

## Validation of the WHOQOL-100: Pain Management Improves Quality of Life for Chronic Pain Patients

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### Abstract:

**Objective:** The study aimed to validate a new, multidimensional, multilingual instrument (the WHOQOL-100) for assessing QOL in chronic pain patients.

**Methods:** Chronic pain patients (N = 106) who agreed to participate in an established pain management program (PMP) were assessed for quality of life (QOL) before and one month after the intervention. The WHOQOL-100 is a generic profile containing 25 facets of QOL organized in 6 domains. It was administered concurrently with the MOS Short Form-36, the Beck Depression Inventory, and measures of pain intensity, duration, disruption and distress.

**Results:** The patients were outpatients and inpatients with a mean age of 44 years and mean pain duration of 8 years. The sample included 70 (66%) women. After the PMP, QOL had significantly improved generally, and in the physical, psychological and independence domains, as well as in 10 facets of QOL including pain and discomfort. Good QOL is consistently associated with low levels of pain severity and pain distress and little pain disruption. Overall internal consistency reliability was good and for most facets and domains but marginal for the pain facet. When compared with the SF-36, the WHOQOL-100 shows good concurrent validity, greater comprehensiveness and very good responsiveness to clinical change.

**Discussion:** The WHOQOL-100 indicates significant improvements to QOL for those entering a PMP and is validated for the clinical assessment of chronic pain patients and for use in multi-national clinical trials, clinical governance and audit.

**Key Words:** Pain—Pain management—Quality of life—Validity—WHOQOL.

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Despite current economic imperatives, for many clinicians improving quality of life (QOL) is still an important aim of care when treating chronic illnesses. Quality of life outcomes are relevant in many situations but especially in the assessment of treatment where there is only partial recovery, where symptoms are in remission, and where palliative care is needed. Although QOL is often claimed to be an important consequence of pain relief, closer scrutiny of the literature shows that until quite recently it has been infrequently included in con-

trolled, randomized clinical trials as a measure of outcome in pain research and, even more rarely, as a secondary outcome measure. Its importance in outcome measurement is now recognized by the Food and Drugs Administration where its inclusion is required in U.S. randomized, controlled trials.

Implicit in some types of assessment is the view that QOL can be evaluated by assessing a patient's physical state (by counting the number of yards walked,<sup>1</sup> for instance). Others treat QOL as a subjective phenomenon, where it is acknowledged that accurate assessment relies on knowing the meaning and importance of different features of QOL to respondents. These interpretations will vary widely between persons, and hence we take the view that QOL can only be adequately assessed by

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Received April 7, 2001; accepted as revised June 26, 2001.

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asking people about their lives. Quality of life is defined as “an individual’s 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. It is a broad-ranging concept, incorporating in a complex way an individual’s physical health, psychological state, level of independence, social relationships, spiritual, religious and personal beliefs and their relationship to salient features of the environment.”<sup>2</sup>

It is also debatable as to whether QOL should be assessed as a process or whether it should be an evaluation of the outcome or outputs of symptoms; for instance, as the effect that intense pain may have on a person’s social relations or satisfaction with sleep. These are legitimate areas of investigation, but QOL as an outcome probably provides more useful clinical information where interventions have taken place. In some measures, items on processes and outputs are combined so that some aspects of QOL are effectively measured twice; for instance, as the intensity of pain per se and as the disruption to home and work life that intense pain can bring. Where this happens, the measure duplicates information and produces a lack of conceptual transparency. Although these processes are undoubtedly important in understanding QOL, this is neither the same as, nor a satisfactory substitute for, a good outcomes measure.

Where QOL has been formally assessed, researchers have tended to select specific instruments designed for use with a particular problem or diagnostic group. Where cancer pain is in evidence, for example, the Memorial Symptom Assessment Scale<sup>3</sup> or the Functional Assessment of Cancer Therapy—General<sup>4</sup> may have been chosen in preference to a generic measure that could be used to compare different types of patients with cancer, and patients with a wide range of other painful conditions. Specific measures are attractive because they appear to address the patient’s problem more directly and therefore to have higher face validity. However, their specificity means that they rarely cover the concept of QOL in a comprehensive manner. Furthermore, their specificity precludes comparisons with other types of patients and healthy people, creating difficulties in resource allocation. Few generic QOL instruments have been standardized for use with patients with chronic pain, and this information is essential in making decisions about whether the instruments selected show the requisite psychometric properties of accuracy, reliability, validity, and sensitivity (or responsiveness) to changes in clinical condition.

Generic instruments that have been included as outcome measures in pain management programs (PMPs)

include the Sickness Impact Profile<sup>5</sup> and the Medical Outcomes Study Short Form - 36,<sup>6</sup> but these scales have several technical and conceptual problems, and new, improved methodologies have since been developed. Briefly summarized, the 136-item Sickness Impact Profile is lengthy and requires interviewer administration. Furthermore, it does not allow for the measurement of positive functioning.<sup>1</sup> While the 36-item short form health survey (SF-36) shows high reliability and validity on most criteria and is shorter, it is inappropriate for use with some age and illness groups.<sup>7</sup> Perhaps more important are the findings that the Sickness Impact Profile and some SF-36 subscales are not sufficiently responsive to changes in clinical condition,<sup>7-9</sup> and this has given rise to the erroneous view that all generic measures are therefore unresponsive.

Several other issues seem to impede the adequate application of QOL assessment in pain research. One problem is that some scales are claimed to be QOL measures when they assess only a limited portion of the concept. Measures of mood, like the Hospital Anxiety and Depression Scale, for instance, are mistakenly selected as substitutes for a good QOL measure,<sup>6</sup> even though mood represents only a portion of this concept, as the current work will show. Measures of coping strategies (e.g., the Vanderbilt Multidimensional Pain Coping Inventory<sup>10</sup>) and disability (e.g., the Pain Disability Index<sup>11</sup>) have also been mistakenly seen as adequate proxies for a QOL measure in the evaluation of pain. Other scales assess a small cluster of qualities, like mobility and activities of daily living, to represent the area of functional status (e.g., Functional Living Inventory<sup>12</sup>). While functional status is undoubtedly important to QOL, and particularly to those in pain, it is only one of several domains relevant to a comprehensive conceptualization of QOL. Furthermore, where QOL is being investigated in pain research, a result of the shortage of comprehensive and high-quality QOL measures is that an instrument battery is often used with the aim of achieving comprehensive conceptual coverage while simultaneously adding more to the patient burden than might be imposed by a comprehensive generic measure.

The WHOQOL (the World Health Organization Quality of Life Assessment) is a new, multidimensional, multilingual, self-report assessment of subjective QOL that has been recently developed for cross-cultural use. Through an international collaboration of 15 countries world-wide and the World Health Organization (WHO), a generic profile was designed that evaluates 25 facets or dimensions of QOL organized hierarchically into 6 domains: physical; psychological; levels of independence; social relationships; environment; and spirituality,

religion, and personal beliefs.<sup>2,13</sup> These facets were found to be consensually important in 15 countries, and structural equation modeling indicates that this QOL concept has universal acceptance, even though cultures express it in different ways.<sup>14</sup> Focus groups of patients, health professionals, and community members that were convened simultaneously in the 15 collaborating centers proposed items arising out of their discussions; these items were then pooled and considered for inclusion in the WHOQOL. So this patient-centered instrument has been created by the users for the users, and uses their own language and cultural ideas. The WHOQOL provides perhaps the most comprehensive, cross-cultural subjective assessment of QOL to date and facilitates an assessment of areas that are omitted by other generic measures. The different language versions of the WHOQOL show high levels of semantic and conceptual equivalence because they were developed simultaneously from agreed international protocols throughout the qualitative and quantitative stages of development work on the instrument. This new simultaneous method, or “spoke-wheel” methodology,<sup>15</sup> contrasts with the more usual sequential method of language-version development in cross-cultural research, where equivalence between versions is more limited and the process of creating different language versions much slower.

The psychometric properties of the international instrument—the WHOQOL-100—were first tested using a heterogeneous sample of sick and healthy people ( $N = 4,802$ ) drawn from 15 countries and showed excellent properties of internal consistency, reliability, and construct validity.<sup>2,13</sup> Evidence of longitudinal validity is available in the U.K., where it was reported that 24 out of 25 facets of the WHOQOL-100 showed significant improvements to the QOL of depressed patients in primary care, after a course of antidepressant medication.<sup>16</sup> Only the facet “dependence on medication” was not sensitive to change, and this was predicted. The instrument requires further validation before it can be used with confidence in populations of patients with chronic pain.

The WHOQOL-100 was recently used to investigate the relation between pain and QOL in a representative sample (drawn from 16 ICD categories) of 320 sick and “well” people in Britain.<sup>17</sup> Forty-three percent were in pain on the day they completed the WHOQOL-100. The results showed that pain and discomfort made a significant impact on the respondents’ QOL, and 7 key facets were identified as potential criteria against which the success of pain treatments might be evaluated. In addition to pain and discomfort itself, these key facets were: the availability of health and social care, mobility, activities of daily living, positive feelings, and, to a lesser

extent, sleep, and dependence on medication.<sup>17</sup> A small subgroup of patients undergoing pain management was included in this study, and hence it was not possible to draw reliable conclusions about changes to their QOL from this limited data. An aim of the present study was to re-examine some of these issues.

Another aim of the current study was to investigate whether QOL (as measured by the WHOQOL-100) improves significantly during the treatment of chronic pain in an established PMP of known effectiveness.<sup>18</sup> It was expected that not all facets of the profile would change during treatment. An advantage of using a profile (rather than an index of QOL) is that it enables selective predictions to be made about what specific changes in different aspects of QOL would be expected to take place over time, and then to test them. Based on the large amount of research on PMPs and extensive clinical experience, it was predicted that 8 of the 25 facets would not show significant changes one month after treatment: working capacity; (and, related to this) financial resources; the 3 facets of the social relationships domain; physical and home environments; and information with skills. The third aim was to test some important psychometric properties of the WHOQOL-100—in particular, concurrent, predictive, and construct validity, responsiveness to change, and internal consistency reliability—with a view to using this instrument in chronic pain research, clinical trials, clinical governance and audit.

## MATERIALS & METHODS

Two hundred and twelve patients with chronic pain attended an in-patient or out-patient pain management program (PMP) lasting 16 days at INPUT, St Thomas’ Hospital London. They were first assessed (Time 1) during the 2 weeks immediately before commencement. Details of this established program are outlined elsewhere,<sup>18</sup> and the effectiveness of the program has been re-evaluated in the past 5 years.<sup>19</sup> This multidisciplinary program included a consultant anesthetist with specialization in pain management, clinical psychologists, physiotherapists, occupational therapists, and nurses. Patients were included if they had two or more of the following criteria: work or nonwork activity impaired by pain, habitual overactivity/underactivity patterns, significant distress attributable to pain, overuse of analgesic or psychotropic drugs for pain, use of unnecessary aids, and high levels of reported or observed pain behavior. Treatment was delivered to groups of 10 people. Goals of the program were: to minimize the impact of pain on people’s lives by increasing and extending the range of activity across work, leisure, and personal and social goals; to improve the patients’ confidence in the ability to manage

pain; to decrease pain-related distress; and to enable patients to be more self-reliant in pain management and thereby reduce their use of health care and welfare services. The types of treatment offered used cognitive behavioral principles and included education about pain and treatment; changing pain-related behavior; cognitive therapy; exercise and stretch routines to build fitness and flexibility; goal setting, activity scheduling and pacing towards goal attainment; applied relaxation and sleep management; relapse prevention; and maintenance enhancement. The data was collected as part of a randomized control design that consisted of 3 groups: waiting list controls, nonrandomized controls, and randomized controls.

At Time 1, all completed a battery of measures to assess QOL in health (the UK WHOQOL-100), negative mood (the Beck Depression Inventory) and health-related QOL for concurrent validity purposes (the Medical Outcomes Study Short Form-36) together with socio-demographic and health status characteristics. On both occasions, the information was obtained by the same assistant, in person (she was not part of the therapeutic team). Ninety-four percent of patients completed the program 1 month before the Time 2 assessment. One hundred and six of these patients (53%) repeated all the assessments 1 month after program completion, at the first follow-up, when attendance rates are 85%. Patients knew that the information would be stored in the hospital files at INPUT but would not be transmitted to their primary caregivers unless they themselves took a copy.

The WHOQOL-100 contains 100 items about perceived QOL; 4 items assess each of 25 facets that are organized in 6 domains. An additional 32 items inquire about the importance of each facet to a person's QOL. All items are scored on one of five types of 5-point interval, Likert-type response scales, and facet scores range between 4 and 20. The UK version contains 2 extra national items (n) on positive and negative feelings, respectively, that are part of the psychological domain. These items were important and relevant to British focus groups in expressing their QOL (e.g., feeling "fed up."<sup>20</sup>); they were selected from a national pool and accepted only if they performed as well as the core items of the international instrument.<sup>21</sup>

Using replies from over 4,800 respondents in 15 countries, the psychometric properties of the international WHOQOL-100 showed good internal consistency, with the Cronbach  $\alpha$  ranging from 0.65 to 0.93, for facets, and from 0.71 to 0.86, for domains. There is good evidence of construct validity, both from confirmatory factor analysis and intercorrelations between items, facets, and domain scores. There is also good discriminant validity

for domains when responses from sick and well participants are compared.<sup>13</sup> Test-retest correlations from 2 to 8 weeks ranged from 0.68 to 0.95, indicating that the WHOQOL-100 produces comparable scores across time where no interventions or major life events have occurred.<sup>22</sup>

The Beck Depression Inventory<sup>23</sup> assesses depressed mood that commonly co-occurs with chronic pain. In the present study the range of scores (0 to 63) was used to investigate depressive symptom severity, changes in depression, and its relation to the different dimensions of QOL. Because the presence of somatic symptoms and acquiescence of these items in the BDI inflate depression scores for patients with chronic pain,<sup>24</sup> the published norms for this scale are not reliable in assessing levels of depression, so the results will be presented without reference to these norms.

The MOS Short Form 36 (SF-36)<sup>25</sup> contains 36 items covering 2 domains of mental and physical health and scored in 8 subscales. It has been widely tested on more than 10,000 people and is regarded by some researchers as the current "gold standard" in health status/QOL research, although its criterion validity has not been entirely confirmed. A priori predictions were made about the expected relation between some SF-36 dimensions and specified facets and domains of the WHOQOL-100.

Data was obtained from numerical rating scales (from 0 to 100) designed to measure pain duration (in months), pain intensity (ranging from "no pain" to "pain as intense as it could be"), the distress of pain ("not at all distressing" to "pain as distressing as it could be") and the level of disruption due to pain ("activities not at all disrupted due to pain" to "activities completely disrupted"; see Melzack and Katz<sup>26</sup> for a summary of these types of measure). These pain measures enabled the construct and concurrent validity of the WHOQOL-100 to be investigated.

## RESULTS

### Sample

The sample statistics are presented for those who completed the assessments twice, since all analyses (with two exceptions) have been carried out on these results. Sixty-six percent of patients were female and the mean age of the total sample was 44 years. (range 22–79 years). The majority (57%) were married, 42% had received further education, and most (73%) were unemployed. The patients had been in pain for a mean of 8.1 years but duration varied from 15 to 605 months (SD = 103). There were significant decreases in mean scores of other pain measures following treatment (paired *t* test). Pain distress was 65.3 before treatment and 55.4 afterwards

( $p < 0.0001$ ), pain intensity changed from 69.1 to 64.1 ( $p < 0.033$ ), and disruption of activities due to pain from 64.6 to 57.1 ( $p < 0.015$ ). At pretest, the mean BDI score was 16.6 but with considerable variation ( $SD = 9$ ); this decreased to 11.6 ( $p < 0.0001$ ) one month after treatment.

There was little missing data for the WHOQOL-100 items. Many items had no data missing and there was less than 5% missing for all items except for those about sex life, where it reached 10%. Norms for the WHOQOL-100 are not yet available but the midpoint for each facet score is 12.0. Domain means at pretreatment showed that QOL was poorest in the physical health and the levels of independence domains, and best in the social relations (Table 1). Facet means confirm that QOL was poorest for pain and discomfort; this was predicted. Poor QOL relating to energy and fatigue, activities of daily living, and working capacity were also recorded. These findings justify the stated aims of PMPs to improve these areas of QOL.

Importance ratings (5-point scales) in Table 1 showed that being able to perform activities of daily living, being

free from pain and discomfort, and being mobile were the most important facets of QOL to chronic pain patients at the time they entered the PMP; least important was sexual activity, followed by body image. It is worth noting, however, that all facets showed mean importance scores of more than 3.0, demonstrating that all 25 dimensions assessed by this scale are perceived to be either important or very important to the chronic pain patient's concept of QOL. This justifies the use of the WHOQOL-100 as an entire and relevant concept for this patient group.

#### Reliability of the WHOQOL-100

When internal consistency reliability (Cronbach  $\alpha$ ) was calculated for the pretreatment data, the total scale was found to be highly homogenous, showing an excellent result ( $= 0.97$ ). Very high  $\alpha$ 's ( $< 0.9$ ) were also recorded for the psychological, level of independence, and environment domains, indicating that the individual interpretation of scores is reliable in these domains. Other domain scores showed acceptable reliability for

**TABLE 1.** ANOVAs of mean pretreatment and post-treatment facet and domain scores for pain patients completing the WHOQOL-100, with importance ratings and Cronbach  $\alpha$  ( $n = 106$ )

Domain/facet	Pretreatment		Post-treatment		F	p	Importance		
	Mean	SD	Mean	SD			Mean	SD	$\alpha$
DI Physical	9.58	2.20	10.36	2.98	12.23	0.001*	—	—	0.73
F1 Pain and discomfort†	8.69†	2.17†	9.71†	3.03†	17.43†	0.0001*†	4.44	0.76	0.67
F2 Energy and fatigue	9.50	2.69	10.00	3.04	3.81	0.054	4.39	0.59	0.82
F3 Sleep and rest†	10.54†	3.56†	11.40†	4.10†	6.83†	0.010*†	4.26	0.73	0.91
DII Psychological	12.09	2.41	12.84	2.95	17.32	0.0001*	—	—	0.93
F4 Positive feelings†	11.23†	2.59†	12.10†	3.27†	12.95†	0.0001*†	4.22	0.71	0.83
F5 Cognitions	12.32	3.05	12.90	3.53	4.90	0.029	4.17	0.73	0.78
F6 Self esteem	11.31	3.09	12.60	3.40	29.19	0.0001*	4.09	0.77	0.81
F7 Body image	13.47	3.64	13.63	3.78	0.36	0.550	3.69	0.87	0.89
F8 Negative feelings	12.12	3.29	12.98	3.66	9.57	0.003*	4.16	0.77	0.88
DIII Independence	10.27	2.76	11.33	3.36	27.06	0.0001*	—	—	0.93
F9 Mobility	10.50	4.22	11.05	4.00	3.40	0.068	4.41	0.65	0.91
F10† Activities of daily living†	9.53†	2.58†	10.81†	3.42†	20.73†	0.0001*†	4.48	0.62	0.86
F11† Dependence on medication†	11.90†	4.08†	13.84†	4.88†	28.81†	0.0001*†	4.35	0.85	0.88
F12 Working capacity	9.16	3.39	9.64	3.89	4.12	0.045	4.14	0.87	0.90
DIV Social relationships	12.66	2.54	13.04	2.97	3.66	0.059	—	—	0.86
F13 Personal relationships	12.95	3.09	13.31	3.62	2.30	0.132	4.18	0.70	0.65
F14 Practical social support	13.87	2.99	13.55	3.32	1.59	0.210	3.65	0.89	0.81
F15 Sex	11.11	3.55	12.22	3.82	4.12	0.001*	3.43	1.2	0.84
DV Environment	12.29	2.27	12.54	2.65	3.07	0.083	—	—	0.94
F16 Physical safety	12.30	2.94	12.71	2.83	4.02	0.048	4.00	0.83	0.79
F17 Home environment	13.91	3.72	13.93	4.00	0.01	0.936	4.26	0.70	0.90
F18 Financial resources	11.15	4.30	11.49	4.53	1.65	0.202	4.08	0.78	0.93
F19† Health and social care†	11.99†	3.01†	12.61†	3.30†	6.50†	0.012*†	3.79	0.89	0.81
F20 Information/skills	12.33	2.75	12.54	3.12	0.68	0.413	3.69	0.89	0.76
F21 Recreation and leisure	10.40	2.88	11.19	3.28	9.29	0.003*	3.94	0.85	0.80
F22 Physical environments	12.88	3.13	12.93	3.43	0.04	0.837	3.78	0.92	0.78
F23 Transport	13.34	4.08	12.93	4.16	2.03	0.157	4.02	0.79	0.89
DVI/F24 Spirituality, religion and personal beliefs	12.18	3.79	12.05	3.92	0.22	0.638	3.71	1.1	0.90
F25 General QOL	9.93	3.18	11.15	3.73	24.38	0.0001*	4.28	0.69	—

\*Significant at  $p < 0.01$ .

†Facets with confirmed predictions (Skevington, 1998).

WHOQOL-100, World Health Organization Quality of Life assessment form; importance, importance rating;  $\alpha$ , Cronbach  $\alpha$ .

group interpretation (0.7–0.9). Chronbach  $\alpha$  was excellent for facets on sleep and rest, mobility, working capacity, home environment, and financial resources, and a further 18 facets showed acceptable levels of internal consistency (Table 1). Two facets on pain and discomfort and personal relationships were marginal, so these scores should be used with caution. In general, a very high level of internal consistency reliability can be assumed when using the WHOQOL-100 with chronic pain populations.

#### *Validity of the WHOQOL-100*

A repeated-measures design was used to investigate the validity of the WHOQOL-100 by comparing scores from pretest and post-test assessments to see if there were changes to QOL over time. One-way analysis of variance (ANOVA) was used to compare scores from each facet and domain. It was expected that WHOQOL scores would increase with successful treatment, thus representing better QOL on selected dimensions. Patients showed significant improvement to their overall (general) QOL after treatment, confirming the broad hypothesis. A significant improvement in QOL associated with pain and discomfort was also confirmed following the PMP (Table 1), thus validating the pain and discomfort facet. Patients with chronic pain also perceived significant improvements ( $p < 0.01$ ) to their QOL in 9 other facets one month after treatment: sleep and rest, self-esteem, positive and negative feelings, activities of daily living, sexual activity, recreation and leisure, dependence on medication, and the availability of health and social care. Although a more stringent statistical criterion ( $p < 0.01$ ) has been applied to protect against type-1 errors, it is worth noting that physical safety and security, working capacity, and the perceived cognitions of thinking, learning, memory, and concentration also made some improvement ( $p < 0.05$ ). The findings support the aims of PMPs by showing that, 1 month after treatment, QOL is improved in 11 of its 25 dimensions. This list of findings also reconfirms 6 of the 7 facets of QOL earmarked in earlier research as criteria against which the success of pain treatments might be evaluated.<sup>17</sup> The exception is the facet relating to mobility ( $p = 0.068$ ).

For the 8 facets where change was not predicted, 2 significant changes in facets on working capacity and sexual activity did occur. Although sexual activity is perceived to have changed, the social relationships domain score did not show a significant improvement. This means that financial resources, personal relationships, social support, physical and home environment, and information and skills are relatively stable aspects of QOL in patients with chronic pain who participate in PMPs, and do not appear to be affected by this psychological intervention, as expected.

Often clinicians seek to know whether data collected before an intervention is useful in predicting outcome from treatment, and the scores from good assessments in health care should enable such predictions to be made. At the same time, this analysis represents a test of the predictive validity for the WHOQOL-100 by selecting the 7 potential QOL indicators of successful treatment in painful conditions.<sup>17</sup> Stepwise multiple regression was used to examine whether changes in QOL between Time 1 and Time 2 predicted outcomes at Time 2. Two separate analyses were carried out; in the first analysis, scores for pain and discomfort after treatment were entered as a dependent variable into the regression and tested against changes (difference between scores at Times 1 and 2) in the facets on health and social care, mobility, activities of daily living, positive feelings, sleep and rest, dependence on medication and mobility (independent variables).

It was found that change in dependence on medication (29% of the variance) together with activities of daily living (10%), positive feelings (4%), and mobility (2%) best explained pain relating to QOL one month after the PMP was completed ( $F = 21.82$  [4,104];  $p = 0.0001$ ; 45% total variance). Those with the biggest reductions in dependence on medication and improvements in activities of daily living, positive feelings and mobility during the PMP, have the best pain and discomfort outcome a month after treatment. In a second, similar analysis, general quality of life and health at the end of treatment became the dependent variable, and changes to pain and discomfort were included with the other independent variables. This showed that the 4 facets of positive feelings (31%), dependence on medication (8%), activities of daily living (3%), and the availability of health and social care (2%) together predicted 44% of overall QOL at the end of the program ( $F = 25.01$  [3,105];  $p = 0.0001$ ). Together these results point to a more limited but consistent list of 3 key QOL facets as indicators of good QOL at the end of a PMP: positive feelings, dependence on medication, and activities of daily living.

#### *Sensitivity or Responsiveness to Clinical Change*

Being able to demonstrate the responsiveness of scores to clinical change is perhaps the most important of all psychometric properties for any health measure.<sup>22</sup> In addition to the evidence that demonstrated that the scores on 11 facets changed significantly between pretest and post-test, further tests of the sensitivity of scores to clinical change were performed on the WHOQOL-100 domain scores and, for comparison, on the SF-36 subscales. To do this, 5-point responses to a question “How is your current health”—an additional health question included as standard in the sociodemographic and health status information section of the WHOQOL—was used to

**TABLE 2.** Discriminant validity of the WHOQOL-100 for patients with chronic pain

Domain/scale	Physical (D1)	Psychological (D2)	Independence (D3)	Social (D4)	Environment (D5)	Spiritual (D6)	N
Very poor (1)	7.5	10.8	7.3	10.8	10.5	12.1	21
Poor (2)	8.9	11.5	9.3	12.4	11.7	11.9	72
Neither poor nor good (3)	9.9	12.9	10.8	13.4	12.8	12.8	77
Good (4) or very good (5)	11.3	14.4	12.8	14.8	14.5	13.2	36
<i>F</i>	20.68	16.58	30.19	13.55	24.04	1.20	
<i>p</i>	0.0001*	0.0001*	0.0001*	0.0001*	0.0001*	0.311	

ANOVAs of mean domain scores for 4 groups, categorized according to perceptions of current health (N = 206).

\*Significant at  $p < 0.01$ .

WHOQOL-100, World Health Organization Quality of Life assessment form.

place participants into one of 5 health groups on the basis of their replies. However, frequencies showed a skewed distribution; only 4 participants at Time 1 replied that their health was "very good" (rating 5). So participants rating their health as very good (5) or good (4) were then combined into a single category ("good health") before comparing their QOL with those groups who perceived their current health to be very poor (1), poor (2), or neither good nor poor (3). The mean scores for each of the WHOQOL domains and the SF-36 subscales were then compared in separate one-way ANOVAs.

The results in Table 2 show significant changes across the 4 response-scale categories for 5 of 6 WHOQOL-100 domains, with those recording their health as poorest also reporting poorest quality of life, and those with very good or good health, the best quality of life, as predicted. An exception to this trend is in the spirituality domain. When the same test was carried out on the 8 subscales of the SF-36, however, no significant results were found for any subscale, with the probabilities ranging from  $p = 0.304$  (for general health) to  $p = 0.942$  (role physical) (Table 3). These results demonstrate that the WHOQOL-100 domain scores are highly responsive to the clinical condition of patients with different levels of current health and distinguish well between them. The SF-36 is not useful for this purpose for patients with chronic pain.

### Construct Validity

But do WHOQOL-100 scores change in relation to other important clinical parameters? It would be ex-

pected a priori that severe pain would be associated with poor QOL across a range of dimensions in the profile. Tables 4 and 5 show that almost every facet and domain of the WHOQOL-100 was significantly associated with level of pain severity, the distress of pain, and the disruption of activities by pain, even when a stringent criterion of  $p < 0.01$  was applied to adjust for spurious associations arising as a result of multiple correlations. However, there were no significant correlations between pain duration and any of the domains or facets of the WHOQOL-100; the largest was  $r = 0.16$ , thereby demonstrating that the duration of pain per se does not affect any important aspects of QOL. For most facets and domains, however, a good QOL is associated with less severe pain, lower distress, and less disruption as a result of pain. But three areas of QOL are hardly affected by this; these are the perceived availability of health and social care, spirituality, religion and personal beliefs, and, to some extent, perceptions of the physical environment (e.g., pollution, noise). Tables 4 and 5 also confirm that, for every domain and facet, reporting a good QOL is associated with low levels of depressive symptoms and a poorer QOL with higher depression. This does not mean (as is sometimes mistakenly assumed) that a measure of depression is a suitable substitute for a good QOL measure. Instead, mood mediates perceptions of QOL; it has an overall dampening effect on QOL—where mood is negative, people report it as much poorer.<sup>16</sup>

In a test of the integrity of the concept of QOL, it was important to look at whether the dimensions contained

**TABLE 3.** Discriminant validity of the SF-36 for patients with chronic pain

Subscale	Physical function	Role physical	Body pain	General health	Vitality	Social function	Role emotional	Mental health
Very poor (1)	31.8	14.7	23.4	37.6	33.8	41.2	45.1	45.4
Poor (2)	31.9	10.0	21.8	42.6	30.9	43.7	41.9	53.1
Neither poor nor good (3)	34.0	12.5	22.7	46.3	30.1	38.0	32.0	51.4
Good (4) or very good (5)	39.3	12.5	24.1	40.1	29.9	46.2	43.5	51.2
<i>F</i>	0.74	0.18	0.16	1.14	0.18	1.08	0.96	0.65
<i>p</i>	0.529	0.909	0.927	0.333	0.912	0.359	0.415	0.581

ANOVAs of mean subscale scores for 4 groups, categorized according to perceptions of current health (N = 199).

SF-36, the MOS Short Form 36.

**TABLE 4.** Pearson correlations (1-tailed) between pretreatment WHOQOL-100 domain scores, pain measures, and Beck Depression Inventory totals (BDI)

Domain	Pain severity	Pain and distress	Disrupted activities	BDI scores
Physical	-0.44*	-0.49*	-0.44*	-0.49*
Psychological	-0.24*	-0.31*	-0.27*	-0.69*
Independence	-0.39*	-0.37*	-0.48*	-0.42*
Social relationships	-0.21*	-0.31*	-0.24*	-0.54*
Environment	-0.22*	-0.26*	-0.22*	-0.48*
Spirituality	-0.11	-0.04	-0.00	-0.21*
General QOL	-0.25*	-0.32*	-0.30*	-0.53*

\*Significant at  $p < 0.01$ .

WHOQOL-100, World Health Organization Quality of Life assessment form.

within the WHOQOL-100 were viewed as a unified concept. To do this, a correlation matrix was drawn up to examine the strength of the relationship between domains. It was expected that correlations would show an association of  $r = 0.4$  or stronger. Good associations were found between most domains of the WHOQOL-100 (Table 6), but for domain 6 (spirituality, religion and personal beliefs) the correlations were either weaker or nonsignificant, as in the case of independence and physical health. This may owe less to the integrity of the concept itself and more to the fact that only 4 items

assess this domain—the smallest number for any domain.

**Concurrent Validity**

To compare the performance of the WHOQOL-100 against the current “gold standard” measure of QOL, facet and domain scores were correlated with subscales of the SF-36 (Pearson one-tailed). Table 7 demonstrates good concurrent validity for the WHOQOL-100, because, in some predicted domains and a few facets, strong predicted associations were found between QOL and the 8 dimensions of the SF-36. The physical domain and the pain and discomfort facet ( $r = 0.54, p < 0.0001$ ) correlated strongly with bodily pain, as expected. The psychological domain was closely associated with mental health, the physical domain with physical functioning, and the social domain with social functioning. Independence correlates strongly with bodily pain and with social and physical functioning, thereby demonstrating the importance of function to this population. Energy and fatigue is closely associated with vitality ( $r = 0.64, p < 0.0001$ ). The SF-36, however, seems limited in its conceptual scope compared with the 25 facets of the WHOQOL-100, where the spirituality domain is demonstrated as unique by the absence of significant correlations with the SF-36. The 2 national items (not shown)

**TABLE 5.** Pearson correlations (1-tailed) between pretreatment WHOQOL-100 facets, pain measures, and the Beck Depression Inventory (BDI)

Facet	Pain severity	Pain and distress	Disrupted activities	BDI
Pain and discomfort	-0.45*	-0.47*	-0.52*	-0.43*
Energy and fatigue	-0.24*	-0.36*	-0.32*	-0.45*
Sleep and rest	-0.38*	-0.35*	-0.27*	-0.33*
Positive feelings	-0.16	-0.25*	-0.22*	-0.55*
Cognitions	-0.20*	-0.26*	-0.19*	-0.47*
Self esteem	-0.25*	-0.28*	-0.25*	-0.59*
Body image	0.09	-0.12	-0.11	-0.46*
Negative feelings	-0.26*	-0.32*	-0.30*	-0.66*
Mobility	-0.30*	-0.30*	-0.38*	-0.32*
Activities of daily living	-0.30*	-0.36*	-0.44*	-0.38*
Dependence on medication	-0.36*	-0.25*	-0.34*	-0.32*
Working capacity	-0.28*	-0.30*	-0.41*	-0.35*
Personal relationships	-0.18*	-0.28*	-0.22*	-0.57*
Practical social support	-0.14	-0.19*	-0.09	-0.35*
Sex	-0.18*	-0.29*	-0.27*	-0.41*
Physical safety	-0.23*	-0.25*	-0.23*	-0.47*
Home environment	-0.20*	-0.17*	-0.11	-0.27*
Financial resources	-0.12	-0.18*	-0.13	-0.35*
Health and social care	0.0	-0.06	-0.04	-0.21*
Information and skills	-0.17*	-0.17*	-0.14	-0.36*
Recreation and leisure	-0.33*	-0.35*	-0.40*	-0.51*
Physical environments	-0.08	-0.14	-0.04	-0.25*
Transport	-0.15	-0.16	-0.18*	-0.31*
Spirituality	-0.11	-0.04	0.0	-0.21*
General quality of life	-0.25*	-0.32*	-0.30*	-0.53**

\*Significant at  $p < 0.01$ .

WHOQOL-100, World Health Organization Quality of Life assessment form.

**TABLE 6.** Pearson correlations (1-tailed) between WHOQOL-100 domains at pretreatment

Domain	Physical (D1)	Psychological (D2)	Independence (D3)	Social (D4)	Environment (D5)
Psychological (D2)	0.56*†				
Independence (D3)	0.66†	0.45*†			
Social relationships (D4)	0.49*†	0.66*†	0.37*		
Environment (D5)	0.49*†	0.64*†	0.50*†	0.64*†	
Spirituality (D6)	0.13	0.36*	0.10	0.25*	0.19*

\*Significant at  $p = 0.01$ .†Good association ( $r < 0.4$ ).

WHOQOL-100, World Health Organization Quality of Life assessment form.

generally made marginal improvements to the performance of the scale across all evaluative criteria.

## DISCUSSION

This study shows that, 1 month after treatment, an established and proven PMP significantly improved QOL on a wide range of dimensions for those with chronic painful conditions. It was not expected that every facet on the profile would show significant improvements in the period between pretreatment and follow-up, but it was found that improvements to QOL occurred for patients with chronic pain on about half (11 out of 25) of the dimensions of QOL, as measured by the WHOQOL-100. Improvements were found to the broader physical, psychological, and independence dimensions of QOL. These results indicate the commendable widespread impact of PMPs across a comprehensive range of dimensions, but at the same time raise questions about whether the program might be altered to extend improvements to QOL to those areas so far unaffected by this type of intervention. PMPs were never intended as a panacea for the management of chronic pain, and so it would not be expected that the PMP would be the most appropriate way to improve QOL in every area. Economic, political, or even different types of psychological intervention could be sought and tested with this in mind. Nevertheless, the validated WHOQOL-100 now provides a suit-

able vehicle for testing the QOL outcomes of new investigations of pain relief, including randomized controlled trials. Other factors not resulting from the intervention, like regression to the mean, may account for changes in scores. Although a single group design with pretest and post-test does have some limitations in terms of evaluating the intervention qua intervention, it does not affect the reliability of conclusions about the performance of the instrument, which is the main objective of the study.

The follow-up assessment was carried out one month after treatment, and this time lapse may explain why patients perceive no significant expected improvements in their energy and fatigue, and only marginal improvements in their mobility. The initial exhaustion of putting pain management techniques into practice at home as a result of the new skills acquired on the PMP could account for the apparent lack of change in energy and fatigue over time. An improvement in perceived mobility was expected, given that a central aim of PMPs is to increase physical activity and to more favorably orient patients towards it. There is evidence from many other studies to demonstrate that actual mobility does change during the PMP; this result therefore raises questions about the clinical impact of the PMP on perceptions of mobility. In other words, are these changes clinically significant to patients too?

There are several possible explanations for our results. First, QOL may have improved by the end of treatment

**TABLE 7.** Pearson correlations (1-tailed) between WHOQOL-100 domains and SF-36 subscales at pretreatment

Domain	Bodily pain	General health	Mental health	Physical functioning	Role—emotional	Role—physical	Social functioning	Vitality
Physical	0.50*†	0.46*	0.45*	0.49*†	0.35*	0.30*	0.51*	0.57*
Psychological	0.30*	0.39*	0.64*†	0.24*	0.41*	0.15	0.47*	0.49*
Independence	0.58*†	0.36*	0.37*	0.70*†	0.31*	0.35*	0.49*	0.38*
Social relationships	0.28*	0.38*	0.52*	0.26*	0.28*	0.15	0.44*	0.43*
Environment	0.28*	0.41*	0.50*	0.28*	0.28*	0.19*	0.45*	0.44*
Spirituality	0.02	0.15	0.21*	-0.01	0.07	-0.04	-0.02	0.17*
General QOL	0.41*	0.45*†	0.57*	0.32*	0.29*	0.27*	0.53*	0.49*

\*Significant at  $p < 0.01$ .

†Predicted positive correlations.

WHOQOL-100, World Health Organization Quality of Life assessment form; SF-36, the MOS Short Form 36 assessment form.

but perceptions about these significant advances may have been eroded during the month at home. It is conceivable that a longer follow-up period using the WHOQOL-100 might have provided different results. Second, self-reported perceptions about some dimensions of QOL may change more slowly than others, and any improvements begun during the PMP may become evident only some time after the program was completed and cognitive processes have matured. Third, the mobility facet may not be sufficiently sensitive to clinical changes. There is no evidence from research on the WHOQOL-100, however, to support this view,<sup>2,13-17,22</sup> so the finding may be a characteristic of this particular context or sample. It is possible that the inclusion of more items, in the form of a chronic pain module, would increase its sensitivity to clinical change, and this work is currently in progress. Finally, the mobility facet may turn out to provide a useful psychological indicator that could detect relapses in physical exercise before they occur, because they represent perception of mobility in relation to QOL and not actual mobility itself, and this warrants further investigation. The test-retest reliability for the domains of the WHOQOL-100 is acceptable to good (The WHOQOL Group, 1999) in stable health-status populations, so this gives confidence in the current findings. However, only limited conclusions can be drawn from these data about the clinical significance of these significant statistical changes.

Internal consistency reliability of the scale was very good for the domains and for all facets except two. An unexpected finding was the marginal result for the pain and discomfort facet. The 4 items representing QOL relating to this facet many not entirely cover the elaborate and detailed concept of pain and discomfort commonly articulated by chronic pain patients. The WHOQOL-100 was designed to be used by a wide range of sick and well people but it was recognized that small, disease-specific (or problem-specific) modules of extra items addressing particular aspects of QOL relevant to certain subgroups of patients might need to be developed subsequently in separate studies to supplement the international core. For instance, a module on HIV/AIDS might address concerns about sex and stigma for infected people in ways that would not necessarily be appropriate to the general population. Although the validation of the pain and discomfort facet in the WHOQOL-100 is good, the reliability results indicate that the development of a chronic pain module would be useful in enabling more aspects of pain and discomfort to be explored within the WHOQOL-100 framework.

One value of using the WHOQOL-100 is that, although it may take about 20 minutes to complete, it

does provide a comprehensive profile. The importance ratings showed that patients with chronic pain see all 25 facets of QOL as important or very important, so there are no redundant facets in the WHOQOL-100 where the full assessment of those in chronic pain is concerned. However, a short form of 26 items—the WHOQOL-BREF—has been developed for use in situations where a long form is prohibited by the burden of serious illness or in studies where repeated-measures designs are employed (The WHOQOL Group, 1999). To retain its conceptual integrity, the WHOQOL-BREF contains one item from each of the 25 facets of QOL; but the provision of a single item per facet in this instrument necessarily precludes, from the lack of data, any reliable individual facet analysis. So where clinicians wish to identify areas of poor QOL that they can then treat (e.g., sleep and rest), they must use the WHOQOL-100 to be sure of an accurate, comprehensive, and reliable assessment. Our experience shows that the length of the WHOQOL-100 is acceptable to many patients if they have the time to complete it. They welcome its comprehensive and integrated coverage that enables them to systematically consider the state of their own lives, and this multi-faceted feature in itself means that fewer additional measures may need to be included in a test battery. Because it is a self-report instrument, it allows patients to express and record their feelings about their own QOL but is, of course, subject to the same biases as other similar measures. This comprehensive patient perspective can now be set alongside those of other measures that are already available which seek to record a more “objective” view of QOL.

The WHOQOL-100 is validated for use with patients with chronic pain. The results demonstrate the sensitivity of scores to clinical change over time and confirm that changes to 3 of the 7 key facets originally identified—positive feelings, dependence on medication, and activities of daily living—do indeed predict QOL outcomes after treatment. At the same time, these results also provide evidence of predictive validity for the WHOQOL-100 in this population. The SF-36—like the WHOQOL-100—is well able to measure the physical, independence, and psychological aspects of health-related QOL, but beyond that its conceptual scope is limited. Furthermore, the results show how QOL scores of 5 domains of the WHOQOL-100 demonstrate superior discriminant validity to the subscales of the SF-36 in terms of distinguishing between people with different levels of perceived current health. This research supports the use of the WHOQOL-100 as a good generic measures for use with chronic pain patients.

Quality-of-life ratings from many facets were found to be consistently associated with mood. A patient with chronic pain with depressed mood is likely to report poorer QOL across a wide range of dimensions (although the direction of causal influence and nature of the mechanism cannot be discerned from this study). The practical implications here are that clinicians and researchers need to take this into account in the interpretation of individual scores.

In the previous study of a heterogeneous (persons healthy, or with acute or chronic pain) sample<sup>17</sup> it was found that, in relation to pain and discomfort, spirituality, religion, and personal beliefs were largely detached from QOL. A similar conclusion is reaffirmed here. The spirituality domain, unlike the other domains, was shown to have poor associations with pain severity, pain distress, and disrupted activities. This generates additional evidence to suggest that holding spiritual beliefs may provide a useful detachment mechanism for coping with pain, hence a welcome dissociation or distraction from it.<sup>17</sup> This complements work on the Coping Strategies Questionnaire, where praying and hoping were reported to be counterproductive to coping with pain or just not relevant to people's lives. At the same time, it also enhances the validity of the WHOQOL-100. Although the spirituality domain is a different and psychometrically weaker area of the WHOQOL-100, the case is reiterated here not for deletion, but for a broader conceptualization and more elaborate assessment of this important area.

In conclusion, the WHOQOL-100 is a very good instrument for the measurement of quality of life in patients with chronic pain, and especially in the assessment and monitoring of PMPs.

**Acknowledgments:** The authors would like to thank Janice Fernandes and Kanchi Samarantunga for their help with data collection for this paper.

The paper is based on experience obtained as part of the WHO study to develop a quality-of-life measure (WHOQOL). The collaborators in this study have been at WHO Geneva: Dr. J Orley and Dr. Rex Billington, assisted by Dr. Willem Kuyken, Dr. Norman Sartorius, and Dr. Mick Power. In the field research centres, collaborating investigators are Prof. Helen Herrman, Dr. H. Schofield, and Ms. B. Murphy, University of Melbourne, Australia; Prof. Z. Metelko, Prof. S. Szabo, and Mrs. M. Pibernik-Okanovic, Institute of Diabetes, Endocrinology and Metabolic Diseases and Department of Psychology, Faculty of Philosophy, University of Zagreb, Croatia; Dr. N. Quemada and Dr. A. Caria, INSERM, Paris, France; Dr. S. Rajkumar and Mrs. Shuba Kumar, Madras Medical College, India; Dr. S. Saxena, All India Institute of Medical Sciences, Delhi, India; Dr. D. Bar-On and Dr. M. Amir, Ben Gurion University, Beer Sheeva, Israel; Dr. Miyako Tazaki, Department of Science, Science University of Tokyo, Japan; Dr. Ariko Noji, Department of Community Health Nursing, St. Lukes College of Nursing, Japan; Dr. G. van Heck and Mrs. J de Vries, Tilburg University, The Netherlands; Prof. J. Arroyo-

Sucre and Prof. Pichard-Ami, University of Panama, Panama; Prof. M. Kabanov, Dr. A. Lomachenkov, and Dr. G. Burkovsky, Bekhterev Psychoneurological Institute, St. Petersburg, Russia; Dr. R. Lucas Carrasco, Barcelona, Spain; Dr. Yooth Bodharamik and Mr. Kitikorn Meesapya, Institute of Mental Health, Bangkok, Thailand; Dr. D. Patrick, Ms M. Martin and Ms D. Wild, University of Washington, Seattle, U.S.A.; and Prof. W. Acuda and Dr. J Mutambirwa, University of Zimbabwe, Harare, Zimbabwe. An international panel of consultants includes: Dr. N.K. Aaronson, Dr. P. Bech, Dr. M. Bullinger, Dr. He-Nian Chen, Dr. J. Fox-Rushby, Dr. C. Moinpur, and Dr. R Rosser. Consultants who have advised WHO at various stages of the development of the project include: Dr. D. Buesching, Dr. D. Bucquet, Dr. L.W. Chambers, Dr. B. Jambon, Dr. C.D. Jenkinson, Dr. D. De Leo, Dr. L. Fallowfield, Dr. P. Gerin, Dr. P. Graham, Dr. O. Gureje, Dr. K. Kalumba, Dr. Kerr-Corea, Dr. C. Mercier, Mr. J Oliver, Dr. Y.H. Poortinga, Dr. R. Trotter and Dr. F. van Dam.

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