Summary of the Workshop on the Safe Handling of Hazardous Drugs Cohosted by the National Institute for Occupational Safety and Health and the American Society of Clinical Oncology

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INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) and ASCO cohosted the Workshop on the Safe Handling of Hazardous Drugs on November 13, 2015, in Alexandria, Virginia. NIOSH is the US federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness. ASCO is a national organization representing nearly 40,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention.

The Workshop focused on the history of guidance development for safe handling of hazardous drugs and challenges in development of guidance for worker safety. The goal was to promote information sharing and collaboration among stakeholders, including experts in occupational health, drug management and safety, cancer care, and research.

Thomas Connor, PhD, from NIOSH and Robin Zon, MD, Chair of ASCO's Task Force on Safe Handling of Chemotherapy, served as Workshop co-chairs. Participating organizations included the American Nurses Association, American Society of Health-System Pharmacists, ASCO, NIOSH/Centers for Disease Control and Prevention, Hematology Oncology Pharmacy Association, Oncology Nursing Society (ONS), Occupational Safety and Health Administration, US Pharmacopeial Convention, and the Department of Veterans Affairs. A full list of Workshop participants is included in the Appendix (online only).

HISTORICAL OVERVIEW (DR CONNOR)

Health care worker exposure to hazardous drugs emerged as a public health issue in the 1970s. Secondary cancers observed in treated patients raised concern about the health of pharmacists and nurses preparing and administering anticancer drugs. Early occupational health studies showed workplace contamination with hazardous drugs.[1-3]

In response, the ONS, American Society of Health-System Pharmacists, and Occupational Safety and Health Administration released guidelines for handling of hazardous drugs in the 1980s. NIOSH convened a Hazardous Drug Working Group in 2000 that grew to approximately 50 members representing government, professional organizations, industry, labor, and academia. It was disbanded in 2007. NIOSH released safe handling guidelines in 2004 as a product of this workgroup and

ASSOCIATED CONTENT

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Table 1. Issues, Challenges, and Potential Solutions Regarding the Safe Handling of Hazardous Drugs

Issue	Challenges	Potential Solutions
Environmental surveillance: Environmental surveillance involves the use of wipe sampling to measure hazardous drug contamination on various surfaces in a practice	• There are no authoritative exposure limits for hazardous drugs. • There are no standard testing protocols. • There are no wipe tests for most cancer drugs. • Wipe sampling may miss areas of contamination.	• The Joint Commission is working on an environmental wipe sampling protocol. • Environmental wipe sampling could be used to assess whether a spill has been completely cleaned or to evaluate drug residue reduction efforts. • Wipe sampling studies must be carefully designed.
Engineering controls and CSTDs: Issues involving engineering controls include whether or when to externally vent BSCs and whether or when to use CSTDs	• External venting of BSCs may be cost prohibitive or logistically unfeasible. • CSTDs may not function as advertised and may not protect workers from exposure to hazardous drugs.	• NIOSH is developing a testing protocol for CSTDs • Guidance materials to support selection of commercially available engineering controls could be developed • Financial support for research involving the effectiveness of various implementation strategies could be explored
Medical surveillance: Medical surveillance refers to a medical program to monitor worker health as a result potential exposure to hazardous drugs	• There are questions about the medical necessity of medical surveillance programs. • There are no standard medical surveillance protocols. • There is a lack of guidance on what to do with the results of medical surveillance. • Private employee health information must be protected.	• A voluntary, deidentified national registry of workers could be created to answer fundamental questions about the health effects of occupational exposure to hazardous drugs.
Pregnant workers and alternative duty: Pregnant and breastfeeding workers may require special attention in safe handling programs, and there is added complexity for workers looking to conceive	• There is a need for alternate duty best practices to guide better protection among pregnant and breastfeeding workers and workers (male and female) trying to conceive. • There may be special burdens on small practices looking to implement alternative duty programs.	• NIOSH is developing best practices for alternative duty programs for workers who are pregnant, breastfeeding, or actively trying to conceive. There will be an opportunity for public comment on this document.
PPE and establishing a culture of safety: Consistent and correct use of PPE is essential in protecting worker safety	• Compliance with PPE recommendations may be low for a variety of reasons. • Certain types of PPE may not function as advertised.	• Professional societies could develop quality and training programs on PPE. • Materials to support selection of commercially available PPE could be developed. • Financial support for the implementation of worker safety programs in clinical practice could be explored.

Abbreviations: BSC, biologic safety cabinets; CSTD, closed-system drug transfer device; NIOSH, National Institute for Occupational Safety and Health; PPE, personal protective equipment.

plans to release an update in 2017. The US Pharmacopeial Convention published recommendations on February 1, 2016, with an implementation date of July 1, 2018.

Despite these guidelines, research has shown that surface contamination with hazardous drugs persists in the workplace. A 2010 study[4] of surface contamination in the workplace showed similar results to a 1999 study.[3] A 2005 study[5] showed that the exteriors of drug vials are contaminated with their contents as a result of manufacturing processes. A 2014 study[6] showed that 20% of workers in a Canadian hospital who handled hazardous drugs had measurable concentrations of cyclophosphamide on their hands.

Approximately 100 studies have shown workplace contamination based on testing a subset of approximately 5% of hazardous drugs. Antineoplastic drugs have been measured on workers' skin.[6] Adverse reproductive effects have been observed in exposed workers.[7,8] Approximately 60% of 100 published studies show significant association between genetic damage and antineoplastic drug exposure. The incidence of some cancers may be elevated in exposed workers, although no large-scale epidemiologic studies have been performed to quantify this risk or determine how various routes of exposure and safety interventions may interact or contribute to the risk.

PERSPECTIVES FROM MEDICAL ONCOLOGISTS (DR ZON)

Medical oncologists specialize in the prevention, diagnosis, treatment, and research of cancer. They develop, study, and prescribe anticancer treatment regimens, including hazardous drugs. Medical oncologists interpret clinical literature regarding cancer risk and treatment and oversee day-to-day operations at cancer facilities. Consequently, medical oncologists bring important perspectives to the discussion of safe handling of hazardous drugs that have sometimes been missing from past efforts to develop safety standards and recommendations.

The practice of grading the level of scientific evidence supporting various interventions leads to more robust clinical guidelines, promotes transparency, and allows physicians, nurses, pharmacists, and regulators to interpret and implement recommended safeguards. For the safe handling of hazardous drugs, there are gaps in the clinical evidence regarding the impact of some recommended interventions on clinical outcomes for workers who handle these drugs. Additional research is needed to identify the most effective strategies to protect oncology workers. The oncology community should consider collaborating to expedite a clinical data registry to fill these gaps and publish findings regarding worker safety and clinical outcomes.

As evidence-based safety protocols are developed and implemented, it remains important to ensure that oncology facilities are not distracted from taking the steps that are most likely to protect the oncology workforce. For example, there is evidence to suggest that one of the most important steps to take in protecting workers is the effective use of personal protective equipment (PPE). A recent study estimated that the excess lifetime risk of leukemia for oncology nurses with a 40-year career handling cyclophosphamide is approximately one per million oncology nurses.[9] More research on the scope and scale of health effects from occupational exposure to hazardous drugs is necessary.

Community-based oncology practices provide vital points of access to cancer care to serve a vulnerable population of patients throughout the United States. These practices are facing a tremendous increase in financial and administrative burdens in today's environment, and a number have closed over the past few years. Additional uncompensated administrative requirements could reduce resources for patient services and, ultimately, contribute to additional closures. For this reason, requirements should be carefully considered and based in strong scientific evidence.

ENVIRONMENTAL SURVEILLANCE PRESENTATION (DR CONNOR) AND DISCUSSION

Surface contamination occurs when there are residues of hazardous drugs on facility surfaces where drugs are present, including pharmacies and patient care areas. Surface wipe sampling has been used for many years to assess workplace contamination in a variety of industries. Air sampling is common in other industries, but because many hazardous drugs have low vapor pressures and are not detectable in the air, wipe sampling is the most relevant assessment tool.

Wipe sampling is conducted to evaluate potential health risks, manage hazards, evaluate a hazard's source, and assess compliance with safety standards. Surface contamination in pharmacies can occur from contaminated or broken drug vials, leaking vials, overpressurization of vials, leaking or punctured intravenous lines, crushing tablets, automatic dispensing machines, or contaminated hands, gloves, and equipment.

There are several factors to consider when conducting wipe sampling. Tests are not available for all drugs, so practices should focus on testing drugs commonly used in the facility. Most environmental wipe sample studies in oncology settings use cyclophosphamide, which is easy to analyze and is stable in the environment. Environmental wipe sampling studies have been done on approximately 15% of the hazardous drugs used in oncology settings.

Discussion among Workshop participants relating to environmental surveillance highlighted the following:

- There are no existing recommendations for routine environmental wipe sampling. Wipe sampling may miss areas of contamination, and sampling studies must be carefully designed.

- There are no publically available exposure limits for hazardous drugs. Manufacturers have developed occupational exposure limits for the manufacturing setting, but this proprietary information may not apply to the health care setting.
- Wipe sampling could be used to assess whether a spill has been completely cleaned or to evaluate whether efforts to reduce drug residues in the facility have been successful.
- There are no wipe tests for most cancer drugs.
- However, The Joint Commission is working on a protocol for environmental wipe sampling that will address this challenge.
- There are a few companies in the United States that will analyze wipe samples and also some that provide sampling kits.

ENGINEERING CONTROLS AND CLOSED-SYSTEM DRUG TRANSFER DEVICES PRESENTATION (DR HIRST) AND DISCUSSION

Primary engineering controls provide containment and environmental conditions at the point of use, and secondary engineering controls provide containment and environmental conditions for placement of the primary engineering controls. For example, a ventilated cabinet may be a primary engineering control, but the clean room that it is placed within is a secondary engineering control. The 2004 NIOSH Alert recommends engineering controls be put in place to protect workers during preparation and administration activities. The Alert focuses on ventilated cabinets, which are a type of primary engineering control. Certain supplemental controls (eg, closed-system drug transfer devices [CSTDs], glovebags, needleless systems) are also discussed in the Alert, and their use should be considered.

Ventilated cabinets provide worker protection through the following three mechanisms: full or partial enclosure of a contaminant source, use of airflow to capture and remove contaminants near their point of generation, and negative pressure that drives the direction of airflow into the cabinet. The choice of a ventilated cabinet depends largely on the need for aseptic technique. When asepsis is not required, a Class I biologic safety cabinet (BSC) or containment isolator may be sufficient. When asepsis is required, a Class II BSC (A2, B1, or B2), a Class III BSC, or a Compounding Aseptic Containment Isolator can be used. A horizontal laminar flow clean bench should never be used for preparing hazardous drugs. There are several published guidelines on selecting and maintaining BSCs.[10,11]

On September 9, 2015, NIOSH released a draft protocol to evaluate the vapor containment performance of CSTDs.[12] NIOSH defines a CSTD as a device that mechanically prohibits transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system. Containment-type CSTDs are marketed as truly closed (ie, no mass passes through the system boundary) systems that provide a physical barrier to contain gases, vapors, and aerosols. CSTDs with air cleaning technology were not covered by the September 2015 draft protocol. Air-cleaning CSTDs use a sorbent and/or high-efficiency particulate air filter to contain contamination, and these filtration mechanisms generally require specific efficacy testing against the contaminants to which they will be exposed. NIOSH conducted initial testing on five different commercially available models of CSTDs and found that only two met the performance threshold selected by NIOSH. However, the identification of a pass/fail performance threshold is at the discretion of the tester, and it is not clear that any clinical evidence exists to determine what performance threshold is adequate.

Workshop participant discussion relating to engineering controls and CSTDs highlighted the following:

- The marketplace for BSCs and CSTDs is complicated for purchasers to navigate. The US Food and Drug Administration approval process for such devices does not address the relative performance of these devices in protecting workers from exposure to hazardous drugs.
- NIOSH concluded that only two of five commercially available CSTD models were effective at containing contamination. Because NIOSH results do not identify brands, there will be a need for commercial or research entities to perform this testing to evaluate the effectiveness and value of various CSTD models.
- Most participants agreed it is not feasible for individual oncology practices to evaluate CSTD performance using the NIOSH testing protocol and noted that testing should be conducted at a national level. Results should be shared among all potential consumers, perhaps by the manufacturers. Professional societies could play a role in disseminating this information.
- Some attendees expressed concern that construction costs, leasing terms, or existing building designs can render external venting for a BSC infeasible for some

modern oncology practices. Oncology practices that do not own their building, rural practices, and practices in large buildings may be adversely and disproportionately affected by this requirement and may not be able to afford compliance.

- External venting is important in the event that a high-efficiency particulate air filter, which would otherwise return air into the building, develops a leak or allows a vapor to pass through.
- It is unclear whether external ventilation of a BSC provides better protection to workers than not externally venting a BSC. External venting may remove contaminants that otherwise would be present in the work area, thus reducing the potential for worker exposure.
- Oncology practices would benefit from practical guidance materials on how to select engineering controls. Professional societies can collaborate to create and disseminate this information to their members. Materials should include information on how engineering controls protect workers, the different engineering control options available, and the proper selection and use of engineering controls. Engineers who design environmental protection controls should participate in the development of these materials.

MEDICAL SURVEILLANCE PRESENTATION (DR MCDIARMID) AND DISCUSSION

Medical surveillance is used to detect and prevent health effects of exposure early to prevent more serious outcomes. The program may also provide nonspecific feedback on the efficacy of other controls in place and identify workers who are at an increased risk of adverse events as a result of their personal health history.

NIOSH has recommended elements of a medical surveillance program for hazardous drugs, including general and reproductive history, drug handling history, baseline clinical evaluation, and a follow-up plan for health changes or acute exposures. Employers should not be directly involved in the collection of medical surveillance health data of their employees. Instead, employers can engage third-party occupational medicine physicians or companies that provide occupational medicine services. Special biologic monitoring for a specific agent or genotoxic end points should never be required in a medical surveillance program.

Discussion among Workshop participants relating to medical surveillance highlighted the following:

- Concerns about medical surveillance requirements included unclear evidence supporting the medical necessity of these requirements, lack of information about program design, the possibility for misunderstanding and/or overtesting, and implementation issues.
- There are questions about the clinical evidence supporting the medical necessity of medical surveillance programs. Laboratory tests such as CBCs can produce counterproductive "noise," and employers may not be able to identify confounding factors that may affect employee health.
- Employers may not have capacity to compile and evaluate trends in medical surveillance data, and medical surveillance might be more appropriate as a research activity. Stakeholders should support development of large-scale epidemiologic data registries on occupational exposure to antineoplastic drugs, and professional societies can play a role in the development of such a database.
- Research has shown that employees may be more likely to report adverse events and accurate health information if reported outside of an employer-employee relationship.

PREGNANT WORKERS AND ALTERNATIVE DUTY PRESENTATION (DR LAWSON) AND DISCUSSION

The majority of drugs included on the NIOSH list of hazardous drugs have adverse reproductive effects, and many can enter breast milk. Many antineoplastic drugs target rapidly dividing cells, which makes them especially hazardous to a rapidly growing fetus.

The connection between hazardous drugs and reproductive issues has been well documented in both male and female patients. These issues include fertility for men and women, menstrual cycle changes, miscarriages, and congenital abnormalities.[8] Workers who prepare and administer hazardous drugs do not receive therapeutic doses of these drugs, but they do experience long-term, low-dose exposure.

A review of 18 studies published between 1985 and 2012 found increases in congenital anomalies among offspring of women exposed to hazardous drugs in the workplace and increases in miscarriages in these workers.[8] Some evidence suggests a link between occupational exposure to hazardous drugs and subfertility and menstrual cycle abnormalities. Most studies were limited in sample size and unable to adjust for confounding factors. All of these studies report data

collected before 2002, which predates the 2004 NIOSH Alert, highlighting the need for research to obtain more current data.

The most recent study[7] included in a review summarized results from the Nurses' Health Study II, which included 7,482 participants. Nurses in the study self-reported whether they worked with anticancer drugs during their first trimester of pregnancy. After adjusting for age, work schedule, and other factors, the authors found a two-fold increase in spontaneous abortions among exposed nurses and a 3.5-fold increase in spontaneous abortions when it was their first pregnancy.

Together, this research suggests that men and women who are actively trying to conceive, women who are pregnant, and women who are breastfeeding are at risk for reproductive effects. Because of the need for better protection among pregnant and breastfeeding health care workers, a number of organizations support an alternative duty policy. In 2015, NIOSH published a draft guidance in the *Federal Register* for public comment on how to implement an alternative duty program.[13]

Although best practices for alternative duty programs are still being developed by NIOSH, there are core principles that should guide this process. Specifically, the program should apply to both men and women and must be voluntary for employees. Worker privacy must be maintained, and the program must not put undue burden on other employees. Challenges for the employer should be acknowledged and addressed, including the added cost and special burdens that may exist for oncology and other practices with a small number of workers.

Discussion among Workshop participants relating to pregnant workers and alternative duty highlighted the following:

- There was consensus regarding a need to implement and support alternative work policies. However, alternative duty programs need to consider diverse practice settings, including small practices that may not have capacity to easily reassign workers to tasks that do not involve potential exposure to hazardous drugs. The community needs to develop practical suggestions for confronting these issues.
- Alternate duty policies should be clear and formal. They should consider the entire at-risk window, including women actively trying to conceive, breastfeeding mothers, and men.
- Reproductive risks associated with handling hazardous drugs must be clearly communicated to all workers. In the general population, approximately half of pregnancies are unplanned,[14] and approximately 70% of women work during their first pregnancy.[15] A fetus can be exposed to workplace contamination before a woman even knows she is pregnant, and this happens at a critical time of fetal development. All workers need to understand this risk so that they recognize the importance of initiating alternate duty requests when trying to conceive.

PERSONAL PROTECTIVE EQUIPMENT AND ESTABLISHING A CULTURE OF SAFETY DISCUSSION

Workshop discussion frequently focused on creating a culture of safety. Conflicting recommendations and ambiguity in existing standards may create confusion and challenges with translating them into practice. Adherence to PPE standards may be influenced by leadership culture. Adherence also depends on dissemination of clear information to members of the oncology care team about the standards and the reasoning behind them. Creating a culture of safety and increasing worker knowledge about PPE are important to enhancing safety in the future.[16]

Discussion among Workshop participants relating to PPE and establishing a culture of safety highlighted the following:

- Dermal exposure to hazardous drugs by nurses may be exacerbated by cracked hands, which can be the result of washing hands frequently.
- ONS and ASCO training and quality programs could incorporate information about PPE.
- In some instances, commercially available chemotherapy gowns may be untested and/or unsuitable for use in oncology.
- There are currently several research projects under way that will increase the body of knowledge in this area. One study is evaluating efficacy of an audit and feedback intervention program to improve nurses' use of recommended PPE when handling hazardous drugs.[17] Preliminary results from this multisite, prospective study have shown that baseline PPE knowledge was below expected levels and that substantial barriers exist to appropriate PPE use. The study is currently collecting data on the use of PPE and hazardous drug exposure and adverse reproductive events.

STATE EXPERIENCES AND PERSPECTIVES REGARDING GOVERNMENT REGULATION

Limited regulation and enforcement of safe handling activities have been occurring at the state level. Washington, California, and North Carolina have passed safe handling legislation, and Michigan, New Jersey, and Massachusetts have introduced legislation. Maryland has proposed regulatory reforms and enacted legislation in 2015 to exempt oncology practices from the state sterile compounding law, which now only applies to commercial compounding centers.

NEXT STEPS

A dominant theme was stakeholder collaboration on creating a culture of safety. Specific areas for potential collaboration include the following (Table 1):

- Reduction or elimination of contamination on drug vials originating from the manufacturer.
- Creation of a national registry of exposed health care workers and adverse events to answer fundamental epidemiologic questions researchers are currently unable to answer.
- Development of guidance and best practices for alternate duty policies for female workers who are trying to conceive, pregnant, or breastfeeding, and male workers trying to conceive.
- Development and dissemination of evidence-based materials and quality measurement programs that support implementation and assessment of practice safety programs.
- Exploration of potential financial support for the implementation of worker safety programs in clinical practice and for research involving the effectiveness of various implementation strategies.
- Development of materials to support selection of commercially available equipment to promote safe handling of hazardous drugs.
- Continued dialogue among stakeholders. JOP

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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Appendix

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