ABSTRACT

Background. Quality of life is becoming an important component of overall assessment in health care settings. However, satisfactory instruments are not available for use in India.

Methods. Qualitative and quantitative work was conducted at the Delhi centre as a part of the WHOQOL (World Health Organization Quality of Life) project at 15 centres in developing and developed countries to construct a new quality of life instrument (WHOQOL). The pilot field trial at Delhi was conducted on 304 adult subjects using the 236-item questionnaire.

Results. Based on the pilot field trial data, item reduction could be done to develop a 100-item version (WHOQOL-100, Hindi). The items are distributed into 4 domains (physical; psychological, social and environmental health) and 25 facets. Each facet has four items, rated on a five-point scale. The initial psychometric properties of this instrument are satisfactory. A 26-item short version has also been developed (WHOQOL-Bref, Hindi).

Conclusion. The WHOQOL-100, Hindi appears to be a suitable instrument for comprehensively assessing quality of life in health care settings. WHOQOL-Bref, Hindi can be used for intervention studies including drug trials.


INTRODUCTION

Diseases affect human life in a profound way. They cause premature death resulting in decreased ‘quantity’ of life, but more often they cause structural and functional limitations that may seriously affect the ‘quality’ of life. Death is easier to identify and record; hence mortality has been a standard method for quantifying the impact of diseases. Quality of life (QOL) has been difficult to measure, hence its use in health care settings has been comparatively recent.

Assessment of QOL has several uses in health care. It provides a measurement of functioning and well-being rather than of diseases and disorders, hence is more comprehensive and compatible with the WHO’s (World Health Organization’s) concept of health.1 It can guide appropriate management strategies2-5 and also act as one of the outcome measures for comparing them.6-7 including drug trials.8-13 QOL assessment focuses attention on aspects of a patient’s life beyond symptoms and signs. It thus sensitizes health care personnel to look for and correct direct and indirect effects of disease and treatment on individuals. QOL also helps in policy research including programme evaluation and resource allocation.14,15

Quality of life assessments have been used most widely in the area of malignancies16-18 though now their use has become common in a number of other diseases and conditions including diabetes,19,20 hypertension,2,3,21,22 chronic diseases such as arthritis and bronchitis,23-25 mental illnesses,26-29 substance abuse,30 cerebrovascular disease,31 renal disease,32,33 head injury,34 and old age.35

Most instruments used for assessing QOL were constructed in the developed countries of North America and Europe36 and their cross-cultural compatibility has not been demonstrated. This makes their direct application in developing countries questionable. Adaptation and translation of these instruments for use in diverse cultural and linguistic settings poses serious methodological problems.37-40 Simultaneous development in different cultures and languages has been suggested as an appropriate method for ensuring cross-cultural applicability.39,41

QOL assessment has been extremely rare in India.42-44 One of the important reasons for this is non-availability of a suitable instrument. The subjective Well-being Inventory45 has been developed as a QOL instrument in India, but it appears to be more suitable for the general population than for ill patients seen in health care settings.

This paper presents the process involved in developing a QOL instrument (WHOQOL-Hindi) in collaboration with the WHOQOL Group, Division of Mental Health and Prevention of Substance Abuse, World Health Organization, Geneva. The WHOQOL was developed simultaneously in 15 centres across the world. Common elements of methodology and results are described in detail in a series of papers by the WHOQOL Group.13,46-54 The present paper focuses specifically on the work done at the Delhi Centre, which led to the development of WHOQOL-Hindi.

The concept and definition

There has been lack of clarity in the concept of QOL, with different groups of workers using the term in widely different ways.14,55,56 There is also some overlap between functional status, health status, subjective well-being, health-related QOL and subjective QOL. WHO has defined QOL as ‘individuals’ perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns’.49 It is believed to be a broad concept incorporating in a complex way an individual’s physical health, psychological state, level of independence, social relationships, personal beliefs and her/his relationships to salient features of the environment. The definition highlights QOL as a subjective self-
report from the individual which is not based on reports or judgment from others (e.g. family members, clinicians). QOL is also multidimensional, incorporating positive (e.g. feeling happy, contented, energetic) as well as negative aspects (e.g. not having pain, sadness, sexual difficulties).

Though consequences of disease affect QOL in a major way, these are not themselves assessed while measuring QOL. Only the effects of these symptoms on a person’s life are assessed. This method of measuring QOL by generic questionnaires is conceptually more sound because a number of mediating factors determine how much and what kind of effects a disease will have on a person’s QOL. These factors include personal and environmental contextual variables. For example, a knee injury may limit joint movement. For a young man whose aim in life is to become a professional football player, this disability seriously affects his QOL. But for another person whose profession involves mainly reading and writing, the same disability affects the QOL to a lesser extent. Hence, a QOL questionnaire aims to assess the extent to which significant aspects of a person’s life have been affected, rather than what symptoms and disabilities are present. This concept of measuring QOL also makes it easier to construct a generic instrument that can be applied to individuals suffering from illnesses of diverse nature and severity, than to devise an instrument for each condition separately.

METHODS

Development of WHOQOL

Preparatory work. Each step involved in the development of WHOQOL was carried out simultaneously in many centres of the world. These 15 field centres (from developing and developed countries) were selected to take into account the variations in different cultures (e.g. level of industrialization, available health services, etc.).

The first step consisted of establishing an agreed upon definition of QOL. Important characteristics of QOL construct were identified, with special emphasis on cultural relevance. A list of domains and facets were then drafted by each centre. Six broad domains were identified which describe core aspects of QOL cross-culturally (physical, psychological, level of independence, social relationships, environment and personal beliefs/spirituality). Domains were further classified into a number of facets, e.g. psychological domain included facets that assess positive feelings, body image, self-esteem, thinking, memory and concentration, and negative feelings. Facets describe behaviour (e.g. personal relationships), states of being (e.g. fatigue), capacities (e.g. ability to move about) or subjective perceptions of experiences (e.g. pain).

The next stage involved group interviews (focus groups) with patients, well persons and health personnel in each of the field centres, to evaluate the appropriateness of the facet definitions drafted by health professionals and QOL researchers. Based on these reports, the facet definitions were revised. Questions were drafted by focus groups. Thus ideas were generated, within each centre, as to how and in which form questions relating to QOL should be asked. Following the focus group work, a question writing panel in each centre framed a maximum of six questions in their own language. This process ensured that the questions were raised by both health personnel and patients in each of the centres. A conceptual distinction was made between two types of questions: ‘perceived objective questions’, i.e. global evaluation of functioning (e.g. How well do you sleep?) and ‘self-report subjective questions’ i.e. perceived satisfaction/dissatisfaction with functioning (e.g. How satisfied are you with your sleep?). The ‘global question pool’ of some 1800 items was reduced to a set of 1000 items, after excluding duplicate and semantic equivalent questions. These questions were ranked ordered for each facet according to ‘how much it tells you about a respondent’s QOL in your culture’. Questions were further eliminated from the combined ranking for all centres.

Similar care was taken to generate cross-culturally comparable response scales. Each item was rated on a 5-point response scale concerned with intensity (not at all–extremely), capacity (not at all–completely), frequency (never–always) and evaluation (very satisfied–very dissatisfied, very good–very poor). Although endpoints (e.g. never–always) are relatively universal, ambiguity and cultural variations exist for intermediate responses. Descriptors were derived to find words/terms falling at 25%, 50% and 75% positions between the two end-points. Details of these exercises have been described elsewhere.

The pilot field trial

The pilot instrument contained 236 questions covering 6 domains and 29 facets of QOL. This was based on approximately 8 questions per facet; 4 ‘perceived objective’ questions and 4 ‘self-report subjective’ questions. Some of these questions were generated at the Delhi centre and were in Hindi. Others were translated into Hindi according to the WHOQOL translation methodology. In addition, 21 national questions were incorporated in the instrument (Table 1). These questions were selected from a larger list of items developed at the Delhi centre. The items were thought to be culturally relevant but could not be included in the international pilot version.

A cross-sectional design was used to field-test the pilot questionnaire on at least 300 subjects in each field centre. At the Delhi centre, 304 adult subjects were drawn from the Hindi-speaking population.

<table>
<thead>
<tr>
<th>Table I. List of national questions</th>
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<tr>
<td>1. To what extent have you achieved your desired position in life?</td>
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<td>2. How much do you worry about your health?</td>
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<tr>
<td>3. How satisfied are you with your ability to fulfill the sexual needs of your life partner?</td>
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<td>4. How satisfied are you with the number of children you have?</td>
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<td>5. How satisfied are you with your children being sons or daughters?</td>
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<td>6. Do you feel yourself a burden on others?</td>
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<td>7. How satisfied are you with the complexion of your skin?</td>
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<td>8. To what extent are you fed up with life?</td>
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<td>9. To what extent do you feel guilt and remorse?</td>
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<td>10. Does expenditure on medicines cause you financial difficulty?</td>
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<tr>
<td>11. Does expenditure on tobacco, alcohol or intoxicating drugs cause you financial difficulty?</td>
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<td>12. To what extent are you able to express the feelings of your mind in front of others?</td>
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<td>13. To what extent do you feel yourself an integral part of your family?</td>
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<td>14. How satisfied are you with the way responsibilities are shared within your family?</td>
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<td>15. To what extent do you remain worried about your family?</td>
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<td>16. To what extent can you fulfill the needs of your family?</td>
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<td>17. To what extent do you have to ignore your own needs for the sake of others?</td>
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<td>18. How satisfied are you with your capacity to bear sudden major expenses?</td>
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<td>19. To what extent are you able to get essential medical services with the money available with you?</td>
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<tr>
<td>20. To what extent does lack of cleanliness in your physical environment distress you?</td>
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<tr>
<td>21. To what extent do you feel your spiritual beliefs come in the way of your desired activities?</td>
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speaking population; the size being based on the required number of subjects per cell (generated by the sampling quota) needed for analysis of the pilot data. The sampling quota was as follows:

1. **Age** (50% ≤45 years, 50% ≥45 years)
2. **Sex** (50% male, 50% female)
3. **Health status** (250 persons with disease or impairment; 50 well persons)

Purposive sampling was followed in data collection and the sample was not representative of the patient and healthy population at the centre. Of 304 adults, 50.7% were males. The mean (SD) age of the sample was 40.7 (14.3) years. Two hundred and fifty-three persons comprised the ‘unwell’ group. Persons with illness or impairment were outpatients and inpatients from medical and surgical departments of the All India Institute of Medical Sciences (AIIMS), with problems ranging from very mild (e.g. fever, headache, etc.) to severe (e.g. malignancies, renal failure, etc.). Patients with neurological and psychiatric illnesses were not included in the sample. Fifty-one ‘well’ respondents were recruited from amongst the relatives of the patients in the hospital and the general community.

The instrument was largely self-administered. The subjects who were illiterate or had a disability that interfered with self-administration of the questionnaire, were administered the WHOQOL as a structured interview. The subjects were assessed cross-sectionally. Forty-one questions concerning perceived importance of facets were also asked in a separate questionnaire to the same respondents.

**RESULTS**

The data obtained from the New Delhi centre as well as other centres (n = 4802) were analysed with the aim of striking a balance between a minimum number of facets/questions and adequate coverage of key areas across cultures. The selection of items was based on the analyses done at the level of individual field centres, summaries across centres and at the level of the pooled global data.

The analyses carried out at item, facet and domain level for elimination/selection of items/facets is briefly summarized below:

1. **Frequency problem.** Items that had two or more adjacent scale points showing < 10% of the response were deleted. Such problems were present in 43 items.
2. **Reliability problem.** Problems of low item–total correlation (< 0.40) with their own facets led to the deletion of that item. Eleven items had a reliability problem. However, these items were eliminated only if they had problems in the global analyses or in at least 8 centres.
3. **Overlapping.** Fifteen items which overlapped conceptually with other items were deleted.
4. **Multitrait analysis programme (MAP) problems.** MAP analysis was carried out in order to identify items that had higher loadings on another facet rather than on its own predicted facet. No item showed this pattern. However, 7 items that were highly loaded (r > 0.40) on more than one facet were identified and 6 finally eliminated.

Facet and domain inter-correlations were examined. Sexual activity of the physical domain was moved to the social relationship domain. Facets were found to be fairly independent of each other.

5. **Re-analysis for reliability (item–total facet correlation) problem in each centre.** Eleven items that showed non-significant or negative correlations in any centre were excluded (with one or two exceptions). In the Delhi data, 24 items had low correlations (< 0.40).

6. **Validity problem.** Twenty-four items were eliminated as they failed to distinguish significantly between the ‘sick’ and ‘well’ respondents. In the Delhi data, only one item failed to discriminate between the two groups and was eliminated.

The analyses did not suggest that the national questions performed better than the general questions and hence were eliminated. Five problematic facets (activities as provider/supporter, sensory functions, dependence on non-medical substances, communication capacity and work satisfaction) were identified and dropped.

Some facets were excluded because responses to these items were highly skewed (activities as provider/supporter, dependence on non-medical substances, and communication capacity). Further, in facet activities as provider/supporter, nearly half the items showed reliability problems. Two items correlated well with another facet (personal relationships) and hence were moved to this facet. Communication capacity also had reliability problems (low item–total correlation and facet–domain correlation). Sensory function was dropped primarily due to low facet–domain correlation. Items of work satisfaction facet discriminated poorly between ‘sick’ and ‘well’ persons. Some of these items also had problems of low correlations (facet–domain correlations and items–global QOL correlations).

Though some of the facets (e.g. sensory functions, communication capacity) are likely to be important for assessing QOL, the items of these facets could not compete with other items in the global pool. Hence, they were excluded from the generic version of the core instrument and for having poor psychometric properties. Nevertheless, these items are being explored in add-on modules that are being developed for assessing people with specific conditions/situations/diseases (HIV, cancer, refugees, informal care-givers, individuals with communication difficulties, etc.) in which the core module does not provide sufficient detail. For example, the items of sensory functions were thought to be pertinent in the elderly group. Items related to activities as provider/supporter may be explored in the ‘carer group’.

Thus, the analyses of the WHOQOL pilot data eliminated some items and facets, resulting in the development of the WHOQOL field trial form comprising 100 questions grouped into six domains.

Further, multivariate analyses were carried out to confirm the domain and facet structure of the WHOQOL-100. It also examined whether this universal structure could describe most aspects of people’s QOL.

Earlier exploratory and confirmatory factor analyses carried out on the global data (using structural equation modelling) had shown the comparative fit index (CFI) for single-factor model and six-domain model to be 0.875 and 0.888, respectively (CFI > 0.9 is considered to be a good degree of fit). Analyses (on new global data sets) also provided some evidence that a four-domain solution may be the most appropriate (CFI=0.901). The four-domain structure was obtained by merging physical health with the level of independence; and psychological with spirituality domain. Similar analysis of the Delhi data for four-domain structure indicated the CFI to be 0.876 (Table II). By allowing error variances to covary for the environment and social relationships domains, the CFI increased to 0.991, thereby improving the fit index and indicating acceptability of the model in the Hindi-speaking population. In addition, when each of the domains of
WHOQOL-100, Hindi were analysed separately keeping only one factor upon which all facets loaded, the CFI on all the four domains ranged between 0.922 (environment domain) to 0.982 (psychological domain) (Table II). Further analyses to assess other possible structures on new data sets using WHOQOL-100, Hindi are required.

Multiple regression analyses confirmed the four-domain structure (R²=51.9) of WHOQOL-100, Hindi with each domain contributing significantly towards the regression equation (Table II).

The psychometric properties of the WHOQOL-100, Hindi were examined following a series of subscale reliability analyses, and item, facet and domain correlation analyses. Cronbach alpha was found to be moderately high for most of the facets (Table III). All facets correlated significantly with their respective domains. All the facets and domains also correlated significantly with the overall QOL score ranging from r=0.18 (environment) to r=0.65 (psychological). In addition, all items distinguished significantly between the ‘diseased’ and the ‘healthy’.

Thus, the series of analyses at different levels refined the structure of the pilot form into WHOQOL-100 that had satisfactory psychometric properties.

Structure of WHOQOL-100
The WHOQOL-100, Hindi instrument encompasses 24 facets and one general facet that questions overall QOL and health. Each facet is represented by four questions. These facets are grouped into 4 large domains: physical, psychological, social relationships and environment (Table IV).

The period of reporting for all questions is two weeks. This is mentioned in the scale at the beginning of each section (a total of eight times) to ensure that the respondents kept the time-frame of two weeks in mind while responding to each item. All items are rated on a five-point scale (1-5). The WHOQOL-100, Hindi produces individual facet scores (e.g. positive feeling score, social support score, etc.), domain scores (e.g. psychological domain score) and a score relating to overall QOL and general health.

Structure of WHOQOL-Bref, Hindi
Although the WHOQOL-100 provides a comprehensive assessment of QOL, its length can limit its use. As a result, an abbreviated version (WHOQOL-Bref, Hindi) of 26 items was developed using data from the field-trial version of the WHOQOL-100. The WHOQOL-Bref contains two items from the overall QOL and general health, and one item from each of the remaining 24 facets included in the WHOQOL-100. (The WHOQOL-100 and WHOQOL-Bref questionnaires along with details of instructions, headers, question order, response scale and scoring method are available from the corresponding author.)
WHOQOL-Bref, Hindi produces an aggregate score and four domain scores but does not provide individual facet scores. Domain scores produced by the WHOQOL-Bref have been shown to correlate at around 0.9 with the WHOQOL-100 domain scores, and hence provide an excellent alternative to the assessment of domain profile using WHOQOL-100. The brief scale is also likely to be useful in busy clinics and wards since it takes only 5–8 minutes to complete. It can also be conveniently used in studies which assess QOL longitudinally at several time intervals.

The scale has been shown to have good discriminant validity, sound content validity and good test–retest reliability at several international WHOQOL centres. Despite the heterogeneity of facets included within domains, all domains display excellent internal consistency. Acceptable comparative fit indices were achieved when the data from original pilot, field trial and new centres (CFI= 0.906, 0.903 and 0.87, respectively) were applied to the four domain structures using confirmatory factor analysis. When three pairs of error variances were allowed to covary (i.e. Pain and dependence on medication, Pain and negative feelings, Home and physical environment) and two items were allowed to cross-load on other domains (i.e. safety on the global domain and medication negatively on the environment domain), the CFI of new data also increased to 0.901.54

DISCUSSION
Quality of life is often regarded as a concept that is too nebulous to be measured reliably with a structured questionnaire and is subject to too much variability across cultures and individuals to have any useful validity. The WHOQOL project has shown that both these assumptions are incorrect. This international project has demonstrated that QOL can be conceptualized and defined in a uniform way across cultures. It's constituent core domains and facets can be assessed using structured questionnaire methodology, and cross-cultural as well as intra-cultural comparisons can be made. These developments are of major significance to health care professionals, who aim not only to prevent and treat diseases but also to promote health and QOL.

WHOQOL-Hindi is available in two versions, the long 100-item version (WHOQOL-100, Hindi) and the brief 26-item version (WHOQOL-Bref, Hindi). The long version assesses QOL comprehensively and is a suitable instrument for use in studies where QOL is the only or the main determinant. Since it gives a profile of domain scores, effects of a disease or intervention on separate domains (e.g. physical v. psychological) can be studied. For example, WHOQOL-100 may be suitable in a study which compares the survival time and QOL of cancer patients on a new, more aggressive chemotherapy regimen compared to the standard treatment. On the other hand, WHOQOL-Bref may be useful in studies which incorporate QOL as one of several variables or where multiple assessments over a period of time are envisaged. For example, a new antihypertensive drug may be as effective in lowering blood pressure as an older drug, but if QOL is used as one of the longitudinal outcome variables, patients on the new drug may score higher/lower, indicating its superiority/inferiority.

QOL assessment clearly does not replace the existing outcome variables. Mortality and morbidity measurements (e.g. survival rates, symptom-rating scales, disability questionnaires) are all useful, but QOL can be an additional outcome variable giving information about the individual's life that other variables cannot. Since QOL is a relatively stable state (the period of reporting in WHOQOL is 2 weeks), it is not a suitable assessment in studies where short term effects over hours or days are being studied.

Besides use in research studies, WHOQOL can be used in clinical practice to determine the impact of disease, disability and treatment modalities on patients. Specific modules that are being developed as a supplement to the core instrument are likely to lead to a greater understanding of the diverse effects of diseases experienced by the patients on their lives. They may also guide towards better and more comprehensive management strategies, including psychosocial interventions.

In contrast to many other QOL instruments, WHOQOL includes a domain on environment. This is considered necessary as environment plays a major role in determining health states, mediating disease pathogenesis and limiting or facilitating access to health care. Like all other domains in WHOQOL, environment domain is also assessed by a subjective self-report with the underlying belief that even if subjective reports are at variance with objective reality, it is the former that determines QOL.

Since WHOQOL has been developed simultaneously in many centres across the world and the different language and national versions are compatible and comparable with each other, multicentre international studies can be conducted using this instrument. In India, besides Hindi, a version in Tamil is available and a version in Kannada is being developed. WHOQOL cannot be used in other languages after simple translation, but fresh versions can be developed (e.g. for other regions of India) using the WHOQOL methodology.54 This includes preparatory qualitative research followed by a pilot field trial to ensure cultural and linguistic equivalence of different versions.

Although on initial assessment, the psychometric properties of WHOQOL-100 and WHOQOL-Bref appear satisfactory, more studies are needed to determine the reliability, validity and responsiveness to change of these questionnaires. These studies should preferably be from diverse clinical populations to ascertain the suitability of WHOQOL-100, Hindi and its goodness of fit in these settings. Large general population studies are also needed to establish norms for comparison purposes.

WHOQOL-Bref provides a shorter alternative to the assessment of QOL based on the WHOQOL domain profiles. However, analyses on varied data sets are required for replication of selection of items at the Delhi centre.

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