Title of measure:
European Organization for Research and Treatment of Cancer 30-item core quality of life questionnaire (EORTC QLQ C-30)

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Brief overview:
The EORTC QLQ-C30 is a 30-item self-reporting questionnaire developed to assess the quality of life of cancer patients. Presently the QLQ-C30 Version 3.0 is the most recent version and should be used for all new studies. It is grouped into five functional subscales (role, physical, cognitive, emotional and social functioning). In addition, there are three multi-item symptom scales (fatigue, pain, and nausea and vomiting), individual questions concerning common symptoms in cancer patients, and two questions assessing overall QOL. It is a copyrighted instrument, which has been translated and validated into 81 languages and is used in more than 3,000 studies worldwide. It is supplemented by disease specific modules e.g. Breast, Lung, Head & Neck, Esophageal, Ovarian, Gastric, Cervical cancer and Multiple Myeloma, all which are distributed from the Data Center.

Validated:
Yes—the first EORTC QLQ-C30 validation paper was published in 1993 by Aaronson et al, (1).

Psychometric properties:
The EORTC QLQ-C30 questionnaire was administered before treatment and once during treatment to 305 patients with nonresectable lung cancer from centers in 13 countries. Clinical variables assessed included disease stage, weight loss, performance status, and treatment toxicity. The data supported the hypothesized scale structure of the questionnaire with the exception of role functioning (work and household activities), which was also the only multi-item scale that failed to meet the minimal standards for reliability (Cronbach's alpha coefficient > or = .70) either before or during treatment. Validity was shown by three findings. First, while all interscale correlations were statistically significant, the correlation was moderate, indicating that the scales were assessing distinct components of the quality-of-life construct. Second, most of the functional and symptom measures discriminated
clearly between patients differing in clinical status as defined by the Eastern Cooperative Oncology Group performance status scale, weight loss, and treatment toxicity. Third, there were statistically significant changes, in the expected direction, in physical and role functioning, global quality of life, fatigue, and nausea and vomiting, for patients whose performance status had improved or worsened during treatment. The reliability and validity of the questionnaire were highly consistent across the three language-cultural groups studied: patients from English-speaking countries, Northern Europe, and Southern Europe (1). In a subsequent study, further validation was carried out for 535 patients, including patients with breast cancer and ovarian cancer, as well as patients with lung cancer and a heterogeneous group of other cancers (2).

**Normative data:**
Normative data exists for the non-cancer population for age and gender-specific community samples (3, 4).

**Clinically significant changes:**
For the total QOL and other QOL domains of each patient, the difference between the pretreatment score and a follow-up score will be derived and then the patient will be categorized into clinically significant improvement, clinically significant deterioration, or no change. If the positive difference is greater than the SEM, then the patient is classified as having clinically significant QOL improvement. If the negative difference is less than the standard error measurement, then the patient is classified as having clinically significant QOL deterioration. If the difference fails to meet either criterion, then the patient is classified as no change (5).

**Website or how to register to use:**
Go to [http://www.eortc.be/home/qol/downloads/form.asp?d=1](http://www.eortc.be/home/qol/downloads/form.asp?d=1) to get permission to use one or more of the EORTC scales, which can be obtained by completing a user’s agreement and one collaborators project information form per project. The scoring manual will also be provided. The permission information should be given to RTOG headquarters for each RTOG QOL study.

**List any fees for usage:**
Currently, there are no fees for use of any of the versions of the EORTC questionnaire if used in an academic setting; however if a pharmaceutical company is sponsoring – a royalty fee is indicated.

**Languages available:**
The EORTC QLQ questionnaire is now available in more than 81 different languages, permitting cross-cultural comparisons of people from diverse backgrounds. Please check the website for the specific languages available: [http://www.eortc.be/home/qol/ExplQLQ-C30.htm](http://www.eortc.be/home/qol/ExplQLQ-C30.htm).

**Instructions for CRAs and or credentialing for administration:**
There is no credentialing needed for administration of the EORTC QLQ. Each protocol has instructions for the CRAs. As well, a variety of information to assist in the administration of the EORTC QLQ questionnaires is available from the website.

**Time required to complete the instrument:**
The majority of patients complete the questionnaires within 10 to 15 minutes.

**Quality assurance for administration (if needed):**
Each protocol has instructions for the CRA’s.

**Scoring of instrument:**
The QLQ-C30 is composed of both multi-item scales and single-item measures. These include five functional scales, three symptom scales, a global health status / QoL scale, and six single items. Each of the multi-item scales includes a different set of items - no item occurs in more than one scale. All of the scales and single-item measures range in score from 0 to 100. A high scale score represents a higher response level. Thus a high score for a functional scale represents a high / healthy level of functioning, a high score for the global health status / QoL represents a high QoL (i.e., a better state of the patient).

Conversely, a high score for a symptom scale / item represents a high level of symptomatology / problems (ie a worse state of the patient). The QLQ-C30 and its modules have been designed to evaluate change of HRQoL in clinical trials setting. As such, a single individual score is not considered to be informative. Scores are only informative when used in a comparative setting:
- comparing different patient groups
- comparing changes within one group over time
- comparing changes over time between different patient groups.
When comparing scores, one should take into account that statistically significant differences do not necessarily imply clinically relevant differences and vice versa. For the QLQ-C30, a change in any scale of at least 10 points is considered to be clinically relevant (6).

The website has a variety of information to assist in the scoring of the EORTC questionnaires and in the interpretation of the results (http://www.eortc.be/home/qol/ExplQLQ-C30.htm).

**References:**


