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Structures and Processes of Care in Ambulatory Oncology Settings and Nurse-Reported Exposure to Chemotherapy

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Abstract

Purpose—Oncology nurses in ambulatory settings are at increased risk for unintentional chemotherapy exposure, due to the large volumes of agents delivered and the absence of regulatory enforcement. Given the limited data regarding the correlates of exposure, we sought to identify the relationship between the organizational structures and processes of care in ambulatory oncology settings associated with increased risk of unintentional chemotherapy.

Methods—Between April 2010 and June 2010, we surveyed a state-wide sample of oncology nurses who reported their employment outside of hospital inpatient units (n=1,339). We examined the likelihood of self-reported exposure to chemotherapy as a function of perceived quality of the practice environment, nursing workload, and seven ambulatory chemotherapy administration safety standards.

Results—The response rate was 30.4%, with minimal demographic differences observed between respondents and non-respondents. The overall rate of exposure to the skin or eyes in the past year was 16.9%. In multivariable logistic regression models that controlled for demographic characteristics and clustering of nurses in practices, the likelihood of exposure decreased when nurses reported adequate staffing and resources (OR 0.35, 95% CI, 0.17 to 0.73; $P = .001$), and when nurses reported that chemotherapy doses were verified by two nurses frequently or very frequently (OR 0.17, 95% CI, 0.05 to 0.59; $P = .001$).

Conclusions—Oncology nurses in the ambulatory setting report substantial unintentional skin and eye exposure to chemotherapy. Ensuring adequate staffing and resources and adherence to recognized practice standards may protect oncology nurses from harm.

Keywords

Occupational exposure; nursing; antineoplastic agents; safety; outcomes assessment (health care)

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INTRODUCTION

Chemotherapy administration is a high-priority target for quality improvement activities given high patient volumes and high risks to patients and clinicians. In the United States, an estimated 23 million adult patient visits occur annually for chemotherapy. Of these visits, approximately 19 million (84%) are delivered in ambulatory settings, largely by nurses.[1] And despite numerous concerns for chemotherapy safety, less attention is paid to the risks that nurses face when they administer these agents and are unintentionally exposed due to a splash or spill. The antineoplastic drugs used for chemotherapy (e.g., cyclophosphamide, ifosphamide, paclitaxel, methotrexate) confer significant health risks, such as immediate nervous system effects, acute and long-term reproductive effects, and subsequent risk of haematological malignancies.[2,3]

The absence of a consistent regulatory framework for chemotherapy delivery in ambulatory oncology settings exacerbates the potential risk to nurses. Apart from a recent Centres for Medicare and Medicaid Services (CMS) statement[4] that a “physician or non-physician practitioner’s recurrent physical presence” is required during chemotherapy administration, CMS performs little oversight of chemotherapy delivery. The National Institute for Occupational Safety and Health issued an alert on occupational exposure to antineoplastic and other hazardous drugs.[5] However, this alert is merely advisory and has no regulatory enforcement.

Chemotherapy administration processes vary across practices. In 2009, the Oncology Nursing Society (ONS) and American Society of Clinical Oncology (ASCO) acknowledged the potential problems imposed by practice variability and jointly issued voluntary safety standards for ambulatory chemotherapy administration.[6] The adoption rate of these standards is unknown, and only 74 practices are certified currently by ASCO’s Quality Oncology Practice Initiative (QOPI) for standard adherence.[7] The 17 standards assessed for QOPI certification do not address safe handling practices and related policies. Further, no reporting mechanism exists to track unintentional exposures to chemotherapy or the conditions under which the exposure occurred.

Noteworthy challenges to existing efforts to study unintentional exposure include measurement considerations and restricted sampling. Diverse measurement approaches and result interpretation vary across studies and hamper comparability. Studies conducted in the 1980s and 1990s examined both urine mutagenicity and drug levels excreted in urine.[8-10] More recently, biological measures have been correlated to health care workers’ self reports.[11] Self report has been used successfully in assessing needle stick injuries to nurses.[12] A second limitation of the literature is the absence of multi-site, population-based samples. Because of its cost, biological sampling has been limited to convenience samples of single institutions, which limits generalizability to more diverse practices and participants.[13,14] Taken together, these limitations hamper examinations of variation in chemotherapy exposure across settings, and the correlates of increased exposure.

Published studies have not examined the relationship between chemotherapy exposure and the structures and processes employed by oncology practices. The decentralized nature of ambulatory chemotherapy administration hampers research efforts to study this problem. A better understanding of the organizational structures and processes of care that are associated with chemotherapy exposure to nurses in ambulatory oncology settings would inform policymakers, safety officials, managers, and clinicians on how best to reduce exposure risk and minimize harm to oncology nurses. In this context, we conducted a state-wide survey of oncology nurses employed outside of hospital inpatient units to quantify reported exposure and to identify organizational correlates of exposure.

METHODS

Study design and setting

Donabedian's Quality of Care Model[15] guided our study design. This model identified three components of quality: the organizational structures (e.g., staffing, workplace context, leadership, management), the processes of care (e.g., clinical and technical interventions provided), and the outcomes (e.g., safety, satisfaction, and clinical endpoints). This report focuses on the organizational structures and processes of care in ambulatory oncology settings, and their relationship to the safety outcome of nurse-reported chemotherapy exposure.

Completed between April and June, 2010, the Practice Environments of Oncology Nurses Study was a cross-sectional survey that examined nurse reports of the organizational structures, processes of care, and outcomes in ambulatory oncology settings; we have published our methodology previously.[16] Briefly, we used nursing registry data from one state in the southeast United States - updated biennially - to identify registered and licensed practical nurses who resided in the state and who reported a clinical specialty of oncology and a practice setting outside of hospital inpatient units (n=1,339). We modified the Dillman survey method[17] by including a $2 up-front incentive, a shorter interval for reminder notices, and randomized subjects to Internet versus paper survey completion. We observed no significant differences in response rates across arms.[16] We obtained human subjects approval from The University of Michigan's Institutional Review Board-Medicine.

Measures—The Web-based and paper questionnaires had identical content. In addition to sociodemographic variables, the questionnaires included measures of organizational structure, processes of care, and perceived outcomes.

Organizational Structure: nurses completed the Practice Environment Scale of the Nursing Work Index (PES-NWI).[18] The PES-NWI consists of 31 items that assess the presence of organizational features to support professional nursing practice and promote favourable patient outcomes. The original PES-NWI includes five subscales: nurse participation in hospital affairs; nursing foundations for quality of care; nurse manager leadership, ability, and support of nurses; staffing and resource adequacy, and; collegial nurse-physician relationships. The instrument has published evidence of reliability (Cronbach's alpha values between 0.71 and 0.84 across subscales) and validity (higher PES-NWI scores for nurses employed in Magnet hospitals),[19,20] albeit in samples of inpatient nurses.

Using focus groups,[21] clinical nursing expert review, and cognitive interviews, we modified the items slightly for suitability to the outpatient environment. The revised PES-NWI had six subscales: the original five listed above plus the supportive relations with medical assistants subscale. The revised text of the revised items and corresponding subscales is available in the Web Only appendix. In a previous study, we used performed confirmatory factor analysis using structural equation modelling to examine model fit with revised items. In our final model specifying six constructs, a reduced set of 23 items achieved acceptable model fit, as reflected by a comparative fit index of 0.95 and a root mean-square error of approximation of 0.057 (95% confidence interval (CI) = 0.049 – 0.064).[22] Cronbach alpha coefficients for the subscales ranged from 0.80 to 0.90. Items were scored on a five-point Likert scale, where 1 = strongly disagree the characteristic was present in the workplace to 5 = strongly agree the characteristic was present in the workplace. Subscale items were averaged for each nurse, where values above 3.0 suggested the presence of the characteristic in their workplace. Mean PES-NWI subscales were used in bivariate analysis, and later were dichotomized (greater than 3.0 versus 3.0 and under) for use in multivariable models.

In addition to the revised PES-NWI subscales, we asked each participant an additional item: "please describe the current practice environment for you as a nurse to delivery high-quality care." Response options were favourable, mixed, or unfavourable.

To measure nursing workload, we used each nurse's report of the number of patients for whom he/she assumed the primary care on their last shift, and treated this measure as a continuous variable. This measure of nursing workload has been used in prior studies of hospital staffing and patient outcomes, and correlates well with both perceived staffing adequacy and administratively-derived nurse staffing.[19, 23]

Processes of Care: We developed 7 process of care items from the 2009 ASCO/ONS standards for ambulatory chemotherapy administration.[6] Nurses rated the frequency that the process occurred on a 5-point Likert scale (never to very frequently). Items included: the presence of signed informed consent, documentation of treatment intent, and performance of pain assessments. In our exploratory data analysis, we identified only one process of care measure—the frequency that 2 nurses performed verification of the original chemotherapy order against the prepared dosage of chemotherapy—that was associated with the likelihood of chemotherapy exposure. We treated this dichotomously (verified chemotherapy order and dosage very frequently or frequently versus occasionally, rarely, very rarely, or never).

Outcome: The primary outcome was nurse-reported exposure of a chemotherapeutic agent to their skin or to their eyes in the past year. We restricted our analyses to comparing nurses who reported zero versus one or more exposures in the past year (n=242).

Nursing Characteristics: We included the following nurse-reported covariates in our models: race (White or non-White), certification in oncology nursing (certified or not certified), and education level (bachelor's degree or higher or less than a bachelor's degree).

Analysis—First, we examined the response rate and non-response bias by comparing the demographic characteristics of our analytic sample from individuals who either did not respond at all to the survey, or did not answer the question regarding chemotherapy exposure. These demographic variables were provided on the entire sampling frame from the registry. Next, exposure to chemotherapy was treated as a binary variable (exposed versus not exposed), and bivariate analyses of the associations between categorical measures (perception of nurse practice environment, oncology certification and education level) were compared by exposure status using chi-square tests of independence. Differences in PES-NWI subscales (treated as continuous measures) and nursing workloads were conducted using two-sample t-tests of mean differences.

Logistic regression, adjusted for clustering of nurses within practices (SAS GENMOD), was used to model odds of exposure among respondents. Six models were estimated. First, we estimated models to examine likelihood of chemotherapy exposure associated with perceived practice environment (Model I), nursing workload (Model II), and chemotherapy verification (Model III). Two models were estimated for perceived practice environment (Model IV) and chemotherapy verification (Model V) that were adjusted for: (1) nurse characteristics (race, education, experience as a nurse, and oncology certification status), and (2) nursing workload. Model VI examined perceived practice environments and was adjusted for nurse characteristics, nurse workload, and chemotherapy verification. For our final model (VII), we used a backward selection process ($p > .20$) to retain the PES-NWI subscales related to chemotherapy exposure.[24] This model was adjusted for nursing workload, chemotherapy verification, and nurse characteristics. The overall perception of practice environment measure was excluded from this final analysis as the PES-NWI measures are considered components of the overall measure. All tests were two-tailed and

significance was established at an alpha of 0.05. All analyses were performed using SAS 9.2 (Cary, North Carolina).

Sensitivity Analyses—We performed two sets of sensitivity analyses. Because of the relatively high rates of outcome and exposure, we replicated our analytic approach by specifying a Poisson distribution and calculating prevalence ratios that were adjusted for clustering.[25] Second, because missing data on PES-NWI items would exclude the respondent from the logistic regression models, we replicated our models using the multiple imputation function in SAS 9.2.[26] Specifically, we used a maximum likelihood function to replicate five complete datasets, and re-analyze the results from our final logistic regression model.

RESULTS

Response rate and analytic sample

Of the 402 nurses who responded to the survey (response rate of 30.5%),[27] this analysis was restricted to nurses who responded to the chemotherapy exposure item: "In the past year, please indicate the number of times you have been exposed to a chemotherapeutic agent to your skin or eyes" (n=242). First, we examined demographic differences between our analytic sample and nurses who did not respond to the survey (n=937), or respond to the chemotherapy exposure question (n=160) using data provided by the registry on the entire sampling frame (Table 1). Except for a higher proportion of non-responders employed outside of hospital ambulatory or physician practices, we observed no significant differences in observed demographics between our analytic sample and non-responders.

Next, we examined more detailed characteristics of our analytic sample (n=242). The individual characteristics of exposed nurses (race, oncology certification status, and education level) did not differ significantly from unexposed nurses (Table 2). Though not significant, 23 or 62.2% of exposed nurses reported a favourable practice environment versus 142 or 74.7% of nurses not exposed to chemotherapy (p=.12).

Compared with nurses who did not report exposure to chemotherapy within the last year, exposed nurses had lower (worse) scores on several PES-NWI subscales. mean scores on participation in practice affairs and staffing and resource adequacy differed by exposure status: 3.16 for unexposed vs. 2.73 for exposed on a five point scale (p< .01), and 3.61 for unexposed vs. 3.01 for exposed nurses (p<.001). Compared with exposed nurses, the means of the remaining subscales (nurse manager leadership, ability, and support, collegial nurse-physician relations, nursing foundations for quality of care, and supportive medical assistant relations) were higher among those who reported no exposure, but the differences were not significant. Exposed nurses reported an average patient assignment of 11.1 patients per shift versus 8.43 patients per shift reported by unexposed nurses (p= .02). The reported nurse workload across the sample ranged from 0 to 38 patients on the last shift. Chemotherapy orders were verified by two or more nurses on a frequent or very frequent basis 94.5% of the time for the entire sample, although only 82.9% of nurses exposed to chemotherapy indicated this was the case for them (compared with 96.9% of nurses not exposed to chemotherapy, p < .01). Years employed as a nurse did not differ significantly by exposure status (p = .58).

Multivariable models (Table 3) were used to examine the relationships between chemotherapy exposure and organizational structures, and processes of care. Models I-III yielded significant relationships between reported chemotherapy exposure and practice environment, nursing workload, and chemotherapy verification, respectively, and were adjusted for nurse characteristics. In Model IV, after adjusting for nurse characteristics and

nursing workload, nurses who reported favourable practice environments (as opposed to unfavourable or mixed environments) had a significantly lower likelihood for exposure (OR 0.44, 95% CI = 0.21, 0.92). In Model V, after adjustment for nurse characteristics and nursing workloads, frequent or very frequent use of chemotherapy verification was associated with a significant reduction in exposure likelihood (OR 0.21, 95% CI = 0.07, 0.61). Model VI reports a significantly decreased likelihood of exposure for nurses who report favourable environments (as opposed to unfavourable/mixed environments), after adjusting for nurse characteristics, nursing workloads, and chemotherapy verification (OR 0.45, 95% CI = 0.21, 0.95).

One final model (Model VII, right-sided panel of Table 3) included specific PES-NWI subscales, nursing workloads, and verification of chemotherapy. Individual nurse characteristics were included in the model, but not displayed. Nurses were less likely to report chemotherapy exposure when they reported staffing and resources were adequate (OR 0.35, 95% CI = 0.17, 0.73). Nurses who reported that chemotherapy orders and doses were consistently verified by two nurses had a significantly lower likelihood of chemotherapy exposure (OR 0.17, 95% CI = 0.05, 0.59).

Sensitivity Analysis—Our findings did not change when we specified a Poisson distribution and calculated prevalence ratios. Nor did our results change when the entire sample was used in a maximum-likelihood, five-dataset multiple imputation model to address missing data.

DISCUSSION

In this state-wide sample of ambulatory oncology nurses, we identified a high rate of self-reported skin or eye exposure to chemotherapy (16.9 percent). While there is no target level of “acceptable” exposure, unintentional occupational exposure to antineoplastics could be considered a “never” event, given the risks for harm. Both the structure and processes of ambulatory chemotherapy settings were associated with exposure. Favourable practice environments, lower nursing workloads, and adherence to two-nurse chemotherapy verification were protective. These relationships persisted after controlling for clustering of nurses in practices. Individual characteristics of nurses, such as years of experience were not associated with exposure.

While it is not surprising that favourable practice environments and lower workloads for nurses were associated with reduced exposure, our finding of a relationship between chemotherapy exposure and dose verification is intriguing. Practices that adhere to this ASCO/ONS endorsed practice[6] likely are predisposed to a positive safety culture. Thus, the verification process may not directly influence exposure but rather may serve as a proxy for various processes to protect patients and nurses. Direct measures of safety behaviors[28] may clarify the mechanisms by which practices can protect nurses from potential harm.

Our study contributes to the literature in two important ways. First, our study is one of the few to use a sampling frame of a diverse population of nurses employed outside of inpatient care units. The previous studies have focused on purposive samples from settings that have agreed to participate.[8-11, 13,14] Facilities who participate in chemotherapy safety studies are likely to have heightened awareness of the risks and implement processes to protect employees. Second, we included and identified aspects of nurses’ daily working conditions that are associated with increased exposure risk. The contribution of organizational structures and processes to exposure risk has not been reported previously.[29]

It is encouraging to note that the organizational characteristics associated with increased chemotherapy exposure are modifiable by leadership. Practice managers can distribute nursing workloads more evenly, assure the availability of adequate time, space, and personnel for chemotherapy verification, and assure that requisite resources are available to administer chemotherapy in ways that minimize occupational exposure. Our findings also suggest that the current safety culture in ambulatory oncology practices could be strengthened to minimize risks to oncology nurses.

Limitations

We did not measure nurses' use of safety devices, protective equipment, and adoption of protocols to minimize chemotherapy exposure. We also did not obtain information about the activities performed at the time of exposure (e.g., mixing, administering, disconnecting, or disposal). These factors likely influence exposure risk and should be included in future studies. Second, our response rate, while within the range of recently-published response rates of nursing personnel, raises concern for non-response bias. Excepting practice setting, we observe no significant systematic differences in responders versus non-responders; this reduces concerns for bias.[30] Our non-response analysis suggests that non-responders were less likely to practice in hospital ambulatory or private practices, which are the target areas for our study. Third, our study did not include biological measures (e.g., urine, blood, or surface swipe tests) to validate the self report of exposure. Historically, nurses have served as reliable informants on quality and safety phenomena.[12] In some cases, nurse reports of operational failures are lower than independent observation, which suggests that nurses may underreport exposure.[31] This would suggest that our exposure estimates are conservative. Finally, we interpret the relationship between nursing workload and chemotherapy exposure with caution, as the reported workload of respondents ranged from 0-38 patients. However, our discussions with practicing oncology nurses confirm the wide variation in daily workloads.[21]

Summary and practice implications

In this state-wide sample of oncology nurses practicing outside of hospital inpatient units, we observe high rates of nurse-reported chemotherapy exposure to their skin and eyes. Clinicians and managers can partner to manage workloads and implement steps to promote safe practices of hazardous drug administration. These include education, appropriate safety devices, personal protective equipment, and management support to adopt these methods by clinicians. Robust efforts to provide for the safety of patients receiving chemotherapy should be extended to the providers who administer this potentially harmful therapy.

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Table 1

Demographic Characteristics of the Analytic Sample and of Non-Responders

	Analytic Sample (n=242)	Non-Responders in Sampling Frame (n=1,097)	*p*
	n (%)		
Employed full-time	146 (85.4)	913 (88.6)	.25
Employed part-time	25 (14.6)	118 (11.4)	
White	157 (91.8)	973 (94.4)	.22
Non-White	14 (8.2)	58 (5.6)	
Female	166 (97.1)	994 (96.4)	.65
Male	5 (2.9)	37 (3.6)	
Hospital Outpatient	97 (56.7)	575 (55.8)	.01
Physician Practice	65 (38.0)	320 (31.0)	
Other Practice Setting	9 (5.3)	136 (13.2)	
Less than Bachelor's Degree	86 (50.3)	521 (50.5)	1.0
Bachelor's Degree or Higher	85 (49.7)	510 (49.5)	
Resides in an MSA	129 (75.4)	819 (79.4)	.26
Resides outside of an MSA	42 (24.6)	212 (20.6)	

Note: MSA is metropolitan statistical area. Non-responders in the sampling frame include 160 participants who did not answer the chemotherapy exposure question, and 937 nurses who did not return the questionnaire. Demographic characteristics from the state's nursing registry were not available on 254 members of the sampling frame.

Table 2

Nurse-reported exposure to chemotherapy as compared with work environment and individual level characteristics (n= 242).

	Exposed to Chemotherapy		
	Yes 41 (16.9%)	**No 201 (83.1%)**	
	Mean(SD)		***p*** †
Structure			
Revised PES-NWI Subscales			
-Nurse participation in practice affairs	2.73(0.69)	3.16(0.80)	<.01
-Nurse manager leadership and ability	3.37(0.84)	3.57(0.92)	.20
-Collegial nurse-physician relations	3.89(0.63)	4.01(0.73)	.34
-Staffing and resource adequacy	3.01(1.00)	3.61(0.91)	<.01
-Nursing foundations for quality of care	4.04(0.54)	4.17(0.60)	.22
-Supportive relations with medical assistants	3.41(1.06)	3.62(1.02)	.25
Nursing Workloads			
-Number of patients primarily responsible for on last shift	11.11(6.44)	8.43(5.99)	.02
	n(%)		***p*** ‡
Perception of nurse practice environment			
-Unfavourable or Mixed	14(37.8)	48(25.3)	.12
-Favourable	23(62.2)	142(74.7)	
Process			
Chemotherapy orders and dosages are verified by two nurses			
-Infrequently	7(17.1)	6(3.1)	<.01
-Frequently or Very Frequently	34(82.9)	188(96.9)	
Nurse characteristics			
Race			
-Non-White	6(14.6)	15(7.5)	.14
-White	35(85.4)	185(92.5)	
Oncology Certification			
-Not Certified	8(19.5)	56(27.9)	.27
-Certified	33(80.5)	145(72.1)	
Education Level			
-Less than a bachelor's degree	25(61)	106(52.7)	.33
-Bachelor's degree or higher	16(39)	95(47.3)	

PES-NWI: Practice Environment Scale of the Nursing Work Index

† Differences in exposure tested using two sample t-tests

‡ Differences in exposure tested using the chi-square test of independence. In cases of small cell sizes, Fisher's exact test was used.

Table 3

Odds of exposure to chemotherapy, as estimated by structure and process variables , n= 185*

	OR (95% CI) Adjusted for			
	Nurse Characteristics	**Nurse Characteristics and Nursing Workload**	**Nurse Characteristics, Nursing Workload, and Chemotherapy Verification**	**Nurse Characteristics**
Model	I	IV	VI	VII
Favourable Practice environment	0.49(0.24,1.00)	0.44(0.21,0.92)	0.45(0.21,0.95)	-
Model	II			
Nursing Workload	1.07(1.02,1.12)	-	-	1.06(0.99,1.12)
Model	III	V		
Chemotherapy Verification	0.22(0.08,0.62)	0.21(0.07,0.61)	-	0.17(0.05,0.59)
Revised PES-NWI Subscales				
-Nurse Participation in Practice Affairs (favourable versus unfavourable)				0.51(0.24,1.06)
-Staffing and Resource Adequacy (favourable versus unfavourable)				0.35(0.17,0.73)

OR = Odds Ratio; 95% CI = 95 percent confidence interval; PES-NWI = Practice Environment Scale of the Nursing Work Index.

Note: All models adjusted for clustering of nurses within practices using a generalized model function.