

Using Cross-Cultural Input to Adapt the Functional Assessment of Chronic Illness Therapy (FACIT) Scales

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Cross-cultural quality of life measurement and psychosocial assessment in oncology have become reality with the translation and international validation of quality of life questionnaires. The Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System, under development since 1987, produced its 4th version in November 1997. The FACIT system includes the Functional Assessment of Cancer Therapy (FACT), the Functional Assessment of Human Immunodeficiency Virus Infection (FAHI) and the Functional Assessment of Multiple Sclerosis (FAMS). These questionnaires were developed in North America and, to date, many have been translated into almost 30 languages. One of the strengths of this ongoing translation project is its use of input from patients, linguists, psychologists and physicians internationally to assure that the wording of Version 4 is more cross-culturally relevant and more sensitive to measuring the psychosocial impact of illness in cultures outside the United States. Statistical analysis, aggregation of patient comments, and comments from linguists and users of the translated versions are used as needed to revise item wording to ensure clarity and consistency across languages. A 'decentering' approach is also used to adapt the source (English language) document in response to problems encountered during its translation.

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The Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System, under development since 1987, is a collection of quality of life (QOL) questionnaires targeted to the assessment of QOL in chronic illnesses. The FACIT includes the Functional Assessment of Cancer Therapy (FACT) and related subscales, the Functional Assessment of Human Immunodeficiency Virus Infection (FAHI), and the Functional Assessment of Multiple Sclerosis (FAMS). 'FACIT' is a new term created to better describe the expansion of the more familiar 'FACT' series of questionnaires into other chronic illnesses and conditions such as multiple sclerosis, HIV and Parkinson's disease. The core questionnaire, referred to as the FACT-G, comprises 27 general items divided into four primary QOL domains: Physical Well-Being, Social/Family Well-Being, Emotional Well-Being and Functional Well-Being. A disease-, treatment- or symptom-specific 'Additional Concerns' subscale can be added to the FACT-G for assessing more specific issues. For example, the FACT-B is the FACT-G plus the Breast Cancer subscale; the FACT-BMT is the FACT-G plus the Bone Marrow Transplant

subscale, and so on. Currently, there are 12 cancer-specific subscales, 5 treatment-specific subscales, 4 symptom-specific subscales, a Spiritual Well-being scale, and a Palliative Care scale available. Other scales in the measurement system, such as a Treatment Satisfaction questionnaire, are under development.

Changes from Version 3 to Version 4 of the FACIT were designed to enhance clarity and precision of measurement without compromising its established reliability and validity. The following are the significant changes between Version 3 and Version 4. The first three adaptations will form the focus of this paper; the last two are more fully examined in the FACIT manual.

1. Wording of some items has been changed to promote clarity and consistency across all subscales and their translations.
2. The subscale weighting items (# 8, 16, 19, 26, and 34 in Version 3) are now considered optional; a revised version of these domain weighting items is now being developed.

3. The 2-item Relationship with Doctor subscale has been dropped from the core (FACT-G) questionnaire. A Treatment Satisfaction scale is being developed to assess this domain more thoroughly.
4. All items have been converted to a universal alphanumeric coding system for Version 4. This new coding system facilitates comparisons of items across questionnaires in the FACIT Measurement System and allows data to be tracked more easily over time as content and order of items may change.
5. An option is now available for both raw and standardized scoring of the FACIT.

Of these adaptations, the first three were greatly influenced by international collaborative work carried out in the FACIT Multilingual Translation Project. This project has developed and linguistically validated translations of the core FACIT questionnaire (FACT-G) into over 30 non-English languages since 1994. Feedback from international translators, linguists, clinicians, researchers, and patients was incorporated into the Version 4 revision of the FACIT. These contributions, combined with suggestions and analyses obtained from North American data, helped identify problematic issues within the English language version and its subsequent translations. Adapting the English version and translated versions helped assure that the wording of Version 4 is more cross-culturally relevant and more sensitive to measuring the psychosocial impact of illness cross-culturally.

The FACIT translation methodology is an iterative forward-backward-forward technique which concludes with a linguistic validation of the translated subscale with 15–30 patients living in the native countries (1). These patients complete the translated FACIT subscale(s) as well as a post-questionnaire interview focusing on item relevance, phrasing, difficulty, and other important issues. Descriptive statistics, internal consistency reliability analyses, and interview responses are examined by the FACIT translation team. Based on this review, adaptations to the translation are made when necessary. This methodology is similar to the approach used by the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Study Group in module development for the QLQ-C30. The EORTC method focuses more on cross-cultural input during each step of the module development process, beginning with item-generation. This method provides modules that are constructed in several countries or cultures simultaneously, then translated with an iterative forward-backward process and subsequently pilot tested (2, 3). Both the FACIT and the EORTC have thorough methodologies that place great value on input from an international array of dedicated participants in search of both semantic and conceptual equivalence in the translation of the source items.

The FACIT methodology has adopted a method for changing the English source item when problems are encountered in translation, and/or when item review reveals a conceptual/clarity problem in the English version which reveals itself in translation. This process, referred to as ‘decentering’, modifies the source document, thus de-emphasizing the source language so that the final translated product supersedes any single culture. Decentering, first suggested by Werner & Campbell (4), results in a translation methodology that is not solely based upon any one culture or language; rather, all languages contribute to and influence the final version of the questionnaire.

Often in translation it is difficult, if not impossible, to translate the exact literal and inferred meaning that exists in the source language document. In measuring subjective concepts, it is questionable whether it is truly possible to attain a translation with the exact same meaning between the source document and the translated document (4–6). Certainly, each of us has interpreted literature, comments made in conversation, and humor differently from others even within our own native language. Others have suggested that asking the same questions of different cultures trivializes issues which may, in fact, be more important or relevant to a particular culture (5, 7, 8). As we have previously suggested, producing a culturally-equivalent instrument ‘is best understood not as an effort to make different groups of people look the same, but to ensure that different groups of people are evaluated without significant bias. To expect any measure of QOL to be free of cultural influence is unrealistic. However, we must work toward constructing measures based in common cores of items which are neither culture-biased, nor more attractive or repulsive to one group or another’ (9). The ultimate goal of the FACIT Multilingual Translation Project is to apply our thorough methodology, and specifically, decentering, to increase the likelihood that the final documents are more equivalent and relevant across languages and cultures.

The FACIT methodology attempts to attain five dimensions of equivalence in cross-cultural translation: *Semantic/Linguistic*: the *meaning* of the item is the same in the source and translated language; *Content*: the item is *relevant* to both cultures; *Conceptual*: the translated document measures the same *theoretical construct* as the source; *Criterion*: when compared against a known, or *standardized measurement* (criterion), the translation exhibits similar measurement properties as the source; and *Technical*: the *method* of assessment results in comparable measurement in both cultures (10). Challenges were encountered in all five of these dimensions while translating and validating multilingual versions of the FACIT. Each has required a flexible approach based on sound methodological principles to reach a solution that ultimately furthers item, construct, and instrument equivalence across cultures. An examination of these equivalence dimensions and their relevance to this project follows.

SEMANTIC/LINGUISTIC ISSUES IN THE FACIT TRANSLATION

Semantic issues are those related to reflecting the *meaning* of the source item in its translated version. There are three such issues in the FACIT translations: English phrases with no direct translation into the target languages, negotiating the translation of some negatively stated items, and interpreting colloquial speech (notably in the English back-translations).

Phrases with no direct translation

Often in translation, phrases in the source language do not have an exact correlate in the target language. While it is the role of the linguist to solve this dilemma, it can be difficult to verify that such phrases have consistent meaning across numerous different target languages.

For example, the FACIT uses the phrase 'self-conscious' in some disease-specific subscale items. *Merriam Webster's Collegiate Dictionary* defines the term as 'uncomfortably conscious of oneself as an object of the observation of others' (11); this concept does not have a direct translation in most languages. In an effort to capture the 'uncomfortable' meaning in this item, translators sometimes provided target-language versions that were considerably more negative than the source item. For example:

– English source item HN6: I am *self-conscious* about how my face and neck look

Polish translation: *Nie jestem zadowolony(a) z wyglądu mojej twarzy i szyi*

English back-translation: I am *unhappy* with the appearance of my face and neck

In contrast, some translations of the term closely approximated the intended meaning:

– English source item H11: I am *self-conscious* about my appearance

Danish translation: *Mit udseende generer mig*

English back-translation: My appearance *makes me uncomfortable/bothers me*

However, occasionally it happened that the translations were more positive than the source item:

– English source item B2: I am *self-conscious* about the way I dress

Spanish translation: *Doy mucha importancia a la manera de vestirme*

English back-translation: I *place much importance* on the way I dress (inferred: the way I dress is a matter of pride to me)

Because of these inconsistencies in translation, it was difficult to attain semantic equivalence across languages for these phrases. Based on a review of patient comments and a comparison of international and Northern American data, it became clear that being 'self-conscious' is a feeling

to which many can relate, irrespective of culture; therefore, the difficulty was not in capturing a meaning which was alien to other cultures, but in recognizing that this concept was expressed differently in other cultures.

Two solutions have been implemented for phrases with no direct translation:

First, for *existing* translations, the English version can be decentered in order to find a phrase that is more cross-culturally equivalent; if necessary, the translated versions are then re-translated to the new source item meaning. For example, in the above-mentioned case, the solution was to decenter the English phrase from 'self-conscious' to 'unhappy' in all but one of these items. (An exception was made for the Breast subscale item, which remains in English as 'I am self-conscious about the way I dress' in order to be more sensitive to patients coping with the disfiguring effects of mastectomy.) The English word 'unhappy' is less ambiguous and more readily translated than 'self-conscious' for most applications.

Second, during the translation into *new* languages, several alternative or repetitive meanings of the phrase are now provided to translators in English along with the source item. For example, in the translation of *I am self-conscious...*, phrases such as *I am unhappy...*, *I am uncomfortably aware*, and *I lack assuredness*, were also provided to translators. As suggested by Brislin, Lonner & Thorndike (7), providing repetition helps translators put the items in context by allowing the translator to be sure of the passage's meaning. Werner & Campbell (4), and Miller (12) are also proponents of redundancy in communication, stating that ample context, especially for difficult terms such as the one used in this example, provides important information about the intended meaning of the translated item. Phrases with no direct translation, which are nonetheless relevant cross-culturally, are dealt with in this manner within the FACIT translation methodology.

Negatively stated items which can be more simple when stated positively

In order to avoid the problem of a yea- or nay-saying response set, in which patients sometimes provide the same answer repeatedly without carefully reading or absorbing the item's content, the FACIT uses both positively and negatively worded items. The terms 'positive' and 'negative' as used here are not meant to indicate 'good' or 'bad'—rather, they are a function of the item construct's impact on QOL. For example, item GP2 *I have nausea* is a negative item because nausea adversely impacts on a patient's QOL. However, the item GF4 *I have accepted my illness* is positive because acceptance of one's illness is associated with better QOL. In translation, however, some negatively worded items proved easier to paraphrase when worded positively.

For example, item #9 in Version 3, *I feel distant from my friends* has been changed to a positive wording in

Version 4: GS1 *I feel close to my friends*. The concept of emotional distance proved a bit difficult in translation because some languages specifically interpret 'distant' as a *physical* measurement of the space between two objects.

– English source item Version 3 #9: I feel *distant* from my friends (emotionally inferred)

German translation: *Ich fühle mich von meinen Freunden und Bekannten distanziert*

English back-translation: I feel *distanced* from my friends and acquaintances (physically inferred)

Since there were very few translational problems in the positively worded FACT-G item GS6, *I feel close to my partner*, it was decided to reverse the *friends* item since it was simpler to translate as a positively worded statement. The item now reads:

– English source item GS1: I feel *close* to my friends

German translation: *Ich stehe meinen Freunden nahe*

English back-translation: I feel *close* to my friends (emotionally or physically inferred)

These item reversals in the source document provided a method to measure the same construct, and, in some languages, allowed for a less linguistically burdensome phrase.

Colloquialisms

Other linguistic issues arose in interpreting an item's meaning phrased in colloquial speech. Colloquialisms are synonymous phrases that are written or spoken differently, generally for reasons of geography. Recognizing implied meaning in colloquial phrases is critical, especially in an item's back-translation, which is considered to be an important indicator of the target language translation's success. Local parlance sometimes provided colorful examples of one phrase spoken in two different manners:

– American English source item BL3: *It burns when I urinate*

Swedish translation: *Det svider när jag urinerar*

English back-translation, native speaker from Scotland: *I have a smarting sensation when I pass water.*

The back-translation has the same meaning as the American English, but certainly sounds quite a bit different! Nevertheless, the synonymous nature of the source and back-translated item suggests that this was indeed a good Swedish translation.

Additionally:

– English source item L3: *I feel tightness in my chest*

Japanese colloquial translation: *Mu ne ga hi ki shi ma ru kanji ga suru*

English back-translation: I feel my chest become tight (this could be inferred as: I have been exercising and my torso is getting fit). However, after discussion with

the FACIT Japanese coordinator, it was felt that the context provided by the other items on the Lung cancer subscale would infer the correct meaning of 'tightness' in this situation, and no change in the translation ensued.

These colloquialisms were not so much problems to be resolved, but rather provided examples of how the importance of recognizing implied meanings and context in cross-cultural research.

CONTENT-RELATED ISSUES IN THE FACIT TRANSLATION

The importance of making certain that an item's content is relevant in the culture represented by the target language cannot be overlooked; if the construct is not relevant, then comparing translation equivalence between the two languages is meaningless. Much, if not all, of the information provided in the realm of content-related discrepancies and inadequacies in the FACIT has been provided by the linguistic validation phase of the FACIT Translation Methodology. Pretesting with international patients provides an opportunity to improve a translation and its measurement properties before large-scale data are collected with the translated documents.

Content-related issues can present themselves in three different ways: (i) items which are relevant, but which are phrased inappropriately for a particular population. This dilemma requires an adaptation of either the translation or the source document; (ii) constructs which are incompletely captured in the item content; (iii) entire dimensions which are not measured at all but which are important to a particular culture.

The next section summarizes resolutions of these cross-cultural content discrepancies and missing dimensions on the FACIT.

Item phrasing in the translations or the source version

Supportive role of neighbors. In the Social/Family Well-Being subscale of the FACT-G Version 3, item #11 *I get support from my friends and neighbors* was changed in Version 4 to GE3 *I get support from my friends* because the concept of neighbors emotionally supporting one through an illness was not as relevant to some cultures as it is in North America. The German translation, *Ich erhalte Unterstützung von meinen Freunden und Nachbarn*, elicited comments from several German HIV patients such as 'Friends and neighbors cannot be put together in one question; the expression *Nachbar*/neighbors should be deleted'. Similar comments were made by patients in both Western Europe and Asia, so the removal of 'neighbors' from the English source document and all translated versions simplified the item construct and made the item content more relevant to other cultures.

Pride. In the FACT-G Emotional Well-Being subscale,

I am proud of how I am coping with my illness is now GE2 *I am satisfied with how I am coping with my illness*. This change was a direct result of patients stating that 'proud' implied a boastful, negative image to them, and therefore they would not be likely to endorse the item. One physician noted after interviewing patients with the Norwegian version that 'Proud/*stolt* is not the right expression. (It's) provocative to some patients.' Furthermore, one Norwegian patient offered '*Jeg er fornøyd med måten jeg takler sykdommen på*—"I am satisfied with how I'm coping with my illness"—is better'. The change from 'proud' to 'satisfied' in the English version was simple and, again, still measured the same construct in a more content-relevant manner. In fact, we have noted that the revised wording is more acceptable in American culture as well.

Sleeping habits. An interesting example of making a translated version more content-relevant resulted from differences between Western and non-Western sleeping traditions. The item *I am forced to spend time in bed* was adapted to *I am forced to lie down* in some translations. This adaptation in the translation makes the item more relevant in those cultures where some people do not sleep in beds, such as in regions of Japan and South Africa, yet the translated version still measures the same concept.

Dimensions which are not completely captured

It is a challenge to completely capture a QOL dimension on a short questionnaire. Researchers must balance the need to minimize respondent burden—especially with a sick population—with the need to measure those components which patients deem to be important to their QOL. Furthermore, there may be constructs that are relevant to assess in some cultures which are not found in the source document. The FACIT Measurement System has developed a procedure to ensure a more comprehensive measurement of such dimensions:

Expanding subscale constructs more fully. Congruent with Guyatt's 'new philosophy' in cross-cultural translations (6), our approach to dealing with a subscale construct which is not completely captured is to formulate transfer items which help to more fully measure the dimension, and append them to the particular language/culture version. This method has been established for interested researchers who wish to add such items to existing FACIT subscales for their own clinical investigations. Each appended item is assigned a unique alphanumeric code for identification. For example, in Japan the regret of *being a burden on one's family* is a concern to those who fall ill; patients and physicians felt that such an item should be on the Japanese FACIT. Patients also felt that an item was needed to ask how close people feel to their family members. Colleagues in Japan developed these items and added them to the Japanese FACT-G in the Social/Family Well-Being subscale, making the overall subscale content more relevant to Japanese patients.

Absent dimensions

When patients indicate that there is an entire dimension important to their QOL that is not being assessed by the FACIT, efforts are made to meet this need by developing a subscale or a new questionnaire to assess the missing dimension. The FACIT Spiritual Well-Being scale is an example of such an expansion. Developed originally in response to input from North American Hispanic patients, the FACT-Sp was a direct outgrowth of patients' indicating that spirituality was a very important component of coping with their illness. Part of placing such a value on patient input is to respect their wishes for suggestions to improve our questionnaires. In this instance, the expansion strengthened the ability of the FACIT to assess an important aspect of QOL for all populations. World-wide interest in measuring this dimension of QOL has increased dramatically; our Spiritual Well-Being scale is in high demand.

CONCEPTUAL ISSUES IN THE FACIT TRANSLATION

Conceptual issues in translation focus on how well the translated document measures the same theoretical construct as the source. There are two particular examples of interest in this equivalence measure in the FACIT translation experience: the experimental/weighting items and quantifying negatively worded items.

Experimental/weighting items

The experience of translating the experimental/weighting items which appear at the end of each subscale in Version 3 was a challenge in many respects. The role of these items is to determine the comparative importance of the individual subscale domains to patients' QOL. Although these items are not yet included in the scoring, they were designed to determine individual patient weightings which can be particularly useful for clinical interventions. However, capturing this meaning is quite difficult, even in English, and translating the 'domain weighting' concept into other languages proved to be a tremendous challenge. Linguists, translators and patients cross-culturally found them conceptually challenging. Cross-culturally, patients have sometimes expressed an inability to understand the intent of the items and how to answer them. Another problematic area was the 0–10 response category, which differed from the 0–4 Likert scale used for all other subscale questions. Because the domain-weighting notion may be inadequately expressed in the English version, it is difficult, if not impossible, to attain a translation which expresses and measures the dimension in other languages.

To address these dilemmas, the items are being revised in their English form. The translated versions will subsequently be revised and perhaps their role in cross-cultural research revisited. It is hoped that the conceptual problem

in translation will be alleviated through the clarification of the English source item. As previously mentioned, these items are now offered as an option for interested FACIT users. Their use is encouraged primarily for use in clinical research in which personal values and preferences are of interest on an individual patient level.

Quantifying negatively worded items

All FACIT items are written as statements rather than questions, and response choices are Likert-type categories (0 = 'Not at all'; 1 = 'A little bit'; 2 = 'Somewhat'; 3 = 'Quite a bit'; and 4 = 'Very much'). These options are meant to help quantify how applicable each item's content is to the respondent. Finding appropriate translations in most languages has been relatively problem-free. However, the response choices have been problematic for some negatively worded items in Asian translations. In general, within the Chinese and Japanese languages, and therefore, in their way of thinking, the theoretical construct of measuring something which does not exist cannot be done. So, for example, items such as GP1 *I have a lack of energy*, simply cannot be answered 'Not at all' in these languages. The solution was once again found by providing a conceptual, not a direct, translation; the Japanese translation of GP1, is now *I feel a lack of energy*, which can be answered 'Not at all' in the Japanese language. The distinction between *I have...* versus *I feel...* in English may be a subtle one, however, in these Asian languages, it is not. As this issue exists primarily in the Asian languages, these dilemmas are being resolved on a case-by-case basis.

CRITERION ISSUES IN THE FACIT TRANSLATION

Criterion equivalence is established by comparing the results of data collected with a translation to a standardized measurement, or criteria, from the same culture to establish whether they exhibit similar measurement properties. Criterion equivalence can be shown, for example, by establishing a correlation between the QOL score and a clinical parameter such as a performance status rating (PSR), or relevant disease, or laboratory data. To date, equivalent criterion validity to the English document has been accomplished with the Spanish, German and French translations of the FACIT. Criterion validity studies are underway in other languages. Currently, there are several ongoing multinational trials which will provide substantial data, clinical indicators, validated questionnaires and other such benchmarks to which the translated versions can be statistically compared.

TECHNICAL ISSUES IN THE FACIT TRANSLATION

Technical equivalence is evaluated within the context of the method of collecting data. There are several components of technical equivalence that are salient in translation efforts.

First of all, the measurement strategy should be appropriate for the particular culture. In most cultural groups, self-administration of a QOL questionnaire using paper-and-pencil is considered appropriate and acceptable as long as the patient is functionally literate and physically able to write. By standardizing the mode of administration in our pretesting of the FACIT translations, we can better evaluate the equivalence of the data obtained. A second issue concerns equivalence between different methods such as self-administration and interviewer-administration. Establishing such equivalence is especially relevant to the FACIT translations, given the variability of literacy levels in different cultures. Since interviewers must be used to assess the QOL of low-literacy populations, it is important to use methods that have previously been shown to result in technically equivalent measurement. A recent study of the FACIT in North America demonstrated technical equivalence of the English version across literacy levels and mode of administration (13). However, a project studying this equivalence in the translations must be conducted on a language-by-language basis and, to date, this has not yet been accomplished within the FACIT Multilingual Translation Project.

One other issue that merits examination in establishing technical equivalence in the FACIT translations is the potential for bias resulting from the diversified ways in which different cultures indicate their response choices. For example, in North America, most tests and questionnaires (including the FACIT) instruct respondents to *circle* their answer. However, other cultures may prefer to 'tick', underline, or make a mark through their choice. In an effort to reduce response bias which may occur by forcing patients to answer in a manner to which they are not accustomed, the FACIT has allowed the translated documents to reflect the format most preferred by the native culture.

ISSUES THAT SURPASS BOTH LINGUISTICS AND CULTURE

Of course there have also been predicaments that have transcended the above final equivalence dimensions. As with other dilemmas, solutions were reached after much consideration of their impact on the source item and cross-cultural patient interpretation.

Patient satisfaction with their family's communication

Family communication about my illness is poor, #13 on Version 3, is an interesting example of a combination of linguistic/cultural nuances. The intent of this item is to measure patients' satisfaction with the way their family members communicate about their illness. In English, the original item is not difficult to conceptualize with the previously-discussed response categories. However, in translation the item was fraught with problems. First, the

word 'communication' in some instances was translated as 'talking' only, whereas the phrase was intended to capture the more general definition of the word. Next, 'poor' in English can only be defined in context. As a result, some translations of this item inferred that the QUANTITY of communication was insufficient (Dutch: *Wordt in het gezin weinig over mijn ziekte gepraat*/English: In the family, little has been mentioned about my illness), and other translations inferred that the QUALITY of the communication was undesirable (Italian: *In famiglia si è parlato della mia malattia in maniera superficiale*/English: In the family my illness is spoken of in a superficial manner). One Spanish translation even had 'poor' translated as without 'money'! Rarely did the translations measure dissatisfaction with the family's communication, (i.e. *how* the family communicated and/or the quality of the communication) which was the original item's intent. This problem was consistent across many languages and many cultures, and indicated a weakness in the source item. The solution was a change in the English item to GS5 *I am satisfied with family communication about my illness*, which is straightforward and a simpler concept to translate into most languages. (French: *Je suis satisfait(e) de la communication avec ma famille au sujet de ma maladie*/English: I am satisfied with the communication with my family about my illness).

Relationship with Doctor subscale

The two items (in English) which previously comprised the Relationship with Doctor subscale were: *I have confidence in my doctor* and *My doctor is available to answer my questions*. Data from North America indicated that there were ceiling effects associated with these items; i.e. the majority of patients provided the highest possible score for the items. Data from the translated versions echoed this ceiling-effect trend. An additional translation issue involved the use of the singular noun 'doctor'. Because most patients see a team of doctors, rather than just one, patients were sometimes confused, wondering to which doctor the items referred. The items were changed in many translated versions to address this (*I have confidence in my doctor(s)*, *My doctor(s) is/are available to answer my questions*). Nonetheless, the ceiling effect remained; this is reflective of a more general measurement ceiling when assessing satisfaction with treatment or provider.

Because of the lack of response variability in this two-item subscale, and because treatment satisfaction encompasses multiple dimensions, it was decided to remove these two items as a subscale and develop a more comprehensive tool for assessing patient satisfaction with treatment. The FACIT Treatment Satisfaction scale is currently under development, and is taking advantage of our international colleagues' experience by involving

them in the item development phase. Through this effort, the intent is to develop a questionnaire which can be used cross-culturally either as a stand-alone questionnaire, or in combination with other QOL assessment tools to measure more comprehensive QOL and treatment satisfaction issues.

Other cultural perceptions of health

Recognizing and respecting cultural morés in cross-cultural research is of vital importance. From the social-science perspective of health-related QOL, this respect engenders a more complete understanding of the concept of health in a population. The two simple examples that follow allow FACIT data to be collected in societies whose cultures cope with illness in quite disparate ways from Western society.

In some cultures, physicians do not tell the patient they have cancer; the family is informed, but the patient is not. It is left to the family to decide whether they will tell the patient about the diagnosis. Though the FACIT does not use the word 'cancer' on any of its subscales, item GE5 reads, *I worry about dying*, which could be problematic if the patient is not aware of the disease prognosis. In Japan, many patients are not told they have cancer, or even a life-threatening disease. Some of our Japanese physician colleagues are attempting to effect changes in their culture's practice of medicine. Among these changes they are seeking to implement are: (i) the use of QOL as an endpoint in treatment and outcomes research, and (ii) more direct communication wherein the doctor informs the patient directly of the diagnosis, treatment alternatives, and prognosis. So, physicians in Japan have the option of using the FACIT with or without item GE5, depending on the physician's communication preferences. One doctor using the Japanese version of the FACIT with this item has his patients sign a consent form stating that he has informed them of their cancer diagnosis before the patient completes the questionnaire. Our role in this process has been to ensure that the scoring of the questionnaire retains its integrity and can be related to scores from other cultures.

In South Africa, it is considered impolite for a younger woman to ask an older woman about her sex life—even in a health-related setting. The FACT-G has one sex-related question, GS7 *I am satisfied with my sex life*. To circumvent this problem and in order not to insult the elderly female patients, the interviewer first requests an older female patient's permission to ask this item before administering the FACIT (14). This kind of accommodation allows this important area to be assessed with culturally appropriate respect.

These issues are not translation-specific. However, they are relevant in the scheme of cross-cultural research. Adaptations such as this can only further a more true understanding of cross-cultural health-related QOL.

ONGOING EFFORTS

The next challenge in the FACIT Multilingual Translation Project is to begin full-scale validation studies with the FACIT non-English versions. Most of the language versions have now been converted to Version 4 and we have begun working with interested collaborators to initiate validation studies with these documents. These studies will permit cross-cultural comparisons of the FACT-G and subscales, as well as inter- and intra-language equivalence analyses. Further explored will be the scoring and statistical analysis of any newly appended items, and a comparison of raw versus standardized scores for the translations and the English source documents. Any interested investigator who would like to receive more information about these matters, or who is interested in seeing the most up-to-date list of FACIT subscale language availability, is encouraged to contact Dr David Cella by electronic mail at *d-cella@nwu.edu*, or by standard post.

In conclusion, the changes incorporated into Version 4 of the FACIT have enhanced the quality of the questionnaires without compromising their established reliability or validity. We appreciate the opportunity to improve our English language (source) questionnaire based on constructive input from our international colleagues. We consider Version 4 of the FACIT Measurement System to be trial ready and encourage all interested investigators to incorporate it into their research/outcomes programs.

Note: The FACIT manual is available by contacting Kimberly Webster: by email *k-webster@nwu.edu*; by telephone at (847) 570 1731; or by fax (847) 570 1735.

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