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Patient-reported outcomes collected in ambulatory oncology practices: Feasibility, patterns, and correlates

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Abstract

Objective: To examine the feasibility of soliciting outcomes from adults who received chemotherapy treatment for cancer and describe the patterns and correlates of patient-reported toxicities.

Data Sources: Patient survey data from 29 Michigan ambulatory oncology practices collected in 2017.

Study Design: Secondary analysis of patient survey data. Descriptive statistics were generated at the patient and practice levels. Thematic analysis of open-text comments identified clusters of frequently reported toxicities.

Data Collection Methods: Patients completed 11 items from the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events. Using a 5-point Likert scale, patients rated the frequency of nausea, vomiting, diarrhea, and pain; the severity of nausea, vomiting, constipation, numbness/tingling, and pain; and how much numbness/tingling and pain interfered with usual or daily activities. Patients could also report two toxicities in open-text comments. Finally, patients reported unplanned health care service for toxicity or side effect management.

Principal Findings: Of 3565 eligible patients, 2245 participated (63%) and 457 (20%) rated at least one toxicity as severe/very severe. Across practices, the proportion of patients who reported at least one severe/very severe toxicity ranged from 8% to 50%. Troubling toxicities included pain frequency (mean 2.3, SD 1.3), pain severity (2.1, 1.1), and diarrhea frequency (1.9, 1.0). From completed assessments, 1653 (74%) reported at least one toxicity in open-text comments; fatigue (n = 182), stomach discomfort (n = 53), and skin/nail changes (n = 41) were most frequently reported. Regarding consequences, 156 patients (7%) reported unplanned health care service use: 41 (26%) visited an emergency department and 32 (21%) were admitted to a hospital.

Conclusions: Querying patients on chemotherapy treatment experiences and toxicities was feasible. Toxicity rates varied across practices, which informed quality improvement. Toxicity severity and service use incidence exceed previously published trial data, particularly for pain, fatigue, and gastrointestinal issues. Open-text questions enabled exploration with newer treatment regimens.

KEYWORDS
ambulatory care, oncology, patient-reported outcome measures, quality of health care

1 | INTRODUCTION

Increasingly, health services researchers are soliciting patient-reported outcomes in their studies.[1] Measuring patient-reported outcomes anchors research to patient-centered research paradigms.[2] Nimble survey research platforms and measurement advances have increased the feasibility of collecting patient-reported outcomes. In recognition of these advances, the Food and Drug Administration, among other key agencies, has outlined frameworks to consider "real-world evidence" in evaluating therapeutic benefits of drugs and devices.[3] Real-world evidence, including patient-reported outcomes, is important to consider when differences in traditional outcomes such as overall survival or disease-free progression are negligible.[4] In particular, the oncology therapeutic landscape has expanded markedly over the past five years.[5] Patients with cancer and their treatment team need contemporary, actionable data regarding toxicities to inform clinical decision making and supportive care interventions.[6]

Historical reliance on clinician-reported toxicities provides an incomplete picture of the cancer care experience. Compared with clinician-rated toxicity reports, patients rate the severity of their toxicities higher and report toxicities occur sooner in the course of treatment.[7] Advances in patient-reported outcomes measurement enable research teams to collect valid and reliable measures of treatment-associated toxicities directly from patients.[8] Yet, most efforts to date have focused on the population of patients enrolled in clinical trials. Compared with clinical trial participants (approximately 10%-15% of patients with cancer), adults with cancer who are treated off of trials are older, have more advanced cancer, and have important comorbid conditions.[9] Extrapolation of patient toxicity data from carefully screened clinical trial participants to the larger population of adults with cancer in the United States may lead to underreporting of toxicity frequency and burdens experienced by patients. Symptom management[10] and health care utilization[11] theories posit that poorly managed toxicities may lead to costly and inefficient use of health care services. Thus, there is a need to solicit toxicity experiences from a more diverse sample of patients to inform clinical care.

In this context, the current inquiry examines data collected from a large sample of adults with cancer treated in community oncology practices. We sought to understand the frequency and severity of treatment-associated toxicities for patients treated with chemotherapy. We also sought to report how often patients accessed additional health care services to manage toxicities and drug-related infusion reactions. A deeper understanding of the toxicity experience can inform subsequent intervention development and clinical practice change.

What is Known About This Topic

- Most randomized trials conducted in patients with cancer do not represent the patient population treated in community settings; this bias limits our understanding of treatment-associated toxicities.
- Valid, reliable, and easy-to-use toxicity reporting tools are now available for patients to complete but use of these tools is often restricted to clinical trial populations.
- National organizations have adopted the inclusion of patient-reported outcome measures to study the quality of cancer care.

What This Study Adds

- In a large sample of patients treated routinely in community oncology practices, toxicities occurred frequently and were associated with unplanned health care service use.
- American Indians/Alaska Natives reported more severe/very severe toxicities than other patient groups.
- Wide variation is noted in severe/very severe toxicities across medical oncology practices.

2 | METHODS

2.1 | Study overview

The Oncology Communication, Technology and Patient Events (OCTET) study was an observational mixed methods study, conducted in 29 medical oncology practices. The specific patient survey data reported in this manuscript were collected between April 2017 and November 2017. Survey methods have been detailed in a previous publication.[12] Briefly summarized, the patient survey was part of a larger multimodal assessment of quality of care in ambulatory medical oncology settings. Following the survey portion of the project reported below, additional activities included in-depth field observations, shadowing, interviews, and focus groups. The latter results have been reported elsewhere.[13]

2.2 | Practice settings and recruitment procedures

From 55 eligible settings, we recruited 29 ambulatory oncology practices that participate in the Michigan Oncology Quality Collaborative (MOQC). Blue Cross Blue Shield of Michigan launched MOQC in 2009 to improve the experience of Michigan patients

with cancer, regardless of the patient's insurance status or policy carrier.[14,15] MOQC practices participate in regional quality improvement efforts, supported by trained registrars in each practice.

The MOQC program director contacted physician leads and practice administrators to solicit participation. Once practices indicated interest, research project staff led telephone conferences and, upon request, conducted site visits to review study procedures with practice leaders and staff. Participating practices identified at least one staff member as an on-site study champion who completed a 60-minute Web-based training in study procedures and received a tip sheet for data collection procedures. As incentives for participation, practices received a cash honorarium and practice-level summary of survey results. As the questionnaire did not collect personal identifiers, the survey portion of the project was deemed exempt by the Institutional Review Board of the principal investigator's university.

2.3 | Patient eligibility and recruitment

Patients were eligible to participate in the survey if they were diagnosed with Stage I-III invasive cancer and planned to receive systemic chemotherapy. Patients either spoke or read English or had a nonclinician proxy available to assist with survey completion. Practice champions trained in the protocol identified eligible patients at the time of check-in and offered eligible patients the anonymous one-page, two-sided questionnaire. Patients received a cover letter, copy of the survey, and when permitted by the practice, an up-front $10 cash incentive. At the end of their encounter, patients returned completed questionnaires to a secured box in each practice. On a weekly basis, practice champions faxed completed questionnaires to a secure, encrypted virtual fax platform managed by the coordinating center. Practices were instructed to approach all eligible patients within a six-week period, rendering this a convenience sample of eligible patients. Practices tabulated the number of protocol-eligible patients who declined to participate.

2.4 | Measures

In addition to gender, race, and ethnicity, patients completed 11 items from the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE).[8] The PRO-CTCAE was developed by the National Cancer Institute, which houses an online platform to generate questionnaires. Consistent with the National Cancer Institute's guidance,[16,17] all PRO-CTCAE items referenced a timeframe for the past seven days and were rated on a 5-point scale across three pertinent domains: frequency, severity, and interference with daily activities. Patients rated the frequency of their nausea, vomiting, diarrhea, and pain (1 = never, 5 = almost constantly). Patients rated their perceived severity of nausea, vomiting, constipation, peripheral neuropathy, and pain in the past seven days (1 = none, 5 = very severe). Patients rated how much peripheral neuropathy and pain interfered with their usual or daily activities (1 = not at all, 5 = very much). The specific toxicities queried were selected following pilot work that identified the most prevalent and bothersome toxicities experienced across diverse cancer diagnoses.[18] To enable the study team to identify important concerns that may not have been included, patients were invited to write-in up to two additional toxicities that had bothered them in the past seven days and to rate the severity of these toxicities on a 5-point Likert scale (1 = none, 5 = very severe).

Finally, using previously developed measures patients reported whether they required additional health care services for a toxicity they experienced in the past seven days or whether they needed health care services to manage a drug infusion-related reaction.[18] Examples include a hypersensitivity reaction to paclitaxel or a febrile reaction to rituximab. Patients also indicated whether they needed to seek care outside of the ambulatory oncology practice, either in an emergency department or through inpatient admission.

2.5 | Data management

Trained research assistants at the coordinating center entered patient surveys into the Research Entry and Data Capture (REDCap) Web application.[19] REDCap is a password-protected, user-authenticated, encrypted, and firewalled application used to collect and enter sensitive data in compliance with the Health Insurance Portability and Accountability Act. Research assistants double entered all data and the project manager resolved any discrepancies. The project manager and the study team, through weekly team meetings, cleaned all data by examining outliers, aberrant values, and missing data. Once cleaned, datasets were prepared for analysis using a uniquely assigned practice identifier, which enabled analyses at both the patient and practice level.

The primary outcomes assessed were the patient ratings of eleven toxicity measures, as described above. The source of the PRO-CTCAE, the National Cancer Institute's common terminology criteria for adverse events (CTCAE),[20] is routinely collected from clinicians during clinical trial assessments. Outcomes are classified as Grade 1 (mild; observation only, interventions not indicated), Grade 2 (moderate; noninvasive intervention indicated), Grade 3 (severe or medically significant but not life threatening; hospitalization indicated), Grade 4 (life-threatening consequences; urgent intervention needed), and Grade 5 (death). As the PRO-CTCAE rating scale is mapped to the CTCAE anchors, we examined the proportion of patients who reported Grade 3 or Grade 4 assessments.

2.6 | Data analyses

Data analyses were descriptive and correlational. Most analyses were conducted at the patient level. We used chi-square tests to examine demographic characteristics of patients who reported at least one toxicity as severe/very severe, compared with patients who did not. To examine practice-level variation, we calculated each practice's proportion of surveyed patients who reported at least one Grade 3 or 4 toxicity.

TABLE 1 Characteristics of the patient sample

	Total ($N = 2245$)	Did not assess a toxicity as grade 3 or 4 ($n = 1788$)	Assessed one or more toxicities as grade 3 or 4 ($n = 457$)	Chi-square test, P value[a]
Gender		*n* (%)		
Female	1302	1044 (80)	258 (20)	1.62, .41
Male	873	682 (78)	191 (22)	
Other response or missing	70	62 (89)	8 (11)	
Race[b]				
Black	194	148 (76)	46 (24)	1.47, .23
Asian, Hawaiian, or Pacific Islander	47	37 (79)	10 (21)	0.03, .86
American Indian/Alaska Native	76	42 (55)	34 (45)	28.4, <.001
White	1856	1486 (80)	370 (20)	1.17, .28
Other (self-report)	58	44 (76)	14 (24)	0.53, .47
Hispanic or Latino/a Ethnicity	44	34 (77)	10 (23)	0.11, .74
Treated in rural setting	257	212 (82)	45 (18)	1.45, .23

[a]Compares differences between those who reported at least one toxicity as Grade 3 or 4 versus those who did not.
[b]Patients could indicate more than one race.

To characterize patients' write-in comments, one member of the study team reviewed verbatim text comments and organized comments into thematic codes. During a group meeting, the study team reviewed the thematic codes and revised them collaboratively until 100% consensus was achieved at the meeting. At this stage, duplicate reports were consolidated and organized. We tabulated the frequency of these recoded reports and the distribution of toxicity scores across the same 5-point grading scale reported above.

Analyses were performed using the SAS statistical software (version 9.4; SAS Institute). The 0.05 level of significance was used for all analyses. No weighting of the sample was performed throughout the study.

3 | RESULTS

3.1 | Patient characteristics

Of 3565 patients identified as eligible respondents by practice study champions, 2245 (63%) individuals completed surveys. Patient characteristics are shown in Table 1 with comparisons shown between patients who reported at least one toxicity at the severe or very severe category and patients who did not endorse at least one severe or very severe toxicity assessment. Patient characteristics were not available for survey nonrespondents, due to human subjects policies. Relative to other racial categories, a higher proportion of American Indian/Alaska Native patients reported at least one toxicity as severe or very severe ($\chi^2 = 28.4$(DF), $P < .001$). No other significant differences in toxicity reporting by patient characteristics were observed.

3.2 | Distribution and reported severity of patient-reported toxicities

Table 2 shows the mean(SD) of each toxicity rating and the proportion rates as Grade 3 or 4. The three toxicities with the highest mean scores were pain frequency, pain severity, and diarrhea frequency, reflecting higher patient toxicity burden. Over one in five participants reported the frequency of pain at a level of Grade 3 or 4. Severe or very severe pain severity and diarrhea frequency were reported by 13% and 10% of respondents, respectively.

3.3 | Variation in toxicity assessments across practices

In the Appendix S1, the proportion of patients who reported at least one toxicity as severe or very severe is plotted by practice. The proportion of patients with severe/very toxicities ranged from 0 to 50 percent across the 29 practices, with the median(IQR) proportion across practices as 19(13)%.

As an incentive to participate, practices received dashboards with site-specific patient data, in addition to the data obtained across all 29 practices. A de-identified version of one dashboard is also available in the Appendix S1. Study team members reviewed the dashboard data with individual practices upon request and presented the de-identified data at a scheduled biannual meeting of the entire quality consortium. At this meeting, oncology clinicians and practice leaders reviewed the data and posited strategies for subsequent quality improvement efforts.

TABLE 2 Patient-reported toxicity ratings during the past 7 d of chemotherapy treatment ($N = 2245$)

	Mean (SD)	Reported as Grade 3 or 4 *n* (%)
Pain frequency	2.31 (1.3)	467 (21)
Pain severity	2.10 (1.1)	287 (13)
Diarrhea frequency	1.92 (1.0)	230 (10)
Numbness/Tingling Severity	1.87 (1.0)	133 (6)
Nausea frequency	1.84 (1.0)	178 (8)
Pain interference	1.82 (1.1)	224 (10)
Constipation severity	1.71 (0.9)	116 (5)
Nausea severity	1.67 (0.8)	83 (4)
Numbness/tingling interference	1.53 (0.9)	115 (5)
Vomiting Frequency	1.21 (0.6)	33 (1)
Vomiting severity	1.20 (0.6)	30 (1)

TABLE 3 Frequency of potentially adverse health care use during chemotherapy treatment ($N = 2245$)

	N	%
Had a side effect following chemotherapy treatment that required attention	156	7
Treated in emergency department for side effect	41	26
Admitted to the hospital for side effect	32	21
Experienced a drug reaction during the last treatment	132	6
Treated in emergency department for reaction	21	16
Admitted to the hospital for reaction	20	15

3.4 | Unplanned health care service use

When considering the relationship between toxicities and unplanned health care service use, Table 3 shows the frequency of health service use outcomes across the sample. Of all respondents, 156 (7%) reported that one of their toxicities required management via unplanned health care service use. Of these, 41 (26%) received treatment in an emergency department and 32 (21%) were admitted to the hospital for toxicity management. These findings were similar for the management of a drug infusion-related reaction: 132 (6%) experienced a drug infusion-related reaction, 21 (16%) required emergency department care, and 20 (15%) were hospitalized.

3.5 | Patient-provided toxicities

After thematic analyses and study team consensus on categories were completed on the 1653 open-text comments received, study staff collapsed comments into 737 discrete toxicity reports (in some cases, patients reported similar toxicities in both questions). The overall mean(SD) severity of open-text toxicity reports was 3.1(0.9). Fatigue was the most frequently reported open-text toxicity, followed by general stomach discomfort (distinct from nausea, vomiting, diarrhea, and constipation), and skin or nail changes (see Table 4). Most patients who wrote in fatigue (81 percent) rated it as severe/very severe.

4 | DISCUSSION

In this multisite, mixed methods, observational study of medical ambulatory oncology practices, a high proportion of patients receiving chemotherapy treatment successfully completed brief assessments about their toxicity experience. Practice study champions strongly endorsed paper-based questionnaires for patient completion, and the high participation rate validates their preference. The patient-reported data provided valuable insights into the patient experience of cancer treatment outside of the usual data reported in clinical trials with strict eligibility criteria. The increased proportion of American Indian/Alaska Native patients who reported Grade 3 or 4 toxicities merits increased focused effort, as this population is routinely underrepresented in clinical trials.

In this large sample of patients treated under routine clinical circumstances, three toxicities emerged as particularly troublesome: pain frequency, pain severity, and diarrhea frequency. These results suggest that despite numerous evidence-based guidelines, current toxicity management approaches remain suboptimal and that novel approaches are needed to address these problems. The urgent need for non–opioid-based pain treatments remains especially important in the context of lingering concerns for opioid misuse and barriers to optimal pain management reported by patients with cancer.[21] Cancer-related pain is often multifactorial and requires multiple pharmacologic and nonpharmacologic interventions.[22,23] Clinic efforts to implement proactive patient education and routine toxicity monitoring for problems before they escalate are promising strategies to mitigate negative consequences of these toxicities. To date, results of such efforts have been mixed, due in part to variation in clinicians' response to adverse toxicity reports.[24,25]

The most frequently reported toxicity provided directly by patients was fatigue and most respondents endorsed their fatigue as severe/very severe. Fatigue is a notable toxicity for patients undergoing routine chemotherapy treatment. Given its high frequency and severity, fatigue should be assessed routinely as part of routine oncology care. Systematic fatigue assessment can prompt early interventions, such as moderate exercise, which has demonstrated quality-of-life benefits among adults undergoing chemotherapy treatment.[26] The open-text data shared by patients identified several toxicities that could be added to future assessments, particularly given the additional time and effort needed to categorize open-text comments. Subsequent research teams who wish to collect open-text comments should identify a coding schema up-front and consider the resources required during study planning.

TABLE 4 Frequency and severity of open-text toxicities reported by patients

Symptom	Total	Mean(SD) severity grading	*n* (%) Rated ≥ 3
Fatigue	182	3.2 (0.8)	148 (81.3)
Stomach discomfort	53	3.0 (1.0)	32 (60.38)
Skin/nail changes	41	2.9 (0.8)	26 (63.4)
No appetite/taste changes	37	3.0 (0.8)	32 (86.49)
Pain	36	3.3 (0.8)	32 (88.89)
Dizziness/balance problems	34	3.0 (0.6)	20 (58.82)
Mouth sores/pain/trouble chewing	29	3.3 (0.8)	22 (75.9)
Headache/migraine	27	2.7 (0.7)	16 (59.3)
Dry/bloody nose	22	2.5 (0.5)	10 (45.45)
Muscle aches/soreness	17	2.8 (0.7)	12 (70.59)
Insomnia/trouble sleeping	16	2.8 (1.0)	9 (56.25)
Swelling/water retention	16	3.4 (0.8)	13 (81.25)
Dry/watery eyes	16	2.8 (0.6)	11 (68.75)
Runny nose/congestion	15	2.7 (0.6)	9 (60)
Tooth/throat sensitivity	14	3.1 (0.9)	10 (71.43)
Confusion/forgetfulness	13	2.5 (0.5)	6 (46.15)
Hair loss	13	3.5 (1.1)	8 (61.54)
Shortness of breath	12	3.4 (0.6)	12 (100)
Neuropathy	11	3.7 (0.9)	10 (90.91)
Cough	11	3.1 (0.8)	8 (72.73)
Chills	9	3.1 (0.9)	7 (77.78)
Photosensitivity	9	2.9 (0.8)	5 (55.56)
Anxiety/depression	8	3.6 (1.4)	6 (75)
Diarrhea	8	3.8 (0.8)	8 (100)
Involuntary movements/shaky hands	8	3.1 (0.3)	7 (87.5)
Nausea/vomiting	8	3.1 (0.9)	6 (75)
Tinnitus	8	2.6 (0.7)	4 (50)
Constipation	7	2.9 (1.1)	4 (57.14)
Hot flashes/sweating	7	2.7 (1.2)	3 (42.86)
Fever	6	3.5 (0.8)	6 (100)
Trouble urinating	6	3.0 (0.6)	5 (83.33)
Other (symptom report frequency ≤ 5)	59	3.1 (1.0)	41 (69.49)
Nonclinical comments	36	3.0 (1.0)	25 (69.44)
Total	737	3.1 (0.9)	

The data presented are unique in that the toxicity data do not derive from clinical trials with strict eligibility criteria. The study results reflect the population of adults treated every day in cancer centers—from academic institutions to privately owned practice—across the United States. Compared with clinical trial populations, respondents to our survey are likely to be older, have advanced cancer, and have co-occurring chronic conditions.[27,28] Such characteristics would render them ineligible for most clinical trials. Clinical trial toxicity report frequency and severity rates are historically lower than patient-reported toxicity reports.[4,9] The investigators selected outcome measures that have been tested for readability, reliability, and validity. Clinicians caring for adults with cancer can interpret the toxicity scales used in this study. Importantly, patient toxicity studies rarely report health care service use for toxicity management. Study data suggest that many patients require health care service use, which can be costly, inconvenient, and inefficient.

Despite the unique strengths of our study, several limitations merit mention. Because the larger project examined an array of patient and clinician-reported measures, granular details on patients—including cancer stage, cancer drugs received, and comorbid conditions—were not collected. The project highlighted an efficient strategy to collect toxicity data from a large sample of patients across multiple practices. However, the heterogeneity of health record systems across consortium practices, staffing constraints, and human subjects challenges precluded detailed chart abstraction and, thus, risk adjustment of patient-reported outcomes. Subsequent investigators may overcome these challenges as health record interoperability and human subjects flexibilities increase. Comparing patient characteristics from survey respondents and nonrespondents would assess the potential for response bias. Studies that solicit and analyze open-text toxicity reports from patients could adopt strategies to assess inter-rater reliability of the coding schema. Despite a large sample of practices and patients, all participating practices belong to a statewide quality improvement consortium. Therefore, the sample may not reflect the diversity of medical oncology practices across the United States.

The study results have several implications for practice and research. First, medical oncology practices can collect toxicity data from patients in a straightforward manner to inform clinical quality improvement. Second, collection of patient toxicity data outside of clinical trials could accelerate community recognition of toxicity patterns not observed in pivotal studies. Third, correlation of rich patient-reported toxicity data with key covariates would strengthen the approach and interpretability of findings. In conclusion, the study's partnership with a broad array of community oncology practices provides a novel approach to quantify the burden of toxicity experienced by adults with cancer. The results provide an important rationale for soliciting patient-reported outcomes outside of clinical trials: the opportunity to learn rapidly and improve care delivery for a high-risk, high-volume population.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest to disclose.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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