Hazardous Drug Exposure

Case report analysis from a prospective, multisite study of oncology nurses' exposure in ambulatory settings

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BACKGROUND: Hazardous drug exposure is an occupational health hazard to oncology nurses. Sparse data are available regarding the frequency and characteristics of hazardous drug spills.

OBJECTIVES: This article aims 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 RNs administering chemotherapy in ambulatory infusion settings completed brief questionnaires. Descriptive statistics were used to summarize equipment use and spill events.

FINDINGS: Spills were common, despite the use of closed-system transfer devices. Over two years, 51 nurses from 12 participating academic infusion centers reported 61 unique spills. Spills commonly involved highly toxic drugs. Personal protective equipment use during drug spills was suboptimal. These foundational data reveal gaps in clinical practice.

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

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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). Real and potential adverse health events have been correlated with hazardous drug exposure (National Institute for Occupational Safety and Health [NIOSH], 2018). In response, NIOSH, the Oncology Nursing Society, the American Society of Health System Pharmacists, and the U.S. Pharmacopeial Convention have issued guidance on how clinicians can minimize hazardous drug exposures (Connor et al., 2017). An array of control measures—use of closed-system transfer devices, externally ventilated biologic safety cabinets for compounding activities, training/education, and consistent use of personal protective equipment (PPE)—reduces the potential for indirect and direct exposures. However, nurses and clinical settings do not adopt these evidence-based control measures consistently. According to the Nurses' Health Study 3, 25% of nurses reported that they never wore 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 spill) sources. To date, no prospective studies have examined direct exposures in detail. 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 clinical oncology nursing practice.

As part of a larger randomized controlled trial of an educational intervention, the current study team collected detailed data on hazardous drug spills that occurred during the project, including PPE worn when a hazardous drug spill occurred. The analyses reported in the current article 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 clinical practice.

Methods

Sample 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 et al., 2019). The study protocol received institutional review board approval from the University of Michigan; because of the educational intervention, the study team registered the protocol on ClinicalTrials.gov (NCT02283164). Twelve academic-affiliated cancer centers with high-volume ambulatory infusion practices in the United States agreed to participate. Eligibility criteria included working as an RN at least 40% 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.

Procedures

The DEFENS study protocol has been previously published (Friese, Mendelsohn-Victor, 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 possible after the event occurred. This survey was pilot tested in one site prior to implementation (Friese, McArdle, et al., 2015).

Measures

The authors examined personal characteristics of nurses (years in practice, education, gender, race, ethnicity, and certification) from the DEFENS study baseline survey. Nurses reported the number of patients for which they provided direct care 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 spilled, spill volume, whether a closed-system transfer device was used (and, if used, if it functioned properly), skin or eye contact, hand hygiene after the spill (e.g., alcohol-based hand gel, soap and water, nothing), and PPE 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 data 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.

"In more than half of the drug spills in which a closed-system transfer device was in use, nurses reported a malfunction."

Results

Sample 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. Nurses who reported other certifications included pediatrics, critical care, hospice/palliative care, and medical/surgical nursing. Nurses were similar in the following characteristics: 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 12 sites over two years. Participants completed 61 spill reports. Ten participants reported more than one spill. Of 12 participating sites, 11 reported at least one spill (range of reported spills across sites = 0–10). The most frequently spilled drugs were paclitaxel, gemcitabine, and anthracycline. The mean volume of drug spilled was 28.8 ml (SD = 42.3 ml), with a range of "a few drops" to 250 ml. Forty-one participants indicated they used a closed-system transfer device during the drug-handling activity, but 21 of those participants reported the device did not work properly during the spill.

Regarding exposure, 11 participants reported skin exposure, the only type of exposure from this dataset. At the time of the spill, 38 respondents wore a single-use, disposable gown; 26 wore two pairs of chemotherapy-tested gloves; 18 wore a respirator; and 14 wore eye protection. Of the 61 spills, respondents indicated spill kits were used in 42 events. After hazardous drug-handling and clean-up duties were completed, six respondents used alcohol-based hand gel.

TABLE 1.
PARTICIPANT CHARACTERISTICS FROM 12 PARTICIPATING SITES

	TOTAL (N = 378)		DID NOT REPORT A SPILL (N = 327)		REPORTED A SPILL (N = 51)			
CHARACTERISTIC	**n**	**%**	**n**	**%**	**n**	**%**	**STAT**	**p**
Years of oncology nursing experience							1.11	0.77
0–10	214	57	183	56	31	61		
11–20	103	27	92	28	11	21		
21–30	44	12	37	11	7	14		
More than 30	16	4	14	4	2	4		
Missing data	1	< 1	1	< 1	–	–		
Education							3.14	0.21
High school diploma or associate degree	86	23	76	23	10	20		
Bachelor's degree	263	70	229	70	34	67		
Graduate degree	29	7	22	7	7	13		
Gender							1.18	0.28
Female	354	94	308	94	46	90		
Male	24	6	19	6	5	10		
Race							0.03	0.86
White	323	85	279	85	44	86		
Not White	55	15	48	15	7	14		
Ethnicity							0.004	0.96
Not Hispanic or Latino	355	94	307	94	48	94		
Hispanic or Latino	23	6	20	6	3	6		
Certification[a]							3.2	0.36
OCN®	186	49	159	49	27	53		
ONS/ONCC Chemotherapy Immunotherapy	144	38	119	36	25	49		
Other	22	6	21	6	1	2		
None	92	24	81	25	11	22		
CHARACTERISTIC	**$\bar{X}$**	**SD**	**$\bar{X}$**	**SD**	**$\bar{X}$**	**SD**	**STAT**	**p**
Number of patients cared for during shift								
Patients provided direct care	7.8	6.5	8	6.9	6.4	2.9	1.67	0.1
Patients who received chemotherapy	5.5	3.4	5.5	3.5	5.3	2.6	0.5	0.62

[a] Participants could report more than one certification.
ONCC—Oncology Nursing Certification Corporation; ONS—Oncology Nursing Society; STAT—statistic (chi-square test or t test)
Note. Because of rounding, percentages may not total 100.

TABLE 2.
CHARACTERISTICS OF SPILL EVENTS (N = 61)

CHARACTERISTIC	$\bar{X}$	SD
Estimated volume of spilled drug (ml)	28.8	42.3
Patients provided direct care during shift	5.3	4
Patients who received chemotherapy during shift	4	2.6
CHARACTERISTIC		**n**
Drug involved		
Paclitaxel		12
Gemcitabine		9
Anthracycline[a]		8
Carboplatin		5
Cisplatin		5
5-Fluorouracil		3
Docetaxel		3
Etoposide		3
Bendamustine		2
Cyclophosphamide or evophosphamide		2
Oxaliplatin		2
Pertuzumab		2
Irinotecan		1
Pemetrexed		1
Rituximab		1
Tarextumab		1
Trastuzumab		1
Used a CSTD		
Yes		41
No		17
Missing data		3
CSTD functioned properly (N = 41)		
No		21
Yes		7
Missing data		13

Continued in the next column

TABLE 2. *(CONTINUED)*
CHARACTERISTICS OF SPILL EVENTS (N = 61)

CHARACTERISTIC		n
Skin contact with hazardous drug		
No		50
Yes		11
Type of PPE worn during spill response[b]		
Single-use, disposable gown		38
One pair of chemotherapy gloves		33
Two pairs of chemotherapy gloves		26
Respirator or mask		18
Eye protection		14
Shoe covers or booties		7
Number of PPE items worn during spill		
None		2
1		19
2		16
3		14
4		7
5		3
Used a spill kit		
Yes		42
No		19
Alcohol-based hand gel used after spill		
No		37
Yes		6
Missing data		18

[a] Adverse effects from these vesicant chemotherapy agents include severe skin and tissue damage. Anthracyclines consisted of amrubicin, doxorubicin, and liposomal doxorubicin.
[b] Participants could choose more than one response.
CSTD—closed-system transfer device; PPE—personal protective equipment
Note. Of the 61 spills, there were a total of 51 unique participants. 10 participants reported more than 1 spill.

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

During 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 PPE as recommended. These 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 (2016) hazardous drug list. The U.S. Food and Drug Administration classifies all three as Pregnancy Category D (positive evidence of human fetal risk) (U.S. Department of Health and Human Services, 2019). The International Agency for Research on Cancer (Cogliano et al., 2011) lists doxorubicin and other anthracyclines as "probably carcinogenic" (p. 1,827), and the National Toxicology Program (2019) classifies them as "reasonably anticipated to be carcinogenic" (p. 52) based on their chemical composition and completed studies.

Within the established hierarchy of controls for occupational health, engineering controls rank second among strategies to protect workers (NIOSH, 2019). Because elimination of the hazard (i.e., avoiding use or contact with the offending agent) is not available to oncology nurses, the most reliable approach to controlling hazardous drug exposure remains use of engineering controls, such as using closed-system transfer devices. However, in more than half of the drug spills in which such a device was in 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. These 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

FIGURE 1.
PROTECTING NURSES FROM HAZARDOUS DRUG EXPOSURE: KEY LESSONS FROM THE DEFENS STUDY

PREVENTION

- 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 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.
- Ensure 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 ensure nurses can use the device correctly.
- Conduct chemotherapy spill drills to maintain spill clean-up competency.

DURING DRUG ADMINISTRATION

- 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.
- Ensure that IV 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, do the following:
  - ☐ Remove and dispose of gowns immediately. Do not reuse.
  - ☐ Wash hands with soap and water after removing PPE.
  - ☐ Avoid use of alcohol-based hand gel.

SPILL MANAGEMENT

- 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 alcohol-based 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.

DEFENS—Drug Exposure Feedback and Education for Nurses' Safety; PPE—personal protective equipment; USP—U.S. Pharmacopeia
Note. Based on information from Friese et al., 2019; National Institute for Occupational Safety and Health, 2018; Polovich & Olsen, 2018; U.S. Pharmacopeial Convention, 2017.

consultants is a promising strategy for meaningful improvements in these products (Mullaney et al., 2012).

The study findings also highlight the importance of ongoing education, practice, and leadership support for nurses' use of PPE. Hazardous drug educational content cannot solely be delivered through certification because about one-fourth of the sample did not hold such certification. During most spills, PPE use did not conform to professional organizations' recommendations. Although few studies have focused on PPE use during hazardous drug spills, relatively low rates of optimal PPE use have been reported previously (Friese et al., 2019; Lawson et al., 2019; Polovich & Martin, 2011). In addition, peer and leadership attitudes influence individual PPE use (Friese et al., 2019; He et al., 2017). Similar to successful handwashing campaigns, positive reinforcement and audit and feedback targeted to groups of nurses may be successful in improving PPE use during spills (Ivers et al., 2012). Strategies implemented to prevent and manage hazardous drug spills include a free multimodal training program for preventing and managing hazardous drug spills that combined didactic and simulation training to respond to a spill (University of Michigan School of Nursing, 2018). To date, over half of the workshop participants have reported clinical practice or policy changes following workshop attendance.

Limitations

This study had several 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 PPE use and frequent spills have been confirmed in other investigations (Connor et al., 2010; Lawson et al., 2019). The study design also 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.

Implications for Nursing

Oncology publications and curriculums guide nurses about how they can protect themselves from hazardous drug exposure (Polovich & Olsen, 2018). These sources provide strategies for clinical practice assessment and for policy and procedural changes to meet established standards.

As a practical consideration, nurses are best protected in clinical practice by ensuring PPE and spills kits are accessible before administering hazardous drugs. To improve quality of care, nurses who experience drug spills can document their experience by accessing risk management and occupational health reporting platforms. 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 exposure when spills occur. Nurses can partner with pharmacy and environmental services departments in their settings 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). Figure 1 highlights strategies to reduce hazardous drug exposure and manage spills.

IMPLICATIONS FOR PRACTICE

- Remain vigilant throughout the drug preparation, administration, infusion, and removal processes to prevent hazardous drug exposure.
- Wear personal protective equipment as recommended, and wash hands with soap and water after handling hazardous drugs.
- Report hazardous drug spills and the contributing factors via institutional safety reporting systems to facilitate learning.

Conclusion

This study found that hazardous drug spills occurred frequently across 12 ambulatory oncology practices and that nurses remain at notable risk for hazardous drug exposure. In addition, closed-system transfer devices did not always work as intended. When responding to spills, nurses rarely wore PPE as recommended. To protect nurses adequately from exposure, multifaceted, concerted efforts to ensure that nurses handle, administer, and dispose of hazardous drugs properly are 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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