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Patient-Reported Outcomes

Perceptions of Response Burden Associated with Completion of Patient-Reported Outcome Assessments in Oncology

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ABSTRACT

Background: Patient response burden is often raised as a human subject concern in consideration of the length or complexity of patient-reported outcome (PRO) instruments used in oncology. **Objectives:** To quantify patient response burden and identify its predictive factors. **Methods:** Data were collected presurgically during a prospective trial that used a comprehensive symptom and health-related quality-of-life (HRQOL) PRO assessment. A subset of patients also completed HRQOL interviews. Response burden was captured using an internally developed six-item instrument. Demographic and clinical characteristics as well as HRQOL scores were examined as potential predictors using hierarchical regression. Response burden was used to predict participant dropout at the first follow-up interval. **Results:** A total of 275 patients (mean age 67.5 years; 23.6% female) completed surveys (n = 126) or surveys in addition to interviews (n = 149). Patients experienced low response burden (mean 12.19 ± 11.65). Repetitive questions were identified by 60 patients (21.8%), whereas 31.6% indicated that additional information should be gathered; 35 patients (12.7%) identified repetitive questions and expressed a desire for additional items. Low self-reported cognitive function was a significant predictor of higher response burden ($\beta = -0.20$; $t(270) = -3.38$; $P = 0.01$; model-adjusted $R^2 = 0.04$). Response burden was not a significant predictor of study dropout. **Conclusions:** Despite completing a large battery of PRO measures and interviews, patients reported minimal response burden, with nearly one-third expressing that more questions should have been asked. Patients with lower cognitive function are more likely to report higher response burden when completing PRO measures. Further examination of patient characteristics related to response burden may reveal useful pathways for tailoring patient-centered interventions.

Keywords: clinical outcome assessments, neoplasms, patient-centered outcomes, patient-reported outcomes, response burden.

Introduction

Patient-reported outcomes (PROs) are becoming widely accepted for use in clinical trials and routine cancer care as an indicator of the patient subjective experience, including their symptoms related to disease and/or treatment, quality of care, or health-related quality of life (HRQOL) [1–7]. Despite the increased use of PRO measures, relatively little is known about the degree of response burden that is experienced by patients as they complete PRO questionnaires with respect to their time and expended effort, nor is there consensus for the most effective method of capturing response burden from patients.

Response burden can be conceptualized in several different ways, depending on the research setting of interest. For example, in the context of completing business surveys, researchers have found that response burden is not associated with time to completion of a survey or frequency of survey administration; burden is instead thought of as being related to the quality of data that is provided [8–10].

In the health care setting, especially in oncology, response burden is a particularly challenging concept to define. Sicker patients with advanced stage disease might find that responding to PRO questionnaires is more burdensome than those who are diagnosed in earlier stages and are relatively healthier. The 2009 US Food and Drug Administration Guidance for Industry on the use of PRO measures in medical development to support labeling claims posits several potential factors that may be related to response burden [11]. These include the length and/or formatting of the questionnaire or interview, issues with literacy level, issues related to the mode of administration (e.g., paper-, telephone-, or Web-based surveys), issues related to sensitive content of items

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that participants may be unwilling to answer, or patients' perception that an interviewer expects a specific response.

A recent meta-analysis found that the length of a given PRO questionnaire may not necessarily be associated with participant response burden [12]. As such, there may be other underlying factors that influence and predict patient response burden. For instance, there may be differences in response burden that depend on perceived difficulty of questionnaire completion because of the cognitive demand characteristics related to the mode of data capture (e.g., recognition-based questionnaires vs. recall-based interviews) [13]. In addition, various cancer disease types have a wide range of levels of severity and potential effects on a given patient's health status. This necessitates the use of numerous PRO questionnaires and/or lengthy one-on-one interviews to capture all information relevant to the project's domains of interest.

Because patients with cancer are considered a vulnerable population of interest, such requirements may make key stakeholders reticent with respect to including lengthy or complex PRO questionnaires in a given study [14–16]. There is a strong bias toward less is more with respect to eliminating redundant or noninformative items [17–19]; nevertheless, the pressure to limit the number of measurement items can mean that aspects of HRQOL central to the patient experience may be ignored.

The purpose of the present study was to quantify levels of patient response burden associated with participation in a methodologically rigorous HRQOL study in which a comprehensive battery of questionnaire-based PRO measures was completed using paper-and-pencil and interview modes of administration. In addition, we sought to characterize potential predictors of burden associated with the PROs, as well as whether response burden was a predictor of study dropout. Given the established willingness of patients to become more involved in their health care and treatment-related decisions [20–23], we anticipated that patients would be minimally burdened by the collection of this HRQOL information, with our results providing greater insight into whether demographic, disease experience, or appraisal factors are important predictors of perceived response burden.

Methods

Patients

Data for this study were collected presurgically as part of a prospective trial that examined patient-reported symptoms and HRQOL of those undergoing radical cystectomy and urinary diversion for high-risk bladder cancer between 2008 and 2014 at Memorial Sloan Kettering Cancer Center. Patients were eligible to participate in the study if they had nonmetastatic bladder cancer and were scheduled for radical cystectomy and urinary diversion, could speak English, were aged at least 18 years, and were able to provide informed consent. This study was approved by the Memorial Sloan Kettering Internal Review Board (ClinicalTrials.gov identifier NCT00745355).

PRO Questionnaires

All patients completed a brief questionnaire that captured demographic information (e.g., employment status and marital status). In addition, patients were asked to complete a set of 14 validated and standardized PRO questionnaires in their entirety, with the exception of females being asked to complete the Female Sexual Function Index [24] and males being asked to complete the International Index of Erectile Function [25]. These PRO measures assessed various symptom or HRQOL domains (Table 1). Females completed a total of 180 items, with males completing a total of 176 items.

Table 1 – Patient-reported outcomes measures administered by domain assessed.

Patient-reported outcomes measure	Domains assessed
EORTC QLQ-C30 [31]	30-Item measure of physical, role, emotional, and social functioning, as well as cognition, symptoms (e.g., fatigue, pain, and dyspnea), and global quality of life in patients with cancer
EORTC QLQ-BLM30 [35]	30-Item assessment of urination, bowel functioning, and sexual functioning in patients with muscle-invasive bladder cancer
EORTC QLQ-CR38 [36]	7-Item bowel function subscale from a larger scale of quality-of-life concerns in patients with colorectal cancer
Female Sexual Function Index [24] (females only)	19-Item measure of desire and subjective arousal, lubrication, orgasm, satisfaction, and pain/discomfort
International Index of Erectile Function [25] (males only)	15-Item assessment of erectile function, orgasmic function, intercourse satisfaction, sexual desire/arousal, and overall satisfaction
Urinary Distress Inventory [37]	6-Item assessment of the degree to which symptoms of incontinence cause distress
Incontinence Impact Questionnaire [37]	7-Item measure of the impact of urinary incontinence on activities and emotions
American Urological Association Symptom Index [38]	7-Item assessment of urinary functioning
MSKCC Bowel Function Questionnaire [39]	18-Item assessment of bowel functioning
Decisional Conflict Scale [40]	16-Item measure of the decision-making process in health care and levels of conflict attributed to treatment-related decisions
Satisfaction with Life Scale [41]	5-Item assessment of global cognitive judgments of one's life
Fear of Recurrence Questionnaire [42]	22-Item measure of cancer-related fears and health concerns
Mental Health Inventory [43]	5-Item measure of anxiety, calmness, depression, happiness, and behavioral/emotional control
FACIT-TS-G [44]	8-Item measure of general treatment satisfaction

EORTC, European Organization for Research and Treatment of Cancer Quality of Life (QLQ-C30, Cancer Quality of Life Questionnaire—30 Items; QLQ-BLM30, Cancer Quality of Life Questionnaire—Muscle-Invasive Bladder Module; QLQ-CR38, Cancer Quality of Life Questionnaire—Colorectal Module); FACT-TS-G, Functional Assessment of Chronic Illness Therapy—Treatment Satisfaction, General; MSKCC, Memorial Sloan Kettering Cancer Center.

Interview Measures

One-on-one idiographic interviews with patients included two key components: goal assessment and activity assessment [26–29]. The basic structure of the research interaction asks patients to name the primary goals they would like to accomplish, what problems they would like to solve, what they would want to prevent or avoid, what they would want to keep the same as they are now, and what commitments they would want to let go, what things that they want to be able to accept as they currently are, and what special events or milestones they are looking forward to reach to have the most satisfying life possible. Each of these separate areas is followed by probes asking what the patient has been doing over the last month to reach these goals, as well as which activities matter the most in achieving these goals. These idiographic methods have been previously summarized [26,28,30].

Response Burden Questionnaire

Given the lack of a standard, validated measure to capture response burden, we developed a brief six-item PRO measure that captures key aspects of this multidimensional construct with respect to how the patient perceives the following: 1) how well the questions related to their actual concerns, 2) how comfortable the patients were with answering the questions, 3) how well the interview characterized their health and well-being, 4) the length of time to complete the questionnaires, 5) whether questions seemed unimportant or repetitive, and 6) what additional information should have been gathered (Table 2). Items 1 to 4 of the response burden questionnaire were reverse-scored. A composite score was then calculated to create a weighted representative index of concern, comfort, and well-being relative to time to completion (i.e., items 1, 2, and 3 were summed and multiplied by item 4) for a range of 0 to 72, with higher scores indicative of elevated endorsed response burden. For example, a patient may indicate that the PRO questions took too long to complete, but otherwise feel that the questions were relevant to their concerns (e.g., score range 0–10), whereas another patient may endorse that the duration of time taken to complete the PRO questionnaires was just right, but that they were very uncomfortable in responding to the questions, resulting in a similar score range. The open-ended questions of the response burden questionnaire were summarized thematically.

Table 2 – Patient response burden items and response scale.

Item	Response scale
1. How well did these questions *relate to your actual concerns?*	0 (not at all related) to 10 (very related)
2. How *comfortable* were you in answering questions?	0 (not at all comfortable) to 10 (very comfortable)
3. How well did this interview *describe your health and well-being?*	0 (not at all) to 10 (very well)
4. How did you feel about the *length of time* to complete this section?	1 (much too long), 2 (a bit too long), 3 (just right/no problem)
5. What questions seemed *unimportant or repetitive?*	Open-ended
6. What *additional information* should we gather?	Open-ended

Note: To calculate a composite score, items 1–4 were first reverse-scored, followed by summing items 1–3 and multiplying them by item 4, for a range of 0–72. Items 5 and 6 are summarized thematically.

Procedure

Enrolled patients were sent the PRO battery via US postal service at baseline (pretreatment). Participants were asked to complete the measures and return them to the research team using postage-paid envelope. For the subset of patients who also completed the one-on-one idiographic interview, this took place via telephone.

Statistical Methods

We used multivariate hierarchical linear regression to determine predictors of response burden. Using a three-tiered backward-selection process, the model included (in order) patient demographic variables (i.e., age at surgery, sex, race, marital status, and employment status), clinical characteristics (age-adjusted Charlson comorbidity score, cancer stage, body mass index, as well as binary variables for whether patients had previous neoadjuvant chemotherapy, intravesical treatment, or pelvic radiation treatment), and subscale scores from the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30 [31]) (i.e., global health status, physical function, role function, emotional function, cognitive function, social function, fatigue, nausea-vomiting, pain, dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial problems). EORTC QLQ-C30 subscale scores were selected for inclusion in the model because of its general assessment of key aspects of HRQOL. Model goodness of fit was assessed using adjusted R^2. Statistically significant ($\alpha = 0.05$) predictors, if any, were included in a final combined predictive model. Differences in levels of response burden between patients who completed both a PRO assessment and an idiographic interview and those who completed only the PRO questionnaires were explored using independent *t* tests and nonparametric tests for dichotomous variables. General linear modeling was used to predict study dropout at the first postsurgical assessment time point (i.e., 3 months). Dropout was defined as having incomplete EORTC QLQ-C30 data at the three-month post-surgical assessment. SPSS version 24 (IBM Corp., Armonk, NY) [32] was used for all quantitative analyses.

Results

From the overall sample of 550 patients, a total of 275 patients (50% response rate; 23.6% female, 4.4% nonwhite) had evaluable presurgical data and were included in the analysis. There were no instances of missing data in the completed surveys. The mean age at time of surgery was 67.48 (range 36.4–91.4) years, with mean age-adjusted Charlson comorbidity score of 2.41 ± 2.41 (range 0–9). Those who completed idiographic interviews in addition to the PRO battery (n = 149) were significantly older, had higher mean age-adjusted Charlson comorbidity scores, were less likely to be employed or to have underwent neoadjuvant chemotherapy, and had lower mean EORTC QLQ-C30 Nausea-Vomiting scores than those who completed only the PRO questionnaires (n = 126). A summary of demographic and clinical characteristics and HRQOL scores for these patients is presented in Table 3.

Response Burden

Overall mean response burden was 12.19 ± 11.65 with a median of 8.0 and a range of 0 to 72. Levels of response burden did not significantly differ ($t(273) = 0.96$; $P = 0.33$) between those patients who completed only the PRO questionnaires (mean 12.88 ± 12.15) and those who completed idiographic interviews in addition to the PRO battery (mean 11.58 ± 11.07).

Table 3 – Demographic and clinical characteristics and HRQOL subscale scores of patient sample.

Characteristic	Total (N = 275)			Survey only (n = 126)			Survey + interview (n = 149)			Survey vs. survey + interview		
	N	Mean ± SD	%	n	Mean ± SD	%	n	Mean ± SD	%	t(*df*)	χ^2	*P* value
Age at surgery (y)		67.48 ± 9.29			66.05 ± 8.98			68.68 ± 9.40		−2.36 ± 272		0.02
Age-adjusted Charlson comorbidity score		2.41 ± 2.41			1.91 ± 2.32			2.82 ± 2.42		−3.15 ± 269		0.01
Response burden composite score		12.19 ± 11.65			12.88 ± 12.15			11.58 ± 11.07		0.96 ± 273		0.33
EORTC QLQ-C30 subscales												
Global health status—QOL		73.43 ± 20.43			72.47 ± 19.58			74.26 ± 20.41		−0.73 ± 269		0.46
Physical function		90.93 ± 13.31			90.11 ± 14.20			91.62 ± 12.52		−0.94 ± 272		0.35
Role function		85.58 ± 23.18			85.19 ± 22.73			85.92 ± 23.63		−0.26 ± 272		0.79
Emotional function		74.73 ± 20.39			74.60 ± 23.66			74.85 ± 17.15		−0.10 ± 270		0.92
Cognitive function		86.70 ± 16.88			86.51 ± 18.34			86.87 ± 15.56		−0.18 ± 270		0.86
Social function		76.84 ± 25.90			74.74 ± 26.89			78.65 ± 24.97		−1.25 ± 270		0.21
Fatigue		20.88 ± 18.83			21.78 ± 19.94			20.11 ± 17.86		0.73 ± 271		0.47
Nausea-vomiting		3.48 ± 10.26			5.29 ± 13.28			1.93 ± 6.33		2.73 ± 271		0.01
Pain		11.92 ± 21.35			11.90 ± 21.28			11.94 ± 21.48		−0.01 ± 272		0.99
Dyspnea		9.85 ± 17.24			9.79 ± 17.42			9.91 ± 17.15		−0.06 ± 272		0.95
Insomnia		26.13 ± 27.73			25.93 ± 27.29			26.30 ± 28.20		−0.11 ± 271		0.91
Appetite loss		8.18 ± 17.68			8.73 ± 19.40			7.71 ± 16.11		0.48 ± 271		0.64
Constipation		14.76 ± 22.84			16.80 ± 23.04			13.01 ± 22.62		1.36 ± 269		0.17
Diarrhea		7.35 ± 17.51			7.67 ± 18.46			7.08 ± 16.71		0.28 ± 270		0.78
Financial problems		16.23 ± 26.17			17.20 ± 26.02			15.40 ± 26.36		0.56 ± 267		0.57
Sex, female	65		23.6	33		26.2	32		21.5		0.48	0.49
Race, nonwhite	12		4.4	4		3.2	8		5.4		0.69	0.41
Marital status, married/partner	208		75.6	92		73.0	116		77.9		0.51	0.48
Employment status, employed	127		46.2	74		58.7	53		35.6		6.64	0.01
Cancer stage												
Ta, Tis, T1	121		44.3	49		38.9	72		49.0		0.90	0.34
T2–T4	152		55.7	77		61.1	75		51.0			
Neoadjuvant chemotherapy, yes	123		44.9	66		52.8	57		38.3		4.72	0.03
Previous intravesical treatment, yes	105		38.2	53		42.1	52		34.9		2.04	0.15
Previous pelvic radiation treatment, yes	24		8.7	15		11.9	9		6.0		1.98	0.16
Body mass index												
Normal (18.5–25)	59		21.5	29		23.0	30		20.1		4.66	0.10
Overweight (25–30)	124		45.1	50		39.7	74		49.7			
Obese (>30)	92		33.5	47		37.3	45		30.2			

EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire—30 Items; HRQOL, health-related quality of life; QOL, quality of life.

A total of 60 patients (21.8%; PRO questionnaires only, n = 29; PRO questionnaires and idiographic interviews, n = 31) indicated that there were unimportant or repetitive questions in the PRO battery. Eighty-seven patients (31.6%) reported via the response burden questionnaire that additional information should have been gathered as part of the PRO battery. These qualitative findings were not significantly correlated with overall response burden (Pearson $r = 0.05$ and -0.05 and $P = 0.40$ and 0.39, respectively). A subset of these patients (n = 35, 12.7%) acknowledged that there were unimportant or repetitive questions in the PRO battery, but also suggested that additional information should have been included.

Predictors of Response Burden

In examining the multivariate hierarchical linear regression models of patient demographic and clinical characteristics or HRQOL subscale scores as potential predictors of patient response burden (Table 4), low self-reported cognitive function was a significant predictor of higher response burden ($\beta = -0.20$; $t(270)$

Table 4 – Final hierarchical regression model.

Variable	Unstandardized coefficients		Standardized coefficients			
	β	Standard error	β	t	p	Adjusted R^2
Cognitive function	−0.14	0.41	−0.20	−3.38	0.01	0.04

= −3.38; $P = 0.01$; model-adjusted $R^2 = 0.04$). Clinical and demographic characteristics and HRQOL subscale scores did not significantly predict response burden.

Predictors of Dropout

A total of 207 (75%) patients had complete EORTC QLQ-C30 data at the 1-month postsurgical follow-up. Participant response burden was not significantly associated with participant dropout ($F(1, 273) = 2.05$; $P = 0.15$).

Discussion

Despite the potential response burden associated with the completion of PRO measures in routine care and clinical trials, a growing number of patients with cancer are willing to self-report their experiences to not only inform the care that they personally receive but also assist others who may share similar disease-related experiences in the future [3,7,21,33,34]. We found that patients who complete a lengthy battery of PRO assessments experience minimal response burden as defined by our brief burden measure. No significant increase in response burden was observed for the subset of patients who also completed a 30-minute interview about their HRQOL experiences. Although approximately 22% of our sample indicated that we asked questions that were repetitive or not relevant to their concerns, more than half of these patients and a larger proportion of overall participants (32%) reported that we should have asked additional items about their condition. In addition, participant response burden was not found to be a significant predictor of dropout at the 3-month postsurgical follow-up assessment. These findings should provide key stakeholders with confidence that the inclusion of a battery of psychosocial or behavioral PRO questionnaires in clinical trials or routine care is not perceived as burdensome, even by very sick patients with cancer.

We also found that cognitive impairment, as captured by the EORTC QLQ-C30, is a significant predictor of higher patient response burden. This finding is intuitive, because individuals who have difficulty with memory or concentration may be more easily frustrated with questionnaire wording and length. Screening for cognitive impairment at trial entry or during an early routine care visit may facilitate the identification of patients who are more prone to experiencing burden. Future work should prioritize the use of interview-based PRO data collection with these impaired individuals, which may help in minimizing missing data and improving data quality in prospective studies.

Our internally developed measure of patient response burden was designed to include a number of key features. First, we wanted to avoid social desirability bias and intentionally did not ask about whether our specific measures were burdensome. We feel that the multidimensional item content (i.e., relationship of questions to actual concerns, comfort in answering questions, relevancy of questions to health, and feelings about time to completion) encompasses key elements of response burden. The two open-ended questions serve as an avenue through which patients can express their desire for fewer or larger number of items. Finally, we wanted this to be a brief assessment, so as to not introduce additional response burden. We acknowledge that this homegrown measure has not been previously validated. A future direction of this work is to provide formal validation of our response burden tool such that it can be used in similar contexts.

This study is not without a number of limitations. The study was completed at a single tertiary cancer center with limited diversity of the patient population in terms of racial background, and only a single disease type was included. All PRO questionnaires were mailed to participants for home completion, thus not allowing us the opportunity to capture average length of time to completion, ultimately making it difficult to explore the association between perceived response burden and time to questionnaire completion. On the basis of the open-ended question responses, patients did not report being burdened by the questionnaire or interview aspects of the study and indicated that, on average, these assessments did not take up a tremendous length of their time; nevertheless, future studies of response burden should seek to quantify the length of time to complete questionnaires and/or interviews. Patient completion of these surveys at home rather than at the clinic site also removed the possibility of having study staff available to provide real-time assistance for questionnaire completion.

Conclusions

This is the first study that provides evidence that rigorous PRO assessment of multiple disease-related domains may not be perceived as burdensome to patients with cancer as previously thought. Although this work should be replicated across a broad range of patient and disease types, it is encouraging to find that patients are not only willing to complete these questionnaires and brief interviews regarding their disease but are also minimally burdened in doing so.

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