

HALT-C Trial

Quality Of Life

Form # 40 Q x Q Version A: 06/15/2000 (Rev. 03/07/2001)

Purpose of Form #40: The Quality of Life form collects information about the patient's self-reported quality of life. This information will be used to measure changes in health-related quality of life over the course of the HALT-C trial.

When to complete Form #40: Form #40 can be administered in either English or Spanish. The Quality of Life form should be completed by all patients at the following visits:

- **Screening Phase patients:** Screening visit 1 or 2 (S01 or S02).
- **Responder Phase patients:** Week 72 visit (W72).
- **Randomization Phase patients:** Month 12 (M12), Month 24 (M24), Month 36 (M36), Month 48 (M48), and Month 54 (M54) visits.

SECTION A: GENERAL INFORMATION

- A1. Affix the patient ID label in the space provided.
 - If the label is not available, record the ID number legibly.
- A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.
- A3. Enter the three-digit code corresponding to this visit.
- A4. Record the date the form was completed using MM/DD/YYYY format.
- A5. Enter the initials of the person completing Section A of the form.

SECTION B: QUALITY OF LIFE

Section B of this form should be self-administered by the patient. However, it may be necessary to read the questions to a patient, for example, if administered over the telephone or if the patient has a difficult time reading.

If the patient is not able to complete this form by her/himself, the interviewer may read the questions and answers to the patient and circle the number on the form that corresponds to the answer given by the patient. If the interviewer completes the form in this manner, please note so in the margins of the form by writing "form completed by interviewer" with the initials of the interviewer. The data entry person should add this written statement as a form level comment in the DMS.

The Quality of Life Form requires approximately 10 to 15 minutes to complete. This questionnaire should be given to patients before a provider sees them or asked about other health questions so that any discussion of health problems does not influence the respondent's answers to the Quality of Life Questionnaire.

The following script is suggested for introducing Section B of the questionnaire:

We would like to better understand how you and other persons in this study feel, how well you are able to do your usual activities, and how you rate your own health. To help us better understand these things about you and other persons, please complete this questionnaire about your general health.

The questionnaire is simple to fill out. Be sure to read the instructions on the top of the first page (point to them). Remember, this is not a test and there are no right or wrong answers. Choose the response that best represents the way you feel. I will quickly review the questionnaire when you are done to make sure that all the items have been completed.

You should answer these questions by yourself. Spouses, or other family members or visitors, should not assist you in completing the questionnaire.

Please fill out the questionnaire now. I will be nearby in case you want to ask me any questions. Return the questionnaire to me when you have completed it.

The patient should complete the form by circling the number corresponding to the statement that best describes the answer to the particular question.

It is important that patients complete all of the items on the form.

- Review the form for any missing items.
- Make sure that each item has a single statement marked.
- Please ask the patient to complete any missing or doubly marked items.
- If an unanswered item is due to the respondent's having trouble understanding a particular item, you may reread the question for them verbatim, but do not rephrase the question. If the respondent is still unable to complete the survey, accept the survey as incomplete, and indicate that the respondent was unable to complete the survey due to difficulty understanding questions. Write "not done" in the margin next to each unanswered question.
- If the patient is not able to complete this form by her/himself, please note so in the margins of the form and enter the initials of the person completing the forms as delineated above.

Interview

What if the respondent asks for clarification?

- The interviewer may reread the question for respondent verbatim. If the respondent asks what something means, do not try to explain what the question means, but suggest that the respondent use her/his own interpretation of the question.

What if the respondent says, "I don't know" or something different than what is stated on the questionnaire?

- Gently guide the respondent to a pre-set category with a script such as:
I know that it may be hard for you to think this way, but which of these categories most closely expresses what you are thinking or feeling?

What if the patient asks if certain items, particularly the pain items, are limited to a specific health problem?

- Explain that these questions ask about their health in general.

Specific Instructions for Section B:

3: a – j: If the patient responds that s/he does not do activity, probe:

- *Is that because of your health?*
 1. Yes, limited a lot.
 2. Yes, limited a little.
 3. No, not limited at all.

4-10 and 12 – 16: All these questions refer to events over the past four weeks.