

## **Appendix D- Review of instruments assessing health-related quality of life**

**Excerpted from “A review of approaches and instruments for assessing health-related quality of life”**

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### **Part 1: Generic Instruments**

**WHOQOL-100** (World Health Organization Quality of Life 100 item questionnaire)

The WHOQOL-100, Hindi was designed to determine the impact that disease and health intervention has on QOL. One of the initial testing sites was in India at the New Delhi center as part of the WHOQOL project in 1997. The WHOQOL-100-Hindi categorizes 100 items in four dimensions (physical, psychological, social, and environmental health) and 24 facets. Each facet contains four items and is rated on a five-point scale. Also included is one facet examining overall QOL and general perceptions of health (The WHOQOL Group 1998). The WHOQOL-100, Hindi was reported to be qualified for use in health care settings to provide a comprehensive assessment of QOL (Saxena, Chandiramani, and Bhargava 1998).

Strengths: The WHOQOL-Bref has been developed through rigorous methodological development over a number of years for measuring quality of life in India (WHOQOL Group 1993). The main analysis found that data from 15 worldwide centers in developing and western countries supported the notion that some aspects of QOL are universal throughout different cultures (The WHOQOL Group 1999). Statistical analysis of the WHOQOL-100, Hindi questionnaire shows that there are basic factors inherent to quality of life worldwide and that they do not differ substantially across cultures. The WHOQOL-100, Hindi provides an internally reliable and valid method for assessing QOL. The WHOQOL is being expanded to test the universality of the WHOQOL-100, Hindi in other cultures beyond the initial 15 (The WHOQOL Group 1998). This instrument has been translated into Hindi, Tamil, and English (Prabha Chandra, personal communication, 23 September, 1999).

Limitations: The data were collected using a cross-sectional design and test-retest reliability in a longitudinal study has yet to be conducted, but this is currently underway. The sensitivity of this measurement is also currently being tested. Until longitudinal studies are conducted to determine further validity of this questionnaire it appears that the major limitation of this instrument is its long length.

**WHOQOL-BREF** (The WHO Quality of Life Abbreviated Questionnaire)

The WHOQOL-BREF, Hindi was developed to provide a brief version of the WHOQOL-100, Hindi for use in studies needing the practicality of a short questionnaire, in large-scale epidemiological studies, for audit, and clinical work and intervention evaluation (WorldHealth Organization 1997). The WHOQOL-Bref encompasses 24 facets and provides a profile of scores on four dimensions of quality of life: physical health, psychological, social relationships, and environment (The WHOQOL Group 1998). Each facet is rated on a five-point scale. This instrument also provides one global rating on QOL and general health.

Strengths: The WHOQOL-Bref has been developed through rigorous methodological development over a number of years for measuring quality of life in India (WHOQOL Group 1993). The WHOQOL-Bref, Hindi correlated well (at about 0.9) with the WHOQOL-100, Hindi. The WHOQOL-Bref, Hindi may adequately be used in place of the WHOQOL-100, Hindi because it includes items directly from each facet of the WHOQOL-100, Hindi. The WHOQOL-Bref, Hindi provides an aggregate score as well as scores in four quality of life related dimensions. The dimension scores exhibited good content validity, discriminate validity, test-retest reliability, and internal consistency. This instrument should provide a quick, useful alternative to the WHOQOL-100, Hindi where time is a consideration in administration and scoring of the instrument. It also covers a large number of domains that are integral for assessing QOL (WHOQOL Group 1998). The WHOQOL-Bref, Hindi is available in Tamil and is currently being developed for use in the Kannada language as well (Prabha Chandra, personal communication, 23 September, 1999).

Limitations: This instrument does not provide an assessment of the individual facets within the dimensions (Gill & Feinstein 1994; Saxena, Chandiramani, & Bhargava 1998). This instrument is longer than some other measures (i.e., the SF-12).

### **MOS (Medical Outcomes Study-derived quality of life measures)**

Questionnaires developed from the Medical Outcomes Study are the most widely used health status instruments in HIV research (Wu et al. 1997b). These measures include the MOS-HIV, SF-12, SF-20, SF-21, SF-36, SF-38, SF-56, and the HIV Cost and Service Utilization Study (HCSUS). There is also a version called the IQOLA being developed for international use. These questionnaires cover between two and 11 dimensions and utilize between 12 to 56 questions (as per their names). The MOS instruments generally take a short time to complete (<15 minutes) with sub-scales scored from 0-100. Most of these instruments provide overall scores and often include the separation of physical and mental health scores. In addition, there is extensive credibility for the construct and predictive validity, reliability, and responsiveness of these instruments as these instruments have been administered to over 20,000 patients (Wu et al. 1997a). The most commonly used instruments for HIV research are the MOS-SF-36, MOS-SF-20, and the MOS-HIV.

### **MOS-SF-36 (Medical Outcomes Study 36 item questionnaire)**

This multidimensional tool is the most widely used health status instrument worldwide (Hays & Shapiro 1992; Wood-Dauphinee 1999). This instrument uses a short 36 item questionnaire on eight dimensions:

physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, general mental health, social functioning, energy/fatigue, and general health perceptions. In addition to this, it provides a single item for perceived change in health. Items are scored and aggregated to provide a scale ranging from 0-100 (0 = poor health and 100 = good health).

Strengths: The SF-36 can be either self-administered or administered by a trained interviewer and takes about 5-10 minutes to complete (Bowling 1997). This questionnaire has high internal consistency and strong psychometric properties (Vanheem et al. 1996). The SF-36 has demonstrated high reliability (Hays & Shapiro 1992). The SF-36 has good responsiveness to change in clinical conditions (Bowling 1997). The results can be machine scored and has been evaluated in large population studies (Kaplan 1998).

Limitations: The sub-scales are not aggregated to give the global score making it more complicated to score. Mean scores are obtained on each sub-scale, which has a tendency to distort the results due to outlying values. The questionnaire has not been developed through extensive consultation with the general population. This questionnaire does not contain age-specific questions and may not be appropriate at each age level (Kaplan 1998). The bodily pain scale has been reported to show low convergent validity with severity of illness and independent pain scores. Furthermore, floor and ceiling effects have been reported for the SF-36 (Bowling 1997).

#### **MOS-SF20** (Medical Outcomes Study 20 item questionnaire [Short Form])

This instrument utilizes a brief 20-item questionnaire for assessing HRQOL in both a cross-sectional and a longitudinal design (Hays & Shapiro 1992). The SF-20 consists of six dimensions: physical functioning, mental health, role functioning, social functioning, health perceptions, and pain.

Strengths: Data for the SF-20 have shown high reliability and construct validity.

Limitations: The SF-20 has shown floor effects with hospitalized patients and contains no sexual dimension.

#### **IQOLA** (International Quality of Life Assessment Project)

The IQOLA project was designed to provide validated translations for use in international health research and multinational clinical trials. A modification of the MOS-SF-36, has been translated and adapted in 15 European countries (Sullivan, 1994). The IQOLA measures the same sub-dimensions as the MOS-36, but the questionnaire needed to be shorter so the SF-12 was adapted for use with two dimensions - physical and mental health (Gandek et al. 1998). This shorter version has high product moment correlations between the summary measures of the SF-36 and the SF-12 ranging from .94-.96 for the physical dimension and from .94-.97 for the mental dimension (Gandek et al. 1998).

Strengths: This project is currently being translated and developed for use in over 40 countries, including India and other developing countries (Gandek et al. 1998).

Limitations: Summary scores from the European countries differed from US measures necessitating further research into the IQOLA's cross-country compatibility (Gandek et al. 1998).

### **Nottingham Health Profile (NHP)**

The NHP has been influential in Europe and consists of two parts. The first part contains 38 items in six dimensions: sleep, physical mobility, energy, pain, emotional reactions, and social isolation. These 38 items are rated on level of relative importance, then rescaled to allow them to vary between 0 and 100 within each dimension (Kaplan 1998).

The second part includes seven statements related to health-affected areas of life: employment, household activities, social life, home life, sex life, hobbies and interests, and holidays (Kaplan 1998). For each statement, the respondent indicates if a health condition affected that area of his/her life. The instrument is self-administered.

Strengths: This questionnaire is short and easy to administer with patients or the general population. Many studies have provided evidence for this instrument's validity and reliability (Kaplan 1998). This instrument was derived from definitions of health given by lay people in the community and designed with easily interpretable language that meets minimum reading requirements (Kaplan 1998). This instrument is useful for the assessment of severe health problems (Bowling 1997).

Limitations: The NHP was not designed to measure HRQOL and does not make relative weights across dimensions available for comparing dimensions directly with each other (Kaplan 1998). Hunt (1984) pointed out that this instrument is not sensitive to detecting health conditions or mild symptom severity and diagnostic data would be needed to explain what kind of health problem was experienced (cited in Bowling 1997: 44). Furthermore, this instrument may not detect minor health improvements (Bowling 1997). The NHP focuses on negative experiences while excluding the positive experience of a condition or disease. In addition, some of the statements in the second part of the questionnaire may not be relevant for some populations (Bowling 1997).

### **SIP (Sickness Impact Profile)**

The SIP was designed as a measure of perceived health status to measure across demographic and cultural groups and to provide outcome measures for health care in a wide variety of health conditions and diseases (Bowling 1997). The SIP is a 136-item self- or interview-administered health status questionnaire that is behaviorally based and utilizes two HRQOL dimensions; psychosocial and physical. Everyday activities in 12 facets are measured and include: sleep and rest, emotional behavior, body care and movement, home management, mobility, social interaction, ambulation, alertness behavior, communication, work, recreation and pastimes, and eating. Patients mark items that describe themselves on that day in terms of individual health. The SIP is scored according to the number and type of items endorsed. Scoring

can be done for each facet, dimension and composite HRQOL with a range of 0-100 (the lower the score, the better the patients' health status) (Bowling 1997).

Strengths: The SIP may be interviewer- or self-administered. The SIP is able to discriminate between severity of sickness and has been reported to have good convergent and discriminant validity. The SIP has good test-retest reliability and high internal consistency. The SIP has been successfully used in clinical trials and can assess the impact of illness among the chronically ill (Bowling 1997).

Limitations: The SIP emphasizes dysfunction related to sickness in daily activities rather than disease and doesn't measure subjective QOL facets such as feelings. The SIP also doesn't measure positive functioning. The SIP takes about 20-30 minutes to complete and requires a large amount of time to train the interviewers. The results of the scores can be unclear and are sometimes positively skewed which doesn't allow it to clearly measure improvements in health. The SIP has also been reported to be insensitive to change over time and condition, yet these results are mixed (Bowling 1997).

### **FQLS (Fanning Quality of Life Scale)**

The FQLS is a scale designed for evaluating the impact of HIV infection on psychological and physical health, daily activities, social activities, relationship with healthcare provider, and personal identity (Vanheems et al. 1996).

Strengths: The FQLS has reported scores of acceptable validity and reliability. This scale included questions on relationships with friends/lovers (Vanheems et al. 1996).

Limitations: This is a relatively new instrument that needs to be validated in other populations and stages of disease (Vanheems et al. 1996).

### Global Indices

#### **A VAS**

A single item assessment of a patient's global health-related quality of life that uses a scale from 0-100 (worst imaginable health state to best imaginable).

Strengths: Provides a reliable, valid assessment of HRQOL that is easy to complete and has widely been used to assess patient outcomes.

Limitations: It only provides a global rating of HRQOL.

### *Patient-preference Scales*

#### **QWBS (Quality of Well-Being Scale)**

Developed to operationalize "well-being," the QWBS was an attempt to provide an alternative to a cost-benefit analysis (Bowling 1997). This standard HRQOL instrument combines mortality with quality of life estimates and gives a summary of health status as quality adjusted life years. The content of the QWBS

scale consists of three dimensions of daily activity: mobility, physical, and social activity. This instrument uses weighted scores that are then transformed into a single number. The QWBS quantifies HRQOL into a single number from 0-1 (death to perfect health). This instrument can also be scored and used to achieve a profile of scores

Strengths: This instrument can be applied to any disease and can be used in general populations. The instrument has good reliability, content, construct, and criterion validity. The QWBS gives an easy to understand overall impact of medical and mental health score for HIV patients. The QWBS has shown the ability to predict outcomes among HIV patients and includes death, which avoids having death appear to improve the health status of the population. This also permits the ability to distinguish between individuals with similar functional disability by weighting items to consider if the illness is terminal. The QWBS has been shown to correlate with functional ability and broader health status scales. The questionnaire takes about 10-15 minutes to complete and can be given to proxy respondents when a patient is unavailable. The QWBS's universality allows it to be used in policy analysis (Bowling 1997).

Limitations: The QWBS needs to have a meticulously trained interviewer to administer the questionnaire and the interview uses a long, 30-page manual (Bowling 1997). This instrument is weighted more toward physical aspects of HRQOL than psychosocial. This questionnaire also has no HIV specific questions (Hays & Shapiro 1992).

#### **Q-TWIST** (Time without disease symptoms and drug toxicity)

Assesses QOL and the quantity of life after adjustment. This instrument was specifically designed to estimate the ZDV impact on QOL (Vanhem's et al. 1996).

Strengths: The Q-TWIST estimates both quality of life and quantity of life at the same time (Vanhem's et al. 1996).

Limitations: May be difficult to apply outside of clinical trials because symptoms must be correlated with repeated biological tests, it has no psychosocial or behavioral dimensions and has no self-assessment items (Vanhem's et al. 1996).

### **Part 2: Specific Instruments**

#### **WHOQOL-HIV/AIDS** (World Health Organization Quality of Life HIV/AIDS module)

This module of the WHOQOL is designed specifically for use in the HIV/AIDS population. The WHOQOL - HIV/AIDS has been translated into Kannada, Tamil and Hindi (Prabha Chandra, personal communication, 23 September, 1999). Standardization of the instrument in India is currently taking place and should be completed in February 2000 (Miriam Lotfy, personal communication, 27 September 1999).

#### **MOS-HIV** (Medical Outcomes Study-HIV)

Taken from the MOS Short Form, this instrument is a brief, comprehensive 35-item HRQOL questionnaire. The MOS-HIV includes a global health assessment and these 10 dimensions of HRQOL: health perceptions, pain, physical functioning, role functioning, social and cognitive functioning, mental health, energy/fatigue, health distress, and quality of life. These scales discriminate between symptomatic and asymptomatic patients. The MOS-HIV is self-administered and takes a relatively short time (< 5 minutes) to complete. Subscales are scored on a 0-100 scale with 100 indicating better health (Wu et al. 1997c). This instrument also includes a single-item measurement to assess health transition. The MOS-HIV also provides both a physical and mental health summary score. The MOS-HIV has been used as a standard for hypothesis testing on newer instruments (Wu et al 1997c).

Strengths: The MOS-HIV provides good reliability with internal consistency reliability scores ranging from 7.0 to .92, most Chronbach alpha coefficients exceed .80 and it has good construct validity (Burgess 1993; Redvicki et al. 1998; Wu et al. 1997c). This instrument is sensitive to changes in QOL over time. The MOS-HIV has also demonstrated that it discriminates between groups, predicts outcomes, it correlates with concurrent measures of health and is responsive to change over time. This questionnaire also has acceptable reliability and validity across various demographic groups. The questionnaire is easy to administer, complete, and score. The MOS-HIV has been widely used in clinical trials and observational studies (Wu et al. 1997c). The MOS-HIV provides a profile of scores that is particularly useful in obtaining the detailed patient descriptions needed for cohort studies (Copfer et al. 1996). This instrument can be either self-administered or interview-administered.

Limitations: The MOS-HIV has shown ceiling effects, causing a potential lack of responsiveness. The MOS-HIV needs to be compared to other HIV specific measures of HRQOL (Wu et al. 1997b). The MOS-HIV needs to be compared to other HIV specific measures of HRQOL (Wu et al. 1997b).

### **Revised FAHI (Functional Assessment of Human Immunodeficiency Virus Infection)**

This instrument has been developed by combining the FACT-G for cancer and measures quality of life on the following sub-scales: physical well being, emotional well being, function and global well being, social well being, cognitive functioning, and three items reflecting both general illness and HIV/AIDS specific HRQOL concerns. This tool has recently been revised with content reflecting HIV/AIDS specific concerns that also include general chronic illness (Peterman, Cella, & McCain 1997). This tool is appropriate for clinical practice and trials and allows for both individual sub-scale scores and a global quality of life score (Peterman et al. 1997).

Strengths: This instrument has been shown to have good internal consistency (.91 for the total scale and ranged from .73 to .90 for the subscales), has strong construct validity, known group's validity and is sensitive to change. The FAHI has good psychometric properties that are broad in covering emotional and social concerns for HIV/AIDS patients that may be useful for asymptomatic patients or early stage HIV. This instrument contains the entire FACT-G (for cancer) and HIV/AIDS specific concerns, thus allowing for

cross-disease comparison. This instrument is short, easy to score, and has been translated into a nine languages (Peterman et al. 1997).

Limitations: Further investigation is needed to determine the validity of data for asymptomatic patients (Peterman et al. 1997).

### **HOPES** (HIV Overview of Problems/Evaluation)

This self-administered assessment tool is used to measure HRQOL and rehabilitation needs for HIV patients. The revised questionnaire consists of 142 items. Dimensions are divided into the following five classifications: physical, psychosocial, medical interaction, sexuality, and Partner. There is one dimension leftover that is miscellaneous. These dimensions can be added to provide a global score, profile scores of the six dimensions and summary scores of the 33 sub-scales (De Boer et al. 1996).

Strengths: The HOPES has demonstrated good internal consistency reliability and good face and content validity. This survey has convergent and item-discriminate validity and can discriminate between asymptomatic and symptomatic patients. The HOPES was also able to record changes in QOL over time and was responsive to CD4 counts over time. The HOPES allows for detailed reports of HIV infected patients' daily problems, it includes sexuality and health care worker relationships not generally captured in other HRQOL instruments (De Boer et al. 1996).

Limitations: The revised HOPES is a long, detailed survey that may require some assistance in filling out. The global score did not change over time, indicating that it may be necessary for the global assessment to be validated by checking the summary scales (De Boer et al. 1996).

### **MQOL** (Mcgill Quality of Life Questionnaire)

Consisting of 16 questions, the MQOL measures existential concerns (freedom, meaning of life, death) with little emphasis given to physical functioning. This self-administered questionnaire attempts to determine positive effects from HIV/AIDS.

Strengths: Short questionnaire that has good validity.

Limitations: Has only acceptable reliability ratings and must be used with other instruments.

### **AIDS-HAQ** (Health Assessment Questionnaire)

The AIDS-HAQ includes nine subscales: disability, energy, general health, pain, cognitive functioning, mental health, social functioning, health distress and symptoms.

Strengths: This instrument has demonstrated the ability to distinguish between the severity of disease. The subscales have high internal consistency (.79-.88) and it demonstrated concurrent validity as decrements with disease progression on all domains except cognitive functioning was significant. This instrument provided a thorough assessment of HRQOL in early HIV+ individuals. This instrument may be

useful for assessing within group changes and comparing group differences in observational research (Lubeck & Fries 1997).

### **HAT-QOL** (HIV/AIDS-Targeted Quality of Life Instrument)

This instrument is one of the first HIV/AIDS targeted QOL questionnaires that was developed with QOL concerns given by individuals with HIV/AIDS (Homes & Shea 1998). Nine dimensions were identified for measuring quality of life in HIV/AIDS patients: overall function (OF), sexual function (SF), disclosure worries (DW), health worries (HW), financial worries (FW), HIV mastery (HM), life satisfaction (LS), medication concerns (MS) and provider trust (PT).

Strengths: Results of a study by Holmes and Shea (1997) found that the psychometric properties were good on dimensions of OF, DW, HW, FW, and LS for asymptomatic HIV seropositive individuals. Assessments for validity using HIV disease severity and sociodemographic variables indicated expected relationships across all dimensions of the instrument. This tool displays good psychometric properties with low floor and ceiling effects, good internal consistency, and there is evidence for construct validity. (Holmes & Shea 1998)

### **MQOL-HIV** (Multidimensional Quality of Life Questionnaire-HIV/AIDS)

The MQOL-HIV is a multi-dimensional HRQOL measure designed for PLHA. This instrument utilizes 40 items on 10 HRQOL dimensions: physical function, medical care, social support, physical health, cognitive function, intimacy, social function, finance, sexual function, and mental health.

Strengths: The questionnaire may be self administered or interview-administered and can be completed in less than 10 minutes. This instrument has been shown to be internally consistent, reliable, and sensitive to symptom change over time. The MQOL-HIV may be helpful by supplementing clinical measures of HIV/AIDS (<http://www.neri.org/HTML/INSTRU/instmqol.htm>)

### *Function specific Instruments*

#### **KPS** (Karnofsky Performance Scale)

The KPS is widely used in HIV-related clinical trials to assess health status in HIV medicine and research (O'Dell et al. 1995). The Karnofsky Performance Scale assesses physical function, symptoms and ability to work, which are aggregated to provide a global rating scale from 0 to 100 (normal to moribund).

Strengths: The KPS is relatively simple to use and values are easily obtained. The KPS is often used in addition to other instruments because it is simple and fast to complete. The KPS has high predictive validity; for example, low-moderate KPS scores predicted low survival in Aids patients (Bowling 1997; O'Dell

et al. 1995). Use of the KPS with the QWBS has permitted efficacious treatment assessment in clinical trials (Vanheems et al. 1996).

Limitations: The Karnofsky Scale gives only information on physical dysfunction and doesn't give information on well being, social, or psychological dimensions (Bowling 1997; O'Keefe & Wood 1996). It is often criticized for its lack of metric examination and ceiling effects for some individuals. The KPS may have difficulty assessing clinical change over time (O'Dell et al. 1995). The procedure for scoring the instrument has not been validated (Bowling 1997). The KPS is strongly weighted toward physical dimensions of QOL and has shown mixed results when tested for inter-rater reliability (Bowling 1997).

### **ADL** (Index of Activities of Daily Living)

One of the oldest disability scales, the ADL index developed by Katz et al (1963) was developed to describe functional states of elderly patients (cited in Bowling 1997: 25). It is currently used for assessing health status for health care needs. This scale has patients rank five categories of 'need': no disability, restricted activity with no chronic conditions, restricted activity with chronic condition, mobility limitations and bed disability (Bowling 1997). Patients are rated on ordinal scales by interviewers on the ability to bathe, dress, transfer (or move to a chair, use the toilet, continence and feed oneself. Unweighted individual scales are aggregated to provide an composite single score (Bowling 1997).

Strengths: This scale was able to predict mortality. It is a useful index that has had widespread use.

Limitations: Using a single index reduces variability information. There isn't much evidence for validity. ADL scores for mobility provided moderate correlation (.50), while house confinement was very low (.37). This index is not sensitive to minor changes in severity of disease and it doesn't take into consideration how one adapts to one's environment. Few tests of reliability have been conducted and it doesn't have strong inter-rater reliability. The range of disabilities are not complete (Bowling 1997).

### *Condition-Specific Instruments*

#### **EORTC QLQ-C30** (European Organization for Research and Treatment of Cancer-Quality of Life Questionnaire-HIV adaptation)

The QLQ-C30 is a 30-item questionnaire that is self-administered. This instrument was first developed for use with cancer patients. The C30 uses five functional scales, (physical, role, emotional, cognitive and social functioning), three symptom scales (pain, fatigue, and nausea and vomiting) and a global QOL scale. HRQOL is scored on a 0-100 scale.

Strengths: This instrument takes less than 10 minutes to complete and has shown acceptable levels of validity and reliability. The instrument will be available in Hindi. Scales were able to assess distinct dimensions of HRQOL (<http://www.atsqol.org/instframe.html>).

#### **FACT-G** (Functional Assessment of Cancer Therapy-General questionnaire)

This standard HRQOL assessment is administered to cancer patients and other patients with life threatening conditions. HRQOL measurement is on four dimensions: Physical, social/family, emotional, and functional well-being. This 27-item instrument may be summed to produce profile scores and an overall QOL score (Cella et al. 1996).

Strengths: The FACT-G is short (<5 minutes) and easy to administer. The FACT-G has been validated in over 2000 patients with cancer and has high internal consistency. This instrument has the ability to differentiate between patients according to disease stages and is sensitive to change over time. The FACT-G is a 'core' instrument that can also be combined with an HIV component to create the FAHI (Functional assessment of HIV) (Cella et al. 1996). The FACT-G has been translated into many languages.