

Title of measure:**Functional Assessment of Cancer Therapy-Trial Outcome Index (for Lung Cancer) -- (FACT-TOI)**

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DISCLAIMER:

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Brief overview:

FACT-TOI is a measure of 21 items that sum the functional well being (FWB), physical well being (PWB), and the lung cancer subscale (LCS) of the Functional Assessment of Cancer Therapy - Lung (FACT-L) QOL instrument, which has been extensively used for measuring QOL in patients with lung cancer. In a review of the literature, the FACT-L scale has been used in more than 5,000 patients and has been found to be sensitive to changes in performance status, treatment response. The full FACT-L questionnaire can be completed in less than 10 minutes. This instrument has not only been shown to be prognostic for survival, but also sensitive to changes in QOL on serial evaluations throughout treatment.

Importantly, the FACT-TOI has been associated with clinically meaningful changes in patients with lung cancer. The lung cancer sub-scale (LCS) consists of 9 items, involving lung cancer specific symptoms. All items are rated on a 5 item (point) Likert Scale, from 0 (not at all) to 4 (very much). It has been determined that a 2-3 point difference on the LCS subscale is associated with a meaningful difference in clinical indicators, versus a 5-6 point difference on the TOI .

Validated:

Yes--the first FACT-TOI validation paper was published in 1995 by Cella et al, see references below.

Psychometric properties:

FACT-G was developed initially with 135 patients with advanced cancer, then validated on a second sample of 630 patients with a variety of cancers of different stages. Patients rate all items using a 5-point rating scale ranging from "not at all" to "very much". The measure yields information about total quality of life as well as the dimensions listed above. FACT-G is able to distinguish between stage I, II, III and IV disease ($p < .05$). The initial paper documenting development and validation of this general measure is: Cella et al 1993, see references below.

The nine LCS questions were administered along with the FACT-G to 116 patients with lung cancer. Internal consistency (coefficient alpha) was improved from 0.53 to 0.68 by dropping two questions which were uncorrelated with the others. A subset of 41 patients was tested again at 2 months to evaluate sensitivity to change in performance status rating (PSR) and to obtain estimates of a

clinically meaningful change score for the FACT-G and the 7-item LCS. Using a linear test for trend, sensitivity to change in performance status rating (PSR) was obtained with the Total score ($P = 0.03$), the Physical Well Being (PWB) subscale ($P = 0.02$), the Functional Well Being (FWB) subscale ($P = 0.05$), and the LCS ($P = 0.03$). A 21-item Trial Outcome Index (TOI), combining scores on PWB, FWB and LCS, was highly reliable (coefficient $\alpha = 0.89$) and sensitive to change in PSR $F(1,38) = 4.84$ ($P = 0.01$). This TOI is probably the most relevant and precise indicator of patient-reported quality of life available for lung cancer patients who complete the FACT-L while participating in an oncology clinical trial.

Normative data:

Normative data are currently being developed with reference tables.

Clinically significant changes:

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Website or how to register to use:

Go to www.facit.org and click on “Registration+Requests” to use one or more of the FACT scales, which can be obtained by completing a User’s Agreement and one Collaborator’s Project Information Form per project. This information can be found under the “User’s Agreement” link on the website. 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 English versions of the FACT questionnaires.

Languages available:

FACT questionnaires are now available in more than 45 different languages, permitting cross-cultural comparisons of people from diverse backgrounds. Please check the website for the specific languages available for FACT-TOI.

Instructions for CRAs and or credentialing for administration:

There is no credentialing needed for administration of FACT-TOI. Each RTOG protocol has instructions for the CRAs. As well, a variety of information to assist in the administration of the FACT questionnaires is available from the website (under the administration and scoring guidelines link).

Time to administer instrument:

Five minutes

Quality assurance for administration (if needed):

Each protocol has instructions for the CRA’s.

Scoring of instrument:

FACT-TOI is scored by summing the individual scale scores, with higher scores indicating better quality of life (Webster K, et al, see references below). Each domain, as well as the overall QOL score is calculated according to the scoring instructions for FACT. Briefly, after reversing the scoring of negatively worded items (so that a higher score always indicated a favorable response), item responses are summed. The average value of

the items for a subscale is computed for missing values, as long as >50% of the questions in the subscale were answered. The website has a variety of information to assist in the scoring of the FACT questionnaires and in the interpretation of the results.

References:

1. Cella, D.F., Tulsky, D.S., Gray, G. et al. The Functional Assessment of Cancer Therapy (FACT) scale: Development and validation of the general measure. *Journal of Clinical Oncology* 11(3): 570-579, 1993.
2. Cella, D.F., Bonomi, A.E., Lloyd, S.R. et al. Reliability and validity of the FACT-L quality of life instrument. *Lung Cancer* 12(3): 199-220, 1995.
3. Cella, D.F., Eton, D.T., Fairclough, D.L. et al. What is a clinically meaningful change on the FACT-L Questionnaire? Results of ECOG study 5592. *J Clin Epidemiology* 55(3): 285-95, 2002.
4. Cella, D, Hahn, EA, Dineen, K. Meaningful change in cancer-specific quality of life scores: differences between improvement and worsening. *Qual Life Res* 11:207-21, 2002.
5. Webster K, Cella D, Yost K. The functional assessment of chronic illness therapy (Facit) measurement system: properties, applications and interpretations. *Health Qual Life Outcomes* 1:1-13, 2003.