Administration and Scoring Guide for the Cancer Therapy Satisfaction Questionnaire (CTSQ)

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1. Introduction

The Cancer Therapy Satisfaction Questionnaire (CTSQ) is a 16-item questionnaire measuring three domains related to patients’ satisfaction with cancer therapy: Expectations of Therapy (ET), Feelings about Side Effects (FSE) and Satisfaction with Therapy (SWT). The CTSQ was developed for use in a wide range of cancer types and stages, and is specific to adult patients receiving cancer therapy. In particular, this instrument can be used for both IV and oral cancer therapy assessments. The CTSQ was developed based on extensive interviews with 70 oncology patients (breast cancer, colorectal cancer, and lung cancer), seven clinicians, and focus groups with 18 nurses. Interviews took place in the United States, the United Kingdom and France. Additional cognitive debriefing interviews were conducted with 10 breast cancer patients in the US who were taking oral hormonal therapy. At the conclusion of the qualitative research phase of the development of the CTSQ, the questionnaire contained 21 items and 6 tentatively hypothesized domains; in addition to the three domains already mentioned, the questionnaire also included Convenience (CON), Oral Therapy Compliance (OTC), a single-item Stopping Therapy (ST) domain, and a “check-all-that-apply” question asking patients to indicate reasons for non-compliance with oral therapy.

A stand-alone, observational, psychometric validation study was then conducted on the US English version of the CTSQ which included 15 clinical sites across the US and a total of 361 cancer patients (137 with breast cancer, 121 with colorectal cancer, 91 with lung cancer, and 12 with melanoma). Psychometric testing led to decisions to modify the domain assignments of some of the items. The single-item ST domain was eliminated because the item was moved to the SWT domain. In addition, decisions were made to eliminate five items and two domains from the CTSQ (OTC and CON). This resulted in the current 16-item, three-domain version of the CTSQ. The revised ET, FSE and SWT domains of the CTSQ were found to have acceptable reliability and validity for use in group-level research in breast, colorectal and lung cancer populations, as well as in a mixed cancer population similar to the sample used in the psychometric validation study. Details can be found in the final report (Psychometric Validation of the Cancer Therapy Satisfaction Questionnaire (CTSQ), report version 3.0, October 25, 2006).
2. Guidelines for Patient Self-Administration

2.1. Site Staff Preparation for Administering the CTSQ

The CTSQ may be administered as part of a research study, such as a clinical trial. As such, in addition to this Administration & Scoring Guide, site staff should review the following carefully for any additional study-specific information:

- The study protocol
- The study manual

2.2. Administration Setting and Materials

Before administration of the CTSQ, site staff should ensure that the following have been provided for the patient:

- Verbal instructions on how to complete the CTSQ
- Ready access to site staff in case of questions
- A quiet, well-lit, private space
- A functioning writing implement such as a black ballpoint pen
- A hard writing surface such as a clipboard
- Approximately 10 minutes to complete the questionnaire

Site staff should be trained on proper administration techniques, should reference this Administration & Scoring Guide and the study operational manual and/or protocol as needed, and/or call their study contact for additional clarification of guidelines as needed.

2.3. When Should the CTSQ be Administered?

To achieve unbiased assessments, the CTSQ should be administered before:

- The patient's clinical examination
- The patient receives any test or test results
- The patient's health, health data or emotions are discussed

**NOTE: Administering the CTSQ after examining the patient may bias their responses.**
2.4. **General Rules for Administering the CTSQ**

Site staff should be aware of the following:

- The patient should complete the CTSQ without assistance from a family member, friend or site staff
- If possible, the patient should be alone when completing the CTSQ
- Site staff should not minimize the importance of any item
- Site staff should not interpret or explain what a question means. Instead, emphasize that the patient should use their own interpretation and best judgment when reading and answering the questions

2.5. **Steps for Administering the CTSQ**

When the administration of the CTSQ is ready to begin, site staff should:

- Describe the procedure that the patient should follow if a mistake is made
- Describe the procedure that the patient should follow if he/she does not understand a question
- Describe the procedure that the patient should follow if he/she cannot decide between two response options

2.5.1. **General Instructions for the Completion of the CTSQ**

The completion instructions are provided on the coversheet of the CTSQ.

2.5.2. **Procedure if a Patient Makes a Mistake**

- The patient should cross out the incorrect response with a single line and date and initial the change
- The patient should then check off the correct response

2.5.3. **Procedure if a Patient Does Not Understand a Question**

- The patient should re-read the question and response options and answer based on what he or she thinks that the question means
- If the patient still does not understand, he or she can leave the response blank and move on to the next question
- The reason for this should be noted by the clinical staff
2.5.4. *Procedure if a Patient Cannot Decide between Two Response Options*

- If the patient is truly unable to decide between two response options, advise them to use the more severe or worse of the two response options.

2.6. *Quality Assurance Guidelines*

Before the patient leaves the site, site staff should:

- Review the CTSQ for completeness (e.g., pages stuck together, skipped pages, questions unanswered)
- Point out any unclear or missing responses

If there is an unclear response, site staff should:

- Ask the patient to clarify his/her answer and make the corrections.

If a patient has left an item blank, site staff should:

- Encourage the patient to give his/her opinion
- Emphasize confidentiality—but only to the degree that confidentiality of the patient’s information is actually assured by the study protocol, research program, and relevant informed consent and/or release forms signed by the patient.
- Stress the importance of each separate question for the study

2.7. *Frequently Asked Questions by Patients*

**What Are You Going To Do With This Information?**

The answer to this question depends on the particular study or research program in which the CTSQ is being used. Patients should informed of the purpose of the study or the research program, the way their information may be used, and who may have access to their information.

**Am I Answering This Correctly?**

- Tell the patient that there are no right or wrong answers.
- Tell the patient that he/she should continue to answer as sincerely as possible.
- Tell the patient that we are interested in what he/she thinks or feels, not what he/she thinks we want to hear.
3. **Scoring**

3.1. **Initial (Raw) Item Response Coding**

All 16 CTSQ items have five response options. Initially, the raw responses for all 16 CTSQ items should be integer-coded on the data collection form with the leftmost response option having a value of 5 and the rightmost response option having a value of 1 (see the copy of the CTSQ in the appendix). For the sake of simplicity, we will assume that the raw responses for the 16 CTSQ items have been stored in a SAS dataset with the variable names Q1 through Q16.

3.2. **Reverse-Coding Required for Four Items**

The first step in scoring the CTSQ is to create new variables containing the reverse-coded response values for four of the CTSQ items (Q5, Q6, Q9, and Q11). This is done by subtracting the initial (raw) response value for each of these items from 6. For example, the following SAS statements can be used to create the new variables Q5R, Q6R, Q9R and Q11R which contain reverse-coded response values for items Q5, Q6, Q9 and Q11:

\[
\begin{align*}
Q5R &= 6 - Q5; \\
Q6R &= 6 - Q6; \\
Q9R &= 6 - Q9; \\
Q11R &= 6 - Q11;
\end{align*}
\]

Creating new variables containing the reverse-coded response values for these four items ensures that when scoring the CTSQ domains the highest-coded value (5) for each CTSQ item is associated with the best possible response (better therapy expectations, feeling less impact of side effects, greater satisfaction with therapy, etc.), and the lowest-coded value (1) is associated with the worst possible response.

3.3. **Domain Structure & Scoring Procedures**

Table 1 provides a summary of the domain structure and critical information required for scoring each CTSQ domain.
Table 1. Summary of domain structure and scoring information for CTSQ domains

<table>
<thead>
<tr>
<th>CTSQ Domain</th>
<th>Description of Content of Items in Domain</th>
<th>Item numbers*</th>
<th>Total # of items</th>
<th>Minimum # of completed items required to score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expectations of Therapy (ET)</td>
<td>Return to normal life, Get rid of cancer, Prevent cancer from coming back, Stop cancer from spreading, Help you live longer</td>
<td>Q1, Q2, Q3, Q4, Q8</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Feelings about Side Effects (FSE)</td>
<td>Cancer therapy (CT) limited daily activities, Upset about side effects, Taking CT as difficult as expected, Were side effects as expected</td>
<td>Q5R, Q6R, Q11R, Q13</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Satisfaction with Therapy (SWT)</td>
<td>Worth taking even with side effects, Think about stopping CT, How worthwhile was CT, Benefits meet expectations, Satisf. with form of CT, Satisf. with recent CT, Would you take this CT again</td>
<td>Q7, Q9R, Q10, Q12, Q14, Q15, Q16</td>
<td>7</td>
<td>5</td>
</tr>
</tbody>
</table>

* "R" following item number indicates that reverse-coded version of the item is used in calculating the domain score.

For each domain, if the number of completed items is greater than or equal to the minimum number indicated in Table 1 the domain is scored using the formula:

\[
\text{Domain score} = \left( \frac{\text{Sum of completed item responses} - 1}{\text{Number of completed items} - 1} \right) \times \frac{100}{\text{Maximum possible item response value} - \text{Minimum possible item response value}}
\]

However, if fewer items are completed than the minimum number indicated in Table 1, then the domain is not scored (i.e. a missing value is assigned).

Since the maximum possible item response value is 5 and the minimum possible response value is 1 for all CTSQ items, a simpler way to represent the above formula for the CTSQ domains is:

\[
\text{CTSQ domain score} = (\text{Mean of completed item responses} - 1) \times 25
\]

In terms of SAS programming code, these scoring procedures can be performed as follows:

```sas
if n(of Q1 Q2 Q3 Q4 Q8) >= 3 then
    ET = (mean(of Q1 Q2 Q3 Q4 Q8)-1)*25;
else ET = . ;

if n(of Q5R Q6R Q11R Q13) = 4 then
    FSE = (mean(of Q5R Q6R Q11R Q13)-1)*25;
else FSE = . ;

if n(of Q7 Q9R Q10 Q12 Q14 Q15 Q16) >= 5 then
    SWT = (mean(of Q7 Q9R Q10 Q12 Q14 Q15 Q16)-1)*25;
else SWT = . ;
```
These procedures result in a score ranging from 0 to 100 for each CTSQ domain, with a higher score associated with the best outcome on each domain.

### 3.4. Scoring Example

A patient has the following raw responses on the items in the Satisfaction with Therapy (SWT) domain:

- Q7 = 4 (“Most of the time”)
- Q9 = 2 (“Rarely”)
- Q10 = Missing response
- Q12 = 3 (“Met my expectations”)
- Q14 = Missing response
- Q15 = 5 (“Very satisfied”)
- Q16 = 4 (“ Probably yes”)

The raw response for Q9 must first be reverse-coded by subtracting it from 6, which results in a reverse-coded response value of 4 for that item, because $6 - 2 = 4$. Because the total number of completed items (5) is equal to or greater than the minimum number specified in Table 1 for the SWT domain (5), the domain is scored as follows:

$$\text{SWT} = \left[ \frac{(4 + 4 + 3 + 5 + 4)}{5} - 1 \right] \times 100 \div (5 - 1)$$

or

$$\text{SWT} = \left[ \frac{(20)}{5} - 1 \right] \times 100 \div 4$$

or

$$\text{SWT} = (4 - 1) \times 25$$

or

$$\text{SWT} = 3 \times 25$$

or

$$\text{SWT} = 75$$

### 3.5. How the Minimum Number of Completed Items Required to Score Each Domain was Determined

The minimum number of completed items required to score each domain was determined in the psychometric validation study by performing sequential testing on each domain to determine how
many items in each domain must be complete in order for the internal consistency reliability estimate (Cronbach’s alpha) to remain \( \geq 0.70 \). This was done by sequentially removing the item in each domain whose removal reduced Cronbach’s alpha the most, until Cronbach’s alpha dropped below 0.70. Using this technique it was determined that internal consistency reliability of the ET domain remained above 0.70 with up to 2 out of the 5 items missing. For the FSE domain, removing even one item resulted in Cronbach’s alpha dropping below 0.70, and thus none of the 4 items is allowed to be missing. For the SWT domain, Cronbach’s alpha remained above 0.70 with up to 2 out of the 7 items missing.