

# Development of the Cancer Therapy Satisfaction Questionnaire: Item Generation and Content Validity Testing

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## ABSTRACT

**Objectives:** This study was undertaken to develop a new questionnaire, the Cancer Therapy Satisfaction Questionnaire (CTSQ), to focus on the issues oncology patients consider when evaluating chemotherapy in terms of expectations and satisfaction.

**Methods:** Items of the CTSQ were generated through the review of responses from interviews with oncology patients, physicians, and nurses. Analysis of the data was stratified by disease stage, disease type, and country to explore potential differences between these groups. Two rounds of face and content validity testing were then conducted.

**Results:** Patients explained their hopes for efficacy and factors related to treatment satisfaction. Content validity testing in 30 patients, followed by additional testing in 10 patients on oral therapy, suggested that patients felt the questionnaire was clear, comprehensive, relevant, and

easy to complete. Minor revisions were implemented to improve clarity, resulting in deletion of 12 items, modification of 17 items and the rewording of “chemotherapy” to “cancer therapy” to ensure patients on oral therapy were able to respond. The CTSQ contains 21 items and assesses seven domains: Expectations of cancer therapy, Feelings about side effects, Oral cancer therapy adherence, Convenience, Satisfaction with cancer therapy, Stopping cancer therapy, and Reasons for nonadherence. **Conclusions:** The CTSQ was designed for adults with a wide range of cancer types and stages, receiving a variety of cancer treatment formulations. A validation study is currently underway to examine the psychometric properties, further refine the questionnaire and develop scoring methods for the CTSQ.

**Keywords:** cancer, chemotherapy, patient outcome assessment, questionnaire design, satisfaction.

## Introduction

Patients receiving chemotherapy tend to work closely with their physicians and are typically involved in their treatment decisions. When making decisions to start or continue treatment, patients often consider numerous factors, including treatment expectations of efficacy and side effects, satisfaction with medical care, satisfaction with the management of side effects, satisfaction with treatment modality or dosage form (intravenous [IV] or oral) and, possibly, life satisfaction [1–3]. All of these factors can directly influence patients’ satisfaction with treatment overall. Moreover, patients’ preferences and their assessments of the risks/bene-

fits associated with chemotherapy may influence their decisions to continue treatment and ultimately determine their satisfaction with the outcome of therapy [1,3].

Because patient satisfaction might reveal additional factors relevant to the treatment process and outcome of chemotherapy, a literature review [4] was conducted to determine whether an instrument that assesses oncology patients’ expectations, satisfaction, and preferences related to chemotherapy treatment has been developed. No instruments that adequately assess patient expectations or satisfaction with chemotherapy were identified. The satisfaction measures identified in this review primarily addressed patients’ satisfaction with care [1,2], satisfaction with adjuvant therapy [3] or preferences related to chemotherapy-induced emesis [5]. Few articles offered descriptions about the outcome tool used [6] and most asked the simple question: “Which treatment do you prefer? [7–9]” Most arti-

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cles focused on decision tree analysis, time trade-off and decision aids—that is, the ways in which patients make decisions to take or refuse treatment [10–13]. Patient preferences identified in this literature review included oral chemotherapy rather than IV chemotherapy medication [14], home treatment over outpatient clinic care [1] and follow-up care with primary physicians rather than oncologists [15]. Identified patient preferences for taking chemotherapy also indicated that survival and toxicity trade-offs may differ among patients with different tumor types. For example, breast cancer patients have been found to accept aggressive treatment with severe side effects while knowing that the chances of increased survival time may be minimal [16]. However, another study indicated that nonsmall cell lung cancer patients were not willing to undergo chemotherapy if minimal survival benefits and severe side effects were to be expected [17].

### *Measuring Satisfaction*

The measurement of satisfaction is an emotive evaluation, which enables the assessment of the appropriateness of the perceived quality of treatment to patient expectations. Satisfaction is defined as a pleasant feeling caused by the fulfillment of expectations [18–20].

Satisfaction is the result of a psychological process, which involves the comparison of the perceived performance of a given treatment to the patient's initial expectations [18,21]. The positive or negative opinion and the future use or discontinuation of the treatment depends mainly on patient satisfaction or dissatisfaction. The relationship between patient satisfaction, intentions and adherence behavior has been demonstrated in both commercial and health-care fields [22–24]. Indeed, in the field of health care, adherence with treatment largely depends on the patient's satisfaction with the treatment or medical service received.

The main objective of this study was to design a questionnaire for use in the United States (American English) to assess satisfaction with and preference for chemotherapy treatment. The questionnaire would be used across a range of cancer types/stages and treatment formulations, suitable for cross-cultural adaptation and in multinational clinical trials.

## **Methodology**

### *Stage 1: Item Generation Interviews and Focus Group Discussions*

Oncology patients in the United States ( $n = 60$ ), UK ( $n = 5$ ) and France ( $n = 5$ ) were interviewed prima-

rily during face-to-face interviews. Some interviews were conducted over the telephone. In-depth interviews were conducted in the UK and France to consider any cultural differences. Oncologists recruited patients between 18 and 75 years of age, who were diagnosed with breast, colorectal or lung cancer and who were fluent in the native tongue of the target country. Patients were in either the early or advanced stage of disease. For breast cancer only, survivors were also included. Patients must have completed at least one cycle of chemotherapy during the past 12 months, except for breast cancer survivors, who must have completed at least one cycle of chemotherapy two to 10 years ago. These interviews explored global assessments of the patient experience, including current health and health-related quality of life (HRQoL), as well as more specific issues related to expectations, perceptions, satisfaction with treatment and associated factors.

In addition to patient interviews, nurse and physician interviews were conducted to identify key issues relevant to the management and treatment of cancer from the health professionals' point of view. Focus group discussions were conducted with 14 oncology nurses in the United States and telephone interviews were conducted with nurses in the UK ( $n = 2$ ) and in France ( $n = 2$ ), all specializing in oncology. Nurses represented hospital, academic and clinic settings and were currently treating cancer patients. During these discussion groups and interviews, nurses' perceptions of patients' opinions and expectations about chemotherapy treatment and overall management and treatment of cancer were collected. The objectives of the discussions and interviews were to identify aspects of the management and treatment of cancer that are important to patients and to explore the nurses' perceptions of the patients' preferences, expectations, and satisfaction with treatment.

Additionally, seven physicians were interviewed by telephone for approximately 1 h per interview. Physicians represented hospital, academic, and clinic settings and were currently treating oncology patients. These interviews specifically enquired into physicians' opinions about actual disease management, cancer treatments, perceptions of treatments, improvements needed in the treatment and management of symptoms and the physicians' opinions regarding patients' most bothersome symptoms and factors that influence patient adherence.

### *Stage 2: Qualitative Analysis and Item Generation*

Data collected through structured interviews were recorded and transcribed verbatim. Verbatim

patient, nurse, and physician comments were comprehensively reviewed and analyzed, then organized by domains and types of psychosocial correlates. These domains, correlates and framework formed the basis for the patients' perceptions conceptual model and hypotheses. Responses and concerns were grouped together to elicit the domains important to this patient population. Potential differences in patient perspectives by cancer type, stage of disease, country, and treatment type were evaluated by reviewing the similarities and differences in patients' responses.

Using the results of the qualitative analysis, items were generated to use, as much as possible, patient phraseology. Items, response choices and recall periods were developed for clarity, conciseness, and with lack of jargon.

### **Stage 3: Content Validity Testing**

The content validity of the newly developed questionnaire was tested in 10 patients with breast cancer, 10 patients with colorectal cancer and 10 patients with lung cancer in the United States with early- and advanced-stage disease, using established cognitive debriefing techniques. These 1-h, in-person interviews involved different participants than those who participated in the item generation phase. The interviews aimed to assess the clarity, understandability, and appropriateness of all instructions, questionnaire items, and response continuums. Furthermore, content validity testing was performed to ensure ease of comprehension on first reading.

Each interview transcript was comprehensively reviewed and analyzed qualitatively for content; items which were not well-understood or problematic were reworded. In addition, responses to each item on the questionnaire were entered into an Excel database to calculate means, standard deviations and floor and ceiling effects for each item. If more than 60% of the population reported the highest level of satisfaction for a particular item, the item was considered a candidate for deletion, because the ceiling effect would be quite high. Correlations between item responses were examined for particular items that respondents felt were redundant with other items. If the correlation was greater than 0.7, the item was flagged as a candidate for deletion. It is important to note that items were not deleted using these statistical criteria if the item was mentioned by several patients or nurses in the interview stage, because these were then felt to be of great importance to patients and therefore should be tested further in psychometric validation.

### **Stage 4: Qualitative Retesting of Revised Questionnaire**

To ensure the questionnaire was understood by those taking oral therapy and to assess whether changes to the questionnaire implemented pursuant to the content validity testing (Stage 3) were still understood by respondents, an additional content validity test was conducted with 10 adults with breast cancer who were taking oral therapy. Half of the patients recruited were in stage I or II and the other half were in stage III or IV. One-hour face-to-face interviews were conducted with patients with early-stage cancer and telephone interviews were conducted with patients with advanced-stage cancer. After completion of the questionnaire, the participants were asked specific questions about their impressions of the questionnaire, their understanding of each question and their opinion of using the word "chemotherapy" throughout the questionnaire and if the questionnaire encompassed all therapies and in particular their own therapy.

Using the same qualitative methodology as previously described, additional modifications to the wording of the questionnaire were undertaken based on the results of the interviews.

## **Results**

### **Results of Item Generation**

*Patient interviews.* Seventy patients were interviewed: 60 from the United States, five from the UK and five from France. In general, differences in responses from patients and clinicians between the countries were minor and, because of the small sample size, they are not discussed in detail. Table 1 provides the clinical and sociodemographic characteristics of the study sample. The majority of patients were newly diagnosed with cancer, mean time since diagnosis was 2.57 years ( $\pm 2.9$ ), and most patients stated their health was good (34%,  $n = 24$ ), very good (24%,  $n = 17$ ), or fair (20%,  $n = 14$ ). In accordance with the study design, the population was well distributed by cancer type; 40% ( $n = 28$ ) were diagnosed with breast cancer, 34% ( $n = 24$ ) with colorectal cancer and 26% ( $n = 18$ ) with lung cancer. All survivors were breast cancer survivors (11%,  $n = 8$ ), and the remaining population included early-stage (46%,  $n = 32$ ) and advanced-stage patients (43%,  $n = 30$ ). Although the majority of patients had received only IV therapy (87%,  $n = 61$ ), three patients (4%) had received oral chemotherapy only and six patients (9%) had received both oral chemotherapy and IV treatment.

**Table 1** Item generation—patients' clinical and sociodemographic characteristics

Total patients	USA = 60	UK = 5	France = 5	Total = 70
Sex				
Male	13 (22%)	2 (40%)	2 (40%)	17 (24%)
Female	47 (78%)	3 (60%)	3 (60%)	53 (76%)
Age				
Mean	59 ± 9.8	56.2 ± 15.5	69.8 ± 6.0	61.6 ± 10.5
Range	38–75	39–74	70–76	38–76
Education level				
High school without graduation or less	11 (18%)	1 (20%)	2 (40%)	14 (20%)
High school diploma/GED	19 (32%)	0	2 (40%)	21 (30%)
Vocational school or some college	14 (23%)	1 (20%)	1 (20%)	16 (23%)
College degree; undergraduate	10 (17%)	0	0	10 (14%)
Graduate degree	5 (8%)	0	0	5 (7%)
Missing data	1 (2%)	3 (60%)	—	4 (6%)
Patient-reported health status				
Excellent	6 (10%)	0	1 (20%)	7 (10%)
Very good	17 (28%)	0	0	17 (24%)
Good	21 (35%)	2 (40%)	1 (20%)	24 (34%)
Fair	10 (17%)	2 (40%)	2 (40%)	14 (20%)
Poor	6 (10%)	1 (20%)	1 (20%)	8 (11%)
Cancer type and stage				
Breast (100% female)	26 (43%)	1 (20%)	1 (20%)	28 (40%)
Early	12	1	0	13
Advanced	7	0	0	7
Survivor	7	0	1	8
Colorectal (71% female)	20 (33%)	2 (40%)	2 (40%)	24 (34%)
Early	10	1	1	12
Advanced	10	1	1	12
Lung (44% female)	14 (23%)	2 (40%)	2 (40%)	18 (26%)
Early	5	1	1	7
Advanced	9	1	1	11
Chemotherapy administration route				
IV	53 (88%)	4 (80%)	4 (80%)	61 (87%)
Oral	3 (5%)	0	0	3 (4%)
Oral and IV	4 (7%)	1 (20%)	1 (20%)	6 (9%)

GED, General Educational Development.

Table 2 details the sex of patients by cancer type and stage.

*Clinician interviews: oncology nurses and oncologists.* The nurse and oncologist characteristics are provided in Table 2. Two focus groups including seven nurses each were conducted in the

United States (one in Los Angeles and one in Philadelphia) with nurses specializing in oncology. Additionally, nurses were interviewed in the UK ( $n = 2$ ) and in France ( $n = 2$ ). The majority of nurses practiced in a private setting (67%,  $n = 12$ ) versus a hospital setting (33%,  $n = 6$ ). Seven oncologists were interviewed: five in the United States, one in

**Table 2** Nurse and oncologist characteristics

Total nurses and oncologists characteristics	USA = 19		UK = 3		France = 3	
	Nurses ( $n = 14$ )	Oncologists ( $n = 5$ )	Nurses ( $n = 2$ )	Oncologist ( $n = 1$ )	Nurses ( $n = 2$ )	Oncologists ( $n = 1$ )
Sex						
Male	0	4	0	1	0	0
Female	14	1	2	0	2	1
Type of practice						
Hospital/academic	5	3	1	1	0	0
Private	9	2	1	0	2	1
Number of years in oncology: Mean (years)	10	21	12	8	20	6
Tumor type treated (%)	N/A		N/A		N/A	
Lung cancer		23%		0%		10%
Colorectal cancer		17%		50%		40%
Breast cancer		33%		0%		40%
Other cancers		27%		50%		10%

N/A, not applicable; distribution of tumor types treated was not collected from oncology nurses.

the UK and one in France. The majority of oncologists were men (71%,  $n = 5$ ), and the majority practiced in either a hospital or academic setting (57%,  $n = 4$ ). Predominately, these physicians had experience using chemotherapy to treat breast cancer, colorectal cancer and, to lesser degree, lung cancer patients.

*Expectations.* Predominately, patients described their rationale for deciding to undergo chemotherapy treatment as a necessity rather than a choice. They often described the decision as a choice between life and death. Nonetheless, patients' expectations about the treatment experience and its outcomes varied significantly. Some patients stated they did not have expectations, either because they felt chemotherapy was their only option or because they had no background knowledge about chemotherapy. Others expressed generalized hopes that chemotherapy would "help" them or would "work," without expressing specific expectations.

Breast cancer patients were far more likely to expect remission or eradication of their cancer due to chemotherapy treatment. However, when asked why they chose chemotherapy, colorectal and lung cancer patients were less optimistic. They tended to view chemotherapy as a means by which to prolong life or decrease the severity of their cancer, rather than actually offering a cure.

Although breast cancer patients' expectations were more optimistic than those of lung and colorectal cancer patients, these differences may be due to the fact that the majority of advanced-stage patients (77%) suffered from colorectal ( $n = 12$ ) or lung ( $n = 11$ ) cancer. Both colorectal and lung cancers are typically diagnosed at a more advanced stage than breast cancer and treatment is less likely to result in remission. Indeed, when examining the data by stage, it was observed that advanced-stage patients were less optimistic or hopeful for a cure and were more likely to hope for prolonged life or decreased disease severity; this was even the case for advanced breast cancer patients.

According to nurses and physicians, patients' hopes for survival were very strong and expectations regarding the efficacy of medications took the form of hope mixed with denial. This situation results in patients who are overly optimistic about the effects of chemotherapy, and are therefore disappointed when chemotherapy does not eliminate their tumors. Nurses and physicians further explained that expectations of side effects depend on patients' previous experiences with other family or friends with cancer, what they have heard about

chemotherapy from others and/or the portrayal of the chemotherapy experience in the media. Results from the patient interviews suggest that patients with early stage or breast cancer had high expectations for a cure, whereas patients with advanced-stage cancer did not. This indicates a slight departure from the nurse and oncologist perspective, although it is certainly possible that the early-stage patients were overly optimistic. However, this conclusion is not confirmed, as nurses and physicians did not indicate which groups of patients were more likely to be overly optimistic.

*Critical treatment success factors.* Patients identified three main factors contributing to the successful management and treatment of cancer: having the support of others, maintaining a positive attitude and interacting with medical professionals (Fig. 1). The majority of those who described the importance of moral support were women; however, there was no difference by age group. Patients stressed the importance of positive interaction with medical professionals, citing the support and guidance they received from the doctors, nurses, and medical staff who cared for them. One patient described the help she received from her doctor: "He gave me confidence to get through this, that it would all be worth it."

Perceptions of how patients cope with their diseases and treatments were consistent among clinicians and, for the most part, corroborated patients' opinions. Emotional support was the predominate factor related to patient ability to cope with cancer in a positive way. Clinicians explained that family and friends are the primary source of this support. Other support sources mentioned were nurses, social workers, therapists, and support groups. One nurse felt strongly that positive attitudes affect patients' outcomes. She explained, "If they don't have that positiveness that they will get better, if they don't have that faith, that something, to me, they're just not going to live as long as the positive one who is in a positive state." One physician also cited antidepressants, alternative medicines, and imaging as examples of ways patients cope with their illnesses. The coping methods mentioned by the patients, clinicians, and nurses, of which these are just a few examples, may be essential factors in effective disease management and ultimately, satisfaction.

*Satisfaction.* Throughout the interview, patients were asked a series of questions that attempted to assess their satisfaction with chemotherapy treatment and their faith in their medical team—both



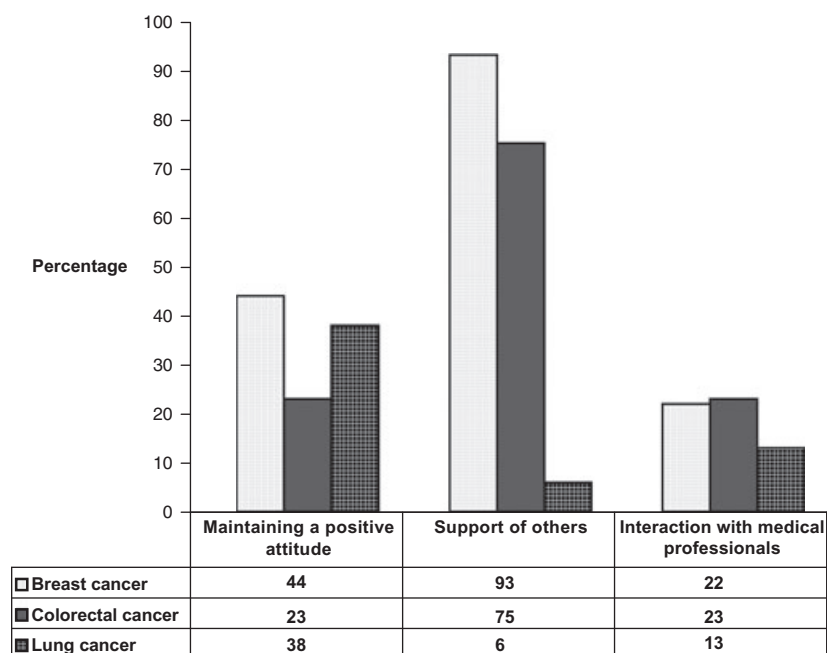


Figure 1 Success factors by cancer type.

important factors in patient adherence. To assess whether or not they were satisfied with their treatment and its outcomes, patients were asked specifically whether they believed chemotherapy was worthwhile, if their hopes of chemotherapy had been met and, if given the choice, whether they would choose to be treated with chemotherapy again. The vast majority of patients interviewed stated that they found chemotherapy worthwhile, either because of remission of cancer or the opportunity to live longer. Most patients also reported that treatment was not as bad as they had anticipated. One patient said, "I was surprised that I wasn't as sick as I thought I would be." The majority of participants also stated that they would repeat the chemotherapy again if given the choice.

Regarding the benefits of chemotherapy, breast cancer patients most often cited the reduction or elimination of cancer. Colorectal cancer patients reported increased general well-being almost as often as they reported the reduction or elimination of cancer, whereas lung cancer patients most often reported prolonged life as the key benefit. For early-stage patients, prolonging life and reducing or eliminating cancer were equally important. Advanced-stage patients, on the other hand, felt that prolonged life was the most fundamental gain. Finally, survivors stated that reducing or eliminating the tumor was chemotherapy's most significant benefit. Nurses and physicians indicated that patients perceive satisfaction as directly related to whether or

not treatment was successful. Some nurses did mention patients who had high hopes for a cure and became very angry after finding out their tumors had progressed despite treatment.

Patient satisfaction with treatment is a function that is intrinsically tied to patients' treatment expectations. Thus, it is not surprising that patients' descriptions of satisfaction reflect their expectations. Breast cancer, early-stage and survivor patients detailed expectations for tumor reduction and a cure. They also described reduction or elimination of cancer as a treatment benefit. Therefore, these patients were most satisfied with treatment when they experienced tumor shrinkage or remission. Conversely, colorectal, lung, and advanced-stage patients, who most often expected prolonged life or decreased disease severity, were most satisfied when treatment improved the quality of their life or helped them live longer.

*IV chemotherapy versus oral chemotherapy and Adherence.* Patients' negative reactions toward receiving chemotherapy intravenously can be grouped into two main categories. One group of reactions focused on the inconvenience of IV treatments, particularly in terms of the amount of time needed for treatment and the burden of arranging transportation. The other set of negative reactions concerned the physical and mental effects of receiving medication through a needle and in a medical environment. Although some patients described the

positive experience of interacting with other patients when receiving treatment, patients' comments indicate that visiting the hospital or clinic is at times depressing. For example, one patient described the emotional impact of visiting the clinic: "I have to watch everybody else receive treatment . . . It's sad. It's very sad, and that can bring down your mental attitude."

The United States, UK, and French patients cited concern about needles and associated pain as their primary fear related to IV therapy. This concern was noted by more than half of the breast, colorectal, and lung cancer patients. Constraints on time, concerns about transportation, depression associated with the treatment experience and the constant reminder of serious illness were secondary concerns expressed across the three groups. Concern about pain and needles was the primary source of anxiety across all three cancer stages. Early-stage cancer patients were most likely to express this concern, with 56% ( $n = 18/32$ ) citing it as a central issue. Additionally, early-stage patients described depression as a primary concern (13%,  $n = 4/32$ ), but were also most likely to note positive aspects of IV therapy, such as regular contact with medical staff and social support. These differences most likely emerge because early-stage patients are relatively healthy and generally have not adjusted to seeing people ill and close to death, have greater levels of fear due their lack of experience with chemotherapy and may therefore seek out support from both medical staff and other patients more enthusiastically.

Moreover, patients cited many positive aspects of oral chemotherapy treatment, including convenience, timesavings, and the painless method of administration. These positive attributes of oral chemotherapy directly counter the negative aspects of IV therapy (inconvenience and mental and physical pain) cited in the previous section. Additionally, patients stated that taking an oral chemotherapy medication at home versus IV medication in a medical setting, helped them to feel more "normal" and in control of their lives. For instance, one patient stated, "If I could just have the pills it would still give more freedom in my life . . . I guess I would feel that my whole life wasn't necessarily involved around my cancer treatment."

Subjects expressed mixed opinions about whether it would be easier to comply with an IV or an oral chemotherapy treatment regimen. The majority of patients who believed it would be easier to take oral chemotherapy were individuals in the 65 to 75 years age group. Patients who thought that an oral chemotherapy regimen would be more dif-

ficult to follow generally fell into the 38 to 54 years age group. Nonetheless, many participants were unsure and felt unable to judge whether or not adherence with an oral chemotherapy regimen would be easier.

Breast and lung cancer patients were more likely than colorectal cancer patients to perceive convenience as an advantage of oral chemotherapy. Time appeared to be a more important issue for colorectal cancer patients, whereas breast cancer patients noted general concerns about side effects more frequently. Convenience was the primary advantage of oral chemotherapy reported by both advanced-stage and survivor patients. In contrast, the issue of convenience was less important to early-stage patients, who viewed time and independence as the two most significant advantages of oral chemotherapy. Both early-stage and survivor patients were concerned about the side effects of oral chemotherapy.

Clinicians' perceptions regarding differences between IV treatment and oral chemotherapy were similar. They generally stated that different side effects present in patients receiving IV versus oral chemotherapy. Clinicians explained that patients receiving oral chemotherapy have more gastrointestinal side effects, thus raising concerns about whether the drug gets absorbed completely before any vomiting that may occur. However, one nurse commented that IV medications were "stronger" and therefore caused more side effects. Another nurse mentioned that neutropenia (a blood disorder that may be caused by chemotherapy) was a more common problem with IV medications.

Regarding treatment efficacy, clinicians generally did not perceive significant differences between IV and oral chemotherapy treatments. However, one physician did discuss the potential for oral chemotherapy medication to be less effective, adding that this is "related to noncompliance." Conversely, another physician used the example of Xeloda (an oral chemotherapy agent), and explained that this treatment has equal efficacy to IV drugs. In his opinion, IV is "not the only way to administer drugs, except that it bypasses the intestinal tract, where they may not be absorbed properly or may be destroyed."

Physicians stated that the primary advantage of oral chemotherapy medication is that patients can take the medication at home. This enables patients to spend less time at the clinic, away from their daily life activities. However, physicians also explained that they would be concerned about whether patients were taking the medication prop-

erly or not, and whether the drug has consistent absorption rates when taken orally. When provided with a hypothetical scenario in which a particular medication has the same efficacy and bioavailability in both oral and IV forms, physicians indicated that patient preference is the deciding factor for whether patients would receive oral or IV chemotherapy. The majority of physicians perceived patient preference to be for oral chemotherapy.

Overall, patients cited efficacy as their foremost treatment priority. In addition, the majority of patients, regardless of cancer type, stage or nationality, cited concern about needles and associated pain as the primary disadvantage of IV chemotherapy. Moreover, their primary treatment concern after efficacy was convenience. Patients felt that convenience was the primary advantage of oral chemotherapy over IV, particularly for the ways convenient treatment decreases disruption of daily life activities, increases feelings of normality and independence, provides more time to spend with family and friends and reduces limitations. Early-stage patients were more specific than advanced-stage or survivor patients when discussing oral chemotherapy's improved convenience. These patients indicated that time and independence are the primary advantages of oral chemotherapy.

#### Item Generation Summary

The item generation interviews were conducted to identify the issues patients consider when evaluating the overall risks and benefits of chemotherapy in terms of life extension, tumor reduction/eradication and side effects. The perceptions and comments participants offered in these interviews and their

verbatim word choices were the primary sources for developing questions. The analysis of patient, physician, and nurse interviews resulted in the generation of a draft of the Cancer Therapy Satisfaction Questionnaire (CTSQ) that contained 33 items and assessed the following domains: Confidence in treatment, Activities of daily living/side effects or pain, Adherence, Satisfaction with treatment, and Treatment preference/Trade-off. Skip patterns were included for those items that were not applicable to patients taking only IV cancer therapy versus those taking only oral therapy. This questionnaire was designed to be used in a range of oncology trials to assess patients' satisfaction with chemotherapy treatments. The next step in the instrument development process was to test the CTSQ in a group of patients to assess the content validity of the items.

#### Content Validity Testing

Thirty respondents, 14 male and 16 female, completed the CTSQ. Ten respondents with breast cancer, 10 respondents with lung cancer and 10 respondents with colorectal cancer participated. Advanced-stage respondents represented 43% ( $n = 13$ ) of the population and early-stage and survivor respondents represented 30% ( $n = 9$ ) and 27% ( $n = 8$ ), respectively. The majority of advanced-stage respondents had colorectal cancer. Three percent of the total population ( $n = 1$ ) was taking oral chemotherapy and 20% ( $n = 6$ ) was taking a combined IV and oral regimen. The mean age of the study population was 58 years ( $\pm 11$ ). The mean age of colorectal cancer respondents was higher than that of lung and breast cancer respondents by three and six years, respectively. Table 3

**Table 3** Content validity—demographics by cancer type

	Breast	Lung	Colorectal	Total
Sex, n (%)				
Male	0 (0%)	9 (90%)	5 (50%)	14 (47%)
Female	10 (100%)	1 (10%)	5 (50%)	16 (53%)
Age	55 $\pm$ 14 (37–74)	58.7 $\pm$ 11.5 (41–75)	61.6 $\pm$ 7 (51–72)	58.5 $\pm$ 11
Stage, n (%)				
Early	1 (10%)	4 (40%)	4 (40%)	9 (30%)
Advanced	2 (20%)	5 (50%)	6 (60%)	13 (43%)
Survivor	7 (70%)	1 (10%)	0 (0%)	8 (27%)
Receiving chemotherapy currently, n (%)				
Yes	2 (20%)	9 (90%)	9 (90%)	20 (67%)
No	8 (80%)	1 (10%)	1 (10%)	10 (33%)
Form of chemotherapy, n (%)				
IV	8 (80%)	8 (80%)	7 (70%)	23 (77%)
IV and oral	1 (10%)	2 (20%)	3 (30%)	6 (20%)
Oral	1 (10%)	—	—	1 (3%)
Number of cycles of chemotherapy in the last year (for nonsurvivors)	5.5 $\pm$ 2	8 $\pm$ 6	7.2 $\pm$ 5	6.9 $\pm$ 1.3



provides the demographic information of respondents included in the content validity interviews.

The mean amount of time it took to complete the questionnaire was 13 min ( $\pm 6.5$ ), which ranged from 6.5 to 19.5 min. Overall, respondents felt the questionnaire was clear, comprehensive, relevant, and easy to complete. Some revisions were suggested to improve clarity, resulting in deletion of 12 items and modification of 17 items. Deleted items tended to be those that specified patient preferences for one type of product over another. These items were not relevant to those who had only taken one type of product. Modifications were minor and pertained to removing the word “confident” from the expectation questions, and using the word “take” instead of “have” in relation to chemotherapy. This version of the CTSQ is comprised of 21 items and five multi-item domains: Expectations of chemotherapy, Feelings about side effects, Oral chemotherapy adherence, Convenience related to treatment, and Satisfaction with chemotherapy. Two single items assess two additional concepts related to adherence: Frequency of thinking about stopping chemotherapy and Reasons for nonadherence.

#### *Retesting of the Questionnaire*

Results from the retest of the revised questionnaires suggested that although the content and the objectives of the questionnaire were clearly understood and endorsed by patients on oral therapy, patients had difficulty relating to a questionnaire that used the word “chemotherapy (IV/pills)” throughout, thinking that this included only chemotherapy treatment and not hormonal therapy. Consequently, patients tended to recall back to the time they were receiving chemotherapy, which may induce recollection bias and was not the focus of the administration. Based on this set of cognitive debriefing interviews, the CCSQ was modified to address patients’ oral and IV therapy by replacing “chemotherapy” with “cancer therapy (IV/pills),” making it applicable to those on hormonal therapy. This wording was also tested in the cognitive debriefing and found to be acceptable to patients. This prevalidated version of the questionnaire can be found in the appendix.

#### **Discussion**

The CTSQ has been developed following a rigorous methodology and is currently undergoing psychometric validation to assess its reliability and validity in a number of tumor types. This validation study may also be used to further refine the questionnaire

and to develop final scoring methods, thus the items and hypothesized domains provided herein may change pending the results of the validation study.

In developing the CTSQ, care was taken to design questions that are relevant to many cancer patients to produce a questionnaire that would be applicable regardless of cancer stage and type, country of residence or cancer therapy. Differences by country were minor. However, several differences in responses by patient type and stage in a number of areas were noted, although the main concepts were similar across patients. However, all breast cancer patients and the majority of early-stage patients were female, thus it is unclear if observed differences by treatment type and stage were due to type or stage of cancer, or to sex differences. If implemented in larger scale studies, the CTSQ may help to further understand the experiences of patients in different stages or types of cancer or treatment.

The CTSQ encompasses several key components of satisfaction: expectations and the meeting of those expectations which may ultimately result in satisfaction and potentially enhanced treatment adherence. The CTSQ focuses on patients’ satisfaction with efficacy, tolerability, and convenience. Adherence has also been included, because this may be an important issue in oral therapy regimens.

In line with the above theory, patients in our study who had higher expectations of chemotherapy also expressed greater satisfaction with therapy. For example, breast cancer patients, survivors, and early-stage patients expressed high treatment expectations, often including a cure. Consequently, these patients discussed treatment satisfaction and treatment benefits in terms of the treatment’s ability to reduce or eliminate cancer. Advanced-stage, colorectal, and lung cancer patients were less optimistic or perhaps, realistic given their situation, and, accordingly, were more likely to detail expectations of prolonged life or decreased cancer severity.

Patients across all types and stages of cancer discussed efficacy as their main treatment priority, cited concern about needles and associated pain as the primary disadvantage of IV chemotherapy and stated that convenience was the central advantage of oral over IV chemotherapy. When discussing oral chemotherapy’s improved convenience, early-stage patients were more specific than advanced-stage or survivor patients, describing time and independence as primary advantages. Patients, clinicians, and nurses also identified other critical treatment success factors, such as social support, positive attitude, and positive patient/doctor interactions and

communication, which may play important moderating roles in the assessment of treatment satisfaction; further research in this area is warranted utilizing appropriate questionnaires to assess these constructs.

Although the CTSQ was developed for use throughout stages of cancer, the study was conducted with ambulatory patients and additional research is warranted if it is to be used in nonambulatory advanced-stage patients. Further quantitative research utilizing the CTSQ would help to answer these questions.

## Conclusion

The CTSQ was developed multiculturally and was based on extensive interviews with 70 oncology patients with a variety of cancer types/stages, seven clinicians (from community and academic settings), four nurses and focus groups with 14 nurses (from hospital and community settings) and following by content validity testing in 30 patients and retesting in an additional 10 patients. The CTSQ assesses pertinent domains identified from the satisfaction literature and domains that match issues most relevant to patients. The CTSQ's practical aim makes it a very good communication tool because it addresses the concerns of clinicians and patients. In addition, the CTSQ may address some needs of health authorities that are increasingly requesting information regarding the trade-offs that patients make when assessing whether or not to continue treatment. It is hoped that with psychometric validation the CTSQ will be appropriate for use in a range of oncology areas to assess patient satisfaction with cancer therapy.

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### Appendix: Cancer Therapy Satisfaction Questionnaire (Prevalidated Version)

- The following pages ask some questions about your cancer therapy (IV/pills). Within this questionnaire, “Cancer therapy (IV/pills)” refers to your current or most recent cancer therapy or cancer pills (including: hormonal therapy, IV therapy, and cancer pills).
- Please read each question and answer as honestly as you can without the help of anyone.
- There are no right or wrong answers; the answers should be based on your own personal experiences.
- All of your answers will remain confidential.
- This questionnaire will take about 10 min to complete.

#### Your Thoughts about Cancer Therapy (IV/pills)

The following statements ask you to share your thoughts about cancer therapy (IV/pills). Please answer each question below by checking the box that best represents your opinion (check only one box per question).

In general, in the last four weeks, how often did you feel:

	Always	Most of the time	Sometimes	Rarely	Never
1. That cancer therapy (IV/pills) would help you to return back to a normal life?	<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
2. That cancer therapy (IV/pills) would get rid of the cancer?	<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
3. That cancer therapy (IV/pills) would help prevent the cancer from coming back?	<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
4. That cancer therapy (IV/pills) would stop the cancer from spreading?	<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
5. That your cancer therapy (IV/pills) limited your daily activities?	<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
6. Upset about the side effects?	<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
7. That cancer therapy (IV/pills) was worth taking even with the side effects?	<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
8. That cancer therapy (IV/pills) would help you live longer?	<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>

9. In general, in the last four weeks, how often did you think about stopping your cancer therapy (IV/pills)?

<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
Always	Most of the time	Sometimes	Rarely	Never

If you are receiving only IV cancer therapy, skip 10, 11, and 12 and continue with question 13. If you are receiving cancer pills, please answer the questions below.

In general, <u>in the last four weeks</u> , how often did you:	Always	Most of the time	Sometimes	Rarely	Never
10. Have trouble remembering to take your cancer therapy pills?	<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
11. Take your cancer therapy exactly as directed by your doctor?	<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>

If you answered “always” to question 11, please skip question 12 and continue with question 13.

12. If you did not always take cancer pills as directed, why didn't you?

(Please check all that apply)

- <sub>1</sub> I forgot  
<sub>2</sub> It was inconvenient  
<sub>3</sub> I felt I needed a break  
<sub>4</sub> I felt I did not need it  
<sub>5</sub> Side effects.

#### Satisfaction with Cancer Therapy (IV/pills)

The following statements are about your satisfaction with your most recent cancer therapy (IV/pills). Please answer each question below by checking the box that best describes your level of satisfaction (check only one box per question).

13. **Overall**, how inconvenient was it for you to take your cancer therapy (IV/pills)?

<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
Very convenient	Convenient	Neither convenient nor inconvenient	Inconvenient	Very Inconvenient

14. **Overall**, how bothered were you by the amount of time it took to take your cancer therapy (IV/pills)?

<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
Very bothered	Quite bothered	Moderately bothered	A little bothered	Not bothered at all

15. **Overall**, how worthwhile was your cancer therapy (IV/pills)?

<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
Very worthwhile	Quite worthwhile	Moderately worthwhile	A little worthwhile	Not worthwhile at all

16. **Overall**, was taking cancer therapy (IV/pills) as difficult as you expected?

<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
Much more difficult than I thought it would be	Somewhat more difficult than I thought it would be	As difficult as I thought it would be	Somewhat easier than I thought it would be	Much easier than I thought it would be

17. **Overall**, how well did the **benefits** of cancer therapy (IV/pills) meet your expectations?

<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
Much better than my expectations	Somewhat better than my expectations	Met my expectations	Somewhat worse than my expectations	Much worse than my expectations

18. **Overall**, were the **side effects** of cancer therapy (IV/pills) as you expected?

<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
Much better than I expected	Somewhat better than I expected	Exactly as I expected	Somewhat worse than I expected	Much worse than I expected

19. How satisfied were you with the **form** of your cancer therapy (IV/pills)?

<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied

20. **Overall**, how satisfied were you with your most recent cancer therapy (IV/pills)?

<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied

21. Taking everything into consideration, if given the choice again, would you decide to take this cancer therapy treatment?

<input type="checkbox"/> <sub>5</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>1</sub>
Yes, definitely	Probably Yes	I don't know	Probably not	Definitely not

Thank you for your help.