazards at the source through exhausted handling systems or local exhaust hoods was not common, with fewer than 10% of nurses reporting the use of these devices despite their effectiveness at controlling hazardous chemical exposures.

Special Precautions and Personal Protective Equipment

Nurses who work with hazardous drugs either crushing solids or mixing liquids in the workplace indicated their routine use of special procedures or PPE as indicated on Figure 3. Seventy percent reported using some form of PPE, which was gloves in most cases. The use of face shields to prevent eye or mouth exposure and gowns or lab coats to protect their skin were much less likely. Interestingly, when broken down further, the data show that the nurses who were both aware of and had read their hospital's hazardous drug programs were much more likely to wear PPE (85.6%) than nurses who were not aware of the program (63.4%). Fewer than 35% of the facilities where hazardous drugs were manipulated had dedicated chemical spill kits available to the nurses.

Safety controls used by nurses when working with patients or administering drugs are shown in Figure 4. Although more than 60% of the nurses report wearing gloves, there are still major shortcomings regarding the use of a larger variety of systems or controls. Alarming, 36% of the nurses surveyed do not use any special controls or PPE when working with patients receiving hazardous drugs.



It is interesting and important to note here that other administrative controls to minimize exposures to the public from hazardous drugs are not implemented thoroughly. Fewer than 10% of the nurses reported segregating visitors from areas where hazardous drugs are administered. Fewer than 20% reported the use of conscientious contamination control of metabolites in urine or feces in toilet areas, the use of increased distance or isolation, or the special handling of patient contaminated linens. Only 22% of the nurses reported the use of warning signs in the treatment areas to warn workers or patients' families who often sit with patients during treatments using hazardous drugs.

Health Effects and Symptoms

The results of self-reported health effects data and their relationships to working with hazardous drugs did not identify any strong associations in the data. A detailed and rigorous assessment of health effects data is limited due to a variety of reasons. It is in part due to the unavailability of detailed data about the nursing sample pool. Another factor is the low response rate and resultant small data set. Self-reported data are also often difficult to verify in such an important topic area.

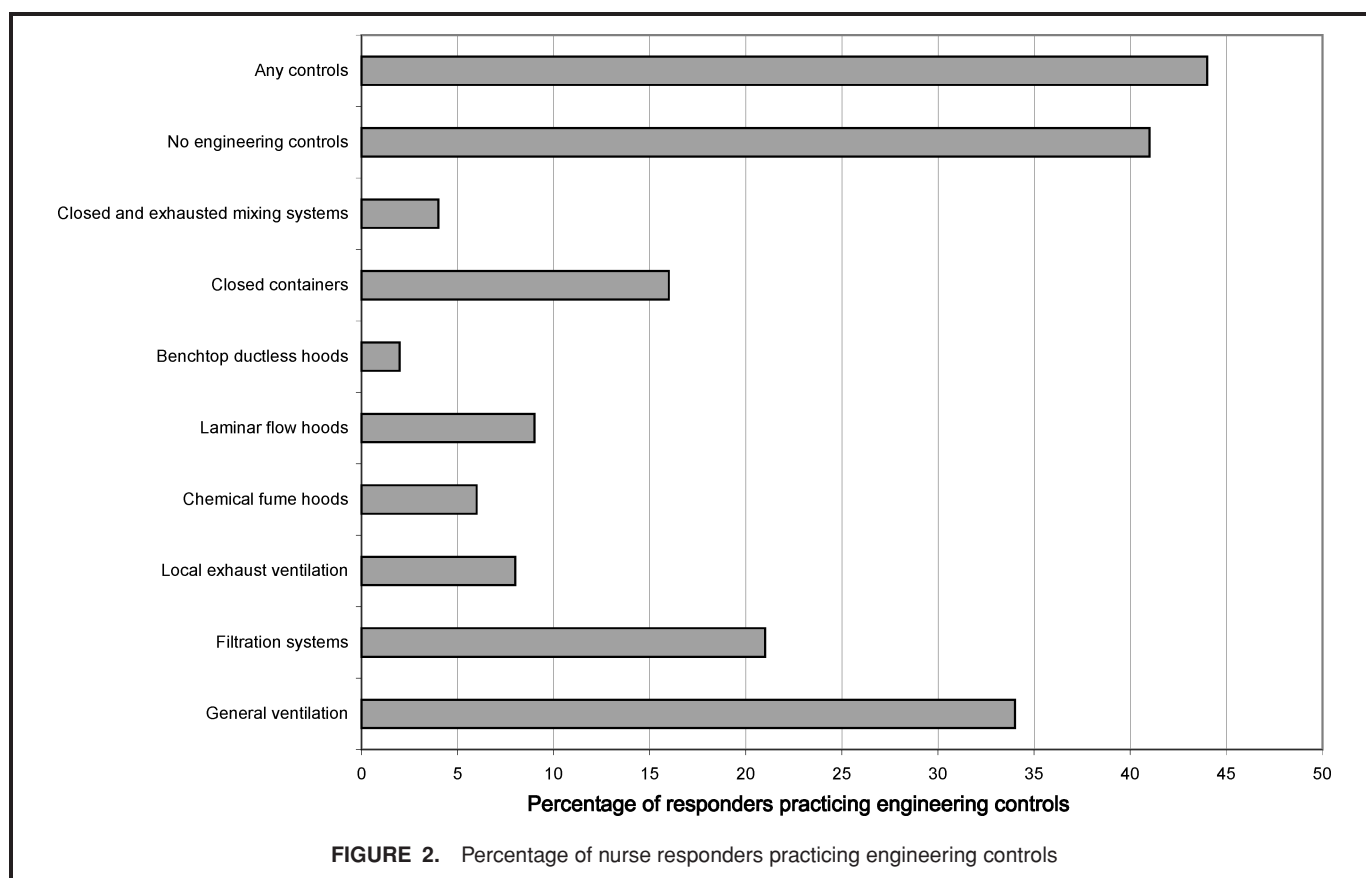
It was noted that 55 nurses (13.9%) reported failed pregnancy in the last 2 years. Among the nurses who reported handling hazardous drugs, 32 (13.6%) reported failed pregnancy in last 2 years compared with 23 (14.3%) among those who did not report handling hazardous drugs. Without the

additional controls mentioned above, more rigorous analyses are not possible, and thus, any detailed conclusions about the relationships to health effects are not possible here. The results are presented as a possible basis or justification for more detailed analyses in the future.

Only 9.3% of nurses reported symptoms they believe were related to their hazardous drug exposures in the workplace. It is interesting to note that 301 (75.8%) of the nurses reported working with at least one of the hazardous drugs listed on the information form. But of these workers, only 206 (68.4%) also checked having worked with hazardous drugs. This means that 31.6% of the nurses did not know they were handling one of the hazardous drugs listed in the questionnaire. In other words, these workers did not consider the sample of NIOSH-listed drugs that they worked with and administered as "hazardous."

DISCUSSION

Although the survey response rate was low, it is comparable to similar surveys conducted of the MNA organization in the past. The low response rate is partly because the questionnaires were sent to their homes, since direct contact at work is not possible. In addition, nurses have demanding jobs with considerable responsibility, little control, and significant stress. They are difficult to persuade to complete a lengthy survey form after leaving work. Despite the low response, we



believe that the survey results are representative as indicated by the broad range of responder departments, years in the field, and types of hospitals.

Despite the NIOSH Alert and other papers that have more recently indicated the likelihood of continued occupational exposures to hazardous drugs in nursing and pharmacy staff, there are indications that at least the hospitals in this study have not fully implemented recommendations. The lack of worker awareness about written programs or policies, absence of training, and the lack of appropriate controls or protective equipment demonstrate that there is still much work to do to evaluate worker exposures to hazardous drugs and to identify appropriate controls.

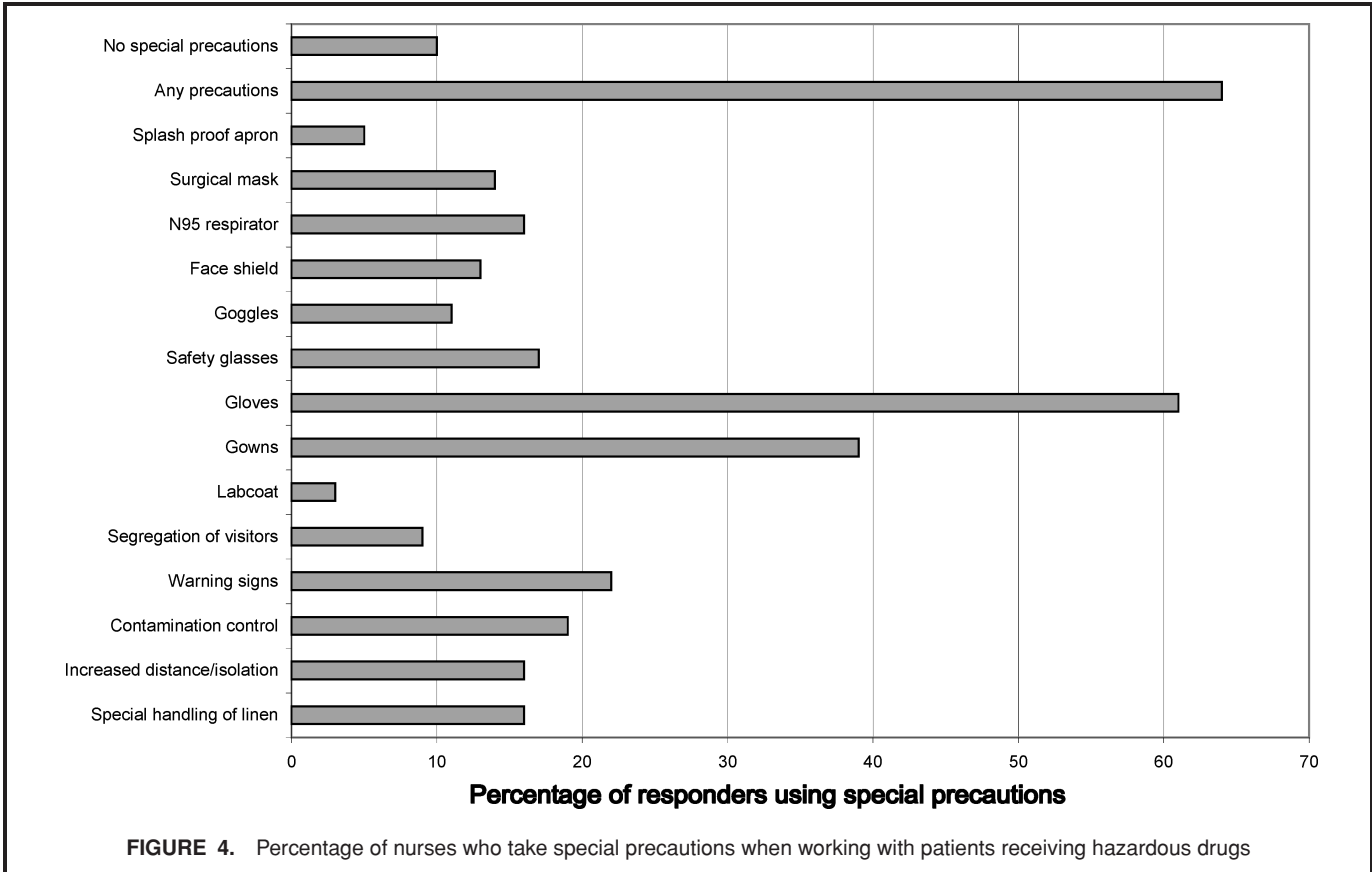
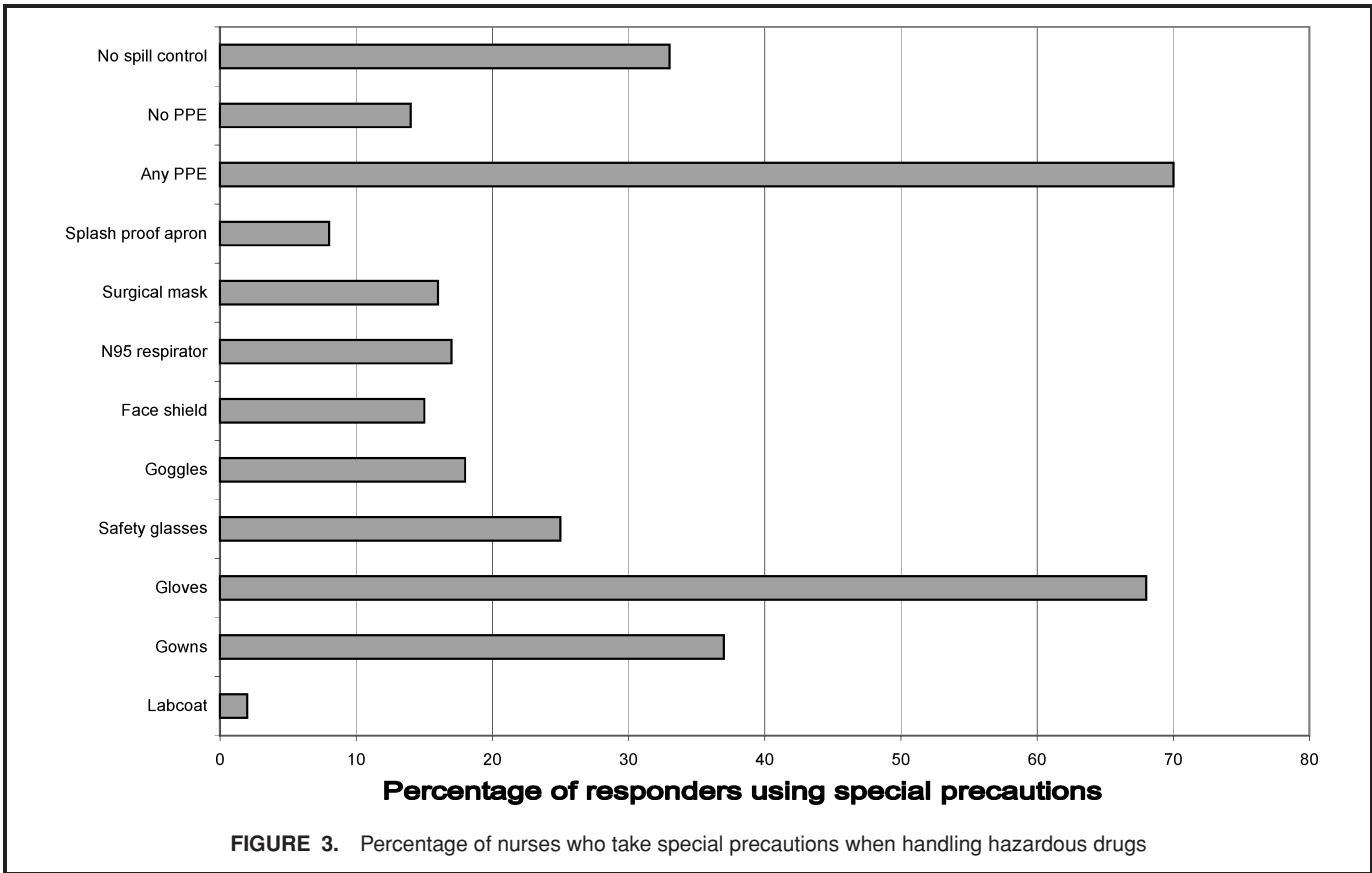
In addition to the results of the survey study, it has been the experience of the authors through interaction with numerous pharmacy and nursing staff that there is still considerable misunderstanding of the definition of a “hazardous” drug. Typically, workers quickly identify chemotherapeutic agents as hazardous, but they seldom consider such drugs from the NIOSH list—as estrogen, ganciclovir, or fluoxymesterone—as hazardous. Cancer-fighting drugs are not the only ones in the health care workplace that can cause harm to workers if they are exposed, but due to the assumption that only chemotherapy agents are harmful, there is less concern for control and worker protection in other hospital areas outside those departments.

In 1998, thalidomide was approved by the FDA to treat leprosy. It has also recently been approved for use in studies

and treating multiple myeloma, AIDS, Behcet disease, lupus, Sjogren syndrome, rheumatoid arthritis, inflammatory bowel disease, and macular degeneration.⁽²⁰⁾ Thalidomide is rated as a Pregnancy Category X drug by the FDA, meaning that the risk to the unborn fetus clearly outweighs any possible benefit to the pregnant mother. A single dose of 50 mg may cause birth defects.⁽²⁰⁾ Yet, according to the results of this study, this drug may be handled by nurses who may not be aware of the hazards and appropriate controls to protect themselves.

There are hundreds of new drugs and drug applications developed and approved each year. The NIOSH list was developed in 2004 and should not be considered “all inclusive” at this time. The potential exposures and appropriate controls for each new drug and new application should be evaluated by an industrial hygienist who works closely with medical, nursing, and pharmaceutical staff. Employers are ultimately responsible for identifying the hazards of agents that workers are exposed to and for implementing engineering, administrative, and personal protective equipment controls for ensuring the safety of the staff and the public.

While formal institutional hazardous drug programs are being developed, nurses and other workers are encouraged to learn as much as possible about the hazards and appropriate controls for the drugs they work with and to take appropriate action. They should consult material safety data sheets (MSDSs), which employers are required to provide. However, because pharmaceutical company MSDSs are often lacking in



information and direction, additional sources of information should be sought and precautionary practices used to minimize exposures wherever possible.

CONCLUSIONS

There is significant and ongoing misunderstanding regarding the extent and risks of occupational exposure to hazardous drugs in the health care setting. Besides studies to identify potential risks to patients, the pharmaceutical industry (researchers and manufacturers) pursues risk and exposure evaluations for some pharmaceuticals to protect their workers. This often includes estimates of safe exposure levels, monitoring techniques, and exposure control methodologies to protect their workers and minimize liabilities. This information is not typically available to the general public.

As a result of the lack of available information on safe levels, potential occupational health effects, monitoring techniques, and appropriate worker protection systems or methods there is insufficient awareness of the risks and exposures. Most nurses and other health care staff are truly not aware of all the potential exposure pathways and risks from hazardous drugs, even after the NIOSH Alert. Despite numerous other reports of ongoing worker exposures and potential hazards, large institutions and the health and safety field itself has not fully come to terms with or addressed this ongoing and still growing problem of worker exposures, particularly that of nurses, to hazardous drugs as part of their jobs.

There is a continued misconception that only chemotherapy agents are hazardous and that only workers directly involved in administration or preparation are exposed. Again, this is contrary to the available and recent literature and observed practice in the health care setting. Many other drugs can be considered hazardous, and many are used throughout the hospital by a variety of health care providers. Other ancillary workers and even the general public can be exposed easily through cross contamination and patient excretion or exhalation. There is still much to learn about these potential pathways.

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