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Development and validation of the Functional Assessment of Human Immunodeficiency Virus Infection (FAHI) quality of life instrument

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The Functional Assessment of Human Immunodeficiency Virus (HIV) Infection (FAHI) quality of life instrument was developed using a combination of conceptual and empirical strategies. The core, general health-related quality of life instrument is the Functional Assessment of Cancer Therapy—General (FACT-G) questionnaire. The FACT-G was selected to enable comparison of data across two similar, life-threatening conditions and because of its desirable psychometric properties. Initial data on both the relevance (applicability) of the FACT-G to the HIV population and the generation and testing of questions for an HIV-specific subscale were encouraging. Consequently, the FACT-G and a 9-item HIV-specific subscale were combined and tested in 196 patients in three categories: an English-speaking stress management sample from Chicago, Illinois ($n = 110$); an English-speaking urban, mixed race sample from Chicago ($n = 71$); and a Spanish-speaking urban sample from Chicago and San Juan, Puerto Rico ($n = 64$). With the exception of the Social Well-being subscale, the subscales of the FACT-G demonstrated good internal consistency reliability across all three samples (α range = 0.72–0.88). Total FAHI scores produced consistently high alpha coefficients (0.89–0.91). Concurrent validity data included moderately strong associations with other measures of similar concepts and an ability to distinguish groups of patients by activity level and disease severity. Sensitivity to change in mood disturbance and responsiveness to a stress management intervention were also evident. The 9-item HIV-specific subscale demonstrated relatively low α coefficients (range = 0.53–0.71) and marginal sensitivity to change, leading to supplementation of content with an additional 11 items, creating a 20-item HIV-specific subscale that is currently being tested. Clinical trial and clinical practice investigators are encouraged to use the FACT-G in its current (version 3) form when evaluating group differences and within-group change over time. It should prove particularly useful when comparing clinical trial and clinical practice data for cancer vs. HIV-infected patients and in the evaluation of treatments for HIV disease and HIV-related malignancy. The supplemental 20 questions comprising the revised HIV-specific subscale are undergoing further testing, and may ultimately enhance the value of this measurement system.

Introduction

Receiving a diagnosis of human immunodeficiency virus (HIV) infection can be a life-defining and psychologically devastating event.[1] Understandably, the period surrounding diagnosis can be overwhelming, as one must instantly face one's mortality, usually at a relatively early age. This is further complicated by the multiple losses suffered in the social network of many persons newly diagnosed with HIV infection.

Notwithstanding the impact of initial diagnosis, in the absence of cure, there has been a steady lengthening of survival time in people diagnosed with HIV disease. HIV disease is increasingly being conceptualized and treated as a chronic, life-threatening illness. The development of more effective approaches for prevention and treatment of opportunistic infections and other AIDS-related complications have kept people with HIV infection in healthier states for longer periods of time, with median survival now at

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11–12 years.[2,3] Still, progressive dysfunction of the immune system brings about apparently inexorable physical and functional decline.[4] When such decline does occur, the impact upon quality of life (QOL) is considerable.

The similarities between HIV/AIDS and cancer have not escaped medical practitioners. Both are chronic, life-threatening conditions and the medical management of HIV disease shares much in common with that of cancer, particularly in advanced stages of disease. In the absence of a cure for these illnesses, medical treatment focusses on extending the length of life and/or improving the quality of that life. However, decisions about such treatment must weigh the potential benefits (expressed as either added time or improved QOL) against cost (expressed as either side effects or monetary units). Determining treatment effects on QOL requires information, either on an individual clinical level or from pooled data from clinical trials, about patient values and personal judgments regarding health status. Because of the similarities between cancer and HIV disease, and in the interest of scientific parsimony and pragmatic comparability, we set out to determine whether a QOL instrument designed for cancer patients could be applied reliably and validly to an HIV-infected population. Because our primary target arena for the instrument is the clinical trial setting, we wished to derive a questionnaire that sampled the relevant general and HIV-specific dimensions of QOL and yet was relatively brief and easy to complete. Our rules of thumb for these requirements were that the average completion time should be below 15 minutes, and most patients should be able to complete the questionnaire without interviewer assistance.

Background

Health-related QOL can be defined as a person's subjective experience of the impact of illness and treatment upon physical, psychological, social and functional well-being.[5,6] HIV disease is among the most catastrophic of medical illnesses, with multiple, profound effects on each of these dimensions. Physical consequences of HIV infection itself include numerous serious illnesses, along with persistent fatigue, intractable pain, diarrhea and wasting syndrome.[4] Pharmacological treatment with antiretroviral drugs can have side effects such as pancytopenia, peripheral neuropathy, anorexia, nausea and vomiting, while medications to prevent or treat opportunistic infections can cause a similarly wide range of negative side effects.[7] Documented psychological reactions to both initial HIV diagnosis and illness progression include anger, depression, anxiety, guilt and fear.[1,8] The social stigma associated with HIV infection also often has a negative impact on well-being, as disclosure of one's diagnosis can precipitate a withdrawal of affection and support from friends and family struggling with their own fears and anger about HIV disease.[9] Finally, the physical decline associated with AIDS often brings about difficulties in maintaining participation in valued roles and activities: persons with advanced HIV disease are frequently forced to quit work, to curtail or alter normal social activities, and eventually, to obtain help with basic household and personal tasks.[10]

Although previous research is limited, both generic and disease-specific measures of QOL have been used with persons with HIV disease.[6,11,12] The best-known generic measures include the Quality of Well-being (QWB) scale, the Sickness Impact Profile (SIP), and the Medical Outcomes Study (MOS) scales. The QWB scale defines health-related QOL on a continuum from death to optimum well-being and integrates morbidity and mortality into a single numerical index, thereby summarizing quality-adjusted life years.[13] The SIP provides a summary of current functioning in several domains of health-related QOL.[14] Various forms and adaptations of the generic MOS health rating scales have been used with the HIV-infected population.[6] At least two disease-specific additions to MOS scales have been devised by adding HIV-relevant items: Wu *et al.*[15] developed the MOS-HIV short-form health survey, and Lubeck and Fries[16,17] designed the hybrid AIDS Health Assessment Questionnaire (AIDS-HAQ), which incorporates several MOS scales.

Most pertinent to the current work are three adaptations of cancer-specific QOL instruments for use with the HIV population. The European Organization for Research and Treatment of Cancer, Quality of Life Questionnaire (QLQ-C30) has been supplemented by a 20-item AIDS-specific module, but psychometric data for that module have not yet been reported.[18] The HIV Overview of Problems-Evaluation System (HOPES) was derived from the Cancer Rehabilitation Evaluation System (CARES). Psychometric data support the reliability and validity of the HOPES for assessment of needs and QOL in persons with HIV disease. Because the instrument was designed to elicit detailed information on the daily impact of HIV disease, the HOPES is lengthy (165 items) and, thus, may not be feasible for multicentre trials and/or for frequent administrations.[19–21] Finally, from its inception, the Functional Assessment of Cancer Therapy (FACT) measurement system was

designed to be tested with chronic diseases other than cancer.[22] Preliminary reports of its performance with the HIV-infected population have indicated success.[23,24] For example, of five instruments used to measure the influence of a stress management intervention on people with HIV, the FAHI was the only one sufficiently sensitive to detect change[30] (all other planned comparisons produced changes in the predicted direction, but the changes were not statistically significant). In addition, the FACT-G discriminated between subjects with cancer and subjects with HIV disease, matched for gender and age: the HIV+ group had higher total FACT-G scores, as well as higher Physical and Functional Well-being scores, but lower Social/Family Well-being scores, than did the cancer group.[23]

This paper is the first to focus specifically on the development and psychometric characteristics of the FAHI. Given that there is no 'gold standard' for measurement of QOL in HIV disease, and given that the FACT-General (FACT-G) scale possesses a number of desirable qualities, including excellent reliability, validity, brevity, ease of administration and scoring, and responsiveness to problem areas considered to be relevant to chronic diseases,[25] we sought to validate the FACT-G with an HIV-infected population. This report presents data on both the relevance (applicability) of the FACT-G to the HIV population and the generation and testing of questions for an HIV-specific subscale. In line with the recommendations of Aaronson and colleagues[26] and Cella and colleagues[27,28] validation of such a QOL measure would address concerns of general relevance to persons with chronic diseases (allowing for comparisons across diseases) as well as problems specific to those with HIV disease (providing maximum sensitivity to concerns of this population).

Methods

Overview

Data on the reliability and validity of the FAHI were gathered from three different samples of subjects. The first sample consisted of subjects participating in a stress management intervention programme: the psychometric data on the FAHI collected from this sample was obtained prior to the stress management intervention. The second and third samples consisted of subjects participating in a validation study of the FACT and FAHI measurement system: the second sample was English-speaking and was administered the FAHI in English, while the third sample was Spanish-speaking and completed the FAHI in Spanish.

Instrument development

The Functional Assessment of HIV Infection (FAHI) scale is comprised of the FACT-G plus a finite set of symptoms and concerns specific to HIV infection which complement the content already sampled in the FACT-G. In its current form, the FACT-G is a 34-item instrument with 28 scored items, five experimental items and one new item. The HIV-specific subscale tested in this study, referred to as HIV subscale 1, contained nine items.

FACT-G. The original FACT-G was developed using interview data from 135 cancer patients and 15 oncology specialists. It has subsequently been validated in over 2,000 patients with various types of cancer.[22,29] It contains five subscales, tapping the domains of physical, functional, social/family, and emotional well-being, as well as relationship with the physician; scores on the subscales are summed to produce the total QOL score. Administration of the FACT-G to 545 patients with mixed cancer diagnoses demonstrated high internal consistency for the subscales (coefficient α range = 0.65–0.82) and the total scale score ($\alpha = 0.89$). Excellent validity of the FACT-G was demonstrated by moderate to high correlations with other measures of QOL and psychological distress; by its ability to differentiate between patients according to stage of disease, performance status and location of administration (inpatient, outpatient or community support centre); and by its sensitivity to change in patient activity level over time.[25]

HIV subscale item derivation. Item content for HIV subscale 1 was determined using structured interviews with 15 HIV-infected individuals and five health professionals with expertise in treating patients at all stages of HIV disease. Knowledge from the literature available at the time of HIV subscale 1 development (1988–1989) was also used to inform item-writing. The complete FAHI instrument tested in this study (FACT-G plus HIV subscale 1) can be found in the Appendix. This is referred to as the FAHI (Version 2) because it was introduced at the same time as Version 2 of the FACT-G.

Pretesting for acceptability. In 1989, the FAHI (version 2) was pretested with 85 volunteers of the ACT-UP New York organization in order to determine the

perceived relevance and acceptability of the wording and content of the items to people living with HIV disease. Specific characteristics of this group, including HIV serostatus, are unknown. All of the general and HIV-specific questions were rated by the volunteers as very important to the determination of their QOL. These volunteers also rated the instrument as easy to complete. Group consensus was generated and the meeting attendees voted unanimously in favour of continued development and promotion of the instrument.

Procedures and samples

Stress management study procedure. Data for psychometric evaluation of the FAHI were collected as part of a psycho-neuro-immunological (PNI) research programme related to stress management in persons with HIV disease.[23,30] Data were collected before and after a stress management intervention with groups of men at varying stages of HIV disease. A pretest–post-test design (with 6-week wait-list and 6-month assessment-only comparison groups) was used to compare the effectiveness of a 6-week stress management training programme to standard outpatient care on the outcomes of QOL, stress level, coping pattern, psychological distress, illness-related uncertainty, CD4+ T-lymphocyte level, and natural killer (NK) cell cytotoxicity. Pretest data from both control and experimental group subjects were employed for the reliability analyses presented below. Pretest–post-test data from subjects receiving the stress management intervention were used to explore the FAHI's sensitivity to change: other results from the stress management intervention are reported elsewhere.[30]

All participants gave their fully informed, written consent and were at least 18 years of age, were able to read and speak English, were aware of their HIV serostatus, had no history of intravenous drug use, had no severe psychopathology or cognitive impairment and had Karnofsky Performance Index (KPI; 31) scores of at least 60 (i.e., 'requires occasional assistance, but is able to care for most of needs').

In addition to the FAHI, four instruments were used to measure selected aspects of the stress process: comparison of the FAHI with these instruments provided data on convergent validity. Stress levels and coping patterns were assessed by the Dealing with Illness Scale (DIS).[32] Psychological distress was measured by the Total Mood Disturbance Score (TMDS) of the Brief Profile of Mood States (Brief POMS)[33] as well as the Impact of Event Scale (IES)[34] a measure of the subjective impact of a specific stressful life event (in this case, having HIV disease). Illness-related uncertainty was measured by the Mishel Uncertainty in Illness Scale (MUIS).[35,36]

Stress management sample. The initial FAHI validation sample consisted of 110 men at various stages of HIV disease progression enrolled in the PNI research programme. Based on the 1992 Centers for Disease Control and Prevention (CDC)[37] classification system, 71 participants (65%) were asymptomatic (CDC categories A1 or A2), and 39 participants (35%) were symptomatic or had AIDS (CDC categories A3 through C3). The great majority of participants (93%) were taking antiretroviral medications. The median age was 37.5 years, and the median educational level was 16 years (with no participant having less than nine years of education). The racial/ethnic mix of the sample was 72% Caucasian, 23% African-American, and 5% Hispanic. The predominant risk factor for infection was homosexual or bisexual behaviour (89%); 7% of subjects reported heterosexual risk behaviours or blood exposure and 4% had a combination of risk factors (but none reported any history of intravenous drug use). Table 1 presents selected demographic and disease characteristics of this and the other samples in this report.

Bilingual Intercultural Oncology Quality of Life (BIOQOL) Procedure. FAHI validation data were also collected on subjects who were part of the BIOQOL project. BIOQOL is a 3-year validation study of the FACT and FAHI measurement system. The FACT measurement system, including the FAHI, is being validated across levels of language (Spanish vs. English), culture (Hispanic vs. Black non-Hispanic vs. White non-Hispanic), literacy (high vs. low) and mode of administration (self- vs. interviewer-administered). This report concerns itself only with the currently available data for patients with HIV disease, both Spanish- and English-speaking: the Spanish version of the FAHI was developed using a modification of the back translation technique.[22,29] Data for each language sample are presented separately.

Data available for these subjects included CD4+ T lymphocyte counts obtained from a review of patients' records. The most recent count was included, although the time interval between the CD4+ cell count and QOL assessment varied from several weeks to a year prior to FAHI data collection. ECOG Performance Status Ratings (PSR)[38] also were made for all subjects at the time of FAHI completion. The PSR is a clinican-rated measure of patients' functional ability. To ensure accuracy, the PSR was obtained by direct interview with the patient. This rating ranges

Table 1. Sample characteristics

	Stress management sample (English) $n = 110$	BIOQOL English-speaking $n = 71$	BIOQOL Spanish-speaking $n = 64$
Gender			
Male	110 (100%)	61 (86%)	62 (97%)
Female	0	10 (14%)	2 (3%)
Age			
Median (range)	37.5 (18–61)	36 (20–57)	39 (21–63)
Ethnicity			
African-American	25 (23%)	37 (52%)	0
Caucasian	80 (72%)	22 (31%)	0
Hispanic	5 (5%)	12 (17%)	64 (100%)
Educational level (yrs)			
Median (range)	16 (9–22)	12 (4–21)	11 (0–21)
Disease classification/CD4+ count			
	CDC A1 or A2 71 (65%)	CD4 > 200 21 (33%)	CD4 > 200 30 (50%)
	CDC A3 to C3 39 (35%)	CD4 < 200 43 (67%)	CD4 < 200 30 (50%)
Karnofsky Performance Index*			
100	38 (56.7%)	(not available)	(not available)
90	15 (22.4%)		
70–80	14 (20.9%)		
ECOG PSR**			
0	(not available)	16 (22.5%)	26 (40.6%)
1		23 (32.4%)	19 (29.7%)
2		15 (21.1%)	15 (23.4%)
3		15 (21.1%)	4 (6.3%)
4		2 (2.8%)	0

*KPI: 100 = no evidence of disease; 90 = minor symptoms, normal activity; 80 = some symptoms: normal activity with effort; 70 = cares for self; but unable to do active work

**ECOG PSR: 0 = fully ambulatory; 1 = ambulatory with symptoms; 2 = requiring bedrest < 50% of waking day; 3 = requiring bedrest > 50% of waking day; 4 = bedridden

from 0, which indicates that the patient is asymptomatic and ambulatory, to 4, which indicates that the patient is bedridden.

The KPI is conceptually similar to the PSR rating, except that scores range from 0 (dead) to 100 (fully ambulatory without symptoms). The KPI rating has 11 decile categories (0, 10, 20, ... 100), whereas the ECOG PSR has only five categories. Both are included in this report because of the preferences of the investigators working with the different samples of patients.

BIOQOL samples. Data from the BIOQOL project were available for two samples, an English-speaking and a Spanish-speaking sample (see Table 1). The English-speaking sample in this project consisted of 71 participants, 61 (86%) of whom were male, with a median age of 36 years. The median level of education was 12 years and ranged from 4–21 years. The ethnic mix of these participants was 52% African-American, 31% Caucasian and 17% Hispanic. The most recent CD4+ cell count indicated that 43 (67%) of the participants had AIDS, with a CD4+ T-lymphocyte count of less than 200; 21 (33%) people had CD4+ counts greater than 200 and no recent CD4+ counts were available on the remaining seven individuals. Participants were approximately evenly distributed throughout PSR categories 0–3, while

only two people received a rating of 4 indicating bedridden status.

The third FAHI validation sample was comprised of 64 Spanish-speaking participants. All but two of the participants (97%) were male. The median age was 39 years and the median educational level was 11 years, with a range from 0–21 years. CD4+ cell counts were available for 60 of the 64 subjects and indicated that 30 (50%) had cell counts less than 200. The majority of the participants were classified in the PSR categories 0 and 1, indicating that they were primarily ambulatory, with no symptoms or minor symptoms. A comparison of sample characteristics is summarized in Table 1.

Results

FAHI scores and internal consistency

Means, standard deviations and Cronbach's alpha coefficients for the FAHI and its subscales are presented in Table 2. Internal consistency estimates for the FACT-G were uniformly high across all three samples (range = 0.89–0.91). FACT-G subscale α coefficients for the stress management sample were all in the acceptable to good range (α = 0.73–0.83). The Social Well-being subscale produced relatively low alphas in the English- (α = 0.70) and Spanish- (α = 0.65) speaking BIOQOL samples. All other FACT-G subscales produced acceptable to very high α coefficients in the English- and Spanish-speaking samples (range = 0.72–0.90). The 9-item HIV subscale, however, produced relatively low coefficients in all three samples (range = 0.53–0.63). The FAHI total (FACT-G plus HIV subscale 1) demonstrated excellent internal consistency, with alphas of 0.91 and 0.92.

Concurrent validity

Stress management sample. Validity of the FAHI and its subscales was evaluated in the stress management sample through correlational analyses with the major stress intervention study concepts as well as the physical health indicators of KPI status and CDC (1992) disease classification. It was expected that convergent validity would be demonstrated through negative associations between the FAHI (on which higher scores indicate higher QOL) and additional psychosocial measures (on which higher scores indicate more problems). In addition, it was expected that FAHI scores would differ between patients with differing performance status and disease progression, with higher QOL scores expected for those with less impaired performance and less severe disease.

Overall QOL, as indicated by the FAHI total score, was inversely related ($p < 0.01$) to negative stress ($r = 0.63$), a pattern of emotion-focused coping ($r = -0.56$), psychological distress (including avoidant [$r = -0.43$] and intrusive thinking [$r = -0.44$] as well as mood disturbance [$r = -0.59$]), and illness-related uncertainty ($r = -0.44$).

As expected, one-way analyses of variance (ANOVAs) demonstrated that participants differing in KPI also differed significantly in their Physical, Functional and Total Well-being indicators (Physical $F(2,65) = 30.73$, $p < 0.0001$; Functional $F(2,65) = 7.67$, $p = 0.001$; FAHI $F(2,67) = 7.03$, $p < 0.005$). Scheffé post-hoc comparisons confirmed that participants with KPI scores of 90 or 100 had significantly higher Physical and Functional Well-being than did those with KPI scores of 70–80. In addition, participants with KPI

Table 2. Means, standard deviations, and Cronbach's α coefficients for the FAHI

Scale/Subscale	Stress mgmt. sample (*n* = 109)			BIOQOL English (*n* = 71)			BIOQOL Spanish (*n* = 64)		
	Mean	(SD)	α	Mean	(SD)	α	Mean	(SD)	α
Physical Well-being	23.0	(4.4)	0.80	17.4	(6.3)	0.80	21.5	(6.1)	0.90
Social Well-being	17.8	(6.2)	0.78	17.2	(6.8)	0.70	16.9	(6.5)	0.65
Relationship with MD	6.6	(1.7)	0.83	6.7	(1.9)	0.88	6.6	(1.6)	0.85
Emotional Well-being	14.7	(3.4)	0.73	14.4	(5.1)	0.79	17.8	(4.7)	0.72
Functional Well-being	19.9	(5.4)	0.81	16.5	(6.4)	0.81	17.8	(6.5)	0.86
FACT-G Total	82.7	(15.8)	0.89	72.3	(19.9)	0.89	76.6	(20.0)	0.91
HIV Subscale 1	21.2	(5.4)	0.55	19.3	(6.8)	0.63	19.0	(5.9)	0.60
FAHI	104.4	(20.2)	0.91	92.1	(24.8)	0.91	96.0	(24.9)	0.92

Table 3. One-way ANOVAs: FAHI by Karnofsky Performance Index,† Stress Management Study Sample ($n = 67$)

Subscale	Physical*	Social/ Family	Relation. with MD	Emotional	Functional**	HIV Subscale 1	FAHI** Total
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Karnofsky 70–80 ($n = 14$)	16.52 (3.17)	16.97 (7.28)	6.43 (1.74)	13.64 (3.93)	15.50 (4.77)	19.93 (6.33)	88.99 (19.76)
Karnofsky 90 ($n = 15$)	22.60 (4.00)	15.92 (5.01)	6.80 (1.52)	14.00 (3.65)	19.92 (3.28)	19.62 (5.59)	98.85 (12.70)
Karnofsky 100 ($n = 38$)	24.82 (3.20)	18.48 (6.57)	6.36 (1.90)	15.15 (2.75)	21.06 (4.87)	22.26 (4.47)	107.80 (16.39)
Scheffé $p < 0.05$	90 & 100 > 70–80				90 & 100 > 70–80		100 > 70–80

† KPI category description can be found in Table 1; *$p < 0.0001$; **$p < 0.01$

Table 4. *t*-tests: FAHI by CDC Group, Stress Management Sample ($n = 67$)

Subscale	Physical*	Social/ Family	Relation. with MD	Emotional	Functional	HIV Subscale 1	FAHI Total
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Asymptomatic ($n = 42$)	24.25 (3.69)	16.75 (6.80)	6.30 (1.96)	15.17 (2.90)	20.36 (5.22)	20.79 (4.74)	103.31 (18.42)
Symptomatic/ AIDS ($n = 25$)	19.81 (4.89)	18.99 (5.56)	6.76 (1.39)	13.59 (3.61)	18.44 (4.41)	21.85 (5.99)	99.44 (16.98)

*$p < 0.001$

scores of 100 reported higher Total Well-being than did those with KPI scores of 70–80 (Table 3).

Finally, the Physical Well-being score was found to be inversely related to the CDC categories for HIV disease progression. With participants categorized as either asymptomatic or symptomatic/AIDS, *t*-tests indicated that those who were asymptomatic had significantly higher Physical Well-being scores ($t(67) = 4.21$, $p < 0.001$) (Table 4). Other FAHI subscales did not differentiate patients by disease severity.

BIOQOL samples. Validity data for the FAHI in the English-speaking and Spanish-speaking samples in the BIOQOL investigation were derived from comparisons of the FAHI and its subscales across groups differing in ECOG PSR.[38] For the purpose of analyses, it was necessary to combine participants having PSRs of three and four in the English-speaking sample and participants having a PSRs of two and three in the Spanish-speaking sample.

For the English-speaking sample, a one-way ANOVA demonstrated that the Physical, Functional, and Social/Family Well-being subscales and the FAHI total score differentiated between groups differing in PSR ratings [Physical $F(3,66) = 15.27$, $p < 0.0001$; Functional $F(3,65) = 9.03$, $p < 0.0001$; Social/Family $F(3,66) = 2.95$, $p < 0.05$; FAHI $F(3,62) = 7.93$, $p < 0.005$]. In addition, the Emotional Well-being and HIV subscales were marginally significantly different in groups differing in PSR ratings [Emotional $F(3,65) = 2.48$, $p < 0.07$; HIV subscale $F(3,62) = 2.65$, $p < 0.06$]. In the Spanish-speaking sample significant differences between PSR groups also were found for the Physical and Functional Well-being subscales and the FAHI total score [Physical $F(2,61) = 32.27$, $p < 0.0001$; Functional $F(2, 61) = 11.27$, $p = 0.0001$; FAHI $F(2,58) = 9.11$, $p < 0.0005$]. A marginally significant difference between PSR groups was found for Emotional Well-being [$F(2, 61) = 2.92$, $p < 0.07$]. Results from Scheffé and Tukey post-hoc comparisons can be found in Tables 5 and 6.

Sensitivity to change in mood

Using the TMDS of the Brief POMS as a criterion of mood change, we were able to test the sensitivity of the FAHI to change in mood over time. These results are presented in Table 7.

Table 5. One-way ANOVAs: FAHI by performance status ratings, English-speaking sample from BIOQOL study ($n = 70$)

Subscale	Physical****		Social/ Family*		Relation. with MD		Emotional		Functional****		HIV Subscale 1		FAHI** Total	
	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)
PSR = 0 ($n = 16$)	23.6	(4.0)	20.1	(5.9)	7.5	(0.8)	17.1	(2.7)	21.5	(3.1)	23.5	(6.2)	114.0	(14.8)
PSR = 1 ($n = 23$)	18.4	(5.3)	18.5	(5.0)	6.7	(1.8)	13.9	(5.8)	17.2	(6.5)	17.8	(6.5)	92.5	(23.2)
PSR = 2 ($n = 15$)	14.0	(4.5)	13.9	(7.5)	5.9	(2.6)	12.4	(5.0)	15.1	(5.6)	18.6	(7.4)	82.2	(23.7)
PSR = 3, 4 ($n = 16$)	13.1	(5.5)	15.4	(8.1)	6.8	(1.9)	14.2	(5.1)	11.6	(5.6)	18.1	(6.2)	79.2	(22.8)
post-hoc comparisons $p < 0.05$	0 > 1,2,3[s,t] 1 > 2[t] 1 > 3[s,t]								0 > 2,3[s,t] 1 > 3[s,t]				0 > 1,2,3s,t	

[s] Scheffé; [t] Tukey

*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$; ****$p < 0.0001$

Table 6. One-way ANOVAs: FAHI by performance status ratings, Spanish-speaking sample from BIOQOL study ($n = 64$)

Subscale	Physical****		Social/ Family		Relation. with MD		Emotional		Functional****		HIV Subscale 1		FAHI*** Total	
	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)
PSR = 0 ($n = 26$)	24.5	(3.1)	17.9	(7.1)	6.8	(1.5)	15.3	(4.4)	20.8	(6.4)	21.3	(6.4)	108.7	(23.7)
PSR = 1 ($n = 19$)	21.8	(3.5)	17.3	(6.5)	6.7	(1.7)	13.7	(5.0)	18.6	(5.3)	17.6	(6.3)	95.7	(22.9)
PSR = 2,3 ($n = 19$)	15.3	(6.2)	15.1	(5.4)	6.7	(1.4)	12.0	(4.3)	12.9	(4.6)	17.4	(3.8)	79.3	(18.6)
post-hoc comparisons $p < 0.05$	0 > 1,2[s,t] 1 > 2[s,t]								0 > 1,2s,t				0 > 2[s,t]	

[s] Scheffé; [t] Tukey

*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$; ****$p < 0.0001$

The sensitivity of the FAHI to changes in the TMDS from pre-intervention to immediate post-intervention was evaluated by linear tests for trend. *F*-values were significant for changes in psychological distress with the Emotional and Functional Well-being subscales and with the FACT-G and FAHI total scores. A non-significant trend in the predicted direction also was found on HIV subscale 1.

HIV subscale revisions

While the original (core) FACT-G was reliable, valid and sensitive in this HIV-infected sample, the 9-item disease-specific subscale did not appear to add substantially to data provided by the FACT-G. The internal consistency coefficients for the subscale were relatively low in all samples, suggesting that the additional concerns specifically related to HIV infection may be too diverse to be captured in a single, brief unidimensional index.

Two strategies were utilized in an attempt to improve the current HIV subscale.* First, correlations between the individual items of the HIV subscale and the subscale itself were examined to determine whether the internal reliability of the subscale might be improved by removing one or two items that correlated poorly with the rest. However, in no case did this improve the α significantly: the highest α obtained with this strategy was 0.65, only slightly higher than that of the 9-item subscale. The second

* These analyses were performed using the data from the English-speaking sample of the BIOQOL investigation.

Table 7. Sensitivity of the FAHI to changes in mood disturbance (TMDS, Brief POMS) from pre- to post-intervention ($n = 28$)

Scale/subscale	TMDS groups[†]	Mean change Score (SD)	Linear trend F (2,25)
Physical well-being	Decreased TMDS	0.6 (3.2)	$F = 0.52$, $p = 0.478$
	No change	1.3 (2.4)	
	Increased TMDS	–0.6 (2.4)	
Social/Family well-being	Decreased TMDS	1.1 (3.6)	$F = 1.44$, $p = 0.242$
	No change	1.1 (3.0)	
	Increased TMDS	–1.0 (3.4)	
Relationship with physician	Decreased TMDS	0.2 (0.4)	$F = 0.01$, $p = 0.944$
	No change	0.2 (0.6)	
	Increased TMDS	0.2 (1.5)	
Emotional well-being	Decreased TMDS	2.6 (2.3)	$F = 4.76$, $p = 0.039$*
	No change	1.0 (1.8)	
	Increased TMDS	0.6 (1.5)	
Functional well-being	Decreased TMDS	4.5 (5.4)	$F = 11.64$, $p = 0.002$**
	No change	0.5 (1.8)	
	Increased TMDS	–1.9 (3.8)	
FACT-G Total	Decreased TMDS	8.9 (4.1)	$F = 14.17$, $p = 0.001$**
	No change	4.0 (7.3)	
	Increased TMDS	–3.0 (7.5)	
HIV subscale 1	Decreased TMDS	2.0 (3.5)	$F = 3.17$, $p = 0.087$
	No change	2.2 (3.9)	
	Increased TMDS	–1.2 (1.8)	
FAHI Total	Decreased TMDS	10.9 (6.1)	$F = 12.83$, $p = 0.001$**
	No change	6.2 (10.0)	
	Increased TMDS	–4.2 (8.3)	

[†] Decreased TMDS $n = 10$; no change $n = 11$; Increased TMDS $n = 7$

* $p < 0.05$; ** $p < 0.01$

strategy employed was a principal components analysis with varimax rotation of the nine HIV subscale items to examine the possibility that several shorter, but more homogeneous, HIV subscales might be created. The principal components analysis resulted in three factors with an eigen-value > 1. Despite high factor loadings, the three factors were not readily interpretable on any conceptual or theoretical basis.

Because neither strategy resulted in significant improvement or apparent utility of HIV subscale 1, we chose to expand it to more fully capture the diverse illness-related issues that accompany HIV disease. While this lengthens the instrument, it should enhance internal consistency and thereby increase the probability that a single HIV subscale score can reliably be applied to future patient samples.

Using a process combining data reported herein, expert committee review and literature update, 11 new HIV-specific items were generated, creating version 3 of the FAHI. To address the issue of mental concentration, two items were added. Items reflecting concern regarding the effects of stress and feelings of self-consciousness about the disease also were

added. Studies are currently underway to evaluate these added items and psychometric data will be available shortly.

Discussion

These results provide converging evidence to support the use of the Functional Assessment of HIV Infection (FAHI) scale to measure health-related quality of life in HIV-infected individuals. This is particularly true for the 'core' instrument, the Functional Assessment of Cancer Therapy—General (FACT-G) scale. Internal consistency, concurrent validity and sensitivity to change data are comparable (and at times even superior) to those available with cancer patients. This should encourage the investigator interested in using the FACT-G to measure general quality of life in HIV-infected individuals. In diverse patient samples across two languages, the psychometric characteristics of the FACT-G core instrument range from acceptable to quite strong. This allows prospective investigators to exploit the advantages associated with the use of an established instrument developed for a similar life-threatening chronic illness, cancer. It should prove particularly useful when one wishes to compare clinical trial and clinical practice data for cancer vs. HIV-infected patients. It has already proven useful in the evaluation of experimental treatments for HIV-related malignancies, and has become the standard questionnaire within the Eastern Cooperative Oncology Group which conducts clinical trials in HIV-related malignancies.

Using the Sickness Impact Profile and Symptom Distress Scale, Ragsdale and Morrow[14] found that the greatest disruptions to patient quality of life were in the psychosocial (as opposed to physical) areas among patients with advanced HIV disease. In the current sample, quality of life in the physical and functional domains, but not psychological or social domains, was positively related to patient performance status (activity level) and negatively related to more advanced disease. Previously, we reported matched patient comparisons of HIV disease to cancer, suggesting that while Physical and Functional Well-being (as measured by the FACT-G) are higher in patients with HIV disease as compared to cancer patients, their Social Well-being was lower.[23] This speaks not only to the construct validity of the FACT-G and the importance of subscale measurement, but also to the nature of quality of life impairment in this population of patients.

Given the reduced psychosocial well-being of patients with HIV disease, interventions to offset distress and dysfunction are important. Our stress management intervention was associated with immediate post-intervention increases in the individuals' perceptions of the emotional well-being dimension of quality of life. Interestingly, the TMDS of the Brief POMS did not show comparable sensitivity to change induced by the stress management intervention,[30] and yet the FACT-G Emotional Well-being subscale is independently sensitive to changes in mood as measured by the TMDS.

Interestingly, the 9-item HIV subscale 1, designed to augment the FACT-G for use in the HIV treatment setting, did not appear to add significantly to the FACT-G foundation. This can be explained in at least three ways. First, the subscale was only subjected to a limited number of evaluations in a relatively small group of patients. Future studies of these questions may well find them to be of value in specific settings where the item content is relevant to the study aims or the target of an intervention. They were initially introduced because patient and expert interviews revealed them to be important yet inadequately sampled by the FACT-G.

Second, related to the relatively low internal consistency, it is possible that the diversity of issues related to HIV disease precludes the likelihood that such a subscale will ever emerge as a reliable indicator of a single underlying dimension. Although Nunnally[39] suggests a value of 0.70 as a lower acceptable bound for alpha, it is not unusual to see published scales with lower alphas.[40] This issue has been addressed by Helmstadter,[41] who points out that the adequacy of an internal consistency coefficient must be evaluated in terms of the homogeneity of the analysis group, the content measured, the success with which other similar instruments have eliminated error and the purpose of the test. The item content of HIV subscale 1 is diverse; by design the HIV subscale is a 'miscellaneous' category. There are no other similarly conceived measures that have demonstrated superior reliability, and the primary purpose of the test is to evaluate *groups* of patients rather than individuals. For such an application, alphas as low as 0.50 may be adequate. Applying Spearman's correction for attenuation, which is the basis for the rule of thumb that validity coefficients cannot exceed the square root of reliability, alphas as low as 0.50 still allow for validity coefficients as high as 0.70, higher than what is observed in most concurrent validity studies. This is not to say that the HIV subscale cannot be improved: in fact, we have done so in response to these findings. Testing of the longer, 20-item subscale which covers a fuller range of HIV-specific concerns is underway.

Finally, a third explanation for the lack of additional contribution of HIV subscale 1 to the FACT-G may be that the domain of additional concerns specific to HIV disease was inadequately sampled. As mentioned in the introduction, our assessment goal was to be as parsimonious as possible, given the constraints of the clinical medical setting, particularly as related to clinical trials. However, parsimony should never override adequacy of content coverage. Thus, to account for this last possibility, 11 new questions were added to the HIV subscale, resulting in a 55-item instrument, which can still be completed within 15 minutes by most patients.

In summary, the Functional Assessment of HIV Infection (FAHI) quality of life instrument has demonstrated sufficient internal consistency reliability, concurrent validity and sensitivity to change to encourage clinical trial and clinical practice investigators to use it in evaluating group differences and within-group change over time. Use of the instrument for individual patient measurement either at one or multiple time points should proceed with caution, however, due to the relatively low internal consistency reliability for some subscales, most notably the Social Well-being and HIV-specific subscales (HIV subscale 1). In general, the performance of the FACT-G in HIV disease is comparable and at times even superior to that of the FACT-G in cancer. The FACT-G should prove particularly useful when one wishes to compare clinical trial and clinical practice data for cancer vs. HIV-infected patients, and in the evaluation of treatments for HIV disease and HIV-related malignancy. Work continues toward improving upon the additive value of the HIV-specific subscale.

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Appendix

FAHI

Below is a list of statements that other people with your illness have said are important. By circling one number per line, please indicate how true each statement has been for you during the past 7 days.

PHYSICAL WELL-BEING	Not at all	A little bit	Somewhat	Quite a bit	Very much
1. I have a lack of energy	0	1	2	3	4
2. I have nausea	0	1	2	3	4
3. Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
4. I have pain	0	1	2	3	4
5. I am bothered by side effects of treatment	0	1	2	3	4
6. I feel sick	0	1	2	3	4
7. I am forced to spend time in bed	0	1	2	3	4

8. Looking at the above 7 questions, how much would you say your **physical well-being** affects your quality of life? **Circle one number**

0 1 2 3 4 5 6 7 8 9 10
Not at all — Very much so

SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Somewhat	Quite a bit	Very much
9. I feel distant from my friends	0	1	2	3	4
10. I get emotional support from my family	0	1	2	3	4
11. I get support from my friends and neighbors	0	1	2	3	4
12. My family has accepted my illness	0	1	2	3	4
13. Family communication about my illness is poor	0	1	2	3	4
14. I feel close to my partner (or the person who is my main support)	0	1	2	3	4
15. Have you been sexually active during the past year? No ___ Yes ___ If yes: I am satisfied with my sex life	0	1	2	3	4

16. Looking at the above 7 questions, how much would you say your **social/family well-being** affects your quality of life? **Circle one number**

0 1 2 3 4 5 6 7 8 9 10
Not at all — Very much so

RELATIONSHIP WITH DOCTOR	Not at all	A little bit	Somewhat	Quite a bit	Very much
17. I have confidence in my doctor(s)	0	1	2	3	4
18. My doctor is available to answer my questions	0	1	2	3	4

19. Looking at the above 2 questions, how much would you say your **relationship with the doctor** affects your quality of life? **Circle one number**

0 1 2 3 4 5 6 7 8 9 10
Not at all — Very much so

EMOTIONAL WELL-BEING	Not at all	A little bit	Somewhat	Quite a bit	Very much
20. I feel sad	0	1	2	3	4
21. I am proud of how I'm coping with my illness	0	1	2	3	4
22. I am losing hope in the fight against my illness	0	1	2	3	4
23. I feel nervous	0	1	2	3	4
24. I worry about dying	0	1	2	3	4
25. I worry that my condition will get worse	0	1	2	3	4

26. Looking at the above 6 questions, how much would you say your **emotional well-being** affects your quality of life? Circle one number

0 1 2 3 4 5 6 7 8 9 10
Not at all — Very much so

FUNCTIONAL WELL-BEING	Not at all	A little bit	Somewhat	Quite a bit	Very much
27. I am able to work (include work in home)	0	1	2	3	4
28. My work (include work in home) is fulfilling	0	1	2	3	4
29. I am able to enjoy life	0	1	2	3	4
30. I have accepted my illness	0	1	2	3	4
31. I am sleeping well	0	1	2	3	4
32. I am enjoying the things I usually do for fun	0	1	2	3	4
33. I am content with the quality of my life right now	0	1	2	3	4

34. Looking at the above 7 questions, how much would you say your **functional well-being** affects your quality of life? **Circle one number**

0 1 2 3 4 5 6 7 8 9 10
Not at all — Very much so

ADDITIONAL CONCERNS*	Not at all	A little bit	Somewhat	Quite a bit	Very much
35. I have been short of breath	0	1	2	3	4
36. I am self-conscious about my appearance	0	1	2	3	4
37. My thinking is clear	0	1	2	3	4
38. It is hard to tell other people about my infection	0	1	2	3	4
39. I have people to help me if I need help	0	1	2	3	4
40. I am bothered by a change in weight	0	1	2	3	4
41. I feel sexually attractive	0	1	2	3	4
42. I worry about spreading infection	0	1	2	3	4
43. I am concerned about what the future holds for me	0	1	2	3	4

44. Looking at the above 9 questions, how much would you say your **additional concerns** affect your quality of life? **Circle one number**

0 1 2 3 4 5 6 7 8 9 10
Not at all — Very much so

* Please note that this subscale is not recommended for general use, and has been supplemented with 11 additional questions which are undergoing further testing. Contact Dr. Cella for more information.