A Pre and Post Test Assessment of a Web Based Tutorial to Reduce Occupational Exposure Risks to Oncology Nurses

In partial fulfillment of requirements for the Doctorate of Nursing Practice

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Executive Summary

The purpose of this project was to offer new knowledge through educational training to oncology nurses highlighting health risks related to inconsistent handling of hazardous drugs. Nurses who administer chemotherapy are exposed to aerosols and droplets of drugs during compound mixing, administration and disposal. As a result of exposure, oncology nursing poses many occupational risks. Precautions for safe handling have been available for over two decades; however there is evidence showing continued occupational exposure related to lack of education. By educating nurses on the safe handling of these drugs, workplace safety can be improved, significantly reducing their exposure risks and minimizing future adverse effects among these nurses.

This project focused on piloting a safe handling web-based course with pre-test/post-test evaluations to oncology nurses who are members of the Willamette Valley Chapter of the Oncology Nursing Society (ONS) in the state of Oregon. The objectives for this project were: 1) Develop and implement a web-based learning tutorial regarding safe handling of hazardous drugs; 2) Develop and implement a pre-test and post-test to evaluate the effectiveness of a web-based tutorial to increase the awareness of safe handling practices among oncology nurses; 3) Present results of research in poster presentation at the 38th Annual ONS Congress Conference on April 25-28, 2013 in Washington, DC; and 4) Disseminate this tutorial through the Oncology Nursing Society as a web-based CEU course potentially reaching 37,000 national members.

This project focused on the development of a web-based tutorial and a two-part survey. After Institutional Review Board (IRB) approval, the program was distributed to 389 registered nurses affiliated with ONS. Concentration focused on elements most often overlooked in safe handling practices. Key findings of the pre- and post-test included the misconception that the outside of packaging material is safe from hazardous drug. Another key finding was a high percentage of nurses could not correctly identify appropriate personal protective equipment (PPE) in regards to safe handling. Both of these findings showed marked improvement in the post-test, highlighting the effectiveness of the web-based tutorial in increasing the awareness of safe handling practices among the Beta group.

This project has been submitted to the Oncology Nursing Society (ONS) as a means of dissemination as a poster presentation during their 38th Annual ONS Congress Conference on April 25-28, 2013 in Washington, DC.


The committee chair for this project was David Winmill, DNP, ANP, CDE, BC-ADM. Martha Polovich, Ph.D., RN, AOCN provided expertise as and Oncology Clinical Content Expert; and Marianne Bundalian-Tejada, MSN, RN, PHN providing expertise as Adult Learning Teaching Content Expert.
Introduction

It is known that chemotherapy medications are antineoplastic (cytotoxic) drugs, designed to kill cancer cells. However, these drugs are not cell specific in their mechanism of action and thus kill non-cancerous cells in their efforts as well. Intended for exposure to only the oncology patient, the nurses caring for them have an increase in occupational hazards through casual exposures, subjecting them to unnecessary increased risk for developing malignancies, in particular leukemia, breast, thyroid, nervous system and brain cancers, of their own in their lifetime (National Institute for Occupational Safety and Health, 2004).

Precautions for safe handling have been available for over two decades; however there is evidence showing continued risk for occupational exposure, confirming that these recommendations are not being universally employed. Potential reasons include no formalized and up-to-date national administration procedures in place for nurses to refer to as well as lack of knowledge on the potential hazards to the nurse from continued exposure.

Nurses who administer chemotherapy are exposed to aerosols and droplets of drugs during compound mixing, administration and disposal. Oncology nurses are at an increased risk for exposure to these drugs and thus have hazardous working conditions. Modifying the administration and improving safety in the workplace can significantly decrease their exposure risks. The goal of this project was to develop a web-based learning tutorial utilizing Knowles’ “Andragogical Model” (1984) (as cited in Darbyshire, 1993) of adult learning theory regarding safe handling of hazardous drugs and deliver it to a select group of nurses.

Oncologic treatment care has shifted to the outpatient setting in the past two decades. As a result of this transition, nurses in these areas have increased time spent with patients due to
series visitations (patients seen repeatedly for the same treatment) and lengthy infusion sessions. This also means greater time spent with their respective hazardous drugs.

Decreasing exposure to HDs will reduce the potential for adverse health outcomes and improve the safety and quality of life of all health care workers.

**Problem Statement**

The lack of occupational safety education specific to frequent exposure to hazardous drugs creates acute and chronic dangers to nurses and other health care workers.

**Purpose**

The purpose of this project was to address concerns related to lack of education and knowledge regarding safe handling and administration of hazardous drugs among registered nurses actively participating in the Willamette Valley Chapter of the Oncology Nursing Society (ONS) in Eugene, Oregon.

The term “hazardous drugs” was first used by the American Society of Hospital Pharmacists (ASHP) in 1985, and is currently used by the Occupational Safety and Health Administration (OSHA) to universally represent these agents. Drugs are classified as hazardous if studies in animals or humans indicate that exposures to them have a potential for causing cancer, developmental or reproductive toxicity, or harm to organs (ASHP, 1990).

It is known that chemotherapy medications are antineoplastic (cytotoxic) drugs, designed to kill cancer cells. Many chemotherapy agents are also genotoxic, causing mutations as they interact with DNA. Genetic mutations are a known risk factor for developing cancer.

While designed for exposure to only the oncology patient, the oncology nurses and employees caring for them have an increase risk in occupational hazards through accidental
exposures. These drugs are not cell specific in their mechanism of action and thus kill non-cancer cells as well. Known effects include hepatic and renal toxicity, cardiotoxicity, hematopoietic toxicity, pulmonary toxicity, immunotoxicity, ototoxicity, dermal toxicity, and particularly injury to tissues with a rapid turnover rate.

Precautions for safe handling of hazardous drugs have been available for over two decades; however there is evidence showing continued risk for occupational exposure as these recommendations are not being universally employed. Potential reasons for this could be that there are no formalized and up-to-date chemotherapy administration policies and procedures in place for nurses to refer to as well as lack of knowledge on the potential hazards of continued exposure.

Nurses who administer chemotherapy are exposed to aerosols and droplets of drugs during mixing and administration. While the majority of the nurses polled through the ONS Willamette Valley Chapter reported that they are not mixing chemotherapy medications, it is important to remember that in many facilities, nurses are responsible for compounding as part of their patient care. Oncology nurses are at an increased risk for exposure to these drugs and thus have hazardous working conditions. Modifying the administration and improving safety in the workplace can significantly decrease exposure risks.

Understanding the occupational risks and the appropriate precautions and techniques to prevent HD exposure are essential to workplace safety (Power & Polovich, 2012). The goal of this project was to develop a web-based learning tutorial utilizing Knowles’ “Andragogical Model” of adult learning theory regarding safe handling of hazardous drugs for a select group of nurses as a Beta group practicing in the oncology setting, both inpatient and outpatient. With this in mind, this project utilized the current research findings to educate nurses in the oncology
settings and provide updated procedures that meet the national recommendations issued by National Institute of Occupational Safety and Health (NIOSH) and have the potential to minimize occupational exposure.

**Objectives**

1. Developed and implemented a web-based learning tutorial utilizing Knowles’ “Andragogical Model” of adult learning theory regarding safe handling of hazardous drugs for a select group of nurses as a Beta group.

2. Developed and implemented a pre-test and post-test to evaluate the effectiveness of a web-based tutorial to increase awareness of safe handling practices among oncology nurses.

3. Mid-range goal: presented results of research in poster presentation at the 38th Annual ONS Congress Conference on April 25-28, 2013 in Washington, DC.

4. Long-term goal: disseminated this training through the Oncology Nursing Society as a web-based CEU course potentially reaching 37,000 national members.

**Clinical Significance**

Pharmaceutical agents have a successful long history of use in treating illnesses and injuries, and significantly contribute to many medical advances. Although the potential therapeutic benefits of hazardous drugs outweigh the risks of side effects for ill patients, exposed health care workers risk these same side effects with no therapeutic benefit. Occupational exposures to hazardous drugs can lead to a range of acute effects from skin rashes (McDiarmid, 2010) to chronic effects, such as reproductive disorders and possibly cancer (Polovich & Whitford, 2009). In addition, it is known that exposures to even very small concentrations of certain drugs may be hazardous for workers who handle them or work near them.
Risks to personnel working with Hazardous drugs (HD’s) are a function of the drugs' inherent toxicity and the extent of exposure. The main routes of exposure are: inhalation of dusts or aerosols, dermal absorption, and ingestion. Contact with contaminated food, cosmetics, or cigarettes represents the primary means of ingestion. Opportunity for exposure to HD's may occur at many points in the handling of these drugs (NIOSH, 2004).

For the past several decades, there has been growing concern regarding the safety and health of healthcare workers who are occupationally exposed to chemotherapy and other drugs. The occupational activities that create the greatest risks are preparing and administering antineoplastic agents, cleaning up chemotherapy spills, and handling patient excreta (Martin, 2005). During the course of patient treatment, healthcare professionals may inadvertently be exposed by these handling activities, thus placing themselves at risk.

Healthcare workers handling chemotherapeutic agents report an increased incidence of acute health symptoms such as nausea, vomiting, headaches, lightheadedness, dizziness, cough, rash and hair loss (Newman, 1994). Additionally, many studies have identified an association between exposure to the drugs and adverse effects on reproductive health among staff members, including infertility (Martin & Larson, 2003; Valanis et al, 1992), preterm deliveries (Elshamy, 2010), fetal abnormalities, spontaneous abortions (Lawson, 2012, Schardein, 2000; Valanis et al, 1992). Long-term effects to offspring include learning disabilities and small-for-gestational-age (Martin & Larson, 2003).

An occupational exposure to hazardous agents is defined as “the degree of internal exposure to hazardous antineoplastic agents after a healthcare worker’s inadvertent occupational contact with chemotherapy drugs during the preparation, administration, and/or disposal process. The degree of internal antineoplastic chemotherapeutic exposure reflects the quantity of drug
uptake, the metabolism of the drug in the body, and evidence of cellular manipulation after an accidental exposure with cytotoxic agents during the handling process” (Martin & Larson, 2003, p. 398).

The conceptual framework associated with occupational exposure is based on the epidemiological triad of host, agent, and environment (Figure I). Martin and Larson (2003) hypothesized that the adverse health effects identified in oncology healthcare workers are a product of an interaction between the person at risk (host), the exposure to hazardous drugs (agent), and the environment (handling practices). Each component of this triad affects the validity and reliability of tools that attempt to quantify exposure to these agents. Individual variations such as genetic prevalence, BMI, gender and lifestyle habits in the host affect the absorption as well as the sensitivity and specificity of the measurement method. The metabolism of the agent, its pharmacokinetics, and the agent’s physiological toxicity may significantly affect the outcome data. Lastly, the handling practices of the subjects, such as the use of personal protective equipment and biological safety cabinets, affect the quantity of internal absorption of these substances (Martin and Larson, 2003).
Validation/Persuasion

Proper administration of chemotherapy is a critical component of the practice of oncology. There are safety concerns not only for the patients, but also for hospital personnel and clients that may come into contact with these toxic agents or their metabolites. It is important that a climate of safe procedures be established to insure that the danger associated with the use of these agents is minimized. Hazardous drugs have a very narrow margin of safety, and overdoses or improper administration can be deadly or cause severe tissue damage (Connor, 2006).

According to the U.S. Department of Labor (1998) (as cited in NIOSH, 2004), the Hierarchy of Hazard Control is a four tiered process from most to least effective (see Figure II). The first tier is removal or substitution of the hazard. Unfortunately, this is not an option in the oncology setting. The second tier is the use of engineering controls to isolate or contain the hazard preventing exposure including ventilated Biological Safety Cabinets (BSC) & Closed System Transfer Devices (CSTDs). The third tier focuses on administrative controls, suggesting efforts be steered towards safe handling practices (ex. bag spiking in BSC hood) as well as education and training. The last tier is personal protective equipment (e.g. gloves, gowns, goggles, and mask/respirator) which offer limited individual protection without an impact on environmental contamination or exposure.
NIOSH (2004) recommends minimizing exposure to hazardous drugs through “primary prevention measures”. They define these as engineering controls, administrative controls, and personal protective equipment (PPE). This subset corresponds and encompasses the lower three tiers of the U.S. Department of Labor’s Hierarchy of Hazard Control (1998) (as cited in NIOSH, 2004), detailed above.

NIOSH defines engineering controls as Class II or III biological safety cabinets (BSC), compounding aseptic containment isolators, closed system transfer devices, and needleless systems. Administrative controls include implementing work practices, management policies, and training programs to reduce worker risk. Further, they suggest a medical monitoring or surveillance program as a form of secondary prevention by identifying indicators of exposure or early disease (NIOSH, 2004). PPE should be used when engineering controls and/or administrative controls are not feasible in reducing exposures to hazardous drugs or when other control measures are not available or practical (NIOSH, 2010). PPE should always be used in the
context of an overall health and safety program that provides adequate training, retraining, and periodic testing of the workers’ knowledge of the proper use of PPE (NIOSH, 2010).

In compliance with the Hazard Communication Standard (NIOSH, 2010), all personnel involved in any aspect of the handling of hazardous drugs, including but not limited to physicians, nurses, pharmacists, housekeepers, employees involved in receiving, transport or storage, must receive information and training on safe handling and occupational exposure prevention of hazardous drugs in the work area. The frequency of training should be at the initial hiring or assignment, as needed when new hazardous drugs are introduced and annually to ensure employees have the most current information and training.

The National Study Commission on Cytotoxic Exposure (ONS, 1996) has recommended that knowledge and competence of personnel be evaluated after the first orientation or training session, and then yearly or more often if a need is perceived. Evaluation should involve direct observation of an individual’s performance on the job. In a post-health hazard investigation report issued by NIOSH in 2010, the findings and recommendations of an anonymous oncology clinic in Florida offered several pearls of wisdom to consider. They found that employees reported insufficient training on occupational exposure and prevention of hazards as a primary driver for inconsistent use of PPE (NIOSH, 2010). While training was consistently administered annually, the depth and accuracy of that training had not been evaluated. This exposed a deficit offering insight to the value that an up-to-date comprehensive training program can provide to employee compliance with safe handling. Elshamy (2010) found that only 22.9% of nurses reported receiving any training program about occupational health and safety and only 8.6% reported nursing guidelines for precaution during the care of patients receiving cytotoxic agents.
Stakeholders:

Developing, maintaining and evaluating a safe handling training plan requires the support of all stakeholders including employers (hospitals, infusion centers, and healthcare organizations) and health care workers (physicians, advanced practitioners, nurses, pharmacy, and non-licensed personnel). The benefits are vast; including a reduction in “no” or “minimal” notice call offs due to illness among staff, improved occupational climate in respect to employer’s perceived positive commitment to safety as well as increased organizational integrity (Polovich, 2010).

The depth of a comprehensive safety program greatly impacts the associated cost. Under the Hierarchy of Hazard Control (as cited in NIOSH, 2010), the use of a single use closed system transfer device (Tier 2) such as the PhaSeal ® system requires approximately $25-37 on average of additional cost per patient (Poirier, 2004; Miyamatsu & Sakamoto, 2006). With no reimbursement from insurers, the financial burden of providing safe engineering equipment falls onto the employers.

Under Tier 3, the administrative costs are more difficult to quantify. The cost to provide a medical surveillance program is estimated at $216 to $432 per employee per year, including a complete blood count (CBC) panel with differential and a complete urinalysis with dipstick annually per high risk employee (Massoomi, 2008). Other costs include the personnel time to provide education and training, which is frequent and evolving as data emerges. Massoomi cautions that these costs could fluctuate vastly as the learning needs of the employees are further individualized.
Comparative Evaluation

Worldwide, more than 11 million new cases of cancer are diagnosed each year, and that number is expected to rise to 16 million by 2020 (ONS, 2012). In the United States, over 11.4 million people have been diagnosed with cancer. According to the American Cancer Society (ACS) 1.53 million new cancer cases were diagnosed in 2010 (ACS, 2011). The National Cancer Institute predicts that this figure will double by the year 2050 because the US population is growing and aging. This increased patient load, along with the use of higher-dose chemotherapy, more combinations of drugs, increase in production of novel (experimental) agents, and the use of hazardous drugs for diseases other than cancer, will increase the potential for exposure of the health care worker to these drugs (Connor, 2006) (Figure III).

Health care workers who handle, prepare, or administer hazardous drugs may face risks to their own health such as skin rashes, cancer, and reproductive disorders. NIOSH recommends
that employers establish a medical surveillance program to protect workers who handle hazardous drugs in the workplace (NIOSH, 2004).

The toxicity of anticancer chemotherapy has been well known since its initial clinical use. Indeed, it has often been these drugs’ toxic side effects that have limited their therapeutic value. The risk-benefit equation for a cancer patient often determines these drugs’ appropriate use despite acknowledged side effects. Although these drugs present the same potential toxicities to exposed health care workers, that risk-benefit ratio is distorted without the presence of a malignant diagnosis. A balance must be achieved to continue the use of these beneficial drugs in patients, while assuring the health of personnel administering them is protected. A body of guidance now exists on how to achieve this goal. Much of it revisits the long standing elements of a comprehensive safe handling program and reminds us that the risks remain thus vigilance is required. The consensus is that safe handling practices have continued to be adopted which minimizes risk to workers who provide lifesaving therapies to their patients (Polovich & Whitford, 2009).

**Project Description**

**Literature Search Strategy**

**Keywords:** hazardous drugs, chemotherapy, cytotoxic drugs, occupational exposure, safe handling, antineoplastic precautions, nurse safety, oncology exposure, work place learning, adult learning, clinical competence.

**Databases:** PubMed, CINAHL, and Google Scholar

**Language:** English
To gain a better perspective on hazardous drug exposure, a thorough literature review was performed including articles from industry-specific (medical, nursing, pharmacy and healthcare safety) journals. Research search engines included PubMed, CINAHL, and Google Scholar. Language was filtered to limit result to English only publications. With the scarce availability of data in this research area, timeframe limitations were not restricted. However, due to the relatively new labeling of these agents, the depth of information available was self-limited, thus the extent of this literature review spans from 1985 to 2012. As one would suspect, there was sparse and limited data available for the first decade (1985-1995). While it has increased over the past 17 years (1995-2012), there remains a dearth of research in this area.

The objectives for this literature review were to establish the extent of exposure, provide a foundation of knowledge of current recommendations and identify variables in adherence. With these goals identified, a clinical education program on effective safe handling could be developed.

**Review of the Literature**

Dr. Melissa McDiarmid (2004), a scholar and pioneer in the research of oncology occupational hazard, states that “occupational exposure to anticancer drugs has been shown to be associated with both increased incidence of malignancy in male and female healthcare workers, as well as fetal developmental effects in their offspring” (p.84), therefore it is essential for oncology nurses to be aware of the potential effects of cytotoxic agents, and diligent in taking the steps needed to minimize exposure hazards.

Health care employees who work with or near hazardous drugs are exposed to these agents in the air, on work surfaces, clothing, medical equipment, or patient excrement. Due to their nature, hazardous drugs are genotoxic, carcinogenic, teratogenic (fetal impairment) or cause
developmental toxicity (ex. organ failure). These agents are not selective to cancer cells and thus do not distinguish between normal and cancerous cells when causing disruption of the genetic material and cell growth. Prolonged exposure to hazardous agents can cause significant and detrimental outcomes including adverse reproductive outcomes and organ toxicity even at low doses (Polovich & Whitford, 2009).

It is important that safety precautions are taken by the employees and the employers to provide the best safety standards available, evidenced by current research to prevent occupational exposures to antineoplastic and other hazardous drugs in the healthcare setting (NIOSH, 2004).

**Historical Perspective**

The toxicity of anti-neoplastic drugs has been well known since they were introduced in the 1940’s. In World War I, sulphur mustard gas (parent drug of nitrogen mustard) was first used as a chemical weapon. Designed to cause bone marrow and lymph tissue regression in exposed service men, this drug’s non-selective destruction of cells (mechanism of action) garnered attention by early scientists working on cancer therapies. Nitrogen mustard gas became the forefather of hazardous drugs when healthcare providers began utilizing it for lymphoid malignancies. Now it is considered the beginning of modern chemotherapy raising the practice of medical oncology treatment.

While surgery and radiation therapy were the primary treatments for cancer in the 1950s, the National Chemotherapy Program, federally funded in 1955, supported the development of new chemotherapy agents. Due to advances in science, chemotherapy is now commonly administered for the treatment of cancer in patients with both solid tumors and hematologic malignancies. Today, the United States Food and Drug Administration (FDA) has approved
approximately 225 drugs used in the treatment of cancer with new drug developments increasing in frequency (FDA, 2004). Addressing these drugs’ formidable toxicity profile, however, has been an ongoing campaign for clinicians and more recently, for the occupational health community (Connor, 2006).

In the 1970s, secondary malignancies were reported in patients who had previously received antineoplastic drugs for other malignancies; the most common were leukemia, Hodgkin’s disease, lymphomas and bladder cancer (NIOSH, 2004). Since that time, a number of the antineoplastic drugs, especially many of the alkylating agents (ex. cyclophosphamide and mechlorethamine hydrochloride/nitrogen mustard), have been associated with secondary cancers in treated patients (Vanchieri, 2005). In support of these findings, numerous laboratory studies have identified these agents as genotoxic and carcinogenic in rodents (Skov, 1992).

In addition to their mutagenic and carcinogenic properties, many of the antineoplastic drugs have been associated with adverse reproductive effects that have been observed in animals as well as treated patients. Currently, the FDA has listed 45 antineoplastic drugs as Pregnancy Category D and six as Category X (FDA, 2004; see Appendix A). Reproductive and developmental effects similar to those observed in patients have been reported in health care workers who are exposed to antineoplastic drugs at considerably lower doses than those administered to patients.

In 1990, the American Society of Health-System Pharmacists (ASHP) published its revised Technical Assistance Bulletin (TAB) on handling cytotoxic and hazardous drugs (ASHP, 1990). Continuing reports of workplace contamination and concerns for health care worker safety prompted the Occupational Safety and Health Administration (OSHA) to issue new guidelines on controlling occupational exposure to hazardous drugs in 1995. Subsequently in
2004, the National Institute for Occupational Safety and Health (NIOSH) issued the “NIOSH Alert: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings”, reviewing the most recent research, providing recommendations for practice and promoting a program of safe handling during their use. Collectively, these have become the guidance behind safe handling of hazardous drugs, yet remain unenforceable.

Since the inception of the OSHA Guidelines (1986), and the NIOSH Alert (2004), adherence has been sporadic (Polovich & Whitford, 2009). In addition, measurable concentrations of hazardous drugs continue to be documented in the urine of health care workers who prepared or administered them even after safety precautions had been employed (Newman, 1994). Further, environmental studies of patient-care areas have documented measurable concentrations of drug contamination, even in facilities thought to be following recommended handling guidelines (Connor, 2005). This modification of procedures without significant improvements in safety has caused frustration and complacent behavior, which regresses safe practice efforts, creating a persistent problem (NIOSH, 2004).

Poorly designed and executed research practices have been linked to inaccurate serum and urine sampling in exposed employees in earlier years (Newman, 1994). Appropriately designed studies have begun and are continuing to characterize the extent and nature of health hazards associated with these ongoing exposures. When all the data are considered, evidence associates hazardous drug exposures at work with increased genotoxicity (Connor, 2003).

Until recently, experts were fairly confident that the workplace was safe because workers were following OSHA Guidelines and the NIOSH Alert. However, Dr. Susan Martin (2003) states, “The assumption was always that if we used the protective equipment and the biological safety cabinets, they provided enough protection, but new studies showed otherwise” (p. 579). In
1994, Newman reported significant findings with the presence of several drugs in the urine of employees, by measuring the Salmonella typhimurium reverse and forward mutagenicity, total thioethers, and D-glucaric acid. This epidemiological tracing back to hazardous drug handling provided several reporting areas of discussion. The forward mutation assay detects DNA large base deletions and insertions, base-pair changes, and frameshifts. Thioethers reflect the glutathione detoxification of electrophiles, putative mutagens. D-glucaric acid reflects microsomal mixed function oxidation in the liver and kidney and bladder f-glucuronidase activity. NIOSH (2004) reports it is currently conducting studies to further identify potential sources of exposure and methods to reduce or eliminate worker exposure to these drugs.

According to the Centers for Disease Control and Prevention (CDC) the exposure of healthcare workers who, as part of their work practices, are exposed to hazardous drugs should employ all known precautions to eliminate or reduce exposure as much as possible. An estimated 8 million health care workers are potentially exposed to hazardous drugs annually (NIOSH, 2010). Pharmacists and nurses are the two highest exposed occupational groups and require the greatest attention (Vanchieri, 2005). According to Howell (1980) there is an increased relative risk (RR) of leukemia among occupationally exposed pharmacy technicians (RR=1.1-3.6). McDiarmid et al. (1990) reports that oncology nurses have a relative risk of 10.65. These findings are further supported by McDiarmid et al. (2010) findings of chromosomal damages from hazardous drug exposure with a 2-fold to 4-fold increased risk with exposure to alkylating agents.

Surveys of U.S. cancer centers and oncology clinics reveal wide variation in work practices, equipment or training for personnel preparing hazardous drugs. This lack of standardization results in a high prevalence of potential occupational exposure. According to the
OSHA Technical Manual (2004), one survey found that 40% of hospital pharmacists reported a skin exposure at least once a month, and only 28% had medical surveillance programs in their workplaces (Wilkes, 2010). Nurses, particularly those in outpatient settings, were found to be even less well protected than pharmacists. Such findings emphasize current lack of protection for all personnel who risk potential exposure to HD’s.

Workers who are potentially exposed to chemical hazards should be monitored in a systematic program of medical surveillance intended to prevent occupational injury and disease. The purpose of surveillance is to identify the earliest reversible biologic effects so that exposure can be reduced or eliminated before the employee sustains irreversible damage. The occurrence of exposure-related disease or other adverse health effects should prompt immediate re-evaluation of primary preventive measures (e.g., engineering controls, personal protective equipment). In this manner, medical surveillance acts as a check on the appropriateness of controls already in use.” (Friese et al., 2011, p. 44)

Employee safety and long term effects of exposure to hazardous drugs have created a need for further research. Several reports have addressed the relationship of cancer occurrence to health care workers’ exposures to antineoplastic drugs. Iatrogenic transmission has been linked back to early epidemiological investigations. A significantly increased risk of leukemia has been reported among oncology nurses identified in the Danish cancer registry for the period 1943–1987 (Naumann & Sargent, 1997). Further concerns have ignited research on teratogenic effects of hazardous drug exposure. Concerning findings have shown a propensity towards adverse reproductive effects, including increased fetal loss; congenital abnormalities, low birth weight and infertility have been reported throughout the past decade indicating significant concerns for employee safety and their offspring (Valanis, 1991).
The routes of exposure have also created areas of research development. A number of studies have attempted to measure airborne concentrations of antineoplastic drugs in health care settings. In most cases, the percentage of air samples containing measurable airborne concentrations of hazardous drugs was low, and the actual concentrations of the drugs, when present, were quite low. These results may be attributed to the inefficiency of sampling and analytical techniques used in the past (Sargent et al, 2002). Both particulate and gaseous phases of one antineoplastic drug, cyclophosphamide, have been reported in three studies (Baker et al, 1987; Connor et al, 2002; Harrison et al, 2006).

Surface contamination using wipe samples has become increasingly valuable to research, as it is relatively a simple process that yields accurate and reliable results. In reviewing the most current literature, most investigators measured detectable concentrations of one to five hazardous drugs in various locations such as biological safety cabinet (BSC) surfaces, floors, countertops, storage areas, tables and chairs in patient treatment areas, and locations adjacent to drug-handling areas. All of the studies (Connor et al., 1999; Connor et al., 2002; Connor et al., 2010; DePrijck et al., 2008; Dranitsaris, 2005; Friese et al., 2011; Jacobson et al., 2009; Jorgenson et al., 2008; McDiarmid, 1991; Yoshida et al, 2009) reported some level of contamination with at least one drug, and several (Harrison et al., 2006; McDevitt et al., 1993; Polovich & Clark, 2010; Timpe et al., 2004) reported contamination with all the drugs for which assays were performed. Such widespread contamination of work surfaces makes the potential for skin contact highly probable in both pharmacy and patient areas (Spivey & Connor, 2003).

In a more recent trial, Connor and colleagues (2010) studied surface contamination in pharmacy and ambulatory areas in six cancer centers in the United States and Canada. These researchers found that 75% of pharmacy areas and 43% of medication administration areas were
contaminated with at least one cytotoxic agent, and that locations adjacent to drug handling areas were also contaminated (Eisenberg, 2009). This caused a huge outcry as all of the facilities, three being NCI-designated, were adhering to the OSHA guidelines established in 1986. Other studies conducted at the same time as Dr. Connor’s work have found that pharmacists and nurses who handled cyclophosphamide were exposed to enough of the drug so that it appeared in their urine (Vanchieri, 2005).

Evidence indicates that workers are being exposed to hazardous drugs and are experiencing serious health effects despite current work practice guidelines. Protection from hazardous drug exposures depends on safety programs established by employers and adhered to by the staff. The likelihood that a worker will experience adverse effects from hazardous drugs increases with the amount and frequency of exposure and the lack of proper work practices.

This literature review produced many important findings and perspectives which helped to shape and support this research. It is important to note, that with any literature review, there are limitations to its scope and scale. The intention of the literature review for this study was to uncover sufficient essential preexisting literature to properly support this work. It is understood that there might be significant amounts of literature available which could be considered relevant to this research that was either not found or noted. Of the literature, there are some findings that are more important than others.

**Theoretical Framework**

The development of a comprehensive hazardous drug program requires multidisciplinary planning in the hospital setting with input from administration, medicine, nursing, pharmacy, risk management, safety, and environmental services staff. Such interdisciplinary groups should
review national guidelines regularly and develop policies and procedures based on the current data (Polovich & Whitford, 2009).

Health care professionals are trained to problem solve through critical thinking; with a scientific underpinning. This is often classified as “professional clinical judgment” (Lasater, 2011). This clinical judgment is invaluable to quality improvement. The goal is to spark this intrinsic process with new and current information creating a synergistic effect to cultivate further adherence.

**Adult Learning**

Adult education according to Knowles (1984) (as cited in Darbyshire, 1993) has a five point framework (see Figure III). As we mature, education becomes more independent versus dependent during adolescents and young adulthood. He also presents the value of bringing one’s life experiences in order to strengthen the learned experience. Utilizing social roles, adult learners create developmental tasks that enhance their desire or readiness to learn while shifting from subject-centric to problem-centric learning. For these reasons, case studies and group discussions were key elements of the learning experience.

*Figure III*
*Source: jmu.edu*
The first step is to perform a needs assessment of the audience and channel the learning components towards their identified needs. Reviewing the profiles of the distribution of nurses, their work place settings ranged from in-patient, outpatient, home health and hospice. These were further distributed between non-profit, for-profit and academic institutions. In total there were 389 registered members of the Willamette Valley Chapter of the Oncology Nursing Society. Four members were excluded from the data as they were community liaisons, working as laypersons at American Cancer Society and the LiveStrong Foundation.

**Components of a Comprehensive Safe Handling Program**

A comprehensive safe handling program has four components: clinical surveillance, engineering controls, environmental sampling and educational training (Figure I). This project will focus on the educational training component with introductions made into the other three components, as an effort to educate oncology nurses on their comprehensive benefits.

Utilizing current data, nurses will feel more prepared to address the hidden occupational dangers and take appropriate measures to protect themselves. It is the hope that this new awareness will empower nurses to become champions within their own health care settings; engaging employers to partner their efforts in developing comprehensive safe handling programs that meet their individual work place needs.

**Clinical Surveillance**

Clinical surveillance is one element of a comprehensive approach to minimizing employee exposure and should be used as part of a safety and health program that includes engineering controls, good work practices, and PPE. Employers should ensure that health care workers who are exposed to hazardous drugs are routinely checked. This includes workers who directly handle hazardous drugs, such as nurses, pharmacists, and pharmacy technicians and
ancillary/support staff that may come directly into contact with patient wastes within 48 hours after a patient has received a hazardous drug (Connor, 2006). Such safety programs must be able to identify potentially exposed workers and those who might be at higher risk of adverse health effects due to this exposure.

Medical surveillance involves collecting and interpreting data to detect changes in the health status of working populations potentially exposed to hazardous substances. The elements of a medical surveillance program are used to establish a baseline of workers’ health and then monitor their future health as it relates to their potential exposure to hazardous agents to determine whether there is a deviation from the expected norms (ASHP, 2006; NIOSH, 2004; Arrington & McDiarmid, 1993). The comprehensive nature of a clinical surveillance program requires extensive planning and implementation over several months.

Suggested components of the Medical Surveillance Program (adapted from NIOSH Alert, 2004) include:

1. Reproductive and general health questionnaires completed at the time of hire, annually and periodically as needed.

2. Laboratory work, including complete blood count and urinalysis completed at the time of hire, annually and periodically as needed. Additional tests, such as liver function and transaminase tests, may also be considered.

3. Physical examination completed at the time of hire and then as needed for any worker whose health questionnaire or blood work indicates an abnormal finding.

4. Follow-up for those workers who have shown health changes or have had a significant exposure (e.g., substantial skin contact, cleaning a large spill such as a broken bag, leaking IV line, etc.)
Periodic health questionnaires and laboratory results should be looked at for trends that may be a sign of health changes because of exposure to hazardous drugs. If health changes are found, the following actions should be employed:

1. Evaluate current protective measures:
   
   I. Engineering controls (biological safety cabinets/ isolators, ventilation, closed system transfer devices, and closed IV systems)

2. Compare performance of controls with recommended standards.

3. Conduct environmental sampling when analytical methods are available.
   
   I. Policies for the use of PPE and employee compliance with PPE use and policies.
   
   II. Availability of appropriate PPE such as double gloves, non-permeable gowns, and respiratory protection. It is important to note that all PPE, including polypropylene-coated gowns to prevent absorption of hazardous drugs, are single-use items.

   III. Develop plan of action that will prevent further employee exposure.

4. Ensure confidential notification of any adverse health effect to an exposed worker and offer alternative duty or temporary reassignment.

5. Provide ongoing clinical surveillance of all workers at risk to determine whether the new plan is effective including reevaluation of staff competency.

While outside of the scope of this project, the value is relevant. This program was introduced to the nurse members in their training as a recommendation for their respective employers, labor unions and state legislation.
In 2011, the State of Washington became the first in the nation to adopt specific workplace safety rules to protect healthcare workers who are potentially exposed to antineoplastic drugs and other hazardous medications. Issued by the State’s Department of Labor & Industries, it passed legislation and was signed into law State of Washington § 62nd Legislature § 2011 Regular Session § Engrossed Substitute Senate Bill 5594 (ESSB 5594) in April 2011. Slated to take effect January 1, 2014, it is consistent but not excessive of the NIOSH and OSHA recommendations for safe handling.

This comprehensive, 100-page manual of statutes, mandates that employers provide a hazardous drug control program, with required components for inventory control, hazard assessments, written policies and procedures, engineering controls (e.g. biological safety cabinets, laboratory fume hoods), safe handling practices, personal protective equipment (e.g. chemotherapy gloves, gowns, and goggles), spill controls and waste handling and disposal guidelines. Further, the Department of Occupational Safety & Health (DOSH) of Washington has assigned the Washington State Department of Labor and Industries to address all violation reports and investigations. This has created a new level of accountability among employers to not only provide safer work places but also to enforce employee compliance with PPE, training, and surveillance. This is a major accomplishment in the awareness and educational efforts of HD exposure. Vigilant support of this important safety issue will maintain its momentum for adherence.

The health and safety of workers who handle hazardous drugs should be a high priority. There are challenges to implementing a comprehensive program for the protection of workers. Some barriers are related to administrative issues, such as cost or staffing, comfort, lack of time/pressure (Vanchieri, 2005) while others are related to personnel’s knowledge, attitudes, and
compliance (Polovich & Whitford, 2009). As barriers increase, the use of self-protective precautions (PPE) decreased (Polovich, 2010). A study (Maisarah & Said, 1993) on the use of hearing protection devices in factory workers concluded similar results indicating that the challenge of compliance is not unique to nursing or health care.

**Engineering Controls**

IV equipment was designed with patient safety in mind, not health care worker protection. In drug administration areas, spiking IV containers with IV tubing and un-spiking to remove tubing results in leakage (Lowry, 2009). Bag spiking and priming have been shown to result in significant exposure risk. NIOSH (2004) and ASHP (2006) recommend that these activities be performed in a BSC with priming solution being a neutral compatible agent (i.e. saline or dextrose) in a measure to reduce the risk of occupational exposure. Recent studies have focused on the contamination reduction benefits of using a CSTD in compounding and administration (Spivey & Connor, 2003; Yoshida et al, 2009).

According to NIOSH (2004) a closed system is “a device that does not exchange unfiltered air or contaminants with the adjacent environment. It mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system” (NIOSH, 2004, p. 165). The PhaSeal® system by Carmel Pharma, is the only Closed System Transfer Device available in the United States that meets the NIOSH definition.

PhaSeal® consists of several components with a double-membrane system that traps drug aerosols, prevents leakage when withdrawing drug from a vial, allows leak-free drug transfers, and provides for a "dry-spike" of an IV bag. Several studies have demonstrated the effectiveness of the closed-system device in reducing surface contamination (Connor, 2002; Spivey, 2003;
Lowry, 2009). While current data supports its use, consumers are mainly restricted to large academic research institutions; which accounts for just 20% of chemotherapy administration sites. This isolation of superior engineering controls is largely related to its associated high cost of use (Polovich, 2010). According to Williamson (2008) more than 80% of patients receive treatment in private physician-based offices and clinics. This translates to a great disparity of safety among clinical settings.

A U.S. investigation demonstrated that use of a closed-system device for 6 months reduced both the concentration of cyclophosphamide or ifosfamide in the urine of exposed health care workers and the percentage of samples containing these drugs (Steiner, 2006). Hazardous drugs have also been documented in the urine of health care workers who did not handle hazardous drugs but were potentially exposed through fugitive aerosols or secondary contamination of work surfaces, clothing, or drug containers (Sargent & Kirk, 1988). For these reasons, part of this project’s training will include the introduction to the benefits of the PhaSeal® system for chemotherapy admixture and administration.

With a push from our neighbors to the north, the State of Washington, most health care organizations in Oregon have moved towards incorporating PhaSeal® into their pharmacy and nursing practices for hazardous drug admixing and administration. However, the efficacy of the equipment is dependent upon the correct application by the user. Ensuring that nurses who work in oncology have been properly trained on this equipment will increase its protection. For these reasons, a component of the educational training course will pay close attention to the proper techniques for using the PhaSeal® system and mastery of its individual components.
Environmental Contamination

In the conceptual design of this project, environmental sampling for surface contamination was considered. The goal of this component was to offer concrete and objective data of the actual risks employees have to hazardous drugs in their work setting. Surface Safe®, a two-step application process had shown to be effective in inactivating several anticancer drugs (Polovich & Whitford, 2009). Surface Safe® is a two-step inactivator application, with pad 1 containing hypochlorite and pad 2 containing thiosulfate (inactivates bleach; binds to platinum, other alkylators). The hypochlorite/thiosulfate combination neutralizes the potential hazards of the bleach and works to inactivate cytotoxic drugs via two separate mechanisms. Surface Safe can be used to clean spills up to 10 mL (using two sets of pads), and appears to be safe for use on wood, metal, and a variety of hard surfaces.

Martin and Larson (2003) spiked clean stainless steel sheets with several anticancer agents; treated with either isopropyl alcohol or Surface Safe (two wipes each). Preliminary results show remaining cyclophosphamide and ifosfamide levels to be significantly reduced with Surface Safe (18.9% versus 4.1% cyclophosphamide remaining; 100% versus 3.6% ifosfamide remaining). In a study done in Arizona, a 1-mg/mL solution of doxorubicin was placed into PVC plastic 150-mL bags and the bags were externally wiped with Surface Safe pads. The results showed no loss of drug over a 24-hour period, and no smearing of pre-printed labeling on the bags (Dorr, 2004).

These results indicate that Surface Safe is a useful intervention for employee safety by wiping bags prior to delivery to units or upon exit from the hood/mixing area. Unfortunately, Surface Safe® was discontinued in 2011. Covidien®, a global healthcare product manufacturer has developed a similar product due for release in late 2012; however there are no replacement
products currently available on the market. For this reason, the environmental sampling component of the comprehensive program overview were limited; yet its value remains clinically significant, therefore it is important to continue to incorporate this into the training. This will serve three folds, first as an introduction to new nurses and a reintroduction to seasoned nurses on the rebirth of this product and its efficacy. Second, as reinforcement of the lasting impact that each individuals has in the workplace on their colleagues, further supporting the environmental exposure risk. Last and possibly the most common misconception; that the wiping of surfaces and equipment with the clinical standard disinfecting agent, Cavicide ®, is ineffective in neutralizing antineoplastic agents. This is important since many nurses have expressed receiving misinformation on the efficacy of Cavicide ® on chemotherapy decontamination.

**Educational Training**

Continuing education is built on the concept of layering basic education and experiential factors of professional nursing with enhanced practice outcomes. Cancer care is a rapidly growing and expanding field with changes and developments continuously being presented (Holland & Weiss, 2008; Jacobson, 2008). In order to stay current with these changes, purposeful comprehensive education and training must be delivered to staff. Further, these efforts must be measured to ensure the approach of recognizing the adult learner according to Knowles’ “Andragogical Model” of autonomy; self-direction, life experiences, readiness to learn and problem orientation to learning are being met. With this framework in mind, key strategies will include learner involvement and interactive learning, reinforcing key points to promote retention as well as open discussion periods for peer learning through critical thinking. While peer story telling can be effective in creating a realistic scenario, it is important that this does not overshadow the learning experience.
While some research has looked at measuring the frequency of individual nurse’s use of HD safe handling precautions, newer data is considering the specific personal or behavioral characteristics that directly impact compliance. Understanding factors that impact, both positively and negatively, the use of HD safe handling precautions will aid in targeted efforts in the future.

A common theme in the literature includes the individual nurse’s perception of risk and knowledge of hazardous drug risks; a cyclical process (Coyle & Polovich, 2004; CANO, 1995; Collins et al, 2009; Garber, 2009; Joshi, 2007). It is hypothesized that as knowledge of exposure increases so does the perceived risk, creating a positive correlation for increased HD safe handling precautions. According to Barton-Burke (1996), perceived risk is a cognitive function that intrinsically appraises the magnitude of susceptibility and threat of a given situation. When perception is high, risk reducing behavior is elevated.

Hazardous drug knowledge is defined as “information about the risks of HD exposure and the effectiveness of precautions in preventing exposure. Knowledge is necessary for an individual to begin thinking about a health hazard” (Polovich, 2010, p.7). Direct knowledge of the hazards is the second factor that must be considered (Valanis & Shortridge, 1987, Valanis & Vollmer, 1992). Nursing knowledge is vast and varying among providers. It cannot be assumed that all providers have received training in safe handling. Providing safety training is key to supporting a safe occupational climate. Providing education to increase knowledge regarding workplace safety and hazard reduction supports the adoption of safety-related behaviors (Polovich, 2010).

Knowledge is related to self-efficacy, which is negatively impacted by barriers such as physical (unavailability) or social (organizational or peers). Developing attitudes of
encouragement and support, such as social modeling, have shown to be significant predictors in long term success of safe handling programs (Bryant, 2007). Martin & Larson (2003) found that seasoned nurses were less likely to wear PPE regularly and reported a lower perceived risk of harm from HD. This cavalier approach may help to explain the increasing prevalence of organizational climates that do not support HD safe handling to its fullest extent.

Safety reinforcement and expectations are a culture (Coyle & Polovich, 2004). This includes principles, norms, values, beliefs and assumptions. The literature is clear that the climate for safety among staff includes the positive, negative and neutral components (McDiarmid, 2004; McDiarmid & Gurley, 1991). To improve safety, climate we must decrease the barriers and increase precaution use (Polovich, 2010).

Overcoming the barriers to implementing a comprehensive safe handling program requires collaborative support. In order to protect nurses, we must demonstrate our commitment to providing a safe environment. While safety is undoubtedly important, nurses must have the knowledge of safe practices and exposure risks in order to champion these efforts. Harrison et al. (2006) found that education and training alone directly improved HD safe handling among pharmacists. For these reasons, the foundation of this educational training was heavily weighted with information on the effects of hazardous drug exposure and their risk to humans exposed over a long duration of time such as employment.

**Implementation Methods**

This project will focus on the development, execution and delivery of a safe handling of hazardous drugs educational course designed for nurses working in the oncology setting. Included in this training class was commonly reported “behavior or practice” patterns. Addressing these barriers such as discomfort associated with wearing PPE (Polovich, 2010,
A PRE AND POST TEST ASSESSMENT OF A WEB BASED TUTORIAL

Harrison, 2006; Connor, 2006), lack of concern for potential health effects associated with occupational exposure and non-adherence to recommended precautions (Polovich & Whitford, 2009). By providing factual data it is the goal to increase awareness among the nurses, empowering them to take the necessary precautions to protect themselves and others. This presentation was through a one-hour structured web-based teaching presentation, including printouts, case studies and scenarios.

The implementation of this project was through a collaborative effort, working with other healthcare professionals including, the Oncology Nursing Society, the ONS Willamette Valley Chapter, professional nurses and health care leaders within Oregon. To ensure its successful incorporation into practice, an assessment was conducted prior to the training session and immediately following the training to determine foundational and newly obtained knowledge. These results were stratified in order to identify areas of further improvement, as well as to establish efficacy and optimization of outcomes of this project. An Institutional Review Board (IRB) application was submitted and approved prior to administration of the tests and training interventions to assure ethical obligations and requirements.

Who

Participants were recruited using a current membership email list provided by the National ONS office. The investigator sent an introduction letter with an embedded link and URL link to each potential learner. Participation was voluntary and information de-identified to maintain anonymous resulting.

What

Curriculum development was completed by first considering the foundational knowledge of the learners and incorporating Knowles’ Adult Learning Theory into the eLearning software
program. While there are several customizable software programs commercially available, the selected program needed to meet all three threshold criteria: on-demand capabilities, universal device accessibility (including mobile and tablets), and instant learner access without requiring downloads to the learner’s computers. For this project Adobe Captivate 6 met all of these criteria and was selected as the software system to design and deliver the eLearning training. All components for the training program were published under the Adobe Captivate 6 software program, including the creation of a flash-based eLearning CBE (Computer Based Education) and CBT (Computer Based Test).

The evaluation measures to verify the efficacy of the planned interventions was obtained using a test-retest method at two intervals. The evaluation was obtained through self-reported surveys: pre-test and post-test, built into the eLearning training. The data was de-identified and analyzed using descriptive statistics. The goal of this evaluation was to identify trends in practice or behaviors.

Identification of need to develop survey analyzing the knowledge of oncology nurses in regard to safe handling of hazardous drugs

Project initiated

Stakeholders identified

Input sought from stakeholders and other with regard to content

Preexisting tools researched and appraised for value.

Review of the literature

Draft tool and obtain validation from experts on content and completeness

Final version of survey deployed.
Where

Learners were able to access the web-based learning from any internet accessible devices, including mobile “smart phones” and tablets. With an “on-demand” framework, learners were able to access and complete the educational course at their leisure, 24-hours a day, 7 days a week, within the open course period.

When

The following is a Gantt chart providing a timeline schedule for this project. The eLearning web-based tutorial was projected to be open to the learners from September 1, 2012 through September 31, 2012. This was subject to the approval of the Institutional Review Board (IRB) projected for September 1, 2012. The IRB approval was obtained on September 17, 2012. On September 25, 2012 the initial email was distributed to the ONS ListServ, introducing the project and requesting participation. This elicited approximately 47 participants as of October 4, 2012; far less than the desired participation rate for half way through the established survey period.

A second email reminder was sent on October 5, 2012. This email was identical to the first email and was sent to all participants since by design the data was de-identified thus the investigator could not ascertain the prior participants.

The study closed on October 15, 2012. The total time for participant’s contribution to this study was 21 days. At the close of the study, a total of 91 surveys were collected. Of those surveys, 7 were incomplete of one or more parts, thus the final participation total was corrected to 84.
How

An email was sent to all members of the ONS Willamette Valley Chapter from the investigator. The body of the email was the IRB Cover Letter explaining the research, the voluntary participations as developed and approved by the University of Utah’s Institutional Review Board. Within this email, URL links was accessible for participants to immediately participate in the study. Each link from the email will take the participant to the 5 sections of the study, allowing them to start and stop at 5 intervals within the survey. Further, each link section of the survey will have the successive link to the next part of the survey, allowing participants the opportunity to navigate through the survey in one fluid process without returning to the original email for redirection. This should help to create a seamless navigation for the participants and avoid participant fatigue; optimizing full participation.

Learners will not be required to enter their contact information or any other identifiable information, thus de-identification was a passive process. Clinical questions built into the web-based tutorial were analyzed using usual techniques for descriptive statistics. Reporting was presented with mean, median and average results for clinical questions.
**Evaluation Plan**

This project was evaluated based on criterion metrics derived from the Capstone project objectives:

<table>
<thead>
<tr>
<th>Objective</th>
<th>Evaluative Metric</th>
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<tbody>
<tr>
<td>Develop a web-based learning tutorial utilizing Knowles’ “Andragogical Model” of adult learning theory regarding safe handling of hazardous drugs to a select group of nurses as a Beta group. Goal: 40% participation of 389 email addresses on member list (approx. n=156)</td>
<td>Acceptance by content experts (clinical and teaching) by September 1, 2012</td>
</tr>
<tr>
<td>Develop a pre-test and post-test to evaluate the effectiveness of the web-based tutorial to increase awareness of safe handling practices among oncology nurses.</td>
<td>Acceptance by content experts (clinical and teaching) by September 1, 2012</td>
</tr>
<tr>
<td>Disseminate the tutorial program to the members of the Oncology Nursing Society (ONS) Willamette Valley Chapter.</td>
<td>The metric for achievement of this goal was set at 40% participation of the 389 email addresses on the member list (approx. n=156)</td>
</tr>
<tr>
<td>Mid-range goal: present results of research in poster presentation at the 38th Annual ONS Congress Conference on April 25-28, 2013 in Washington, DC.</td>
<td>April 25-28, 2013 *Outside the scope of this project</td>
</tr>
<tr>
<td>Long-term goal: disseminate this training through the Oncology Nursing Society as a free web-based CEU course potentially reaching 37,000 national members.</td>
<td>Summer 2013 *Outside the scope of this project</td>
</tr>
</tbody>
</table>
The objectives for this project were fulfilled as follows:

1. Develop a pre-test and post-test to evaluate the effectiveness of increasing the awareness of safe handling practices among oncology nurses.
   - This metric was achieved with acceptance from both the clinical and teaching content experts on August 24\textsuperscript{th} and 30\textsuperscript{th}, respectively.

2. Develop a web-based learning tutorial utilizing Knowles’ “Andragogical Model” of adult learning theory regarding safe handling of hazardous drugs to a select group of nurses as a Beta group. This objective was fulfilled upon acceptance of content from clinical and teaching content experts by September 1, 2012.
   - This metric was achieved with acceptance from both the clinical and teaching content experts on August 24\textsuperscript{th} and 30\textsuperscript{th}, respectively.

3. Disseminate the tutorial program to the members of the Oncology Nursing Society (ONS) Willamette Valley Chapter. The metric for successful achievement of this goal was set at 40% participation of the 389 email addresses on the member list (approx. n=156).
   - Upon approval from the IRB on September 17, 2012 the project deliverables were completed and all links checked and corrections made to errors that were identified. On September 25, 2012 the initial email was distributed to the ONS ListServ, introducing the project and requesting participation. This elicited approximately 47 participants as of October 4, 2012; far less than the desired participation rate for half way through the established survey period.
   - A second email reminder was sent on October 5, 2012. This email was identical to the first email and was sent to all participants since by design the data was de-identified thus the investigator could not ascertain the prior participants.
III. The study closed on October 15, 2012. The total time for participant’s contribution to this study was 21 days. At the close of the study, a total of 91 surveys were collected. Of those surveys, 7 were incomplete of one or more parts, thus the final participation total was corrected to 84. This represented 21.6% of the 389 members of the ONS Willamette Valley Chapter. While less than the original goal of 40% (n=156), this offered a respectable Beta group to consider. This low response rate for web based research is an expected finding based on the web-based design and not indicative of inherent errors. Despite convenience and ease of completion, online survey collection commonly produces the lowest response rate when compared to other types of distribution methods (Fan and Yan, 2010).

Results of Research

The survey included four sections: Section 1: Nursing Education for Occupational Safety with Hazardous Drugs Pre-Test (Appendix A), Section 2: Nursing Web-Based Educational Tutorial (Appendix B), Section 3: Nursing Education for Occupational Safety with Hazardous Drugs Post-Test (Appendix C), Section 4: Demographic Profile (Appendix E). Section 4 was a previously validated survey instrument, published by Dr. Martha Polovich (2010) and used with written permission.

Data were collected electronically using SurveyMonkey.com, an online web-based survey tool. The surveys were closed on October 15, 2012 for data collection analyses. Data analysis was performed by the researcher using Microsoft Excel® 2010. The data were manually entered over a period of several days during October 16-20, 2012. Questions were entered into the spreadsheet the same as they appeared on the questionnaire, e.g. with corresponding answers
of A, B, C, or D. For answers that were dichotomized into a yes/true or no/false response, the value of A was entered into the spreadsheet for yes/true responses and value of B was entered for a response of no/false. To ensure there were no data entry errors, the data was double checked for accuracy at two different times. Both times were on separate days and also completed independently by two different individuals. This resulted in a total of four accuracy reviews between two individuals, all of which took place on separate occasions.

The design of this project is a comparative study of safe handling of hazardous drug awareness among oncology nurses. The evaluation of this research is obtained through a pre-test post-test questionnaire with the implementation of a web-based learning tutorial specifically targeted to the sample population. Due to the study design, the pre-test and post-test are the two components being evaluated in this research results. Incomplete surveys were not considered as their value could not be appreciated without having both arms of the data to compare the results. The educational awareness garnered from the safe handling pre-test and post-test surveys produced a total of 84 valid questionnaires to analyze.

There are many methods for interpreting research findings. The analysis used in this study incorporates research methods and analyses that are used in many different disciplines. This includes methods and analyses that are used in natural science disciplines, the social sciences as well as medical studies. It was the goal of the researcher to adapt multidisciplinary approaches to the research methodology used in this study and present the findings in a clear, concise and understandable manner. Questions were evaluated independently versus aggregate as total scoring was not a criterion measured in this study. This method further allowed for better visual displays, highlighting any trends or patterns as depicted in the following graphs.
In question #1, the question of appropriate cabinet or hood was evaluated. In the pre-test, it was noted that 39.3% of participants answered this question correctly. One interesting finding was that approximately 85% of participants knew that some form of safety cabinet should be employed when preparing hazardous drugs. This is especially important in that the preparation of chemotherapy has shifted to non-nursing personnel (i.e. pharmacy staff). However, the risk to nursing is a down-stream effect of the safety of this preparation thus the value of the information is clearly important to our audience. Within the training modules, the Vertical-flow Class II biological safety cabinet was introduced and its safety features highlighted. In the post-test analysis, we find a two-fold increase in the participants who correctly identified the appropriate safety cabinet.

Correct Answer: B: Vertical-flow Class II biological safety cabinet
In question #2, we found many areas for consideration. First, the breakdown of the pre-test answers were stratified into a somewhat equivocal four way split, with “acute effects tend to be less serious in nature” as the most commonly selected answer. While incorrect, this represented just 32.1% of the total incorrect answers of 73.8%. With nearly one in four answers incorrect, this question was evaluated for clarity. In this evaluation, several internal errors were identified. First, the question is asking for a false answer yet the correct answer is negatively worded with a true response. The overall findings for this item calls to question that the internal error skewed the results with the post-test results showing limited improvement despite concentrated education within the web based tutorial. It is hypothesized that this could have created confusion among the participants, thus a true bell curve could not be ascertained. Due to the nature of this evaluation as a pre-test and post-test design, this question could not be reformatted to improve clarity but was a recommendation prior to future research consideration.
Correct Answer: A: Hair Loss

Question #3 represented a well written question with expected outcome responses. In question validation, the results should represent a true bell curve. In this question we achieve this structure with two strong front running answers, one being the correct answer of hair loss (34.5%) and menstrual dysfunction (32.1%). It is important to note that infertility and miscarriage were both relatively considered at 14.3% and 19.0% respectively. This indicates that participants were unclear of the correct answer yet all of the possible options were plausible considerations. In the post-test, the participants showed a marked increase in their identification of the correct answer, indicating that the information contained within the tutorial was useful knowledge.
Correct Answer: D: Any of the above

This question proved to be an area that is well understood prior to the tutorial with nearly 60% of the participants understanding that a hazardous drug could be defined as carcinogenic, teratogenic, or genotoxic. The post-test results further support that this information was garnered by additional participants with an increase of over 32% for a total of 91.7% of participants understanding this criteria.
Question #5 presented a dichotomous split in the pre-test data; supporting that this was an area that required further teaching. This training was incorporated into the web-based tutorial, which resulted in an outcome of 91.7% of participants understanding that the exterior of the vials should be considered contaminated.
#6. Which of the following is NOT a general characteristic of closed system drug transfer device?

<table>
<thead>
<tr>
<th>Option</th>
<th>Pre-Test</th>
<th>Post-Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. It protects integrity of IV fluid container</td>
<td>9.5%</td>
<td>22.60%</td>
</tr>
<tr>
<td>b. It creates a needle-free closed system</td>
<td>6.0%</td>
<td>21.40%</td>
</tr>
<tr>
<td>c. The device improves the shelf-life of most drug products</td>
<td>28.6%</td>
<td>73.8%</td>
</tr>
<tr>
<td>d. The device seals and closes upon disconnect</td>
<td>10.7%</td>
<td>27.4%</td>
</tr>
</tbody>
</table>

*Note: Due to rounding, figures may not sum to 100%*

Correct Answer: C: The device improves the shelf-life of most drug products

Question #6 offered insight into the familiarity of the participants with closed system transfer devices. While not a requirement for administering hazardous drugs, the use of these systems are growing in response to staff and federal demands to increase safety in this field. This question offered insight that participants considered all four options heavily, with “c” and “d” being the most frequent choices in the pre-test evaluation. After the tutorial, the post-test evaluation showed marked delineation with roughly three out of four participants correctly identifying the incorrect characteristic for closed system transfer devices.
Question #7 offered choices for consideration of a CSTD. Some participants were able to ascertain in the pre-test (36.9%) that there are multiple considerations to incorporating a closed system transfer device into their workplace clinical practices. In the post-test assessment, there was a notably marked difference with 95.2% of participants accurately identifying that compliance, customization of application, cost, and ease of use were all variables in considering incorporating these engineering controls into practice.
Correct Answer: B: Devices work only with lipid-based drugs

Question #8 showed a disparity in the pre-test, with answers dispersed among all independent variables. This was valuable information to validate that participants were unclear as to the correct answer and that more training could potentially assist with their knowledge development and awareness. In the post-test evaluation, 77.4% of participants correctly answered this question supporting this original hypothesis.
While expected to be a very straightforward and high yielding question, the pre-test results indicated that roughly 60% of participants were not aware of the criteria for personal protective equipment (PPE). In an effort to increase this knowledge, a portion of the tutorial was dedicated to PPE and included pictures and graphics to help illustrate the differences between appropriate and not appropriate personal protective equipment. The post-test results showed a two-fold increase in the participants choosing the correct answer; supporting that the training offered an increase in awareness.
Questions #10 proved mastery by nearly 50% of the participants in the pre-test with an increase to 91.7% correctly answered in the post test evaluation. This question was an important concluding question to ensure that nurses understand that no workplace is exempt from these criteria, regardless of their size or affiliations. Often times, smaller practices do not have the financial resources to invest in building robust safe handling programs. This lack of resources however cannot be the justification for not adhering to national guidelines. Without a national organization to police organizations, it is important that nurses advocate for themselves and understand the policies and procedures outlined for employers to follow. When deficits are recognized, remediation can be expeditious; thus improving community and occupational health.
Discussion

Overall there was a significant improvement seen in the pre-test versus the post test after the web based tutorial. This indicates that the majority of the participants demonstrated some mastery of the content delivered in the web based tutorial; indicating an increase in awareness of safe handling knowledge. Further, this marked improvement in scoring on each test item (question) helps validate participants understood the content delivered to them in the tutorial. As members of the Oncology Nursing Society, these participants may have been introduced to these concepts in other educational opportunities offered through this national association for oncology nurses. Further, this information may have been presented in their workplace orientation or through other non-formal educational method. Regardless of the source, the results of this research shows that reinforcement through concentrated efforts helps to refresh this knowledge and supports the revisions and changes coming forward in this area.

Areas that showed greater variances in the responses were questions # 2 and 3. While more difficult to hypothesize the reasons for these variances, it is important to appreciate these findings as opportunities for further directive training and education through the formal education routes. These variances are great reminders of the value of continual learning as these questions specifically address short and long term effects of hazardous drug exposure; two areas of great concern in oncology.

The results of this research will be presented to the Oncology Nursing Society in a formal application for a poster presentation at the ONS Congress Conference in April 2013 (Appendix G). It is this researcher’s goal to highlight the deficits identified among the Beta group in an effort to validate emphasis placed in these areas on the initial and renewal processes for the Chemotherapy/ Biotherapy Provider card. With continued weight given to these areas, we can
help close the knowledge gap identified with this research; further improving the education of safe handling of hazardous drugs.

**Demographic Profile Findings**

Included in the survey invitation was the Demographic Profile Survey developed by Dr. Martha Polovich. This tool was used with written permission by Dr. Polovich, who is also the content expert for this Scholarly Project. The demographic profile, being a validated survey tool (Polovich, 2010), was considered reliable as measured by Cronbach’s Alpha. It was added to this research in an effort to provide greater insight into the profile of the participants.

The profile includes demographic characteristics such as age, education and experience levels. Results were stratified as follows: Age by five groups: <30 years, 30-39 years, 40-49 years, 50-59 years, and 60+ years. Nursing education was also broken into five groups: Diploma, Associate’s degree, Bachelor’s degree, Master’s degree, and Doctoral Degree. Oncology specific post nursing certification was stratified into three categories: Not Certified, OCN and AOCN.

Other variables including ONS membership status and ONS Chemotherapy/ Biotherapy Provider status were dichotomized into a yes or no classification. Clinical demographics were considered including occupational setting, number of patients the participant directly treat and the number of patients served daily in their workplace. These offered insight to the variability of exposure risk and potential linkage between nurses who treat more chemotherapy patients with those with the most training and education related to hazardous drug safety.

The instructions were clear that this was a voluntary contribution to the survey and not part of the main research study; the pre-test and post-test. No errors in data entry were found using the data entry screening process. There were, however, questions found that were deemed to have poor data quality because of missing values. The questions with missing values were
considered to be invalid and therefore not used in the data analysis for this study. Of the seven questionnaires collected, three provided poor data quality, leaving four useable questionnaires for measureable consideration. While undoubtedly a great benefit to this project, the participation in this demographic profile survey was virtually non-existent (n=4) thus the results were not analyzed as part of this project.

There could be a number of logical reasons why these surveys had a greater number of missing values than in Dr. Polovich’s research in 2010. The first consideration is that this was a complimentary survey to the research data on Safe Handling of Hazardous Drug knowledge. The time required to complete the pre-test and post-test along with the web-based tutorial is estimated at 30-35 minutes in duration. This in itself was a large commitment by the participants; precluding their interest in committing more time to completing the demographic profile.

Secondly, the depth of the demographic profile may have deterred participants from completing this; evident in the number of incomplete surveys. Further, participants were ensured that no identifiable data would be collected. While complete anonymity was always maintained; societally Americans are sensitive to the amount of personal information that is extended due to privacy concerns. Nurses are inherently more aware of such privacy concerns due to HIPAA regulations and patient confidentiality. This awareness may lend itself to less willingness to provide private or personal information regardless of the anonymity of the information, thus a larger number of questions left blank. In light of these incomplete demographic surveys, this additional information was not analyzed as part of this project.

Regardless of the reasons, it is important to note that the demographic profile was not part of the study design and did not hinder the results of the primary research.
Limitations

It is important to recognize a limitation of this sample population. As members of ONS, these participants have access to many safe handling educational resources through this organization. There is minimal education outside of this organization specific to safe handling for non-members to receive. Approximately half of all oncologic nursing professionals are members of this organization (ONS, 2012), which equates to a dichotomy of education from members versus non-members. Because of the access to resources, ONS nurse members may have presented with bias towards safer handling practices (Polovich, 2010).

The results of this study support many other studies suggesting that nurses who are active members of a national association, in this case, the Oncology Nursing Society; are more educated and informed on current (safe handling) practices. While not a causative link, the association of these variables is further strengthened by these findings.

Participants of this study are members of the Willamette Valley Chapter of the Oncology Nursing Society. This is a paid membership association of the national association, the Oncology Nursing Society. With a financial investment into their oncology practices, the participants have a great interest in ensuring that they remain current in their profession. Further, there was no randomization of subjects with this study, hampering the generalizability of these results outside of this group.

Future Research

This research has pointed out some important factors which appear to influence the knowledge of safe handling practices among oncology nurses. Some of these findings are new to the literature and some may contribute to existing theory. Therefore, additional research could be useful to understand in greater detail how the findings affect attitudes and nursing practices.
Recommendations

The project was built on the foundation of education supported by the Oncology Nursing Society’s Principles of Preparation, Administration and Disposal of Hazardous Drugs (Polovich, 2010). ONS is an organization that supports safe handling of hazardous drugs by nurses. Nationally recognized as the leader in evidenced based practice, ONS represents current advancements including collaboration with medicine, pharmacy, and government agencies such as NIOSH and OSHA.

The presentation/teaching session was timed at approximately 20-25 minutes, not including a question and answer period, which varies based on participation. With individual pretest and posttest of ten questions, it was calculated that one hour would be an appropriate time frame to conduct this training session and evaluate the participant’s performance. Utilizing current technologies, this program was available on-demand, with participant log in to the curriculum and survey website. CEU’s were not available for this course for the Beta group; however this might be a desirable consideration in future developments. Of note, the state of Oregon does not require registered nurses to maintain continuing education hours so long as they are practicing in the profession of nursing. This is important to consider as part of future recommendations to ensure that the efforts put forth to validate the training by a state or national governing body for continuing education units (CEUs), will be desirable for the participants.

It is also the recommendation of this researcher that once accepted on the national level by the Oncology Nursing Society, this work be expanded to other agencies such as NIOSH and OSHA for non-nursing consideration and publication in an effort to reach non-nursing personnel who may be at risk for hazardous drug exposure. The appropriate agency should be determined.
through discussions with the leadership at the Oncology Nursing Society as they will be the champion for this project at the national level.

**Conclusion**

Without enforceable national guidelines, we as oncology nursing leaders must champion efforts towards closing the gap of knowledge by being advocates for one another and for our communities. Reducing hazardous drug exposure will impact the safety and quality of life for millions of healthcare workers by decreasing adverse health outcomes related to occupational exposure.

The environment for administering hazardous drugs is being expanded almost daily. With wider applications for treatment, these drugs are being used in arthritis, multiple sclerosis, tubal ectopic pregnancies, HIV/AIDS and even in veterinary medicine without consideration for safe handling and exposure risks. There is no known education being distributed outside of the oncology in these various settings (Polovich, 2010).

HD exposure is associated with adverse outcomes (reproductive complications, learning disabilities in offspring of nurses exposed during pregnancy, and cancer occurrences). Safe handling precautions (safety equipment and PPE) minimize exposure risks to HDs and decrease the potential for adverse outcomes. Despite existing OSHA recommendations, adherence to precautions is below recommendations. (Polovich, 2010).

A safe handling precaution program includes three of the four tiers of the Hierarchy of Hazard Control issued by the US Department of Labor in 1998 (as cited in NIOSH, 2004). These tiers include engineering controls such as equipment, administrative controls such as work place practices and personal protection equipment (PPE). All precautions, when used correctly and consistently, can reduce occupational exposure to hazardous drugs (NIOSH, 2004).
The safe handling program must be a collaborative effort, with input from all affected departments, such as pharmacy, nursing, medical staff, housekeeping, transportation, maintenance, employee health, risk management, industrial hygiene, clinical laboratories, and safety. Maintaining up to date policies and procedures for the safe handling of hazardous drugs ensures health care workers are adequately prepared to protect themselves and others in their workplace from unnecessary exposure. While the development of a comprehensive safe handling program is beyond the extent of this project, educating nurses on their risks and safety precautions are important first steps.

Caregiver staffing models vary among inpatient, outpatient, academic, home health and hospice settings. Exposure risks, while slightly varied among these groups, pose a risk to licensed and non-licensed health care workers. Each member of the health care team plays an integral part in the safety of the entire team in prevention and containment of hazardous drug exposure. For these reasons, expansion of training to other caregivers, including those preparing and administering in non-oncology settings is important to occupational health.

Recognizing that educational training will need to be tailored to the varying workplace settings and staff levels will allow for greater understanding and comprehension of the education delivered. When fully achieved, the collective efforts of the team can be realized with everyone’s complete appreciation. The ripple of impact will be vast including facilities, housekeeping, materials management, pharmacy, nursing, providers, patients, families and the general public.

Hazardous drug handling is potentially risky work and the employees that work in an environment of exposure should be educated and informed of these risks and ways to protect themselves. OSHA, ASHP, ONS, and NIOSH all provide guidelines for the safe handling of
hazardous drugs. While not providing complete protection, it is believed that adherence to current recommendations will reduce health care workers’ exposure.

The results of this research pinpoint areas within safe handling education that should be evaluated for weight adjustments and further educational emphasis. These results further validate that knowledge is a continuous process and despite years of nursing practice and education, reinforcement and reeducation on new and current practice is still an important aspect to knowledge dissemination and retention among oncology nurses. These are important considerations as future training and guidelines are published in this area which has a large impact on the development of safe handling practices.

This project has created a foundation of awareness among oncology nurses in the state of Oregon. With this newfound awareness, it is this researcher’s goal that the efforts of one nurse can ignite an interest among these clinicians; making a lasting and impactful difference in the lives and safety of many who have are exposed to HD’s in their occupations. “It is time for nurses to take their own occupational safety as seriously as the safety of the patients under their care” (Polovich & Whitford, 2009, p. 152).

This author is optimistic that this study has exposed some directions for further research that will influence a greater appreciation and awareness for safe handling awareness and attitudes among oncology nurses within the Beta group. If the only outcome of this research is the increase in education and awareness regarding safe handling of hazardous drugs among 84 nurses; then this research study was a successful accomplishment.
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A PRE AND POST TEST ASSESSMENT OF A WEB BASED TUTORIAL


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Appendix A:

Occupational Safety Pretest
Nursing Education for Occupational Safety with Hazardous Drugs Pre-Test

1. Which drug preparation cabinet (hood) provides greater protection to a person preparing a mutagenic substance?
   a. Horizontal-flow biological safety cabinet
   b. Vertical-flow Class II biological safety cabinet
   c. Both provide equal safety
   d. Neither provides safety

2. Which of the following statements is **false** regarding an acute effect from exposure to chemotherapy?
   a. Acute effects tend to be more common
   b. Acute effects tend to be less serious in nature
   c. Acute effects tend to be more generalized
   d. All of the above statements are true

3. Which of the following adverse effects is generally not linked to long-term exposure to hazardous drugs?
   a. Hair loss
   b. Menstrual dysfunction
   c. Infertility
   d. Miscarriages

4. According to NIOSH, a drug is considered hazardous if it meets which of the following criteria?
   a. Carcinogenic
   b. Teratogenic
   c. Genotoxic
   d. Any of the above

5. It is safe to assume that intact vials that contain antineoplastic agents received from the manufacturer are not contaminated with drug on the outside surface.
   a. True
   b. False

6. Which of the following is **NOT** a general characteristic of closed system drug transfer device?
   a. It protects integrity of IV fluid container
   b. It creates a needle-less closed system
   c. The device improves the shelf-life of most drug products
   d. The device seals and closes upon disconnect

7. All of the following should be considered when comparing closed system transfer devices.
   a. Compliance
   b. Customization of application
   c. Cost
   d. Ease of use
8. NIOSH recommends that closed system transfer devices have all of the following safety features except:
   a. Cannot be deactivated and remains protective until disposal
   b. Devices work only with lipid-based drugs
   c. Tell the user whether or not the safety feature is activated
   d. Can perform reliably

9. Which of the following is not an acceptable piece of personal protective equipment?
   a. Chemotherapy-resistant gloves
   b. Eye protection
   c. Cloth gown
   d. Closed-toe shoes

10. Which of the following sites is exempt from having policies and procedures based on current national guidelines?
    a. Single physician office
    b. Ambulatory clinic
    c. Community-based hospital
    d. Comprehensive cancer center
    e. None of the above are exempt
Appendix B:

RN Safety Program Presentation
Preventing Cancer: Developing a Comprehensive Hazardous Drug Exposure Program

Jennifer Lewis, APRN, MSN, AOCNS

Purpose
The purpose of this project is to identify areas to increase safe handling and administration of hazardous drugs among registered nurses who are members of the Willamette Valley Chapter of the Oncology Nursing Society.

Objectives
- Identify the exposure potential for the nurses who prepare, handle, administer, and dispose of hazardous drugs.
- Evaluate nurses perception of hazard risks.
- Educate on the acute and chronic effects that arise from exposure to hazardous drugs.
- Highlight new recommendations and guidelines for handling hazardous drugs.

Introduction
While information about the occupational risks of chemotherapy and other hazardous drugs has been available for more than 20 years, evidence for worker exposure is still being reported. The Occupational Safety & Health Administration (OSHA) published the first national guidelines for safe handling of chemotherapy in 1986, and yet these recommendations are not universally used. The short and long term effects from exposure to hazardous drugs are serious concerns for healthcare providers. NIOSH, OSHA, ONS, and ASHP have all identified the problem and offer guidelines for the safe handling of these substances.

Problem Statement
With multiple organizations recognizing the safety hazards of hazardous drug handling, there has not yet been a unified report published regarding safe handling of hazardous drugs. Further, the lack of occupational safety education specific to continuous exposure to hazardous drugs creates a disparity among nurses in oncology.

Significance
Source = Thomas Connor, Ph.D., NIOSH
Increasing number of cancer patients
More Drug Combinations
Higher Doses & More Potent Drugs
Increasing non-oncology use & a shift in treatment settings
Increasing evidence of exposure despite national recommendations
Compounding Risk to Nurses
Slide 7

Historical Perspective

WW: Use of mustard gas led to changes in bone marrow.

WW2: Mustard gas analogs (nitrogen mustard and sulfur mustard) led to remission in Hodgkin's disease.

British Soldiers blinded by mustard gas, 1918.

Slide 8

Knowledge Deficit/Risk of injury related to inappropriate handling of and exposure to hazardous drugs

94% of nurses report eating in an area where chemotherapy is administered (Elshamy et al., 2010).

Slide 9

- There is no known safe threshold limit for exposure to cytotoxic drugs
- Even low-level exposure to cytotoxic drugs should be avoided as much as possible
- Implementation of suitable safety precautions reduces the incidence of adverse health effects
- Personal protective equipment (gloves, gowns, mask), equipment (Class II BSC), technical equipment (CSTD), good working practices

Slide 10

Potential Routes for Exposure:

- Inhalation—from breathing contaminated air, such as from aerosolized drugs
- Dermal contact—from touching drugs directly or touching contaminated surfaces
- Ingestion—from contaminated food or drink or other hand-to-mouth contact
- Accidental injection—from needle stick or other sharps injury

Slide 11

Possible Side Effects of Exposure

Short Term:
- GI - Nausea, Vomiting, Diarrhea
- Mucosa and Skin - Enteral Irritation, Respiratory Irritation and Cough, Dermatitis, Hair Loss
- Neurological - headache, lightheadedness, vertigo, syncope
- Reproductive - irregular menses

Long Term:
- Cancer - Leukemia
- Reproductive - Infertility, Miscarriages, Birth Defects

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Summary of Literature Review

- General Long Term effects of exposure (Connor, 2010)
- Liver damage was reported in three nurses (working 6-16 years) (Sotaniemi, 1983)
- Cardiotoxicity related to the use of anthracyclines (Chaudhary, 2012)
- Overall increased cancer risk (OR = 3.27) (Martin, 2005) (Boughattas, 2010)
- Leukemia in nurses (RR = 10.65) (Skov et al, 1992)
- Cyclophosphamide exposure causes an additional 1.4-10 cancer cases/million each year (Sessink et al, 1993)
- NHL & skin cancer (SIR = 3.7) (Bouraoui, 2011; Hansen & Olsen, 1994)
- Published studies
  - Positive florescent scans (Roth & Smith, 2012; and Valanis, 1998)
  - 16 Positive urine tests for drug exposure (Maeda, 2010; Green, 2009)
  - In 4 studies, drugs were found in the urine of workers with no direct HD contact
  - Contaminated vials - 13 studies since 1992 (Bigelow, 2009)
  - Surface contamination - 15 studies since 1994; meta-analysis (Roth & Smith, 2012)
Summary of Literature Review

- Fetal abnormalities (Hemminki et al, 1985)
  - Spontaneous abortions (Bouve & Lusardi, 1991; Bouve et al, 1997)
  - Stillbirths, neonatal deaths, health-related disabilities in offspring (ASHP, 1999)
- Increased risk for miscarriages by 40% (Jones, 2012)
- Increased risk for low birth weight by 17% (Kaiser Permanente Center for Health Research, 2008)
- Other Hazardous Drugs in Healthcare Settings (NIOSH, 2004, 2007)
- Increased risk for congenital malformations by 5-fold
  - Relative Risk (RR)
  - Standardized Incidence Rate (SIR)
  - Odds Ratio (OR)

Hierarchy of Hazard Control

1. Elimination or substitution of the hazard: not feasible with chemotherapy medications
2. Engineering controls to isolate or contain the hazard
3. Administrative controls: safe handling practices (ex. bag spiking in BSC hood)
4. Personal protective equipment: gloves, gowns, goggles, and mask/respirator

History of Safe Handling

1970s
- Double bagging
- Respirator
- Protective clothing

1980s
- Horizontal laminar airflow devices
- Compounding area

1990s
- Vertical hoods
- Continuously vented hoods
- New Vertical Hoods

2000s
- Remote preparation
- Computerized control for blisters

Chemotherapy & Hazardous Drugs

Case Study

39 year old pharmacist suffered episodes of painless hematuria and was found to have bladder cancer (papillary cell carcinoma). She had worked for 10 years as a pharmacist, and 5 years before her diagnosis, she had worked full time for 20 months in a hospital pharmacy for preparation of cyclophosphamide and ifosfamide. When symptoms started, she used a horizontal laminar airflow hood. She was a nonsmoker and had no other known occupational or environmental risk factors. Her bladder cancer was attributed to her exposure to antineoplastic drugs. (Levin et al, 1993)
NIOSH ALERT

WARNING!
Working with or near hazardous drugs in healthcare settings may cause skin rashes, infertility, miscarriage, birth defects, and possibly leukemia or other cancers.

Source: NIOSH Alert, 2004

Recommended Institutional Responsibilities from NIOSH Alert 2012

- Define agency policies and procedures (OSHA, 1999)
  - Delineation of hazardous materials
  - Develop HD list with Quality & Safety department
  - Labeling, storage, personnel issues, spill control
  - Education, preparation, administration, and disposal
- Ventilated cabinets
- Orientation to hazardous chemicals
  - Key contacts within the organization
  - Location of policies & MSDS
  - Have material safety data sheets (MSDSs) available (OSHA, 1999)
  - Develop medical surveillance program (Polovich, 2009)
  - Develop a monitoring system for reviewing incident reports involving hazardous drugs
  - Annual review of critical process and hazardous chemicals
  - Plan for patients to educate on new therapies
  - Develop a plan to educate on available treatments
  - Develop a plan to educate on less hazardous alternative therapies
- Accommodations for nurses who are pregnant, trying to conceive, or breastfeeding or those have other medical reasons for not being exposed (Brown et al., 2001; Polovich, 2009)

Comprehensive Safety & Training Program

Safety
- Ensuring adequate supply of Personal Protective Equipment
  - Chemotherapy-approved Gloves
  - Chemotherapy-approved, Single-use Gowns
  - Goggles
  - Chemotherapy-approved Drapes
  - Single-use N95 Respirators
- Ensuring adequate supply/budget for Engineering Equipment
  - PhaSeal® Closed Transfer System

Training
- Tying instruction and maintenance
  - Spill response kit for closed system transfer devices
  - Drug preparation, transport & administration
  - developer video
  - Management of hazardous drug spills acute exposure

Interventions: Preparation & Administration

Minimize exposure during preparation (Brown et al., 2001; OSHA, 1999; Polovich, 2010)

- Follow manufacturer’s recommendations
- Dedicated environment
- Special equipment and procedures when preparing drugs

The PhaSeal System is the only clinically proven closed-system drug transfer device on the market. This system is designed to prevent leakage of drugs into the environment during preparation and administration through waste disposal (ONS 2005).

Drug Transfer With Needle & Syringe

Photographs courtesy of L. Hampton, RN, MS, FNP; onayre Cancer Center, Whiteville, NC. Reproduced with permission.
External Contamination
Photographs courtesy of L. Hampton, RN, MS, FNP; Donayre Cancer Center, Whiteville, NC. Reproduced with permission.

Closed System Drug Transfer Device (CSTD)
NIOSH (2005) defines a closed-system drug transfer device as:
“A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system.”

The PhaSeal® System is leakproof and airtight and is the only system that currently satisfies the NIOSH’s definition of a closed system.

Appropriate mastery of the PhaSeal® system can reduce environmental contamination through three sources:
– Aerosols formed during drug preparation
– Drug vapors formed during drug preparation
– Droplets released during transfer and administration

Intervention: Administration
Minimize exposure during administration (ASHP, 1990; OSHA, 1999; Polovich, 2010).
• PPE during administration including double gloving. Studies show that some HDs can permeate gloves in as little as 15 mins (ASTM, 2005).
• Safe handling guidelines for biologic agents to maintain consistency of nursing practice and limited occupational exposure data.
• Use gloves handling oral agents; face shield if risk for splashing; use absorbent, plastic-backed pad; wash hands thoroughly after administration.

Standard Syringe Drug Transfer

Administration Area Contamination
Photographs courtesy of L. Hampton, RN, MS, FNP; Donayre Cancer Center, Whiteville, NC. Reproduced with permission.
Slide 31

Where else?

Slide 32

Even on the floor…

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Interventions: Disposal
- Minimize exposure during disposal (ASHP, 1990; OSHA, 1999; Polovich, 2003)
- Contaminated materials and personal protective equipment in a sealable puncture-proof, leak-proof container labeled “hazardous waste”;
- Disposal of sharps and needles, without recapping, directly into puncture-proof container designed for hazardous waste;
- Wash hands after disposal;
- Don gloves and decontaminate equipment used (Polovich, 2003).

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Contaminated Vials during Shipping

<table>
<thead>
<tr>
<th>Drug name</th>
<th># of vials</th>
<th>% Contaminated</th>
</tr>
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<tbody>
<tr>
<td>Cyclophosphamide</td>
<td>105</td>
<td>75%</td>
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<tr>
<td>Cyclophosphamide</td>
<td>100</td>
<td>100%</td>
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<tr>
<td>5-FU</td>
<td>50</td>
<td>100%</td>
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<tr>
<td>5-FU</td>
<td>100</td>
<td>100%</td>
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<tr>
<td>Ifosfamide</td>
<td>40</td>
<td>100%</td>
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<tr>
<td>Etoposide</td>
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<td>100%</td>
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<tr>
<td>Doxorubicin</td>
<td>47</td>
<td>100%</td>
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<tr>
<td>Carboplatin</td>
<td>30</td>
<td>100%</td>
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Reference: (Connor et al. 2005)

Slide 35

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</tbody>
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Reference: (Connor et al. 2005)

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Direct Exposure Risks

- Minimize incidence and severity of direct exposure
- Direct contact; accidental spill; environmental contamination (NIOSH, 2012; OSHA, 1999)
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**Indirect Exposure Risks**

- Minimize risk of indirect exposure
- 48 hours standard precautions recommended (NIOSH, 2012, ASHP, 1990; OSHA, 1999)
- Avoid splattering body fluids during disposal
- Consider measures to reduce exposure from body fluids, limiting transfers of contaminated fluids from one container to another, and using closed systems of drainage collection
- Double flush toilets for 48 hours following HD administration (Polovich, 2009)

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**Appropriate Personal Protective Equipment (PPE)**

- Gloves
- Eye Protection
  - When splashing is possible

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**Indirect Contamination**

What % of chemotherapy is excreted unchanged in urine within first 24 hours:

- Etoposide ______%
- Cyclophosphamide ______%
- Fludarabine ______%
- Dacarbazine ______%

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**Appropriate Personal Protective Equipment (PPE)**

- Gowns
  - Wear gowns that are disposable, made of a lint-free, low-permeability fabric.
  - They should have a solid front (back closure) and knit or elastic cuffs.
  - Laboratory coats and other cloth fabrics absorb fluids, so they provide an inadequate barrier to hazardous drugs and are not recommended.
  - The existing guidelines do not contain a recommendation for the maximum length of time that a gown should be worn. Because no recommendations are stated in the literature, at a minimum, change the gown every time it is contaminated or gloves are changed. However, it is important to note that this is classified as a "single-use" item.
- Respirator/masks
  - For aerosols & spill clean-up

Source: Safe handling of cytotoxic drugs: an independent study module. 2nd ed. Pittsburgh (PA): Oncology Nursing Society; 2009. p26

Slide 39

**Indirect Contamination**

What % of chemotherapy is excreted unchanged in urine within first 24 hours:

- Etoposide 55%
- Cyclophosphamide 40%
- Fludarabine 25%
- Dacarbazine 40%

Slide 42

**Conclusion**

The health and safety of workers who handle hazardous drugs should be a high priority. Policies and procedures for the safe handling of hazardous drugs must be in place for all situations in which these drugs are used. A comprehensive safety program must be developed that addresses all aspects of the safe-handling of hazardous drugs.

"It is time for nurses to take their own occupational health seriously as the safety of the patients under their care" (Polovich, 2009)
References


Appendix C:

Occupational Safety Post Test
Nursing Education for Occupational Safety with Hazardous Drugs Post-Test

1. Which drug preparation cabinet (hood) provides greater protection to a person preparing a mutagenic substance?
   a. Horizontal-flow biological safety cabinet
   b. Vertical-flow Class II biological safety cabinet
   c. Both provide equal safety
   d. Neither provides safety

2. Which of the following statements is false regarding an acute effect from exposure to chemotherapy?
   a. Acute effects tend to be more common
   b. Acute effects tend to be less serious in nature
   c. Acute effects tend to be more generalized
   d. All of the above statements are true

3. Which of the following adverse effects is generally not linked to long-term exposure to hazardous drugs?
   a. Hair loss
   b. Menstrual dysfunction
   c. Infertility
   d. Miscarriages

4. According to NIOSH, a drug is considered hazardous if it meets which of the following criteria?
   a. Carcinogenic
   b. Teratogenic
   c. Genotoxic
   d. Any of the above

5. It is safe to assume that intact vials that contain antineoplastic agents received from the manufacturer are not contaminated with drug on the outside surface.
   a. True
   b. False

6. Which of the following is NOT a general characteristic of closed system drug transfer device?
   a. It protects integrity of IV fluid container
   b. It creates a needle-less closed system
   c. The device improves the shelf-life of most drug products
   d. The device seals and closes upon disconnect

7. All of the following should be considered when comparing closed system transfer devices.
   a. Compliance
   b. Customization of application
   c. Cost
   d. Ease of use
   e. All of the above
8. NIOSH recommends that closed system transfer devices have all of the following safety features except:
   a. Cannot be deactivated and remains protective until disposal
   b. Devices work only with lipid-based drugs
   c. Tell the user whether or not the safety feature is activated
   d. Can perform reliably

9. Which of the following is not an acceptable piece of personal protective equipment?
   a. Chemotherapy-resistant gloves
   b. Eye protection
   c. Cloth gown
   d. Closed-toe shoes

10. Which of the following sites is exempt from having policies and procedures based on current national guidelines?
    a. Single physician office
    b. Ambulatory clinic
    c. Community-based hospital
    d. Comprehensive cancer center
    e. None of the above are exempt
Appendix D:

Occupational Safety Education Answer Key
Occupational Safety to Hazardous Drugs Education Answer Key

1. Which drug preparation cabinet (hood) provides greater protection to a person preparing a mutagenic substance?
   a. Horizontal-flow hood
   b. Vertical-flow Class II biological safety cabinet
   c. Both provide equal safety
   d. Neither provides safety

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   a. Acute effects tend to be more common
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5. It is safe to assume that intact vials that contain antineoplastic agents received from the manufacturer are not contaminated with drug on the outside surface.
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   b. False

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   a. It protects integrity of IV fluid container
   b. It creates a needle-free closed system
   c. The device improves the shelf-life of most drug products
   d. The device seals and closes upon disconnect
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   b. Customization of application
   c. Cost
   d. Ease of use
   e. All of the above

8. NIOSH recommends that closed system transfer devices have all of the following safety features except:
   a. Cannot be deactivated and remains protective until disposal
   b. Devices work only with lipid-based drugs
   c. Tell the user whether or not the safety feature is activated
   d. Can perform reliably

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   b. Eye protection
   c. Cloth gown
   d. Closed-toe shoes

10. Which of the following sites is exempt from having policies and procedures based on current national guidelines?
    a. Single physician office
    b. Ambulatory clinic
    c. Community-based hospital
    d. Comprehensive cancer center
    e. None of the above are exempt
Appendix E:

Nursing Questionnaire with Scoring

(Developed by Dr. Martha Polovich, 2010

used with written permission)
Thank you for agreeing to participate in this study of nurses who handle chemotherapy. “Handling” refers to chemotherapy preparation, administration, disposal, and coming into contact with patient’s excreta that may be contaminated with chemotherapy.

- By **drug preparation**, we mean transferring chemotherapy drugs from vials or ampules to syringes or IV containers.

- By **administration**, we mean giving chemotherapy to patients by IV, injection, orally, etc.

- By **disposal**, we mean discarding equipment used in chemotherapy preparation or administration.

- By handling **excreta**, we mean emptying bedpans, urinals or emesis basins.

Do you personally handle chemotherapy at work, either drug **preparation** or **administration**?

- Yes (1)

- No (0) → If you answered “No” **STOP HERE**.

If you answered “Yes”:

1. Please read each item carefully

2. Place a check in the box next to your selection from the list of options

3. Please answer all of the questions that apply to your chemotherapy handling.
Section 1

Does your workplace have written policies and/or procedures for handling chemotherapy?

☐ Yes (1)    ☐ No (2)

Where is chemotherapy prepared in your workplace?

<table>
<thead>
<tr>
<th>Pharmacy</th>
<th>☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs are delivered to the infusion area (prepared in an off-site location)</td>
<td>☐</td>
</tr>
<tr>
<td>Specially designated room separate from the patient care area</td>
<td>☐</td>
</tr>
<tr>
<td>Area within the patient treatment area / room</td>
<td>☐</td>
</tr>
<tr>
<td>Other (specify)________________________</td>
<td></td>
</tr>
</tbody>
</table>

What personal protective equipment is available for performing the following handling activities? Check all that apply.

<table>
<thead>
<tr>
<th></th>
<th>Gloves</th>
<th>Gowns</th>
<th>Eye Protection</th>
<th>Respirator/ Mask</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Administration</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Handling Excreta</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Disposal</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Cleaning Spills</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
Section 2 Chemotherapy Preparation:

Are you responsible for preparing chemotherapy?

☐ Yes (1) ☐ No (0) → If you answered “No” proceed to Section 3.

Complete section 2 ONLY if you prepare chemotherapy drugs.

What type of gloves do you wear while preparing chemotherapy?

- None ☐
- Chemotherapy designated gloves ☐
- Vinyl (polyvinyl chloride, PVC) ☐
- Latex examination gloves ☐
- Sterile surgical gloves ☐
- Other (specify) ____________________ ☐

What type of protective clothing do you wear while preparing chemotherapy?

- None ☐
- Chemotherapy-designated gown ☐
- Personal lab coat ☐
- Lab coat provided by office ☐
- Cloth gown ☐
- Isolation gown ☐
- Other (specify) ____________________ ☐
Please indicate how much of the time you use the following while preparing chemotherapy:

<table>
<thead>
<tr>
<th>Item</th>
<th>Always</th>
<th>76-99%</th>
<th>51-75%</th>
<th>26-50%</th>
<th>1-25%</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological Safety Cabinet</td>
<td>□ (5)</td>
<td>□ (4)</td>
<td>□ (3)</td>
<td>□ (2)</td>
<td>□ (1)</td>
<td>□ (0)</td>
</tr>
<tr>
<td>Closed system transfer device</td>
<td>□ (5)</td>
<td>□ (4)</td>
<td>□ (3)</td>
<td>□ (2)</td>
<td>□ (1)</td>
<td>□ (0)</td>
</tr>
<tr>
<td>Gloves labeled for use with chemotherapy</td>
<td>□ (5)</td>
<td>□ (4)</td>
<td>□ (3)</td>
<td>□ (2)</td>
<td>□ (1)</td>
<td>□ (0)</td>
</tr>
<tr>
<td>Other gloves (e.g. vinyl)</td>
<td>□ (5)</td>
<td>□ (4)</td>
<td>□ (3)</td>
<td>□ (2)</td>
<td>□ (1)</td>
<td>□ (0)</td>
</tr>
<tr>
<td>Double gloves</td>
<td>□ (5)</td>
<td>□ (4)</td>
<td>□ (3)</td>
<td>□ (2)</td>
<td>□ (1)</td>
<td>□ (0)</td>
</tr>
<tr>
<td>Gowns labeled for use with chemotherapy</td>
<td>□ (5)</td>
<td>□ (4)</td>
<td>□ (3)</td>
<td>□ (2)</td>
<td>□ (1)</td>
<td>□ (0)</td>
</tr>
<tr>
<td>Other gowns (e.g. cloth)</td>
<td>□ (5)</td>
<td>□ (4)</td>
<td>□ (3)</td>
<td>□ (2)</td>
<td>□ (1)</td>
<td>□ (0)</td>
</tr>
<tr>
<td>Do you re-use disposable gowns?</td>
<td>□ (5)</td>
<td>□ (4)</td>
<td>□ (3)</td>
<td>□ (2)</td>
<td>□ (1)</td>
<td>□ (0)</td>
</tr>
<tr>
<td>Eye protection</td>
<td>□ (5)</td>
<td>□ (4)</td>
<td>□ (3)</td>
<td>□ (2)</td>
<td>□ (1)</td>
<td>□ (0)</td>
</tr>
<tr>
<td>Respirator/mask</td>
<td>□ (5)</td>
<td>□ (4)</td>
<td>□ (3)</td>
<td>□ (2)</td>
<td>□ (1)</td>
<td>□ (0)</td>
</tr>
</tbody>
</table>
Section 3  Chemotherapy Administration:

Are you responsible for administering chemotherapy?

☐ Yes  ☐ No → If you answered “No” proceed to Section 4.

Complete section 3 ONLY if you administer chemotherapy drugs.

What type of gloves do you wear while administering chemotherapy?

<table>
<thead>
<tr>
<th>Type of Gloves</th>
<th>☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Chemotherapy designated gloves</td>
<td></td>
</tr>
<tr>
<td>Vinyl (polyvinyl chloride, PVC)</td>
<td></td>
</tr>
<tr>
<td>Latex examination gloves</td>
<td></td>
</tr>
<tr>
<td>Sterile surgical gloves</td>
<td></td>
</tr>
<tr>
<td>Other (specify)</td>
<td></td>
</tr>
</tbody>
</table>

What type of protective clothing do you wear while administering chemotherapy?

<table>
<thead>
<tr>
<th>Type of Clothing</th>
<th>☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Chemotherapy-designated gown</td>
<td></td>
</tr>
<tr>
<td>Personal lab coat</td>
<td></td>
</tr>
<tr>
<td>Lab coat provided by office</td>
<td></td>
</tr>
<tr>
<td>Cloth gown</td>
<td></td>
</tr>
<tr>
<td>Isolation gown</td>
<td></td>
</tr>
<tr>
<td>Other (specify)</td>
<td></td>
</tr>
</tbody>
</table>
Please indicate how much of the time you use the following while administering chemotherapy

<table>
<thead>
<tr>
<th>Item</th>
<th>Always</th>
<th>76-99%</th>
<th>51-75%</th>
<th>26-50%</th>
<th>1-25%</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closed system transfer device</td>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>Gloves labeled for use with chemotherapy</td>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>Other gloves (e.g. vinyl)</td>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>Double gloves</td>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>Gowns labeled for use with chemotherapy</td>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>Other gowns (e.g. isolation)</td>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>Do you re-use disposable gowns?</td>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>Eye protection</td>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>Respirator/mask</td>
<td>(5)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
</tbody>
</table>
Section 4  Chemotherapy Disposal:

Are you responsible for handling chemotherapy disposal?

☐ Yes    ☐ No → If you answered “No” proceed to Section 5.

Complete section 4 ONLY if you dispose of chemotherapy.

Please indicate how much of the time you use the following when disposing of chemotherapy:

<table>
<thead>
<tr>
<th></th>
<th>Always</th>
<th>76-99%</th>
<th>51-75%</th>
<th>26-50%</th>
<th>1-25%</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gloves labeled for use with chemotherapy</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>Other gloves (e.g. vinyl)</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>Double gloves</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>Gowns labeled for use with chemotherapy</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>Other gowns (e.g. isolation)</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>Do you re-use disposable gowns?</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>Eye protection</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>Respirator/mask</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
</tr>
</tbody>
</table>
Section 5  Handing Contaminated Excreta:

Are you responsible for handling chemotherapy-contaminated excreta?

☐ Yes  ☐ No → If you answered “No” proceed to Section 6.

Complete section 5 ONLY if you handle chemotherapy-contaminated excreta.

Please indicate how much of the time you use the following when handling excreta:

<table>
<thead>
<tr>
<th></th>
<th>Always 76-99%</th>
<th>51-75%</th>
<th>26-50%</th>
<th>1-25%</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gloves labeled for use with chemotherapy</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
</tr>
<tr>
<td>Other gloves (e.g. vinyl)</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
</tr>
<tr>
<td>Double gloves</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
</tr>
<tr>
<td>Gowns labeled for use with chemotherapy</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
</tr>
<tr>
<td>Other gowns (e.g. isolation)</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
</tr>
<tr>
<td>Do you re-use disposable gowns?</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
</tr>
<tr>
<td>Eye protection</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
</tr>
<tr>
<td>Respirator/mask</td>
<td>☐ (5)</td>
<td>☐ (4)</td>
<td>☐ (3)</td>
<td>☐ (2)</td>
<td>☐ (1)</td>
</tr>
</tbody>
</table>

Section 6

Are chemotherapy spill kits available in your work area?  ☐ Yes (1)  ☐ No(0)

During the most recent chemotherapy spill in your workplace, did you use the materials in the spill kit?  ☐ Yes(1)  ☐ No(0)  ☐ N/A (mis)

Please write the name of three chemotherapy drugs that you handle most frequently:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
### Section 7

Select one answer to each of the following statements about chemotherapy **exposure**.

<table>
<thead>
<tr>
<th>Number</th>
<th>Statement</th>
<th>True</th>
<th>False</th>
<th>Don’t Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Chemotherapy can enter the body through breathing it in</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>2.</td>
<td>Chemotherapy can enter the body through ingesting it</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>3.</td>
<td>Chemotherapy cannot enter the body through contact with contaminated surfaces</td>
<td>☐ (0)</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>4.</td>
<td>Chemotherapy can enter the body through contact with spills and splashes</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>5.</td>
<td>Chemotherapy gas and vapor in air can enter the body through the skin</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>6.</td>
<td>Oral forms of chemotherapy do not have the potential to be absorbed</td>
<td>☐ (0)</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>7.</td>
<td>Chemotherapy in liquid form can be absorbed through the skin</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>8.</td>
<td>A surgical mask provides protection from chemotherapy aerosols</td>
<td>☐ (0)</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>9.</td>
<td>All types of gloves provide the same level of protection</td>
<td>☐ (0)</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>10.</td>
<td>Chemotherapy can more easily enter the body through damaged skin</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>11.</td>
<td>Alcohol hand sanitizer is as effective as soap and water in removing chemotherapy residue</td>
<td>☐ (0)</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>12.</td>
<td>Chemotherapy can enter the body through contaminated foods, beverages, or cosmetics</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>13.</td>
<td>Intact chemotherapy vials received from the manufacturer are not contaminated with drug on the outside surface</td>
<td>☐ (1)</td>
<td>☐ (0)</td>
<td>☐ (0)</td>
</tr>
</tbody>
</table>
Section 8

Indicate your level of agreement with each of these statements about using personal protective equipment (PPE) when handling chemotherapy.

SA = Strongly Agree; A = Agree; D = Disagree; SD = Strongly Disagree:

<table>
<thead>
<tr>
<th></th>
<th>SA</th>
<th>A</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I am confident that I can use PPE properly</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. I am confident that I can protect myself from chemotherapy exposure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. I am given enough information on how to protect myself from chemotherapy exposure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. My supervisor goes out of his/her way to make sure I am protected</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Reuse of disposable PPE makes me feel less protected</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. I am provided with the best available PPE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. My supervisor goes out of his/her way to make sure I am provided with proper fitting PPE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Section 9

Indicate your level of agreement with each of the following statements.

SA = Strongly Agree; A = Agree; D = Disagree; SD = Strongly Disagree:

Some reasons that I may not wear PPE regularly when handling chemotherapy are:

<table>
<thead>
<tr>
<th></th>
<th>SA</th>
<th>A</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I don’t think PPE is necessary</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. I don’t think PPE works</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. I don’t have the time to use PPE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. I was not trained to use PPE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. PPE is uncomfortable to wear</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Section 10

Indicate your level of agreement with each of the following statements about the risks of chemotherapy exposure.

SA = Strongly Agree; A = Agree; D = Disagree; SD = Strongly Disagree:

(Item #3, 5, 6, 7 are reverse coded)

<table>
<thead>
<tr>
<th>Statement</th>
<th>SA</th>
<th>A</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Exposure to chemotherapy is a serious problem at work</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. I am concerned about chemotherapy exposure at work and how it might affect my health</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Compared to co-workers, my chance of harm from chemotherapy exposure is lower</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. If exposed to chemotherapy, there is a real chance that I might experience bad effects</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Chemotherapy exposure is not as harmful as some people claim</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Compared to other work-related health risks, chemotherapy exposure is less serious</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. I am not worried about future negative health effects from chemotherapy exposure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Section 11

How often do the following people wear personal protective equipment when handling chemotherapy?

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Sometimes</th>
<th>About Half</th>
<th>Usually</th>
<th>Does not apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your co-workers</td>
<td>☐ (0)</td>
<td>☐ (1)</td>
<td>☐ (2)</td>
<td>☐ (3)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>Other nurses you know</td>
<td>☐ (0)</td>
<td>☐ (1)</td>
<td>☐ (2)</td>
<td>☐ (3)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>Oncology nurses in general</td>
<td>☐ (0)</td>
<td>☐ (1)</td>
<td>☐ (2)</td>
<td>☐ (3)</td>
<td>☐ (0)</td>
</tr>
</tbody>
</table>

According to the following people, how important is wearing PPE when handling chemotherapy?

<table>
<thead>
<tr>
<th></th>
<th>Not at all important</th>
<th>Sort Of important</th>
<th>Very important</th>
<th>Does not apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your co-workers</td>
<td>☐ (0)</td>
<td>☐ (1)</td>
<td>☐ (2)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>Other nurses you know</td>
<td>☐ (0)</td>
<td>☐ (1)</td>
<td>☐ (2)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>Your supervisor or manager</td>
<td>☐ (0)</td>
<td>☐ (1)</td>
<td>☐ (2)</td>
<td>☐ (0)</td>
</tr>
<tr>
<td>Your employer</td>
<td>☐ (0)</td>
<td>☐ (1)</td>
<td>☐ (2)</td>
<td>☐ (0)</td>
</tr>
</tbody>
</table>
## Section 12

Indicate your level of agreement with each of the following statements.

SA = Strongly Agree; A = Agree; D = Disagree; SD = Strongly Disagree:

<table>
<thead>
<tr>
<th></th>
<th>SA</th>
<th>A</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Personal protective equipment keeps me from doing my job to the best of my abilities.</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>2. Wearing personal protective equipment makes my patients worry.</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>3. Patient care often interferes with my being able to comply with using precautions.</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>4. I cannot always use safe handling precautions because patient’s needs come first.</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>5. Sometimes I have to choose between wearing PPE and caring for my patients</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>6. Wearing personal protective equipment makes my patients feel uncomfortable.</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>
Section 13

Indicate your level of agreement with these statements regarding safety in your work place:

SA = Strongly Agree; A = Agree; N = Neutral; D = Disagree; SD = Strongly Disagree:

<table>
<thead>
<tr>
<th></th>
<th>SA</th>
<th>A</th>
<th>N</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Chemotherapy gloves are readily accessible in my work area</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Chemotherapy gowns are readily available in my work area</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. The protection of workers from occupational exposure to chemotherapy is a high priority with management where I work</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. On my unit, all reasonable steps are taken to minimize hazardous job tasks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Employees are encouraged to become involved in safety and health matters</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Managers on my unit do their part to insure employees’ protection from occupational exposure to chemotherapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. My job duties do not often interfere with my being able to follow chemotherapy safe handling precautions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. I have enough time in my work to always follow chemotherapy safe handling precautions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. I usually do not have too much to do so that I can follow chemotherapy safe handling precautions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. On my unit, unsafe work practices are corrected by supervisors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. My supervisor talks to me about safe work practices</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. I have had the opportunity to be properly trained to use personal protective equipment so that I can protect myself from chemotherapy exposures</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Employees are taught to be aware of and to recognized potential health hazards at work</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. In my work area, I have access to policies and procedures regarding safety</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>A</td>
<td>N</td>
<td>D</td>
<td>SD</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>----</td>
<td></td>
</tr>
<tr>
<td>15. My work area is kept clean</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>16. My work area is not cluttered</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>17. My work area is not crowded</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>18. There is minimal conflict within my work area</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>19. The members of my work area support one another</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>20. In my work area, there is open communication between supervisors and staff</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>21. In my work area we are expected to comply with safe handling policies and procedures</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>
Section 14

In what type of setting do you handle chemotherapy?

- Inpatient
- Outpatient
- Both

Please indicate the type of facility you work in:

- Academic health center
- Private physician office
- Community non-teaching hospital
- Public/Government hospital
- Community teaching hospital
- Home care
- Health Maintenance organization
- Other _________________________

What is your highest level of NURSING education?

- Diploma
- Bachelor’s degree
- Doctoral Degree
- Associate degree
- Master’s degree

Are you a member of the Oncology Nursing Society?

- Yes
- No

Are you an ONS Chemotherapy/Biotherapy Provider Card?

- Yes and it is current
- Yes but it has expired
- No
- Unknown

Are you certified in nursing?

- Not certified
- AOCN®
- NP
- Other _________________
- OCN®
- AOCNS®
- AOCNP®
Please enter the number requested:

Your age in years: 

Years of nursing experience:

Years of oncology nursing experience:

Years of chemotherapy handling experience:

Number of patients for whom you personally prepare and/or administer chemotherapy per day

Number of patients receiving chemotherapy per day at your work place:

Is there anything else you would like to tell us about safe handling in your work place?

Thank you for participating in this study!
Appendix F:

Operational Definitions
Operational Definitions

- **Adherence**: The degree or extent of conformity to the provider’s recommendations about day-to-day treatment with respect to timing, dosing, and frequency.

- **ANSI**: American National Standards Institute

- **Antineoplastic**: an agent that prevents the development, growth, or proliferation of malignant cells.

- **Aseptic containment isolator**: A ventilated isolator designed to meet the requirements of both an aseptic isolator and a containment isolator.

- **Aseptic isolator**: A ventilated isolator designed to exclude external contamination from entering the critical zone inside the isolator.

- **Aseptic**: Free of living pathogenic organisms or infected materials.

- **ASHP**: American Society of Hospital Pharmacists

- **Barrier isolator**: This term has various interpretations, especially as they pertain to hazard containment and aseptic processing.

- **Barrier system**: An open system that can exchange unfiltered air and contaminants with the surrounding environment.

- **Biohazard**: An infectious agent or hazardous biological material that presents a risk to the health of humans or the environment. Biohazards include tissue, blood or body fluids, and materials such as needles or other equipment contaminated with these infectious agents or hazardous biological materials.

- **Biological Response Modifier**: cancer treatment using substances involved in the body’s biological response to the development of cancer
- **Biomarker**: A biological, biochemical or structural change that serves as an indicator of potential damage to cellular components, whole cells, tissues, or organs.

- **BSC**: Biological Safety Cabinet

- **CD**: Cytotoxic Drug

- **Chemotherapy Certified Nurse**: A registered nurse who has successfully completed the ONS or APHON chemotherapy / biotherapy course, followed by a supervised clinical practicum; certification is renewed every two years through national standards.

- **Chemotherapy glove**: A nitrate, medical glove that has been approved by the FDA for use when handling antineoplastic drugs.

- **Chemotherapy waste**: Discarded items such as gowns, gloves, masks, IV tubing, empty bags, empty drug vials, needles and syringes, and other items generated while preparing and administering antineoplastic agents.

- **Chemotherapy**: All antineoplastic agents used to treat cancer, given through oral and parenteral routes or other routes as specified. Types included targeted agents, alkylating agents, antimetabolites, plant alkaloids and terpenoids, topoisomerase inhibitors, antitumor antibiotics, monoclonal antibodies, and biologics and related agents.

- **Chemotherapy Regimen**: One or more chemotherapeutic agents used alone or in combination on a well-defined protocol, generally administered in a cyclical schedule.

- **Chemotherapy Setting**: All chemotherapy treatment sites, including inpatient and outpatient.

- **Clinical Encounter**: includes each inpatient day, practitioner visit and chemotherapy treatment visit.
- **Closed system drug-transfer device:** A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system.

- **Closed system:** A device that does not exchange unfiltered air or contaminants with the adjacent environment.

- **Containment isolator:** A ventilated isolator designed to prevent the toxic materials processed inside it from escaping to the surrounding environment.

- **Cytotoxic:** A pharmacologic compound that is detrimental or destructive to cells within the body.

- **Deactivation:** Treating a chemical agent (such as a hazardous drug) with another chemical, heat, ultraviolet light, or other agent to create a less hazardous agent.

- **Decontamination:** Inactivation, neutralization, or removal of toxic agents, usually by chemical means.

- **Engineering controls:** Devices designed to eliminate or reduce worker exposures to chemical, biological, radiological, ergonomic, or physical hazards. Examples include laboratory fume hoods, glove bags, retracting syringe needles, sound-dampening materials to reduce noise levels, safety interlocks, and radiation shielding.

- **EPA:** Environmental Protection Agency

- **Extravasation:** The inadvertent administration of a vesicant solution or medication into surrounding tissues as a result of catheter dislodgement. This can lead to blistering, or sloughing or tissues as a result of necrosis.

- **Genotoxic:** Capable of damaging the DNA and leading to mutations.
- **Glove bag**: A glove box made from a flexible plastic film. Operations are performed through sealed gloved openings to protect the worker, the work environment, and/or the product.

- **Glove box**: A controlled environment work enclosure providing a primary barrier from the work area. Operations are performed through sealed gloved openings to protect the worker, the ambient environment, and/or the product.

- **HCS**: Hazard Communication Standard

- **Hazardous drug (HD)**: Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, or new drugs that mimic existing hazardous drugs in structure or toxicity.

- **Hazardous waste**: Waste that may cause or significantly contribute to an increase in mortality or an increase in serious irreversible or incapacitating reversible illness or pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed or otherwise managed. Any waste that is a RCRA-listed hazardous waste (or that meets a RCRA characteristic of ignitability, corrosivity, reactivity, or toxicity).

- **Health care settings**: All hospitals, medical clinics, outpatient facilities, physicians’ offices, retail pharmacies, and similar facilities dedicated to the care of patients.

- **Health care worker**: All workers who are involved in the care of patients. These include pharmacists, pharmacy technicians, nurses (registered nurses, licensed practical nurses, nurses aids, etc.), physicians, home health care workers and environmental services workers (housekeeping, laundry, and waste disposal).
- **HEPA filter**: High-efficiency particulate air filter rated 99.97% efficient in capturing 0.3-micron-diameter particles.

- **Horizontal laminar flow hood (horizontal laminar flow clean bench)**: A device that protects the work product and the work area by supplying HEPA-filtered air to the rear of the cabinet, producing a horizontal flow across the work area and out toward the worker.

- **Hormonal Therapy**: cancer treatment that removes, blocks or adds hormones

- **IARC**: International Agency for Research on Cancer

- **Isolator**: A device that is sealed or is supplied with air through a microbiologically retentive filtration system (HEPA minimum) and may be reproducibly decontaminated. When closed, an isolator uses only decontaminated interfaces (when necessary) or rapid transfer ports (RTPs) for materials transfer. When open, it allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contaminants or unfiltered air to adjacent environments. An isolator can be used for aseptic processing, for containment of potent compounds, or for simultaneous asepsis and containment. Some isolator designs allow operations within the isolator to be conducted through attached rubber gloves without compromising asepsis and/or containment.

- **MSDS**: Material safety data sheet. These sheets contain summaries provided by the manufacturer to describe the chemical properties and hazards of specific chemicals and ways in which workers can protect themselves from exposure to these chemicals.

- **Mutagenic**: Capable of increasing the spontaneous mutation rate by causing DNA changes.

- **NIOSH**: National Institute for Occupational Safety and Health
- **NTP**: National Toxicology Program
- **OEL**: Occupational exposure limit. An industry or other nongovernment exposure limit usually based on scientific calculations of airborne concentrations of a substance that are considered to be acceptable for healthy workers.
- **OSHA**: Occupational Safety and Health Administration
- **PDA**: An international trade association serving pharmaceutical science and technology. Formerly known as the Parenteral Drug Association.
- **PEL**: OSHA permissible exposure limit: The time-weighted average concentration of a substance to which nearly all workers may be exposed for up to 8 hours per day, 40 hours per week for 30 years without adverse effects. A PEL may also include a skin designation.
- **PPE**: Personal protective equipment. Items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures.
- **REL**: NIOSH recommended exposure limit: An occupational exposure limit recommended by NIOSH as being protective of worker health and safety over a working lifetime. The REL is frequently expressed as a time-weighted average exposure to a substance for up to a 10-hour workday during a 40-hour work week.
- **Respirator**: A type of PPE that prevents harmful materials from entering the respiratory system, usually by filtering hazardous agents from workplace air. A surgical mask does not offer respiratory protection.
- **Risk assessment**: Characterization of potentially adverse health effects from human exposure to environmental or occupational hazards. Risk assessment can be divided into
five major steps: hazard identification, dose-response assessment, exposure assessment, risk characterization, and risk communication.

- **Sister chromatid exchange**: The exchange of segments of DNA between sister chromatids.

- **Spills**:
  - Small Spills (less than or equal to 100cc): A small spill is defined as any incident resulting in a chemotherapy spill of quantities less than or equaling 100ml or 100cc. Proper clean up procedures shall be followed as outlined in this document.
  - Large Spills (> 100cc): A large spill is defined as any incident resulting in a chemotherapy spill of quantities more than 100ml or 100cc. Management of large spills will be coordinated through Environmental Health & Safety (EH&S).

- **Standard precautions** (formerly universal precautions): The practice in health care of treating all patients as if they were infected with HIV or other similar diseases by using barriers to avoid known means of transmitting infectious agents [CDC 1987, 1988]. These barriers can include nonporous gloves, goggles, and face shields. Careful handling and disposal of sharps or the use of needleless systems are also important.

- **Targeted Therapy**: cancer treatment that blocks the growth of cancer cells by interfering with specific targeted molecules needed for tumor growth; small molecules, monoclonal antibodies

- **TLV**: Threshold limit values. These values are exposure limits established by the ACGIH. They refer to airborne concentrations of chemical substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed, day after day, over a working lifetime, without adverse health effects.
- **Ventilated cabinet**: A type of engineering control designed for purposes of worker protection (as used in this document). These devices are designed to minimize worker exposures by controlling emissions of airborne contaminants through the following:

- **Vesicant**: Drug that has the potential for causing soft tissue damage if administered outside the vascular system.

- **WEEL (workplace environmental exposure level)**: Occupational exposure limits developed by the American Industrial Hygiene Association as a chemical concentration to which nearly all workers may be repeatedly exposed for a working lifetime without adverse health effects.
Appendix G:

ONS Congress Abstract Submission