NECESSARY DRUGS, UNNECESSARY CONSEQUENCES: AN INTERVENTION TO PROTECT HEALTHCARE WORKERS FROM EXPOSURE TO CHEMOTHERAPY

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ABSTRACT

According to the American Cancer Society, nearly 1 in 2 people in the United States will develop cancer in their lifetime. Chemotherapy, prepared by pharmacists and given by nurses, is often part of their treatment. While necessary for patients with cancer, chemotherapy poses an unnecessary risk of serious, negative health effects to workers. Eight million health care workers per year are potentially exposed to chemotherapy, putting them at risk of exposure to agents that are known to be reproductive toxicants and probable carcinogens. Safety precautions that could reduce their exposure are neither required nor universal and barriers to their use have been identified.

The purpose of this study was to develop and test a worksite intervention to protect healthcare workers who handle chemotherapy from work-related exposures to them. All nurses and pharmacy staff from a university hospital and outpatient clinic (N=163) were invited to participate. A self-report survey measured workplace and individual factors, such as perceived risk and workplace safety climate. The associations between these factors and Personal Protective Equipment (PPE) use were measured. Wipe samples tested for surface contamination with chemotherapy. An intervention was developed with worker input. PPE use was lower than recommended and improved slightly post-intervention. Self-efficacy and perceived risk increased on the posttest. Chemotherapeutic residue was found in several areas, including places in which PPE was not required. Awareness of safe handling precautions improved post intervention. The unit worked was an important predictor of safety climate and PPE use on the pretest but less so following the intervention. Involving staff in developing an intervention for

safety ensures that changes made will be efficient. Units that implemented workflow changes had decreased contamination. Work-site analysis is important to identify specific, tailored interventions that will improve chemotherapy safety.

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ORGANIZATION

This thesis is organized beginning with an introduction chapter, followed by background information and descriptions of previous research done on chemotherapy safe handling. The following two chapters describe the methods and results of the dissertation project in detail. The next two chapters are two papers based on the research that were submitted for publication in peer-reviewed journals. Because of this, there is some redundancy in regards to the background literature and the methods of the main study. Following these papers, the dissertation concludes with a discussion section.

CHAPTER 1: INTRODUCTION

Statement of Purpose

The research objective for this dissertation was to develop and test worksite interventions that protect against actual and potential worksite exposures to nurses and pharmacists handling chemotherapy or antineoplastic drugs for cancer patients. Our central hypothesis was that health care workers' and institutions' compliance with published guidelines, the National Institute of Occupational Safety and Health (NIOSH) 2004 Alert for Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings (National Institute for Occupational Safety and Health, 2004), would be increased by maximizing involvement of workers and managers in an intervention designed using quality improvement methodology. Through the research process we identified the barriers and facilitators to compliance, created and tested innovative solutions, and measured the impact on workers' knowledge, attitude, behaviors and exposures. Our long term goal was to identify key factors that reduce health care workers' exposures to antineoplastic drugs and protect their health and to translate those findings into sustainable work change.

Specific Aims

1. Assess current self-reported workplace handling practices using an online self-report survey of personal protective equipment (PPE) use and measure surface contamination using a ChemoAlert™ test kit(Bureau Veritas Laboratories, 2013).
2. Assess association of individual, interpersonal, and organizational factors with levels of workplace surface contamination.

3. Develop and test a worksite quality improvement intervention to increase health care workers' use of safe handling techniques and thereby decrease their risk of exposure to antineoplastic agents.

Significance

Antineoplastic drugs are very important to the more than 11 million people diagnosed with cancer worldwide each year (Connor, 2006). These drugs can improve quality of life, decrease length of illness, and even cure cancer. Increasingly, the drugs are also being used for other diseases such as Rheumatoid Arthritis, Nephritis, Multiple Sclerosis and Lupus (Vioral & Kennihan, 2012). Use of the drugs has also expanded to more frequent administration in outpatient settings, homes and in veterinary medicine (Hall, Davies, Demers, Nicol, & Peters, 2013). A new forecast has predicted that as a result of the aging US population, the number of cancer cases may double by 2050 (Edwards et al., 2002). This will result in an increase in the use of antineoplastic drugs. As many as 8 million health care workers have the potential for exposure to antineoplastic drugs (National Institute for Occupational Safety and Health, 2004). Workers are incurring the exposures on a repeated basis and often for many years. Even a small exposure of such concentrated drugs can cause harmful effects (Vioral & Kennihan, 2012). While nurses and pharmacists have the highest incidence of exposure, many healthcare staff have the potential for exposure including drug manufacturers, delivery personnel, cleaning staff, patient care assistants, volunteers, and waste disposal personnel (National Institute for Occupational Safety and Health, 2004). These workers may also put their families and friends at risk of exposure if they are bringing traces of chemotherapy home on their clothing or shoes. Research designed to improve safe handling of antineoplastic agents is important and study findings will benefit a significant population of workers.

CHAPTER 2: BACKGROUND INFORMATION

History of Chemotherapy Development and its Use in Humans

Paul Ehrlich, a pioneering German chemist active in the early 20th century, is largely responsible for providing the model for modern-day chemotherapy (DeVita & Chu, 2008). According to DeVita and Chu (2008), his treatment method, which he coined "chemotherapy," is defined as the use of chemicals on patients to treat disease. Using an animal model, he was initially successful in treating syphilis, a common and deadly disease at the time, with arsenic. He paved the way for the development of drugs commonly used in the treatment of cancer patients during the early to mid-20th century (DeVita & Chu, 2008).

The next major phase in the development of modern-day chemotherapy occurred quite by accident during World War II, when it was discovered that naval personnel who were exposed to mustard gas experienced toxic depletion in their bone marrow cells (American Cancer Society, 2014; DeVita & Chu, 2008). It was at this time that the U.S. Army was researching chemicals similar to mustard gas for use in war. The discovery of the depletion in bone marrow of those exposed led to a contract between the U.S. Office of Scientific Research and Development and two Yale pharmacologists to study the use of the agents for treatment of Lymphoma (cancer in the lymph nodes) in 1943 (American Cancer Society, 2014; DeVita & Chu, 2008). The treatments led to remission in many cases; however it was brief and incomplete. The results of this work were not published until the end of the war in 1946 due to war gas program secrecy (DeVita & Chu, 2008). Shortly thereafter, Sidney Farber provided conclusive evidence that a compound related to the folic acid, aminopterin, works to block a chemical reaction needed for DNA to replicate, thus producing remission in children with acute leukemia (American Cancer Society, 2014). This drug led to the development of Methotrexate, a drug commonly used today in the treatment of cancer (American Cancer Society, 2014).

According to the American Cancer Society (2012), the first documented treatment for metastatic cancer was in 1956 with Methotrexate. In spite of this successful treatment, the medical community as a whole remained skeptical of the use of chemotherapy in the treatment of cancer patients (American Cancer Society, 2014). Vincent T. Devita Jr. and Edward Chu, two prominent oncologists in the 1960's, provide a telling example of the predominant attitude of the medical community towards chemotherapy at the time, concluding that: "the main issue of the day was whether cancer drugs caused more harm than good, and talk of curing cancer with drugs was not considered compatible with sanity" (2008, p. 8647). According to them, the drugs were also referred to with hostility by the public and medical community as "poison". In addition, Yale University was the first institution to test chemotherapy drugs such as Methotrexate in the course of treating human cancer patients, a decision which then met great controversy in the medical community (DeVita & Chu, 2008). As a result, the founding father and distinguished professor, Paul Calabresi was forced to leave the institution due to his involvement in testing early anticancer drugs. In the years that followed, chemotherapy drugs successfully resulted in many instances of long-term remission and the curing of patients with Hodgkin disease and childhood Acute Lymphoblastic Lymphoma (DeVita & Chu, 2008). Testicular cancer cures were documented in the next decade and other cancers were controlled for long periods of time (American Cancer Society, 2014). The consistent pattern of successful treatment of cancer patients through the use of chemotherapy challenged the prevailing attitude of critics, resulting in the gradual acceptance of its use within the medical community. These successes spurred the passage of the Cancer Act of 1971 and the nation's controversial "war on cancer" (DeVita, 2002; DeVita & Chu, 2008).

The 1970s provided many milestones that were instrumental in the modern practice of chemotherapy. It was at this time that practitioners began to use multiple chemotherapy drugs (combination chemotherapy) over single agents (DeVita & Chu, 2008) . The multiple-drug approach is especially useful in patients with leukemia and lymphoma cancers, due to their fast growing tumors (American Cancer Society, 2014). Using chemotherapy after surgery (called adjuvant therapy) was first tested and found to be effective in breast cancer (American Cancer Society, 2014).

Today, the use of clinical trials, which compare new treatments to standard care continue to contribute to the understanding of cancer care (American Cancer Society, 2014). According to DeVita and Chu (2008), the incidence and mortality rates of cancer started to decline and mortality in 1990 and has continued to decline yearly since then (DeVita & Chu, 2008). They also found that in 2007, the rate of mortality decline doubled (half attributed to prevention and early diagnosis; the other to inclusion of chemotherapy in treatment programs). According to 2014 reports on cancer survivorship, there are nearly 14.5 million cancer survivors (over 4% of the population) living in the

United States, with the number projected to grow to almost 19 million by 2024 (National Cancer Institute, May 30, 2014).

Known Health Effects of Chemotherapy

The toxicity and health risks associated with antineoplastic drugs are well understood (Boiano, Steege, & Sweeney, 2014; Odraska et al., 2014). Most antineoplastic drugs are nonspecific in their action and can kill healthy cells, making them carcinogenic, mutagenic, and harmful to reproductive health (Connor et al., 2010; National Institute for Occupational Safety and Health, 2004).

Beginning in the 1970’s, evidence has indicated that health care workers were at risk of harmful effects from their occupational exposure, including serious health problems (Polovich & Clark, 2012a). These include acute effects such as skin rashes, nausea, hair loss, abdominal pain, nasal sores, allergic reactions, skin or eye injury and dizziness (Polovich & Clark, 2012a). Chronic effects linked with exposure have included reproductive harms such as infertility and birth defects, genotoxic changes, and cancers (National Institute for Occupational Safety and Health, 2004).

Reproductive Effects

Patients receiving chemotherapy are advised to take precautions so as not to become pregnant for fear of harming their child (Azim, Pavlidis, & Peccatori, 2010). Antineoplastic drugs work on rapidly proliferating cells, which is why they are of particular concern for the developing fetus (Azim et al., 2010). The research on reproductive outcomes for healthcare workers exposed to chemotherapy has shown inconclusive results (Fransman et al., 2007). Two early studies (1985 and 1990) done by researchers in France and Finland found positive associations between exposure to antineoplastic drugs and increased risk of spontaneous abortion and have been frequently referenced since their publication (Fransman et al., 2007; Lawson et al., 2012). The 1985 study, published in the New England Journal of Medicine, was a case-control study of nurses in 17 Finnish hospitals (87% response rate) and found a significant association between fetal loss and exposure during the first trimester (OR 2.30; 95% CI:1.20-4.39) (Selevan, Lindbohm, Hornung, & Hemminki, 1985). The 1990 study, published in the Scandinavian Journal of Workplace and Environmental Health, also a case control study of nurses, this time in French hospitals (87% participation rate) found that there was a significant increase in frequency of spontaneous abortion between those exposed and unexposed (OR 1.7; 95% CI: 1.2-2.5) (Stucker et al., 1990). Subsequently, a systematic review and meta-analysis conducted by Dranitsaris G, Johnston M, Poirier (2005) identified 14 studies from 1966-2004 that evaluated whether or not oncology workers were at a higher risk of cancer, reproductive complications and acute toxic events. The authors identified an association between chemotherapy exposure and spontaneous abortion (OR: 1.46, 95% CI:1.11, 1.92) although estimation of pooled odds ratios were not possible for the risk of cancer and acute toxic events. However, the authors also concluded that the literature did not show a significant association between exposure and congenital malformations or stillbirths (Dranitsaris et al., 2005).

Evidence of an increased risk of spontaneous abortion (OR = 1.5; 95% CI: 1.2-1.8) and combined risk of spontaneous abortion and still birth (OR = 1.4; 95% CI: 1.2-1.7), but not stillbirth alone in association with exposure to antineoplastic agents during pregnancy was reported by Valanis B, Vollmer WM, Steele P (1999). This US study was particularly strong with a large sample size (2976 nurses and pharmacy staff) and statistical control for potential confounders (e.g., age during pregnancy, prior gravidity, maternal smoking during pregnancy, and occurrence of spontaneous abortion or a stillbirth during a previous pregnancy) (B. Valanis, Vollmer, & Steele, 1999).

The most recent evidence for reproductive outcomes and antineoplastic exposure comes from 6707 participants in the Nurses' Health Study II (Lawson et al., 2012). Exposed nurses had a 2-fold increased risk of spontaneous abortion, particularly with early spontaneous abortion before the 12th week, and a 3.5-fold increased risk in nulliparous women (Lawson et al., 2012).

All of these studies were reviewed in the most recent analytic review of the data on reproductive health in 2014 published by Connor et al. Their conclusion was that despite the variability in the size of the adverse outcomes, results point to an increased risk of adverse reproductive outcomes with occupational exposure which was especially evident during the first trimester (Connor, Lawson, Polovich, & McDiarmid, 2014).

Genotoxic Effects

Because antineoplastic agents are mutagenic, endpoints that measure genetic damage are often used to assess healthcare worker exposure (Connor et al., 2010). Evidence of induced chromosomal damage in patients undergoing chemotherapy suggests this is a feasible way to detect possible long-term effects of chemotherapy exposure in workers (Sorsa, Hameila, & Jarviluoma, 2006). Many studies done prior to 2000 found a significant increase in genotoxic effects to workers exposed to antineoplastic agents and the 2004 NIOSH Alert concludes that the weight of the evidence supports this association. Most recently, three case control studies have found evidence of genetic damage among exposed (not unexposed) health care workers. McDiarmid and colleagues reported finding abnormalities in Chromosome 5 and 7 in oncology personnel handling antineoplastic drugs despite workers' use of safe practices (McDiarmid, Oliver, Roth, Rogers, & Escalante, 2010). In this study, an excess of structural (0.18 vs 0.02, p=0.040 and total abnormalities (0.29 vs 0.04, p= 0.01) of chromosome 5 were seen in an identified high-exposure group when compared to unexposed individuals. Primary DNA damage significantly increased in leukocytes of exposed Italian nurses compared to controls (2.73 vs 1.67, $p < 0.0001$) reported by Villarini and colleagues (2011). DNA damage was observed in the lymphocytes and buccal cells in exposed nurses compared to controls ($p<0.05$) (Rekhadevi et al., 2007). These recent studies and historical evidence all lead readers to conclude there is a risk of genotoxic damage to workers exposed to chemotherapy.

Cancer Risk

The International Agency for Research on Cancer (IARC) has identified many antineoplastic drugs as either suspected or known human carcinogens (World Health Organization, International Agency for Research on Cancer, 2009). Secondary tumor risks for patients receiving these drugs have been confirmed by several studies and patients are warned of these risks (Deniz, O'Mahony, Ross, & Purushotham, 2003; Josting et al., 2003; Sherins & DeVita, 1973; Spiers, Chikkappa, & Wilbur, 1983). Chemotherapy is individualized to patients as part of their treatment regime. For patients with cancer, the benefit of treatment improving their current disease outweighs the risk of a secondary malignancy in the future. No safe limit of exposure for healthcare workers, who will not benefit from exposure, exists (Merger, Tanguay, Langlois, Lefebvre, & Bussieres, 2013). Antineoplastic agents known as alkylating agents are known to carry a risk of carcinogenesis, as evidenced by experimental carcinogenicity bioassays and genotoxicity tests (Sorsa et al., 2006). They have also been found to produce secondary cancers in patients (Sorsa et al., 2006). Because workers are exposed to these drugs at low levels for long periods of time and cancer has multiple risk factors, the link between exposure at work and cancer risk is difficult to address. However, a significantly increased risk of leukemia was found among oncology nurses identified in the Danish cancer registry (National Institute for Occupational Safety and Health, 2004).

Safe Handling Guidelines and Policy

There is currently no federal policy regarding safe handling of antineoplastic agents in the workplace. National Institute for Occupational Safety and Health (NIOSH) recommended exposure limits (RELs), Occupational Safety and Health Administration (OSHA) permissible exposure limits (PELs), or American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLVs) for hazardous drugs in general do not exist (National Institute for Occupational Safety and Health, 2004). OSHA published guidelines related to antineoplastic use in 1986 and current guidelines include a hazard communication standard, occupational exposure to hazardous chemicals in laboratories standard, and a related chapter in the OSHA Technical Manual (National Institute for Occupational Safety and Health, 2004).

Based on current scientific knowledge, it is impossible to set a level of exposure to antineoplastic drugs that is safe (Polovich, 2005). Federal guidelines for hazardous drug safe handling were updated in 2004 by NIOSH. These are recommendations only and there are no federal policies that healthcare facilities must follow detailing recommendations for safe handling (Smith, 2011). There have been recent state based attempts to standardize hazardous drug safety in Washington, California, North Carolina and Maryland (Kohl-Welles, 2011). Washington became the first state in the nation to require standardized protection for these health-care workers in April of 2011 when Senate Bill 5594, a bill that directs the Department of Labor & Industries to adopt requirements for the handling of chemotherapy and other hazardous drugs, was signed into law (Kohl-Welles, 2011). The rule will be implemented in Washington in three stages (develop and implement written hazardous drugs control plan, provide employee training and install appropriate ventilated cabinets) beginning in January of 2015 and will be enforced by the Washington State Department of Labor and Industries (Kohl-Welles, 2011). Other states lack a regulatory body to enforce hazardous drug handling. This lack of consistency in policy may lead to differences in health care workers' knowledge and use of safe handling throughout sites of administration (Environmental Working Group, 2007).

There is currently no policy restricting nurses from giving chemotherapy while pregnant, although there are recommendations from NIOSH that workplaces provide alternative duties to nurses if they request them (Connor et al., 2014). The NIOSH Alert published in 2004 did not outline specific recommendations for pregnant workers;

however an updated alert with guidelines for pregnant healthcare workers was published in 2014 (Connor et al., 2014). Alternative duties for nurses could prove to be difficult because of demographics---there are over 3 million women employed as nurses and women less than 50 comprise about 2/3 of the practicing nursing workforce (U.S. Department of Health and Human Services, 2010).

CHAPTER 3: REVIEW OF PREVIOUS LITERATURE ON SAFE HANDLING

Use of Personal Protective Equipment

The National Institute of Occupational Safety and Health (NIOSH) published recommendations for personal protective equipment (PPE) use during handling of antineoplastic agents in a published alert in 2004. This alert recommends the use of double gloves, goggles and protective gowns during administration of hazardous drugs (National Institute for Occupational Safety and Health, 2004).

There have been a number of recent US studies asking workers about their reported use of personal protective equipment (PPE) during various chemotherapy related activities. The largest study with a national sample to date was done in 2014 by Boiano et al. The survey had 2069 respondents to their web based survey. Eighty six percent of respondents reported to always wearing chemotherapy gloves during administration, 60% to always wearing gowns, and only 20% to always wearing double gloves (Boiano et al., 2014). Two other studies of smaller sample sizes were published in the US. Polovich and Martin (2011) surveyed 330 nurses at the Oncology Nursing Society Congress in 2006 and found that glove use was high (95-100% report usually wearing gloves), gown use was lower (23-65% of respondents reported usual use) and double-gloving was rare (11-18% reported usual use). The differences in use was based on the activity of handling- with highest use reported during preparation, with administration, disposal, and handling patient excreta lower still, respectively (Polovich & Martin, 2011a). Martin and Larson (2003) surveyed 263 randomly selected Oncology Nursing Society members who worked in outpatient and office based settings and found similar results. Ninety four percent of these respondents reported to glove use and 55% to gown use during handling of antineoplastic agents (Martin & Larson, 2003).

Attitudes and Barriers to Safe Handling

The reasons for healthcare workers not adopting the recommended precautions while handling antineoplastic agents have more recently begun to be investigated in studies. A 2011 survey of 1069 hospital workers who handling antineoplastic drugs (AD) investigated predictors of safe handling (Silver, Steege, & Boiano, 2015). They found that reported PPE use was associated with training and familiarity of safe handling. They also found that nurses who reported higher availability of PPE also reported a higher use of PPE. The adoption of safe handling practices was associated with the organizational structure of the facility in which a nurse works in two US studies. Organization structure included factors such as staffing, workplace context, and leadership. One study published in 2011 by Friese et. al sampled 1330 nurses who worked in outpatient facilities in one state. This study found that safety behavior in other areas of the organization was strongly associated with an increase in outpatient chemotherapy safety (Friese, Himes-Ferris, Frasier, McCullagh, & Griggs, 2012). A study by Polovich and Clark (2012) examined 165 nurses in both inpatient and outpatient settings across the US for factors that affect use of PPE. This study found that higher use of safety precautions was associated with few barriers, better workplace safety climate, and fewer patients per nurse per day (Polovich & Clark, 2012a). From these studies, it could be concluded both that familiarity with guidelines, having enough time to adhere to them, and making improvements that are specific to a given organizational unit are all important in changing safety.

Exposure Potential and Surface Contamination

According to the National Institute of Occupational Safety and Health (2004), occupational exposure to antineoplastic drugs may occur at any stage in the drugs' life cycle, including less apparent times such as transport to and distribution around a health care setting and waste disposal. They report more obvious times for potential exposures for health care workers include drug preparation, administration, and handling of patient body fluids. Routes of exposure that are most likely for health care workers are inhalation, skin contact or absorption. Unintentional ingestion (hand to mouth contact) or injection (needle stick or sharps injury) are also possible (National Institute for Occupational Safety and Health, 2004). A recent study which sampled the hands of hospital workers for chemotherapy residue found that the job category with the highest proportion of samples greater than the level of detection were workers not responsible for drug administration (volunteer, oncologist, ward aide and dietician) (Hon, Teschke, Demers, & Venners, 2014).

The NIOSH guidelines published in 2004 recommend surface sampling for contamination should occur every six months to a year, or following concerns about worker health. This is important because there is not an accepted safe level of exposure to antineoplastic drugs (National Institute for Occupational Safety and Health, 2004). There have been a number of studies done throughout the world examining whether surface contamination exists in worksites and they overwhelmingly report levels of chemotherapy that are detectable throughout patient care and work areas. Connor et al published a study in 2010 that tested 143 areas in three university based US hospitals. They found at least one of the five drugs they were checking for were present above the level of detection in 60% of their samples, and 32% had more than one drug present (Connor et al., 2010). Another study by Sessink et al. (2011) took 114 wipe samples across 22 US hospital pharmacies. This study considered whether or not a closed-system drug transfer device would reduce surface contamination. Prior to the implementation of the new device between 33% and 78% of samples were positive for chemotherapy (results varied by drug). While a significant decrease in positive samples occurred following the introduction of the device, it remained that between 20% and 68% of samples had significant contamination (Sessink, Connor, Jorgenson, & Tyler, 2011). While the authors of this study concluded that closed system drug transfer devices were effective because of the decrease in contamination, it is clear that there are a number of changes to work practices that also need to occur to improve safety. A large Canadian multisite study which tested 25 locations using 269 samples found that all of the locations tested had at least one positive sample for at least one of drugs tested (Bussieres, Tanguay, Touzin, Langlois, & Lefebvre, 2012). These authors also reviewed related literature and found 14 studies between January 1, 2010, and April 1, 2012 which published quantitative measures of surface contamination with cyclophosphamide in pharmacy and patient care areas. The studies represented a total of 1958 samples in 92 hospitals in 7 different countries including Germany, Italy, Australia, and the Czech Republic. These studies showed a range of positive samples from 14-94% in places without a closed-system transfer device and 45-82% in places with them (Bussieres et al., 2012). These results show that surface contamination is a persistent problem in hospitals and clinics.

CHAPTER 4: METHODS

Conceptual Model

This study adapted a theoretical model by Polovich entitled "Factors Predicting Use of Hazardous Drugs Safe Handling Precautions (PHDP)" (Polovich & Clark, 2012). This model was based on the Heath Promotion Model and originally used to predict hearing protection use in loud work environments (Lusk, Ronis, & Hogan, 1997; Pender, Murdaugh, & Parsons, 2010). This model shows that knowledge of the hazards around chemotherapy handling are hypothesized to be associated with perceived risk and perceived barriers; years of experience is considered to be associated with perceived risk and also perceived conflict of interest. The other predictor variables are all thought to affect the use of safe handling techniques, which in turn affects the level of surface contamination. The theoretical model is displayed in Figure 1 at the end of this chapter.

Study Design

This study used a pre-post design to test an intervention to improve antineoplastic drug safe handling in nurses and pharmacy staff potentially exposed to chemotherapy. Nurses, pharmacists and pharmacy technicians (N=163) from four units (inpatient oncology, inpatient bone marrow transplant, outpatient chemotherapy infusion center, and pharmacy) of a university hospital participated. The survey combined questions on personal protective equipment use with questions based on the model described above to test predictor variables. Exposure assessment was tested using area surface sampling to measure contamination before, during and following the intervention. The survey was offered online for three weeks in October of 2014 (pretest) and three weeks in August of

2015 (posttest). Reminder emails were sent weekly and two days prior to the end of the survey close date. Surveys were administered on-line and data stored securely using the Research Electronic Data Capture (REDCap) Data System which is hosted by The University of Minnesota (Harris, P.A., Thielke, R., Payne, Gonzalez, & Conde, 2009). Survey respondents were entered into a drawing for a $50 Visa Gift Card (one winner for each unit). Surface samples were collected a day prior to the survey release. The University of Minnesota's Institutional Review Board (IRB) approved this study with an exempt status and the University of Minnesota Medical Center's Nursing Research Council also approved it.

Directed Acyclic Graph

The regression model for multivariable estimation was based on the use of Directed Acyclic Graphs (DAGs). According to Greenland et al. (1999), the purpose of using DAGs in observational studies is to ensure the regression models address the aims of the study by understanding the causal assumptions and avoiding confounded models. DAGs visually display the underlying assumptions of the causal relationships between the exposure of interest, covariates, and the outcome of interest (Greenland, Robins, & Pearl, 1999). Use of DAGs facilitated the selection of potential confounders for testing the causal association between specific exposures and the outcome, use of safe handling techniques. Three DAGs are included and they are displayed in Figures 2-4 following this chapter. The first DAG shows the association of workplace safety climate with the use of PPE adjusting for unit, perceived barriers, interpersonal influence, gender and age. The second DAG illustrates the association of self-efficacy with PPE use, controlling for perceived barriers, age and gender. The third DAG displays the relation of unit of employment with PPE use, controlling for gender and age.

Survey Measures

Self-reported Survey Measures: Survey items were taken from instruments with established reliability and validity used in a study by Polovich (2012). The survey investigated personal factors such as age, race and years of experience.

Dependent or Outcome Variable: Use of Safe Handling Techniques were measured on a five-point scale with questions adapted from the Revised Hazardous Drug Handling Questionnaire 1, which was based on the current federal guidelines for safe handling (National Institute for Occupational Safety and Health, 2004; Polovich & Clark, 2012). Questions asked about availability and use of PPE during four categories of potential exposure: preparation, administration, disposal, and handling patient excreta. PPE use questions were scored from 5 (always use) to 0 (never use). Higher scores showed higher use of PPE. Use of PPE was calculated as a score for each respondent based on their reply to the use of gloves, double gloves, gowns, whether or not they reused disposable gowns, and eye protection. For example, if a respondent answered “always use” for wearing gloves, double gloves, gowns, eye protection and “never use” for reusing disposable gowns during administration they would end up with a score of 25/25 (100%) for that activity. Scores were then averaged for any activity that reported doing that for their job.

Independent Variables: Predictor Variables and their attributes are outlined in Table 1. All survey measures except knowledge of the hazard were adapted from Geer et al. and Gershon et al. (Geer et al., 2007; Gershon et al., 1995; Gershon et al., 2007). Knowledge of the hazard was measured based on adaptation of items from the NIOSH Survey of Safe Handling for Workers and the Chemotherapy Exposure Knowledge Scale (National Institute for Occupational Safety and Health, 2004).

Pregnancy and alternative duty: Respondents were also asked whether or not they had been pregnant during their current job, and if so, whether they sought alternative duty. If they had not been pregnant, they were asked if they would seek alternative duty if they became pregnant.

Analytic Plan for Survey Data

The data analysis for this paper was generated using SAS software, Version 9.3 of the SAS System for PC (SAS Institute Inc., 2010). To prepare the data for estimation, descriptive statistics were conducted for all variables in the model. Descriptive analysis of the variables included calculation of means and standard deviations. Univariate and multivariate regressions were done. Multiple linear regressions were done to help show which variables have an effect on PPE use in order to highlight areas to focus on to improve safety. Multivariate regression models should check for four assumptions, according to Institute for Digital Research and Education (2015). First, that there is multivariate normality of the residuals, second that the variances of residuals are homogenous, third that there is a common covariance structure across observations, and fourth, that the observations are independent (Institute for Digital Research and Education, 2015), i.e., the independent variables can be considered fixed in repeated samples. To test the first assumption, a scatterplot of the residuals was created and formed an ellipse, which shows the assumption was met. The second assumption was tested with the F-statistic. The third assumption found a small difference between the covariance matrices, likely because the group's sizes were not the same. Finally, the fourth assumption is presumed because the survey respondents had unique links to the survey and we are assuming that their answers were independent of each other. Additionally, use of DAGs to specify the estimation models minimized the potential for problems that stem from violation of the independence assumption including 1) avoiding auto regression, or a lagged value of the dependent variable as an independent variable, and 2) avoiding simultaneous equation bias (Kennedy, 2008). The potential for the third possible problem from violating the independence assumption, errors in measuring the independent variables was minimized by using measures previously validated in other studies.

Paired t-tests were done for PPE use and predictor variables to determine if the intervention caused a statistically significant change. This test was appropriate because there was one outcome variable measured with a continuous score (PPE use or predictor variables, tested separately) and two nominal variables (value pre- and posttest (with values varying by measure). The paired t–test assumes that the differences between pairs are normally distributed (and not that those observations within each group are normal) (McDonald, 2014). This assumption was met by the data.

A short survey was sent to individuals not completing the comprehensive survey by the deadline to address potential selection bias. It did not address predictor variables, but did ask about unit, gender, age, years of experience, and PPE use during drug handling activities.

Environmental Measures

Prior to collection of survey data, wipe samples for surface detection of chemotherapy were collected in patient care, nursing and pharmacy areas. Sampling locations were selected in relation to each job task associated with potential chemotherapy exposure: drug preparation, administration, disposal, and handling excreta. Areas on each unit were tested based on work flow and the locations in which the selected drugs were most commonly used. For example, the nursing desk in the inpatient oncology unit was tested based on charge nurse feedback that workers set their chemotherapy bags there to perform a double check for the right drug, right patient, right dose and right time. Previous studies have shown that repeated wipe sampling results have low variability in surface contamination and that a single wipe sample seemed to reflect contamination levels over time rather well (Hedmer, Tinnerberg, Axmon, & Jonsson, 2008). A total of 27 locations were tested on both the pre and posttest, accounting for 62 unique antineoplastic agents by location combinations. Subsequently, the hospital staff identified additional areas of concern that resulted in expanded testing to try to find out why the pretest contamination existed. Twelve additional wipe samples were taken during the intervention (hereafter referred to as intervention samples). Areas on each unit were tested based on work-flow and the locations in which the selected drugs were most commonly used. Having a variety of job tasks associated with potential chemotherapy exposure (drug preparation, administration, disposal, and handling excreta) was also considered. An experienced industrial hygienist provided guidance on the planning and implementation of the exposure assessment and wipe sampling. Selection of the antineoplastic agents to be tested was based upon those agents with the highest volume of use, consistent with the approach used in similar studies (National Institute for Occupational Safety and Health, 2004). The area of test sites was between 100cm^2 and 200 cm^2 for this study, based on size availability and recommendations from an exposure assessment consultant. An exposure assessment tool developed in response to the NIOSH Drug Alert (2004) and a housekeeping standard recommendation, USP 797, ChemoAlert™ (Bureau Veritas Laboratories, Lake Zurich), was used for testing. The number of swab strokes was standardized and the lab provided a sample blank that was not used to sample a surface to assure accurate testing.

The collection procedure steps were as follows (Bureau Veritas Laboratories, 2013):

1. Surface and areas to be sampled were chosen with input from employees and management. Surface type, contamination level, date and time were recorded. Samples were either 100 or 200 cm squared. Prior to collection, a sample frame was taped to the area to be tested. This author did the swabbing, while an Industrial Hygienist recorded and observed the work.

2. An appropriate volume of swab solvent was place onto a TX714A swab head such that the swab head was thoroughly wetted. Excess swab solvent was shaken from the swab prior to use in surface sampling.

3. While holding the prepared swab, the broad, flat face of the swab head was placed against the substrate surface with moderate pressure (enough to flex the swab so the entire flat surface of the swab contacts the substrate surface), and moved back and forth over the entire surface area. The number of strokes was standardized for each particular sampling area (e.g., 7 strokes with one side of swab, swab was flipped and 7 more lengthwise; 10 strokes with one side of swab widthwise before swab was flipped).

4. Two swabs were used for each area and placed in the same vial per lab recommendation, head first with the swab handle cut to approximately one inch length.

5. The surface type, location, date, and area were recorded for each sample, and the vials were clearly marked for identification purposes.

6. The lab provided a sample blank (solvent wetted and placed in a vial) that was not used to sample a surface.

Analytic Plan for Environmental Wipe Sampling

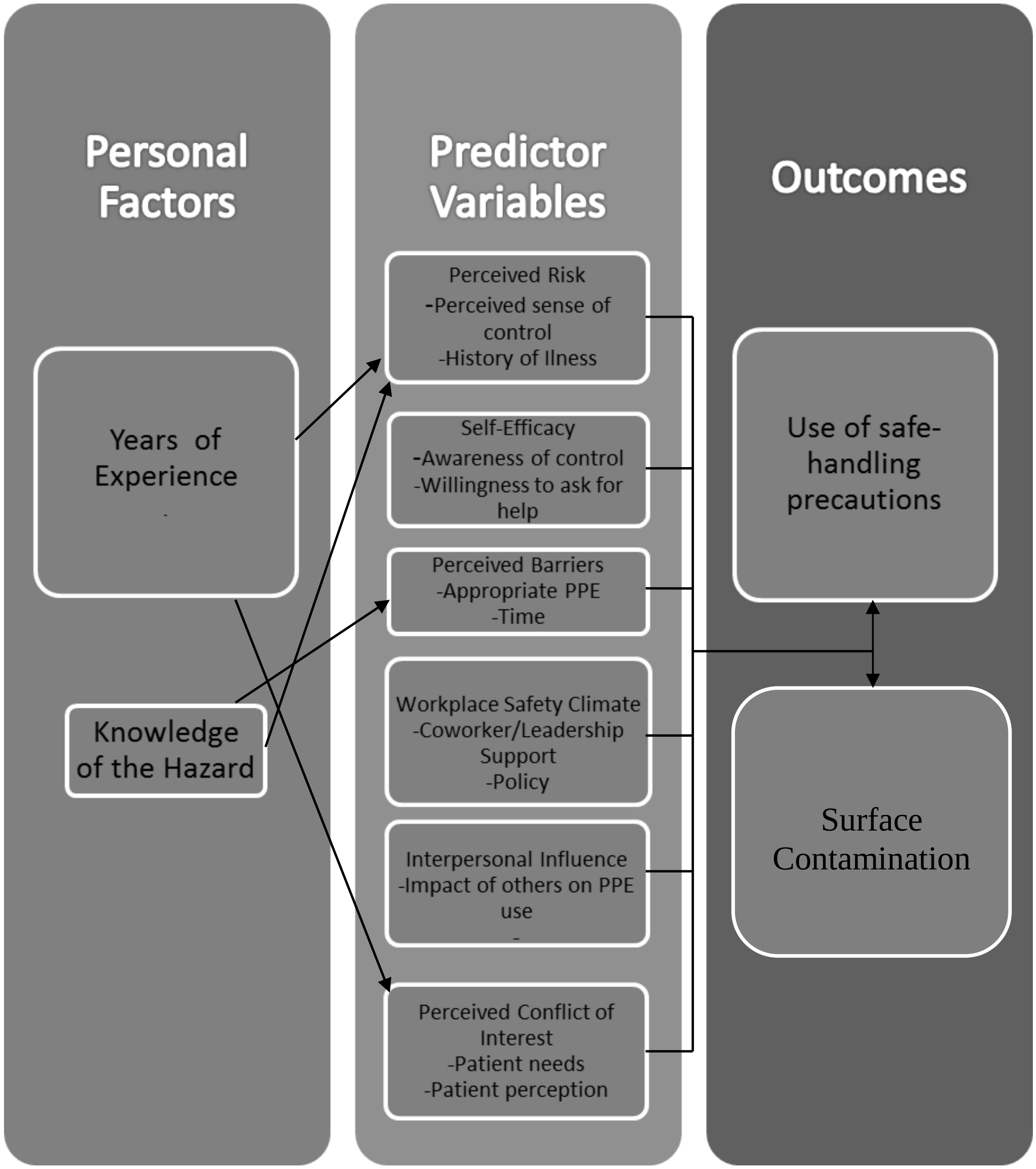
Lab analysis of wipe samples was performed by Bureau Veritas Laboratories based on each antineoplastic agent's unique level of detection (Bureau Veritas Laboratories, 2013). As there is no safe level of antineoplastic agent, any result over its level of detection was considered "contaminated" (Turci, Sottani, Spagnoli, & Minoia, 2003). For this dissertation a comparison between the pre- and posttest environmental sampling results was conducted to assess if the intervention was successful in lowering levels of surface contamination below the level of chemical detection.

Quality Improvement Process

A goal of this project was to understand the experience of this type of workplace exposure in the hopes that this would be helpful in tailoring safety training changes to maximize the implementation of protective measures in the work environment. While Maslow's Hierarchy of Needs assumes that humans' motivation for self-preservation should override all else, statistics show otherwise, stimulating researchers to try to understand the paradox (Maslow, 1943). Zohar suggests that learning the short-term gains of unsafe behavior (e.g., more comfort and quicker paced work) typically outweigh the benefits of using safety equipment (i.e., no immediate adverse consequence typically occurs) (Zohar & Luria, 2005). This applies to antineoplastic handling because although there can be immediate, negative health effects, much of the harm from these agents can be attributable to very small accumulated doses over time. Thus, interventions in the safety literature that fit into this category often attempt to be solved using interventions that are based on publicly displayed feedback charts and observations by co-workers which provide more immediate incentive for change (Zohar & Luria, 2005). Dov Zohar describes group climate level being a mediator for the effect of organization climate on safety behavior. This project implemented an intervention at the unit level and tested its effectiveness on the organizational climate consistent with Zohar's findings. A recent study in chemotherapy safe handling by Silver et al. concluded that the consideration of training components and engineering controls are important for tailoring interventions to improve chemotherapy safety (Silver, Steege, & Boiano, 2015). This research combined both of these recommendations- it used recommendations by workers to affect group level change while also considering workflow change.

Management and staff were invited to hear the pretest results during staff and nurse council meetings. Small workgroups formed that addressed areas of concern for each unit. Consistent with the quality improvement literature, small changes were made on each unit and changes were tested with surveys or qualitative interviews to address how staff felt the changes were working. Interventions on each unit were tested for effectiveness using the Plan-Do-Study-Act cycle for quality improvement processes (Langley, Moen, Nolan, Norman, & Provost, 2009). Wherever possible, short surveys were conducted to see if the changes made were perceived by employees as improvements in addition to the analysis of pre and posttest data from the survey and environmental wipe sampling described above. Feedback from managers and qualitative interviews were also done after changes were made. Observation was done on all units during the intervention phase to determine common work practice. During observation, workflow was noticed which helped determine the ways in which it was possible for common work areas to be contaminated. For example, during one session a nurse was observed pulling the inner chemotherapy bag out of its outer bag without gloves and place it directly on the main nursing desk. This demonstrated that proper PPE was not being used and that there was a potential for contamination of the nursing desk because of the placement of the inner bag, and possibly the computer keyboard as the nurse was using it while touching the bag. These observations gave us a platform to discuss ways in which process change might directly impact the surface contamination of work areas with chemotherapy.

Figure 1: Theoretical Model



Adapted with permission from Polovich and Clark (Polovich & Clark, 2012a)

Figure 2: Directed Acyclic Graph (DAG) Used to Select Confounders for Multivariate Estimation of Use of PPE and Workplace Safety Climate

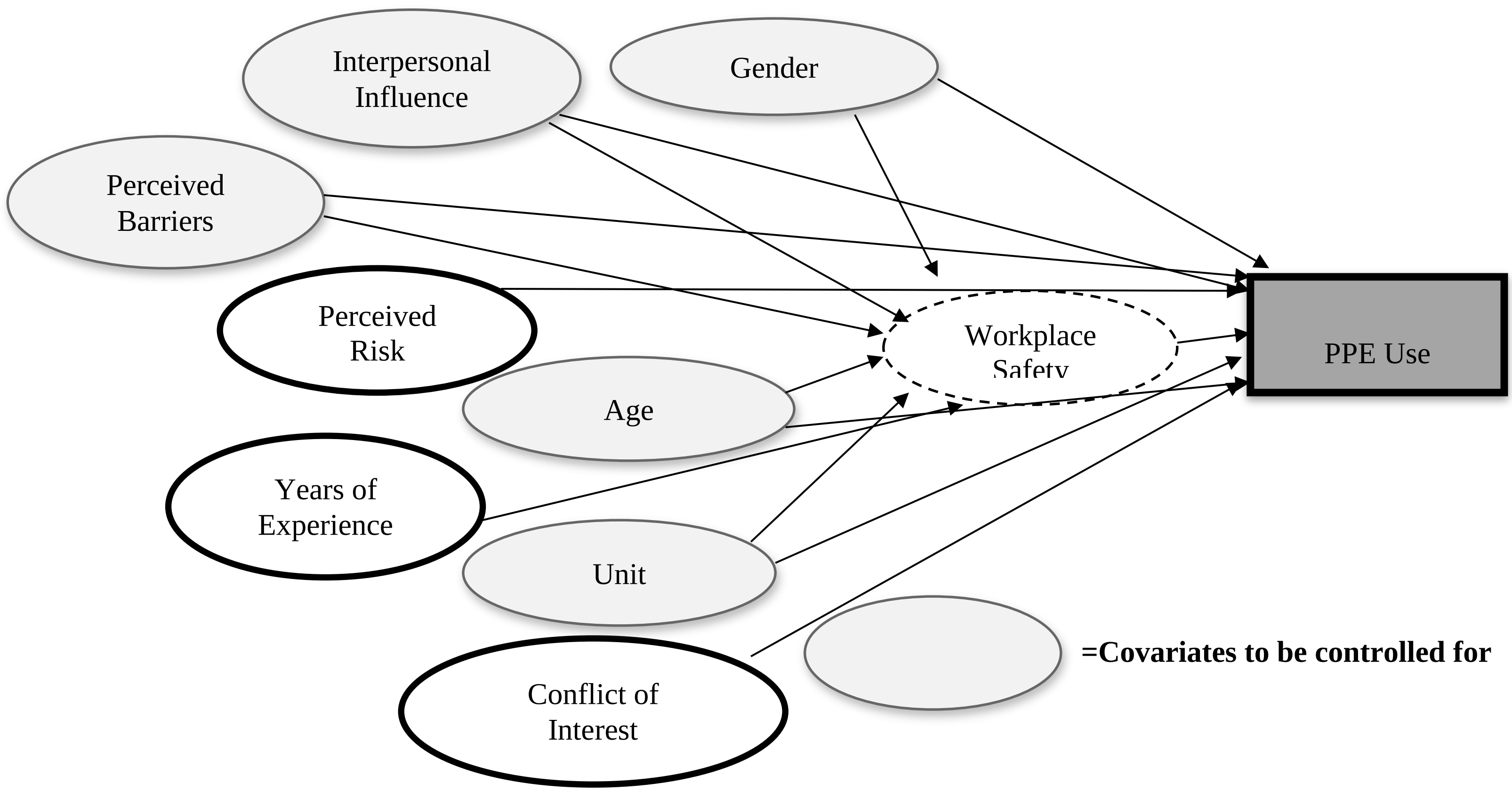


Figure 3: Directed Acyclic Graph (DAG) Used to Select Confounders for Multivariate Estimation of Use of PPE and Self-Efficacy

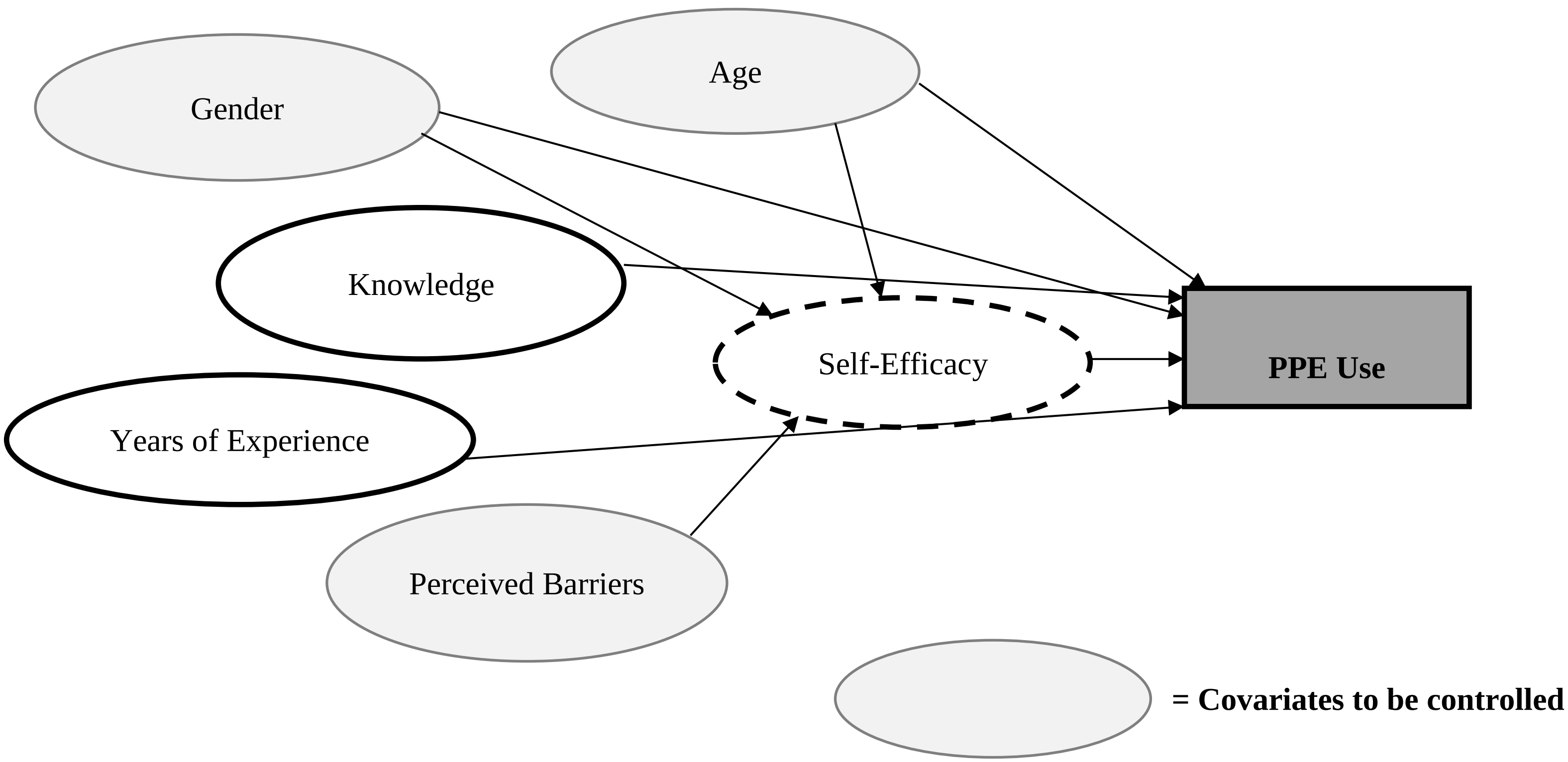
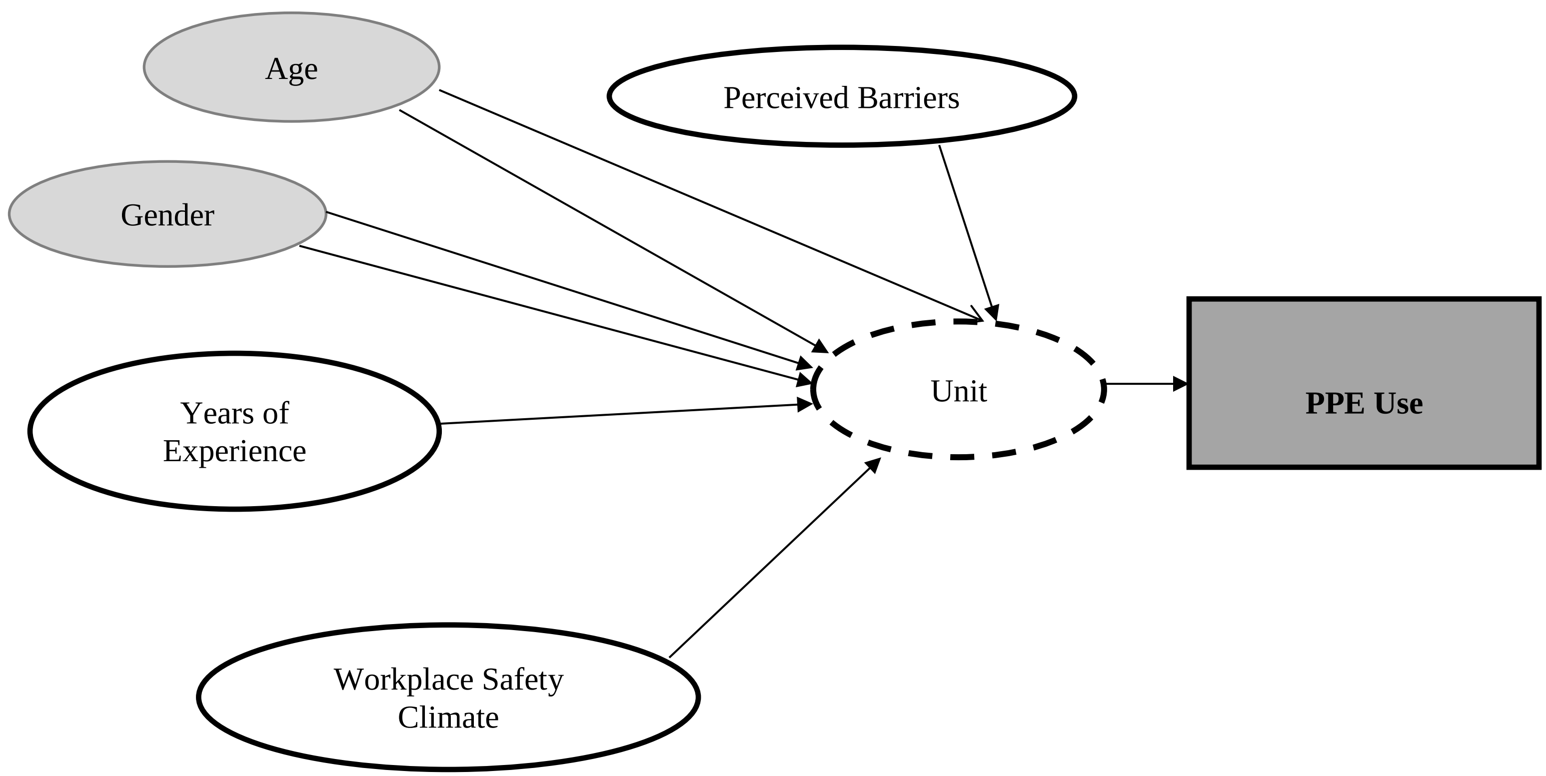


Figure 4: Directed Acyclic Graph (DAG) used to select confounders for multivariate estimation of use of safe handling techniques (PPE) and Unit



CHAPTER 5: RESULTS

Survey Results

Respondent Characteristics

Overall, the survey response rate was 62% of 163 employees on the pretest and 72% on the posttest. Demographic results are outlined in Table 1: The 100 survey participants on the pretest included 11 pharmacists and 89 nurses. The majority of all survey respondents were female (88%), Caucasian (88%), and their highest degree earned was a bachelor's degree (79%). Just under half (45%) of the pretest respondents were age 36 and over and more than half of the posttest respondents (63%) were 36 and over. Experience in handling chemotherapy was fairly evenly distributed among all respondents: experience of five years or less (34%), six to 10 years (32%) and more than 10 years (35%). Specific to the nurse study participants, 41% reported status as a member of the Oncology Nursing Society and 35% reported nursing certification as either an Oncology Certified Nurse (OCN), an Advanced Oncology Certified Clinical Nurse Specialist (AOCNS) or both.

The number of survey respondents declined from pretest (100) to posttest (71). Attrition was greatest among the oncology unit (37%), with inpatient bone marrow transplant (29%), pharmacy (27%) and outpatient chemotherapy (18%) slightly less so. However, the distribution of demographic factors among pre- and posttest respondents was similar on gender, race and education (e.g., from 88% to 86% female, 88% to 91% Caucasian, 78% to 79% bachelor's degree on the pre and posttest, respectively). In contrast, a difference was seen in the distribution of respondents by years of experience with chemotherapy handling (e.g., participants with five or fewer years of experience declined from the pretest (34%) to the posttest (26%). The respondents to the comprehensive pretest survey were similar to those who answered the short version of the survey with respect to average age (38 vs 36 years), experience (10.5 vs 12.5 years) and reported PPE use (total score of 40 vs 40.3).

Personal Protective Equipment Use

Results of questions asking about PPE use by activity are shown in Table 2. They revealed that overall, glove use was high; use of gowns and double gloving were lower, and use of respirator or eye protection lower still. On the pretest survey, glove use was particularly high among pharmacy staff when preparing chemotherapy (100%), and less so, but still relatively high among all staff in other job tasks. Comparison of pre- and posttest results reveal increased use of gloves after the intervention when administering chemotherapy (83% to 92%), disposing of chemotherapy and items such as PPE they are potentially contaminated with PPE (80% to 87%) and when handling patient excreta (70% to 77%).

Use of double gloves and chemotherapy gowns among pharmacists preparing chemotherapy increased from pre to posttest levels. Double gloving scores improved from pretest (0) to posttest (90%) while gown use was consistently at 100%. Among all survey respondents double gloving scores remained constant during chemotherapy administration (34%) and disposal (33% to 32%), but improved when handling excreta (9% to 15%) from pre to posttests, respectively. The use of gowns during chemotherapy administration improved from pre (82%) to posttest (90%), and when handling patient excreta, from pre (21%) to posttest (28%), but remained constant for disposal tasks (56%).

Eye protection use was low among all job tasks and changes in use from pre to posttest were inconsistent. For example, use of eye protection during drug administration by pharmacists declined from pre (33%) to posttest (22%), and for all survey participants use remained relatively constant during administration (28%) but declined during disposal (22% to 18%) and increased when handling excreta (15% to 17%) for pre and posttest, respectively.

Respirator use was also low among all job tasks. Reported use increased for the activities of preparation (from 11% on the pretest to 22% on the posttest), administration (12% to 15%), and handling patient excreta (5% to 9%), while reported use during disposal decreased (9% to 6%).

Predictor Variable Questions

Knowledge of the hazards associated with chemotherapy was addressed with a twelve question survey. Results of this are displayed in Table 3. Overall, average scores on knowledge were high and the scores increased slightly on the posttest. Survey respondents were most frequently correct (90% or more) on pretest items assessing their knowledge of the risks of chemotherapy related to ingestion, spills and splashes, and dermal absorption in general and through damaged skin and these scores were essentially maintained on the posttest. Items with higher levels of error included the following questions, “A surgical mask provides protection from chemotherapy aerosols” (pretest: 33% wrong and 25% answered don’t know; posttest: 30% wrong and 17% answered don’t know), “Chemotherapy cannot enter the body through contact with contaminated surfaces” (pretest: 16% wrong and 8% answered don’t know; posttest: 29% wrong and 3% reporting don’t know), and “Chemotherapy gas and vapor in air can enter the body through the skin" (pretest: 8% wrong and 30% answering don't know; posttest 16% wrong and 17% answering don't know).

Self-efficacy is the next predictor variable addressed, and results are displayed in Table 4. The averages for these scores also increased on the posttest reflecting a slight increase in self efficacy (mean on pretest was 22.1; posttest mean was 23.2). The question with the highest increase in average respondents reporting "strongly agree" on the posttest was "I am confident that I can use PPE properly" (pretest: 63%; posttest: 74%). The question with the next highest increase in the percentage of respondents reporting that they "strongly agree" was "I am provided with the best available PPE" pretest: 34%; posttest: 43%, respectively).   The two questions with the lowest number of respondents reporting feeling a high level of self-efficacy were "My supervisor goes out of his/her way to make sure I am protected" and "My supervisor goes out of his/her way to make sure I am provided with proper fitting PPE", although both measures did increase in self-efficacy on the posttest by about 6 percentage points (pretest: 24%, posttest:31% and pretest:25%, posttest 31%, respectively).

Perceived barriers were measured with twelve questions related to respondents' answers about factors that they perceive might keep them from using PPE; the results are displayed in Table 5. The two reasons most likely to be considered barriers were "PPE is uncomfortable to wear" (pretest: 38% reporting agree or strongly agree; posttest: 48% reporting agree or strongly agree) and "PPE makes me too hot" (pretest: 55% reporting agree or strongly agree; posttest: 64% reporting agree or strongly agree). No respondents agreed or strongly agreed with the statements "I don't think PPE is necessary" or "I don't think PPE works." Only a small number of respondents agreed with the statement “I don’t have the time to use PPE” (pretest: 8%; posttest: 3%), and none reported that they strongly agree with it.

Perceived risk was measured with three questions and the results are displayed in Table 6. These questions addressed how worried respondents were about health effects from chemotherapy and how harmful they felt it was. No respondents strongly agreed with the statement “Chemotherapy exposure is not as harmful as some people claim”, and a very small percentage agreed with it (pretest: 5%; posttest: 4%). There were no large changes in responses between the pre and posttests. The largest change from pre to posttest was the number of respondents who disagreed or strongly disagreed with the following statement, “I am not worried about future negative health effects from chemotherapy exposure” (pretest: 54% disagreed and 31% strongly disagreed; posttest: 47% disagreed and 29% strongly disagreed).

Tables 7a and 7b display the results of questions measuring interpersonal influence. This measure asked respondents their perception of the use of PPE by other groups in the workforce as well as their perception of how important PPE use was to the other groups. When asked about PPE use in other groups, no respondent reported that their coworker, other nurses, or oncology nurses in general felt PPE use was “never” important. The majority of respondents reported their perceptions that PPE use was “usually” used by these other groups (pretest co-workers: 82%; posttest coworkers 90%; other nurses they know: pretest 76%; posttest 83%; oncology nurses in general: pretest 81%, posttest 81%). When asked how important they felt PPE use was to others, 96% percent of respondents felt that chemotherapy safe handling was “very important” to their manager on the posttest, compared to 86% on the pretest. There was also an increase in their reports of PPE importance on the posttest for co-workers, other nurses they know, and their employer (from 77% to 89%, from 74% to 86%, and from 90% to 93%, respectively).

Conflict of interest was measured with six questions and the results from these six questions are displayed in Table 8. Most of the questions for this measure had about 80% of respondents disagreeing or strongly disagreeing (showing less reported conflict of interest). There were only small changes between pre and posttest scores. The two questions with the highest percentage of change were related directly to patient needs, “Wearing personal protective equipment makes my patients worry” (percentage who agreed with this statement increased by six percentage points from pre to posttest) and “I cannot always use safe handling precautions because patients’ needs come first” (percentage who agreed with this statement decreased by 53% from pre to posttest).

The last predictor variable, workplace safety climate was a 21 question variable displayed in Table 9. The two questions that had the biggest change between pre and posttest were “On my unit, unsafe work practices are corrected by supervisors” (pretest: 56% agree or strongly agree; posttest: 76% agree or strongly agree) and “My supervisor talks to me about safe work practices” (pretest: 51% agree or strongly agree; posttest: 67% agree or strongly agree). There were also notable differences in scores when these questions were analyzed by unit. The outpatient nurses had lower average scores (meaning lower reported workplace safety climate) on all questions except the two pertaining to availability and accessibility of gloves. The average workplace safety climate score for the outpatient area was 62%, as compared to the bone marrow transplant area which had an average score of 79%.

Total average predictor variable scores from both the pre and posttest of this survey were also compared to those from the national survey of Oncology Nursing Society members that used the same variables. The results are compared in Table 10. Overall, Polovich's respondents had slightly higher scores on all predictors other than self-efficacy and the latter difference was small. The greatest difference in scores between this study and the Polovich study was the score for workplace safety climate. While this study's safety climate score increased from 61% to 64% the Polovich study score was 88%.

Figures 1-4 display the average reported PPE scores during the four tasks of chemotherapy handling- preparation, administration, disposal and handling patient excreta. The score of each respondent included responses to questions regarding the use of gloves, double gloves, gowns, respiratory protection, and not re-using disposable gowns.

Univariate regression was used to assess the strength of the relationship between PPE use and variables measuring constructs in the theoretical model including: Personal Factors (age, gender, and years of chemotherapy experience), and Predictor Variables (knowledge, perceived risk, self-efficacy, interpersonal influence, perceived barriers, workplace safety climate, and conflict of interest). Unit and patients cared for were also considered as it was found to be strongly correlated with PPE use. Significant univariate associations were found for workplace safety climate, self-efficacy, perceived risk, perceived barriers, knowledge, conflict of interest, patients per day, and selected workplace units on the pretest. The outpatient infusion center and the inpatient oncology unit in the hospital had lower PPE use scores whereas the pharmacy had higher scores when compared to inpatient bone marrow transplant group. The posttest showed somewhat different results, where perceived barriers, self-efficacy and workplace safety climates were the only predictor variables that had significant associations. PPE use changed for some units from pretest to posttest. The unit effect on PPE use for inpatient oncology compared to BMT declined from pre- to posttest (-10.8 to -15.8) respectively, in contrast to the change in unit effect for outpatient infusion relative to BMT which increased from pre-to posttest (-14.5 to -9.84), respectively. The pharmacy unit no longer showed a significant difference from the bone marrow transplant (BMT) reference group on the posttest. These results are displayed in Table 11.

Multivariate results reveal that the unit in which one worked was significantly associated with use of PPE on the pre-test and one unit remained significantly different from the reference group, BMT on the posttest. Self-efficacy was also associated with PPE use after controlling for appropriate confounders on the pretest, but this was not the case on the posttest. Two models of workplace safety climate were estimated which varied only by the inclusion or exclusion of the variable, unit. The findings revealed the more parsimonious model, without unit, was statistically significant on the pre-test, while inclusion of unit in the model decreased the parameter estimate from 0.5 to 0.23 and slightly widened the confidence interval leading to nonsignificant findings. Results of regression models are shown in Table 12. The posttest did not show significant results based on workplace safety climate with either model.

Paired t-test results are displayed in Table 13. The biggest change in the predictor variables was an increase in perceived risk after the intervention. Self-efficacy also showed a significant increase. PPE use increased for all but one unit, but the increase was significant for only one (the outpatient infusion center).

Pregnancy and Alternative Duty

Twenty eight percent of respondents reported having been pregnant while working their current job on the pretest and 30% on the posttest. Of those who became pregnant, 15% on the pretest and 30% on the posttest reported having sought alternative duty. Of the 72% who have not been pregnant while employed at their current job, 33% reported that they would seek alternative duty if they became pregnant and 26% reported being unsure whether they would or not on the pretest. On the posttest, there were 70% who had not been pregnant while employed at their current job, and of these 50% reported they would seek alternative duty and 27% reported being unsure whether or not they would. Institutional policy is that alternative duty work will be provided if requested.

Environmental Sampling Results

Overall, there were five samples from a total of 62 that tested above the limit of detection (8%) on the pretest and three of 62 (5%) on the posttest. The targeted samples done as part of the intervention showed positive results for 50% of samples (6 of 12). The unit with the highest number of areas that tested positive on the pretest (three sites) and posttest (two sites) was the outpatient chemotherapy infusion center. The inpatient bone marrow transplant and inpatient oncology units each had one contaminated area on the pretest, two during the intervention sampling, and none and one (respectively) during the posttest. One of the pharmacy areas had no positive samples, and the other pharmacy had one positive sample, which was a countertop shared between pharmacy and the outpatient chemotherapy infusion center. During the posttest, that counter was negative for contamination but a new area was positive (the floor underneath the preparation area in the pharmacy). Table 14 in the Appendix shows results for the areas sampled.

Intervention Results

Each unit had different concerns during the intervention phase and therefore cycles of Plan-Study-Do-Act were begun following staff meeting in which results of the survey were displayed. A summary of PDSA's and results are summarized by unit below.

Bone Marrow Transplant Unit

<u>Pretest Sampling and Findings</u>

On the BMT Unit, three antineoplastic agents were sampled: Ifosfamide, Etoposide, and Cyclophosphamide from six pre-intervention surfaces. These sites included: a patient bedside table, a cleaning cart used by custodial staff, a printer keyboard used by all staff, a physicians' workroom keypad, nurses work phones, and a cytocart with chemotherapy handling PPE in drawers. Pre-intervention test results showed only the patient bedside table had residue above the level of detection (1.5 N, Cyclophosphamide).

<u>Pretest Survey and Findings</u>

The BMT unit had a 63% response rate from 45 nurses. On average, the nurse respondents had 14 years of professional nursing experience, but reported an average PPE use score of 48.9%. The respondents on this unit scored 41% on perceived barriers, and 79% for workplace safety climate.

<u>PDSA #1 and Results</u>

Plan: To increase proper staff use of Personal Protective Equipment during chemotherapy safe handling.

Do: Move chemotherapy gowns to hallway closets.

Place "Do not re-use disposable gowns" signs in closet.

Add yellow disposable bags to nurse cart in room.

Study: Survey staff to determine if the above changes are convenient and increase proper use of PPE.

Act: If convenient, determine a way to keep equipment in these convenient locations and if not, use staff comments to determine alternative next steps.

Results of PDSA #1 survey revealed 97% of 37 survey respondents found the change in location of the chemotherapy gowns to be convenient. About 50% of the respondents reported that moving the chemotherapy gowns had increased their usage and an additional 34% felt that it would increase their usage in the future. 78% of respondents felt that the increase in locations of the yellow chemotherapy waste bags would be helpful. About 60% of respondents reported that the reminders to not re-use disposable gowns would help.

PDSA #2 and Results

Plan: To educate Nursing Station Technicians (NST's) on chemotherapy safe handling

Do: Provide mandatory training to NSTs.

Study: Have NST's fill out a pre and posttest to determine effectiveness of training.

Act: Decide on how frequently training needs to occur and who will train new staff.

Results of the PDSA#2 and the NST training showed that 100% of the 17 survey respondents reported feeling better able to protect themselves from exposure. Additionally, 87.5% of respondents reported wearing PPE most or all of the time after the intervention vs. 60.5% before the intervention.

Interim Sampling Tests and Results

In response to the results from the pretest, one antineoplastic agent (Cyclophosphamide) was again tested in two locations (in addition to the six pre-intervention sites). These included a patient bathroom floor – sides of toilet and a nurses' cart in patient room. Two samples were taken from each of those sites to decrease random variability. Both sides of the toilet had increased levels of contamination (0.35ng/cm^2 and 0.18 ng/cm^2). One of the samples from the nurses' cart had an increased level of contamination (0.12 ng/cm^2), and the other did not.

Posttest Results

Levels of residue from Cyclophosphamide at the patient bedside table were successfully reduced to below the level of detection in response to this interim sampling.

Oncology Unit

Pretest Sampling and Findings

On the Oncology Unit, three antineoplastic agents were sampled: Ifosfamide, Etoposide, and Methotrexate from six pre-intervention surfaces. These sites included: a nurses cart and keyboard in a patient room, the bathroom wall in a patient bathroom, the chemotherapy intake bin in the medication room, and a biohazard bin in the dirty utility room. Pre-intervention test results showed only the patient bedside table had residue above the limit of detection (1.5 N, Cyclophosphamide).

Pretest Survey and Findings

The oncology unit had a 68% response rate from 27 nurses. Nurse respondents had an average of 14 years of professional nursing experience. They reported an average PPE use score of 38.2%. On average, the nurse respondents scored 42% on perceived barriers, and 69% for workplace safety climate.

PDSA #1 and Results

Plan: Decrease surface contamination at the nurse desk where chemotherapy is double checked.

Do: Move gloves to desk where chemotherapy is double-checked.

Change policy to not removing inner chemotherapy bag during the double check.

Change policy to not initial chemotherapy bags during double check.

Study: Survey employees to see if changes are being followed and gloves are being used more.

Act: If survey results show positive results and decrease in surface contamination, keep policy change and educate on it.

Results: Survey results for PDSA #1 showed that 91% of the 12 respondents reported that moving the gloves closer to the double check area was convenient and 33% reported they were more likely to glove during the double check process. However, a couple of weeks later the gloves had been moved and it was realized that this was not a sustainable change which contributed to PDSA #2.

Interim Sampling Tests and Results:

In response to the results from the pretest, one antineoplastic agent (Ifosfamide) was again tested from two locations (in addition to the six pre-intervention sites). These included another area of the main nursing desk counter and the outside of a bag of Ifosfamide, prepared by the pharmacy and delivered to the unit. The outside of the bag was tested to determine if it was contaminated with chemotherapy, and nurses placing it on the main nursing desk counter might be inadvertently contaminating it. Two samples were taken from each of those sites to decrease random variability. Both areas of the bag of Ifosfamide were highly contaminated (34.4ng/cm2 and 9.42/cm2). One of the samples from the main nursing desk also had an increased level of contamination (0.008 ng/cm2), and the other did not.

PDSA#2 and Results:

Plan: Decrease surface contamination at the nurse desk where chemotherapy is double checked.

Do: Move location of chemotherapy double check from nursing desk to red-taped area in locked medication room.

Have dedicated pens for double checking bags.

Use chemotherapy pads to cover taped area.

Study: Resample surface of nursing desk; qualitative interviewing with staff and management.

Act: If negative, policy change to location of double check in medication room.

Results: When the counter area was resample one month after this change, it was below the limit of detection. Nurses and management felt the change was successful and feasible for the workflow on the unit. This policy was implemented for sustainable change.

Posttest Results

Levels of Ifosfamide at the nursing desk were below the limit of detection on the posttest. Samples from the other five pretest locations were also below the level of detection.

Outpatient Infusion Center

Pretest Sampling and Findings

Gemcitabine and Paclitaxel were the two antineoplastic agents sampled in the outpatient infusion center. Six surfaces were tested. These sites included: the floor under the laundry bin, a patient chair armrest after infusion and prior to cleaning by nursing staff, a patient chair armrest after infusion and after cleaning by nursing staff , the counter area shared by both nursing and pharmacy for return of medication bins, a breakroom table, and a nursing desk. Pre-intervention test results showed results above the level of detection for the floor under the laundry bin (0.03 ng/cm2, Paclitaxel), the patient chair armrest following infusion and before cleaning (0.02 ng/cm2, Paclitaxel), and the counter between the nursing and pharmacy areas (0.05 ng/cm2, Paclitaxel).

Pretest Survey and Findings

There was a 57% response rate on this unit from 17 nurses. On average, the nurse respondents had 10 years of professional nursing experience and reported an average PPE use score of 36.4%. On average, the nurse respondents scored 51% on perceived barriers, and 62% for workplace safety climate.

PDSA #1 and Results:

Plan: Improve use of PPE by staff.

Do: Change policy on disposable gowns to NEVER reuse.

Treat patient area as though it is a “room” and remove PPE prior to exiting the area.

Study: Survey staff to see if change is occurring and positive for employees.

Act: Continue with new practice.

Results: Upon survey of 14 employees, 100% reported that they had learned about the change in NOT reusing disposable gowns. Additionally, 92% of employees reported they used to reuse, but no longer do. When surveyed about treating the patient area as a room, 100% of respondents reported learning about keeping PPE in patient bay area and 72% of those employees reported this change made their job more challenging. Because of this, qualitative interviewing was conducted and the feedback led to a change of placing new bags on the IV poles to collect used PPE. Staff were also encouraged by management to support each other.

PDSA #2 and Results:

Plan: Decrease surface contamination.

Do: Replace IV end caps with caps that match tubing brand.

Study: Re-sample patient chair armrest.

Act: Continue with replacement.

Results: It was decided that this was effective based both on results of research proving that closed system drug transfer devices reduce the likelihood of contamination and the fact that the posttest results showed no contamination on patient chair armrests. Interim sampling results, done following the change in caps, were also negative.

Interim Sampling:

Additional samples were taken in two locations including a computer cart that is used by nurses to prepare medications and check data on patients, and the inside drawer of a bedside nursing cart in which chemotherapy is sometimes placed in an outer bag while waiting for proper time to administer. All of these samples were below the limit of detection.

Posttest Results:

The floor of the nursing area remained contaminated and tested higher on the posttest (0.13 ng/cm^2, Paclitaxel) than on the pretest. Because of this persistence in contamination, it was recommended to staff that they have a dedicated pair of shoes for work and home. The other pretest locations were all below the level of detection on the posttest.

Pharmacy

Pretest Sampling and Findings

Two pharmacy areas were sampled during this study, each for two antineoplastic agents. In one pharmacy area (the one associated with the outpatient infusion center), Paclitaxel and Gemcitabine were sampled. Sites tested here were: the counter between the nursing and pharmacy areas (explained above), the inside of the plastic pharmacy to nursing bins, and a pharmacy counter and pharmacy floor in the pressurized antineoplastic drug preparation room. The only site above the limit of detection on the pretest was the counter between the nursing and pharmacy area.

In the other area, a pharmacy associated with an outpatient transplant center that also prepares antineoplastic agents, Cyclophosphamide and Gemcitabine were sampled. The sites tested in this pharmacy were the medication intake cooler tote, the medication transfer bin, the biohazard lid, a chemotherapy pad in the antineoplastic drug preparation room, and a bin which held Gemcitabine and one which held Cyclophosphamide. All of these sites tested were below the limit of detection.

Pretest Survey and Findings

There was a 58% response rate in the pharmacists (N=11) who averaged 7 years of experience. These staff reported their PPE use at 54.1%. Their perceived barriers score averaged 32%; their workplace safety climate score average: 87%.

PDSA #1 and Results:

Plan: Decrease surface contamination at nursing/pharmacy counter.

Do: Clean counter with bleach daily.

Inform staff of contamination in area.

Study: Re-sample counter.

Act: Continue cleaning process if re-sample is negative.

Results of PDSA #1:

Counter between nursing and pharmacy area was uncontaminated after working with nurses on keeping PPE in bay area and doing focused, consistent cleaning in the area.

Interim Sampling:

No interim sampling was done in this area.

Posttest Sampling Results:

Upon resampling, one pharmacy area had no positive samples. The other pharmacy area had one area above the limit of detection, the floor in the chemotherapy preparation room (0.08 ng/cm^2).

Table 1 : Demographic Characteristics of Survey Respondents

Characteristic	Pretest (n=100) N (%)	Posttest (n=71) N (%)	Pretest Only (n=33) N (%)	Short Survey (n=10) N (%)
Setting Employed				
Pharmacy	11 (11%)	8 (11.2%)	2 (6.1%)	0
Outpatient Chemotherapy	17 (17%)	14 (19.7%)	5 (15.2%)	0
Inpatient Bone Marrow Transplant	45 (45%)	32 (45%)	16 (48.5%)	5 (50%)
Inpatient Oncology	27 (27%)	17 (23.9%)	10 (30.3%)	5 (50%)
Gender				
Male	12 (12.5%)	10 (14.3%)	5 (17.2%)	1 (10%)
Female	84 (87.5%)	60 (85.7%)	24 (82.8%)	9 (90%)
Age (years)				
Less than 25	8 (8.6%)	1 (1.5%)	4 (14.3%)	
25-35	43 (46.2%)	23 (35.3%)	13 (46.4%)	
36-45	14 (15.0%)	20 (30.8%)	4 (14.3%)	
Over 45	28 (30.1%)	21 (32.3%)	7 (25%)	
Race				
American Indian/Alaskan Native	3 (3.1%)	0	1 (3.4%)	
Black/African American	3 (3.1%)	2 (2.9%)	1 (3.4%)	
Asian	3 (3.1%)	2 (2.9%)	2 (6.9%)	
Hispanic/Latino	0	1 (1.4%)	0	
Native Hawaiian	0	0	0	
White	85 (87.6%)	64 (91.4%)	24 (82.8%)	8 (80%)
Two or more	2 (2.1%)	1 (1.4%)	1 (3.4%)	2 (20%)
Other	1 (1%)	0	0	
Highest level of nursing education				
Diploma	1 (1.1%)	1 (1.4%)	0	
Associate degree	11 (11.7%)	7 (9.9%)	4 (13.8%)	

Bachelor's degree	74 (78.7%)	56 (78.9%)	20 (69%)	
Master's degree	8 (8.5%)	7 (9.9%)	5 (17.2%)	
Oncology Nursing Society member				
Yes	40 (41.2%)	27 (38.6%)	11 (37.9%	2 (20%)
No	57 (58.2%)	43 (61.4%)	18 (62.1%)	8 (80%)
Certified in nursing				
Not certified	58	41 (61.2%)	14 (48.3%)	
OCN	33	25 (37.3%)	15 (51.7%)	
AOCNS	2	1 (1.5 %)	0	
Years of chemotherapy handling experience				
0-2	21 (22.1%)	13 (19.7%)	5 (17.2%)	
3-5	11 (11.6%)	4 (6.1%)	5 (17.2%)	
6-10	30 (31.6%)	21 (31.8%)	7 (24.1%)	
>10	33 (34.7%)	28 (42.4%)	12 (41.4%)	

Table 2: Reported Personal Protective Use

Equipment	Always: Pre	Always: Post	51-99%: Pre	51-99%: Post	1-50%: Pre	1-50%: Post	Never: Pre	Never: Post
Preparation (Pharmacy)								
Biological Safety Cabinet	9 (90%)	9 (90%)	1 (10%)	0	0	0	0	1 (10%)
Closed system transfer device	2 (20%)	1 (10%)	1 (10%)	4 (40%)	2 (20%)	2 (20%)	5 (50%)	3 (30%)
Chemotherapy gloves	9 (100%)	10 (100%)	0	0	0	0	0	0
Other gloves	3 (33.3%)	3 (37.5%)	0	1 (12.5%)	0	0	6 (66.7%)	4 (50%)
Double gloves		9 (90%)	0	1 (10%)	0	0	0	0
Chemotherapy gown	10 (100%)	10 (100%)	0	0	0	0	0	0
Eye protection	3 (33.3%)	2 (22%)	0	0	0	0	6 (66.7%)	7 (77.8%)
Respirator/mask	1 (11.1%)	2 (22.2%)	0	1 (11.1%)	2 (22.2%)	1 (11.1%)	6 (66.7%)	5 (55.6%)
Administration								
Closed system transfer device	51 (60%)	42 (61.8%)	6 (7.1%)	7 (10.3%)	3 (3.6%)	2 (2.9%)	25 (29.4%)	17 (25.0%)
Chemotherapy gloves	68 (83%)	55 (91.7%)	3 (4%)	2 (3.3%)	2 (2%)	1 (1.7%)	9 (11.0%)	2 (3.3%)
Other gloves	8 (10.7%)	3 (5.4%)	5 (6.7%)	2 (3.6%)	2 (2.7%)	3 (5.4%)	61 (80.3%)	48 (85.7%)

Double gloves	26 (33.8%)	20 (33.9%)	9 (11.7%)	7 (11.9%)	10 (13%)	9 (15.3%)	32 (41.6%)	23 (39.0%)
Chemotherapy gown	67 (81.7%)	55 (90.2%)	13 (15.8%)	6 (10.0%)	1 (1.2%)	0	1 (1.2%)	0
Other gown (e.g. isolation)	2 (2.6%)	0	1 (1.3%)	0	4(5.2%)	1 (1.8%)	70 (90.9%	56 (98.2%)
Re-used disposable gowns	2 (2.6%)	0	13 (16.9%)	0	6 (7.9%)	6 (10.8%)	56 (72.7%)	50 (89.3%)
Eye protection	22 (27.8%)	17 (28.8%)	9 (11.4%)	8 (13.6%)	14 (17.7%)	7 (11.9%)	34 (43.0%)	27 (45.8%)
Respirator	9 (11.8%)	9 (15.3%)	6 (7.9%)	8 (13.6%)	12 (15.6%)	5 (8.5%)	50 (64.9%)	37 (62.7%)
Disposal								
Chemotherapy gloves (n=94)	75 (79.8%)	61 (87.1%)	7 (7.5%)	4 (5.7%)	2 (2.1%)	2 (2.9%)	10 (10.6%)	3 (4.3%)
Other gloves (n=76)	8 (11%)	5 (8.1%)	4 (5%)	3 (4.8%)	3 (4%)	1 (1.6%)	61 (80.3%)	53 (85.5%)
Double gloves (n=79)	26 (32.9%)	20 (31.3%)	6 (7.6%)	5 (7.8%)	8 (10.1%)	10 (15.6%)	39 (49.4%)	29 (45.3%)
Chemotherapy gown (n=81)	45 (55.6%)	37 (56.9%)	16 (19.7%)	11 (16.9%)	9 (11.2%)	5 (7.7%)	11 (13.6%)	12 (18.5%)
Other gown (e.g. isolation) (n=75)	2 (2.6%)	0	0	1 (1.7%)	4 (5.3%)	1 (1.7%)	70 (92.1%)	58 (96.7%)
Re-used disposable gowns (n=76)	3 (4%)	5 (8.1%)	6 (7.9%)	1 (1.6%)	8 (10.5%)	4 (6.4%)	59 (77.6%)	52 (83.9%)
Eye protection (n= 77)	17 (22.1%)	11 (17.5%)	5 (6.5%)	3 (4.8%)	11 (14.3%)	9 (14.3%)	44 (57.1%)	40 (63.5%)
Respirator (n=77)	7 (9.1%)	4 (6.3%)	4 (5.2%)	2 (3.2%)	11 (14.3%)	8 (12.7%)	55 (71.4%)	49 (77.8%)

Handling Excreta								
Chemotherapy gloves (n=91)	64 (70.3%)	54 (77.1%)	7 (7.7%)	4 (5.7%)	2 (2.2%)	4 (5.7%)	18 (19.8%)	8 (11.4%)
Other gloves (n=74)	13 (17.8%)	6 (10.5%)	2 (2.7%)	3 (5.3%)	6 (8.2%)	1 (1.8%)	53 (71.6%)	47 (82.5%)
Double gloves (n=76)	7 (9.2%)	9 (15.3%)	6 (7.9%)	8 (13.6%)	11 (14.5%)	9 (15.3%)	52 (68.4%)	33 (55.9%)
Chemotherapy gown (n=77)	16 (20.8%)	16 (27.6%)	16 (20.8%)	13 (22.4%)	22.1 (13%)	11 (18.9%)	28 (36.4%)	18 (31%)
Other gown (e.g. isolation) (n= 76)	7 (9.2%)	3 (5.2%)	12 (15.8%)	11 (19.0%)	11 (14.4%)	7 (12.0%)	46 (60.5%)	37 (63.8%)
Re-used disposable gowns (n=74)	0	3 (5.5%)	7 (9.5%)	1 (1.8%)	7 (9.5%)	5 (12.1%)	60 (81.1%)	46 (83.6%)
Eye protection (n=75)	11 (14.7%)	10 (17.2%)	2 (2.6%)	3 (5.1%)	19 (25.3%)	7 (12.1%)	43 (57.3%)	38 (65.5%)
Respirator (n=74)	4 (5.4%)	5 (8.8%)	3 (4.1%)	3 (5.3%)	14 (19%)	8 (14.0%)	53 (71.6%)	41 (71.9%)

Table 3: Exposure Knowledge Measures

Question	True (N, %)	False (N, %)	Don't Know (N, %)
1. Chemotherapy can enter the body through breathing it in			
Pre (N = 98)	**73 (74.5%)**	12 (12.2%)	13 (13.3%)
Post (N = 71)	**55 (77.5%)**	11 (15.5%)	5 (7.0%)
2. Chemotherapy can enter the body through ingesting it			
Pre (N=99)	**97 (98%)**	0	2 (2%)
Post (N=70)	**69 (98.6%)**	0	1 (1.4%)
3. Chemotherapy cannot enter the body through contact with contaminated surfaces			
Pre (N=99)	16 (16.2%)	**75 (75.8%)**	8 (8.1%)
Post (N=70)	20 (28.6%)	**48 (68.6%)**	2 (2.9%)
4. Chemotherapy can enter the body through contact with spills and splashes			
Pre (N=99)	**99 (100%)**		
Post (N=71)	**70 (98.6%)**	1 (1.4%)	0
5. Chemotherapy gas and vapor in air can enter the body through the skin			
Pre (N=99)	**61 (61.6%)**	8 (8.1%)	30 (30.3%)
Post (N=71)	**48 (67.6%)**	11 (15.5%)	12 (16.9%)
6. Oral forms of chemotherapy do not have the potential to be absorbed			
Pre (N=99)	1 (1%)	**94 (94.9%)**	4 (4%)
Post (N=71)	3 (4.2%)	**68 (95.8%)**	0
7. Chemotherapy in liquid form can be absorbed through the skin			
Pre (N=99)	**94 (94.9%)**	3 (3%)	2 (2%)
Post (N= 70)	**68 (97.1%)**	1 (1.4%)	1 (1.4%)
8. A surgical mask provides protection from chemotherapy aerosols			
Pre (N= 99)	33 (33.3%)	**41 (41.4%)**	25 (25.3%)
Post (N=71)	21 (29.6%)	**38 (53.5%)**	12 (16.9%)
9. All types of gloves provide the same level of protection			
Pre (N=99)	1 (1%)	**97 (98%)**	1 (1%)
Post (N=70)	0	**70 (100%)**	0
10. Chemotherapy can more easily enter the body through damaged skin			
Pre (N=98)	**98 (100%)**		
Post (N=71)	**69 (97.2%)**	1 (1.4%)	1 (1.4%)
11. Alcohol hand sanitizer is as effective as soap and water in removing chemotherapy residue			
Pre (N=99)	6 (6.1%)	**83 (83.8%)**	10 (10.1%)
Post (N=71)	7 (9.9%)	**61 (85.9%)**	3 (4.2%)
12. Chemotherapy can enter the body through contaminated foods, beverages, or cosmetics			

Pre (N=99)	**79 (79.8%)**	4 (4%)	16 (16.2%)
Post (N=70)	**60 (85.7%)**	3 (4.3%)	7 (10%)

***Correct answer bolded**

Table 4: Self-efficacy Measures

Question	Strongly Agree (N, %)	Agree (N, %)	Disagree (N, %)	Strongly Disagree (N, %)
1. I am confident that I can use PPE properly				
Pre (N=98)	61 (62.9%)	32 (32.7%)	4 (4.1%)	1 (1%)
Post (N=70)	52 (74.3%)	16 (22.9%)	2 (2.9%)	0
2. I am confident that I can protect myself from chemotherapy exposure				
Pre (N=99)	46 (46.5%)	45 (45.5%)	7 (7.1%)	1 (1%)
Post (N=70)	38 (54.3%)	30 (42.9%)	2 (2.9%)	0
3. I am given enough information on how to protect myself from chemotherapy exposure				
Pre (N=99)	52 (52.5%)	35 (35.4%)	10 (10.2%)	2 (2%)
Post (N=70)	40 (57.1%)	26 (37.1%)	4 (5.7%)	0
4. My supervisor goes out of his/her way to make sure I am protected				
Pre (N=99)	24 (24.2%)	48 (48.5%)	24 (24.2%)	3 (3%)
Post (N=70)	22 (31.4%)	40 (57.1%)	7 (10%)	1 (1.4%)
5. Reusing disposable PPE makes me feel less protected				
Pre (N=99)	41 (41.4%)	37 (37.4%)	18 (18.2%)	3 (3%)
Post (N=69)	31 (44.9%)	24 (34.8%)	12 (17.4%)	2 (2.9%)
6. I am provided with the best available PPE				

Pre (N=98)	33 (33.7%)	52 (53.1%)	12 (12.2%)	1 (1%)
Post (N=70)	30 (42.9%)	31 (44.3%)	9 (12.9%)	0
7. My supervisor goes out of his/her way to make sure I am provided with proper fitting PPE				
Pre (N=99)	25 (25.3%)	52 (52.5%)	17 (17.2%)	5 (5.1%)
Post (N=70)	22 (31.4%)	37 (52.9%)	10 (14.3%)	1 (1.4%)

Table 5: Perceived Barriers

Question	Strongly Agree (N, %)	Agree (N, %)	Disagree (N, %)	Strongly Disagree (N, %)
1. I don't think PPE is necessary				
Pre (N=99)	0	0	21 (21.2%)	78 (78.8%)
Post (N=71)	0	0	17 (23.9%)	54 (76.1%)
2. I don't think PPE works				
Pre (N=99)	0	0	29 (29.6%)	70 (70.7%)
Post (N=71)	0	0	20 (28.2%)	51 (71.8%)
3. I don't have the time to use PPE				
Pre (N=99)	0	8 (8.2%)	33 (33.7%)	58 (58.6%)
Post (N=70)	0	2 (2.9%)	29 (41.4%)	39 (55.7%)
4. PPE is uncomfortable to wear				
Pre (N=98)	2 (2%)	35 (35.7%)	28 (28.6%)	33 (33.7%)
Post (N=71)	6 (8.5%)	28 (39.4%)	17 (23.9%)	20 (28.2%)
5. PPE makes it harder to get the job done				
Pre (N=99)	2 (2%)	11 (11.1%)	45 (45.5%)	41 (41.4%)
Post (N=71)	3 (4.2%)	19 (26.8%)	24 (33.8%)	25 (35.2%)
6. PPE is not always available				
Pre (N=99)	0	10 (10.1%)	41 (41.4%)	48 (48.5%)
Post (N=71)	1 (1.4%)	11 (15.5%)	28 (39.4%)	31 (43.7%)
7. Others around me don't use PPE				
Pre (N=99)	5 (5.1%)	32 (32.3%)	31 (31.3%)	31 (31.3%)
Post (N=71)	1 (1.4%)	19 (26.8%)	30 (42.3%)	21 (29.6%)
8. There is no policy				

requiring PPE				
Pre (N=98)	1 (1%)	3 (3.1%)	44 (44.9%)	50 (51%)
Post (N=71)	1 (1.4%)	1 (1.4%)	30 (42.3%)	39 (54.9%)
9. People would think I'm overly cautious				
Pre (N=99)	1 (1%)	23 (23.2%)	38 (38.4%)	37 (37.4%)
Post (N=71)	5 (7.0%)	11 (15.5%)	33 (46.5%)	22 (31.0%)
10. It is hard to get chemotherapy-designated PPE				
Pre (N=99)	0	3 (3%)	50 (50.5%)	46 (46.5%)
Post (N=71)	0	2 (2.8%)	35 (49.3%)	34 (47.9%)
11. PPE is too expensive to use it all the time				
Pre (N=97)	0	6 (6.2%)	41 (42.3%)	50 (51.5%)
Post (N=70)	0	3 (4.3%)	29 (41.4%)	38 (54.3%)
12. PPE makes me feel too hot				
Pre (N=99)	12 (12.1%)	42 (42.4%)	24 (24.2%)	21 (21.2%)
Post (N=71)	9 (12.7%)	36 (50.7%)	16 (22.5%)	10 (14.1%)

Table 6: Perceived Risk

Question	Strongly Agree (N, %)	Agree (N, %)	Disagree (N, %)	Strongly Disagree (N, %)
1. Chemotherapy exposure is not as harmful as some people claim				
Pre (N=97)	0	5 (5.2%)	58 (60.4%)	34 (35.1%)
Post (N=70)	0	3 (4.3%)	38 (54.3%)	29 (41.4%)
2. Compared to other work-related health risks, chemotherapy exposure is less serious				
Pre (N=98)	0	6 (6.1%)	61 (62.2%)	31 (31.6%)
Post (N=71)	2 (2.8%)	4 (5.6%)	41 (57.7%)	24 (33.8%)
3. I am not worried about future negative health effects from chemotherapy exposure				
Pre (N=97)	2 (2.1%)	13 (13.4%)	52 (53.6%)	30 (30.9%)
Post (N=68)	2 (2.9%)	14 (20.6%)	32 (47.1%)	20 (29.4%)

Table 7a: Interpersonal Influence: PPE use in other groups
Measure: How often the following groups wear PPE when handling chemotherapy?

	Never (N, %)	Sometimes (N, %)	About Half (N, %)	Usually (N, %)	Does not apply (N, %)
Your co-workers					
Pre (N=99)	0	9 (9.1%)	8 (8.1%)	82 (82.8%)	0
Post (N=70)	0	5 (7.1%)	1 (1.4%)	63 (90.0%)	1 (1.4%)
Other nurses you know					
Pre (N=98)	0	12 (12.4%)	4 (4.1%)	74 (75.5%)	8 (8.2%)
Post (N=69)	0	4 (5.8%)	1 (1.4%)	57 (82.6%)	7 (10.1%)
Oncology nurses in general					
Pre (N=99)	0	9 (9.1%)	5 (5.1%)	80 (80.8%)	5 (5.1%)
Post (N=69)	0	3 (4.3%)	1 (1.4%)	56 (81.2%)	9 (13.0%)

Table 7b: Interpersonal Influence: PPE importance in other groups
Measure: How important wearing PPE is when handling chemotherapy to the following groups:

	Not at all important (N, %)	Sort of important (N, %)	Very Important (N, %)	Does not apply (N, %)
Your co-workers				
Pre (N=99)	0	23 (23.2%)	76 (76.8%)	0
Post (N=71)	0	8 (11.3%)	63 (88.7%)	0
Other nurses you know				
Pre (N=99)	0	21 (21.2%)	73 (73.7%)	5 (5.1%)
Post (N=69)	0	7 (10.1%)	59 (85.5%)	3 (4.3%)
Your supervisor or manager				
Pre (N=99)	0	12 (12.1%)	85 (85.9%)	2 (2%)
Post (N=62)	1 (1.4%)	2 (2.9%)	59 (95.7%)	0
Your employer				
Pre (N=97)	0	9 (9.3%)	87 (89.7%)	1 (1%)
Post (N=70)	1 (1.4%)	4 (5.7%)	65 (92.9%)	0

Table 8: Conflict of Interest

	Strongly Agree (N, %)	Agree (N, %)	Disagree (N, %)	Strongly Disagree (N, %)
1. Personal protective equipment keeps me from doing my job to the best of my abilities				
Pre (N=98)	1 (1%)	2 (2%)	52 (53.1%)	43 (43.9%)
Post (N=69)	0	4 (5.8%)	41 (59.4%)	24 (34.8%)
2. Wearing personal protective equipment makes my patients worry				
Pre (N=98)	0	19 (19.4%)	45 (45.9%)	34 (34.7%)
Post (N=69)	1 (1.4%)	17 (24.6%)	30 (43.5%)	21 (30.4%)
3. Patient care often interferes with my being able to comply with using precautions				
Pre (N=97)	1 (1%)	11 (11.3%)	50 (51.5%)	35 (36.1%)
Post (N=69)	1 (1.4%	7 (10.1%)	36 (52.2%)	25 (36.2%)
4. I cannot always use safe handling precautions because patient's needs come first				
Pre (N=98)	1 (1%)	16 (16.3%)	49 (50%)	32 (32.7%)9
Post (N=69)	1 (1.4%)	7 (10.1%)	37 (53.6%)	24 (34.8%)
5. Sometimes I have to choose between wearing PPE and caring for my patients				
Pre (N=98)	1 (1%)	14 (14.3%)	46 (46.9%)	37 (37.8%)
Post (N=69)	1 (1.4%)	12 (17.4%)	32 (46.4%)	24 (34.8%)
6. Wearing personal protective equipment makes my patients feel uncomfortable				
Pre (N=97)	0	16 (16.5%)	46 (47.4%)	35 (36.1%)
Post (N=69)	1 (1.4%)	10 (14.5%)	33 (47.8%)	25 (36.2%)

Table 9: Workplace Safety Climate

Question	Strongly Agree (N, %)	Agree (N, %)	Neutral (N, %)	Disagree (N, %)	Strongly Disagree (N, %)
1. Chemotherapy gloves are readily accessible in my work area					
Pre (N=99)	68 (68.7%)	23 (23.2%)	3 (3%)	3 (3%)	2 (2%)
Post (N=71)	50 (70.4%)	17 (23.9%)	2 (2.8%)	1 (1.4%)	1 (1.4%)
2. Chemotherapy gowns are readily accessible in my work area					
Pre (N=98)	64 (65.3%)	31 (31.6%)	1 (1%)	2 (2%)	0
Post (N=71)	42 (59.2%)	25 (35.2%)	4 (5.6%)	0	0
3. The protection of workers from occupational exposure to chemotherapy is a high priority with management where I work					
Pre (N=99)	41 (41.4%)	40 (40.4%)	14 (14.1%)	4 (4%)	0
Post (N=71)	27 (38.0%)	35 (49.4%)	6 (8.5%)	3 (4.2%)	0
4. On my unit, all reasonable steps are taken to minimize hazardous job tasks					
Pre (N=99)	38 (38.4%)	47 (47.5%)	9 (9.1%)	5 (5.1%)	0
Post (N=71)	28 (39.4%)	32 (45.1%)	10 (14.1%)	1 (1.4%)	0
5. Employees are encouraged to become involved in safety and health matters					
Pre (N=98)	32 (32.7%)	46 (46.9%)	15 (15.3%)	4 (4.1%)	1 (1%)
Post (N=71)	25 (35.2%)	36 (50.7%)	7 (9.9%)	3 (4.2%)	0
6. Managers on my unit do their part to insure employees' protection from occupational exposure to chemotherapy					
Pre (N=99)	32 (32.3%)	45 (45.5%)	11 (11.1%)	10 (10.1%)	1 (1%)
Post (N=71)	24 (33.8%)	37 (52.1%)	8 (11.3%)	2 (2.8%)	0
7. My job duties do not often interfere with my being able to follow chemotherapy safe					

handling precautions					
Pre (N=98)	29 (29.6%)	52 (53.1%)	12 (12.2%)	4 (4.1%)	1 (1%)
Post (N=71)	26 (36.6%)	35 (49.3%)	4 (5.6%)	6 (8.5%)	0
8. I have enough time in my work to always follow chemotherapy safe handling precautions					
Pre (N=99)	22 (22.2%)	44 (44.4%)	17 (17.2%)	14 (14.1%)	2 (2%)
Post (N=70)	17 (24.3%)	37 (52.9%)	7 (10.0%)	8 (11.4%)	1 (1.4%)
9. I usually do not have too much to do so that I can follow chemotherapy safe handling precautions					
Pre (N=99)	12 (12.1%)	32 (32.3%)	26 (26.3%)	18 (18.2%)	11 (11.1%)
Post (N=70)	9 (12.9%)	25 (35.7%)	12 (17.1%)	21 (30.0%)	3 (4.3%)
10. On my unit, unsafe work practices are corrected by supervisors					
Pre (N=98)	15 (15.3%)	40 (40.8%)	28 (28.6%)	14 (14.3%)	1 (1%)
Post (N=70)	13 (18.6%)	40 (57.1%)	12 (17.1%)	5 (7.1%)	0
11. My supervisor talks to me about safe work practices					
Pre (N=98)	15 (15.3%)	35 (35.7%)	29 (29.6%)	16 (16.3%)	3 (3.1%)
Post (N=68)	11 (16.2%)	35 (51.5%)	17 (25.0%)	5 (7.4%)	0
12. I have had the opportunity to be trained to use personal protective equipment so that I can protect myself from chemotherapy exposures					
Pre (N=99)	35 (35.4%)	49 (49.5%)	9 (9.1%)	6 (6.1%)	0
Post (N=71)	23 (32.4%)	43 (60.6%)	4 (5.6%)	1 (1.4%)	0
13. Employees are taught to be aware of and to recognize potential health hazards at work					
Pre (N=99)	34 (34.3%)	51 (51.5%)	8 (8.1%)	6 (6.1%)	0
Post (N=71)	26 (36.6%)	38 (53.5%)	6 (8.5%)	1 (1.4%)	0
14. In my work area, I have access to policies and procedures regarding safety					
Pre (N=97)	35 (36.1%)	56 (57.7%)	5 (5.2%)	1 (1%)	0
Post (N=71)	26 (36.6%)	41 (57.7%)	3 (4.2%)	1 (1.4%)	0

15. My work area is kept clean					
Pre (N=99)	31 (31.3%)	45 (45.4%)	16 (16.2%)	5 (5.1%)	2 (2%)
Post (N=70)	21 (30.0%)	37 (52.9%)	6 (8.6%)	6 (8.6%)	0
16. My work area is not cluttered					
Pre (N=98)	29 (29.6%)	35 (35.7%)	18 (18.4%)	14 (14.3%)	2 (2%)
Post (N=70)	17 (24.3%)	31 (44.3%)	12 (17.1%)	10 (14.3%)	0
17. My work area is not crowded					
Pre (N=99)	30 (30.3%)	31 (31.3%)	20 (20.2%)	16 (16.2%)	2 (2%)
Post (N=71)	16 (22.%)	26 (36.6%)	13 (18.3%)	16 (22.5%)	0
18. There is minimal conflict within my work area					
Pre (N=97)	24 (24.7%)	50 (51.5%)	17 (17.5%)	4 (4.1%)	2 (2.1%)
Post (N=71)	16 (22.5%)	39 (54.9%)	11 (15.5%)	5 (7.0%)	0
19. The members of my work area support one another					
Pre (N=99)	39 (39.4%)	52 (52.5%)	7 (7.1%)	0	1 (1%)
Post (N=71)	24 (33.8%)	40 (56.3%)	7 (9.9%)	0	0
20. In my work area, there is open communication between supervisors and staff					
Pre (N=98)	20 (20.4%)	46 (46.9%)	15 (15.3%)	12 (12.2%)	5 (5.1%)
Post (N=70)	20 (28.6%)	36 (51.4%)	6 (8.6%)	7 (10.0%)	1 (1.4%)
21. In my work area we are expected to comply with safe handling policies and procedures					
Pre (N=99)	40 (40.4%)	56 (56.6%)	2 (2%)	1 (1%)	0
Post (N=70)	31 (44.3%)	38 (54.3%)	1 (1.4%)	0	0

Table 10: Respondents Mean Scores for Predictor Variables

Variable	Mean (SD) Pre-Test	Mean (SD) Post-Test	Previous Study Results Mean (SD)(Polovich & Clark, 2012a)	Observed Range	Possible Range	Meaning
Exposure knowledge	9.8 (2.18)	10.2 (1.3)	10.9 (1.07)	5-12	0-12	Higher score=higher knowledge
Self-efficacy	22.1 (4.83)	23.2 (4.2)	20.8 (2.96)	12-28	7-28	Higher score=higher self-efficacy
Perceived barriers	20.0 (6.3)	21.1 (5.5)	21.94 (6.5)	12-34	12-48	Higher score=higher perceived barriers
Perceived risk	3.11 (0.75)	3.15 (0.6)	3.14 (0.58)	2-4	0-4	Higher score=higher perceived risk
Interpersonal influence	2.09 (0.54)	2.16 (0.44)	2.21 (0.44)	1-2.4	0-3	Higher score= more positive view of coworker attitudes
Conflict of interest	1.70 (0.64)	1.77 (0.67)	1.83 (0.62)	1-2.5	1-4	Higher score=higher conflict
Workplace safety climate	61.2 (15.4)	64.2 (11.4)	88.39 (12.03)	38-84	0-84	Higher score=better safety climate

Table 11: Results of Univariate Regressions: Factors Influencing Personal Protective Equipment Use

	Pre		Post	
Variable	Parameter Estimate	Confidence Interval	Parameter Estimate	Confidence Interval
Age	-0.16	-0.48, 0.16	-0.29	-0.59, 0.01
Years of Oncology Experience	-0.04	-0.36, 0.29	0.02	-0.33, 0.37
Knowledge	2.56	0.54, 4.6*	0.8	-2.14, 3.74
Patients[1]	0.67	0.3, 1.04	0.21	-0.23, 0.64
Patients[2]	-1.78	-3.5, -0.10	-1.35	-3.7, 1.0
Gender			4.5	-6.80, 15.7
Perceived Barriers	-1.1	-1.66, -0.5*	-1.02	-1.7, -0.34*
Perceived Risk	-0.57	-1.8, -0.67*	3.06	-3.46, 9.57
Self-Efficacy	1.8	0.89, 2.7*	0.99	0.08, 1.9*
Safety Climate	0.6	0.35, 0.85*	0.46	0.13, 0.79*
Interpersonal Influence	0.11	-1.0, 1.2	0.78	-0.50, 2.05
Conflict of Interest	-1.1	-2.08, -0.15*	0.67	-1.65, 0.30
Bone Marrow Transplant	Reference		Reference	
Pharmacy	20.3	8.96, 31.7*	-5.34	-18.1, 7.5
Inpatient Oncology	-10.8	-18.0, -3.6*	-15.76	-25.0, -6.6*
Outpatient Infusion	-14.5	-23.0, -6.1*	-9.84	-19.7, -0.02*

1=The regression includes both nurses and pharmacists

2= The regression is restricted to nurses

*=Statistically significant

Table 12: Results of Multivariate Regression: Factors Influencing Personal Protective Equipment Use Score at Pretest and Posttest and as a Difference Score

Primary Independent Variables	PPE Use Pretest Score Parameter Estimates (95% CI†)	PPE Use Posttest Score Parameter Estimates (95% CI)	PPE USE Difference Score Parameter Estimates (95% CI)
Unit[1]	Pretest	Posttest	Posttest - Pretest
1. Bone Marrow Transplant	Reference	Reference	Reference
2. Pharmacy	17 (3.7, 30.3)*	-10.9 (-22.9, 1.02)	2.46 (-29.96, -1.13)
3. Oncology	-8.9 (-17.2,-0.6)*	-11.95 (-20.9,-3.0)*	-4.0 (-13.06, 5.66)
4. Masonic Outpatient	-10.6 (-20.3,0.9)*	-6 (-15.8, 3.8)	2.46 (-9.03, 13.94)
Self-Efficacy[2]	1.4 (0.36, 2.45)*	0.53 (-0.34, 1.41)	-0.26 (-1.69, 1.18)
Workplace Safety Climate[3]	0.23 (-0.10, 0.55)	0.19 (-0.19, 0.57)	0.19 (-0.28, 0.66)
Workplace Safety Climate[4]	0.5 (0.19, 0.81)*	0.18 (-0.21, 0.58)	0.18 (-0.30, 0.66)
Perceived Barriers[5]	-0.47 (-1.1, 0.18)	-0.54 (-1.32, 0.23)	-0.56 (-1.43, 0.31)

1= Controlling for perceived barriers, safety climate, interpersonal influence, age and gender
2= Controlling for perceived barriers, age and gender
3= Controlling for unit, perceived barriers, interpersonal influence, age and gender
4= Controlling for perceived barriers, interpersonal influence, age and gender
5=Controlling for unit, safety climate, interpersonal influence, age and gender
†= Confidence Interval
* = Statistically significant

Table 13: Paired T-Test Results: Comparison of Personal Protective Equipment Use and Predictor Variable Use Pre and Post Intervention

Variable	T-Value	95% Confidence Interval
PPE Use by Unit		
Outpatient Infusion*	2.43	0.81, 18.3
Bone Marrow Transplant	1.79	-0.50, 7.66
Oncology	-0.03	-4.49, 4.37
Pharmacy	0.72	-5.2, 9.5
PPE Score (all units combined)	0.48	-4.67, 2.87
Knowledge Score	1.06	-0.58, 0.18
Self-Efficacy*	2.33	-1.58, -0.12
Perceived Barriers	1.24	-2.08, 0.48
Perceived Risk*	13.58	1.19, 1.60
Conflict of Interest	0.61	-0.59, 1.11
Interpersonal Influence	-0.64	-0.89, 0.46
Safety Climate	0.56	-1.51, 2.69

*Statistically Significant

Table 14: Surface Contamination Results

Location	Antineoplastic Drug Tested	Results: Pretest	Results: Posttest	Results: Intervention
Pharmacy Area A				
Chemotherapy Tote	Cyclophosphamide[1] Gemcitabine[2]	< Limit of Detection (LOD)	< Limit of Detection (LOD)	-
Plastic Drug Bin	Cyclophosphamide Gemcitabine	< LOD	< LOD	-
Biohazard Lid	Cyclophosphamide Gemcitabine	< LOD	< LOD	-
Chemotherapy Pad	Cyclophosphamide Gemcitabine	< LOD	< LOD	-
Cyclophosphamide Bin	Cyclophosphamide		<LOD	-
Gemcitabine Bin	Gemcitabine	<LOD	<LOD	-
Outpatient Pharmacy B/Nursing Infusion Center				
Break room Table	Paclitaxel[3] Gemcitabine[2]	< LOD < LOD	< LOD < LOD	-
Nursing Desk Pod A	Paclitaxel Gemcitabine	< LOD	< LOD	-
Floor under Laundry Bin	Paclitaxel Gemcitabine	**0.03 ng/cm^2** < LOD	**0.13ng/cm^2** < LOD	**-**
Patient Chair Armrest Following Paclitaxel Infusion- DIRTY	Paclitaxel	**0.02ng/cm^2**	< LOD	**-**
Patient Chair Armrest Following Gemcitabine Infusion- CLEAN	Gemcitabine	< LOD	< LOD	-
Pharmacy to Nursing Drug Bins	Paclitaxel Gemcitabine	< LOD < LOD	< LOD < LOD	-
Nursing to Pharmacy Counter under	Paclitaxel	**0.05ng/cm^2**	< LOD	**-**

Bin Return	Gemcitabine	< LOD	**< LOD**	
Pharmacy Negative Pressure Room Counter	Paclitaxel	< LOD	< LOD	-
	Gemcitabine	< LOD	< LOD	
Pharmacy Negative Pressure Room Floor	Paclitaxel	< LOD	**0.08ng/cm²**	
	Gemcitabine	< LOD	<LOD	
Chemo Cart	Paclitaxel[3]	-	-	<LOD
Computer Cart	Paclitaxel	-	-	<LOD
Outpatient Bottom Drawer 1	Paclitaxel	-	-	<LOD
Outpatient Bottom Drawer 2	Paclitaxel	-	-	<LOD
Inpatient Oncology				
Room Keyboard	Ifosfamide[4]	<LOD	<LOD	-
	Etoposide[5]	<LOD	<LOD	
	Methotrexate[6]	<LOD	<LOD	
Bathroom Wall	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Methotrexate	<LOD	<LOD	
Nurses Cart	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Methotrexate	<LOD	<LOD	
Nurses Station Counter Opposite Charge (Place Chemotherapy Double-Checked)	Ifosfamide	**0.06ng/cm²**	<LOD	**-**
	Etoposide	<LOD	<LOD	
	Methotrexate	<LOD	<LOD	
Med Room Refrigerated Chemo Bin A-M	Ifosfamide	<LOD	**0.63 ng/cm²**	-
	Etoposide	<LOD	**0.29 ng/cm²**	
	Methotrexate	<LOD	<LOD	
Lid of Biohazard Bin	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Methotrexate	<LOD	<LOD	

7D Charge Desk Counter Spot A	Ifosfamide[2]	-	-	**0.008 ng/cm^2**
7D Charge Desk Counter Spot B	Ifosfamide	-	-	<LOD
7D Bag of Ifosfamide Front	Ifosfamide	-	-	**34.4ng/cm^2**
7D Bag of Ifosfamide Back	Ifosfamide	-	-	**9.42ng/cm^2**
Inpatient Bone Marrow Transplant				
Cleaning Cart after Cleaning Chemo Precautions Room	Ifosfamide[4]	<LOD	<LOD	-
	Etoposide[5]	<LOD	<LOD	
	Cyclophosphamide[7]	<LOD	<LOD	
Patient Side Table	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Cyclophosphamide	**0.008ng/cm^2**	<LOD	
Nurses Station Printer Keyboard	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Cyclophosphamide	<LOD	<LOD	
Physician’s Workroom Door handle and KeyPad	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Cyclophosphamide	<LOD	<LOD	
Cordless Phones at Nurses’ Station	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Cyclophosphamide	<LOD	<LOD	
Cytocart (Chemotherapy Supplies)	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Cyclophosphamide	<LOD	<LOD	
BMT Pt Bathroom Floor (Left)	Cyclophosphamide[1]	-	-	**0.18 ng/cm^2**
BMT Pt Bathroom Floor (Right)	Cyclophosphamide	-	-	**0.35 ng/cm^2**
BMT Chemo Cart Spot A	Cyclophosphamide	-	-	**0.12 ng/cm^2**

BMT Chemo Cart Spot B	Cyclophosphamide	-	-	<LOD

[1] Limit of Detection = 0.015 Nanograms/cm^2

[2] Limit of Detection = 0.005 Micrograms/cm^2

[3] Limit of Detection = 0.010 Nanograms/cm^2

[4] Limit of Detection = 0.005 Nanograms/cm^2

[5] Limit of Detection = 0.10 Nanograms/cm^2

[6] Limit of Detection = 0.005 Nanograms/cm^2

[7] Limit of Detection = 0.005 Nanograms/cm^2

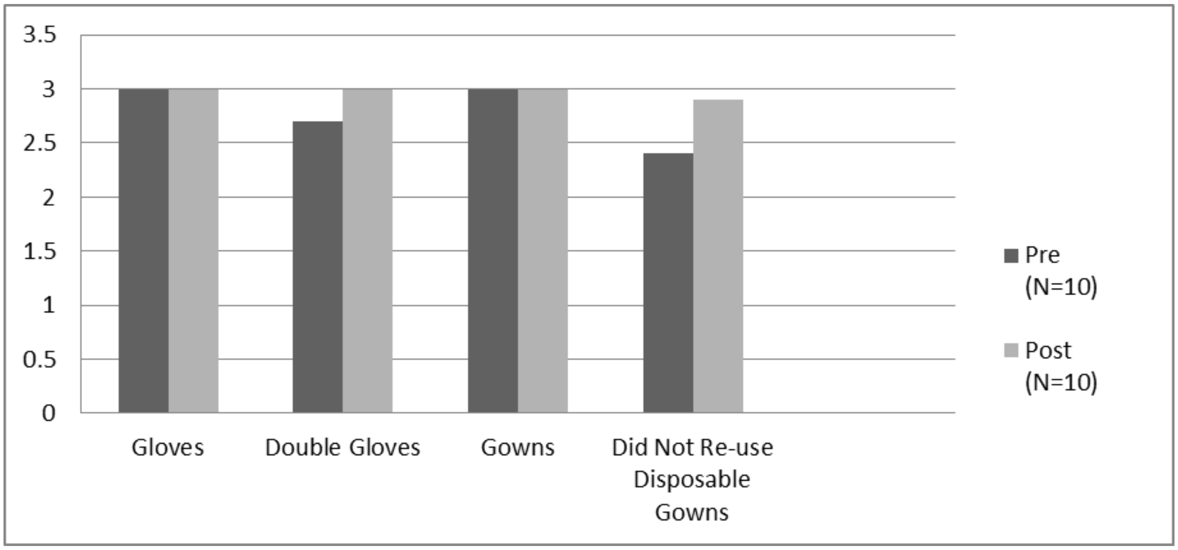


Figure 5: Reported PPE Use Score during Preparation of Antineoplastic Agents

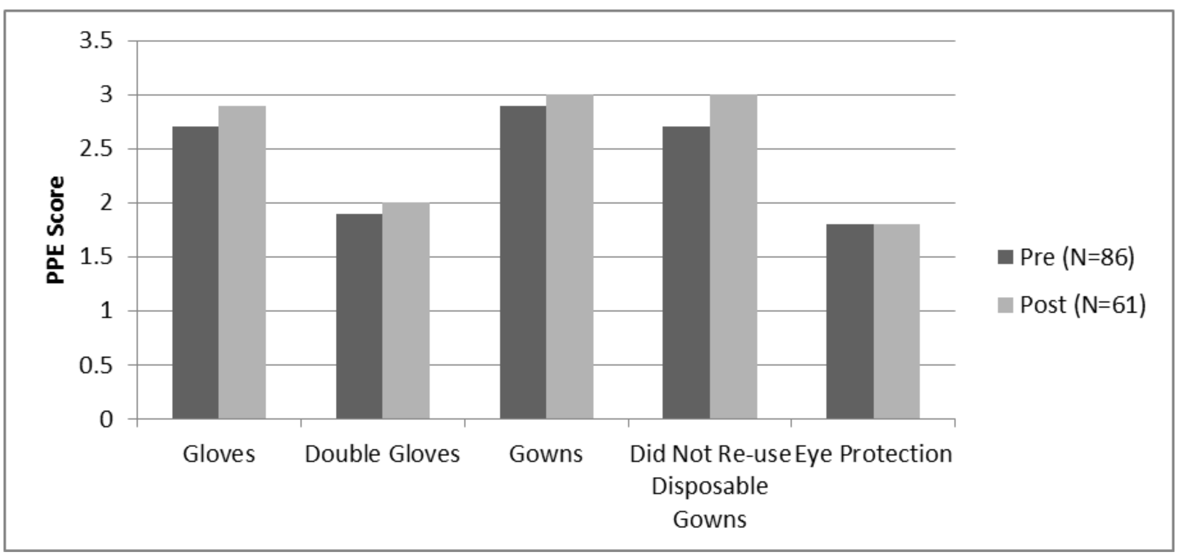


Figure 6: Reported PPE Use Score during Administration of Antineoplastic Agents

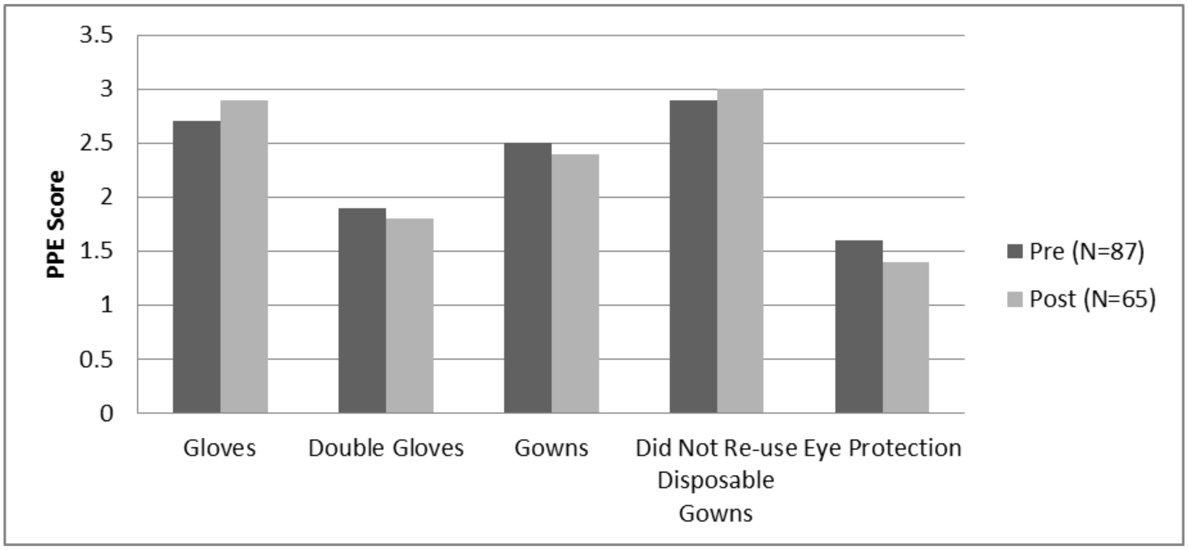


Figure 7: Reported PPE Use Score during Disposal of Antineoplastic Agents

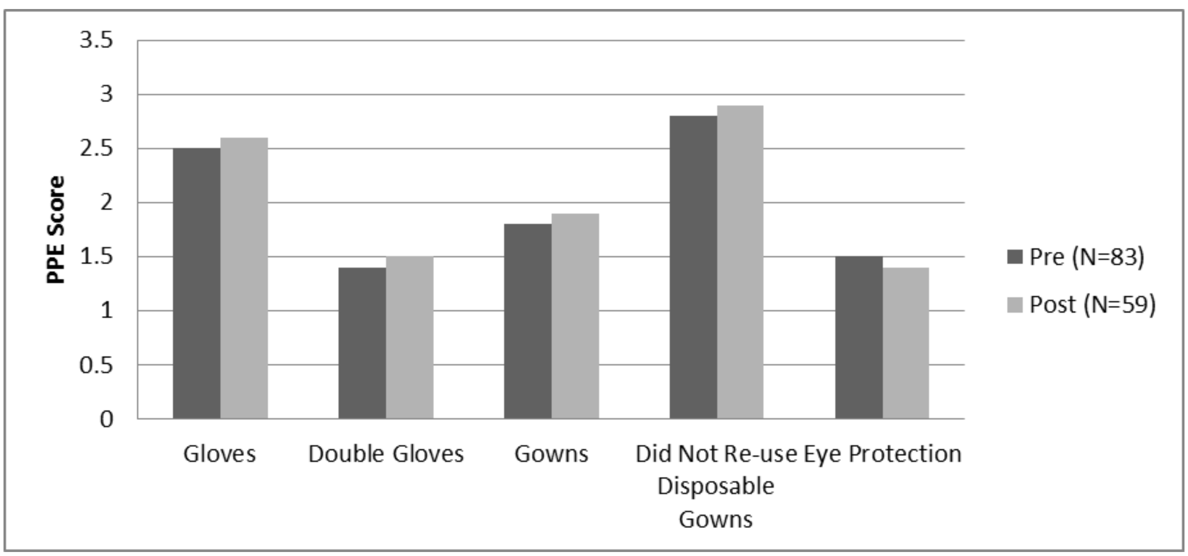


Figure 8: Reported PPE use Score While Handling Excreta from Patients who have had Antineoplastic Agents

CHAPTER 6: PAPER 1, OCCUPATIONAL EXPOSURE TO ANTINEOPLASTIC AGENTS: AN ANALYSIS OF HEALTHCARE WORKERS AND THEIR ENVIRONMENTS

Abstract

Background: Approximately 8 million health care workers are potentially, unnecessarily exposed to the highly toxic drugs used to treat cancer leading to serious, negative health effects. Antineoplastic drugs have been detected in the urine of workers and on the floors and counters of worksites. Additionally, safety precautions that could reduce their risk of exposure are underutilized by workers.

Objective: To identify potential exposures to antineoplastic drugs and factors influencing safety behavior among health care workers.

Methods: This was a cross-sectional study of 163 oncology healthcare workers in one health care setting. A survey measured workplace and individual factors potentially associated with personal protective equipment (PPE) use. Potential confounders were determined and accounted for in multivariate regressions. Environmental samples were tested for surface contamination.

Findings: PPE use was lower than federal recommendations and unit of employment was significantly associated with PPE use. Chemical residue from antineoplastic drugs was found in several areas, revealing potential exposure for workers. Workplace safety must be a higher organizational priority to influence PPE use. The contamination of common work areas where health care workers are not expected to use PPE was of utmost concern.

Implications for Nursing Practice

1. Healthcare workers need to understand the risks associated with handling antineoplastic agents and follow safe handling guidelines to prevent unnecessary exposures.

2. Surface monitoring should occur on a routine basis to understand where unnecessary exposures may be occurring.

3. Improvement of safe handling of antineoplastic agents should involve management and all staff members in order to affect workplace safety climate.

Introduction

Antineoplastic drugs are critical to the more than 11 million people diagnosed with cancer worldwide each year (Connor, 2006). These drugs can improve quality of life, decrease length of illness, and cure cancer (American Cancer Society, 2015). Increasingly, the drugs are also being used for other diseases such as Rheumatoid Arthritis, Nephritis, Multiple Sclerosis and Lupus (Vioral & Kennihan, 2012). Use of the drugs has also expanded to more frequent administration in outpatient settings, homes and in veterinary medicine (Hall et al., 2013). A new forecast has predicted that as a result of the aging US population, the number of cancer cases may double by 2050, resulting in an increase in the use of antineoplastic drugs (Edwards et al., 2002).

The toxicity and health risks associated with antineoplastic drugs are well understood (Boiano et al., 2014; Polovich & Clark, 2012a). The International Agency for Research on Cancer (IARC) has identified a number of antineoplastic drugs as carcinogenic to humans (Group 1), probably carcinogenic to humans (Group 2a), or possibly carcinogenic to humans (Group 2b) (Turci, Sottani, Spagnoli, & Minoia, 2003). Healthcare workers are incurring the exposures on a repeated basis and often for many years. Even a small exposure of such toxic drugs can cause adverse outcomes to the more than 8 million healthcare workers potentially exposed (Connor et al., 2010; Vioral & Kennihan, 2012). Beginning in the 1970's, evidence has indicated that health care workers were at risk of harmful effects from their occupational exposure to antineoplastic drugs (National Institute for Occupational Safety and Health, 2004). These include acute effects such as skin rashes, nausea, hair loss, abdominal pain, nasal sores, allergic reactions, skin or eye injury and dizziness (B. G. Valanis, Vollmer WM FAU - Labuhn,K T., Labuhn KT FAU - Glass,A G., & Glass, 1993). Chronic effects linked with exposure have included reproductive harm such as delayed time to conception (Fransman et al., 2007) and spontaneous abortion (Lawson et al., 2012), genotoxic changes (McDiarmid et al., 2010; Rekhadevi et al., 2007; Villarini et al., 2011), and cancers (Skov et al., 1992). Secondary tumor risks for patients receiving these drugs have been confirmed by several studies and patients are warned of these risks (Deniz et al., 2003; Josting et al., 2003; Sherins & DeVita, 1973; Spiers et al., 1983). For patients with cancer, the benefit of treatment outweighs the risk of a secondary malignancy in the future. For all others, it does not.

While the hazards associated with antineoplastic drugs are recognized, there is not an accepted safe level of exposure (Turci et al., 2003). Federal guidelines for safe handling of hazardous drugs were first published in 1986 and updated in 2004 by NIOSH (National Institute for Occupational Safety and Health, 2004). In addition, guidelines for safety of hazardous drugs are also published by the Oncology Nursing Society (Polovich,

2011) and the American Society of Health System Pharmacists (Polovich & Clark, 2012a). These guidelines are only recommendations and federal policies on safe handling practices for healthcare facilities are lacking. However, there have been recent state-based laws passed to standardize hazardous drug safety practices beginning in Washington in 2011 (Smith, 2011), with California (California Legislature, October 9, 2013), and North Carolina following (North Carolina Nurses Association, May 3, 2014). This lack of consistency in state policies may lead to differences in health care workers' knowledge and use of safe handling throughout sites of administration (Boiano et al., 2014; Environmental Working Group, 2007).

Studies have shown an improved rate of workers wearing gloves when handling antineoplastic drugs ever since the first safe handling guidelines were published in 1986 (Martin & Larson, 2003; Polovich & Martin, 2011a; Polovich & Clark, 2012a). However, a recent large study of health care workers conducted by NIOSH found that nearly one in seven of 2,069 respondents reported not always using gloves while handling antineoplastic agents (Boiano et al., 2014). These studies also found lower than recommended use of chemotherapy gowns and double gloving (Boiano et al., 2014; Martin & Larson, 2003; Polovich & Martin, 2011a). A study of 165 nurses published by Polovich also found PPE use varied by activity, with the lowest adherence to recommendations for use during activities involving the handling of patient excreta (Polovich & Clark, 2012a). Reasons for the lower than recommended uses of PPE are beginning to be considered by researchers (Friese et al., 2012; Polovich & Clark, 2012a). Two recent papers reported that organizational factors such as a workplace's positive safety culture, as well as a higher nurse to patient ratio can positively affect adoption of safe handling practices (Friese et al., 2012; Polovich & Clark, 2012a) in contrast to the lack of evidence supporting an association between individual characteristics and safe handling practices (Polovich & Clark, 2012a). A study published in the *Journal of Patient Safety* also found a link between employee safety climate and patient safety culture in health care, meaning improving one will inadvertently help improve the other (Mohr, Eaton, McPhaul, & Hodgson, 2015). There is scant intervention research to determine what strategies might translate into improved worker safety. To date, only one study has reported the results of an intervention to impact safer work practices by oncology nurses; Hennessy and Dylan (2014) reported findings from a program implemented at the Dana-Farber Cancer Institute, which improved compliance with PPE over time (Hennessy & Dynan, 2014). The program incorporated monitoring and reporting compliance of the use of PPE, and also engaged the staff in audit activities. Further research is needed to develop and test interventions that will minimize unnecessary worker exposure to hazardous drugs.

Objectives

The objectives of this study were to determine key factors influencing exposure to antineoplastic agents for nurse and pharmacy staff working in oncology and whether their work surfaces were contaminated with these agents. The central hypothesis, based on previous research, is that reported PPE use will be relatively higher for gloves, and lower for double gloving, donning gowns and using a face shield or mask (Boiano et al., 2014; Polovich & Clark, 2012a). It was also predicted that, consistent with other studies, organizational factors such as workplace safety climate will better predict PPE use than individual factors (Friese et al., 2012; Polovich & Clark, 2012a). It was also hypothesized that surface contamination with antineoplastic drugs would be present at about 50% of locations based upon results of a previous study done in university hospitals which found that 60% of antineoplastic drug wipe samples had contamination above the level of detection (Connor et al., 2010).

Methods

Research Design

The study adapted a model by Polovich which outlines factors associated with safe handling techniques for antineoplastic drug administration (Polovich & Clark, 2012a) in nurses and pharmacy staff potentially exposed to antineoplastic drugs at a university hospital and outpatient clinic. It combined a self-report staff survey with exposure assessment using area surface sampling to measure contamination from chemotherapy drugs. The population invited to participate in the survey was nurses, pharmacists and pharmacy technicians (N=163) from a university hospital's inpatient oncology and bone marrow transplant units and outpatient chemotherapy infusion center nursing and pharmacy areas (four units). The survey was offered online to staff for three weeks in October of 2014. Those who completed the survey were entered into a drawing for a $50 Visa Gift Card (one winner for each unit). Surface samples were collected in the areas in which the surveyed staff worked a day prior to the survey release. The University of Minnesota Institutional Review Board (IRB) reviewed and approved this study with an exempt status. Approval was also granted from the hospital's Nursing Research Council.

Environmental Assessment

Prior to collection of survey data, wipe samples for surface detection of chemotherapy were collected in patient care, nursing and pharmacy areas. Sampling locations were selected in relation to each job task associated with potential chemotherapy exposure: drug preparation, administration, disposal, and handling excreta. The sampling plan was reviewed by an experienced industrial hygienist who provided guidance on the planning and implementation of the exposure assessment and wipe sampling. Areas on each unit were tested based on work-flow and the locations in which the selected drugs were most commonly used. For example, the nursing desk in the inpatient oncology unit was tested based on charge nurse feedback that workers set their chemotherapy bags there to perform a double check for the right drug, right patient, right dose, right route and right time. Selection of the antineoplastic agents to be tested was based upon those agents with the highest volume of use, consistent with the approach used in similar studies (Connor et al., 2010). A total of 27 locations were tested, accounting for 65 unique antineoplastic agents by location combinations. The area of test sites was 200 cm^2 for this study based on recommendations from an exposure assessment consultant. Previous studies have used a 100 cm^2 area, which produced varied results. An exposure assessment tool, ChemoAlert™ (Bureau Veritas Laboratories, 2013), a custom kit designed to collect chemotherapy drug residues in healthcare workspaces for evaluation of contact exposure, was used for testing. This method was developed in response to the NIOSH Drug Alert and a housekeeping standard recommendation, USP 797 (Bureau Veritas Laboratories, 2013). Areas to be sampled were chosen with input from employees and management. The number of swab strokes was standardized for each sampling area. Two swabs were used for each area and placed in the same vial per lab recommendation. The lab provided a sample blank (solvent wetted and placed in a vial) that was not used to sample a surface to assure accurate testing.

Survey

Self-reported Survey Measures: The survey investigated personal factors such as age, race and years of experience and predictor variables such as knowledge, perceived risk, self-efficacy, conflict of interest, perceived barriers, workplace safety climate, and interpersonal influence to determine if these factors predicted reported use of safe handling techniques. Survey items were taken from instruments with established reliability and validity used in a previous study by Polovich (Polovich & Clark, 2012a).

Dependent or Outcome Variable: Use of Safe Handling Techniques were measured on a five-point scale with questions adapted from the Revised Hazardous Drug Handling Questionnaire (Polovich & Clark, 2012a), which was based on the current guidelines for safe handling (National Institute for Occupational Safety and Health, 2004). Questions asked about availability and use of PPE during four categories of potential exposure: preparation, administration, disposal, and handling patient excreta. PPE use questions were scored from 5 (always use) to 0 (never use). Higher scores showed higher use of PPE. Use of PPE was calculated as a score for each respondent based on their reply to the use of gloves, double gloves, gowns, whether or not they reused disposable gowns, eye and respiratory protection.

Independent Variables: Predictor Variables and their attributes are outlined in Table 1. These measures were adapted from Geer et al. (Geer et al., 2007) and Gershon et al. (Gershon et al., 1995; Gershon et al., 2007) and include perceived risk, self-efficacy, conflict of interest, perceived barriers, workplace safety climate, and interpersonal influence. Knowledge of the hazard was measured based on adaptation of the NIOSH Survey of Safe Handling for Workers and the Chemotherapy Exposure Knowledge Scale (Polovich & Clark, 2012a).

Pregnancy and alternative duty: Respondents were also asked whether or not they had been pregnant during their current job, and if so, whether they sought alternative duty because of their pregnancy. If they hadn't been pregnant, the survey asked if they thought they would seek alternative duty if they became pregnant. These questions were pilot tested with nursing management.

<u>Data Analysis</u>

Environmental Assessment

Analysis of wipe samples was performed by Bureau Veritas Laboratories based on each antineoplastic agent's unique level of detection.(Bureau Veritas Laboratories, 2013) Because there is no safe level of antineoplastic agent, any result over its level of detection was considered "contaminated" (Turci et al., 2003).

Survey

Descriptive analysis of the variables included calculation of frequency distributions, means and standard deviations. Univariate regression was used to assess the strength of the relationship between PPE use and age, years of oncology experience, unit, knowledge, perceived barriers, perceived risk, workplace safety climate, self-efficacy, interpersonal influence, and conflict of interest.

The regression model for multivariable estimation was based on the use of Directed Acyclic Graphs (DAGs) (Greenland, Pearl, & Robins, 1999). The purpose of using DAGs in observational studies (including cross-sectional studies) is to ensure the regression models address the aims of this study by understanding the causal assumptions and avoiding confounded models. DAGs visually display the underlying assumptions of the casual relationships between the exposure of interest, covariates, and the outcome of interest. This facilitated the selection of potential confounders for testing the casual association between specific exposures and the outcome, use of safe handling techniques.

Surveys were administered on-line and data stored securely using the Research Electronic Data Capture (REDCap) Data System (Harris, P.A., Thielke, R., Payne, Gonzalez, & Conde, 2009) which is hosted by The University of Minnesota.

Additionally, to identify any potential selection bias between respondents and non-respondents, a short survey was sent to individuals not completing the comprehensive survey by the deadline, which assessed unit, gender, age, years of experience, and PPE use during drug handling activities. The short survey did not address the predictor variables. The data analysis was generated using SAS software, Version 9.3 of the SAS System for PC (SAS Institute Inc., 2010).

Results

Environmental Assessment

Overall, there were five samples from a total of 62 that tested above the limit of detection (8%). The unit with the highest number of areas that tested positive was the outpatient chemotherapy infusion center, with three specific areas that tested as contaminated with chemotherapy. The inpatient bone marrow transplant and inpatient oncology units each had one area with high levels of contamination. One of the pharmacy areas had no positive samples, and the other pharmacy had one positive sample, which was a countertop shared between pharmacy and the outpatient chemotherapy infusion center. Table 2 shows results for the areas sampled.

Survey

Overall, the survey response rate was 62% of 163 employees, with each unit having a response rate of at least 57%. There were 11 of 19 pharmacy staff and 89 of 144 nurses who responded to the questionnaire. The average age of survey respondents was 38 and the sample was 85% Caucasian. Nurse respondents had about 12 years of nursing experience, 10.5 of which were reported to be oncology nursing experience. Forty-one percent of the nurse participants were oncology nursing certified. Demographic results are outlined in Table 3. The respondents to the full survey were similar to those who answered the short version of the survey with respect to average age (38 vs 36), years of experience (10.5 vs 12.5) and reported PPE use (combined measure score of 40 vs 40.3). Reported PPE use is outlined in Table 4. Overall, glove use was high; use of gowns and double gloving were lower, and use of respirator or eye protection lower still.

Multivariate regression models were estimated to determine the association of unit, self-efficacy, workplace safety climate, and perceived barriers respectively, with use of PPE. Potential confounding variables were identified with the aid of Directed Acyclic Graphs. The findings reveal that the unit one worked was significantly associated with use of PPE. Self-efficacy was also associated with PPE use after controlling for appropriate confounders. Two models of workplace safety climate were estimated which varied only by the inclusion or exclusion of the variable, unit. The findings revealed the model which did not include unit was statistically significant. Results of regression models are shown in Table 5.

Pregnancy and alternative duty

Twenty eight percent of respondents reported having been pregnant while working their current job, and four of these respondents reported having sought alternative duty. Of the 72% who have not been pregnant while employed at their current job, 33% reported that they would seek alternative duty if they became pregnant and 26% reported being unsure whether they would or not. Institutional policy is that alternative duty work will be provided if requested.

Discussion

Our findings revealed that the organizational unit where a nurse or pharmacist worked was the factor that was most strongly associated with use of personnel protective equipment when adjusting for other factors such as perceived barriers, safety climate, interpersonal influence, gender and age. Models estimating the relation of safety climate and perceived barriers to PPE use were not associated with PPE use when adjusted for organizational unit. Organizational unit is likely a proxy measure for many factors potentially influencing workplace safety, including variables for which we lacked data such as staffing ratios. Our results showed that workplace safety climate was associated with PPE use, and the association was graded for each organizational unit, as workplace safety climate score increased, PPE use also increased and perceived barriers decreased. The association between safety climate and PPE use is consistent with a previous study using the "Factors for Determining Use of Antineoplastic Drug Safe Handling Techniques" (Polovich & Clark, 2012a) model and studies of workplace safety climate in diverse industries including healthcare (Christian, Bradley, Wallace, & Burke, 2009; Friese et al., 2012; Polovich & Clark, 2012a; Zohar, 2010). Use of PPE, a proxy for safe handling techniques, was highest for pharmacy staff and nurses who worked on the bone marrow transplant (BMT) floor. The nurses who worked on the BMT floor also reported caring for the lowest number of patients during a shift, and the pharmacy environment does not involve direct patient care. The unit with the highest number of contaminated areas was the outpatient chemotherapy infusion center with three areas that tested positive for chemotherapy residue. These included a counter in between the outpatient nursing area and the pharmacy area where antineoplastic agents are picked up by nurses, the floor under a laundry bin and an arm rest of a patient chair following Paclitaxel infusion. The inpatient bone marrow transplant (BMT) and inpatient oncology units each had one area with surface contamination. In the BMT unit it was a patient's bedside table that showed detectable levels of chemotherapy residue. In the inpatient oncology unit the area of contamination was at the nurses' station desk where chemotherapy is double-checked for patient safety with the computer chart prior to bringing it in a patient room. It was this latter finding that was of most concern among all the surface wipe samples as it had the highest level of contamination, and it was a space frequently used by multiple healthcare staff without wearing PPE. Additionally, drink containers have been placed on and near this area, raising questions about potential exposure through dermal absorption and possibly ingestion as well.

The differences found in PPE use and surface levels of chemotherapy residue between the pharmacy and nursing work environments were unexpected and curious. It may be partially due to the different job tasks performed by each discipline. Nurses performed multiple job tasks involving chemotherapy which required the use of PPE including drug administration, and the disposal and handling of patient excreta. Such tasks typically involve many interruptions. In contrast, the pharmacists' contact with chemotherapy primarily involved drug preparation, a specific job task, which is done without patient and family member interruption. Because this is one of the only studies the authors found that surveyed both nursing and pharmacy staff, additional research is needed to see if these differences are replicated in other oncology settings.

Survey results regarding reported PPE use were similar to other published studies where glove use was high and double gloving was much lower (Boiano et al., 2014; Polovich & Clark, 2012a). This is likely because double gloving takes extra time and may make tasks more cumbersome. It also confirmed other studies findings that PPE use varied by task, with preparation and administration having much higher use of PPE than disposal or handling patient excreta. This is likely due to the nature of the activities —administration is often a planned event, whereas disposal and handling body fluids are more dynamic.

Predictor variable scores for this study were compared with findings from the study by Polovich who used a national sample of outpatient nurses (Polovich & Clark, 2012a). Results were similar between the studies. Overall, knowledge of the exposure and self-efficacy scores were high. Conflict of interest and perceived barriers were low. Workplace safety climate scores were moderate, and lower than the mean of the Polovich study (Polovich & Clark, 2012a).

The number of nurses who felt that they would ask for alternative duty if they became pregnant was much higher than the number who actually did ask. It's unclear if this is because priorities change once staff members become pregnant, if there was social desirability bias, i.e., the survey somehow suggested that they should ask, or if staff members who work on these units and enjoy their job and their patient population find it difficult to imagine asking for alternative duty and working elsewhere in the hospital or they worry about any unanticipated longer-term job consequences of asking for it.

Limitations

There are important limitations to be noted when interpreting this study. While the PPE use and answers to the predictor variables of the non-responders is unknown, it may be hypothesized that they would score lower on the workplace safety climate measure (as they didn't take the time to complete the survey). Those who responded to the short survey did report equal PPE use; however this was a small group of ten respondents. Because better workplace safety climate was correlated with higher PPE use, it might also mean that these non-responders may have slightly lower use of PPE during safe handling. While the survey did have responses from the majority of staff in each area, the responses were from individuals working in one institution thus the generalizability of the study findings to other settings is unknown. Ultimately the study needs to be replicated at a variety of institutions and oncology service units to assess its generalizability. Additionally, an important factor associated with PPE use in some studies is nurse patient ratio which was not possible to measure in our study and will be important for future researchers to consider. The hypothesis would be that a higher nurse to patient ratio (nurse has less patients to care for) would result in higher PPE use, as nurses would have more time to focus on each patient and their safety behavior.

While we conducted environmental sampling in 27 key locations accounting for 65 unique antineoplastic agent by location combinations based upon expert, management and staff advice and resources, ultimately the findings of surface contamination could vary by day, based on the antineoplastic agents given, staff safety behaviors, cleaning techniques, and whether or not recent spills have occurred. Future studies could benefit from a more comprehensive sampling approach to account for potential variability over time. Despite these limitations this study was able to combine findings on surface contamination, reported PPE use, and influencing group variables such as workplace safety climate among both inpatient and outpatient oncology nursing and pharmacy staff. Because the organizational unit is likely a proxy measure for many factors potentially influencing workplace safety, future research could identify the relative contribution of factors that vary by unit and may influence use of PPE such as safety climate, self-efficacy and staffing ratios. Future research is also needed to better understand why surface areas are contaminated with chemotherapy in order to protect healthcare workers and hospital visitors. The contamination of common work areas where health care workers are not expected to use PPE is of utmost concern.

Implications for Practice

The organizational unit where oncology staff works is a significant driver of the use of personal protective equipment during chemotherapy handling. These findings suggest the importance of focusing on organizational, rather than individual, factors in striving to understand the use of PPE. Surface contamination is a risk to healthcare workers and others on these oncology units and precautions need to be taken to prevent unnecessary exposure to these dangerous agents. According to the NIOSH recommendations, work surfaces should be cleaned with an appropriate deactivation agent before and after each activity and at the end of the work shift (National Institute for Occupational Safety and Health, 2004). Surface monitoring should occur every six months to a year, or following concerns about worker health (National Institute for

Occupational Safety and Health, 2004). While this study focused on nurses and pharmacy staff, other members of the health care team such as patient care assistants, cleaning staff, and delivery personnel also have the potential for exposure. Family members, friends, and other visitors to the hospital similarly may be at risk and all of these populations should be addressed in future studies.

Applying Research to Practice

- Health Care Facilities that prepare, administer or care for patients receiving antineoplastic drugs should review their policies around safe handling and provide proper training to all members of the healthcare team.
- These facilities should also perform a worksite analysis to better understand where there might be gaps in safety behavior.
- Worksites should create a culture of both patient and worker safety.

Worksites should review and follow, at a minimum, the National Institute for Safety and Health's *2004 Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings* (National Institute for Occupational Safety and Health, 2004).

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Table 1: Predictor Variables

Predictor Variable	Description	Example Question	Number of Items	Response Options
Knowledge of the Hazard[7]	Address chemotherapy exposure routes and appropriate use of PPE	"Chemotherapy can enter the body through breathing it in."	12	True/False/Don't Know
Perceived Risk[34]	Seriousness of the occupational exposure for one's health, probability of current and future harm to oneself and one's risk in relation to coworkers	"Exposure to chemotherapy is a serious problem at my work."	7	Four-point scale from strongly agree to strongly disagree
Perceived Barriers[34]	Address the need for and efficacy of PPE, time for use, and other physical and emotional discomfort hindrances to wearing PPE	"PPE makes it harder to get the job done."	12	Four-point scale from strongly agree to strongly disagree
Self-efficacy[34]	One's confidence in their use of PPE, the ability of PPE to protect them, available resources and managerial support during the handling of chemotherapy	"I am confident that I can protect myself from chemotherapy exposure."	7	Four-point scale from strongly agree to strongly disagree
Workplace Safety Climate[35]	Accessibility of PPE, how safety is assessed by managers, training, the cleanliness of the workplace, co-worker support, and safety policy	"On my unit, reasonable steps are taken to minimize hazardous job tasks."	21	Five-point scale, ranging from strongly agree to strongly disagree (includes neutral)

Perceived Conflict of Interest[35]	How PPE use might be affected by a workers' ability to protect themselves and provide patient care	"Wearing personal protective equipment makes my patients worry."	6	Four-point scale ranging from strongly agree to strongly disagree
Interpersonal Influence[34]	How often coworkers use PPE and how important respondent feels use of PPE is to coworkers	"How often do your co-workers wear personal protective equipment when handling chemotherapy?"	6	Range from never to usually, with additional option of "does not apply"

Table 2: Surface Contamination Results

Location	Antineoplastic Drug Tested	Results
Pharmacy Area A		
Chemotherapy Tote	Cyclophosphamide[1] Gemcitabine[2]	< Limit of Detection (LOD)
Plastic Drug Bin	Cyclophosphamide Gemcitabine	< LOD
Biohazard Lid	Cyclophosphamide Gemcitabine	< LOD
Chemotherapy Pad	Cyclophosphamide Gemcitabine	< LOD
Cyclophosphamide Bin	Cyclophosphamide	<LOD
Gemcitabine Bin	Gemcitabine	<LOD
Outpatient Pharmacy B/Nursing Infusion Center		
Break room Table	Paclitaxel[3] Gemcitabine[2]	< LOD
Nursing Desk Pod A	Paclitaxel Gemcitabine	< LOD
Floor under Laundry Bin	Paclitaxel Gemcitabine	**0.03 Nanograms (ng)/cm^2** < LOD
Patient Chair Armrest Following Paclitaxel Infusion- DIRTY	Paclitaxel	**0.02ng/cm^2**
Patient Chair Armrest Following Gemcitabine Infusion- CLEAN	Gemcitabine	< LOD
Pharmacy to Nursing Drug Bins	Paclitaxel Gemcitabine	< LOD
Nursing to Pharmacy Counter under Bin Return	Paclitaxel Gemcitabine	**0.05ng/cm^2**
Pharmacy Negative Pressure Room Counter	Paclitaxel Gemcitabine	< LOD
Inpatient Oncology		
Room Keyboard	Ifosfamide[4] Etoposide[5] Methotrexate[6]	<LOD
Bathroom Wall	Ifosfamide Etoposide Methotrexate	<LOD
Nurses Cart	Ifosfamide Etoposide	<LOD

	Methotrexate	
Nurses Station Counter Opposite Charge (Place Chemotherapy Double-Checked)	Ifosfamide Etoposide Methotrexate	**0.06ng/cm^2** <LOD <LOD
Med Room Refrigerated Chemo Bin A-M	Ifosfamide Etoposide Methotrexate	<LOD
Lid of Biohazard Bin	Ifosfamide Etoposide Methotrexate	<LOD
Inpatient Bone Marrow Transplant		
Cleaning Cart after Cleaning Chemo Precautions Room	Ifosfamide[4] Etoposide[5] Cyclophosphamide[7]	<LOD
Patient Side Table	Ifosfamide Etoposide Cyclophosphamide	<LOD <LOD **0.008ng/cm^2**
Nurses Station Printer Keyboard	Ifosfamide Etoposide Cyclophosphamide	<LOD
Physician's Workroom Door handle and KeyPad	Ifosfamide Etoposide Cyclophosphamide	<LOD
Cordless Phones at Nurses' Station	Ifosfamide Etoposide Cyclophosphamide	<LOD
Cytocart (Chemotherapy Supplies)	Ifosfamide Etoposide Cyclophosphamide	<LOD

[1] Limit of Detection = 0.015 Nanograms/cm^2

[2] Limit of Detection = 0.005 Micrograms/cm^2

[3] Limit of Detection = 0.010 Nanograms/cm^2

[4] Limit of Detection = 0.005 Nanograms/cm^2

[5] Limit of Detection = 0.10 Nanograms/cm^2

[6] Limit of Detection = 0.005 Nanograms/cm^2

[7] Limit of Detection = 0.005 Nanograms/cm^2

Table 3: Demographics of Survey Respondents

Demographic Characteristics	Original Survey Total Number of Respondents	Original Survey Percent of Respondents	Percent of Unit Employees
Setting Employed (N=100/163)			
Pharmacy	11	11%	58%
Outpatient Chemotherapy	17	17%	57%
Inpatient Bone Marrow Transplant	45	45%	63%
Inpatient Oncology	27	27%	68%
Gender (N=96)			
Male	12	12.5%	
Female	84	87.5%	
Age (years) (N=93)			
Less than 25	8	8%	
25-35	43	46%	
36-45	14	15%	
Over 45	28	31%	
Race/Ethnicity (N=97)			
American Indian/Alaskan	3	3.1%	
Black/African American	3	3.1%	
Asian	3	3.1%	
Hispanic/Latino	0	-	
Native Hawaiian	0	-	
White	85	87.6%	
Two or more	2	2.1%	
Other	1	1%	
Highest level of nursing education (N=94)			
Diploma	1	1.1%	
Associate degree	11	11.7%	
Bachelor's degree	74	78.7%	
Master's degree	8	8.5%	
Doctoral degree	0	-	
Oncology Nursing Society member (N=97)			
Yes	40	41.2%	
No	57	58.8%	
Years of chemotherapy handling experience (N=95)			
0-2	21	22.1%	
3-5	11	11.6%	

5-10	30	31.6%
>10	33	34.7%

Table 4: Frequencies of Personal Protective Equipment Use among Personnel in Different Job Tasks

Equipment	Always (%)	51-99% (%)	1-50% (%)	Never (%)
Preparation (Pharmacy)				
Biological Safety Cabinet (n=10)	90	10	0	0
Closed system transfer device (n=10)	20	10	20	50
Chemotherapy gloves (n=9)	100	0	0	0
Other gloves (n=9)	33.3	0	0	66.7
Chemotherapy gown (n=10)	100	0	0	0
Other gown (n=10)	100	0	0	0
Eye protection (n=9)	33.3	0	0	66.7
Respirator/mask (n=9)	11.1	0	22.2	66.7
Administration				
Closed system transfer device (n=85)	60	7.1	3.6	29.4
Chemotherapy gloves (n=82)	83	4	2	11
Other gloves (n=76)	10.7	6.7	2.7	80.3
Double gloves (n=77)	33.8	11.7	13	41.6
Chemotherapy gown (n=82)	81.7	15.8	1.2	1.2
Other gown (e.g. isolation) (n=77)	2.6	1.3	5.2	90.9
Re-used disposable gowns (n=77)	2.6	16.9	7.9	72.7
Eye protection (n= 79)	27.8	11.4	17.7	43
Respirator (n=77)	11.8	7.9	15.6	64.9
Disposal				
Chemotherapy gloves (n=94)	79.8	7.5	2.1	10.6
Other gloves (n=76)	11	5	4	80
Double gloves (n=79)	32.9	7.6	10.1	49.4
Chemotherapy gown (n=81)	55.6	19.7	11.2	13.6
Other gown (e.g. isolation) (n=75)	2.6	0	5.3	92.1
Re-used disposable gowns (n=76)	4	7.9	10.5	77.6
Eye protection (n= 77)	22.1	6.5	14.3	57.1
Respirator (n=77)	9.1	5.2	14.3	71.4
Handling Excreta				
Chemotherapy gloves (n=91)	70.3	7.7	2.2	19.8
Other gloves (n=74)	17.8	2.7	8.2	71.6
Double gloves (n=76)	9.2	7.9	14.5	68.4
Chemotherapy gown (n=77)	20.8	20.8	13	36.4
Other gown (e.g. isolation) (n= 76)	9.2	15.8	14.4	60.5
Re-used disposable gowns (n=74)	0	9.5	9.5	81.1
Eye protection (n=75)	14.7	2.6	25.3	57.3
Respirator (n=74)	5.4	4.1	19	71.6

Table 5: Results of Multivariate Regressions: Factors Influencing Personal Protective Equipment Use

Variable	Parameter Estimate[1]	95% Confidence Interval
Unit[2]		
1. Bone Marrow	Reference	
Transplant	17	3.7, 30.3
2. Pharmacy*	-8.9	-17.2, -0.6
3. Oncology*	-10.6	-20.3, -0.9
4. Masonic Outpatient*		
Self-Efficacy[3]*	1.4	0.36, 2.45
Workplace Safety Climate[4]	0.23	-0.10, 0.55
Workplace Safety Climate[5]*	0.5	0.19, 0.81
Perceived Barriers[6]	-0.47	-1.1, 0.18

[1]= Parameter Estimate refers to the regression coefficient for the effect of the exposure variable (e.g., the Oncology Unit compared to the reference category, Bone Marrow Transplant Unit) on the dependent variable (PPE use score) controlling for all other variables in the model. For a dummy variable, the parameter estimate corresponds to the difference in mean PPE score compared to the reference level (e.g., working in pharmacy is associated with a 17 point increase in mean PPE score relative to working on the Bone Marrow Transplant Unit). For the continuous exposure variable, e.g., Workplace Safety Climate, model 4, it is the change in PPE score corresponding to a 1-unit increase in the value of the exposure, a one unit increase on the workplace safety climate score means a 0.5 unit increase in PPE score.

[2]= Controlling for perceived barriers, safety climate, interpersonal influence, age and gender

[2]= Controlling for perceived barriers, age and gender

[4]= Controlling for unit, perceived barriers, interpersonal influence, age and gender

[5]= Controlling for perceived barriers, interpersonal influence, age and gender

[6]=Controlling for unit, safety climate, interpersonal influence, age and gender

*=Statistically significant

CHAPTER 7: PAPER 2, "FIRST, DO NO HARM": HOW A QUALITY IMPROVEMENT INTERVENTION DECREASED HEALTHCARE WORKERS' EXPOSURE TO ANTINEOPLASTIC AGENTS

Abstract

Purpose: To develop and test a worksite intervention that protects healthcare workers who handle antineoplastic drugs from work-related exposures to these highly toxic drugs.

Design: This was a pre-post-intervention study.

Setting: A university hospital and its affiliated outpatient chemotherapy infusion clinic.

Sample: 163 nurses, pharmacists, and pharmacy technicians who work with antineoplastic agents on four different units of one health care system.

Methods: A self-report survey measured workplace and individual factors before and after the intervention. The associations between these factors and self-reported Personal Protective Equipment (PPE) use were measured using multivariate estimations that adjusted for confounding factors. Wipe samples from the environment were tested for surface contamination. An intervention was developed with worker input and Plan-Do-Study-Act cycles(Langley, Moen, Nolan, Norman, & Provost, 2009) of change were completed, consistent with the quality improvement literature.

Main Research Variables: PPE use was the dependent variable and the independent predictor variables included knowledge of the hazard, perceived risk, perceived barriers, interpersonal influence, self-efficacy, conflict of interest, and workplace safety climate. Surface contamination was tested for residue above the limits of detection for each drug.

Findings: PPE use was lower than recommended and improved slightly (but not statistically significantly) post-intervention. Self-efficacy and perceived risk increased on the posttest. Chemical residue from antineoplastic drugs was found in several areas, indicating potential exposure for workers. Awareness of safe handling precautions by support staff improved following the intervention. The unit worked was an important predictor of safety climate and PPE use on the pretest but less so following the intervention.

Conclusion: Involving managers and unit staff in developing and implementing an intervention for safety improvement ensures that changes made will be efficient and will not conflict with the workers' ability to do their job. Units that implemented workflow changes had decreased contamination following the intervention.

Implications for Nursing: Worksite analysis identifies specific targets for interventions to improve antineoplastic drug handling safety.

Knowledge Translation:

1. Healthcare workers must understand the risks associated with handling antineoplastic agents and the safe handling precautions that reduce exposure.

2. Periodic surface contamination monitoring should be performed to identify sources of potential exposure.

3. All staff who work in areas where antineoplastic agents are handled, including nurses' aides and cleaning staff, must be trained to use safe handling precautions.

Keywords: antineoplastic drug safe handling, personal protective equipment, chemotherapy safety

Introduction

Over one million Americans are newly diagnosed with cancer each year (American Cancer Society, 2013). Chemotherapy drugs are often part of effective treatment, with medication prepared and tailored for individual patients. Patients receiving chemotherapy often become very sick and require supportive care during and following their chemotherapy infusions. Other potential adverse outcomes of treatment are the future risk of secondary cancers and negative reproductive outcomes (Deniz et al., 2003; Josting et al., 2003; Sherins & DeVita, 1973). For patients, the benefits of treatment outweigh the risks. Health care workers, such as nurses and pharmacists, are pivotal in taking care of these patients but, unfortunately providing this care has the potential to put these workers at risk. Previous studies have documented chemotherapy residues on countertops and floors in pharmacy, nursing and patient care areas (Connor et al., 2010). Eight million health care workers are potentially exposed to chemotherapy, with pharmacists and nurses being among the groups with the highest incidence of exposure (Connor et al., 2010; Polovich & Clark, 2012a). There is not an accepted safe level of exposure to antineoplastic drugs (Turci et al., 2003), Even a small exposure to these drugs can cause adverse outcomes, including skin rashes, nausea, hair loss, abdominal pain, nasal sores, allergic reactions, skin or eye injury and dizziness (B. G. Valanis et al., 1993; Vioral & Kennihan, 2012). Yet healthcare workers incur exposure on a repeated basis and often for many years. Chronic effects linked with exposure include reproductive harm such as delayed time to conception, (Fransman et al., 2007) spontaneous abortion, (Lawson et al., 2012) genotoxic changes, (McDiarmid et al., 2010; Rekhadevi et al., 2007; Villarini et al., 2011) and cancers.[16]

Safe-handling practices, such as the use of personal protective equipment (PPE) by staff, are known to reduce exposure and likelihood of health effects from chemotherapy (National Institute for Occupational Safety and Health, 2004). Federal guidelines for safe handling were first published by NIOSH in 1986 and updated in 2004 (National Institue of Occupational Safety and Health, 2004). Guidelines are also published by the Oncology Nursing Society (Polovich, 2011) and American Society of Health System Pharmacists (Polovich & Clark, 2012a). These guidelines are only recommendations and federal policies are lacking. There have been recent state-based laws passed to standardize hazardous drug safety practices in Washington (first in 2011) (Smith, 2011), California (2013) (California Legislature, October 9, 2013), and North Carolina (2014) (North Carolina Nurses Association, May 3, 2014). The lack of consistency in state policies leads to differences in health care workers' use of safe handling precautions (Boiano et al., 2014; Environmental Working Group, 2007). A positive workplace safety climate and a higher nurse to patient ratio can positively affect adoption of safe handling practices (Friese et al., 2012; Polovich & Clark, 2012).

Quality improvement processes have been used in healthcare to improve patient safety (Langley et al., 2009). However, use of the quality improvement process to improve chemotherapy safe handling has only recently been described in the literature. Hennessy and Dylan (2014) reported study findings from a program implemented to improve safe handling of chemotherapy at the Dana-Farber Cancer Institute. The program incorporated monitoring and reporting compliance on the use of PPE along with engaging staff in audit activities (Hennessy & Dynan, 2014).

Objective

The objectives of this study were to: 1. Determine key factors influencing exposure to antineoplastic agents for nurses and pharmacy staff, 2. Determine if work surfaces were contaminated with antineoplastic drugs, 3. Develop and test a sustainable intervention to improve the safety of chemotherapy handling.

Methods

Research Design

This study used a pre-post design to test an intervention to improve antineoplastic drug safe handling by nurses and pharmacy staff who are potentially exposed to chemotherapy because of their work responsibilities. Nurses, pharmacists and pharmacy technicians (N=163) from four units (inpatient oncology, inpatient bone marrow transplant, outpatient chemotherapy infusion center, and pharmacy) of a university hospital participated. A self-report survey was administered combining questions about PPE use with questions based on a model used by Polovich (Polovich & Clark, 2012b) to test predictor variables. The survey was offered online for three weeks in October of 2014 (pretest) and three weeks in August of 2015 (posttest). Survey respondents were entered into a drawing for a $50 Visa Gift Card (one winner for each unit). Surface samples were collected a day prior to the survey release. An exposure assessment was conducted using area surface sampling to measure contamination before (pretest), during and following (posttest) the intervention. The study was approved as exempt by the University of

Minnesota Institutional Review Board (IRB) and the hospital's Nursing Research Council.

Environmental Assessment

Wipe samples

An exposure assessment tool, The ChemoAlert™ kit, (Bureau Veritas Laboratories, Lake Zurich), was used for testing surfaces for contamination. This is an exposure assessment tool developed for facilities to measure surface chemotherapy contamination in response to recommendations for periodic testing from the NIOSH Alert(National Institute for Occupational Safety and Health, 2004) and a housekeeping standard recommendation, USP 797 (Lee, 2010). The number of swab strokes per wipe sample was standardized. The laboratory provided one sample blank as a control for each set of samples that was delivered to them to assure accurate testing. A total of 27 locations were selected for surface wipe sampling for antineoplastic drug residue. Selection of the antineoplastic agents to be tested was made based on those agents with the highest volume of use, consistent with the approach used in similar studies (Connor et al., 2010). Sampling sites on each unit were selected based on work-flow and the locations in which the selected drugs were most commonly used. The variety of job tasks associated with potential chemotherapy exposure (drug preparation, administration, disposal, and handling excreta) was also considered. An experienced industrial hygienist provided guidance on the planning and implementation of the exposure assessment and wipe sampling. The size of the test sites was between 100cm^2 and 200 cm^2 based on the size of the surface and recommendations from an exposure assessment consultant. All locations were tested both pre- and posttest, accounting for 62 unique antineoplastic drug-by-location combinations. When pretest samples were reported as positive, the hospital staff identified additional areas of concern that resulted in expanded testing. Twelve additional wipe samples were taken during the intervention in relation to the positive samples (hereafter referred to as intervention samples).

Survey

Surveys were administered on-line and data stored securely using the Research Electronic Data Capture (REDCap) Data System (Harris, P.A., Thielke, R. et al., 2009) which is hosted by the University of Minnesota.

Self-reported Survey Measures: Survey items were taken from instruments with established reliability and validity used in a study by Polovich (Polovich & Clark, 2012). The survey included items about personal factors such as age, race and years of experience.

Dependent or Outcome Variable: Use of Safe Handling Techniques was measured on a five-point scale with questions adapted from the Revised Hazardous Drug Handling Instrument (Polovich & Clark, 2012), which was based on the current federal guidelines for safe handling (National Institue of Occupational Safety and Health, 2004). Questions included items about availability and use of PPE during four categories of potential exposure: preparation, administration, disposal, and handling patient excreta. PPE use questions were scored from 5 (always use) to 0 (never use). Higher scores indicate higher use of PPE. Use of PPE was calculated as a score for each respondent based on their responses to the use of gloves, double gloves, gowns, whether or not they reused disposable gowns, and eye protection.

Independent Variables:

Predictor Variables and their attributes are outlined in the Appendix, Table 1. All survey measures except knowledge of the hazard were adapted from Geer et al. (Geer et al., 2007) and Gershon et al.(Gershon et al., 1995; Gershon et al., 2007). Knowledge of the hazard was measured based on adaptation of items from the NIOSH Survey of Safe Handling for Workers and the Chemotherapy Exposure Knowledge Scale (Polovich & Clark, 2012a).

Pregnancy and alternative duty:

Female respondents were asked whether or not they had been pregnant during their current job, and if so, whether they sought alternative duty that did not include chemotherapy handling. If they had not been pregnant, they were asked if they would seek alternative duty if they became pregnant. These questions were pilot tested with nursing management. Males were asked if they would ask for alternative duty if they were in the position of a pregnant woman. They were also asked to comment on why they felt a pregnant woman might choose to ask.

Intervention

Management and staff were presented with the pretest results during staff and nurse council meetings. Small workgroups of nursing practice council members were formed to address areas of concern for each unit. Consistent with the quality improvement literature, small changes such as moving chemotherapy gowns from one location in a locked room to hallway closets outside patient rooms to increase individual nurse's convenience and placing signs on the units reminding staff not to reuse disposable gowns were made as described in the results section of this paper and changes were tested with brief surveys or qualitative interviews to address how staff felt the changes were effective, e.g., acceptable to staff, improving their PPE use, and decreasing the number of surfaces that tested positive for chemotherapy residue. Interventions on each unit were tested for effectiveness using the Plan-Do-Study-Act cycle for quality improvement processes (Langley et al., 2009).

Data Analysis

Environmental Assessment

Analysis of wipe samples was performed by Bureau Veritas Laboratories. The limit of detection (LOD) varies with the antineoplastic agent, and all are reported in Table 2 (Bureau Veritas Laboratories, 2013). Any result over the LOD was considered "contaminated" (Turci et al., 2003).

Survey

Descriptive analysis of data for all variables included calculation of means and standard deviations. Pre- and posttest measurements for PPE use and the predictor variables were compared using paired t-tests to measure the effects of the intervention.

The regression model for multivariable estimation was based on the use of Directed Acyclic Graphs (DAGs) (Greenland, Pearl J FAU - Robins,J M., & Robins,) to ensure the regression models addressed the study's aims by understanding the causal assumptions and avoiding confounded models. DAGs visually display the underlying assumptions of the causal relationships. This facilitated the selection of potential confounders for testing the causal association between specific exposures and the outcome.

To address potential selection bias, a shortened survey was sent to individuals who had not completed the comprehensive survey by the deadline. The shorter survey did not address predictor variables, but collected data about unit worked, gender, age, race/ethnicity, years of experience, and PPE use during drug handling activities. It was designed to facilitate a comparison between study participants and nonresponders to the comprehensive survey.

The data analysis was performed using SAS software, Version 9.3 of the SAS System for PC (SAS Institute Inc., 2010).

Results

Environmental Assessment

Overall, there were five surface wipe samples from a total of 62 that tested above the LOD (8%) on the pretest and three of 62 (5%) on the posttest. 50% of the intervention samples tested positive (6 of 12). The outpatient chemotherapy infusion center was the unit with the highest number of positive surface wipe samples on the pretest (three sites) and posttest (two sites). The inpatient bone marrow transplant and inpatient oncology units each had one contaminated area on the pretest, two during the intervention sampling, and none and one (respectively) during the posttest. One positive sample was identified at one of the two pharmacies tested - a countertop shared between pharmacy and the outpatient chemotherapy infusion center. During the posttest, that counter was negative for contamination, but the floor underneath the preparation area in the pharmacy was positive. Table 2 in the Appendix shows results from the surface wipe sampling.

Survey

Overall, the comprehensive survey response rate was 62% of 163 employees on the pretest and 71% of 100 on the posttest. Additionally, 10 individuals, (6%) of 163 employees completed a short version of the pretest survey. Demographic results are presented in Table 3 of the Appendix. The respondents to the full survey were similar on demographic factors to those who answered the short survey with respect to average age (38 vs 36), years of experience (10.5 vs 12.5) and on reported PPE use (combined measure score of 40 vs 40.3), but were about 20% less likely to be a Oncology Nursing Society member relative to those who responded to the full survey. Reported PPE use is shown in Figures 1-4 as a combined average score. Overall, reported glove use was high (73-100% depending on activity); use of gowns and double gloving were lower (25-100% and 13-85%, respectively and depending on activity), and use of eye protection or respirator was very low (15-28% and 7-17%, respectively and depending on activity). Use of double gloves and not re-using disposable gowns increased (staff became safer) from the pre- to posttest. Use of gloves and gowns increased slightly for most activities.

The findings reveal that the unit in which one worked was significantly associated with use of PPE on the pretest adjusting for all confounders and one of the three units also remained significantly lower on PPE use compared to the reference group, Bone Marrow

Transplant on the posttest. Self-efficacy was significantly associated with PPE use after controlling for appropriate confounders on the pretest, but this was not the case on the posttest. Two models of workplace safety climate were estimated which varied only by the inclusion or exclusion of the variable, unit. The findings revealed the more parsimonious model, without unit, was statistically significant on the pretest, while inclusion of unit in the pretest model decreased the regression estimate from 0.5 to 0.23 and widened the confidence interval leading to nonsignificant findings. Results of regression models are shown in Table 4. In contrast to pretest findings, the posttest results for safety climate were nonsignificant regardless of model specification.

Paired t-test results are displayed in Table 5. The biggest change in the predictor variables was an increase in perceived risk after the intervention. Self-efficacy showed a significant increase following the intervention. PPE use increased for all but one unit, but the increase was significant for only one (the outpatient infusion center).

Pregnancy and alternative duty

Twenty eight percent of respondents reported being pregnant while working their current job on the pretest and 30% on the posttest. Of those who became pregnant, 15% on the pretest and 30% on the posttest reported having sought alternative duty that did not include chemotherapy handling. Among study participants who had not been pregnant while employed at their current job (72% pretest, 70% posttest) the intent to seek alternative duty if they became pregnant varied (33% pretest, 50% posttest) while those unsure about seeking alternative work duty was similar (26% pretest to 27% posttest).

Comments made by male staff included “this issue doesn’t affect me since I’m male” and “I’m a man, so I touch the chemotherapy bags bare-handed”.

Intervention

The intervention phase of the study involved different changes that were made to each unit based on staff feedback. Staff and management were first presented with the results of the survey and wipe sampling conducted for the pretest in their area. They were asked to identify concerns they had for their unit’s chemotherapy safety. The process of involving staff that worked on the units and would be directly affected by the changes is consistent with the quality improvement literature. When a change was made, it was followed up with qualitative interviewing of staff by survey to assure that it was feasible and actually improved safety. It is important to consider that not only the concrete changes in practice were instrumental in improving safety, but also the process of change and the collaborative learning and focused thinking about ways in which the units could improve.

The bone marrow transplant unit decided to have their nursing practice council suggest changes to be made. This group summarized desired changes in writing after the first meeting using the Quality Improvement framework of Plan-Do-Study-Act. The changes included: 1) Move chemotherapy gowns to hallway closets rather than one location in locked room, 2) Add yellow chemotherapy disposable bags to the nurse’s cart in the room, 3) Place reminder signs; “Do not re-use disposable gowns” near chemotherapy gowns. After three weeks of implementation, staff were surveyed online about their awareness of and thoughts about the effectiveness of the changes. The majority of staff surveyed were aware of the gown location change (35 of 37, 95% of respondents) and 80% of those surveyed reported the change had or was likely to increase their gown usage. A few respondents said it was not likely to increase their usage because they already used gowns as recommended. Moving the yellow chemotherapy disposal bags to a more accessible location also resulted in a majority of respondents reporting that it would increase their use (78%). However, the nurse practice council identified that stocking was an issue and therefore this change may not be sustainable. When surveyed on the reminder signs, staff satisfaction was mixed. Thirty seven people responded to the survey, and of these 60% approved of the change and 40% felt it was unnecessary.

During a second meeting with the nursing practice council, it became apparent that Nursing Station Technicians (NST's), i.e., nursing aides who often help patients to the bathroom, lacked formal training on chemotherapy precautions. Because chemotherapy stays in the body for about 48 hours(National Institute for Occupational Safety and Health, 2004), it is recommended that workers use PPE when coming into contact with patient body fluids during that time. To address this and other issues of safe handling, a training was developed and provided to the NST's, with a pre- and posttest showing that the training was effective in improving both their knowledge and reported use of PPE during at-risk activities. Knowledge scores increased for all of the respondents to the NST survey. Respondents reported feeling better prepared to protect themselves from chemotherapy exposure on the posttest after their training.

The inpatient oncology unit also had their results shared with management and a nursing practice council. The biggest concern was the high level of surface contamination on the nursing desk. This nursing desk was being used by health care staff for both double checking chemotherapy and for duties that do not involve chemotherapy handling. Because this area was contaminated, it is not safe for both types of activities. Staff were unclear as to why the desk had a high level of contamination, and therefore additional surfaces were tested (results in table 2) to identify the source of this contamination. High contamination levels on the outside of Intravenous (IV) chemotherapy bags and observation of workflow showed that nurses were using this desk to double check bags en route from the pharmacy to patient rooms. Most nurses did not wear double gloves when touching bags, despite Oncology Nursing Society recommendations (Fonteyn, 2006). As part of the intervention, nurses were advised to consider the outside of bags contaminated. The task of double-checking chemo bags was assigned to a dedicated location in the locked medication room. The pictures in the appendix display the change of practice from chemotherapy double checking taking place in many separate locations in the main area, to only being allowed in an area delimited by red tape in the locked chemotherapy room. The main nursing desk was cleaned on a continued basis and upon re-testing following the change, had chemotherapy levels below the limit of detection.

The outpatient infusion unit also made many changes as a result of this intervention. During quality improvement (QI) discussions, the staff discovered that reuse of disposable gowns was common practice. In the past, there had been hooks placed on walls in patient care areas to encourage reuse of gowns to save money. Following the QI discussions, a policy change was implemented to discourage gown reuse. Policy also changed to include the idea of treating each outpatient bay area as “a separate room”, meaning that PPE had to be removed before leaving the bay area and not worn in the hallway. This was important to prevent potentially contaminated PPE being worn throughout the unit. Additionally, this unit switched to an improved, closed system drug transfer device. Staff meetings were held and staff was encouraged to support each other to wear PPE. Staff was also encouraged to keep dedicated shoes at work as the hallway floor was contaminated during both the pre- and posttest.

Two outpatient pharmacy areas were involved in this research. One area had no positive pretest surface contamination results and high reported PPE use. Therefore, this area was excluded from the intervention. The other pharmacy area had one area of high contamination that it shared with the nursing unit. Pharmacy staff felt this was possibly due to nursing staff wearing contaminated gowns in the hallway and leaning on the counter to return the plastic bins that held chemotherapy. In addition to the nurses' change in not wearing these gowns to that counter, the pharmacy reviewed and updated its cleaning procedure. The counter area was retested during the posttest and was not contaminated.

Discussion

Health care organizations teach their employees to put patient needs first. While this is very important for patient health and safety, patients with cancer would not want their caregivers to develop illness because of their care. It is also clear that healthcare workers continue to be exposed to antineoplastic drugs. A thorough worksite analysis of each area where chemotherapy is prepared and given to patients must be conducted to identify potential areas in which exposure occurs. In this study, we found surface contamination in places where PPE use is not typical, such as commonly used counters. Identifying these areas led to changes in work processes to eliminate the exposure. For example, in the outpatient area, work practices were modified requiring nurses to take off all potentially contaminated PPE prior to leaning on the counter. In the inpatient area, the location for “double checking” chemotherapy was moved from the main nursing desk to the locked medication room. Locations with chemotherapy residue were cleaned and remained uncontaminated one month after implementation of the changes. If not for surface sampling, these units would never have known which areas were contaminated and required cleaning and critical review of associated work processes thus highlighting the importance of an objective monitoring and feedback system. Tailored interventions can decrease surface contamination of a unit, but it must be preceded by a worksite analysis to see the workflow and where there are gaps in safety.

NIOSH identified a hierarchy of controls to ensure occupational safety to ensure adequate management of exposure and human health risk (National Institute for Occupational Safety and Health Education and Information Division, April 21, 2015). The hierarchy outlines the following activities from most effective to least effective as follows: Elimination, Substitution, Engineering, Administrative and Personal Protective Equipment (PPE).(National Institute for Occupational Safety and Health Education and Information Division, April 21, 2015) This and other studies have found that workers reported use of PPE has been variable and compliance is not as high as recommended (Lawson et al., 2012; Polovich & Martin, 2011). Since elimination and substitution of chemotherapy agents are not options (patients need individualized chemotherapy regimens to treat their cancer), we focused our interventions on the next most effective control strategies-- engineering and administrative processes to improve worker protection from chemical exposures. Engineering controls are designed to remove the hazard before it comes in contact with the worker. Moving the location of PPE to facilitate appropriate use and re-engineering work processes to remove areas where workers might be exposed to chemotherapy residue was effective in changing the environment to improve worker safety, rather than only relying on education to improve PPE use.

Perceived risk increased significantly following the intervention. This is consistent with the predictor model that suggests increased information and discussion of potential risk will increase PPE use and improve worker safety behavior. The goal was not to scare employees, but to remind them of their risk with objective information about their exposures.

Floors were tested in two patient care areas and the outpatient pharmacy and all three were contaminated. One area was an inpatient bathroom floor and another was an outpatient hallway. Staff moved their laundry bin out of the outpatient hallway and cleaned the area, but contamination persisted. It was recommended to staff that floors be considered contaminated and that they keep a dedicated pair of shoes at work to prevent bringing chemotherapy home. Further research could investigate cleaning products that may do a better job erasing this persistent contamination to prevent patients and visitors from being exposed.

There were two occasions in which it was clear that support staff were not aware of their potential for exposure. One involved nurses' aides not having been trained on safety precautions and the other was that cleaning staff were not using proper PPE when being called in to clean outpatient bathrooms. Safety training was conducted for cleaning staff by their management. This is important because it illustrates how trace chemotherapy may be inadvertently contaminating other locations.

The number of nurses who reported they would ask for alternative duty if they became pregnant was much higher than the number who actually did ask. It's unclear if this is because priorities change once staff members become pregnant, if the survey somehow suggested that they should ask, or if staff members who work on these units enjoy their jobs and find it difficult to imagine working in another setting. Additionally, 50% more nurses reported having asked for alternative duty in the posttest compared to the pretest which may relate to the increase in perceived risk.

Limitations

There are important limitations to be noted when interpreting the results of this study. Because this was a pre-posttest study, there is an inherent limitation in how participants may have been influenced by the study itself. There is always the concern that it was not the intervention itself which changed things, but simply the focus on the issue (i.e., the Hawthorne effect). Since the survey was self-report data, it is also possible that recall bias occurred.

While we conducted environmental sampling in 39 key locations accounting for 76 unique antineoplastic agents by location the resources available did not permit repeated sampling over time to more comprehensively assess exposure. It is likely that surface contamination can vary by day, based on a variety of factors. Despite these limitations, this study is one of the first in the literature to test an intervention that used a quality improvement process and data surface contamination, self-reported PPE use, and information on organizational variables such as unit worked and workplace safety climate among both inpatient and outpatient oncology nursing and pharmacy staff to minimize workers' exposures to chemotherapy.

Conclusion

Given that no level of chemotherapy exposure is safe for health care workers' it is important for healthcare workers to understand the risks associated with handling antineoplastic agents and the safe handling precautions that reduce exposure. Targeted interventions did decrease potential exposure of workers. A thorough investigation involving surface monitoring and feedback from staff who worked on the units identified areas where improvement was needed. Periodic surface contamination monitoring to identify sources of potential exposure should be mandated by governmental regulations or health care institutional policies (e.g., Joint Commission standards). Without public or private policy to require such measures, however, it is up to healthcare professionals to monitor their oncology environments for safety and unnecessary exposures.

While this study focused on nurses and pharmacy staff, other staff members such as patient care assistants, cleaning staff, and delivery personnel, and patients' visitors are potentially exposed to chemotherapy. All of these populations warrant attention in future studies. All staff who works in areas where antineoplastic agents are handled, including nurses' aides and cleaning staff, must be trained to use safe handling precautions.

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Table 1: Predictor Variable Explanation

Predictor Variable	Description	Example Question	Number of Items	Response Options
Knowledge of the Hazard[5]	Address chemotherapy exposure routes and appropriate use of PPE.	"Chemotherapy can enter the body through breathing it in."	12	True/False/Don't Know
Perceived Risk[39]	Seriousness of the occupational exposure for one's health, probability of current and future harm to oneself and one's risk in relation to coworkers.	"Exposure to chemotherapy is a serious problem at my work."	7	Four-point scale from strongly agree to strongly disagree
Perceived Barriers[39]	Address the need for and efficacy of PPE, time for use, and other physical and emotional discomfort hindrances to wearing PPE.	"PPE makes it harder to get the job done."	12	Four-point scale from strongly agree to strongly disagree
Self-efficacy[39]	One's confidence in their use of PPE, the ability of PPE to protect them, available resources and managerial support during the handling of chemotherapy.	"I am confident that I can protect myself from chemotherapy exposure."	7	Four-point scale from strongly agree to strongly disagree
Workplace Safety Climate[40,41]	Accessibility of PPE, how safety is assessed by managers, training, the cleanliness of the workplace, co-worker support, and safety policy.	"On my unit, reasonable steps are taken to minimize hazardous job tasks."	21	Five-point scale, ranging from strongly agree to strongly disagree
Perceived Conflict of Interest[40,41]	How PPE use might be affected by a workers' ability to	"Wearing personal protective	6	Four-point scale ranging from strongly agree to

	care protect themselves and provide patient care.	equipment makes my patients worry."		strongly disagree
Interpersonal Influence[48]	How often coworkers use PPE and how important respondent feels use of PPE is to coworkers.	"How often do your co-workers wear personal protective equipment when handling chemotherapy?"	6	Range from never to usually, with additional option of "does not apply"

Table 2: Surface Contamination Results

Location	**Antineoplastic Drug Tested**	**Results: Pretest**	**Results: Posttest**	**Results: Intervention**
Pharmacy Area A				
Chemotherapy Tote	Cyclophosphamide[1] Gemcitabine[2]	< Limit of Detection (LOD)	< Limit of Detection (LOD)	-
Plastic Drug Bin	Cyclophosphamide Gemcitabine	< LOD	< LOD	-
Biohazard Lid	Cyclophosphamide Gemcitabine	< LOD	< LOD	-
Chemotherapy Pad	Cyclophosphamide Gemcitabine	< LOD	< LOD	-
Cyclophosphamide Bin	Cyclophosphamide	<LOD	<LOD	-
Gemcitabine Bin	Gemcitabine	<LOD	<LOD	-
Outpatient Pharmacy B/Nursing Infusion Center				
Break room Table	Paclitaxel[3] Gemcitabine[2]	< LOD < LOD	< LOD < LOD	-
Nursing Desk Pod A	Paclitaxel Gemcitabine	< LOD	< LOD	-
Floor under Laundry Bin	Paclitaxel Gemcitabine	**0.03 ng/cm^2** < LOD	**0.13ng/cm^2** < LOD	**-**
Patient Chair Armrest Following Paclitaxel Infusion- DIRTY	Paclitaxel	**0.02ng/cm^2**	< LOD	**-**
Patient Chair Armrest Following Gemcitabine Infusion- CLEAN	Gemcitabine	< LOD	< LOD	-
Pharmacy to Nursing Drug Bins	Paclitaxel Gemcitabine	< LOD < LOD	< LOD < LOD	-
Nursing to Pharmacy Counter under Bin Return	Paclitaxel Gemcitabine	**0.05ng/cm^2** < LOD	< LOD **< LOD**	**-**
Pharmacy Negative Pressure Room Counter	Paclitaxel Gemcitabine	< LOD < LOD	< LOD < LOD	-

Chemo Cart	Paclitaxel[3]	-	-	<LOD
Computer Cart	Paclitaxel	-	-	<LOD
Outpatient Bottom Drawer 1	Paclitaxel	-	-	<LOD
Outpatient Bottom Drawer 2	Paclitaxel	-	-	<LOD
Inpatient Oncology				
Room Keyboard	Ifosfamide[4]	<LOD	<LOD	-
	Etoposide[5]	<LOD	<LOD	
	Methotrexate[6]	<LOD	<LOD	
Bathroom Wall	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Methotrexate	<LOD	<LOD	
Nurses Cart	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Methotrexate	<LOD	<LOD	
Nurses Station Counter Opposite Charge (Place Chemotherapy Double-Checked)	Ifosfamide	**0.06ng/cm^2**	<LOD	**-**
	Etoposide	<LOD	<LOD	
	Methotrexate	<LOD	<LOD	
Med Room Refrigerated Chemo Bin A-M	Ifosfamide	<LOD	**0.63 ng/cm^2**	-
	Etoposide	<LOD	**0.29 ng/cm^2**	
	Methotrexate	<LOD	<LOD	
Lid of Biohazard Bin	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Methotrexate	<LOD	<LOD	
7D Charge Desk Counter Spot A	Ifosfamide[2]	-	-	**0.008 ng/cm^2**
7D Charge Desk Counter Spot B	Ifosfamide	-	-	<LOD
7D Bag of Ifosfamide Front	Ifosfamide	-	-	**34.4ng/cm^2**
7D Bag of Ifosfamide Back	Ifosfamide	-	-	**9.42ng/cm^2**
Inpatient Bone Marrow Transplant				
Cleaning Cart after Cleaning Chemo Precautions Room	Ifosfamide[4]	<LOD	<LOD	-
	Etoposide[5]	<LOD	<LOD	
	Cyclophosphamide[7]	<LOD	<LOD	

Patient Side Table	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Cyclophosphamide	**0.008ng/cm^2**	<LOD	
Nurses Station Printer Keyboard	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Cyclophosphamide	<LOD	<LOD	
Physician's Workroom Door handle and KeyPad	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Cyclophosphamide	<LOD	<LOD	
Cordless Phones at Nurses' Station	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Cyclophosphamide	<LOD	<LOD	
Cytocart (Chemotherapy Supplies)	Ifosfamide	<LOD	<LOD	-
	Etoposide	<LOD	<LOD	
	Cyclophosphamide	<LOD	<LOD	
BMT Pt Bathroom Floor (Left)	Cyclophosphamide[1]	-	-	**0.18 ng/cm^2**
BMT Pt Bathroom Floor (Right)	Cyclophosphamide	-	-	**0.35 ng/cm^2**
BMT Chemo Cart Spot A	Cyclophosphamide	-	-	**0.12 ng/cm^2**
BMT Chemo Cart Spot B	Cyclophosphamide	-	-	<LOD

[1] Limit of Detection = 0.015 Nanograms/cm^2
[2] Limit of Detection = 0.005 Micrograms/cm^2
[3] Limit of Detection = 0.010 Nanograms/cm^2
[4] Limit of Detection = 0.005 Nanograms/cm^2
[5] Limit of Detection = 0.10 Nanograms/cm^2
[6] Limit of Detection = 0.005 Nanograms/cm^2
[7] Limit of Detection = 0.005 Nanograms/cm^2

Table 3 : Demographic Characteristics of Survey Respondents

Characteristic	Pretest (n=100) N (%)	Posttest (n=71) N (%)	Pretest Only (n=33) N (%)	Short Survey (n=10) N (%)
Setting Employed				
Pharmacy	11 (11)	8 (11.2)	2 (6.1)	0
Outpatient Chemotherapy	17 (17)	14 (19.7)	5 (15.2)	0
Inpatient Bone Marrow Transplant	45 (45)	32 (45)	16 (48.5)	5 (50)
Inpatient Oncology	27 (27)	17 (23.9)	10 (30.3)	5 (50)
Gender				
Male	12 (12.5)	10 (14.3)	5 (17.2)	1 (10)
Female	84 (87.5)	60 (85.7)	24 (82.8)	9 (90)
Age (years)				
Less than 25	8 (46.2)	1 (1.5)	4 (14.3)	
25-35	43 (15.1)	23 (35.3)	13 (46.4)	
36-45	14 (30.1)	20 (30.8)	4 (14.3)	
Over 45	28 (8.6)	21 (32.3)	7 (25)	
Race				
American Indian/Alaskan Native	3 (3.1)	0	1 (3.4)	
Black/African American	3 (3.1)	2 (2.9)	1 (3.4)	
Asian	3 (3.1)	2 (2.9)	2 (6.9)	
Hispanic/Latino	0	1 (1.4)	0	
Native Hawaiian	0	0	0	
White	85 (87.6)	64 (91.4)	24 (82.8)	8 (80)
Two or more	2 (2.1)	1 (1.4)	1 (3.4)	2 (20)
Other	1 (1)	0	0	

Highest level of nursing education				
Diploma	1 (1.1)	1 (1.4)	0	
Associate degree	11 (11.7)	7 (9.9)	4 (13.8)	
Bachelor's degree	74 (78.7)	56 (78.9)	20 (69)	
Master's degree	8 (8.5)	7 (9.9)	5 (17.2)	
Oncology Nursing Society member				
Yes	40 (41.2)	27 (38.6)	11 (37.9)	2 (20)
No	57 (58.2)	43 (61.4)	18 (62.1)	8 (80)
Certified in nursing				
Not certified	58 (62)	41 (61.2)	14 (48.3)	
OCN	33 (35)	25 (37.3)	15 (51.7)	
AOCNS	2 (2)	1 (1.5)	0	
Years of chemotherapy handling experience				
0-2	21 (22.1)	13 (19.7)	5 (17.2)	
3-5	11 (11.6)	4 (6.1)	5 (17.2)	
6-10	30 (31.6)	21 (31.8)	7 (24.1)	
>10	33 (34.7)	28 (42.4)	12 (41.4)	

Table 3: PPE Score and Predictor Variable Average Scores by Unit

Unit	PPE Score	Know-ledge	Perceived Barriers	Perceived Risk	Self-Efficacy	Conflict of Interest	Interpersonal Influence	Workplace Safety Climate
Mean and Standard Deviations (SD)								
BMT								
Pre	25.9 (6.03)	10.2 (1.4)	20.1 (5.7)	1.8 (0.4)	23.4 (3.2)	10.4 (3.9)	15.3 (2.7)	65.8 (11.1)
Post	28.5 (4.7)	10.2 (1.5)	20.2 (5.3)	3.2 (0.4)	24.4 (3.5)	10.2 (4.2)	15.1 (3.3)	65.8 (11.5)
Short Survey	17.5 (3.7)	-	-	-	-	-	-	-
Pretest Only	40.8 (6.5)	10.1 (1.6)	19.8 (5.9)		23.8 (3.0)	11.2 (3.2)	14.8 (3.4)	66.5 (10.3)
Pharmacy*								
Pre	14.5 (6.1)	10.2 (1.9)	17.6 (5.2)	1.4 (0.7)	24.2 (3.3)	7.3 (2.1)	14.4 (4.1)	72.3 (2.1)
Post	16.6 (2.5)	10.8 (1.3)	17.8 (4.3)	2.9 (0.6)	25.6 (2.2)	8.9 (2.8)	16.4 (1.7)	72.1 (10.0)
Short Survey	-	-	-	-	-	-	-	-
Pretest Only	25 (0)	11.5 (0.7)	15.5 (0.7)		27 (1.4)	9 (4.2)	16.5 (0.7)	77.5 (7.8)
Oncology								
Pre	23.7	9.8	20.5	1.8 (0.5)	21.9	11.2	15.8	60.6

	(3.8)	(1.8)	(6.0)		(3.9)	(2.6)	(2.2)	(10.4)
Post	23.4 (4.1)	10.2 (1.2)	21.8 (5.9)	3.1 (0.6)	22.7 (2.2)	11.2 (3.5)	15.2 (3.0)	63.4 (8.8)
Short Survey	16.1 (5.6)	-	-	-	-	-	-	-
Pretest Only	34.4 (6.3)	10.2 (2.0)	20.3 (5.5)		19.8 (5.2)	10.7 (4.1)	14.8 (4.1)	54.6 (16.2)
Outpatient								
Pre	32.8 (4.9)	9.8 (1.5)	23.5 (5.6)	1.9 (0.4)	20.9 (1.9)	12.1 (3.6)	15.2 (2.3)	53.6 (9.3)
Post	42.4 (3.9)	9.5 (1.0)	25.9 (3.0)	3.2 (0.6)	20.6 (1.8)	13.5 (2.0)	14.5 (3.0)	52.5 (8.9)
Short Survey	-	-	-	-	-	-	-	-
Pretest Only	26.6 (3.8)	9.0 (2.9)	25.6 (2.6)		19.2 (3.3)	10.2 (6.4)	10.2 (4.4)	44.6 (7.4)

*PPE Score includes reported use of gloves, double gloves, gowns, not reusing disposable gowns and eye protection

Table 4: Results of Multivariate Regression

Dependent Variable	Parameter Estimate (Confidence Interval)	Parameter Estimate (Confidence Interval)
Unit[1]	Pre	Post
1. Bone Marrow Transplant	Reference	Reference
2. Pharmacy	**17 (3.7, 30.3)***	-10.9 (-22.9, 1.02)
3. Oncology	**-8.9 (-17.2, -0.6)***	**-11.95 (-20.9, -3.0)***
4. Masonic Outpatient	**-10.6 (-20.3, -0.9)***	-6 (-15.8, 3.8)
Self-Efficacy[2]	**1.4 (0.36, 2.45)***	0.53 (-0.34, 1.41)
Workplace Safety Climate[3]	0.23 (-0.10, 0.55)	0.19 (-0.19, 0.57)
Workplace Safety Climate[4]	**0.5 (0.19, 0.81)***	0.18 (-0.21, 0.58)
Perceived Barriers[5]	-0.47 (-1.1, 0.18)	-0.54 (-1.32, 0.23)

1= Controlling for perceived barriers, safety climate, interpersonal influence, age and gender
2= Controlling for perceived barriers, age and gender
3= Controlling for unit, perceived barriers, interpersonal influence, age and gender
4= Controlling for perceived barriers, interpersonal influence, age and gender
5=Controlling for unit, safety climate, interpersonal influence, age and gender
***=Statistically significant**

Table 5: Paired T-Test Results: Comparison of Personal Protective Equipment Use and Predictor Variable Use Pre and Post Intervention

Variable	T-Value	95% Confidence Interval
PPE Use by Unit		
Outpatient Infusion*	**2.43**	**0.81, 18.3**
Bone Marrow Transplant	1.79	-0.50, 7.66
Oncology	-0.03	-4.49, 4.37
Pharmacy	0.72	-5.2, 9.5
PPE Score (all units combined)	0.48	-4.67, 2.87
Knowledge Score	1.06	-0.58, 0.18
Self-Efficacy*	**2.33**	**-1.58, -0.12**
Perceived Barriers	1.24	-2.08, 0.48
Perceived Risk*	**13.58**	**1.19, 1.60**
Conflict of Interest	0.61	-0.59, 1.11
Interpersonal Influence	-0.64	-0.89, 0.46
Safety Climate	0.56	-1.51, 2.69

***=Statistically significant**

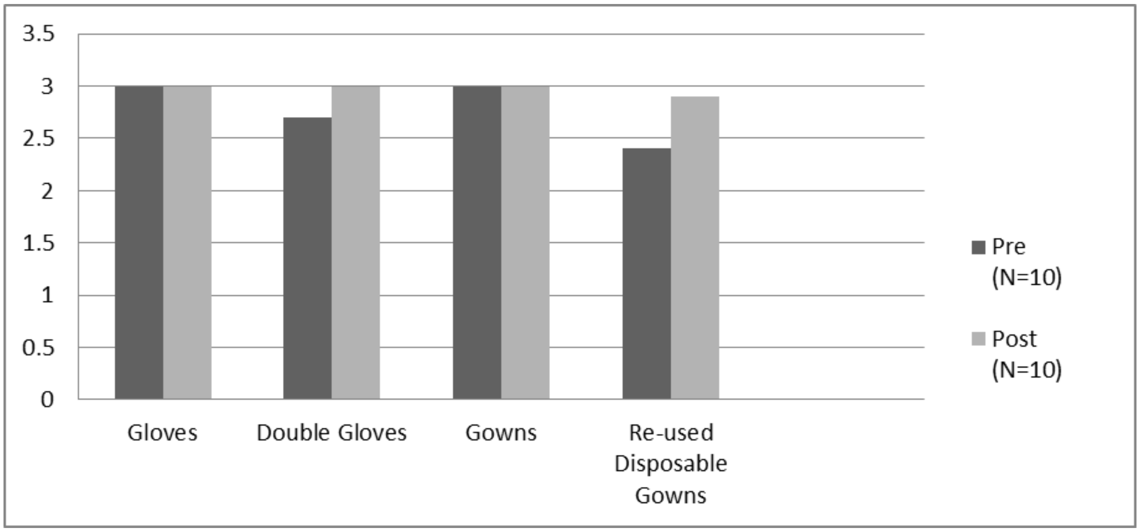


Figure 1: Reported PPE Use Score during Preparation of Antineoplastic Agents

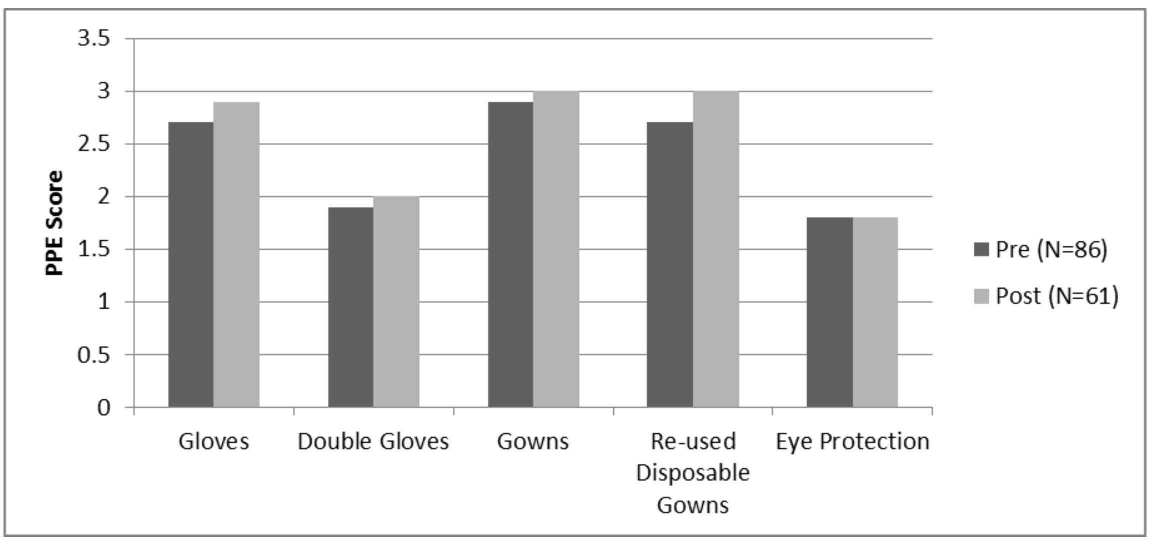


Figure 2: Reported PPE Use Score during Administration of Antineoplastic Agents

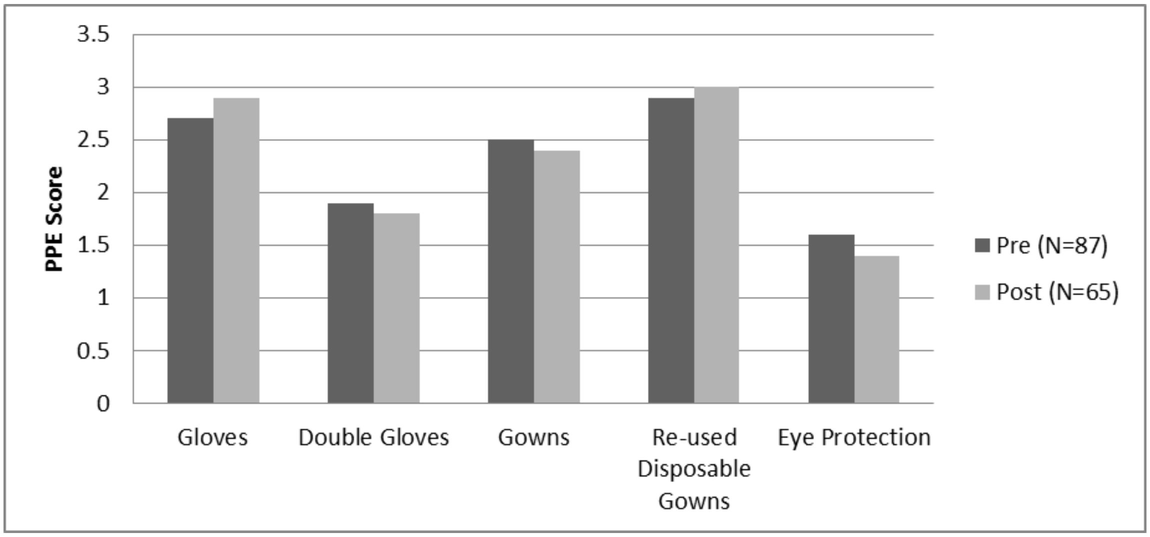


Figure 3: Reported PPE Use Score during Disposal of Antineoplastic Agents

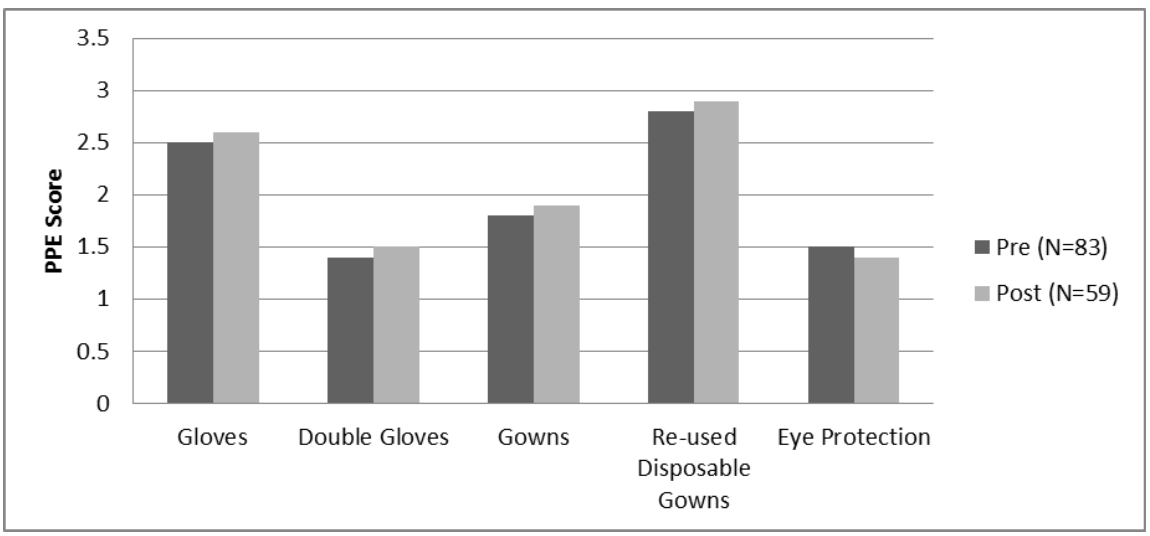
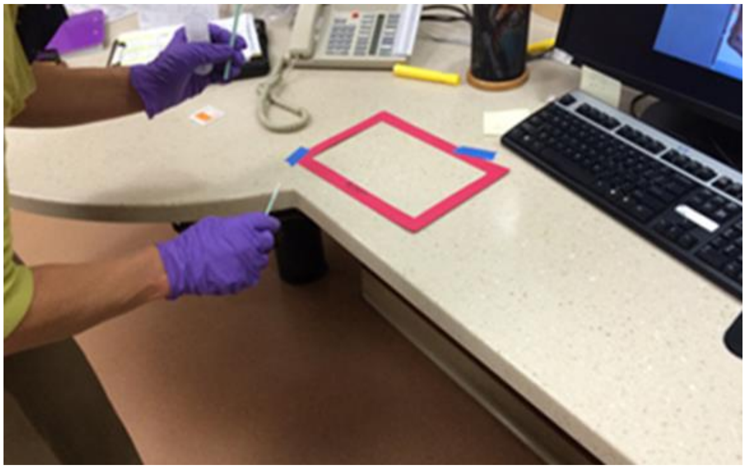


Figure 4: Reported PPE Use Score While Handling Excreta from Patients who have had Antineoplastic Agents



Picture 1: Location of chemotherapy double check pre-intervention (main nursing desk)

Picture 2: Location of chemotherapy double check post-intervention (in red tape of locked medication room)

CHAPTER 8: DISCUSSION, LIMIATIONS AND CONCLUSION

Discussion

Alternate Hypothesis

While the published literature to date has reported surface contamination of areas where chemotherapy is administered (Connor et al., 2010) and leadership at the study site's hospital has identified a need for increased safety precautions, we knew it was possible that levels of surface contamination would be low prior to the intervention and therefore insufficient to motivate behavior changes among oncology personnel. We also considered the possibility that any changes we identified in relation to an intervention would not be statistically significant, nor meaningful for the health care workers. Finally, we recognized the possibility that the intervention we tested would be successful in increasing workers' awareness of potential exposures, but changes in their work practices would not be realized from the surface wipe sampling due to methodological issues such as the limited selection of environmental locations for sampling, or that changes in workers' awareness would simply not translate into behavior change for reasons we did not measure (omitted variables).

Environmental Sampling

Health care organizations teach their employees to put patient needs first. While this is very important for patient health and safety, patients with cancer would not want their caregivers to develop illness because of their care. In this study, we found gaps in employee safety associated with environmental surface contamination from chemotherapy residue and with employees' inadequate use of Personal Protective

Equipment (PPE). We identified contaminated surfaces in places where PPE use is not typical, such as commonly used counters. Identifying these areas and implementing intentions based on a quality improvement approach led to changes in work processes to eliminate the exposure. For example, in the outpatient area, work practices were modified requiring nurses to take off all potentially contaminated PPE prior to leaning on the counter. In the inpatient area, the location for "double checking" chemotherapy was moved from the main nursing desk to the locked medication room. Locations with chemotherapy residue were cleaned and remained uncontaminated one month after implementation of the changes.

Another example which required a different approach was the contamination found from testing floors in two patient care areas and the outpatient pharmacy where all three areas were contaminated. One area was an inpatient bathroom floor and another was an outpatient hallway. Following discussion of the findings, the staff moved their laundry bin out of the outpatient hallway and cleaned the area, but contamination persisted. It was recommended to staff that floors be considered contaminated and that they keep a dedicated pair of shoes at work to prevent bringing chemotherapy home. If not for surface sampling, these units would never have known which areas were contaminated and required cleaning, nor would they have engaged in a critical review of the associated work processes to understand the extent of the problem and the options for resolution. These findings highlight the importance of an objective monitoring and feedback system. Tailored interventions can decrease surface contamination of a unit, but must be preceded by a worksite analysis to observe the workflow and identify where there are gaps in safety.

During the process of conducting the interventions, concerns arose about employees other than the study participants. There were two occasions in which it was clear that support staff were not aware of their potential for exposure. One involved nurses' aides not having been trained on safety precautions and the other was that cleaning staff were not using proper PPE when being called in to clean outpatient bathrooms. Safety training was conducted for cleaning staff by their management. This is important because it illustrates how trace chemotherapy may be inadvertently contaminating other locations. Additionally, it showed that management was taking seriously the potential exposure of all employees to chemotherapy.

Survey Findings

In this study, survey results regarding reported PPE use, a proxy for safe handling techniques, were similar to other published studies where glove use was high and double gloving was much lower (Boiano et al., 2014; Polovich & Clark, 2012). This is likely because double gloving takes extra time and may make tasks more cumbersome. It also confirmed findings from other studies that PPE use varies by tasks conducted by health care workers, with preparation and administration having much higher use of PPE by staff than tasks involving disposal or handling patient excreta. This is likely due to the nature of the activities —administration is often a planned event, whereas disposal and handling body fluids are more dynamic.

Overall use of PPE was highest for pharmacy (versus nursing) staff in this study and levels of surface contamination were also the lowest. The differences found in PPE use and surface levels of chemotherapy residue between the pharmacy and nursing work environments were unexpected and curious. It may be partially due to the different job tasks performed by each discipline. The pharmacists' contact with chemotherapy primarily involved drug preparation, a specific job task, which is done without patient and family member interruption. In contrast the nurses performed multiple job tasks involving chemotherapy which required the use of PPE including drug administration, and the disposal and handling of patient excreta. Such tasks typically involve many interruptions. Because this is one of the only studies the authors found that surveyed both nursing and pharmacy staff, additional research is needed to see if these differences are replicated in other oncology settings

Among the three groups of nurses, those who worked on the bone marrow transplant (BMT) floor reported the highest PPE use, but they also reported caring for the lowest number of patients during a shift. This finding suggests the potential impact of patient/staff ratios on appropriate use of PPE.

Survey findings revealed that workers' perceived risk increased significantly following the intervention. This is consistent with the study's theoretical model that suggests increased information and discussion of potential risk will increase PPE use and improve worker safety behavior (Polovich & Clark, 2012). The goal was not to scare employees, but to remind them of their risk with objective information about their exposures.

Multivariate analyses of survey data revealed that the organizational unit where a nurse or pharmacist worked was the factor that was most strongly associated with use of personnel protective equipment when adjusting for other factors such as perceived barriers, safety climate, interpersonal influence, gender and age. Organizational unit is likely a proxy measure for many factors potentially influencing workplace safety, including variables for which we lacked data such as staffing ratios as mentioned above. Models estimating the association of safety climate to PPE were generally nonsignificant. Four models were estimated, two using pretest data and two using posttest data. In each time period the models were adjusted for perceived barriers, interpersonal influence, age and gender with the only distinction being adjustment for or omission of the variable of unit from the model. In only one of four models was workplace safety climate significantly associated with PPE; it was significant when using data from the pretest survey and only in the model specification when unit was excluded. These findings were unexpected as descriptive findings showed the association between workplace safety climate and PPE use was graded for each organizational unit. Thus as workplace safety climate score increased, PPE use also increased and perceived barriers decreased. Moreover the multivariate findings were inconsistent with another study of nurses use of PPE which showed a significant association with safety climate reported by Polovich & Clark (2012) and in studies of workplace safety climate in diverse industries including healthcare (Christian, Bradley, Wallace, & Burke, 2009; Friese et al., 2012; Polovich & Clark, 2012; Zohar, 2010). The reason for the multivariate findings is unclear other than there is likely covariance between the measures of unit and workplace safety climate and the inclusion of unit in the model may swamp the unique contribution of workplace safety climate to PPE use, or the model may lack sufficient statistical power, especially on the posttest, as the sample size declined from 100 to 71 respondents.

Finally, a specific policy issue investigated on the survey addressed the issue of nurses seeking alternative duty to avoid working with chemotherapy agents, if they became pregnant. The percentage of nurses who reported they would ask for alternative duty if they became pregnant was much higher than the percentage who actually did ask. It's unclear if this is because individual priorities change once staff members become pregnant, if the survey somehow suggested that they should ask, or if staff members who work on these units enjoy their jobs and find it difficult to imagine working in another setting. Additionally, 50% more nurses reported having asked for alternative duty in the posttest compared to the pretest which may relate to the survey findings of an increase in perceived risk among study participants following the study's interventions.

Limitations

There are important limitations to be noted when interpreting the results of this study. Because this was a pre-posttest study, there is an inherent limitation in how participants may have been influenced by the study itself. There is always the concern that it was not the intervention itself which changed things, but simply the focus on the issue (i.e., the Hawthorne effect). Since the survey was self-report data, it is also possible that recall bias occurred.

While the PPE use and answers to the predictor variables of the non-responders is unknown, it may be hypothesized that they would score lower on the workplace safety climate measure (as they didn't take the time to complete the survey). Those who responded to the short survey did report equal PPE use; however this was a small group of ten respondents. Because better workplace safety climate was correlated with higher PPE use, it might also mean that these non-responders may have slightly lower use of PPE during safe handling. While the survey did have responses from the majority of staff in each area, the responses were from individuals working in one institution thus the generalizability of the study findings to other settings is unknown. Ultimately the study needs to be replicated at a variety of institutions and oncology service units to assess its generalizability. Additionally, an important factor associated with PPE use in some studies is the nurse patient ratio which was not possible to measure in our study and will be important for future researchers to consider.

Because the organizational unit is likely a proxy measure for many factors potentially influencing workplace safety, future research could identify the relative contribution of factors that vary by unit and may influence use of PPE such as safety climate, self-efficacy and staffing ratios. Future research is also needed to better understand why surface areas are contaminated with chemotherapy in order to protect healthcare workers and hospital visitors. The contamination of common work areas where health care workers are not expected to use PPE is of utmost concern.

This study was also done on a small sample of healthcare workers. It was an especially small sample of pharmacist and pharmacy technicians (n=10). A strength of the study was that it was offered to all oncology employees in one healthcare setting, but that did limit the potential number of participants.

While we conducted environmental sampling in 39 key locations accounting for 76 unique antineoplastic agents by location, the findings of surface contamination can vary by day, based on a variety of factors. Despite these limitations, this study is one of the first in the literature to test an intervention that combined a quality improvement process with data on surface contamination, PPE use, and organizational variables among both inpatient and outpatient nursing and pharmacy staff.

Conclusion

It is clear that healthcare workers must understand the risks associated with handling antineoplastic agents and the safe handling precautions that reduce exposure. It is important that units have a safety climate that encourages chemotherapy safety. Managers must be involved in holding staff accountable for their own safety, which will in turn improve the safety of others.

Targeted interventions did decrease potential exposure. A thorough investigation involving surface monitoring and feedback from staff who worked on the units identified areas where improvement was needed. Periodic surface contamination monitoring should be mandated to identify sources of potential exposure. Without clear policy to require such measures, however, it is up to healthcare professionals to monitor their oncology environments for safety and unnecessary exposures.

While this study focused on nurses and pharmacy staff, other staff members such as patient care assistants, cleaning staff, delivery personnel, and patients' visitors are also potentially exposed to chemotherapy. All of these populations warrant attention in future studies. All staff who work in areas where antineoplastic agents are handled must be trained to use safe handling precautions.

IMPLICATIONS FOR FUTURE WORK

The organizational unit where oncology staff works is a significant driver of the use of personal protective equipment during chemotherapy handling. These findings suggest the importance of focusing on organizational, rather than individual, factors in striving to understand the use of PPE. Surface contamination is a risk to healthcare workers and others on these oncology units and precautions need to be taken to prevent unnecessary exposure to these dangerous agents. According to the NIOSH recommendations, work surfaces should be cleaned with an appropriate deactivation agent before and after each activity and at the end of the work shift (National Institute for Occupational Safety and Health, 2004). Surface monitoring should occur every six months to a year, or following concerns about worker health (National Institute for Occupational Safety and Health, 2004). While this study focused on nurses and pharmacy staff, other members of the health care team such as patient care assistants, cleaning staff, and delivery personnel also have the potential for exposure. Family members, friends, and other visitors to the hospital similarly may be at risk and all of these populations should be addressed in future studies.

There is also future work that is needed to explore state and federal policy around safe handling. States are beginning to pass legislation requiring facilities to follow NIOSH recommendations (i.e. California, North Carolina, and Washington). It is important to learn from these states and consider the implications for safety that have been realized there in order to understand how the state where this study took place may benefit from similar legislation. The ultimate goal is that healthcare workers are as safe as possible while helping to care for their patients.

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UNIVERSITY OF MINNESOTA

DETERMINATION OF HUMAN SUBJECT RESEARCH

Route this form to: Human Research Protection Program	**U Wide Form** Aug 2013

Version 1.1

Updated August 2013, go http://www.irb.umn.edu for the latest version

This form is used to help researchers determine if a project requires IRB review. If evidence that IRB review is not required, this form may be used to document that the IRB has reviewed the project description and issued a determinati

and response.

Based on the information provided, this project does not meet the regulatory definition of human subjects research. No further IRB review is required.

By Jeffery Perkey on May 22, 2014

Section 1 Project Title

Provide the project title below

If the project is funded or if funding is pending, the project title must match grant title.

Necessary Drugs; Unnecessary Consequences: An Intervention to Protect Healthcare Workers

Section 2 Contact Information

Name (Last name, First name MI): **Graeve, Catherine U**	Affiliation: ☒U of M ☐Fairview ☐Gillette ☐Other
Email: **grae0040@umn.edu**	U of M x.500 ID (ex. smith001): **grae0040**
Phone Number: **651-488-2342**	U of M Department **Environmental Health Sciences- School of Public Health**

Section 3 Project Description

1. Provide a brief description of your project. Include a description of what any participants will be asked to do

and a description of the data accessed and/or collected (1,000 character limit).

This study will employ a before-after study design to develop, implement and evaluate an intervention to minimize exposures and promote compliance with the NIOSH 2004 Alert for Preventing Occupational Exposure to Antineoplastic and other Hazardous Drugs in Health Care Settings in three different oncology settings in the Fairview University hospital system. The population of all nurses and pharmacists (N=157) from Fairview Hospital's oncology, bone marrow transplant, and outpatient chemotherapy units will be invited to participate in the study. Findings from the survey and the exposure assessment will be used to design and implement a quality improvement intervention and the employee survey will be repeated with the same population following the intervention. Prior to survey collection, wipe samples for surface detection of chemotherapy will be collected in patient care, nursing and pharmacy areas for commonly used antineoplastic drugs confirmed to be given on the units.

UNIVERSITY OF MINNESOTA
MEDICAL CENTER
FAIRVIEW

2450 Riverside Avenue
Minneapolis, MN 55454

August 4, 2014

Catherine Graeve
SPH Environmental Health Division MMC 197
Mayo 8197c
420 Delaware St SE Minneapolis, MN 55455

Dear Ms. Graeve,

Thank you very much for your clarifications. They were very helpful in understanding your proposal “Necessary Drugs; Unnecessary Consequences: An Intervention to Protect Oncology Healthcare Workers”.

Your proposal has been approved with the modifications you have outlined.

When you have completed your research, forward a copy of your report to the Nursing Research Council. You can do that by sending it me. We also request that you support research dissemination by contributing a copy of your abstract for the Nursing Links (Nursing Department newsletter for University of Minnesota Medical Center, Fairview). We also may want to interview you for an internal Fairview publication.

Good luck on your research! This is exciting work and is definitely needed for Nursing!

Sincerely,
Shamsah Rehmatullah, APRN, MS
Clinical Nurse Specialist
Chair, Nursing Research Council Proposal Review Subcommittee

June 6th, 2014

Dear Potential Participant,

You are invited to participate in a study of safe handling of occupational exposure to chemotherapy. You were selected as a possible participant in this study because of your work location. We will be asking for your participation in a similar study in approximately 9 months.

If you decide to participate, please complete the online survey that will be emailed to you. Your completion of the survey is implied consent. The survey will ask about your exposure to chemotherapy, use of personal protective equipment, and workplace culture. It will take about twenty minutes. No direct benefits accrue to you for answering the survey, but your responses will be used to help improve workplace health and safety. Any discomfort or inconvenience to you derives only from the amount of time taken to complete the survey.

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will not be disclosed.

Your decision whether or not to participate will not prejudice your future relationships with your workplace. If you decide to participate, you are free to discontinue participation at any time without prejudice.

If you have any questions, please contact Catherine Graeve at grae0040@umn.edu.

Thank you for your time.

Sincerely,

Catherine Graeve

Chemotherapy Handling Questionnaire

Please complete the survey below.

Thank you!

Thank you for agreeing to participate in this study of healthcare workers 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, or orally.
-By disposal, we mean discarding equipment used in chemotherapy preparation or administration.
-By handling excreta, we mean emptying bedpans, urinals or emesis basins.

Section 1

1a. Does your workplace have written policies and/or procedures for handling chemotherapy?

☐ Yes
☐ No

1b. Where is chemotherapy prepared in your workplace? Check all that apply.

☐ Pharmacy
☐ Drugs are delivered to the infusion area (prepared in an off-site location)
☐ Specially designated room separate from the patient care area
☐ Area within the patient treatment area/room
☐ Not sure

1c. What personal protective equipment is available for performing the following handling activities? Check all that apply.

	Gloves	Gowns	Eye Protection	Respirator/Mask
Preparation	☐	☐	☐	☐
Administration	☐	☐	☐	☐
Handling Excreta	☐	☐	☐	☐
Disposal	☐	☐	☐	☐
Cleaning Spills	☐	☐	☐	☐

Section 2: Chemotherapy Preparation

2a. Are you responsible for preparing chemotherapy?

- ☐ Yes
- ☐ No

2b. What type of gloves do you wear most often while preparing chemotherapy? Choose one.

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

2b. What type of protective clothing do you wear most often while preparing chemotherapy? Choose one.

- ☐ None
- ☐ Chemotherapy-designed gown
- ☐ Personal lab coat
- ☐ Lab coat provided by facility
- ☐ Cloth gown
- ☐ Isolation gown

2c. Please indicate how much of the time you use the following while preparing chemotherapy:

	Always	76-99%	51-75%	26-50%	1-25%	Never
Biological Safety Cabinet	☐	☐	☐	☐	☐	☐
Closed system transfer device	☐	☐	☐	☐	☐	☐
Gloves labeled for use with chemotherapy	☐	☐	☐	☐	☐	☐
Other gloves (e.g. vinyl)	☐	☐	☐	☐	☐	☐
Double gloves	☐	☐	☐	☐	☐	☐
Gowns labeled for use with chemotherapy	☐	☐	☐	☐	☐	☐
Other gowns (e.g. cloth)	☐	☐	☐	☐	☐	☐
Do you re-use disposable gowns?	☐	☐	☐	☐	☐	☐
Eye protection	☐	☐	☐	☐	☐	☐
Respirator/mask	☐	☐	☐	☐	☐	☐

Please indicate how much of the time you use the following while administering chemotherapy?

	Always	76-99%	51-75%	26-50%	1-25%	Never
Closed system transfer device	☐	☐	☐	☐	☐	☐
Gloves labeled designated for use with chemotherapy	☐	☐	☐	☐	☐	☐
Other gloves (e.g. vinyl)	☐	☐	☐	☐	☐	☐
Double gloves	☐	☐	☐	☐	☐	☐
Gowns labeled for use with chemotherapy	☐	☐	☐	☐	☐	☐
Other gowns (e.g. isolation)	☐	☐	☐	☐	☐	☐
Do you re-use disposable gowns?	☐	☐	☐	☐	☐	☐
Eye protection	☐	☐	☐	☐	☐	☐
Respirator/mask	☐	☐	☐	☐	☐	☐

Section 4: Chemotherapy Disposal

4a. Are you responsible for handling chemotherapy disposal?

☐ Yes
☐ No

4b. Please indicate how much of the time you use the following when disposing of chemotherapy:

	Always	76-99%	51-75%	26-50%	1-25%	Never
Gloves labeled for use with chemotherapy	☐	☐	☐	☐	☐	☐
Other gloves (e.g. vinyl)	☐	☐	☐	☐	☐	☐
Double gloves	☐	☐	☐	☐	☐	☐
Gowns labeled for use with chemotherapy	☐	☐	☐	☐	☐	☐
Other gowns (e.g. isolation)	☐	☐	☐	☐	☐	☐
Do you re-use disposable gowns?	☐	☐	☐	☐	☐	☐
Eye protection	☐	☐	☐	☐	☐	☐
Respirator/mask	☐	☐	☐	☐	☐	☐

Section 5: Handling Contaminated Excreta

5a. Are you responsible for handling chemotherapy-contaminated excreta?

☐ Yes
☐ No

5b. Please indicate how much of the time you use the following when handling excreta:

	Always	76-99%	51-75%	26-50%	1-25%	Never
Gloves labeled for use with chemotherapy	☐	☐	☐	☐	☐	☐
Other gloves (e.g. vinyl)	☐	☐	☐	☐	☐	☐
Double gloves	☐	☐	☐	☐	☐	☐
Gowns labeled for use with chemotherapy	☐	☐	☐	☐	☐	☐
Other gowns (e.g. isolation)	☐	☐	☐	☐	☐	☐
Do you re-use disposable gowns?	☐	☐	☐	☐	☐	☐
Eye protection	☐	☐	☐	☐	☐	☐
Respirator/mask	☐	☐	☐	☐	☐	☐

Section 6

6a. Are chemotherapy spill kits available in your work area?
☐ Yes
☐ No

6b. During the most recent chemotherapy spill in your workplace, did you use the materials in the spill kit?
☐ Yes
☐ No
☐ Not Applicable

6c. Please write the names of the three chemotherapy drugs you handle most frequently.
____

6d. Select ONE answer to each of the following statements about chemotherapy exposure.

	True	False	Don't Know
Chemotherapy can enter the body through breathing it in	☐	☐	☐
Chemotherapy can enter the body through ingesting it	☐	☐	☐
Chemotherapy cannot enter the body through contact with contaminated surfaces	☐	☐	☐
Chemotherapy can enter the body through contact with spills and splashes	☐	☐	☐
Chemotherapy gas and vapor in air can enter the body through the skin	☐	☐	☐

Oral forms of chemotherapy do not have the potential to be absorbed	☐	☐	☐
Chemotherapy in liquid form can be absorbed through the skin	☐	☐	☐
A surgical mask provides protection from chemotherapy aerosols	☐	☐	☐
All types of gloves provide the same level of protection	☐	☐	☐
Chemotherapy can more easily enter the body through damaged skin	☐	☐	☐
Alcohol hand sanitizer is as effective as soap and water in removing chemotherapy residue	☐	☐	☐
Chemotherapy can enter the body through contaminated foods, beverages, or cosmetics	☐	☐	☐

6e. Please 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

	SA	A	D	SD
I am confident that I can use PPE properly	☐	☐	☐	☐
I am confident that I can protect myself from chemotherapy exposure	☐	☐	☐	☐
I am given enough information on how to protect myself from chemotherapy exposure	☐	☐	☐	☐
My supervisor goes out of his/her way to make sure I am protected	☐	☐	☐	☐
Reuse of disposable PPE makes me feel less protected	☐	☐	☐	☐
I am provided with the best available PPE.	☐	☐	☐	☐

My supervisor goes out of his/her way to make sure I am provided with proper fitting PPE.	☐	☐	☐	☐

6f. 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:

	SA	A	D	SD
I don't think PPE is necessary	☐	☐	☐	☐
I don't think PPE works	☐	☐	☐	☐
I don't have the time to use PPE	☐	☐	☐	☐
PPE is uncomfortable to wear	☐	☐	☐	☐
PPE makes it harder to get the job done	☐	☐	☐	☐
PPE is not always available	☐	☐	☐	☐
Others around me don't use PPE	☐	☐	☐	☐
There is no policy requiring PPE	☐	☐	☐	☐
People would think I am overly cautious	☐	☐	☐	☐
It is hard to get chemotherapy-designated PPE	☐	☐	☐	☐
PPE is too expensive to use it all the time	☐	☐	☐	☐
PPE makes me feel too hot	☐	☐	☐	☐

6g. 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

	SA	A	D	SD
Exposure to chemotherapy is a serious problem at work	☐	☐	☐	☐
I am concerned about chemotherapy exposure at work and how it might affect my health	☐	☐	☐	☐
Compared to my co-workers, my chance of harm from chemotherapy is lower	☐	☐	☐	☐
If exposed to chemotherapy, there is a real chance I might experience bad effects	☐	☐	☐	☐

Chemotherapy exposure is not as harmful as some people claim	☐	☐	☐	☐
Compared to other work-related health risks, chemotherapy exposure is less serious	☐	☐	☐	☐
I am not worried about future negative health effects from chemotherapy exposure	☐	☐	☐	☐

6h. How often do the following people wear personal protective equipment when handling chemotherapy?

	Never	Sometimes	About Half	Usually	Does not apply
Your co-workers	☐	☐	☐	☐	☐
Other nurses you know	☐	☐	☐	☐	☐
Oncology nurses in general	☐	☐	☐	☐	☐

6i. According to the following people, how important is wearing PPE when handling chemotherapy?

	Not at all important	Sort of important	Very important	Does not apply
Your co-workers	☐	☐	☐	☐
Other nurses you know	☐	☐	☐	☐
Your supervisor or manager	☐	☐	☐	☐
Your employer	☐	☐	☐	☐

6j. Please indicate your level of agreement with each of the following statements.
SA= Strongly Agree; A= Agree; D= Disagree; SD= Strongly Disagree

	SA	A	D	SD
Personal protective equipment keeps me from doing my job to the best of my abilities.	☐	☐	☐	☐
Wearing personal protective equipment makes my patients worry.	☐	☐	☐	☐
Patient care often interferes with my being able to comply when using precautions.	☐	☐	☐	☐
I cannot always use safe handling practices because patient's needs come first.	☐	☐	☐	☐
Sometimes I have to choose between wearing PPE and caring for my patients.	☐	☐	☐	☐
Wearing personal protective equipment makes my patients feel uncomfortable.	☐	☐	☐	☐

6k. 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

	SA	A	N	D	SD
Chemotherapy gloves are readily accessible in my work area.	☐	☐	☐	☐	☐
Chemotherapy gowns are readily available in my work area.	☐	☐	☐	☐	☐
The protection of workers from occupational exposure to chemotherapy is a high priority with management where I work.	☐	☐	☐	☐	☐
On my unit, all reasonable steps are taken to minimize hazardous job tasks.	☐	☐	☐	☐	☐
Employees are encouraged to become involved in safety and health matters.	☐	☐	☐	☐	☐
Managers on my unit do their part to insure employees' protection from occupational exposure to chemotherapy.	☐	☐	☐	☐	☐
My job duties do not often interfere with my being able to follow chemotherapy safe handling practices.	☐	☐	☐	☐	☐
I have enough time in my work to always follow chemotherapy safe handling precautions.	☐	☐	☐	☐	☐
I usually do not have too much to do so that I can follow chemotherapy safe handling practices.	☐	☐	☐	☐	☐
On my unit, unsafe work practices are corrected by supervisors.	☐	☐	☐	☐	☐
My supervisor talks to me about safe work practices.	☐	☐	☐	☐	☐
I have had the opportunity to be properly trained to use personal protective equipment so that I can protect myself from chemotherapy exposures.	☐	☐	☐	☐	☐
Employees are taught to be aware of and to recognize potential health hazards at work.	☐	☐	☐	☐	☐
In my work area, I have access to policies and procedures regarding safety.	☐	☐	☐	☐	☐

My work area is kept clean.	☐	☐	☐	☐	☐
My work area is not cluttered.	☐	☐	☐	☐	☐
My work area is not crowded.	☐	☐	☐	☐	☐
There if minimal conflict within my work area.	☐	☐	☐	☐	☐
The members of my work area support one another.	☐	☐	☐	☐	☐
In my work area, there is open communication between supervisors and staff.	☐	☐	☐	☐	☐
In my work area we are expected to comply with safe handling policies and procedures.	☐	☐	☐	☐	☐

Section 7

7a. In what type of setting do you handle chemotherapy?

☐ Inpatient
☐ Outpatient
☐ Both
(where)

7b. What is your gender?

☐ Male
☐ Female
(Sex)

7c. What is your race or ethnic identity?

☐ American Indian/Alaskan Native
☐ Asian
☐ Black/African American
☐ Hispanic/Latino
☐ Native Hawaiian
☐ White
☐ Two or more
☐ Other

7d. What is your highest level of nursing education?

☐ Diploma
☐ Associate degree
☐ Bachelor's degree
☐ Masters degree
☐ Doctoral degree

7e. Are you a member of the Oncology Nursing Society?	☐ Yes ☐ No
7f. Are you certified in nursing? Check all that apply.	☐ Not certified ☐ OCN ☐ AOCN ☐ AOCNS ☐ NP ☐ AOCNP
7g. What is your age in years?	______________________
7h. How many years of nursing experience do you have?	______________________
7i. How many years of oncology nursing experience do you have?	______________________
7j. How many years of chemotherapy handling experience do you have?	______________________
7k. How many patients do you personally prepare and/or administer chemotherapy to per day?	______________________
7l. How many patients receive chemotherapy per day at your work place?	______________________
7m. Is there anything else you would like to tell us about safe handling in your work place?	______________________

Short Version: Chemotherapy Handling Questionnaire

Please complete the survey below.

Thank you!

On what unit do you work most of the time?	◯ Inpatient BMT ◯ Inpatient Heme/Onc ◯ Masonic Infusion Center ◯ Masonic Pharmacy ◯ SPIC Pharmacy
What is your gender?	◯ Male ◯ Female
What is your race or ethnic identity?	◯ American Indian/Alaskan Native ◯ Asian ◯ Black/African American ◯ Hispanic/Latino ◯ Native Hawaiian ◯ White ◯ Two or more ◯ Other
Are you a member of the Oncology Nursing Society?	◯ Yes ◯ No
What is your age in years?	______________________
How many years of oncology nursing experience do you have?	______________________

Are you responsible for preparing chemotherapy?	◯ Yes ◯ No

If yes, how often do you use the following while preparing chemotherapy?

	Always	76-99%	51-75%	26-50%	1-25%	Never
Biological safety cabinet	○	○	○	○	○	○
Closed system transfer device	○	○	○	○	○	○
Gloves labeled for use with chemotherapy	○	○	○	○	○	○
Double gloves	○	○	○	○	○	○
Gowns labeled for use with chemotherapy	○	○	○	○	○	○
Re-used disposable gowns	○	○	○	○	○	○
Eye protection	○	○	○	○	○	○
Respirator/mask	○	○	○	○	○	○

Are you responsible for administering chemotherapy?

○ Yes
○ No

If yes, how often do you use the following while administering chemotherapy?

	Always	76-99%	51-75%	26-50%	1-25%	Never
Closed system transfer device	○	○	○	○	○	○
Gloves labeled designated for use with chemotherapy	○	○	○	○	○	○
Double Gloves	○	○	○	○	○	○
Gowns labeled for use with chemotherapy	○	○	○	○	○	○

Re-used disposable gowns	○	○	○	○	○	○
Eye protection	○	○	○	○	○	○
Respirator/Mask	○	○	○	○	○	○

Are you responsible for handling chemotherapy disposal?

○ Yes
○ No

If yes, how often do you use the following while disposing of chemotherapy?

	Always	76-99%	51-75%	26-50%	1-25%	Never
Gloves labeled for use with chemotherapy	○	○	○	○	○	○
Double gloves	○	○	○	○	○	○
Gowns labeled for use with chemotherapy	○	○	○	○	○	○
Re-used disposable gowns	○	○	○	○	○	○
Eye protection	○	○	○	○	○	○
Respirator/Mask	○	○	○	○	○	○

Are you responsible for handling chemotherapy-contaminated excreta?

○ Yes
○ No

If yes, how often do you use the following while handling chemotherapy-contaminated excreta?

	Always	76-99%	51-75%	26-50%	1-25%	Never
Gloves labeled for use with chemotherapy	○	○	○	○	○	○
Double Gloves	○	○	○	○	○	○
Gowns labeled for use with chemotherapy	○	○	○	○	○	○
Reused disposable gowns	○	○	○	○	○	○
Eye protection	○	○	○	○	○	○
Respirator/Mask	○	○	○	○	○	○

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

Thank you for taking the time to complete the survey!

Chemotherapy Surface Sampling Recommendations: Fairview September 2015

1. Wipe sampling should take place on a routine basis, preferably **every 6 months**[1] (more often if needed to verify containment). Areas sampled should include:

- Inside the containment primary engineering control (C-PEC) and equipment inside it (pharmacy)
- Work areas near the C-PEC (pharmacy)
- Areas adjacent to the C-PEC (floors under staging and dispensing area) (pharmacy)
- Patient administration areas (nursing)[2]

2. If any measurable contamination is found, action should be taken to identify, document and contain the cause if possible. This may include reevaluation of work practices, re-training workers, performing deactivation/decontamination and cleaning, and improving engineering controls. Sampling should be repeated to validate steps taken were effective.[2]

Cost Estimates for Fairview/Masonic Wipe Sampling (sampling the top 5-7 most commonly used agents recommended by National Institute for Occupational Safety and Health (NIOSH) for testing in each area):

Bureau Veritas Name	Number of Swabs*	Cost per Swab	Total Cost per Sampling for Test Kits**	Antineoplastic Agents Can Pick From
Group A, 10 Scan: Can pick 7 most commonly used antineoplastic drugs	8: 5C 8: 7D 12: Masonic 5: SIPC	$375	**$12,375 x2 if done every 6 months =** **$24,750 a year**	1. 5-FLUOROURACIL 2. CYCLOPHOSPHAMIDE 3. DOXORUBICIN 4. EPIRUBICIN 5. ETOPOSIDE (PHOSPHATE) 6. IFOSFAMIDE 7. IRINOTECAN 8. PACLITAXOL 9. METHOTREXATE 10. VINCRISTINE

*Number of swabs can vary based on areas managers are concerned about for possibly contamination. These numbers take into account areas sampled in the preliminary safety study done on these units in 2014-2015. Inpatient pharmacy is not included in this estimate, as it is unclear how much sampling is already done in these areas at this time.

****Cost is for sampling and analysis. Would need to hire consultant to coordinate and swab if not planning to use internal staff.**

Chemotherapy Surface Sampling Recommendations: Fairview September 2015

Results from Areas Sampled Previously

Table 1: Surface Contamination Results for Outpatient SPIC Pharmacy ($3360)

Location	**Antineoplastic Drug Tested**	**Results- Pre October 2014**	**Results-Post August 2015**
Chemo. Tote	Cyclophosphamide[1] Gemcitabine[2]	< LOD	< LOD
Plastic Drug Bin	Cyclophosphamide Gemcitabine	< LOD	< LOD
Biohazard Lid	Cyclophosphamide Gemcitabine	< LOD	< LOD
Chemo-Pad	Cyclophosphamide Gemcitabine	< LOD	< LOD
Cyclophosphamide Bin	Cyclophosphamide	<LOD	<LOD
Gemcitabine Bin	Gemcitabine	<LOD	<LOD

[1] Level of Detection = 3.0 Nanograms

[2] Level of Detection = 1 Microgram

Chemotherapy Surface Sampling Recommendations: Fairview September 2015

Table 2: Surface Contamination Results for Outpatient Infusion Center ($3760)

Location	**Antineoplastic Drug Tested**	**Results-Pre**	**Results-Post**
Break room Table	Paclitaxel[1] Gemcitabi[2]	< LOD	<LOD
Nursing Desk Pod A	Paclitaxel Gemcitab	< LOD	<LOD
Floor under Laundry Bin	Paclitaxel Gemcitab	**6.64 Nanograms** < LOD	**26 Nanograms** <LOD
Pt Chair Armrest Following Paclitaxel Infusion- NOT cleaned	Paclitaxel	**4.28 Nanograms**	<LOD
Pt Chair Armrest Following Gemcitabine Infusion- CLEANED	Gemcitabine	< LOD	<LOD
Pharmacy to Nursing Drug Bins	Paclitaxel Gemcitab	< LOD	<LOD
Nursing to Pharmacy Counter under Bin Return	Paclitaxel Gemcitab	**10.6 Nanograms**	<LOD
Pharmacy Negative Pressure Room Counter	Paclitaxel Gemcitab	< LOD	<LOD
Pharmacy Negative Pressure Room Floor	Paclitaxel Gemcitab	< LOD	**15.4 Nanograms**

[1] Level of Detection = 2 Nanograms
[2] Level of Detection = 1 Microgram

Table 3: Surface Contamination Results for 7D, October 2014 ($3000)

Location	**Antineoplastic Drug Tested**	**Results- Pre October 2014**	**Re su**
Room Keyboard	Ifosfamide[1] Etoposide[2] Methotrexate[3]	<LOD	<L O D
Bathroom Wall	Ifosfamide Etoposide Methotrexate	<LOD	<L O D
Nurses Cart	Ifosfamide Etoposide Methotrexate	<LOD	<L O D
Nurses Station Counter Opposite Charge (Place Chemo Double-Checked)	Ifosfamide Etoposide Methotrexate	**11 Nanograms** <LOD <LOD	<L O D
Med Room Refrigerated Chemo Bin A-M	Ifosfamide Etoposide Methotrexate	<LOD	**63 Nanograms**
Dirty Utility Room Biohazard Bin Lid	Ifosfamide Etoposide Methotrexate	<LOD	<L O D

[1] Level of Detection = 1 Nanogram
[2] Level of Detection = 20 Nanograms
[3] Level of Detection = 1 Nanogram

Table 4: Surface Contamination Results BMT, October 2014 ($3000)

Location	Antineoplastic Drug Tested	Results- Pre October 2014	Results- Post August 2015
Cleaning Cart after Cleaning Chemo Precautions Room	Ifosfamide[1] Etoposide[2] Cyclophosphamide[3]	<LOD	<LOD
Room 431 Patient Side Table	Ifosfamide Etoposide Cyclophosphamide	<LOD <LOD **1.5 Nanograms**	<LOD <LOD <LOD
Nurses Station Printer Keyboard	Ifosfamide Etoposide Cyclophosphamide	<LOD	<LOD
5-446 Physician's Workroom Door handle and KeyPad	Ifosfamide Etoposide Cyclophosphamide	<LOD	<LOD
Cordless Phones at Nurses Station	Ifosfamide Etoposide Cyclophosphamide	<LOD	<LOD
Cytocart	Ifosfamide Etoposide Cyclophosphamide	<LOD	<LOD

[1] Level of Detection = 1 Nanogram [2] Level of Detection = 20 Nanograms

[3] Level of Detection = 1 Nanogram

Table 5: Interim Sampling Results May 2015 ($1860)

Location	Antineoplastic Drug Tested	Results
BMT Pt Bathroom Floor (Left)	Cyclophosphamide[1]	**18.3 Nanograms**
BMT Pt Bathroom Floor (Right)	Cyclophosphamide	**35.4 Nanograms**
BMT Chemo Cart Spot A	Cyclophosphamide	**1.22 Nanograms**
BMT Chemo Cart Spot B	Cyclophosphamide	<LOD
7D Charge Desk Counter Spot A	Ifosfamide[2]	**1.61 Nanograms**
7D Charge Desk Counter Spot B	Ifosfamide	<LOD
7D Bag of Ifosfamide Front	Ifosfamide	**3440 Nanograms**
7D Bag of Ifosfamide Back	Ifosfamide	**942 Nanograms**
Outpatient Chemo Cart	Paclitaxel[3]	<LOD
Outpatient Computer Cart	Paclitaxel	<LOD
Outpatient Bottom Drawer 1	Paclitaxel	<LOD
Outpatient Bottom Drawer 2	Paclitaxel	<LOD

[1] Level of Detection = 1 Nanogram

[2] Level of Detection = 1 Nanogram

[3] Level of Detection = 2 Nanograms

Cleaning Antineoplastic Agents

General information:

- Decontamination can be defined as deactivating or cleaning, but deactivating a hazardous substance if preferred
- There is NO single process that has been found to deactivate all currently available hazardous drugs [3,4]
- The use of alcohol alone for disinfecting will not deactivate hazardous drugs and may cause spreading of contamination[4]
- Many drugs require Sodium Hypochlorite as a strong oxidizing agent which works as a deactivator[4]
- Wipe down procedures for contaminated vials hasn't been studied, but use of gauze moistened with alcohol, sterile water, peroxide, or sodium hypochlorite solutions might be effective[4]

Commercially Available Products:

1. SurfaceSafe (SuperGen, Dublin, CA): provides a system for decontamination and deactivation using sodium hypochlorite, detergent, and thiosulfate neutralizer. Two wipe system.

   http://iso-med.com/index.php?main_page=index&cPath=35_251

2. HDClean (ChemoGLO, LLC): Two step wiping procedure using towelettes that has been tested to remove docetaxel, paclitaxel, 5-flourouracil, cyclophosphamide, ifosfamide, and cisplatin. Claims to have no overpowering odor.

   www.chemoglo.com

3. Peridox: Commercially available product that states it is 99.95% effective in cleaning (Masonic Pharmacy tried this and is not using it on floors or walls due to its smell. They are using it on the BSC.)

4. Lysol IC foaming Disinfectant Cleaner: Product that Fairview pharmacy and inpatient cleaning currently has in stock. Used in intervention phase on all but one location prior to post-samples and seemed to be effective. The other location (7D nursing desk) used the orange top PDI sani- cloth with bleach wipes during the intervention and also had a negative post-test.

Chemotherapy Surface Sampling Recommendations: Fairview September 2015

Recommendations for cleaning

- Clean work surfaces with an appropriate deactivation agent (if available) and cleaning agent before and after each activity and at the end of the work shift.[5]
- Establish periodic cleaning routines for all work surfaces and equipment that may become contaminated, including administration carts and trays.[5]
- At a minimum, wear safety glasses with side shields and protective gloves for cleaning and decontaminating work and wear face shields if splashing is possible.[5]
- Wear protective double gloves for decontaminating and cleaning work and make sure the gloves are chemically resistant to the decontamination or cleaning agent used.[5]
- Assume the outside of chemotherapy bags are contaminated and double glove
- Assume the floors of areas where chemotherapy is administered to be contaminated and keep work shoes at work if possible; consider different cleaning technique on floors to prevent this persistent contamination

Sources:

1. Thomas H. Connor, PhD, Research Biologist,Division of Applied Research and Technology, National Institute for Occupational Safety and Health

2. USP 800 update: http://www.usp.org/usp-nf/notices/general-chapter-hazardous-drugs-handling- healthcare-settings

3. Queruau Lamerie T, Nussbaumer S, Decaudin B, et al. Evaluation of decontamination efficacy of cleaning solutions on stainless steel and glass surfaces contaminated by 10 antineoplastic agents. Ann Occup Hyg. 2013;57(4):456-469.

4. American Society of Health-System Pharmacists. ASHP guidelines on handling hazardous drugs. 2006;63:1172-93.

5. NIOSH Alert: http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf

Quick Summary of Cost Estimates:

Cleaning- depends on current workflow and who will be assigned to cleaning; also depends on which product will be use

Sampling- estimate $24,750 yearly for sampling kits if use internal personnel, otherwise add consultant fee

****Could sample more or less areas per budget**

This Document can be made available in alternative formats upon request

HOUSE OF REPRESENTATIVES

EIGHTY-NINTH SESSION

03/17/2016 Authored by Murphy, E., and Zerwas

H. F. No. 3288

The bill was read for the first time and referred to the Committee on Job Growth and Energy Affordability Policy and Finance

A bill for an act relating to labor and industry; medical professional safety; creating a chemotherapy drug safety working group; appropriating money.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. CHEMOTHERAPY DRUG SAFETY WORKING GROUP.

(a) The commissioner of labor and industry, in consultation with the commissioner of health, shall convene a working group to address the safe handling of chemotherapy drugs.

(b) The commissioner of labor and industry shall invite participants from each of the following groups:

(1) the Department of Labor and Industry, including representatives of the Minnesota Occupational Safety and Health Administration;

(2) the Department of Health;

(3) the Minnesota Nurses Association;

(4) the Minnesota Hospital Association;

(5) the Minnesota Organization of Registered Nurses;

(6) the Minnesota Advanced Practice Registered Nurses Coalition;

(7) SEIU Healthcare;

(8) the Minnesota Board of Pharmacy;

(9) the Minnesota Pharmacists Association; and

(10) the Minnesota Oncology Nurses Society.

(c) Each invited group may select up to three participants to sit on the working group.

(d) The working group must convene no later than July 1, 2016. The working group must report recommendations for improving the safe handling of chemotherapy drugs to

the legislative committees with jurisdiction over health and labor and industry no later than January 1, 2017.

Sec. 2. APPROPRIATION.

$....... in fiscal year 2017 is appropriated from the general fund to the commissioner of labor and industry to convene and administer the working group described in section 1.

This is a onetime appropriation.

Senator Chris Eaton

Majority Whip
Vice Chair, Environment and Energy Committee

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State of Minnesota

Representative Erin Murphy

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April 19, 2016

Ken Peterson, Commissioner, Minnesota Department of Labor and Industry
443 Lafayette Road N.
St. Paul, MN 55155

Commissioner Peterson,

As chief authors on the Chemotherapy Safety Working Group bill, we write to request that the Minnesota Department of Labor and Industry convene a Chemotherapy Drug Safety working group to study ways to keep our healthcare workers as safe as possible.

Multiple studies have shown that exposure to chemotherapy drugs can have harmful effects on healthcare personnel. In 2004, the National Institute for Occupational Safety and Health (NIOSH) established guidelines for handling hazardous drugs, which includes chemotherapy drugs, but compliance is not required and adherence remains sporadic. While federal agencies recognize NIOSH guidelines, they sometimes defer legislative and regulatory enforcement to state government. For these reasons it is important for Minnesota to look at the issue and come up with best practices that hospitals, clinics and other health care settings can follow in order to ensure that their employees and workplaces are as safe as possible.

Topics that the workgroup could possibly study include evaluating workplaces to identify and assess hazards, establishing policies and training programs for handling chemotherapy drugs, recommending the use of medical equipment designed to reduce exposure, and standardizing reporting of exposures to these drugs.

The following groups have expressed interested in being part of this workgroup:

(1) The Department of Labor and Industry;
(2) The Department of Health;
(3) The Minnesota Nurses Association;
(4) The Minnesota Hospital Association;
(5) The Minnesota Organization of Registered Nurses;

(6) The Minnesota Advanced Practice Registered Nurses Coalition;
(7) SEIU Healthcare;
(8) The Minnesota Board of Pharmacy;
(9) The Minnesota Medical Association;
(10) The Minnesota Medical Group Management Association;
(11) The Twin Cities Medical Society; and
(12) The Minnesota Oncology Nurses Society.

In addition, we request that Catherine Graeve, a University of Minnesota PhD Public Health Nursing student, be included in the workgroup as well.

We hope that the workgroup could start meeting in early summer 2016 and include enough meetings to cover the suggested topics above, as well as any others identified by the members of the working group. We would also respectfully request that the workgroup finish their work by the end of December 2016 and that there be a written summary of the work so that all interested parties can have access to the important work of this group.

Thank you in advance for your time and attention to this important issue.

Chris

Senator Chris Eaton

Representative Erin Murphy

443 Lafayette Road N.
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MINNESOTA DEPARTMENT OF
LABOR & INDUSTRY

(651) 284-5005
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April 28, 2016

Senator Chris Eaton
Majority Whip
Vice Chair, Environment and Energy Committee
3413 Minnesota Senate Building
St. Paul, MN 55155

Representative Erin Murphy
Deputy Minority Leader
331 State Office Building
St. Paul, MN 55155

Dear Senator Eaton and Representative Murphy:

Thank you for your letter of April 19 asking the Department of Labor and Industry (DLI) to convene a Chemotherapy Drug Safety working group to study ways to keep Minnesota healthcare workers safe from possible exposure to chemotherapy drugs.

Your letter summarizes the current state of regulation of handling of chemotherapy drugs. Studies show that exposure to these drugs can cause harm to healthcare workers. The National Institute of Health (NIOSH) has established guidelines for handling chemotherapy drugs, but compliance with these guidelines is not required and federal agencies have left enforcement to states. Your letter indicates that it is important for Minnesota to look at the issue and develop best practices that medical facilities can follow.

Your letter further suggests topics the group can study include:

- Identification and assessment of hazards
- Establishment of policies and training programs for handling these drugs
- Recommended use of medical equipment to reduce exposure
- Standardizing reporting of exposures to these drugs

Your letter provides us a list of organizations that have expressed interest in participating in this discussion and you request that we include Catherine Graeve as well. You further ask that the group begin its work this summer and complete a summary of their work by the end of 2016 so that interested parties can have access to their work.

In response to your letter, I have directed Cynthia Valentine, DLI's Workplace Safety Director, to convene the Chemotherapy Drug Working Group. The group she will lead will include Labor and Industry employees from MN OSHA, along with representatives of the organizations you suggest.

The Department of Labor and Injury takes seriously its mission to keep Minnesotans safe at work. Convening experts and concerned individuals to discuss and develop recommendations related to chemotherapy drug safety for workers in healthcare is consistent with that mission. We thank you for your concern and timely request.

I will keep you posted as to the group's progress and product. If you have questions about our effort or would like to suggest participants from the interested organizations, please direct them to Ms. Valentine via email at cindy.valentine@state.mn.us or 651-284-5602.

If you have other comments or questions, feel free to write or call me at 651-284-5010.

Sincerely,

Ken B. Peterson
Commissioner