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Authors

Mendelsohn-Victor, Kari
Polovich, Martha
McCullagh, Marjorie
et al.

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Oncology Nurses' Exposure to Hazardous Drugs in Ambulatory Settings: Case Report Analysis from a Prospective, Multi-Site Study

Christopher R. Friese, PhD, RN, AOCN®, FAAN[1,2], **Mandy Wong, MS**[3], **Alex Fauer, RN, BSN**[1], **Kari Mendelsohn-Victor, MPH**[1], **Martha Polovich, PhD, RN, AOCN®**[4], **Marjorie C. McCullagh, PhD, RN, FAAOHN, FAAN**[1,2]

[1]Center for Improving Patient and Population Health, Department of Systems, Populations, and Leadership, School of Nursing, University of Michigan, Ann Arbor, MI

[2]Center for Occupational Health and Safety Engineering, University of Michigan, Ann Arbor, MI

[3]Department of Biostatistics, School of Public Health, University of Michigan, Ann Arbor, MI

[4]Independent Consultant

Abstract

Background: Hazardous drug exposures are a key occupational health hazard to oncology nurses. Sparse data are available regarding the frequency and characteristics of hazardous drug spills to inform clinical practice improvement.

Objective: To describe nurses' hazardous drug exposures and use of personal protective equipment during drug spills.

Methods: The Drug Exposure Feedback and Education for Nurses' Safety study launched in March 2015. When drug spills occurred, consented registered nurses administering chemotherapy in ambulatory infusion settings completed brief questionnaires to describe the spill event, protective equipment worn during the spill, and spill containment efforts. Descriptive statistics were used to summarize equipment use and spill events.

Findings: Spills were common, despite the use of closed system transfer devices. Over 24 months, 51 nurses from twelve participating academic infusion centers reported 61 unique spills. Spilled drug volumes ranged from 1 to 250 mLs. Spills commonly involved highly toxic drugs, including paclitaxel (20% of spills), gemcitabine (15%), and anthracyclines (13%). Personal protective equipment use during drug spills is suboptimal; nurses reported wearing disposable gowns (65% of the time), double gloves (52%), single gloves (41%), respirators (28%), and eye shields (26%). Practicing nurses, clinical leaders, and policymakers must address these practice gaps through concerted education, support, and policy changes.

Address correspondence to: Christopher R. Friese, PhD, RN, AOCN®, FAAN, Elizabeth Tone Hosmer Professor, University of Michigan School of Nursing, 400 North Ingalls St., Suite 1174, Ann Arbor, MI 48109, Phone (734) 647-4308, Fax (734) 764-2416, cfriese@umich.edu.

Keywords

oncology nursing; hazardous drugs; occupational health; ambulatory nursing; administration

Introduction

On a routine basis, oncology nurses administer treatments to patients that authorities recognize as hazardous to human health (Connor & McDiarmid, 2006). Since 1942, nurses have prepared and/or administered hazardous drugs to patients with cancer (Yarbro, 1996). Epidemiologists and occupational safety and health researchers have chronicled real and potential adverse health events that correlate with hazardous drug exposure (National Institute for Occupational Safety and Health, 2018). In response, the National Institute for Occupational Safety and Health, the Oncology Nursing Society, the American Society of Health System Pharmacists, and the United States Pharmacopeial Convention have issued guidance on how clinicians can minimize hazardous drug exposures (Connor, Celano, Frame, & Zon, 2017). An array of control measures – use of closed system transfer devices, externally-ventilated biological safety cabinets for compounding activities, training/education, and consistent use of personal protective equipment (PPE) – reduces the potential for indirect and direct exposures. Yet nurses and clinical settings do not adopt these evidence-based control measures consistently. From the Nurses' Health Study 3, 25% of nurses reported never wearing gowns during hazardous drug administration, confirming similar findings from a 2006 study (Lawson et al., 2019; Polovich & Martin, 2011).

Oncology nurses face exposure potential from indirect (e.g., surface contamination) and direct (e.g. drug spills) sources. To date, no prospective studies have examined in detail direct exposures, such as drug spills. A deeper understanding of the patterns and correlates of drug spills may identify opportunities for risk reduction and clinical practice change. Data collection from multiple clinical sites improves the generalizability of these findings across the diverse landscape of oncology nursing practice.

As part of a larger randomized controlled trial of an educational intervention, the study team collected detailed on hazardous drug spills that occurred during the project, including the PPE worn when a hazardous drug spill occurred. The analyses reported herein document the frequency of hazardous drug spills in participating sites and the context in which these exposures occurred. The findings have implications for strengthening the safety net for oncology nurses who handle hazardous drugs in their clinical practice.

Methods

Study Population and Setting

The Drug Exposure Feedback and Education for Nurses' Safety (DEFENS) study was launched in March 2015; primary results of the study have been reported (Friese, Yang, Mendelsohn-Victor, & McCullagh, 2019). The study protocol received Institutional Review Board approval and due to the educational intervention, the study team registered the protocol on ClinicalTrials.gov (NCT02283164). Twelve academic-affiliated cancer centers

with high-volume ambulatory infusion practices agreed to participate. Eligibility criteria included practice as a registered nurse at least 40 percent of a full-time equivalent position. Nurses had to practice in the ambulatory infusion setting. The study protocol excluded nurses who had received treatment with an antineoplastic drug in the previous year.

Study Procedures

The team has previously published the DEFENS study protocol (Friese et al., 2015). The current inquiry focuses on unpublished data that were collected during the project: the baseline survey and prospective data collection of hazardous drug spill events. Consented participants (n=393) completed an encrypted, user-authenticated survey at the time of study enrollment. If a hazardous drug spill occurred, on-site study champions directed participants to complete a spill report as soon as logistically possible after the event occurred. This survey was pilot tested in one site prior to implementation (Friese et al., 2014).

Study Measures

From the DEFENS study baseline survey, the team examined personal characteristics of nurses (years in practice, education, gender, race, ethnicity, and certification). Nurses reported the number of patients they provided direct care for on the shift during the drug spill. Nurses also reported proportion of those patients who received chemotherapy.

To characterize the drug spill, nurses reported the drug(s) spilled, the spill volume(s), whether a closed-system transfer device was used and if used did it function properly, skin or eye contact, hand hygiene after the spill (hand gel, soap and water, or nothing), and personal protective equipment use during spill response and clean up. Specifically, nurses reported whether they wore two pairs of chemotherapy-tested gloves, one pair of gloves, a single-use disposable gown, eye protection, a respirator, and/or shoe covering (Polovich & Clark, 2010).

Statistical Analysis

The unit of analysis for the study was each individual spill report. Descriptive statistics, including frequencies for categorical and means for continuous data were used to report key findings. The study team estimated a generalized linear mixed effects regression model to examine the relationship between nurses' personal characteristics or workplace characteristics on the likelihood of reporting a hazardous drug spill during the reporting period. All analyses were performed in SAS version 9.4 (Cary, NC).

Results

Study Participant Characteristics

Table 1 shows the characteristics of the entire nurse sample, followed by participant characteristics stratified by report of a hazardous drug spill during the study period. Sixty-six participants reported both ONS Chemotherapy/Biotherapy and OCN certification. Nurses who reported "other" certifications included pediatrics, critical care, hospice/palliative care, and medical/surgical nursing, among others. Nurses who reported spills did not differ from

those who did not by years of experience, educational preparation, gender, race/ethnicity, certification, or patient workloads on their last shift.

Spill Event Characteristics

Table 2 summarizes key findings from nurses' hazardous drug spill reports collected across twelve sites over two years. Participants completed 61 spill reports. Ten participants reported more than one spill. Out of 12 participating sites, 11 reported at least one spill (range of reported spills across sites: 0-10). The most frequently drug spilled was paclitaxel (19.7%), followed by gemcitabine (14.8%), and followed by an anthracycline (13.1%). The mean (SD) volume of drug spilled was 28.8(42.3) mLs, with a range of "a few drops" to 250 mLs. The majority (67.2%) of participants indicated they used a closed-system transfer device during the drug handling activity, yet over half (51.2%) reported the device did not work properly during the spill.

Regarding exposure, the only human contact reported was through skin, by 18% of participants. At the time of the spill, 62.3% of respondents wore a single-use, disposable gown, 42.6% wore two pairs of chemotherapy-tested gloves, 29.5% wore a respirator, and 23% wore eye protection. Figure 1 shows the distribution of PPE items worn by respondents during the spill response. Of the 61 spills, respondents indicated spill kits were used in 42 events (68.9%). After hazardous drug handling and clean up duties were completed, 9.8% of respondents applied alcohol-based gel to their hands.

After fitting a generalized linear mixed effects model (results not shown), no individual (years in practice, education, gender, race, ethnicity, and certification), or workplace (number of patients cared for on the last shift) factors examined were significantly associated with the likelihood of reporting a hazardous drug spill during the study period.

Discussion

Over a two-year period, a substantial number of hazardous drug spills occurred across participating cancer centers. In most cases, closed-system transfer devices, when used, did not function properly. Overall, individual nurses' spill response was suboptimal; nurses rarely wore personal protective equipment as recommended. These key findings have important implications for oncology nurses, leaders with oversight over chemotherapy infusion settings, and key policy stakeholders.

All three drugs most frequently cited in spill reports are included on the NIOSH hazardous drug list (National Institute for Occupational Safety and Health (NIOSH), 2016). The Food and Drug Administration classifies all three as Pregnancy Category D - positive evidence of human fetal risk (United States Department of Health and Human Services, 2019). The International Agency for Research on Cancer (2011) lists doxorubicin and other anthracyclines as "probably carcinogenic;" the National Toxicology Program (2019) classifies them as "reasonably anticipated to be carcinogenic," based on their chemical composition and completed studies. Nurses should take all reasonable precautions to minimize exposure to these agents.

Within the established hierarchy of controls for occupational health, engineering controls rank second among strategies to protect workers (National Institute for Occupational Safety and Health, 2019). As elimination of the hazard, i.e., avoid use or contact with the offending agent, is not available to oncology nurses, the most reliable approach to controlling hazardous drug exposure remains engineering controls, such as closed system transfer devices. Yet in over half the drug spills where such a device was use, nurses reported a malfunction. It is unclear from the data whether it was a technical user error or a mechanical defect; additional observational studies are needed to determine root causes. The current study findings underscore the need for novel product design and testing to provide nurses with secure, simple-to-use equipment to reduce the likelihood of a drug spill. Human-centered design approaches that include nurses as end users and product consultants is a promising strategy for meaningful improvements in these products (Mullaney, Pettersson, Nyholm, & Stolterman, 2012).

The study findings also highlight the importance of ongoing education, practice, and leadership support for nurses' use of personal protective equipment. Hazardous drug educational content cannot solely be delivered through certification, as nearly one quarter of our sample did not hold such certification. During most spills, personal protective equipment use did not conform to professional organizations' recommendations. While few studies have focused on PPE use during hazardous drug spills, relatively low rates of optimal PPE use have been reported previously. In addition, prior findings from this research team suggest that peer and leadership attitudes influence individual personal protective equipment use (Friese et al., 2019; He, Mendelsohn-Victor, McCullagh, & Friese, 2017). Similar to successful handwashing campaigns, positive reinforcement and audit and feedback targeted to groups of nurses may be successful in improving protective equipment use during spills. In 2018, study team members launched a free multi-modal training program for preventing and managing hazardous drug spills, which combines didactic and simulation training to respond to a spill (University of Michigan School of Nursing, 2018).

Limitations

The current investigation is among the few prospective studies of direct hazardous drug exposures among oncology nurses conducted across multiple sites. Additional strengths include a high participation rate and use of previously validated measures. However, the team acknowledges several study limitations. First, participating sites were relatively large and held academic affiliations. Site leaders had to endorse the study and have sufficient research capacity to facilitate the project. The study findings may not be generalizable to non-academic infusion centers. However, similar findings of low personal protective equipment use and frequent spills have been confirmed in other investigations (Connor et al., 2010; Lawson et al., 2019). Finally, the study design prohibited examination of factors associated with nurses who did not experience drug spills. Subsequent research efforts to study positive outliers may yield actionable data for clinical practice change. These limitations are presented among one of the largest prospective examinations of hazardous drug exposure among oncology nurses.

Implications for Nursing

The third edition of the Oncology Nursing Society text, *Safe Handling of Hazardous Drugs* provides practicing nurses with useful guidance as to how to protect themselves from hazardous drug exposure (Polovich & Olsen, 2018). This volume provides practical strategies for managers, educators, and nurse clinicians. Nurses can use this volume to assess their personal practice and advocate for policy and procedure changes in their setting to conform with these recommendations. As a practical consideration, infusion nurses should assure that all personal protective equipment and spill kits are within easy reach of patient care areas prior to administering hazardous drugs. If not already in place, nurses who experience a drug spill are encouraged to use their existing risk management and occupational health event reporting platforms to chronicle hazardous drug exposures to motivate quality improvement efforts. Historically, quality improvement efforts in oncology settings have focused on patient-facing concerns. A novel strategy to consider is to apply existing quality improvement practices to promote adoption of evidence-based actions to prevent hazardous drug exposure and minimize exposures when spills occur. Nurses can partner with pharmacy and environmental services departments in their setting to improve spill response procedures. Nurses can provide input to manufacturers of closed system transfer devices. Nursing and other professional organizations could establish registries to monitor device malfunctions to inform subsequent product design, as has been done in other clinical specialties (Resnic et al., 2017). Key take away messages from the paper reported herein and the study team's collective analysis of hazardous drug exposures can be found in Figure 2.

Conclusion

In summary, this study found the hazardous drug spills occurred frequently across twelve ambulatory oncology practices and that nurses remain at notable risk for hazardous drug exposure. Further, closed system transfer devices did not always work as intended, and that when responding to spills, nurses rarely wore personal protective equipment as recommended. To protect nurses adequately from exposure, multi-faceted concerted efforts to assure nurses handle, administer, and dispose of hazardous drugs properly is warranted. Nurses who respond to drug spills are particularly vulnerable and ongoing training is warranted. Routine reporting of drug spills may motivate clinical practice change and aid manufacturers in designing engineering controls that effectively reduce nurses' exposure to hazardous drugs.

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Knowledge Translation

- Spills remain a significant source of hazardous drug exposure among nurses who administer chemotherapy.
- When responding to spills, nurses' use of personal protective equipment was far less than recommended, resulting in avoidable health risk.
- Infusion centers should optimize use of safety reporting systems to track nurse reports of hazardous drug spills to evaluate nurses' health risks and effectiveness of exposure prevention measures.

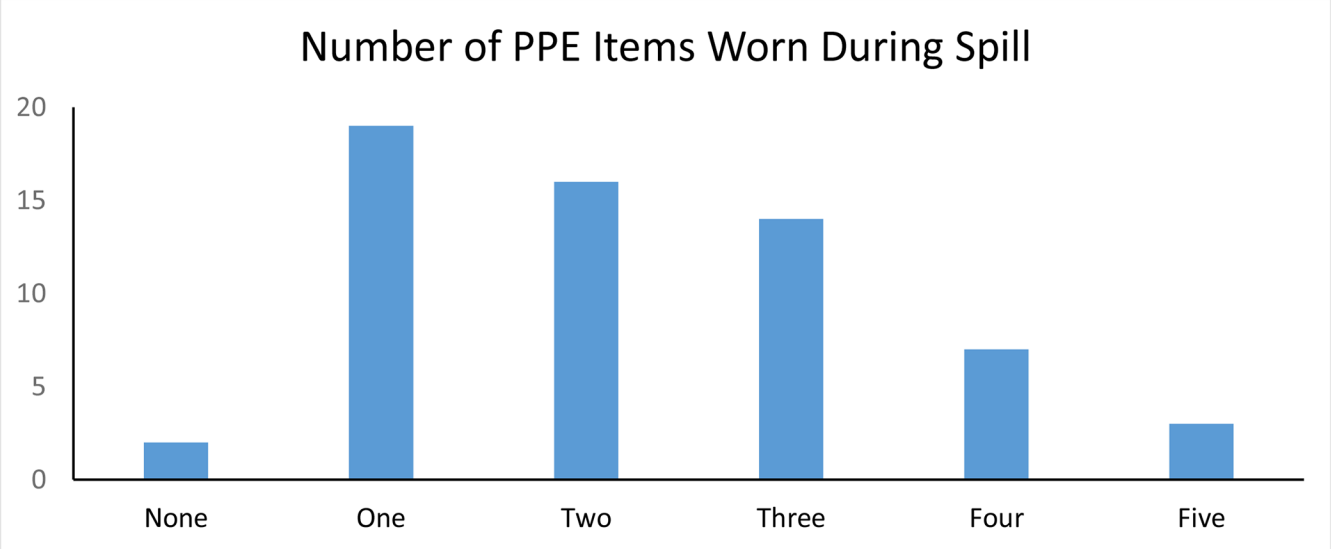

Figure 1. Total PPE[1] Items Worn by Nurses during Spill Response

[1] PPE: Personal protective equipment.

Prevention	During Drug Administration	Spill Management
• Maintain an updated list of hazardous drugs and label drugs as hazardous • Prepare hazardous drugs in accordance with USP <800> standards • Verify that spill kits and personal protective equipment (PPE) – two pairs of chemotherapy-tested gloves, single-use, disposable chemotherapy-tested gowns, eye and face protection and respirators - are readily available in the drug preparation and administration areas. • Assure tubing connected to hazardous drugs is primed with compatible fluid (e.g., 0.9% normal saline) • Avoid crushing/manipulating oral hazardous drugs outside of compounding areas • Visibly inspect drug vials, containers, and/or tubing for any disconnection or leaks prior to handling the drug • Don PPE immediately before handling hazardous drugs • Practice using closed system transfer devices to assure nurse can use the device correctly • Conduct chemotherapy spill drills to maintain spill clean up competency	• Verify function of venous access device and secure tubing connections before administration • For patients with implanted ports, visually assess integrity of Huber needle connection • Inform patients when hazardous drug infusions begin and instruct them to notify staff with wetness or infusion problems • Monitor patients with cognitive impairment closely during infusions • Assure that intravenous bags, tubing, and connections to patient lines are always visible • If using an infusion pump, verify the pump is delivering the drug to the catheter before leaving the patient • If leaving the clinical area, provide a verbal report to the covering nurse as to who is receiving a hazardous drug • After handling hazardous drugs: ○ Remove and dispose of gowns immediately and do not reuse ○ Wash hands with soap and water after removing PPE ○ Avoid hand gel	• Before helping others, immediately don PPE, including a respirator. • Summon help and notify appropriate personnel • Contain liquid with absorbent pads • Use a spill kit to clean up the area, following institutional policy • Remove any contaminated linen • Remove and discard any contaminated clothing • After spill clean up is complete, remove PPE and wash hands with soap and water, not hand gel • Report spill event using the institution's adverse event system, including drug(s) spilled, estimated volume, clean up procedures, details of any known exposure (e.g., to skin or eyes), and contributing factors

Figure 2. Protecting Nurses from Hazardous Drug Exposure: Key Lessons from the DEFENS Study

For more hazardous drug training opportunities and resources, visit www.mosst.nursing.umich.edu

Table 1.

Participant Characteristics

Characteristic	Total (N = 378)	Did Not Report a Spill (N = 327)	Reported a Spill (N = 51)	Chi-Sq or T-test (*p*)
		n (%)		
Years of Oncology Nursing Experience				1.11 (0.77)
0 years to 10 years	214 (57)	183 (56)	31 (61)	
11 years to 20 years	103 (27)	92 (28)	11 (21)	
21 years to 30 years	44 (12)	37 (11)	7 (14)	
Over 30 years	16 (4)	14 (4)	2 (4)	
Education				3.14 (0.21)
Associates or Diploma	86 (23)	76 (23)	10 (20)	
Bachelors in Nursing	263 (70)	229 (70)	34 (67)	
Graduate Degree	29 (7)	22 (7)	7 (13)	
Gender				1.18 (0.28)
Male	24 (6)	19 (6)	5 (10)	
Female	354 (94)	308 (94)	46 (90)	
Race/Ethnicity				0.03 (0.86)
White	323 (85)	279 (85)	44 (86)	
Non-white	55 (15)	48 (15)	7 (14)	
Hispanic or Latino Origin				0.004 (0.96)
Yes	23 (6)	20 (6)	3 (6)	
No	355 (94)	307 (94)	48 (94)	
Certifications[a]				3.20 (0.36)
ONS Chemotherapy/Biotherapy	144 (38)	119 (36)	25 (49)	
Oncology Certified Nurse (OCN)	186 (49)	159 (49)	27 (53)	
Other Certification	22 (6)	21 (6)	1 (2)	
No Certification	92 (24)	81 (25)	11 (22)	
Number of Patients Cared For		Mean (SD)		
Direct Care	7.8 (6.5)	8.0 (6.9)	6.4 (2.9)	1.67 (0.10)
Administered Chemotherapy	5.5 (3.4)	5.5 (3.5)	5.3 (2.6)	0.50 (0.62)

Note: ONS = Oncology Nursing Society

[a]As participants could report more than one certification, totals for this variable do not add up to 100%.

Table 2.

Characteristics of Spill Events

Characteristic	Total (N = 61)[1]
Drugs Involved	n (%)
Paclitaxel	12 (19.7)
Gemcitabine	9 (14.8)
Anthracycline (Amrubicin, Doxorubicin, Liposomal Doxorubicin)[2]	8 (13.1)
Carboplatin	5 (8.2)
Cisplatin	5 (8.2)
5-Fluorouracil	3 (4.9)
Docetaxel	3 (4.9)
Etoposide	3 (4.9)
Bendamustine	2 (3.3)
Cyclophosphamide/Evophosphamide	2 (3.3)
Oxaliplatin	2 (3.3)
Pertuzumab	2 (3.3)
Irinotecan	1 (1.6)
Pemetrexed	1 (1.6)
Rituximab	1 (1.6)
Tarextumab	1 (1.6)
Trastuzumab	1 (1.6)
Used a Closed System Transfer Device	
Yes	41 (67.2)
No	17 (27.9)
Missing/Not Reported	3 (4.9)
Closed System Transfer Device Function Properly (n=41)	
Yes	7 (17.1)
No	21 (51.2)
Missing/Not Reported	13 (31.7)
Skin Contact with Hazardous Drug	
Yes	11 (18.0)
No	50 (82.0)
PPE Items Worn during Spill Response[3]	
Single-use, Disposable Gown	38 (62.3)
One Pair of Chemotherapy Gloves	33 (54.1)
Two Pairs of Chemotherapy Gloves	26 (42.6)
Respirator/Mask	18 (29.5)
Eye Protection	14 (23.0)
Shoe Covers/Booties	7 (11.5)

Characteristic	Total (N = 61)[1]
Used a Spill Kit	
Yes	42 (68.9)
No	19 (31.1)
Missing/Not Reported	0
Hand gel Use after Spill	
Yes	6 (9.8)
No	37 (60.7)
Missing/Not Reported	18 (29.5)
	Mean (SD)
Estimated Volume of Spilled Drug (mL)	28.8 (42.3)
Patient Workload, Shift of Spill	
Number of patients provided direct care	5.3 (4.0)
Number of patients who received chemotherapy	4.0 (2.6)

[1] Of the 61 spills, there were a total of 51 unique participants. 10 participants reported more than 1 spill.

[2] Drugs are classified as vesicant chemotherapy agents. Adverse effects include severe skin and tissue damage.

[3] Participants could choose multiple responses. PPE: personal protective equipment