Chemotherapy Safe Handling

Limiting nursing exposure with a hazardous drug control program

Rachael Crickman, DNP, RN, AOCNS®, and Deborah S. Finnell, DNS, PMHNP-BC, CARN-AP, FAAN

BACKGROUND: Nurses and other healthcare workers are at risk for adverse health consequences from occupational exposure to hazardous drugs.

OBJECTIVES: An evidence-based program for nurses was implemented to improve safe handling practices and reduce exposure to hazardous drugs.

METHODS: A quasi-experimental design was used, with pre- and post-tests of knowledge about chemotherapy exposure and pre- and post-test observations of compliance with donning and doffing personal protective equipment (PPE). Surface wipe tests were conducted to determine hazardous drug contamination in care areas. A toolkit of interventions, including hazardous drug identification, standardization of PPE, and education, was used.

FINDINGS: Mean knowledge scores of chemotherapy improved after education. Correct donning of PPE was high before and after the intervention, and the correct doffing sequence improved post-intervention. One sample was positive for 5-fluorouracil, affirming the difficulty of maintaining an environment free of contamination.

KEYWORDS
occupational exposure; drug therapy; nurses; personal protective equipment

NURSES AND OTHER HEALTHCARE WORKERS are at risk for adverse health consequences from occupational exposure to hazardous drugs when caring for patients. Medications are considered hazardous if they have the potential to cause negative health effects. The majority of these medications are antineoplastic or chemotherapy drugs (National Institute for Occupational Safety and Health [NIOSH], 2014). The use of chemotherapy and hazardous antineoplastic medications is expanding in other areas of health care (Thompson, 2013). The risks of handling hazardous antineoplastic drugs are well documented and include acute and chronic side effects (Polovich, 2011; Suspiro & Prista, 2011; Valanis, Vollmer, Labuhn, & Glass, 1993, 1997; Valanis, Vollmer, & Steele, 1999).

A unique challenge associated with the administration of antineoplastic and other hazardous drugs is the lack of established limits for healthcare worker exposure (Connor, Lawson, Polovich, & McDiarmid, 2014; Gambrell & Moore, 2006). Therefore, how little or how much hazardous drug exposure contributes to adverse health effects is unclear. Despite the lack of evidence, mitigating the potential harm to healthcare workers is warranted. In one systematic review (Crickman & Finnell, 2016), five methods to reduce occupational exposure were identified: (a) the development of engineering controls, (b) personal protective equipment (PPE) use, (c) medical and environmental monitoring for common antineoplastic drugs, (d) hazard identification, and (e) a comprehensive hazardous drug control program that provides education and training for healthcare workers.

Polovich and Clark (2012) examined factors that affect nurses’ PPE use, which included barriers to adherence, workplace safety climate, and patient/nurse ratios. The study revealed that institutional practices and personal behaviors affect occupational exposure. PPE is considered the last line of defense in protecting nurses and other healthcare workers who handle hazardous drugs. Addressing knowledge deficits is essential but may not be sufficient to protect healthcare workers. Knowledge alone does not consistently lead to behavior change; however, acknowledging poor safe handling behavior is critical for reducing exposure (Geer, Curbow, Anna, Lees, & Buckley, 2006).

Legislative change is often needed to effect practice change. Until recently, guidelines for the safe handling of hazardous drugs were primarily...
recommendations for employers instead of mandates. In 2012, Washington became the first state in the United States to pass legislation that required healthcare facilities to implement guidelines based on the NIOSH guidelines for the safe handling of hazardous drugs (Eisenberg, 2015). However, practice change may not occur even with legislation. Compliance with PPE standards for handling chemotherapy remains poor and insufficient to prevent occupational exposure despite the growing body of evidence of PPE efficacy (Gambrell & Moore, 2006; Martin & Larson, 2003; McDiarmid, Oliver, Roth, Rogers, & Escalante, 2010; Polovich & Clark, 2012).

The goal of the current study was to implement an evidence-based program that focused on improving the safe handling practices of and reducing the occupational exposure of nurses to hazardous drugs. Risk concerns at a hospital in Washington state and Washington state legislative March 2014 (WAC 296-62-500) provided the impetus for this project. The risk concerns included chemotherapy spills in multiple locations, healthcare workers’ exposure to hazardous drugs, and the lack of a robust method of capturing staff-related safety events systemwide. Therefore, addressing the quality of care, safety, and cost concerns related to hazardous drug exposures was critical. The specific aims of the current study were to (a) increase knowledge scores of chemotherapy drug exposure among inpatient oncology nurses; (b) increase the compliance of inpatient nurses administering chemotherapy to PPE use; and (c) decrease the environmental contamination of cyclophosphamide (Cytoxan®), 5-fluorouracil (5-FU) (Adrucil®), paclitaxel (Taxol®), ifosfamide (Ifex®), and methotrexate (Trexall®) on surfaces in the inpatient oncology unit.

A sentinel publication by Pronovost, Berenholtz, and Needham (2008) described a model for large-scale knowledge translation across a complex healthcare system. According to the Pronovost framework, four essential steps are required for successful knowledge translation: (a) summarize the evidence, (b) identify local barriers to implementation, (c) measure performance, and (d) ensure that all receive the intervention. A “4 Es” approach is described in the first step: engage, educate, execute, and evaluate. According to Pronovost et al. (2008), the 4 Es approach acknowledges contextual factors, local unit culture, and staff engagement. The framework summarizes interventions with the greatest benefit, combines education with facilitation, approaches barriers up front to mitigate resistance, and uses process and outcome measures for evaluation. This framework was well aligned with the current study because of its ability to address a complex issue that affects a large healthcare system, and it provided a blueprint for addressing the issue of hazardous drug exposure at the institution.

**Methods**

This project was conducted in an inpatient oncology unit at Virginia Mason Medical Center in Seattle, Washington—a 336-bed, not-for-profit hospital. The institutional review board deemed this study a quality improvement project. Participants were RNs working directly with patients receiving chemotherapy. The quasi-experimental design, conducted from October 2014 to April 2015, used a pre-/post-test of knowledge about chemotherapy exposure and pre- and postintervention observations of PPE compliance. Surface wipe tests were conducted to determine environmental contamination of cyclophosphamide, 5-FU, paclitaxel, ifosfamide, and methotrexate in patient care areas.

**Intervention**

Following the Pronovost et al. (2008) framework, a toolkit of interventions, including hazard identification, standardization of PPE, and education, was used. These strategies were identified as evidence-based control measures to reduce occupational exposure. The hazard identification component of the toolkit included standardized labels for all chemotherapy and other hazardous drugs. These labels were generated to alert and assist nurses with identifying hazardous medications. Hazard identification also included standardized messages within the electronic medical record that direct nurses on the specific PPE to wear for administration of chemotherapy and other hazardous drugs.

When the Ebola epidemic gained worldwide attention in 2014, the correct doffing sequence of PPE was brought to public attention as a potential source of exposure. This event raised awareness that the doffing sequence of PPE by nurses handling hazardous drugs should be assessed. The correct doffing sequence of PPE had not been specifically outlined in the Oncology Nursing Society’s (ONS’s) *Chemotherapy and Biotherapy Guidelines and Recommendations for Practice,* and it

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**“Online education targeting knowledge deficits of hazardous drug exposure can help promote safe practices and nurse compliance with personal protective equipment.”**
was not addressed in the training program provided at Virginia Mason Medical Center for nurses to become chemotherapy certified/competent. Expert consultation was sought from Polovich (an editor of ONS’s chemotherapy guidelines [Polovich, Olsen, & LeFebvre, 2014]) to confirm the appropriate sequence of removing PPE for chemotherapy. The correct doffing sequence was then included in the educational intervention and assessment tool, and observations of compliance were collected before and after the educational intervention.

Standardization of PPE involved selecting gloves certified by the American Society for Testing and Materials, face masks with eye shields, and chemotherapy-tested gowns, placing these items in all patient care areas where hazardous drugs were administered. Visual tools were created to alert staff of what PPE was required for chemotherapy administration, handling of body fluids, and responding to spills.

Education was provided via an online educational video created by the authors and shared with all nurses on the unit. The program took about 30 minutes. Four objectives were addressed: (a) describe the risks of handling chemotherapy, (b) describe routes of exposure to hazardous drugs, (c) identify resources to determine if a drug is hazardous, and (d) demonstrate safe practices for handling chemotherapy. To identify local barriers to implementation, in accordance with the study’s framework, participants were given the choice to complete the education during or after work hours and were compensated for their time. The oncology clinical nurse specialist (CNS) and the assistant nurse manager (ANM) administered the knowledge tests before and after the scheduled education and conducted observations of compliance before and after education. Knowledge tests were distributed in October 2014; post-tests, observations of compliance with PPE, and wipe studies were completed by April 2015.

**Instruments**

The 12-item Chemotherapy Exposure Knowledge scale (Polovich & Clark, 2012) was used to measure knowledge scores before (October 2014) and after (February 2015) the educational intervention. The internal consistency of the scale has been reported by Polovich and Clark (2012) as an alpha of 0.7. Each item has three possible responses: “true,” “false,” or “do not know.” Correct responses receive a score of 1, and incorrect responses receive a score of 0. The range of scores is 0–12, with greater scores indicating higher knowledge (Polovich & Clark, 2012).

Direct observations of compliance (donning and doffing) with PPE were measured during the nurses’ preparation for administering chemotherapy. The appropriate PPE is based, in part, on the route of chemotherapy administration. At the institution where the study was conducted, full compliance with PPE during IV chemotherapy administration included wearing double gloves, a disposable chemotherapy gown, and a face mask with an eye shield. The corresponding criteria were included on an observation tool. Compliance was documented as either “yes” or “no” for the PPE chosen. To be marked yes, the nurse had to be fully compliant with every criterion. Before observations began, the CNS and ANM assessed multiple scenarios individually and then discussed them with each other to ensure inter-rater reliability. The initial choices for PPE were documented on the observation tool, providing the opportunity to examine compliance over time for each nurse and to identify common deficits across the group of nurses. Coaching and feedback were provided in the moment to protect nurses from potential risks of exposure and to enhance learning. Nurses who did not choose the correct PPE were corrected immediately before proceeding with drug handling.

**Sample Collection and Analysis**

Six standardized sampling sites were tested for hazardous drug contamination at four time points in patient care areas within the inpatient oncology nursing unit, including the charge nurse table, the flow station desktop outside patient rooms, the top surface of the medication dispensing system, the floor under the sink in patient rooms, the nurse workstation in patient rooms, and the

<table>
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<th>CHARACTERISTIC</th>
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<th>SD</th>
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<tr>
<td>Years of oncology nursing experience</td>
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**TABLE 1. SAMPLE CHARACTERISTICS (N = 31)**

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</tr>
<tr>
<td>Current chemotherapy certification</td>
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bathroom floor in patient rooms. To ensure proper technique in collecting the samples, a training video and written instructions were provided by the reference laboratory ChemoGLO™ and then reviewed by the CNS and ANM who collected the samples. Per the protocol, standardized surfaces of about 144 square inches (12 by 12 in.) were sampled with two wipes each, one vertical wipe and one horizontal wipe, per surface. Wipe swabs were moistened with a proprietary mixture (2 ml per swab) containing isopropyl alcohol. The wipe procedure is able to recover more than 90% of cyclophosphamide from a 12 by 12-in. surface. Sites were sampled in the morning before the surfaces were cleaned by environmental services. Samples were shipped to ChemoGLO and stored at 4°C until processed and analyzed.

Results
Demographics
Thirty-four nurses were included in the sample. One participant left prior to the intervention, and two did not complete the knowledge assessments. The final sample consisted of 31 nurses. Table 1 describes the demographic characteristics of the participants.

Of the 31 participants, 13 (42%) were oncology certified nurses (OCN®), and 26 (84%) were chemotherapy competent. At this institution, chemotherapy competence was defined as having a current chemotherapy/biotherapy provider card from ONS and a completed checklist of chemotherapy verification and administration per policy and procedure. In this sample, all OCN® nurses were also chemotherapy competent.

Chemotherapy Exposure Knowledge Scores
Mean knowledge scores before and after the education intervention are displayed in Table 2. Overall, mean knowledge scores improved from 10.5 (SD = 1.09) to 11.2 (SD = 0.75, p < 0.001) after the intervention (effect size = 0.31). Mean knowledge scores of OCN® nurses were higher than noncertified nurses both before and after the intervention (p < 0.04). The two most commonly missed true-or-false questions were (a) chemotherapy gas and vapor in the air can enter the body through the skin (the answer is true; 39% answered correctly preintervention compared to 52% postintervention), and (b) a surgical mask provides respiratory protection from chemotherapy aerosols (the answer is false; 58% answered correctly preintervention compared to 100% postintervention).

Observations of Compliance
Observations of nine nurses were conducted before the educational intervention. After the intervention, 10 nurses were observed, of which 5 were observed before and after the educational intervention. A total of 14 nurses were observed; only 5 unique nurses (matched pairs) were observed pre- and postintervention. Four nurses were observed preintervention only, and five nurses were observed postintervention only (excluding matched pairs). Compliance with wearing the correct PPE for chemotherapy administration was 100% pre- and postintervention for all nurses observed. Correct doffing sequence showed an improvement from 11% preintervention to 80% postintervention.

Wipe Samples
A total of 24 wipe samples were collected at four time points. The time points for conducting wipe tests were T1 (October 3, 2014), T2 (February 3, 2015), T3 (March 3, 2015), and T4 (April 7, 2015). T1 was conducted before the oncology unit moved to a new building, creating an opportunity to ensure a clean baseline. T4 was conducted about four months after the move to the new unit. As the wipe samples were collected, no spills of chemotherapy were documented. Of all samples collected, only one was positive (5-FU, 20.97 ng per square foot) at the flow station desktop outside patient rooms at T3. All other surface wipe results were below the limit of detection (10 ng per square foot).

Discussion
Favorable results were found for the evidence-based program designed to improve safe handling practices and reduce occupational exposure of nurses to hazardous drugs. Participants had relatively high mean knowledge scores of chemotherapy exposure at baseline and were fully compliant with donning the correct PPE for chemotherapy administration pre- and postintervention. Even prior to the online education, instances of full compliance with PPE were much higher than reports from other studies (Polovich & Clark, 2012; Polovich & Martin, 2011). Improvements in mean knowledge scores and correct doffing sequence of PPE were obtained following an online educational intervention. This study demonstrated that online education targeting knowledge
deficits related to chemotherapy exposure can be an effective means to promote safe practices and compliance with PPE.

Although addressing knowledge deficits is critically important for promoting safe practices among oncology nurses, combining education with coaching and feedback is also important. All routes of potential exposure, including dermal exposure from incorrect PPE removal, must be included in training and curriculum. Three of the participants from this project required coaching on the correct doffing sequence several times during observations. Instead of separately removing first their gloves, then gowns, then the second pair of gloves, they pulled off their gowns and then their gloves and balled them all together, providing an opportunity for exposure. This finding was not surprising, as doffing procedures to date have not been specifically addressed in oncology nursing guidelines. Education and training should address knowledge deficits, as well as correct behaviors that might put nurses at risk for exposure. Although they did not directly address the aims of this project, the observations provided opportunities to answer questions, provide support, and identify additional mechanisms to improve the safe administration of chemotherapy for patients and staff members.

Researchers who examine detectable levels of chemotherapy on work surfaces have indicated that contamination is common and widespread (Connor et al., 2014). Although this project reported only one positive level of 5-FU at one time point, this finding supports the difficulty of maintaining an environment free of contamination despite multiple safety measures. At the site where this study was conducted, engineering controls were used in pharmacy (Class II Type A biologic safety cabinet and closed-system drug transfer device for chemotherapy preparation) and nursing (closed-system drug transfer device for administration). Despite engineering controls, administrative policies, and high compliance with appropriate PPE, one positive finding indicated the potential for occupational exposure. How and when the contamination of the work surface occurred is unclear. Unfortunately, 5-FU and other chemotherapy drugs are environmentally stable and may persist over time, despite routine cleaning (Hedmer, Tinnerberg, Axmon, & Jönsson, 2008). In addition, surface wipe tests represent only a single point in time; they are not indicative of the potential for repeated exposure through multiple contacts with a work surface (Hon, Teschke, Chu, Demers, & Venners, 2013).

Limitations
Because mean knowledge scores of chemotherapy exposure were high at baseline, drawing conclusions about improvement in knowledge scores following the online educational intervention was difficult. In addition, observations of compliance were conducted on only five matched pairs, limiting the ability to test for significant differences. Finally, comparing wipe results between studies was challenging, because several different analytic techniques and reporting measurements exist (Berruyer, Tanguay, Caron, LeFebvre, & Bussières, 2014). In the current study, wipe tests were used as one approach to measure the impact and effectiveness of strategies to control hazardous drug exposure. Additional funds and a longer study would have enhanced the wipe testing in terms of the number of tests and tests over time. Consequently, the wipe results from the current study may not inform practices at other settings.

Implications for Practice
Nurses administering chemotherapy and other hazardous drugs need the knowledge and resources to protect themselves from occupational exposure. Standardized labels and alerts are needed to identify drugs classified as hazardous. PPE, including chemotherapy-tested gowns and gloves certified for use with chemotherapy, should be provided at the point of use with instructions on proper use. Education should be easily accessible, targeted to knowledge deficits identified through assessment and observations, and include the correct doffing sequence of PPE. Compliance with PPE and safe practices should be evaluated to ensure effectiveness. Finally, environmental wipe tests for common chemotherapy drugs should be periodically conducted to assess the effectiveness of hazardous drug control measures. If detected, positive results should be shared with multiple departments (e.g., pharmacy, environmental services, nursing) to improve strategies, reduce contamination, and promote a safe environment for all healthcare workers, patients, and families.

Conclusion
A comprehensive hazardous drug control program, including a feasible toolkit, was developed for and used to test an inpatient oncology unit for hazardous drug contamination. The framework from Pronovost et al. (2008) provided an effective approach to translate evidence into practice. Outcomes included increased knowledge related to chemotherapy drug exposure, increased compliance with PPE, and little evidence of hazardous drug contamination in high-traffic clinical areas.

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CHEMOTHERAPY SAFE HANDLING

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References


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