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Randomized Controlled Trial of an Intervention to Improve Nurses' Hazardous Drug Handling

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Abstract

Objective.—To evaluate whether a web-based educational intervention improved personal protective equipment (PPE) use among oncology nurses who handle hazardous drugs.

Sample and Setting.—From 2015 to 2017, we partnered with 12 ambulatory oncology settings in the United States to enroll 396 nurses, 257 of whom completed baseline and primary endpoint surveys.

Methods and Variables.—In cluster randomized controlled trial, 136 nurses in control settings received a one-hour educational module on PPE use with quarterly reminders and 121 nurses in treatment settings received the control intervention plus tailored messages to address perceived barriers and quarterly data gathered on hazardous drug spills across all study settings. The primary outcome was nurse-reported PPE use.

Results.—Control and intervention sites had suboptimal PPE use before and after the intervention. No significant differences were observed in PPE use knowledge or perceived barriers. Participants reported high satisfaction with their study experience.

Implications for Nursing.—Hazardous drug exposure confers notable health risks to health care workers. To improve hazardous drug handling, occupational health providers, health systems, and professional organizations should consider coordinated efforts to implement policy and practice changes.

Keywords

hazardous drugs; personal protective equipment; occupational exposure; registered nurses; workplace interventions

Efficacy of a Web-Based Intervention to Improve Hazardous Drug Handling Among Oncology Nurses: A Cluster Randomized Controlled Trial

For over 40 years, health care workers have administered drugs known to be hazardous to human health (Connor & McDiarmid, 2006). Antineoplastic drugs – principally used to treat cancer - comprise the largest group of drugs classified by the National Institute for Occupational Safety and Health as hazardous (National Institute for Occupational Safety and Health (NIOSH), 2016). Workers who handle hazardous drugs in their routine work report higher rates of adverse reproductive effects, (Lawson et al., 2012) rare cancers, (National Institute for Occupational Safety and Health, 2017) and an array of ill-defined respiratory and skin ailments (Couch & West, 2012; West & Beaucham, 2014). Studies that establish either a causal relationship between exposure and health effects or a dose-response relationship are missing. The National Institute for Occupational Safety and Health, (National Institute for Occupational Safety and Health, 2004) in addition to other provider organizations, (American Society of Health-System Pharmacists, 2006; Polovich & Olsen, 2018) have published recommendations to reduce hazardous drug exposures, including the consistent use of personal protective equipment when handling hazardous drugs. Despite this evidence, workers continue to report exposure, and documented adherence to risk-reduction actions remains suboptimal. In a multi-state survey of oncology nurses, 16.9% reported unintentional exposure to a hazardous drug in the prior year (Friese, Himes-Ferris, Frasier, McCullagh, & Griggs, 2012). Oncology nurses - who administer the majority of these drugs - report persistently low adoption of personal protective equipment (PPE) use to minimize potential exposure (Polovich & Clark, 2012). Few interventions designed to increase PPE use have undergone systematic study (Crickman, 2017; Keat, Sooaid, Yun, & Sriraman, 2013). To date, no published intervention studies have adopted a randomized controlled design.

Yet there is evidence that when provided with data recently collected in oncology nurses' own practice settings, policy and equipment changes can occur swiftly and worker-level adoption of PPE use can increase (Friese, McArdle, et al., 2015). Motivated by this pilot work, our study team hypothesized that nurses who received feedback about hazardous drug exposures, coupled with messages intentionally designed to address known barriers, would increase PPE use when handling hazardous drugs.

In this context, we conducted a cluster randomized controlled trial to evaluate the efficacy of audit and feedback of hazardous drug exposures, coupled with tailored messages to address known barriers to optimal PPE use. The study's primary outcome was nurse-reported PPE use during hazardous drug administration.

Methods

Settings, Study Participants, and Recruitment

Our team has published our study protocol and corresponding conceptual model for the study and related intervention development (Friese, Mendelsohn-Victor, et al., 2015). A convenience sample of 12 academic health center ambulatory oncology settings with high

patient volume participated after chief nurse executive endorsement of the study. Participant sites were enrolled from March 2015 to March 2017. Settings were included if they had 20 or more employed registered nurses who met participant eligibility criteria.

Eligible participants included registered nurses employed an average of 16 hours weekly or more in ambulatory chemotherapy infusion settings. As part of our efforts to quantify exposures and provide feedback, we obtained blood samples to analyze for participant exposure to hazardous drugs. To reduce the risk of contaminated results, we excluded participants treated with an antineoplastic drug in the past year. Pregnant workers could participate in surveys but did not participate in blood draws. Definitive results from the plasma analyses were inconclusive and thus the study team had no results to share with participants.

To recruit participants, the study team conducted site visits to present a study overview and answer questions. Selected on-site employees served as study champions and shared information with potential participants. All eligible participants received an informational pamphlet, a cover letter, and a $10 no-obligation, upfront cash incentive. The coordinating center sent two reminder email messages to eligible participants. Interested participants received a unique study identifier with instructions to register, complete informed consent, and complete a baseline survey on the project's website. Participants also used the project website to view control or treatment educational interventions (described below). At primary endpoint assessment, enrolled participants received up to three email invitations and reminders from on-site study champions to complete the final survey with another $10 no-obligation, upfront cash incentive.

Randomization occurred at the site level to prevent the likelihood of contamination across study arms. Randomization occurred after participants enrolled and completed the baseline survey. Given the variability of setting size and the potential for baseline differences in PPE use, we used the nonbimatch function from the nbpMatching package in R software to conduct stratified randomization to achieve group balances among the number of nurse participants and their baseline PPE use (Lu, Greevy, Xu, & Beck, 2011; R Core Team, 2013).

Control Intervention

Participants in settings randomly assigned to the control intervention received access to a one-hour educational module on the project website. The module included audio and video content synchronized to a slide presentation that summarized principles of safer hazardous drug handling, congruent with Oncology Nursing Society chemotherapy guidelines, recommendations from the National Institute for Occupational Safety and Health, and the American Society of Health System Pharmacists. After completing the module and a quiz, participants could receive one contact hour of continuing education. Each quarter, participants received an email reminder that reinforced content in the educational module. To measure fidelity to the control intervention, study personnel monitored participants' website login attempts and whether participants viewed the video to completion.

Treatment Intervention

Participants in settings randomly assigned to the treatment intervention also received access to the control intervention described above. The treatment intervention added two components. First, participants received a tailored intervention of up to three short videos that addressed the barriers to PPE use they individually reported on their baseline survey. Second, participants individually reported chemotherapy drug spills they experienced during the study period and submitted plasma samples for analysis. Subsequently, they received email prompts quarterly that directed them to the study website. Each quarter, the study team prepared a brief video that summarized the hazardous drug spill reports across all participating sites during the past quarter. The reports included (1) the number of drug(s) spilled, (2) the context of the spill occurrences, and (3) any pertinent results from the plasma sample analyses. Results from plasma analyses were aggregated across all participants. To assess fidelity to the treatment intervention, study personnel used website paradata to monitor the number of participant login attempts, the number of video(s) viewed to completion, and whether a post-video attestation was completed (see Figure 1).

Protocol Modifications.—Three sites identified challenges with accessing the project website from their setting, due to organizational-level privacy restrictions, outdated web browsers, or authentication challenges. To enable easier viewing of content, the coordinating center sent email messages to all participants with the content embedded directly in the message as well as a link to the website. The email distribution platform also enabled the coordinating center to track the number of participants who viewed educational materials directly from the email message. The change in quarterly video distribution was made starting with the second quarterly video.

Data Collection and Measures

All study data were collected from participants on the project website, which was user-authenticated, password-protected, and encrypted. Study measures were selected in accordance with our published conceptual framework. Details regarding the development, testing, reliability, and validation of these measures were published previously. The study was approved by the principal investigator's institutional review board and participants completed informed consent using the web-based platform. The principal investigator established a data safety monitoring board to review any adverse events; none arose during the study period.

Outcome.—The primary outcome was personal protective equipment use, as measured by the previously-published Revised Drug Handling Questionnaire (Martin & Larson, 2003; Polovich & Clark, 2012). A 5-item measure, PPE use is measured on a five-point Likert scale (5= always wear item, 4=76–99% of the time, 3=51–75%, 2=26–50%, 1=1 to 25%, 0 = never). For each participant, the mean score is calculated for the five items worn during hazardous drug administration: use of chemotherapy gloves, use of double gloves, single-use disposable gowns, disposable eye protection, and respirators.

Personal Factors.—Participants self-reported these measures on the baseline survey. They included oncology nursing experience (years), education (bachelors degree or higher), and oncology nursing certification (yes/no), in addition to race/ethnicity.

Organizational Factors.—We hypothesized that three potential organizational variables – workloads, practice environments, and safety behaviors - would be associated with the primary outcome of PPE use. We aggregated these organizational factors to the setting level by constructing an average score for all participants in respective settings. To measure workload, we asked participants to report the number of patients they delivered chemotherapy to on their last shift as a continuous measure (Friese et al., 2012). The nursing practice environment was measured by Practice Environment Scale of the Nursing Work Index, as revised for ambulatory settings (Friese, 2012). Researchers have published reliability and validity studies for this measure. For each participant, we calculated a mean score across the 23 items that use a 5-point Likert scale to reflect agreement that a favorable element is present in their current practice environment (e.g., nurses participate in decision making, collegial relationships between nurses and physicians).

To measure safety behaviors, participants completed the nine-item Safety Organizing Scale that assesses the observable actions of clinicians to maintain a safety culture, in congruence with high-reliability organization principles (Vogus & Sutcliffe, 2007). Previously studied for validity and reliability, the Safety Organizing Scale is scored on a 7-point Likert scale (1 = not at all, 7 = to a very great extent) to which nurses and other unit-based coworkers engage in safety behaviors.

Knowledge.—We measured knowledge of hazardous drug handling using a team-generated, pilot-tested 10-item questionnaire that assessed knowledge of existing hazardous drug handling science and recommendations. Participants answered ten questions using a four-item multiple choice format, with a range of scores from 0 (no knowledge) to 10 (full knowledge).

Perceived Risk.—Participants completed the three-item Occupational Dermal Survey (Geer, Curbow, Anna, Lees, & Buckley, 2006). Using a four-point Likert scale, values assess the degree to which nurses perceive risk of exposure to hazardous drug in their workplace (1 = strongly disagree, 4 = strongly agree).

Process Evaluation.—At the primary endpoint survey, we asked participants to rate their satisfaction with study participation (5-point scale, very dissatisfied to very satisfied), the usefulness of the content to their clinical practice (5-point scale, strongly disagree to strongly agree), and their willingness to participate in similar studies in the future (yes or no). Participants could also provide free-text feedback on their study experience.

Statistical Analysis

Univariate analyses examined each variable listed above, followed by examination of variation in these measures across participating practices. To evaluate the efficacy of the treatment intervention on PPE use, we used linear mixed models with random intercepts at both the individual and site levels to adjust for repeated measurements from each nurse and

cluster effects due to intervention assignment. The response variable of the models was PPE use and the explanatory variable was the intervention. The covariates related to personal factors and organizational factors were also included in the models to increase the precision.

Sensitivity Analyses.—Participating practices varied in their PPE policies and equipment availability. In some practices, eye protection and respirators were not routinely available or required by policy. Hence, we examined our primary outcome using two versions of the measure: a three-item measure of PPE use (chemotherapy-tested gloves, double gloves, and single-use disposable gowns) and a five-item measure (gloves, double globes, gowns, plus eye shield and respirator). We used the five-item measure for primary analyses and the three-item measure as a sensitivity analysis. Our second sensitivity analysis restricted our attention to the 175 participants who viewed the web-based materials at least one time during the study period.

RESULTS

Of 439 registered nurses eligible to participate across 12 practice sites, 415 (94.5%) enrolled in the study, 189 from practice sites assigned to the treatment arm and 226 from practice sites assigned to the control arm. Of enrolled participants, 378 (91.1%) completed baseline and 257 (61.9%) completed both the baseline and the primary endpoint survey; 121 participants were in treatment arm-assigned practices and 136 participants were in control arm-assigned practices.

We observed differences between participants employed in treatment-assigned settings and control-assigned setting participants by race/ethnicity, years of experience, and workload of patients receiving chemotherapy (see Table 1). There were more Asian nurses in the control arm (12.3% vs. 6.0% in the treatment arm), more Hispanic nurses in the control arm (9.2% vs 1.7%, respectively) and fewer white nurses in the control arm (78.5% vs 92.2%, respectively). Nurses in the control arm reported slightly more years in current role (mean [SD] of 6.7 [7.2] years vs. 5.1 [4.5] years in the treatment arm). Nurses in the treatment arm reported higher workloads of patients receiving chemotherapy than nurses in the control arm (6.2 patients on the last shift versus 5.0 patients). Initial fidelity intervention - defined as viewing the webinar – was 50.4% for the intervention arm and 72.8% for the control arm. Additionally, 57.3 % of intervention participants watched one or more feedback video.

For both the intervention and control arms, differences in PPE use score did not change between study initiation and primary endpoint assessment (see Table 2). At baseline, the mean (SD) five-item PPE use score was 2.4 (0.8) in the treatment arm and 2.4 (0.7) in the control arm. At one-year follow up, the PPE use score was similar in both treatment and control arms (2.3 [0.9] in both groups). Hazardous drug knowledge scores and reported barriers to PPE use did not change significantly between baseline and follow up for nurses in either arm.

Results from a linear mixed model show that PPE use scores between baseline and follow up did not change significantly in the intervention arm, after adjustment for PPE use at baseline ($\beta = 0.1$, SE 0.4, $p = .75$).

In sensitivity analyses using the three-item PPE use score (chemotherapy-tested gloves, double gloves, and single-use disposable gowns), results obtained did not differ appreciably from those reported above when all five PPE items were considered (see Table 3). Results reported above also did not change appreciably when analyses were restricted to participants who had viewed the web-based materials at least once during the study period.

In our process evaluation, 71.4% reported they were satisfied/very satisfied with participating in the study, 4.7% were dissatisfied/very dissatisfied, and 23.9% endorsed a neutral assessment. Just under two-thirds (64.6%) agreed/strongly agreed that the educational content was useful to their clinical practice, 2.0% disagreed/strongly disagreed, and 23.4% endorsed a neutral assessment. Over three-quarters (80.8%) would be willing to receive future invitations for study participation. Thirty-nine nurses provided open-text feedback; 59.0% of which was positive (principally focused on importance of the topic and feedback received), 30.8% was negative (principally focused on time involved and website difficulties), and 10.2% was neutral.

Discussion

In this cluster randomized controlled trial, receipt of a web-based educational intervention that included ongoing feedback on study results and tailored messages to reduce barriers, when compared to a static educational module, did not result in improved PPE use among oncology nurses employed in ambulatory settings. These findings suggest that pervasive challenges exist for nurses to implement fully the recommendations for hazardous drug handling from the National Institute for Occupational Safety and Health and professional organizations.

Baseline PPE use scores across multiple participating clinical settings demonstrated suboptimal use of PPE among nurses in ambulatory infusion settings. This was a discouraging finding, given that the study took place in settings where multiple organizational factors favor excellence in safety, such as academic health centers with high-volume cancer programs. These findings underscore the ongoing risks that healthcare workers take when providing patient care, and the accompanying need for novel interventions to mitigate the risks that are associated with significant health effects, such as reproductive problems and rare cancers.

Our intervention did not improve PPE use among participants. One possible reason for this finding includes suboptimal content in our intervention. Additional possible explanations include too few interactions with participants, and structural barriers to adopting desired behaviors. Prior work among oncology nurses has shown low perceived risks from hazardous drug exposure (Friese, et al., 2015). In addition, the intervention did not personalize feedback to individuals, but reported similar content to all participants. Individualized feedback may have been more effective in influencing participant behavior change. Participation in the educational activities waned over the study period, suggesting that participants did not find additional content useful. The quarterly feedback for participants in the treatment arm may have been too infrequent to challenge existing practice norms and support participants to adopt behavior change.

During site visits, study personnel anecdotally identified structural barriers to participation in the educational activities. These barriers included difficulties accessing web-based content outside the institution, workload demands that limited time for participants to view materials during their scheduled shift, and vague or unclear institutional policies on gowns, eye protection, and respirator use when handling hazardous drugs. Study follow-up efforts have included sharing institution-specific data with leaders and clinicians to develop specific strategies within each organization to reduce hazardous drug exposure risks. This is a promising area for future intervention development and testing.

While exposures remain an important occupational challenge in oncology settings, hazardous drugs are administered with increasing frequency outside of cancer settings. Antineoplastic drugs and biologic agents have expanded approvals in conditions such as rheumatoid arthritis, psoriasis, solid organ transplantation, among others (Friese, McCullagh, & Sutcliffe, 2015). As such, the target audience for education and outreach interventions has expanded beyond cancer center workers. Workers in these emerging areas may need different strategies to increase awareness of hazardous drug exposures and proficiency with PPE use, including ongoing training specific to hazardous drug handling.

Study Limitations.

Despite high participation and response rates for nurses, coupled with a controlled experimental design informed by a theory-based framework, the study has several limitations worthy of comment. First, the study took place in a convenience sample of academic health centers with high-volume cancer programs. Results may not generalize to smaller or community-based oncology settings. Second, the calculated reliability of the outcome measure in our sample was relatively low (0.46 for the three-item measure and 0.50 for the five-item measure considered in the sensitivity analysis). Fidelity to the intervention was high soon after study activation and decayed over time. Thus, assessing the primary endpoint one year after study activation may have limited the ability to detect meaningful changes in PPE use. Future research efforts would benefit from development and testing novel measures of PPE use and evaluating optimal measurement times after delivering educational interventions and delivering study reminders. Novel study designs, such as sequential multiple assignment randomized trials, may address the ongoing challenges of reaching non-engaged participants and titrating interventions based on behavioral response. Implementation science techniques could elucidate factors associated with increased adherence to study protocols and/or PPE recommendations. Participants' knowledge of chemotherapy administration safety was measured using a team-designed instrument. Psychometric testing of the instrument in diverse samples will increase confidence in measure validity. The study focused on nurses who handle hazardous drugs but did not include other workers exposed to hazardous drugs routinely in their workplaces.

Implications for Nursing

Our study findings have important implications for nursing from various perspectives: individual health systems, professional organizations, and regulatory efforts. The challenges that characterize influencing nurse's use of PPE found in this and previous studies

underscore the importance of higher-order hazard control strategies, such as engineering and administrative controls (Hon & Abusitta, 2016). During the enrollment period, we noted inconsistencies in existing institutional policies on hazardous drug handling across participating institutions, despite similar patient populations and care processes. Nursing leaders could standardize educational content and policies on PPE use across oncology settings – with leadership endorsement and accountability – to address existing confusion among health care workers. While nursing and other professional organizations have attempted to address this issue, differences in opinion remain across these organizations (Connor, Celano, Frame, & Zon, 2017; Zon, 2018), and recent efforts to strengthen oversight of hazardous drug handling across cancer settings have been delayed to 2019 (United States Pharmacopeial Convention, 2017). These delays will hamper efforts to improve PPE use. While several states have passed legislation aimed to improve hazardous drug handling, delayed implementation has hampered effectiveness (Walton, Eisenberg, & Friese, 2017). When placed in the context of our study findings, it is clear that education and engagement of nursing personnel is not sufficient to improve PPE use; systematic approaches may result in improved practice.

Conclusion

Despite four decades of evidence to suggest adverse health effects for workers who handle hazardous drugs, nurses persistently do not wear PPE as recommended. An educational intervention tailored to address documented barriers and targeted to practicing nurses did not improve PPE use. When considering the hierarchy of controls, efforts should focus on developing novel and reliable engineering controls, improving existing engineering controls, strengthening clinician adherence to efficacious engineering controls, and developing and evaluating system-level interventions to address pervasive gaps in hazardous drug handling practice. To minimize the risk of hazardous drug exposure, health care workers must receive adequate training and equipment. Policymakers, clinical experts, and health system leaders should encourage clinical settings to adopt guideline-concordant PPE policies and activities.

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Knowledge Translation

1. Despite four decades of research, current use of PPE remains suboptimal in ambulatory oncology settings.
2. A theory-informed, web-based educational intervention to registered nurses failed to improve personal protective equipment use in the ambulatory oncology setting.
3. A multi-faceted strategy (equipment changes, standardized policies, educational efforts, and leadership support) across multiple levels (units, hospitals/health systems, and professional organizations) may be required to improve adherence to hazardous drug handling guidance.

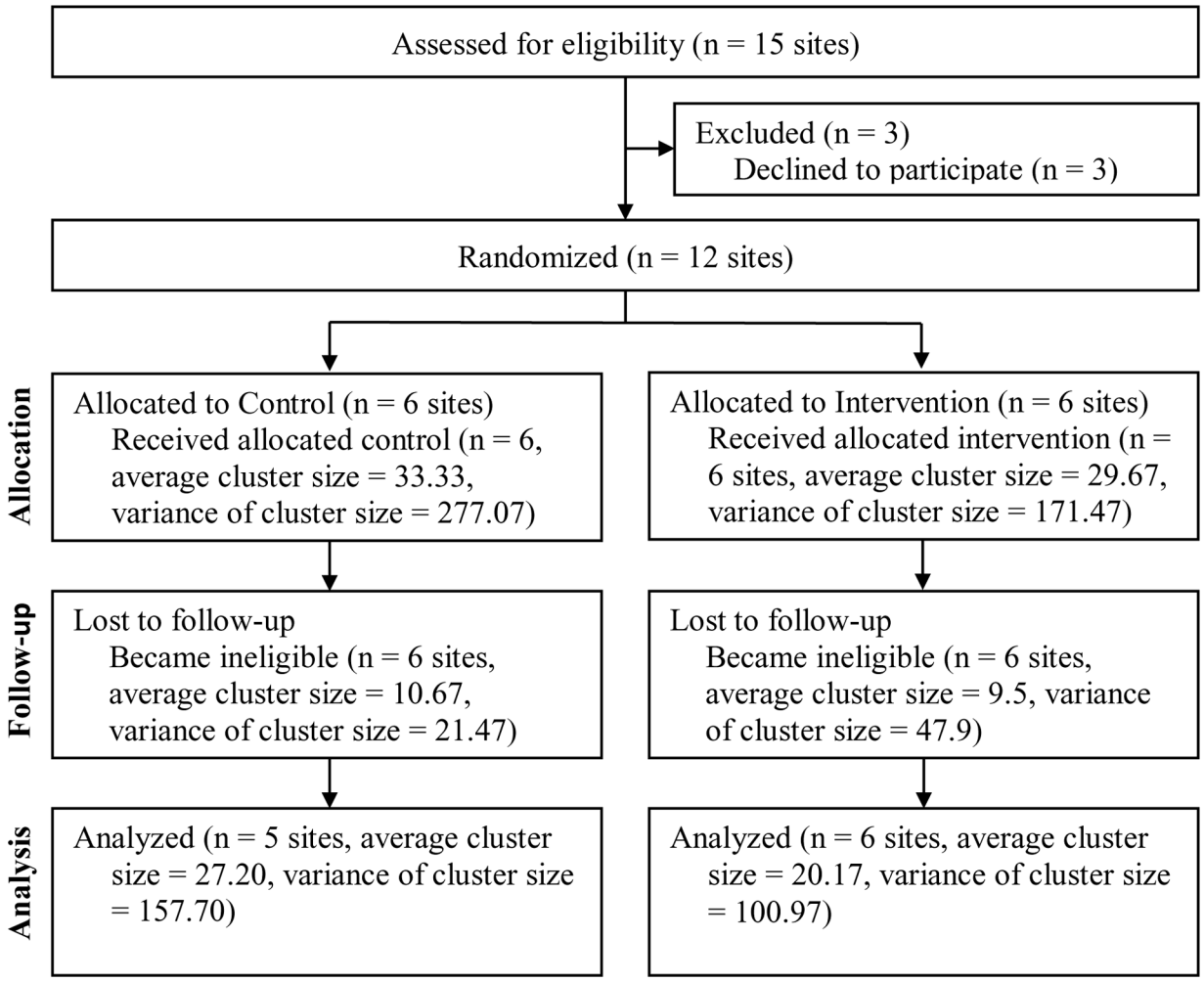

Figure 1.
Flow Diagram for Sample

Table 1.

Participant Characteristics

	Control (N=136)	Experimental (N=121)	Total (N=257)	P-value
Oncology nursing experience				.52
N	136	121	257	
Mean (SD)	12.7 (9.4)	12.0 (8.2)	12.4 (8.8)	
Education (bachelors or higher)				.49
Diploma	5 (3.7%)	5 (4.1%)	10 (3.9%)	
Associates Degree	21 (15.4%)	19 (15.7%)	40 (15.6%)	
Bachelors in Nursing	102 (75.0%)	90 (74.4%)	192 (74.7%)	
Bachelors in Other Field	4 (2.9%)	3 (2.5%)	7 (2.7%)	
Master's degree in Nursing	4 (2.9%)	1 (0.8%)	5 (1.9%)	
Master's degree in other field	0 (0.0%)	3 (2.5%)	3 (1.2%)	
Race/Ethnicity				.01
Missing	6	5	11	
Asian	16 (12.3%)	7 (6.0%)	23 (9.3%)	
Hispanic	12 (9.2%)	2 (1.7%)	14 (5.7%)	
White	102 (78.5%)	107 (92.2%)	209 (85.0%)	
Gender				.78
Male	6 (4.4%)	7 (5.8%)	13 (5.1%)	
Female	130 (95.6%)	114 (94.2%)	244 (94.9%)	
Chemotherapy Workload				.01
N	136	119	255	
Mean (SD)	5.0 (2.6)	6.2 (4.4)	5.5 (3.6)	
Fidelity: Viewed control module				<.01
No	37 (27.2%)	60 (49.6%)	97 (37.7%)	
Yes	99 (72.8%)	61 (50.4%)	160 (62.3%)	
Viewed at least one educational module				N/A
No	0	45 (37.2%)	45 (37.2%)	
Yes	0	76 (62.8%)	76 (62.8%)	

Table 2.

PPE Knowledge, Barriers, and Use Scores before and after the Intervention

Characteristics	Full Sample N= 257		Setting[a] Assigned to Treatment Intervention n=121		Assigned to Control Intervention n=136	
	Pre	Post	Pre	Post	Pre	Post
PPE Knowledge Score	6.5 (1.7)	6.7 (1.5)	6.4 (1.5)	6.5 (1.6)	6.7 (1.8)	6.9 (1.5)
Barriers to PPE Use	1.9 (0.5)	1.9 (0.5)	1.8 (0.4)	1.8 (0.5)	2.0 (0.5)	1.9 (0.5)
PPE Use Score – 5 items	2.4 (0.7)	2.3 (0.9)	2.4 (0.8)	2.3 (0.9)	2.5 (0.7)	2.3 (0.9)
PPE Use Score – 3 items	3.6 (1.0)	3.5 (1.2)	3.5(1.1)	3.6(1.2)	3.6(1.0)	3.5(1.2)

Table 3.

Association between Study Variables and PPE Use[a]

Variable	Model I (5-items) Beta (SE)	*p*	Model II (3-items) Beta (SE)	*p*
Intercept	1.7(−0.5)	<.001	3.2 (0.8)	<.001
Setting assigned to Treatment Intervention	0.1 (0.4)	.75	0.1 (0.6)	.85
Baseline Use of PPE	0.2 (−0.1)	<.001	0.1 (0.1)	.07
Personal Factors				
-Oncology nursing experience	<.01 (<.01)	.92	<.01 (<.01)	.35
-Education (bachelors or higher)	0.03 (0.06)	.56	0.05 (0.08)	.53
-Oncology nursing certification	−0.01(0.11)	.91	0.09 (0.15)	.56
-Race (Asian vs. White)	0.61(0.15)	<.001	0.61 (0.20)	<.01
Organizational Factors				
-Workload	<0.01(0.01)	.63	<0.01(0.01)	.85
-Practice Environment Scale of the Nursing Work Index	0.11 (0.08)	.19	0.12 (0.11)	.30
-Safety Organizing Scale	<0.01(0.05)	.96	<0.01(0.07)	.57
Knowledge				
-Hazardous drug handling knowledge	−0.05(0.03)	.05	−0.06(0.04)	.09
-Perceived risk score	−0.02(0.07)	.78	−0.02(0.10)	.83

[a]Coefficients, standard errors, and *p* values were derived from two linear mixed models: Model I used the five-item PPE use measures. Model II used the three-item PPE use measure.