Quality of life in a Dutch population of sarcoidosis patients

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1. THE EFFECTS OF UNINTENTIONAL INJURY ON CHILDREN’S QUALITY OF LIFE: PARENT AND TEACHER REPORTS OF PSYCHOSOCIAL WELL-BEING 1 AND 6 MONTHS POST-INJURY

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As the leading cause of death and disability for children, injury poses significant challenges for the development of comprehensive rehabilitation programmes. Thus, the influence of paediatric trauma on children’s quality of Life (QoL) is of mounting interest to clinicians, researchers, parents and teachers. This longitudinal study examines the impact of unintentional injury on children’s QoL 1 and 6 months post-injury, as mitigated by demographic factors, injury severity, length of hospital stay and whether or not the child experienced a head injury. Using the Child Behaviour Checklist, parent and teacher reports on children’s behaviour, depressive symptoms and adaptation to school were collected for 114 children between the ages of 6 and 18 years who had been admitted to one of two major paediatric trauma centres in the northeast USA in 1990.

The results indicated that more severe injuries and a longer length of hospital stay were associated with more overall behaviour problems at home and at school 6 months post-injury. The results also suggested the particularly severe impact of a head injury on children 6 months post-injury. The discussion will focus on the need to (1) examine critically inclusion criteria and items in a measure when assessing and interpreting ill children’s psychosocial adjustment, (2) collect data from more than one source when examining QoL in children and (3) examine the physical impact of injury in different ways. The findings suggest avenues for greater attention to psychosocial risk and resilience as factors in recovery from unintentional injury and children’s reintroduction into the home and school system.

2. PSYCHOSOCIAL WELL-BEING OF CHILDREN AT RISK FOR DEPRESSION: MEASURING QOL DOMAINS ACROSS REPORTERS

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Recent studies have shown that quality of life (QoL) domains for children may be conceptually and operationally different from adult QoL. Furthermore, debate exists regarding the optimal reporter for children’s QoL. This study focused on different methods of measuring psychosocial well-being in 45, primarily Caucasian 8-9 year old children from low-income backgrounds in urban areas of the USA who were at risk of depressive disorders. Psychosocial QoL domains (including energy, self-esteem, behaviour, depressed mood and overall adaptation to the school environment) were measured using maternal and teacher reports on the Child Behaviour Checklist and children’s reports on the Dimensions of Depression Profile. The results yielded moderate but significant correlations between reporters, indicating that while the concepts were related, each reporter provided additional information on the child’s QoL. Of note, while significant correlations between child and maternal report were few, children’s reports of depressed mood and self-esteem were correlated with several teacher report subscales. These findings indicate the need to collect information from a variety of sources, particularly when examining internal states. The discussion will include the advantages and disadvantages of using established child development assessment strategies to measure QoL in children.

3. OVERCOMING THE HURDLES ENCOUNTERED DURING CROSS-CULTURAL ADAPTATION OF A BATTERY MEASURE: EXPERIENCES WITH NEWQOL

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With the increase in quality of life (QoL) instruments in the outcomes field, a rising number of assessment strategies are using a battery of existing instruments to capture relevant QoL domains for a particular condition. Using a battery methodology has several advantages in that it allows for comparison across other groups or studies, maximizes resources and often precludes the need for further psychometric validation if well-validated instruments are used. However, problems may be encountered when the battery is to be culturally adapted or translated. This paper discusses the potential solutions to problems encountered when culturally adapting a battery of instruments. To illustrate, we will provide examples from the cross-cultural validation of the NEWQOL, a battery of instruments developed in the UK and designed for use with newly diagnosed epilepsy patients. Examples of the problems include differences in recall periods within the battery (1 week, 4 weeks, 3 months or 1 year), the use of a well-known and widely used UK questionnaire (the Hospital Anxiety and Depression Scale) which was developed prior to the advancement of metric strategies and the use of varied, yet synonymous, response continuums throughout the battery. The advantages and disadvantages of potential solutions to these problems will be discussed.
4. QUALITY OF LIFE FOR PATIENTS WITH OBSESSIVE-COMPULSIVE DISORDER ATTENDING A SELF-HELP GROUP
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While obsessive-compulsive disorder (OCD) is generally believed to be one of the most impairing anxiety disorders, there is surprisingly little data on this subject. We addressed the issue of quality of life (QoL) for OCD patients in a pilot study.

Nineteen out-patients (11 female, mean age 35.6 ± 11.4 years) presently attending a self-help group were administered the Berlin Quality of Life Profile (Priebe et al., 1995) – a translated and adapted version of the Lancashire Quality of Life Profile (Oliver, 1991). The questionnaire addresses objective QoL as well as subjective QoL. Only subjective satisfaction ratings of QoL were included in the analyses. Satisfaction with different QoL areas was rated on a seven-point scale from ‘extremely dissatisfied’ (=1) to ‘extremely satisfied’ (=7). A rating of 4 reflects satisfaction alternating with dissatisfaction.

Of our 19 patients ten patients (52.6%) were married, eight (42.1%) were single and one (5.3%) was divorced. Eight (42.1%) were employed, eight (42.1%) were unemployed, two (10.5%) were students and one (5.3%) was retired. The severity of OCD was measured with the Yale Brown Obsessive-Compulsive Scale (Y-BOCS). A mean Y-BOCS score of 13.1 was found. The QoL ratings for our sample are listed in Table 1. Moderate to severe OCD is associated with impaired QoL. The reduction of QoL observed in our sample is comparable to that of out-patients in a community service for mentally ill (Priebe et al., 1995).

Table 1

<table>
<thead>
<tr>
<th>QoL Dimension</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employment</td>
<td>4.6</td>
<td>1.9</td>
</tr>
<tr>
<td>Leisure time activities</td>
<td>4.3</td>
<td>1.6</td>
</tr>
<tr>
<td>Relationship</td>
<td>4.6</td>
<td>1.7</td>
</tr>
<tr>
<td>Family</td>
<td>5.0</td>
<td>1.4</td>
</tr>
<tr>
<td>Friends</td>
<td>4.3</td>
<td>2.0</td>
</tr>
<tr>
<td>Mental health</td>
<td>3.6</td>
<td>2.0</td>
</tr>
<tr>
<td>Overall QoL</td>
<td>3.9</td>
<td>1.4</td>
</tr>
</tbody>
</table>

5. QUALITY OF LIFE STUDIES IN LONG-TERM SURVIVORS OF CHILDHOOD BONE CANCER UNDERGOING ROTATION PLASTY FOR LOCAL TUMOUR–CONTROL
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2Musculoskeletal Tumor Society (MSTS), the psychosocial evaluation founded on the Sickness Impact Profile, the Cattell Questionnaire, the Wakefield Depression Inventory, the Stait Trait Anxiety Inventory and the QLQ-C30 questionnaire. Coping strategies were evaluated using a standardized interview.

The clinical outcome rated good or excellent in 17 of the 18 patients. Compared to uninvolved controls of the same cultural origin no major differences in personal style of living were detectable. The present educational and occupational status was superior as well as the rate of marriage which was higher compared to individuals of the same age. The majority of patients used offensive coping strategies and showed less emotional but rational attitudes. A correlation between physical outcome and psychosocial parameters was notable.

Rotation plasty offers a high functional and psychosocial outcome in long-term analysis of two decades. Due to its permanent status and low incidence of complications, this treatment is still of choice in distal femur sarcoma.

6. CONCEPTIONS OF HEALTH IN QUALITY OF LIFE RESEARCH
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Like many anacronyms, health-related quality of life (HRQoL) has taken on a life of its own. Indeed if it is said quickly enough, the meaning of what the letters actually stand for can easily be forgotten and perhaps they were never thought about deeply enough in the first place. This paper focuses on the first letter of HRQoL, which stands for ‘health’.

Fieldwork aimed at eliciting lay perceptions of ‘health’ has been undertaken in two areas of Kenya since December 1994, using a wide variety of research methods. The aim of the research is to develop an instrument to assess the effect of biomedical disease control programmes on the lay perceptions of HRQoL. This has facilitated an elucidation of the potential range of conceptions of health that can be adopted.

The following six classifications of health have been highlighted: health as an objective truth, health as an English word which, like any other English word, can be translated, health as the absence of bodily (and possibly psychological) malfunction, health as represented by the local equivalences of its connotations, health as reflected in the overlap of local ways of seeing the world with ways of seeing implied (to English speakers) by the English world health and health as an English word that relates only to the experiences of people who speak English.

The paper demonstrates that even careful translation of HRQoL instruments conveys very particular conceptions of health. It also draws attention to the limitations in approaching HRQoL through the translation of English terms.
7. CHRONIC OBSTRUCTIVE PULMONARY DISEASE CLINICAL STAGING AND HEALTH-RELATED QUALITY OF LIFE

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There is insufficient knowledge about how to stage the clinical severity of chronic obstructive pulmonary disease (COPD). Specifically, it remains to be ascertained to what extent health-related quality of life (HRQoL) deteriorates at different clinical stages and to what degree this pattern of deterioration is affected by coexistent chronic conditions (co-morbidity). We assessed the association of HRQoL with clinically defined stages of COPD severity and the influence of co-morbidity. A cross-sectional study of 321 consecutive male COPD patients recruited from the out-patients clinics of four hospitals and one primary health centre was conducted. Functional respiratory impairment (stages I to III in increasing order of impairment of %FEV1, as proposed by the ATS) and respiratory symptoms were evaluated together with St George’s Respiratory Questionnaire (SGRQ), a specific measure for obstructive Airways disease and the Nottingham Health Profile (NHP), a generic measure.

The SGRQ scores were moderately to strongly associated with disease staging (r, ranging from 0.27 to 0.51). Stage I patients showed substantial deterioration of HRQoL; the SGRQ total score of 34 compared with a score of 6 for the reference population (p < 0.001) and their deterioration was significantly higher among those with co-morbidity (19 versus 36, p = 0.001). Co-morbidity was found in 84% of the patients. The observed pattern of HRQoL deterioration across the different stages was only partly influenced by co-morbidity. ATS staging criteria based on %FEV1 separate COPD patients with varying degrees of HRQoL. Even patients with mild clinical severity show significant HRQoL deterioration. Co-morbidity has an additional impact on HRQoL of COPD patients.

8. HEALTH-RELATED QUALITY OF LIFE AND CHRONIC VULVAR DERMATOSES INVOLVING LICHEN SCLEROSIS

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Vulvar dermatoses is a chronic skin disease affecting the vulvar region. It has many forms and is underdiagnosed and difficult to treat. Persons with lichen sclerosus (LS) can experience mild to severe symptoms including pruritus, fissuring or cracking of skin, inflammation and dryness. The extent of quality of life (QoL) impact with this condition, however, has not been systematically assessed and is known largely from anecdotal reports from patients. We used a focus group to adapt the Dermatology Specific Quality of Life (DSQoL) questionnaire for LS and administered it to 31 patients aged 18 years and over recruited from two medical centres in the southeastern USA.

Forty-three percent of the subjects were new patients, with a median age of 58 years. Twenty-eight percent experienced characteristic symptoms at least one or 2 times a week and 17% affirmed having three or more symptoms rates as severe, causing constant distress. The effect on psychosocial functioning was considerable: 20% reported frequent limitations in activities of daily living (such as self-care, ambulation and bathing) and social activities. Twenty-seven percent frequently felt emotional distress and low self-esteem from their disease. Perhaps the most salient impact was upon the patient’s sexual life: 50% considered that their disease had impaired the quality of their sexual relationship with their spouse or partner and 33% reported severe discomfort from sexual activity. On a global QoL scale, approximately one half of the patients felt that LS had at least moderately affected their QoL (50% were severely effected).

The long-standing suffering from vulvar dermatoses is considerable and affects many aspects of life quality. Clinical trials of treatments for LS are needed which include QoL as a primary efficacy parameter.

9. WHY SHOULD WE MEASURE CARE GIVER WELL-BEING?

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As our society ages, the prevalence of certain disorders, among them Alzheimer’s disease, will increase. These will impact not only on the health care system and the social service system, but also families, including spouses and children. Care givers are crucial in supporting the patient and managing the disease. Care givers are not only the ‘voice’ of the disease and proxy respondents, but also the decision makers. Although many of these diseases are not curable, they are manageable. The health, well-being and quality of life (QoL) of the patient and care giver are integrally related. Therefore, it is necessary to measure the QoL not only of the patient, but also of the care giver. Care givers are a very heterogeneous group and experience many challenges in their care giving role. The literature has documented a number of various consequences, including increased depression, anxiety, emotional and physical exhaustion, hopelessness, helplessness, guilt, anger and feelings of isolation. However, there are also positive aspects to care giving that have been identified. Therefore, it is important to use multidimensional instruments with separate domain scores to identify specific areas in which certain interventions can be recommended and applied, such as educational resources, behaviour training, environmental changes, the availability of services, the use of computer networks, psychoeducational programmes, etc., to help relieve the stresses and burdens and improve the care giver’s QoL.

A number of care giver assessments for care givers of various chronic conditions have been developed. These will be compared and contrasted. If we do not assess the care giver, we are certainly omitting a very important piece of information.

10. QUALITY OF LIFE OF HIV-POSITIVE ASYMPTOMATIC PATIENTS

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HIV-positive patients of clinical categories A, and A, are asymptomatic, but knowledge of their health status could affect their health related quality of life (QoL). In order to measure differences in QoL, using the SF 36, between a sample of these patients...
and the Italian norm, a cross-sectional survey throughout Italy was carried out between April and July 1996.

Eligible patients were males and females aged at least 18 years, aware of their HIV positivity; exclusion criteria were severe acute diseases unrelated to HIV infection and current drug addiction. The SF 36 mean score was compared with the weighted mean of the Italian norm and differences for each domain, expressed as percentage of the norm, were calculated.

Two hundred and one patients filled in the questionnaire (67.2% males, mean age 34 years); sexual intercourse and i.v. drug addiction were the most frequent modality of infection. The mean scores of the SF 36 domains were physical functioning 92.0 (-2.2%), role-physical 82.5% (-6.6%), bodily pain 86.5 (7.1%), general health 55.5 (-24.6%), vitality 65.2 (-3.0%), social functioning 77.3 (-5.2%), role-emotional 74.4 (-11.0%) and mental health 65.4 (-9.2%) (the differences as percentages with the Italian norm are in parentheses).

Knowledge of HIV positivity only affects physical functioning and vitality slightly, gives limitations to physical role and impairs social functioning, mental health and emotionality; moreover, these patients perceive their general health as dramatically lower than norm. The social stigma, the progression of the disease and the lack of curative treatments could explain these results in patients free from significant limitations and symptoms.

11. A NEW QUESTIONNAIRE TO MEASURE PATIENT SATISFACTION WITH GENERAL PRACTICE: THE VERONA PATIENT SATISFACTION QUESTIONNAIRE VPSQ

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Medical Department, Glaxo Wellcome, S.p.A., Verona, Italy

Humanistic outcomes have increased their importance for quality of care assessment as the role of the patient has become central in health care evaluation. General practitioners (GPs) should know how their patients feel about the services they receive and a patients’ satisfaction survey could be an effective tool for general practice.

During 1994, a group of GPs practicing in Verona developed a 27-item questionnaire to determine their patients’ opinions on their relationship with them. This questionnaire was filled in by 7900 patients (approximately 55% of the people who received the questionnaire). The results showed a satisfactory relationship, positively related with age: more than 90% considered their GP qualified or very qualified, 50 and 46% perceived their relationship with their GP as fully satisfactory and satisfactory, respectively, the time spent visiting was considered adequate by 86% and no shortcomings in medical offices were found by 46%.

During December 1996, a team (three GPs, two clinical researchers and a statistician) was set up to derive a new instrument from this questionnaire to measure patients’ satisfaction with general practice. It is called the Verona Patient Satisfaction Questionnaire (VPSQ); an analysis of the 1994 data led to a 17-item questionnaire, measuring four domains of patients’ satisfaction: physician-technical, physician-relationship, access to care and facilities. Tests for reliability and validity have shown that some questions need to be amended as well as ordinal scales used for answers and, hence, a new version of the questionnaire is under development.

12. DEVELOPMENT OF A QUESTIONNAIRE FOR HEPATITIS C PATIENTS

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Chronic hepatitis C (CHC) could have a heavy burden on patients. As no specific instrument to measure patients’ health-related quality of life (QoL) exists, we started a project aimed at developing and validating a specific tool. The project includes a first operational step to identify determinants through medical and patients focus groups and a second step to validate the preliminary questionnaire.

Between July and November 1996 a meeting with a panel of six specialists and six focus group meetings with 71 patients were held to find medical and patients items. A total of 74 items (related to physical functioning, work, leisure, normal life, sexual life, feeding and independence) plus a symptoms checklist have been collected and are under statistical analysis.

The first finding was the different impact of CHC on patients’ QoL depending on whether the patients are treated or not. Untreated patients perceive their QoL as the norm, but they are worried about the progression of CHC to cirrhosis or cancer, minor worries are feeding, drinking and sexual life. Patients treated with interferon perceive a bothering impact on daily life. Most of them reported fatigue, nausea, vomiting, aching muscles and joints, headache, flushes, nervousness, insomnia, etc. Anxiety and fear for the future were similar to untreated patients. Another minor finding is the labelling of CHC patients by friends, colleagues, etc. A further critical issue is that exhaustive information may play a major role in improving the QoL of CHC patients.

The preliminary questionnaire is ready for a validation study.

13. QUALITY OF LIFE OF DIFFERENT HIV CLINICAL CATEGORIES

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HIV-positive patients could be classified into clinical categories (A, to C) according to their clinical conditions and CD4+ T cell number. We aimed to measure how their health related quality of life (QoL) varies between clinical categories and which domains are most subject to change.

Between April and July 1996 we carried out a cross-sectional survey, administering the specific questionnaire MOS-HIV to a sample of Italian HIV-positive males and females of different clinical categories, aged at least 18 years.

Thanks to the cooperation of 46 infectivologists, the MOS-HIV was administered to 649 patients and 635 questionnaires were fully evaluable for the analysis. There were 66% males and the mean age was 35 years. Most of patients were in clinical categories A and B (36 and 37% respectively), while 27% were in clinical category C. The assumption of scale construction and scoring methods was met. Cronbach’s α coefficients exceeded the reliability standards (range 0.76–0.91). The mean scores of each domain of category A were as follows: physical functioning 82.0, bodily pain 76.1, vitality 61.3, physical role 75.6, general health 38.4, cognitive function 80.0, health distress 72.0, mental health
63.4, QoL 61.8 and social functioning 83.1. The scores of category B patients were similar to category A, while those of category C showed a greater difference from category A, in particular in bodily pain (−5.4, \( p < 0.05 \)), physical role (−9.8, \( p < 0.01 \)), general health (−6.1, \( p < 0.01 \)) and social functioning (−8.1, \( p < 0.01 \)).

Our results show that in particular physical limitations, bodily pain, social functioning reduction and a bad perception of general health are responsible for a significant impairment of the QoL of patients who are HIV positive.

14. DEVELOPMENT AND VALIDATION OF A DISEASE-SPECIFIC QUESTIONNAIRE ON QUALITY OF LIFE IN CHRONIC VENOUS INSUFFICIENCY AND CHRONIC LEG ULCER

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Chronic venous insufficiency (CVI) is a chronic disorder of the legs that – in advanced stages such as leg ulcer – can severely impair patients' physical, psychological and social status. Besides the clinical outcome, treatment studies should therefore include parameters of quality of life (QoL), too. The present study was designed in order to develop a disease-specific questionnaire on QoL in CVI that can be used in clinical trials.

After an open interview with 45 CVI patients regarding areas of individual stress due to illness, a preliminary set of questions was designed and then checked by experienced phlebologists and psychologists. The resulting questionnaire of 84 items in German named the Freiburg Life Quality Assessment (FLQA) was then tested in a group of 295 patients of all CVI stages. The convergent validity was checked using the Nottingham Health Profile (NHP), a QoL questionnaire on daily life (ALL-TAG), the symptom check list (SCL-90R) and an inventory on social support (SOZU). Besides this, the feasibility was tested by a short extra questionnaire of 12 items. The general QoL scales of the FLQA were also tested in 225 healthy adults.

The FLQA showed satisfying distributions and good internal consistence (Cronbach’s \( \alpha > 0.70 \), in most scales \( > 0.90 \)). The retest validity (\( r > 0.80 \)) and sensitivity to change in several scales (\( p < 0.001 \)) were good. The convergent validity was satisfying. The discriminant validity was good since there were significant differences related to the CVI stage in most FLQA scales. In addition there were significant differences of QoL between the CVI patients and matched groups of healthy controls. The feasibility tests proved a good acceptance by almost all patients.

The validation tests indicate that the FLQA is a useful instrument for the evaluation of QoL in patients with vein diseases.

15. FRENCH LANGUAGE VALIDATION OF THE CHILDHOOD ASTHMA QUESTIONNAIRE – FORM C

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In 1994, French et al. published the results of a health-related quality of life (QoL) self-questionnaire (CAQ-B) directly addressed to asthmatic children aged 7–11 years. This questionnaire was validated in French; however the authors suggested that it might be advantageous to retain the principal psychometrical properties, but reduce the number of questions. In the original version certain questions do not appear to belong either to the group of questions pertaining to the specific CAQ axes, nor to those related to overall asthma-related QoL. Our objective was therefore to carry out an adaptation of the French version Childhood Asthma Questionnaire – Form C.

Different problems have been raised, but we can now affirm that the linguistic and psychometrical validation of the French version of the CAQ-C, can be retained.

16. FRENCH VERSION OF THE CHILDHOOD ASTHMA QUESTIONNAIRE – B: TOWARDS A SHORT FORM


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In 1994, French et al. published the results of a health-related quality of life (QoL) self-questionnaire (CAQ-B) directly addressed to asthmatic children aged 7–11 years. This questionnaire was validated in French; however the authors suggested that it might be advantageous to retain the principal psychometrical properties, but reduce the number of questions. In the original version certain questions do not appear to belong either to the group of questions pertaining to the specific CAQ axes, nor to those related to overall asthma-related QoL. Our objective was therefore to carry out an adaptation of the French version Childhood Asthma Questionnaire – B by means of an item analysis, thus limiting the number of items to those which seemed to us to be the most important, while retaining the psychometrical properties. Two hundred and eight patients were included in the validation study. A review of the exploitation data in the 23-item CAQ-B shows 14 questions isolated as problematic (either in regard to content or structure). Seven questions were dropped. Therefore the final questionnaire comprises only 16 questions. An analysis of the items provides us with satisfactory results and the discrimination indexes are all greater than 0.90. The item-score correlations are high, much higher even than
those initially reported in the 23-item French version. A factorial analysis carried out showed the four-dimensional structure described by French et al. corresponds to a 14% increase over the original version proposed by the authors. We show that the severity trait is highly correlated with the assessment made by the parents. This correlation is much higher in relation to the one obtained in the 23-item version (0.57 compared to 0.49). In addition, the distress and passive QoL traits, which could not be isolated in the 23-item French questionnaire are also significantly related to this assessment, although to a lesser degree. Asthmatic children show changes from their active QoL scores at inclusion (in comparison to the control population) whereas the passive QoL scores show no difference. The internal consistency results reported are truly an improvement over the results in the 23-item version: distress (0.82), severity (0.70), active QoL (0.61) and passive QoL (0.53). Stability, as explored by the correlation coefficient, shows that the Pearson test–retest correlation coefficients are significantly correlated: above 0.55, except for severity (0.43), greater than those found in the 23-item French version. The psychometrical properties of this new version are greater than with the 23-item version.

17. FRENCH LANGUAGE VALIDATION OF THE CHILDHOOD ASTHMA QUESTIONNAIRE – B
P. Auquier, D. French, L. Pascal, J.C. Delaroziere, A. Beresniak, M.C. Simeoni, J.C. Dubus and J.L. Bernard
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Childhood asthma represents a major public health issue in France. It is a high prevalence disease which affects 5–10% of children and mortality due to asthma is extremely unsettling. In 1994, French et al. published the first results of a health-related quality of life (QoL) self-questionnaire which was developed and validated in Great Britain. This questionnaire, directly addressed to asthmatic children aged 7–11 years, is a multidimensional QoL measure based on four dimensions: active QoL, passive QoL, distress and severity. Only the last two aspects are specifically related to asthma. Our objective was to carry out a linguistic and methodological validation of this questionnaire by directly exploring the QoL of asthmatic children.

Two hundred and eight asthmatic children were recruited between December 1995 and July 1996. The experts made several modifications in order to ensure the validity of the contents. An analysis of the distribution shows a homogeneous distribution. An analysis of the item-scale convergence shows that each one of the constituent items found in the scale subscores has a higher correlation with the score of its own dimension than with the scores of the other dimensions. The correlation between the various dimensions shows a correlation between severity and distress. We performed a factorial analysis to confirm the four-dimensional structure described. Trait validity was explored based upon parental response. Nomological validity was studied by comparing the active and passive QoL scores of the asthmatic children with those of control children. The internal coherence of the dimensions are similar to that reported in the English language validation. The test–retest correlations were used to explore stability in 39 children.

Acceptability was considered to be good by children, parents and doctors. Ninety-eight percent of the population recruited filled out the questionnaire correctly. The percentage of non-responses for each item was low (1%), with the exception of three questions. The rate of non-responses for the question ‘How do you feel most of the time?’ and ‘How do you feel when you play outside and it is cold?’ was reported as 5% and the non-response rate for the question ‘Which drawing shows the way you feel when you wake up in the night because of your asthma’ reached 12.5%. In achieving acceptability, reliability and validity, which were all satisfactory and consistent with the original scales, we believe that we have demonstrated technical equivalence between the two scales.

18. QUALITY OF LIFE AS AN OUTCOME OF RADIATIONAL TREATMENT
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The aim of the investigation was to establish an objective measurement of the results after the implementation of radiological therapy of patients with inoperable cervical cancer.

All patients with inoperable cervical cancer that were going to be treated by radiotherapy in 1997 were included in the project. They were examined and interviewed before the treatment and during the second, third and sixth months after treatment. The patients were categorized according to the number and weights of their risk factors (nine risks). The quality of life (QoL) questionnaire included physical status, mental status, ability for work, social interaction and personal perception of health.

In first 6 months 60 patients were included in the project. They were in clinical stadia Ia (10%), Ib (27%), Ila (15%), Ilb (32%), IIIa (2%) and IIlb (12%); 65% could move without limitation, 30% could only at home and 5% were bedridden. Most of patients (65%) believed in the success of the treatment, 60% were distressed, 45% did not sleep well and 25% had less contact with friends and relatives. Only 37% of the patients described their health as being very bad.

The analyses of the results of the treatment of the first group of patients treated (40) is now in process.

For an assessment of QoL in the case of radiologically treated patients, the risk stratification method was used for the categorization of their health situation and both objective and subjective criteria.

19. INCONSISTENCY IN SCALING METHODS FOR RANKING HEALTH STATES
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Our aim was to determine the level of inconsistency in ranking health states using the rank order method and two different valuation methods: the visual analogue scale (VAS) and time trade-off (TTO).

Three hundred individuals from a primary care centre were recruited randomly by trained interviewers and asked to rate 13 health states using the rank order method and two different valuation methods: the visual analogue scale (VAS) and time trade-off (TTO). They were examined and interviewed before the treatment and during the second, third and sixth months after treatment. The patients were categorized according to the number and weights of their risk factors (nine risks). The quality of life (QoL) questionnaire included physical status, mental status, ability for work, social interaction and personal perception of health.

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The analyses of the results of the treatment of the first group of patients treated (40) is now in process.

For an assessment of QoL in the case of radiologically treated patients, the risk stratification method was used for the categorization of their health situation and both objective and subjective criteria.
the LI was determined by calculating the percentage of individuals who produced inconsistent rankings or valuations using any of the methods. We performed a logistic regression using the existence of inconsistencies for each method as the dependent variable and sociodemographic and health characteristics as independent variables. At the aggregate level, the LI was calculated on the basis of the inconsistencies in the mean ranking or valuations and was determined by the number of inconsistent rankings produced by each method.

At the individual level, 56% of the respondents made inconsistent responses using the TTO, method, compared with 25.9% with the VAS and 23.5% with the rank order method ($p < 0.01$). The significant variables in each regression were for the rank order method, mobility problems (OR = 2.45), higher values on the VAS (OR = 1.04), and low educational level (OR = 0.39) and for the VAS, usual activities (OR = 2.53), old age (OR = 1.03) and higher values on the VAS (OR = 1.02) and none for the TTO. At the aggregate level, no inconsistencies were observed using the rank order method, one with the VAS (the state 32,232 was rated lower than 33,232, 15.9 versus 17.6) and two with the TTO method (states 11,133 and 21,222 rated lower than states 21,133 and 2,222, 0.26 versus 0.29 and 0.60 versus 0.65, respectively). This means that 4.6 and 9.3% of the 243 health states generated by the EQ instrument would be ranked inconsistently using the VAS and TTO methods respectively.

At both the individual and aggregate levels the TTO method generated more inconsistencies than the rank order and VAS methods in ranking health states. No clear pattern of inconsistent individual was found.

20. CHANGES IN THE QUALITY OF LIFE IN PATIENTS SUFFERING FROM LYMPHOMAS

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Within the monitoring and follow-up of patients suffering from malignant lymphomas it is important, besides the assessment of the efficacy of applied therapeutic procedures to life prolongation, to evaluate their influence on the quality of life (QoL) compared with the period before the appearance of the disease. Actual antitumour treatment strategies have a significant impact on the prolongation of life. Various segments of life are disturbed in all stages of lymphomas.

During a prospective study we measured the QoL in 42 cases of patients suffering from Hodgkins lymphoma and 38 patients with non-hodgkins lymphoma, including all stages of the disease. The patients were treated with chemotherapy and HT/RT. They were interviewed by specially designed questionnaires for the assessment of their physical and mental conditions, ability for participating in social life, existence of supportive systems, etc.

After the disease was diagnosed 88% of the patients had experienced an important change in certain segments of all living activities. Their daily activities at home were significantly reduced and they reported changes in their sexual and emotional lives. Primary health care protection is evidently lacking within the process of terminal care of oncologic patients. This paper points out the necessity for including psychotherapists, social workers, physical therapists, club organizations, etc., in the activities of an oncological team.

21. HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH CHRONIC BRONCHITIS: A CROSS-SECTIONAL AND LONGITUDINAL ASSESSMENT OF THE SF-36

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The objective of the present study was to test and document the performance of the SF-36, either with a cross-sectional and longitudinal assessment, in terms of patients’ acceptability, psychometric validity, known group validity and capability to detect meaningful changes over time and conditions. These objectives were considered relevant because of the lack of data about the usefulness of health-related quality of life (QoL) questionnaires, and specifically of the SF-36 Health Survey, when applied longitudinally in a sample of patients with chronic bronchitis. In a randomized clinical trial assessing the efficacy and safety of two different drug regimens (Salmeterol and Theophylline) in the treatment of chronic bronchitis, 224 patients from 22 Italian centres entered the run-in phase and 178 were enrolled in the trial. The patients’ self-reported health perception was evaluated using the Italian version of Short Form 36 Items Health Survey (SF-36).

Data analysis was performed in order to (1) test the applicability of the SF-36 in a population of patients with chronic bronchitis, (2) evaluate the psychometrics performance of the questionnaire, (3) investigate the cross-sectional and longitudinal relationship between the SF-36 scores and a selected list of clinical variables and (4) compare these results with those obtained from others.

Our findings add new evidence about the longitudinal capability of the SF-36 to capture the impact of treatment over time and confirm the data reported by other cross-sectional applications. Furthermore, they support the thesis that, although generic questionnaires may be considered less sensitive than those disease-oriented ones, in specific, well-characterized diseases, when valid and robust instruments are adopted, the findings may be both scientifically sound and clinically understandable.

22. DYSFUNCTIONAL COGNITIONS AND DISABILITIES IN PANIC DISORDER

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Dysfunctional cognitions represent a core element of panic disorder. We investigated the question of whether certain cognitions are associated with disabilities in different areas of life.

In a study on the comparison of paroxetine with group psychotherapy in patients with panic disorder with or without agoraphobia, dysfunctional cognitions were assessed by the Agoraphobic Cognitions Questionnaire and psychosocial impairment was evaluated by the Sheehan Disability Scale.

Of 100 patients included in the study, 88 cases could be analysed regarding this question due to complete data. Dysfunctional cognitions showed a significant correlation with disabilities in social relations and family life but not in functioning at work. As suggested in the literature the most frequently reported cognitions were having a heart attack, the fear of fainting and the fear of dying. However, cognitions which
were associated with disabilities in daily life were characterized by the fear of losing social control and the fear of impairment that would result in dependency on the help of others.

The results suggest that cognitions with an interpersonal aspect have a greater impact on patient’s role functioning aspect of quality of life (QoL) than the cognition of fear of dying. It is concluded that it is advisable to concentrate on these interpersonal cognitions.

23. THE IMPACT OF DEPRESSION ON THE QUALITY OF DAILY LIFE
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Although there have been many studies that show the negative impact of depression on the quality of life (QoL), no clear understanding exists of how decrements in QoL are reflected in everyday experience. Cross-sectional instruments, whether generic or disease specific, miss experiential variables such as individuals’ emotions, motivation and activities in daily life.

We investigate the usefulness of the experience sampling method (ESM), a time-sampling method, in assessing daily QoL in depression. Eighty depressed patients seeking treatment in a primary care setting and a group of 40 healthy controls, similar in sex, age, living circumstances and work status, completed self-report forms ten times a day for 6 days. Patients were then randomized to a double-blind treatment of either placebo or an active antidepressant (imipramine) for 6 weeks, with a possible treatment prolongation to 18 weeks. Both patients and healthy controls completed ESM forms at different periods throughout the follow-up study.

Results presented here will focus on the differences in the quality of daily life (e.g. general happiness, enjoyment of activities, satisfaction in social contexts) between healthy controls and depressed out-patients, prior to treatment. The ESM results will be discussed in relation to cross-sectional QoL measures, such as the Satisfaction With Life Scale.

24. PSYCHIATRIC INVALIDITY UNDER THE CIRCUMSTANCES OF ECONOMIC ISOLATION
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People’s condition in FRY in war surroundings, under the circumstances of economic blockade and poverty, may, as a result, have an increased number of psychotic reactions, which may have a permanent influence on working ability (the meaning of partially or permanent professional invalidity).

In our research we investigated a period of 4 years (from 1990 to 1995), looking for statistical data for psychiatric diseases and invalidity.

The results showed a dramatic increase in the number of psychotic reactions, which, as a result, caused permanent working invalidity. This tendency is probably a result of negative socio-economic circumstances and also poor possibilities for rehabilitation, because of the patient’s reduced motivation for change.

25. THE SCIENCE OF HEALTH-RELATED QUALITY OF LIFE ASSESSMENT
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Three areas of active research which have implication for the development of future health-related quality of life (QoL) instruments will be reviewed.

(1) Cognitive basis of survey responses. Research indicates that respondents select information when responding to survey questions. The question now is how can these characteristics of individual respondents be incorporated into the design of health-related QoL instruments?

(2) Psychological determinants of health-related QoL responses. There is a growing literature that indicates that psychological and emotional factors modify responses to health-related QoL instruments. The implications of these observations will be discussed.

(3) Quantitative estimation. The response shift phenomena suggest that respondents will base their responses to identical questionnaires differently if the questionnaires are administered over a period of time. These data imply that the ‘metric’ that a person uses when responding to a health-related QoL instrument varies over time and this has implications about the validity and interpretability of health-related QoL data. In addition, quantitative estimation is critical to many health-related QoL instruments (e.g. the visual analogue scale).

Sufficient information is available in the cognitive sciences to permit the systematic study of quantitative estimation in health-related QoL instruments.

The research topics discussed suggest that continued refinement of health-related QoL instruments is required in order to ensure the validity of the assessment process.

26. CURRENT HEALTH STATE AS A PREDICTOR OF THE PREFERENCES OF METASTATIC PROSTATE CANCER PATIENTS
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Patients with advanced prostate cancer (N = 80) estimated preferences for their current health state and three alternative health states (asymptomatic, symptomatic and progressive disease states). The health states were described using narratives (e.g. differing levels of fatigue, pain or psychological distress). Preferences were generated using three computer-based methods: visual analogue scaling, standard gambling and time trade-off. Additional psychosocial assessments were performed. Patients systematically altered their preferences as a function of the prognosis implicit in the narrative; the worse the prognosis the lower the preference. Multivariate regression analyses identified current health as the only variable that significantly (p < 0.01) contributed to the variance in preferences for each narrative for all preference assessment methods. These results are consistent with previous studies identifying a patient’s self-described current health data as the major determinant of preferences for health states.
27. LIE OF SEIQoL IN PROSPECTIVE STUDIES
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In individual quality of life (QoL) assessment as the schedule for the evaluation of individual quality of life (SEIQoL), the validity of the changes of cues elicited by the subjects in successive evaluations is still uncertain.

The SEIQoL was administered to 30 subjects the previous day and 7 months after total hip replacement (THR) for arthritis or osteonecrosis. At the second assessment, each subject was again asked to name the five most important areas of their life.

Five patients did not change any cue between the first (t0) and second (t1) evaluations. The others changed around two cues (range one to five); these rated two SEIQoL at the second interview, one with the new cues (t1) and then one with domains they elicited at t0 (t2).

The mean index of the SEIQoL was significantly more positive for patients 7 months after THR. The mean index was 59.3 at t0 and 68.6 at t1 (p < 0.001) or 72.5 at t2 (p < 0.0001).

Nevertheless no statistical difference was noted between the two methods of assessment (t1, t2).

In the case of a population of patients undergoing THR, the two methods of SEIQoL administration are sensitive to changes in individual QoL. Keeping the previous elicited cues seems a little more sensitive, but probably reflect less accurately the real QoL of a subject at the second time point.

28. DECONSTRUCTING THE CONCEPT OF RESPONSIVENESS
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Responsiveness is considered to be an essential property in measures to be used to evaluate change. The purpose of this paper is to challenge the traditional approaches to measuring the responsiveness of health status measures. Defining responsiveness as the ability to detect clinically important differences, this paper will first provide a conceptual matrix for studies of responsiveness and, second, show a method used to determine what change is important.

A conceptual framework was developed. The literature was reviewed and studies classified using the framework. The conceptual matrix has two axes. The first axis is the type of difference (differences between patients, within patients or a hybrid version of the two). The second axis is the character of the difference measured by a questionnaire: precision of the questionnaire, minimally detectable difference (change above noise), the observed difference and finally, the clinically important difference. This can be subdivided by who defines the change as important: patients, clinicians, payers or society?

The second part of this paper describes a qualitative study of 25 workers with upper limb pain used to determine the nature, magnitude and importance of changes experienced over the course of recovery. A grounded theory approach was used. Themes arising from the interviews were coded and contributed to a theory of when and what change is important from the patient’s perspective.

The conceptual framework and literature review showed several different designs all claiming to measure responsiveness. The qualitative study revealed that improved function and symptom relief were common markers of important change, though the magnitude varied. In addition, other ‘unique’ ways of asking about important change arose.

This study found a variety of designs of studies of responsiveness, which differ in the concept of what is being measured and, hence, the statistical summary. The qualitative study supported the uniqueness of the concept of ‘important’ change in studies of responsiveness.

29. QUALITY OF LIFE QUESTIONNAIRES IN THE TREATMENT OF MAJOR DEPRESSION
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In evidence-based medicine subjective well-being is a measure assessed by quality of life (QoL) questionnaires which are used as outcome scales equal to clinical rating scales of symptoms and drug-induced reactions.

Generic QoL scales like the Psychological General Well-Being (PGWB) or SF-36 can appear very similar to depression-specific questionnaires such as the Beck and Zung scales. However, preliminary results show that patients prefer QoL scales to depression scales.

Empirical studies in the treatment of patients with major depression have shown an acceptable responsiveness and ability to predict compliance or relapse of depressive episodes. In long-term treatment the scales are important in defining the goal of therapy. In diagnosing major depression in primary health care the QoL scales appear helpful (case identifier).

30. QUALITY OF LIFE MEASUREMENT IN MENTAL HEALTH: WHAT DO THE DATA TELL US?
Marion Becker and Ronald Diamond
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Quality of life (QoL) is an important outcome measure in mental health for use at both the individual client and group level. QoL is fast becoming a standard measure of outcomes in clinical trials, cost effectiveness analysis and clinical practice. Unfortunately, the methods for combining clinical data with client perceptions and goals for improvement with treatment are not standardized. In addition, there are likely to be differences about the relative importance of different domains. Clinicians, families and the clients themselves may have very different views of the client’s QoL and of the important goals of therapy. QoL is a subjective construct which varies with the population studied. It is generally conceptualized as a multidimensional construct made up of a number of independent domains including physical health, psychological well-being, social relationships, functional roles and subjective sense of life satisfaction. Each QoL domain can be assessed from the point of view of the clinician, client or family and the relative weighting of the importance of each domain can also vary from one observer to another. This paper presents a unique method for incorporating personal values, preferences and different points of view. Research data from the Wisconsin Quality of Life Project are presented to examine and discuss the interaction between different viewpoints and to illustrate how QoL assessments can vary across responder types and among different ethnic groups. We discuss important conceptual issues and the application of the research to clinical practice.
31. SUGGESTIVE PSYCHOTHERAPY FOR CANCER PATIENTS
G. Bengesser

A series of parallel applied sessions of autogenic training and hypnosis was performed with the aim of improving the quality of life (QoL).

Semi-structured interviews at the end of that series evaluated the results. Fourteen of the 24 patients gave answers that could be seen as moderate success with two as a high degree of success.

A realistic view of current studies to the theme ‘cancer and psyche’ is added.

Reference: Bengesser/Sokoloff: Plädoyer für eine mehrdimensionale Psychiatrie, Stuttgart: Enke

32. QUALITY OF LIFE AS PARAMETER FOR THE OUTCOME MEASUREMENT OF THE NEUROREHABILITATION OF CHILDREN AND ADOLESCENTS
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There are no qualified instruments available for a standard measurement of health-related quality of life (QoL) in childhood and adolescence.

This deficit is particularly evident in an area such as the neurorehabilitation of children and adolescents, who, after severe CNS trauma, in the absence of an adaptations process, are suddenly cut off from all previous social relationships. Scientifically, i.e. the quantifiable QoL studies regarding coma or near-coma patients, brings additional methodological problems.

Based on this central change in life as well as in reference to the health terminology of the WHO we carried out a 3 year longitudinal ‘outcomes study’. In addition to somatic–functional aspects, we used the criterion of social reintegration into previous life relationships as a possible measurement for QoL.

Whereas almost 45% of the patients showed severe functional or cognitive damages, three-quarters of all patients could be reintegrated into their families, two-thirds were reintegrated into their previous extrafamilial setting (pre-school nursery or school), contacts to friends could be re-established and reactivation of previous free time activities could be resumed in up to 40% of the patients and in 90% the social net was generally supportive.

33. QUALITY OF LIFE ASSESSMENT IN THE ACUTE MENTALLY ILL – IS DISEASE INTENSITY THE KEY TO INSTRUMENT VALIDITY IN SCHIZOPHRENIC PATIENTS?
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A common phenomenon in patients with acute psychiatric diseases is avoidance or delay of a necessary treatment, due to a ‘lack of disease insight’. This behaviour can contribute to disease aggravation and poor prognosis. Health-related quality of life (QoL) is an important component of disease insight and is inversely associated with the severity of illness in many somatic disorders and in depression. In schizophrenia, however, due to the characteristics of the disease, this relationship remains unclear.

The aim of the study was to evaluate the association between disease severity and self-perceived mental and physical health in patients with schizophrenia requiring hospital treatment.

A cross-sectional study of 115 schizophrenic patients, male and female, admitted to hospital treatment in 1995–1996 in Muenster, Germany, was conducted. Standardized patient interviews and examinations were done by physicians within 24 h after admission. The diagnostic classifications were based on ICD-9. The Brief Psychiatric Rating Scale was used to rate psychiatric symptoms and severity and the SF-36 to evaluate self-reported mental and physical health. Non-parametric methods and linear regression were used in the analysis.

No change of mental health scores across the categories of disease severity was observed, but there was a significant decrease in physical health. Further analysis revealed a significant inverse relationship between the BPRS subscale ‘anxiety/depression’ and self-perceived mental health. In contrast to this finding, significant positive associations with BPRS subscales ‘thought disturbance’ and ‘activation’ were observed. These subscale analyses can explain the observed constancy of mental health scores. In addition, the decrease in self-perceived physical health was mainly contribuable to the BPRS subscale ‘anxiety/depression’.

Increasing disease severity is perceived in self-reported physical health, but not in mental health in acute schizophrenic patients. This finding is in contrast to other studies done in schizophrenic patients with a chronic course of illness. Two characteristics of the disease, ‘thought disturbance’ and ‘activation’, contribute considerably to the observed lack of mental health perception in this population and, thus, seriously question the validity of general QoL instruments such as the SF-36 in severely ill schizophrenic patients.

34. PANIC ATTACKS, ANTICIPATORY ANXIETY AND AGORAPHOBIA DIFFERENTLY AFFECT SPECIFIC DOMAINS OF QUALITY OF LIFE OF PATIENTS WITH PANIC DISORDER
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Panic disorder is a disabling disorder often with a chronic course. The core features of the symptomatology are anxiety attacks, anticipatory anxiety and agoraphobic avoidance. These features may be present to a various degree.

In a study on the comparison of paroxetine with group psychotherapy in 100 patients with panic disorder with or without agoraphobia, panic attacks were assessed by a diary, agoraphobic avoidance by the mobility inventory, anticipatory anxiety by an 11-point rating scale and disabilities concerning work, social relations and family life by the Sheehan Disability Scale. The relationship of the symptomatology at baseline with the different domains of disability was analysed using the Spearman correlation coefficient.

Disability at work was only associated with the extent of agoraphobic avoidance. Social relations were impaired by high anticipatory anxiety and phobic avoidance and impairment of family life was associated with high anticipatory anxiety only. The frequency of panic attacks was not associated with disability in any of the domains.

Various domains of life are differently impaired by the specific features of the symptomatology of panic disorder. In particular anticipatory anxiety and agoraphobic avoidance appear to be strongly disabling.
35. QUALITY OF LIFE IN PATHOLOGICAL GAMBLING
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Pathological gambling is a disorder of impulse control and has a progressive course that usually results in an economic disaster and impairment of family life and social relations. However, some see gambling as a devotion to the pleasure principle. Therefore, we investigated whether quality of life (QoL) is impaired by pathological gambling.

In 42 subjects who actually suffered (n = 24) or were remitted (n = 18) from pathological gambling, QoL was assessed by means of the Wisconsin Quality of Life Questionnaire. Gambling behaviour was assessed by the South Oaks Gambling Screen and symptoms of depression by the Beck Depression Inventory.

Pathological gamblers rate their overall QoL as moderately low. Interestingly the impairment of QoL by symptoms (of depression) was substantially higher than the impairment by the economic situation. Compared to actively gambling subjects, remitted gamblers had a better QoL in nearly all domains of life. The QoL of pathological gamblers is poor and is better is the disorder is in remission. Certain aspects as, for example, the economic situation are seen less dramatic by the gambler, maybe because of coping with the situation or denial as we suppose.

36. QUALITY OF LIFE ASSESSMENT IN PATIENTS RECEIVING ADJUVANT THERAPY FOR BREAST CANCER
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We have developed an approach for assessing the impact of adjuvant therapy for breast cancer on quality of life (QoL) in international clinical trials. Conceptual, methodological and practical issues are summarized. Various linear analogue self-assessment (LASA) scales have been used as indicators of the components of QoL, including global indicators of well-being and functioning and specific indicators of symptoms of disease and treatment. In two trials of 1,475 pre- and 1,212 post-menopausal patients with operable breast cancer, QoL was assessed at baseline, during adjuvant treatment (chemotherapy, endocrine therapy or combination) and follow-up and at recurrence.

The LASA indicators at baseline were responsive to the impact of biomedical factors, including the number of positive lymph nodes and oestrogen receptor status. During the first 18 months of follow-up, the indicators were responsive to adjuvant treatment differences, change over time and recurrence.

The QoL form was revised in 1993 to collect additional information on disease and treatment-related burden. A preliminary analysis of 312 post-menopausal patients in a subsequent trial confirms the responsiveness of the additional indicators to chemotherapy and endocrine therapy. It shows the expected relationship between the various global and specific indicators both on and off chemotherapy.

These results confirm the feasibility, validity and clinical relevance of this approach for studying the impact of adjuvant breast cancer therapy on QoL in international clinical trials.

37. QUALITY OF LIFE: AN INDIVIDUAL EMPIRICAL EMERGENT CONSTRUCT
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That the mental, physical and social domains, each containing many dimensions and items all contribute to quality of life (QoL) is uncontroversial. In human individuals, assuredly complex systems, the many dimensions and items of QoL observably interact, probably also in chaotic ways. In these conditions, the weights of isolated items become for all practical purposes meaningless. Therefore, the much used multi-item questionnaires describe, but do not evaluate QoL, neither in individuals nor in populations.

For example, allergic patients treated with cetirizine scored better than placebo on all nine dimensions of the SF-36. Here there is no doubt that the treatment improved QoL, because it is highly unlikely that any important dimension on which the patient groups would have scored otherwise is missing in the SF-36. However, whether piracetam treatment of acute stroke, which improved the (surrogate end-points) neurological and functional scores also improved QoL is plausible, but will be proven only when comprehensive QoL measurement will have been done. And suppose in a randomized population of metastatic solid cancer patients one would compare chemotherapy with only palliative care and one would, as can be expected, find no significant differences in survival, and chemotherapy superior for the mental domain, but inferior for the physical comfort domain: we would not know which treatment, on aggregate, would be the better.

The problem is that QoL is an individual and emergent construct. Overall QoL can therefore be captured only by global self-assessment.

Just as people in everyday life, while acting under uncertainty, make global assessments all the time, so they can seriously answer the question ‘How have you been?’: A solemn, practical, non-peer relativistic, non-cultural, empirical and well-tolerated way to obtain such responses is anamnestic comparative self-assessment (ACSA) in which the subjects’ memory of the best and the worst times in their life experience defines an individual scale of QoL that is exquisitely individual, and yet generic.

Using both a multi-item questionnaire and a global assessment would by logistic regression therefore allow us to estimate the weight of the dimensions and items in populations and thus identify those whose improvement would most contribute to the QoL of the greatest number. A combined approach to measurement of QoL is necessary to maximize the utility of QoL interventions.

38. ASSESSMENT OF QUALITY OF LIFE AFTER CARDIAC SURGERY: DETERMINATION OF CRITICAL DOMAINS
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Although perioperative morbidity and mortality are frequently measured surrounding cardiac surgery, there is increasing interest in determining the effect of these procedures on...
additional outcomes including health-related quality of life (QoL). Previous studies have utilized standard QoL measures, but have not determined whether these instruments accurately assess those characteristics which are important to cardiac surgery patients. Therefore, we studied a cohort of patients either pre-operatively, on post-operative days 3 – 5 or both using a free-form interview and a validated instrument.

After IRB approval, patients scheduled for elective cardiac surgery were interviewed alone or with their spouse and asked to complete the SF-12, a health-related QoL instrument which included seven domains (general health perception, physical functioning, role limitation secondary to physical and emotional health, bodily pain, general mental health and social functioning). The interview consisted of questions regarding those aspects of functional, physical and emotional well-being (domains) that were of concern after cardiac surgery.

A total of 45 patients (mean age 67 ± 9 years), 35 undergoing CABG, ten valve replacements and one combined were studied. The demographics were 63% male, 78% Caucasian, 18% African-American, 39% attended college, 20% attended graduate school, 67% were married, 22% were working and 15% were on sick leave. Although the acute SF-12 could be used pre-operatively, the questions could not be applied during the early post-operative period. In addition to those domains assessed by the SF-12, additional areas of significant concerns to patients include independence (73%), relief of symptoms (58%), ambulation (42%), diet (42%), life expectancy (36%) and body image (27%).

Our results suggest that standard health-related QoL instruments do not adequately assess important patient concerns after cardiac surgery. In order to better determine the effects of CABG or valve surgery on health-related QoL, we believe that it is important to address these additional patient-specified domains. The use of patient interviews, including inclusion of the spouse, is useful in the development of new validated health-related QoL instruments.

39. RELATIONSHIP BETWEEN QUALITY OF LIFE AND PSYCHOPHARMACOLOGICAL LONG-TERM MAINTENANCE THERAPY IN RECURRENT AND CHRONIC DEPRESSION
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Relapse and recurrence are common following successful short-term treatment of depressive disorders. The best protection against future depression is a maintenance therapy with the same potent pharmacological agent that was used to treat the acute episode successfully. Antidepressants (e.g. imipramine or amitriptyline) and/or lithium have been shown to prevent recurrence and to decrease the frequency and/or the intensity of recurrences. Non-compliance of lithium treatment ranged from 18 to 47%. The rate of non-compliance with tricyclic antidepressants was even higher, ranging from 32 to 76%. The main reasons for non-compliance are the side-effects of the drug. An antidepressant must therefore meet certain demands to be considered suitable for the long-term treatment and prophylaxis of depression. Important for quality of life (QoL) are the absence of anticholinergic effects, no sedation, no impairment of sexual functions, avoidance of weight gain and an equal or better therapeutic effectiveness than TCA. The new selective antidepressants (e.g. selective serotonin, noradrenaline or monoaminooxidase reuptake inhibitors) have shown to be effective and better tolerated than TCA and lithium. The advantages and disadvantages of the new selective antidepressants and the influence of QoL will be discussed.

40. ASSESSING QUALITY OF LIFE IN STROKE PATIENTS’ SPOUSES WITH THE SUBJECTIVE QUALITY OF LIFE PROFILE
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The goal of this study is to recruit a cohort of stroke patients and spouses, who will undergo a 2 year follow-up, in order to observe the evolution of the quality of life (QoL) of stroke patients’ spouses with time. We are presenting preliminary results on 17 couples (stroke patients living at home and spouses acting as care givers). Demographic and medical data were collected. Patients were assessed regarding motor impairment (Fugl-Meyer scale), cognitive impairment (Blessed Dementia Rating Scale) and disability (Functional Independence Measure). Spouses were asked how many hours they could spend outside per day and were assessed regarding anxiety and depression (Hospital Anxiety Depression Scale (HADS)). Spouses’ QoL was assessed with the SQLP, a French self-questionnaire which explores satisfaction (range −2 to +2), importance (0 to 3) and expectations (−2 to +2) in 31 items. Descriptive statistics were generated.

The patients’ mean age was 61.1 ± 15.5 years. Fifty-nine percent presented with right hemiplegia and aphasia. The mean interval from CVA is 5.6 ± 2 months. Most patients were independent for walking, but partially dependent for bathing, dressing and tub transfers. Cognitive impairment was low in our sample.

The spouses’ mean age was 61.5 ± 13.3 years. Fifty-nine percent were female and 30% were working. Forty-seven percent had previously suffered from anxiety and/or depression. The mean time spent outside the home was 3.8 ± 3.2 h per day. The mean anxiety score was higher than the mean depression score on the HADS. On the SQLP, the mean satisfaction level is comprised between 0 and 1 for most items; satisfaction is particularly low for the item ‘projection in the future’ (−0.1) and higher than 1 for ‘relationships with proxies’ (1.2) and ‘living with somebody’ (1.2). The mean expectations level is low for all items (between 0 and 0.5), but always positive. The highest expectations level is observed for the item ‘marital life’.

These preliminary results allow us to describe our sample, in terms of objective and subjective data. They are comparable to other previously published results. We expect satisfaction and expectations scores to change over time among spouses, as the hope for patient’s recovery vanishes and the ‘burn-out’ phenomenon occurs.

41. THE IMPORTANCE OF SOCIAL SUPPORT FOR QUALITY OF LIFE AFTER LYMPHADENECTOMY FOR TESTICULAR TUMOUR
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This study was performed to investigate and compare the morbidity of laparoscopic retroperitoneal lymphadenectomy (LRLA) and open retroperitoneal lymphadenectomy (ORLA) and to elucidate the influence of coping behaviour, social adjustment and social support for quality of life (QoL) in these patients.
 Ninety-two patients participated in the study. Several questionnaires (e.g. the EORTC, FACT and BEFO) were submitted. A personal interview was performed by the psychiatrist with 60 patients and 32 patients answered the questionnaires by mail.

Most important for QoL is the private social support (wife, parents and friends), but the quality of the doctor–patient relationship is also an important factor. Furthermore, the patients prefer the knowledge of the histology of the lymphadenectomy and a close aftercare arrangement for their personal security. The result will be discussed.

42. QUALITY OF LIFE AFTER RADICAL CYSTECTOMY IN OUTCOME RESEARCH – RESULTS OF A PROSPECTIVE PILOT STUDY

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1Department of Urology, University of Münster, 2Department of Urology, University of Bochum and 3Department of Surgery, University of Kiel, Germany

The goal of any treatment strategy for cancer is to improve not only patient survival but also the quality of that survival. The purpose of this prospective study was to obtain relevant data upon which to develop a bladder-specific module according to the guidelines of the EORTC. Between July 1993 and July 1994 the data of 30 patients with non-metastatic bladder cancer were gathered for analysis. The patients underwent a radical cystectomy with an ileum conduit. The first step was to evaluate the symptomatology in the patients by means of open interviews. One day pre-operatively (Z0), the day before discharge (Z1) and one year after surgery (Z2) the patients received symptomatic and psychological questionnaires. The statistical analysis was performed with the SPSS program (DOS system).

The urological symptomatology in patients with bladder cancer showed no significant differences between the pre-operative and 1 year post-operative values (24.5 and 25.6, respectively; range 1 – 100). Comparing the psychological parameters, all patients showed a strong decline of subjective well-being, mostly in vigilance and social extrovertivity. The present study indicates that there is no positive correlation between the results in urological cancer surgery and the individual psychological parameters of the patient. The acceptance of this QoL study was high. Nearly 90% of the patients sent their questionnaire back to our institution. The QoL data were analysed together with the clinical data of the patient. Statistical analysis was done with the SPSS program (DOS system).

Regarding problems concerning sexuality and incontinence after radical prostatectomy, more detailed information was possible due to the newly developed tumour-specific module. All patients answered the questions dealing with sexuality, partnership and incontinence. Fifty-eight percent of the patients admitted severe limitation of their sexuality with consequent problems in their partnership. Details of the multidimensional analysis of QoL data are presented. The present retrospective study will help to increase the reliability and validity of the new instruments. The study will give a more detailed look at all aspects of QoL after radical prostatectomy. In the future it is necessary to test this instrument in a prospective trial with baseline QoL data.

44. PSYCHOMETRIC PROPERTIES OF THE EORTC QLQ C30 VERSION 2.0 IN A SAMPLE OF CANCER PATIENTS IN ARGENTINA

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Fundación Oncológica Argentina, FUNDONAR, La Plata, Argentina

The EORTC QLQ C30 is an integrated measurement system to evaluate the quality of life (QoL) of cancer patients participating in international clinical trials. The purpose of this study is to analyse the psychometric properties of the Argentine version of this instrument in order to determine the feasibility of using it in Argentina.

The Argentinian version of the EORTC QLQ C30 was administered to a sample of 73 cancer patients (38 female and 35 male). Age varied between 21 and 76 years (means 52.48 years). The sample was homogeneous with regard to site and histologic type. The ECOG performance status (PS) was 0 – 2 in 45 patients (61.6%) and 3 – 4 in 28 patients (38.4%). Thirty-three patients (45.2%) were receiving chemotherapy and 40 (54.8%) had completed treatment at the time of the study.

(1) Reliability: this was assessed through internal consistency which measures the extent to which similar questions produce consistent responses. We used Cronbach’s α coefficient to estimate the reliability for the multi-item scales and the coefficients ranged from 0.65 to 0.91.

(2) Validity: inter-scale correlations between the nine scales of the QLQ C30 were statistically significant showing the strongest correlations between the physical functioning and role functioning scales and weak correlation between the emotional functioning and physical scales. Similarly to the original EORTC study, the interscale correlations were of only moderate size indicating that they are assessing different components of the
QoL construct. For measuring clinical validity we compared the mean scores of patients with different PS and different treatment, under the hypothesis that patients with a PS of 3 – 4 and patients receiving chemotherapy should have poor QoL. In our study, the instrument was able to find differences across the different groups as was expected. The Argentine version of the EORTC QLQ C30 was easy to understand and administer and it showed high levels of reliability. In our study the instrument was able to find differences across the different groups of medical conditions as was expected. We considered that this version could be used in Argentina to assess the QoL of cancer patients in international clinical trials.

45. WHOQOL-BREF: SOME PSYCHOMETRIC CONSIDERATIONS OF THE ARGENTINE VERSION
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Fundación Oncológica Argentina FUNDONAR, La Plata, Argentina

The aim of the study was to analyse some psychometric properties of the WHOQOL-BREF, the 26 item short-form of the WHOQOL and compare it with the full WHOQOL 100 item version, when they were consecutively administered to a sample of cancer patients in Argentina. The Argentine version of the WHOQOL-100 and WHOQOL-BREF were given in written format to 54 ambulatory cancer patients, in a disease-free interval, by trained interviewers who remained accessible to the respondents to assist them if it was necessary. The sociodemographic characteristics obtained included age (mean 52.3 years and range 23 – 73 years), sex (10 male and 44 female) and educational level (35 primary school, 13 high school and six college).

The reliability of the WHOQOL-BREF as assessed by Cronbach’s α coefficient was high (0.92) for the total scale and for each domain (physical 0.80; psychological 0.81; environmental 0.83) except for social relationships (0.41). The item domain correlation was also high. We used the Pearson correlation coefficient (r) to quantify the strength of the association between the two forms. This correlation was high for all the domains and reached statistical significance (physical 0.82; psychological 0.86; social 0.76; environmental 0.77; overall health status 0.69). In our small study, the WHOQOL-BREF showed high levels of reliability and item domain correlations. The domain scores were strongly correlated with those obtained from the WHOQOL-100. We think that this short version is a good and rapid alternative for assessing the domain profiles of the WHOQOL-100.

46. EFFECT OF RISPERIDONE ON QUALITY OF LIFE
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Department of Veterans Affairs, Medical Center and Case Western Reserve University, Cleveland, OH, USA

The concept of quality of life (QoL) has become an increasingly important outcome measure in schizophrenia research. Because antipsychotic medications are relatively equally efficacious in treating the major symptoms of the illness, it has become necessary for clinical researchers to develop more sophisticated tools for evaluation of newer, potentially better, but more expensive, medications. QoL offers a broad perspective for this assessment. Within the setting of a large urban hospital dedicated to the treatment of military veterans with serious mental illness, we studied 50 patients with psychotic disorders who were treated with the novel antipsychotic, risperidone. The subjects were followed for 1 year, with assessments at baseline, 6 months and 12 months, using the Lehman’s Quality of Life Interview and the Positive and Negative Syndrome Scale (PANSS). The data were analysed using the paired t-test. The results showed a significant improvement in total subjective QoL indicators (t = 3.16 and p < 0.05), with trends for improvement in each of the subjective and objective indicators except for, interestingly, subjective satisfaction with finances. A reduction in symptoms and a reduction in the utilization of health care resources accompanied these improvements. These results suggest that risperidone treatment improves the QoL of patients with psychotic disorders. This study also reinforces the importance of incorporating a wide range of outcome measures when assessing novel antipsychotic medications.

47. LONG-TERM IMPACT OF CLEFT PALATE ON QUALITY OF LIFE, SOCIAL SUPPORT AND FAMILY LIFE: A QUESTIONNAIRE SURVEY
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In order to explore quality of life (QoL) in patients with a cleft palate, 156 patients were examined with a set of questionnaires. In this survey, which was the most comprehensive conducted with CP patients so far, we used the KINDL (QoL in children), the Short Form-36 (SF-36), the Social Support Scale (SSS) and the Impact on Family-Scale, which was given to the patients’ parents in order to evaluate effects of CP on family life. Furthermore, we used a set of questionnaires which have been designed in our clinic specially for our CP patients and which are used to evaluate problems with speech, social acceptance, sexual behaviour and satisfaction with treatment.

Our results indicate that the overall QoL is very good for CP patients. Social integration as measured with SSS appears to be even higher than in a non-CP population. Parents report that the CP had little or no severe long-term impact on family life. Satisfaction with the treatment is very high. The problems reported by our patients are more specific, as it is revealed by our own questionnaires. The survey demonstrates that our interdisciplinary concept for CP surgery and therapeutic management which closely follows the development of the individual across the life-span is highly effective.

48. DETERMINANTS OF QUALITY OF LIFE IN GENERAL POPULATION
S. Briançon¹, F. Guillèmin², P. Presiosi², P. Galan² and S. Hercbergy²
¹Ecole de Santé Publique, Faculté de Médecine, 54505 Vandoeuvre les Nancy and ²ISTNA-CNAM, 2 rue Conté, 75003 Paris, France

The objective was to identify determinants of health-related quality of life (QoL) in the general population in order to contribute to the evaluation health care and the medical decision process.

French subjects of the cohort Su. ViMAX (prevention trial of cancer and cardiovascular diseases with antioxidant vitamins and oligoelements), 3,614 males aged 45–60 years (mean 52 years) and 3,538 females have completed the Duke Health Profile
48. Table 1

<table>
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<td>1.8</td>
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<td>–7.0</td>
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<td>–3.8</td>
<td>–4.9</td>
<td>–4.0</td>
<td>–3.4</td>
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</table>

(DHP), a generic adapted and validated instrument. It consists of 17 items exploring three main independent dimensions: physical, mental and social. The scores were standardized on a scale from 0 (worst) to 100 (best). Potential determinants of health-related QoL have been assessed separately between males and females, using multiple linear regressions.

The mean and SD values are 79.7 (17.0) and 72.6 (20.1) for the physical dimension among males and females, respectively, 76.8 (19.9) and 68.8 (21.5) for the mental dimension and 65.9 (18.6) and 65.9 (19.3) for the social dimension.

Significant β coefficients of linear multiple regressions indicate the score reduction in the presence of the corresponding determinant.

The level of health-related QoL of adult subjects varies according to sociodemographic, lifestyle and medical factors, with a certain discrepancy between dimensions. These factors should be taken into account for a definition of reference values of the instrument needed for a better interpretation of health-related QoL values in clinical practice.

49. QUALITY OF LIFE ISSUES IN DIABETIC PATIENTS WITH LOWER EXTREMITY ULCERS AND THEIR CARE GIVERS

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Lower extremity ulcers are among the most common and costly complications of diabetes. They are a leading cause of amputation and account for more hospital days than other diabetic complications. Although instruments that measure the impact of diabetes on quality of life (QoL) exist, none are designed to determine the specific QoL impact of lower extremity ulcers on the patient. In order to develop a disease-specific QoL instrument, focus groups were conducted to identify the impact of lower extremity ulcers on the QoL of patients with diabetes and their care givers. Focus group discussions that involved 14 diabetic patients with lower extremity ulcers and 11 care givers were conducted on four consecutive mornings at a central location in Sheffield, UK. Each of the focus groups identified specific issues that addressed four broad QoL domains and related subdomains: social (daily, leisure, family and social life), psychological (emotional health and positive consequences), physical (physical health and treatment impact) and economic (employment and financial). A negative impact on all QoL domains was experienced by both patients and care givers. A differential impact was found for certain domains due to demographic characteristics. Adaptation to a lifestyle different from that before the occurrence of the ulcer was required by both patients and care givers. The negative impact on QoL also affected treatment compliance and psychological status for most patients. This study demonstrates that it is possible to separate the QoL impact of lower extremity ulcers from the general condition of diabetes. This disease-specific focus aids in the development of an instrument to measure the specific impact of lower extremity ulcers on the QoL of both patients and and their care givers.
50. QUALITY OF LIFE IN CHILDREN WITH DUCHENNEN MUSCULAR DYSTROPHY
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1Department of Medical Psychology and 2Department of Orthopaedics, RWTH, Aachen, Germany

Duchenne muscular dystrophy (DMD) is a genetically transmitted disease with limited life expectation, posing great stress on patients and families. Our study intended to assess quality of life (QoL) and family climate in families of patients with DMD. Ninety-one children with DMD and their mothers filled in a questionnaire for health-related QoL in children (KINDL) and two questionnaires assessing family climate (Familien-diagnostisches Testsystem). Furthermore, the patients were asked to give information on their personal and family background, as well as the history of disease and treatment.

Although DMD can be diagnosed 4–6 weeks after birth, the mean age at diagnosis is 3.6 years. Moreover, this period of uncertainty is prolonged by the fact that it takes 10.8 months on average from becoming aware of the first symptoms until diagnosis is certain. In other studies this period was even longer and lasted up to more than 2 years.

The family climate was within the normal range (all sten-values ranging from 4 to 6). Broken families were rare in our sample; only 3.3% of the mothers were divorced, 91.2% were married. Of the mothers, 55.9% stated that their children are well or very well informed about their disease. Of the mothers, 75.4% said that they talk frankly about the disease with their families. As compared to the test norms, the patients indicated lower QoL values in all domains of the QoL scale (satisfaction with everyday life \( t = 4.99, df = 104; p < 0.001 \); satisfaction with body \( t = 5.76, df = 108; p < 0.001 \); satisfaction with psychic \( t = 2.09, df = 107; p = 0.039 \); satisfaction with social life \( t = 5.52, df = 108, p < 0.001 \); total satisfaction \( t = 5.64, df = 107, p < 0.001 \).

Patients in special education for the handicapped evaluated satisfaction with everyday life higher than children in normal education \( t = 2.29, df = 58, p = 0.025 \). The mothers of those patients in special education gave lower independence ratings of their children as compared to mothers of patients in normal education \( t = -2.40, df = 66, p = 0.019 \). Patients in special education rated themselves lower in sense of belonging together \( t = 3.39, df = 66, p = 0.001 \) and organization \( t = 3.16, df = 66, p = 0.002 \) and higher in religiosity \( t = 2.76, df = 66, p = 0.007 \) and control \( t = 3.55, df = 66, p = 0.001 \).

51. QUALITY OF LIFE AMONG CHILDREN WITH A CHRONIC ILLNESS: THE DEVELOPMENT OF THE HOW ARE YOU? (HAY)
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University of Leiden, Section of Health Psychology, Leiden, The Netherlands

The aim of the study was the construction of the ‘How Are You?’ (HAY), a self-report as well as a parent report instrument, designed to assess quality of life (QoL) among children with a chronic illness. The HAY is divided into a generic part, which can be answered by children with distinct chronic illnesses as well as healthy children, and a disease-specific part with items varying for children with asthma, diabetes, epilepsy or juvenile chronic arthritis. The HAY is a multidimensional instrument covering the physical, psychological and social domains and containing items on the prevalence, quality of performance and importance of the child’s everyday life behaviour.

In the main study two successive measurements were carried out on 569 children with a chronic illness (286 children with asthma, 124 children with diabetes mellitus, 97 children with epilepsy and 62 children with juvenile chronic arthritis) and 344 healthy children as a reference group. Next to the HAY, the Child Behaviour Checklist (CBCL) and the Child Attitude Toward Illness Scale (CATIS) were used in this study as validation tools.

The results of the main study provide support for the construct validity as well as the ability of the HAY to differentiate between children with different illnesses. Confirmatory factor analysis identified five general factors with a good internal consistency (\( \alpha \) coefficients ranging from 0.76 to 0.86). The disease-specific part consists of four factors and is analysed for each illness group separately. The differences between children with a chronic illness and healthy children on the prevalence and quality of performance scales are in the expected direction.

Pearson correlations between the CBCL competence scales and the subscales of the HAY measuring the quality of performance on activities was fairly good (correlations ranged from 0.20 to 0.59). As expected, there was a strong correlation between the CATIS and selected subscales of the HAY. The correlations between the child and parent versions for ratings of observable behaviour were satisfactory but also proved that both versions can be used complementarily.

52. QUALITY OF LIFE NOTIONS APPLYING TO HEALTH CARE NETWORKS. THE ROLE OF SELF-HELP GROUPS IN PROVIDING CARE FOR BREAST CANCER PATIENTS
E. Bruyninckx
Political and Social Sciences, University of Antwerp, Belgium

Quality of life (QoL) and health promotion have become central concepts in medical sociological literature, constituting a transformation in conventional professional perspectives about the meaning of health and the appropriate goals of medicine. To examine to what extent and in what sense existing health care facilities reflect this transformation, research was conducted in 1995 in a region of Flanders. The purpose of this study was to explore the magnitude, structure and internal dynamics of the existing network of facilities for breast cancer patients, professional as well as non-professional.

Starting with a list of facilities that were already known to us as organizations that provide care for breast cancer patients, a questionnaire was filled out for every organization. Along with some questions about the structure and activity of the organization itself, the survey also asked about other organizations that they usually refer breast cancer patients to or that they themselves get breast cancer patients from. The new facilities that were mentioned that way by more than one organization were visited in a subsequent round to complete the same questionnaire. The referral data were later used to conduct a network analysis.

In three rounds a total of 57 organizations were interviewed, consisting of a wide range of organizations providing occasionally medical but mostly psychosocial or material care for breast cancer patients. These facilities are provided by the government or are initiated by an organization or originate from the personal initiative of one or more persons. In the network analysis the latter type – mostly self-help groups – proved to be particularly important. It is not only the organizations initiated by
persons that appear to play a key role in the entire care network for breast cancer patients. In addition, for a breast cancer patient the chance of being referred to a facility of the ‘person’-type is much higher than that of being referred to any other type of organization.

When studying a supply of facilities from a more traditional point of view normally one would expect to find a totally different network structure. Here it is not professional/official organizations that play a key role, but rather self-help groups and other non-professional person-driven facilities. This breast cancer care network is in fact an example of a broadened, modernistic type of care that exceeds the professional model and fits in with a reshaped notion of subjective, empowered and self-realized QoL.

53. ENVIRONMENTAL IMPACTS ON QUALITY OF LIFE
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Department for Medical Psychology, University of Hamburg, Germany

The health effects of environmental factors, such as pollutants, radiation or noise, have mostly been described in terms of classical medical indicators of morbidity or mortality.

Impairments of well-being or function in terms of health-related quality of life (QoL), however, have so far been largely neglected in environmental medicine. On the basis of a theoretical model relating environmental factors to subjective health, the results of three studies are reported, in which health-related quality of life (QoL), however, have so far been largely neglected in environmental medicine. On the basis of a theoretical model relating environmental factors to subjective health, the results of three studies are reported, in which health-related QoL was assessed as an outcome variable in persons affected by aircraft noise (n = 400), indoor climate (n = 2000) and complex urban environments (n = 600). The results show that impairments of well-being are present under these conditions and vary according to the degree and type of environmental strain. However, most important for QoL effects is not the environment as such, but its perception by the individual. Together with perception, psychosocial factors, in particular the level of stress experienced, explain up to 48% of the variance of QoL ratings.

The results indicate that environmental strain may affect QoL and thus constitutes a health risk.

54. ELDERLY POPULATION HEALTH STATUS SURVEY
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Measures of health status are increasingly used in studies of the effectiveness of interventions for elderly patients in a variety of settings, but there is a lack of information on health status and its variability in the general elderly population. This study aimed (1) to establish health-related quality of life (QoL) measurement norms for the 65 years and older age groups and (2) to investigate the validity and reliability of several health status questionnaires in an elderly population. People aged 65 years and over were selected at random from GP lists and interviewed at home on sociodemographics, self-reported morbidity and activities of daily living. Four generic questionnaires were used: the Nottingham Health Profile (NHP), the Short Form 36 (SF-36), the Hospital Anxiety and Depression Scale and the EuroQol. In addition to a performance measure of physical function. The test-retest reliability was assessed in a random sample of 94 repeat interviews at a median of 28 days after the first visit. Four hundred and eighty-one people took part, 229 women and 252 men, mean age 77 years (SD, 6.9 years and range 65 – 102 years). These results are limited to describing the NHP and SF-36 scores and test-retest analysis. In both the NHP and SF-36, the scores were clustered towards the healthy end of the scale, although the SF-36 was more sensitive to lower levels of restriction. Physical dimension scores were related to age, e.g. the physical functioning scale of the SF-36 (100 = no limitations) decreased from a median of 80 for women and 85 for men in the 65 – 69 years age group, to 15 and 40 in the 85+ years group (p < 0.0001). The picture is less clear for the emotional dimension scales: there was evidence of deterioration with age in some scales such as the NHP social isolation and emotional reactions and the SF-36 social functioning. Generally, women were more likely to feel restricted than men. The reliability coefficients (RCs) in all dimensions of the NHP and SF-36 were excellent, except for the SF-36 role limitation scales: 0.53 for the physical and 0.25 for the emotional roles. Comparing similar scales in the NHP and SF-36, the RCs indicated better repeatability in the NHP for the pain and energy dimensions (e.g. NHP pain 0.96, and SF-36 pain 0.79). This survey has produced a wealth of that which will be of benefit to a wide range of health service research involving the elderly.

55. QUALITY OF LIFE (QoL) RESEARCH IN CHILDHOOD CANCER IN EUROPE
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By the year 2000 an estimated one in 900 young adults will have survived a childhood malignancy. This improvement in survival is mainly a result of the expertise provided by centralized paediatric cancer studies. Despite this success it is a fact that for some types of cancers (e.g. neuroblastoma stage IV and multifocal Ewing’s) less improvement has been achieved. New definitions for successful treatments may be indicated, since ‘cure’ is not the only goal. There is an increasing awareness that more needs to be done to improve the quality of life (QoL) of children, both in the short- and long-term.

We conducted as survey of all ongoing activities focusing on the long-term effects of QoL in paediatric oncology at the European level. We also made an overview of the instruments and the QoL domains covered. In addition, potential target populations for further QoL research on an international level were investigated.

As a result, 62 European Paediatric Oncology Study Groups responsible for the treatment of all different childhood cancers as well as seven late effect groups were contacted and 72 publications of European investigators were reviewed. At present the UK, Italy, France, Germany, Spain, The Netherlands and a Nordic cooperative group are collecting data on the long-term effects of treatment in childhood cancer survivors. The main topics researched are leukaemia, Hodgkin’s disease, solid tumours and brain tumours. As well as the long-term effects on health status, the main domains for leukaemia are cognitive functioning and psychological development. In solid tumours a wide range of variables are measured such as psychological, social and sexual functioning, educational achievement and occupational status. For brain tumours the investigators focus on psychological and psycho-intellectual functioning.

We identified a large variety between studies in Europe focusing on long-term effects and QoL in paediatric oncology with
respect to study designs, instruments, age groups, diseases, etc.

This overview will be presented together with a proposal of a large European study on the long-term effects of childhood cancer on QoL (sponsored by DG-5/96/CAN/50048).

56. DISABILITY SCALES IN LOW BACK PAIN.
INTEREST OF THE QUEBEC BACK PAIN DISABILITY SCALE
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The assessment of chronic low back pain during therapeutic follow-up necessitates the adjudication of functional and quality of life (QoL) data to the usual clinical elements, because of the important psychosocial consequences of this disease.

Many authors determined the objective clinical elements of low back pain and proposed numerous functional scales. Most of these scales, developed in English, are disease-specific, integrating pain, disability and psychosocial assessments.

The purpose of our work is to present a Canadian scale, built on the ICIDH conceptual framework, which assesses only disability and has been developed in both English and French: the Quebec Back Pain Disability Scale.

In a population of low back pain patients, we performed (1) an assessment of impairment (clinical examination according to Waddell criteria), (2) an assessment of pain (VAS and Saint Antoine questionnaire), (3) an assessment of disability (Dallas scale, FIM and Quebec scale), (4) an assessment of anxiety-depression (HAD Scale) and (5) an assessment of QoL (Reintegration to Normal Life Index (RNLI) and Nottingham Health Profile (NHP)).

The analysis of 42 subjects allows us to determine elements of validity for the Quebec Back Pain Disability Scale and to measure the consequences of low back pain in terms of physical and psychological dimensions, disability, and QoL.

57. COMPONENTS OF SOCIAL SUPPORT AND QUALITY OF LIFE IN SEVERELY MENTALLY ILL, LOW-INCOME INDIVIDUALS AND IN THE GENERAL POPULATION
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An increase in satisfaction with life domains over time for psychiatric patients who have increased their availability of social support and for those who have maintained adequacy of social support has been shown. However, in order to plan specific interventions in a mental health programme with more efficiency, another step has to be taken; it appears quite important to identify precisely which components of social support appear to be the most related to quality of life (QoL) and to which specific aspects of it. This study will examine the pattern of relationships between components of social support and dimensions of QoL of chronic mentally ill patients, low-income individuals and for the general population. Satisfaction with social support and QoL were assessed for 60 psychiatric patients, 79 welfare recipients and 266 people from the general population with the Social Provisions Scale (SPS) and the Satisfaction with Life Domains Scale (SLDS). Psychiatric patients were less satisfied than the general population on all components of social support. They have a comparable level of satisfaction with the low-income population on most of the components except with provisions which permit emotional integration and opportunity for nurturance. However, their level of satisfaction with QoL is quite similar to the general population and even higher in some dimensions than the welfare recipients. Their lower satisfaction with the personal-intimate dimension in QoL, confirms their deficiencies in social support. All components of social support were consistently related to dimensions of QoL in the general population. Attachment and reassurance of worth were systematically related for psychiatric patients, but only attachment related to dimensions of QoL for the low-income group. Finally, the pairing of the SPS and SLDS scales were good instruments for discriminating 75% of psychiatric patients among other groups.

58. QUALITY OF LIFE AS OUTCOME IN THE TREATMENT OF OSTEOPOROSIS: THE DEVELOPMENT OF A QUESTIONNAIRE FOR QUALITY OF LIFE BY THE EUROPEAN FOUNDATION FOR OSTEOPOROSIS (QUALEFFO)
Working Party for Quality of Life of the European Foundation for Osteoporosis, France

The burden of osteoporosis is fracture related. Vertebral fractures cause pain and disability. To analyse better the impact on the quality of life (QoL), we developed a specific questionnaire for patients with established vertebral osteoporosis (QUALEFFO). This questionnaire is intended to assess the burden of the disease and the evolution during treatment. The questionnaire consists of questions in the following area: pain, activities of daily living/jobs around the house, mobility, leisure/social activities, general health perception and mood. The questionnaire currently exists in the following languages: English, French, German, Italian, Swedish, Dutch, Israeli, Spanish and Czechoslovakian.

The questionnaire was validated in a multicentric study involving 159 vertebral osteoporosis clinically diagnosed – and 159 age/sex-matched patients. Thoraco-lumbar X-rays were evaluated for the presence or not of vertebral deformities using the method of McCloskey and Kanis in all patients by a single investigator (J. Kanis). The case – controls were evaluated in pairs in Italy, The Netherlands, UK, Belgium, France, Sweden and Germany.

An evaluation of the generic short form (36) was also done on all the patients. The repeatability was tested by two administrations of the two questionnaires within 1 month.

The results indicate an adequate repeatability for most questions (Kappa around 0.70). QUALEFFO was able to discriminate well between osteoporotic patients and controls. Discrimination was at least as good as SF-36 and better for specific items (pain and social functions). The questionnaire is available on request from the European Foundation for Osteoporosis (EFFO).
59. IMPLEMENTATION AND APPLICATION INTO CROSS-CULTURAL TRIALS
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Most attempts to study quality of life (QoL) in clinical trials fall short of their goals. This shortfall typically occurs because of missing data, most of which is unavoidable. Cross-cultural, multicentre trials are most susceptible to the problem of missing data, particularly when the trial is conducted within a group of QoL-inexperienced investigators. The best-designed QoL study is worthless if a sufficient amount of data are not collected. Successful implementation strategies have been identified and described by some of the more QoL-experienced clinical trials groups. These successful strategies, along with options for data collection that can be tailored to a specific cooperative group, will be presented.

A second problem in contemporary QoL research across cultures is the fact that most current practice assumes that a good questionnaire translation results in interpretive equivalence after the data are collected. Measurement equivalence only begins with good translation. Methods exist for comparing linguistic or cultural subgroups to one another to determine whether they can be set aside when analysing cases in pooled analyses. Measurement equivalence only begins with good translation. Methods exist for comparing linguistic or cultural subgroups to one another to determine whether they can be set aside when analysing cases in pooled analyses. This practice will prevent dilution or confusion of true effects in the data. An item-response, theory-based approach to detecting differential item functioning and analysing group differences within this context will be presented as an illustration of a culture-fair evaluation of multicentre, multicultural QoL data.

60. ESTABLISHING EQUIVALENCE MEASURES FROM DIFFERENT HEALTH-RELATED QUALITY OF LIFE INSTRUMENTS
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Although a number of validated health-related quality of life (QoL) instruments have emerged for use in oncology, their comparability and compatibility have not yet been fully demonstrated. For researchers, health providers and policy makers to review data across clinical trials, standardized measures (converted scores) derived from valid instruments are necessary. The objective of this study was to demonstrate how the equivalence of QoL measures across different instruments can be established and to develop a standard metric (called the Q-score) for five commonly used QoL instruments in applied oncology settings.

The participants ($n = 1,163$) were a heterogeneous group of cancer patients and HIV patients recruited from five institutions in a hospital setting. The mean age of the participants was 54.1 years (SD = 14.9 years) and their mean educational level was 13.8 years (SD = 3.0 years). Most were married and the great majority were White (non-Hispanic). The QoL instruments used were the Cancer Rehabilitation Evaluation System – Short Form for Research (CARES-SF), the European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC QLQ C30), the Functional Assessment of Cancer Therapy – General (FACT-G), Spitzer’s Quality of Life Index (QLD) and the RAND Health Survey (Rand-36). The psychometric methodology was the Rasch Rating Scale Model.

Despite differences in questionnaire development, the five instruments measured a similar QoL construct and their measures could be equated using the Rasch methodology. Comparability and compatibility among these instruments were demonstrated and the Q-score common metric was derived.

61. CROSS-CULTURAL VALIDATION OF THE FUNCTIONAL ASSESSMENT OF CANCER THERAPY (FACT) SCALES
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The cross-cultural adaption of an existing quality of life (QoL) instrument into another language requires rigorous qualitative and quantitative methodologies in scale development, refinement and modification. The aim of this study was to investigate the psychometric properties and statistical equivalence of the Functional Assessment of Cancer Therapy (FACT) scales across a culture variable (Hispanic versus Black non-Hispanic versus White non-Hispanic).

The participants ($n = 1,617$) consisted of English- and Spanish-speaking breast, colorectal, lung and head and neck cancer and HIV patients. An English or translated Spanish language version was administered according to patients’ language preference. The Rasch Rating Scale Model, an extended version based on the probability model of G. Rasch, was used to evaluate the differential item functioning (DIF) issue and to detect culturally biased items.

The results from pairwise comparisons of item statistics showed evidence of test equivalence in both language versions. The factors contributing to the potentially biased items were discussed. The need for researchers to be more sensitive to the possibility of test item bias across cultural contexts was also noted.

62. RELATIONSHIP BETWEEN SYMPTOMS AND OVERALL QUALITY OF LIFE
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The aim of this study was to examine the relationship between symptom intensity and overall quality of life (QoL) in cancer and HIV patients. The participants ($n = 1,163$) consisted of a heterogeneous group of cancer and HIV patients. The patients rated symptom intensity on the symptom scales of the European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC QLQ C30), including fatigue, nausea and vomiting, pain, dyspnoea, sleep disturbance, appetite loss, constipation and diarrhoea, using a four-point rating scale ranging from 1 (not at all) to 4 (very much). Overall QoL was measured using the total score of the Functional Assessment of Cancer Therapy – General (FACT-G). Analyses of variance and multiple comparisons indicated significant differences ($p < 0.01$) between different levels of symptom intensity. For most symptoms, trend analyses also revealed a clear curvilinear relationship between levels of symptom intensity and overall
63. DEVELOPING STANDARDIZED SCORES FOR THE FUNCTIONAL ASSESSMENT OF CANCER THERAPY (FACT) SCALES

Chih-Hung Chang and David F. Cella
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The Functional Assessment of Cancer Therapy (FACT) measurement system was developed to measure quality of life (QoL) in people with cancer. The general version (FACT-G) is a 34-item instrument, with 29 scored items and five experimental items that measure five major QoL domains (physical well-being, social/family well-being, relationship with doctor, emotional well-being and functional well-being). A total score for the FACT-G can be obtained by summing each of the domains.

The main purpose of this study was to develop standardized scores for the FACT scales using the Rasch Rating Scale Model. Item responses obtained from a heterogeneous group of cancer patients were calibrated using the BIGSTEPS computer program. The patients’ interval QoL measures (in logit scale) obtained in each domain and the total were then transformed to standardized scores with a range of 1 to 100. Patients’ QoL profiles were then created for comparisons.

This study also illustrated the use of Rasch methodology in the development of graphical definitions of the scales to assist in the prediction of unanswered item responses. Other applications of the Rasch measurement model to these scales were also discussed.

64. QUALITY OF LIFE AND ALCOHOLISM: WHAT ASPECTS ARE PERCEIVED AS IMPORTANT?

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This study ascertains what issues are perceived as important for quality of life (QoL) by alcoholics undergoing treatment and whether QoL varies during recovery from alcoholism.

Fifty, male, ICD-10 alcoholics, were interviewed based on a pre-designed semi-structured interview proforma to elicit themes and issues perceived as important for QoL by them. The interview focused on domestic/marital, financial/job, social/personal, spiritual/religious and physical health.

The subjects reported ten issues in domestic/marital functioning and stressed mutual understanding and harmony at home. Other themes identified were job related (three), social functioning (five) and personal such as peace of mind, reputation, self-respect, religious, altruistic acts and sensation seeking. Eighty percent reported poor QoL during regular drinking and during acute withdrawal, 50% reported good QoL during abstinence and 80% reported good QoL prior to alcoholism.

Certain alcoholism-related specific issues perceived as important for QoL in alcoholics have been identified. Variations in QoL ratings during different phases of drinking, withdrawal and recovery are noted. An improvement in QoL might influence their long-term recovery.

65. QUALITY OF LIFE RESEARCH AND ACTIVITIES IN ASIA: CURRENT PERSPECTIVES

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Representatives from different Asian nations who attended the session on quality of life (QoL) activities and researchers in Asian countries presented information from their respective countries. The participants were requested to provide information regarding QoL activities and research in their respective countries on a pre-designed proforma. More than 50 professionals participated in the group discussion and 38 returned the proforma after completing it. There were representatives from China, Australia, Indonesia, Hong Kong, Bangladesh, Malaysia, Thailand, Japan, India and The Philippines.

In most Asian countries QoL activities were diverse and in the early stages of development, except in Japan. An attempt has been made here to summarize QoL activities in different Asian countries. Overall the respondents indicated that professionals were gradually getting interested and studies into lifestyle disorders, ageing, urbanization, modernization, industrialization and migration were assuming importance. A special feature reported was the cultural diversity of QoL. It was suggested that QoL should be given due significance as a part of general public health interest.

66. PSYCHOSOMATIC TREATMENT TO IMPROVE THE QUALITY OF LIFE OF THE CHERNOBYL DISASTER AFTERMATH LIQUIDATORS

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The analysis and optimization of treatment of 28 men (outpatients) with residual radiational reactions after contamination (23 – 30 roentgen) which took part in the liquidation of the consequences of the Chernobyl disaster was carried out to improve their quality of life (QoL).

All of these patients complained of weakness, anxiety and astheno-hypochondrical sensations, flabbiness, dizziness, headache, insomnia, cardiac and intestinal pains, constipation, renal cramps, impotence and absence of libido and decline of weight. However, there was no real organic somatic nature to their complaints.

It was shown by phenomenological method that these patients suffered from so-called ‘chronic post-radiational psychosomatosis’ (term of E. Chernosvitov). For the improvement of QoL of these patients special schemes of psychotherapeutic and psychopharmacological treatment were created.

Combinations of rational psychotherapy, autogenic relaxation and hypnotical suggestion with varied psychopharmacotherapy using small doses of egonol–sulpirid, teralen–alimemazin, merlit–lorazepam, phenazepam, xanaxalzolam and tofizopam–grandaxin) were the most effective. At the same time amitryptilin and anxiolitics with sedative components (valium–diazepam and librium–chlordiazepoxid) reinforced manifestations of astheno-hypochondrical.
67. CREATING AN INSTRUMENT TO ASSESS LAY PERCEPTIONS OF HEALTH-RELATED QUALITY OF LIFE: OPTIONS AND IMPLICATIONS

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The aim of our research was to be able to provide an instrument capable of reflecting lay perceptions of health-related quality of life (QoL). The instrument is to be used in evaluations of the effectiveness and efficiency of biomedical disease control programmes in Kenya. This paper provides a description of lay perceptions of health-related QoL and raises a series of methodological, conceptual and political issues affecting the questions for inclusion in our instrument.

Our findings are based on a multiplicity of research methods undertaken between December 1994 and February 1997, including semi-structured interviews (n > 900), focus group discussions and unstructured interviews. In addition to this, two researchers have also lived (one in each site) full-time in the study areas. As well as participating in the usual daily activities, such as farming and cooking, they attended village meetings and other social gatherings and collected detailed weekly case notes on families in the area.

The results show that lay perceptions of health are broader and significantly different from the term usually used by public health professionals, that lay perceptions of health cannot only be addressed on an individual basis (e.g. in relation to food or access to therapies) and that some aspects of life vital to the assessment of good health cannot be discussed openly.

The discussion centres on the implications for policy and future use of the instrument with respect to two related issues: the dissonance between conceptions of ‘health’ represented in an instrument of lay perceptions versus that of biomedical disease control programmes and the fact that issues important in assessing lay perceptions of ‘health’ cannot be captured in a structured questionnaire. Such issues not only affect the type of questions asked in our instruments, but also the range of interventions shown to be ‘effective’ and, hence, the policy options chosen.

68. COMPARISON OF QUALITY OF LIFE BETWEEN AEROBIC DANCE WOMEN AND NON-AEROBIC DANCE WOMEN

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The purpose of this study was to identify how different is the quality of life (QoL) for aerobic dance women from non-aerobic dance women. Ninety-two women aged between 20 and 60 years who participated in aerobic dance and 36 women aged between 27 and 62 years who did not participate in aerobic dance or any other exercise were included as subjects for this study.

QoL was measured by the tool developed by Roh. The tool consisted of 47 items divided into six areas: emotional states, economic life, self-esteem, physical condition and function, neighbourhood relationships and family relationships. Emotional states consisted of nine items, economic life eleven items, self-esteem eight items, physical condition and function nine items, neighbourhood relationships four items and family relationships six items. The Cronbach α of the tool of QoL was 0.88.

The subjects responded to the questionnaire following research assistants who were instructed how to respond. No difference was demonstrated in the total score of QoL between aerobic dance women and non-aerobic dance women.

There was a significant difference in emotional state between the aerobic dance women and non-aerobic dance women. Neighbourhood relationships was the highest of six factors of QoL in the aerobic dance women. Emotional state was the highest of six factors of QoL in the non-aerobic dance women. Fear, loneliness and feeling defeat among the emotional states were the lowest in aerobic dance women compared to non-aerobic dance women. Hobby, recreation, leisure and feeling about appearance among economic life was the highest in aerobic dance women compared to non-aerobic dance women. The degree of activity, vigour state and physical state among physical condition and function was the highest in the aerobic dance women compared to the non-aerobic dance women.

The results suggest that aerobic dance in women can increase neighbourhood relationships, decrease fear, loneliness, feeling defeat and increase hobby, recreation, leisure, feeling about appearance, degree of activity, vigour state and physical condition.

69. FUNCTIONAL AND COSMETIC EFFECTS IN ORAL CAVITY AND OROPHARYNX CANCER PATIENTS AFTER ORGAN-PRESERVING SURGERY

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The purpose of the study was to evaluate the efficacy of function-preserving surgery in patients with oral cavity and oropharynx cancers.

Since 1984 the Head and Neck Department has been working on methods of performing function-preserving surgery in oral cavity and oropharynx cancers. The distinctive feature of this kind of surgery is preservation of the mandible continuity. It makes it possible to avoid rough anatomotopographic disturbances and to preserve the main function (respiration, swallowing and speech) from early in the post-operative period. The patients were divided into two groups. Group 1 included patients who underwent organ-preserving surgery (n = 52). Group 2 consisted of patients with the conventional operation (n = 30).

Complications were observed more rarely in the patients of group 1. The rates of tracheobronchitis were 8.3 and 48.3% in groups 1 and 2, respectively. Local complications (orafistula, oropharyngostoma and mandible osteomyelitis) were found in 17.5% of group 1 and in 22.8% of group 2 patients. Sound speech repair after organ-preserving surgery was achieved in 72% while the speech treatment had no effect after conventional surgery. The 5 year survival rate in patients of group 1 who underwent surgery plus radiation therapy was 46.7% (n = 29). The 5 year survival rate of patients treated with radiation therapy p/w surgery was 40.4% (n = 23).

The results obtained show that the treatment method with preservation of mandible continuity and a high 5 year survival rate in patients with oral cavity and oropharynx cancers have favourable functional and cosmetic effects and improve the quality of rehabilitation measures as well.
70. ANALYSIS OF QUALITY OF LIFE DATA IN A CLINICAL TRIAL OF THE PALLIATIVE TREATMENT OF AIDS-ASSOCIATED KAPOSI’S SARCOMA (KS) IN ZIMBABWE
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The purpose of quality of life (QoL) assessment in a clinical trial is to provide a frequently repeated measure of patients’ functioning over the course of treatment and follow-up. In a palliative treatment trial patients drop out at varying times due to early death or a desire to spend their last days with their families, who may be located in rural areas remote from major treatment centres. A decision must be reached regarding the length of time patients should remain on study before their data are sufficient for an evaluation of treatment options. In this study patients were randomized to one of four treatment options. Previous experience with endemic Kaposi’s sarcoma (KS) has indicated that the optimum response of this tumour to treatment occurs by 2 months at a time when patients are returning for their third assessment. Hence, patients were considered evaluable if they completed baseline plus two subsequent monthly QoL assessments. Since this tumour is very aggressive, only approximately 55% of patients complete the number of assessments required for inclusion in the data analysis.

Substantial differences in QoL between the four groups exist at baseline. Hence, it is necessary to correct for these differences statistically, by using the baseline QoL as the covariate in a repeated measures analysis of covariance. If this is done, it is not possible to compare any changes from baseline to the first monthly assessment. This serves to emphasize that patients should be stratified by their baseline QoL.

Patients frequently miss scheduled visits or have their treatments delayed because of toxicity. This means that assessment intervals are different for each patient. In order to cope with this problem, the assessment times were aggregated into time slots bracketing the expected time of assessment by 2 weeks on either side. This results in certain patients being missing from some time slots. The programme used for the analysis handles missing times of assessment. Treatment groups are not identified at this time since the study is still in progress. The hypothesis of interest in this study is that QoL trends over time differ between groups. If only those completing three times of assessment after baseline are analysed, statistically significant differences in the group time trends are evident.

71. DO IMPLANTED VENOUS ACCESS PORTS IMPROVE THE QUALITY OF LIFE OF PATIENTS ON SALVAGE CHEMOTHERAPY?
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Patients were randomized to receive a port or to receive their chemotherapy by peripheral access techniques. Chemotherapy began after port implantation and quality of life (QoL) was measured at each treatment cycle before chemotherapy was started. The intent of chemotherapy whether adjuvant, induction or salvage was recorded. The Functional Living Index – Cancer (FLIC) was used to assess QoL. The total and subscale scores were calculated.

A repeated measures analysis of variance (ANOVA) showed a statistically significant time trend for the total FLIC score, with patients improving for the first three cycles of chemotherapy after which a plateau was reached. However, there were no differences in this time trend between groups. If the intent of chemotherapy was added as factor in the repeated measures ANOVA a statistically significant three-way interaction between group allocation, intent and cycle of chemotherapy was noted. Examination of the data showed that the cause of this interaction was a difference in time trend between the patients on salvage chemotherapy allocated to the two groups. Patients allocated to a port started out with a relatively high total FLIC score which was maintained throughout their chemotherapy. In contrast, patients allocated to peripheral access started out with a low total FLIC score and increased to a plateau for the remaining cycles of chemotherapy.

Clearly the patients on salvage chemotherapy had a different mean QoL at their first cycle. However, we do not know if this difference occurred as a result of port implantation or was pre-existing. What is now apparent is that there was a design error in this study and patients’ QoL should have been measured prior to the intervention. If it is indeed true that the early cycle differences are due to the port in salvage patients, the explanation might be that these patients are not naive to chemotherapy and may have had considerable difficulty with venous access in the past. Hence, the port improved their perceived QoL. However, this would need to be ascertained in another study where QoL was assessed before port implantation.

This study finding is clear demonstration of the importance of the timing of baseline QoL assessment.

72. A COMPARISON OF TWO APPROACHES FOR OBTAINING PATIENT IMPORTANCE WEIGHTINGS FOR CONDUCTING AN EXTENDED Q-TWIST ANALYSIS
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The purpose of the study was to compare two approaches for obtaining importance weights for deriving Extended Quality-adjusted Time Without Symptoms and Toxicities (Extended Q-TWIST) scores.

A pilot study was conducted with 172 patients with gastroesophageal reflux disease (GORD). Patients completed a quality of life (QoL) questionnaire containing generic and GORD-targeted measures and two approaches for evaluating importance. In the Likert approach, patients were asked to rate the importance of each QoL domain on a 0 to 100 scale. In the idiosyncratic approach, patients completed three items for each QoL domain which tracked how often they thought about the domain, how often it prevented them from doing things they enjoy and how often it interfered with their daily activities. Questionnaires were administered at baseline, week 1 (test – retest) and week 4.

Several exploratory analyses were conducted to ascertain which set of importance weights to use. Test – retest was evaluated by examining intraclass correlation coefficients (ICC). Construct and concurrent validity were assessed using frequency distributions and correlation analyses. These analyses focused on ascertaining which approach generated more variability in frequency distributions and determining which approach correlated least with the QoL domain score. Known-groups validity

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was assessed by comparing patients on degrees of pain severity and the number of days with symptoms during previous 4 weeks.

The reproducibility was lower for the Likert approach (ICC 0.22 - 0.65). We found more variability among the response options for the Likert approach. Correlations between the two approaches were low to moderate ($r = 0.010 - 0.43$). Idiographic items had higher correlations than Likert items with corresponding QoL domain scores (e.g. $r = 0.80$ versus $-0.34$, respectively, for emotional distress). Changes in weights using the idiographic approach were also more highly correlated with changes in the corresponding QoL than for change scores using the Likert approach. This implies that the idiographic items may measure both importance and functional status, but the Likert scale items measure only importance, as desired. Comparable results for both approaches were found for known-groups validity.

Our findings indicate that obtaining a single-item Likert scale importance weight for each QoL domain may be superior to the idiographic approach. Future research will focus on enhancing the reliability of the Likert approach.

73. DEVELOPMENT OF A HEALTH-RELATED QUALITY OF LIFE QUESTIONNAIRE FOR GASTRO-OESOPHAGEAL REFLUX DISEASE PATIENTS: A VALIDATION STUDY

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The purpose of the study was to test the psychometric properties of a newly developed health-related quality of life (QoL) questionnaire containing both generic and gastro-oesophageal reflux disease (GORD)-targeted measures.

A pilot test was conducted with 172 symptomatic GORD patients who completed the health-related QoL questionnaire by telephone at baseline (test), week 1 (retest) and week 4. The 57-item questionnaire assesses the following seven health-related QoL domains: daily activity limitations, emotional distress, heartburn symptoms, eating symptoms, social restrictions, sleep problems and work disability. In addition, items assessing the importance of each domain were included to allow for the calculation of a weighted assessment score (WAS) for conducting an Extended Q-TWiST analysis.

The internal consistency was acceptable for most scales, with Cronbach’s α values ranging from 0.75 to 0.93 (except heartburn symptoms 0.66 and work disability 0.52). The reproducibility ($n = 25$) was acceptable for most scales (ICC 0.74 – 0.85) as was the WAS (0.80), but was low for work disability (0.40). Construct validity was demonstrated based on the correlations between items and scales. Known-groups validity compared scores of patients grouped by pain severity. Statistically significant differences (adjusted for demographics and covariates) were found for all health-related QoL domains, $p < 0.01$ and WAS ($p < 0.001$), except daily limitations ($p = 0.42$) and emotional distress ($p = 0.69$). Responsiveness was measured using Guyatt’s statistic. The improved and worse groups according to change in pain severity were also responsive, although many of the scales for the stable group were also responsive.

The health-related QoL questionnaire is reliable, valid and responsive. Future research will focus on data obtained from this questionnaire to conduct both health-related QoL and Extended Q-TWiST analyses on GORD patients.

74. INTEGRATION OF INTERNATIONAL INPUT INTO INSTRUMENT DESIGN

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The last 20 years have seen the development of a large number of health-related quality of life (QoL) instruments mostly however within and for one culture. As these measures are being used in clinical trials with an emphasis on multinational applications, there is a need for cross-culturally valid instruments. The now standardized translation procedure comprises forward – backward translation, cognitive debriefing and international harmonization. Although this process provides a basis for the establishment of cross-culturally valid and comparable translations, linguistic, structural and conceptual requirements of the target language question the theory of regarding the original as a valid and unmodifiable source. Although this method guarantees the creation of conceptually equivalent translations, it limits these to being mere reflections of the original without the possibility of influencing or modifying it. The importance of translation issues to the design and the conceptual issues of the original instrument should however not be denied and the value of translation feedback for the improvement of the original scale not underestimated.

Drawing from experience in translating a variety of disease-specific instruments (osteoarthritis, BPH, prostate cancer, epilepsy, IBS, etc.) we set out to demonstrate the interdependence of translations and original, definite problematic areas and describe the limitations set by the traditional translation method with practical examples.

As numerous examples show, translation necessarily brings about the discussion of the original concepts. Where translation proves impossible, target language alternatives or modification of the original items (and retesting of psychometric properties) become necessary. These findings lead to a redefinition of the traditional distinction between original and translation, calling into question the validity of translation as an absolute guarantee of cross-cultural and conceptual equivalence.

The traditional process of cultural adaptation is one way of working towards cross-culturally valid and conceptually equivalent instruments. To minimize limitations set by the process, an international component should be implemented into the design of questionnaires, where international development is the ideal and an item translatability review the minimum recommendation.

75. EVALUATING FUNCTIONAL OUTCOME IN LOWER EXTREMITY SARCOMA PATIENTS: A COMPARISON OF FOUR MEASURES

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This study compares the properties of four outcome measures. The Toronto Extremity Salvage Score (TESS), the SF-36 and the Musculoskeletal Tumour Society Rating Scale (MSTS, 1987; MSTS, 1993), that might be used in evaluating functional status following limb preservation for extremity sarcoma. Data from 97 lower extremity sarcoma patients (mean age = 43 years; M : F = 1.25) were used to evaluate the following measurement properties: (1) conceptual framework, (2) purpose, (3) feasibility,
(4) breadth of content, (5) depth of measurement, (6) reliability and (7) validity and responsiveness. Only the TESS was developed from a conceptual framework, the International Classification of Impairments, Disabilities and Handicaps. The TESS was designed to describe and monitor change in groups and individuals undergoing limb preservation for extremity sarcoma. The SF-36 was developed to evaluate whether variations in health status were related to variations in system care with the secondary intent of developing an instrument to monitor groups in clinical practice. The MSTSs (1987, 1993) were developed to evaluate the surgical results of patients treated for extremity tumours. All measures are completed in 10 – 15 minutes. The TESS and SF-36 are patient completed; the MSTSs (1987, 1993) are clinician completed. The TESS evaluates physical disability, the SF-36 is a multidimensional health status measure, the MSTSs (1987) includes pain and clinical measures, and the MSTSs (1993) includes walking ability, gait aid and gait handicap instead of the clinical measures. All measures have a summary score, however, the eight subscale structure of the SF-36 could not be reproduced. The TESS has cross-sectional and longitudinal reliability for groups and individuals with Cronbach’s $\alpha = 0.94$ and ICC $= 0.92 – 0.97$. The reliability of the SF-36 is lower ($\alpha = 0.78 – 0.93$ and ICC $= 0.60 – 0.81$). The cross-sectional reliability for the two MSTS scales was $\alpha = 0.81$ and 0.90. The longitudinal reliability was not tested. The TESS has construct and criterion validity, the SF-36 has been validated with multiple disease populations and the MSTSs (1987, 1993) have never been validated. The TESS detects moderate effect sizes (0.63 – 0.74) whereas the SF-36 and MSTSs (1987, 1993) detect small effect sizes (0.28 – 0.64). In choosing an outcome measure for the extremity sarcoma population, the TESS has superior measurement properties when compared to the SF-36 or the MSTSs (1987, 1993).

## 76. THE IMPACT OF RELAPSES ON THE HEALTH-RELATED QUALITY OF LIFE OF PATIENTS WITH RELAPSE-REMITTING MULTIPLE SCLEROSIS

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The objective of the study was to examine the impact of relapses on the health-related quality of life (QoL) of patients with relapse-remitting multiple sclerosis (RR-MS).

Forty (23F/17M) patients with RR-MS were in the study. To assess health-related QoL, four self-report questionnaires were used: the RAND Short Form-36 (SF-36), the Activities of Daily Living (ADL-MS), the M-S-Related Symptoms (RS-MS) questionnaire and the Multidimensional Fatigue Index (MFI). Neurological status was evaluated with a neurological examination resulting in the Expanded Disability Status Scale (EDSS).

The administration of the health-related QoL questionnaires and EDSS took place at weeks 0, 6, 12 and 24 at the out-patient clinic.

In the first 6 months, we recorded 19 relapses in 17 patients (42.5%). No significant differences in health-related QoL between the relapse and non-relapse group were found on any of the subscales of the SF-36 at 0, 6 12 and 24 weeks follow-up. At 24 weeks, the relapse group reported poorer physical functioning, more pain and a poorer general health perception on the SF-36 than the non-relapse group, although not significantly so. The scores on the ADL-MS and RS-MS indicated that the relapse-group needed more help with everyday activities and that they reported more sensory symptoms.

These data suggest that the impact of relapses on the health-related QoL of MS patients is not significant in the short run but may appear after prolonged observation. The major impact of relapses is on physical functioning.

## 77. HOW MUCH IMPROVEMENT CAN WE DETECT IN THE QUALITY OF LIFE OF PATIENTS RESCUED BY HELITRAUMA TEAMS?

**Frank The. de Charro and Mark W. Heijenbrok**

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It is feared that a relatively high proportion of patients rescued by flying doctors are severely handicapped in the long run. In an experiment in The Netherlands, teams of surgeons are being transported by helicopter to patients who are severely traumatized due to a (traffic or other) accident. The quality of life (QoL) of the rescued patients is investigated. The implications of the use of different health state valuation systems is being explored.

Data on the QoL of approximately 370 polytrauma patients are being collected over a period of 2 years. The treatment mix of a subset of these patients includes helitrauma teams. Approximately 9 months after the accident, patients are interviewed to assess their QoL. The instruments used are the EQ-5D developed by the EuroQol Group and the SF-36. The scores will be analysed using information about the health state of the patient at the location of the accident and on arrival at the hospital. The health state of the patients after 9 months will be generalized using values derived in the UK using the time trade-off methodology and values derived from the EuroQol visual analogue scale in The Netherlands and Finland.

Preliminary results will be presented. The association between the EQ-5D scores on the descriptive system and the scores on the SF-36 will be discussed and the sensitivity of the EQ-5D will be assessed. Moreover, the association of the scores on both the EQ-5D and SF-36 and medical parameters will be determined. A sensitivity analysis will be used to illustrate to what extent judgements about the value of QoL improvements depend on the arbitrary choices between valuation methods and national origin of the valuation data.

Conclusions will be drawn after the analysis. It is expected, but not certain, that QoL improvement will be substantial and that differences in value systems will not affect the interpretation of the QoL improvement, but we await the supporting evidence.

## 78. THE USE OF HEALTH-RELATED QUALITY OF LIFE MEASURES IN DAILY CLINICAL PRACTICE


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Quality of life (QoL) assessment is increasingly being included in clinical trials, but its incorporation into clinical practice is still rare. The first objective of this pilot study was to examine the feasibility of introducing QoL assessment into the daily routine of an outpatient oncology practice. Second, we investigated whether the information so generated facilitated the communication between physicians and their patients regarding QoL issues.
The study sample included six physicians and 18 of their outpatients from the outpatient clinic of The Netherlands Cancer Institute. For each patient, three consultations were observed. The first visit was employed for purposes of a baseline assessment. At the two subsequent visits, the patients were asked to complete the EORTC QLQ C30, a cancer-specific QoL questionnaire. The patients' responses were computer scored and transformed into a graphic summary. The summary included current scores as well as those elicited at the previous visit. Both the physician and the patient received a copy of the summary just prior to the medical consultation.

The procedure proved feasible; the introduction of the questionnaire into the clinic routine proceeded smoothly. While a small increase in the mean number of QoL issues discussed was noted after the introduction of the questionnaire, the most notable trend observed was in the increased responsibility taken by the physicians in raising specific QoL issues. All of the physicians and the majority of the patients believed that the questionnaire facilitated communication and expressed interest in continued use of the procedure.

Based on these encouraging results, a more rigorous study has been initiated to test, with a prospective randomized design, the value of standardized QoL information in facilitating doctor–patient communication, physicians' awareness of patients' problems, patients' and physicians' satisfaction with the medical visit, physicians' medical chart notations and patients' QoL over time. If demonstrated to be effective, the simplicity of the intervention would recommend its use in a wide range of treatment settings.

79. THE DISCUSSION OF QUALITY OF LIFE ISSUES DURING OUT-PATIENT CANCER CONSULTATIONS
The Netherlands Cancer Institute, Amsterdam, The Netherlands

Although improving quality of life (QoL) is an important goal of palliative treatment, very little is known about actual doctor–patient communication regarding QoL topics during the treatment period.

The aim of this study is to describe the communication regarding QoL issues between oncologists and their patients during out-patient follow-up consultations. Additionally, we investigated whether communication about QoL issues was related to patients' preferences to discuss these topics.

The study sample consisted of 60 patients from the out-patient clinics of The Netherlands Cancer Institute who were receiving chemotherapy with palliative intent. The study population included 1,026 sarcoidosis patients (age = 46.8 ± 11.6 years) of which 63% were female. The subjects were asked whether they had any of the listed complaints. Furthermore, they completed the WHOQOL-100. The results indicated that more women than men had complaints ($\chi^2 = 5.62$, $p < 0.05$) and that women also had more complaints than men (covariate age). Looking at the type of complaints, it appeared that women more often reported skin problems, starting problems and joint, breast, back and muscle pain (age as covariate). When men and women were compared on QoL (complaints and age as covariates), differences emerged on the domains physical health and psychological health. Concerning the facets of QoL, differences were found on pain and discomfort, sleep and rest, self-esteem, body image and appearance, mobility and activities of daily living (all $p < 0.01$). From these results it might be concluded that gender is related to having complaints, the number of complaints and in some cases to the type of complaints which sarcoidosis patients report. In addition, gender plays a role in only a few domains and facets of QoL. For reasons of comparison, data concerning gender differences in QoL within a healthy group will be presented.

80. THE INFLUENCE OF GENDER ON THE QUALITY OF LIFE IN SARCOIDOSIS PATIENTS
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The influence of sarcoidosis on quality of life (QoL) has not been studied extensively. In particular, the influence of gender on the complaints that can coincide with the disease is unknown. Therefore, the aim of this study was to examine the influence of gender on the complaints and QoL of sarcoidosis patients. The study population included 1,026 sarcoidosis patients (age = 46.8 ± 11.6 years) of which 63% were female. The subjects were asked whether they had any of the listed complaints. Furthermore, they completed the WHOQOL-100. The results indicated that more women than men had complaints ($\chi^2 = 5.62$, $p < 0.05$) and that women also had more complaints than men (covariate age). Looking at the type of complaints, it appeared that women more often reported skin problems, starting problems and joint, breast, back and muscle pain (age as covariate). When men and women were compared on QoL (complaints and age as covariates), differences emerged on the domains physical health and psychological health. Concerning the facets of QoL, differences were found on pain and discomfort, sleep and rest, self-esteem, body image and appearance, mobility and activities of daily living (all $p < 0.01$). From these results it might be concluded that gender is related to having complaints, the number of complaints and in some cases to the type of complaints which sarcoidosis patients report. In addition, gender plays a role in only a few domains and facets of QoL. For reasons of comparison, data concerning gender differences in QoL within a healthy group will be presented.

81. QUALITY OF LIFE IN A DUTCH POPULATION OF SARCOIDOSIS PATIENTS
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During the last 20 years, chronic non-specific lung disease has consistently been shown to influence quality of life (QoL). However, comparable data on sarcoidosis, a less common multisystemic disorder, are lacking. Therefore, the aim of this study was to evaluate the influence of sarcoidosis on patients' lives. The study population included 1,026 sarcoidosis patients (age 46.8 ± 11.6 years) and 277 healthy persons (age 40.6 ± 12.6 years). In both groups approximately 64% of the sample were female. Sarcoidosis patients were asked whether they had any of the listed complaints. All subjects completed the WHOQOL-100. The results indicated
that patients with and without complaints (covariates age and sex) had significantly different scores on nearly all domains and facets of the WHOQOL-100. With respect to the other domains and facets, the scores of the patients without complaints (covariate age) differed significantly \( (p < 0.01) \) from those of the healthy group on the domains physical health and level of independence and six of its facets as well as on overall QoL and general health. The differences between the patients with complaints and the healthy group (covariate age; \( p < 0.01 \)) emerged on all five domains and all facets. In conclusion, it appeared that the QoL of patients with sarcoidosis is impaired on a large number of aspects of QoL, in particular when the patients have complaints.

82. SOMATIC, PSYCHOSOCIAL AND SPIRITUAL ASPECTS OF QUALITY OF LIFE ASSESSMENT OF TERMINALLY ILL PATIENTS COMPARED WITH NEUROTIC AND HEALTHY PEOPLE
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According to Frankl’s conception there are three dimensions of human life – somatic, psychological and spiritual. In difficult situations man refers to these three dimensions. It applies to patients with neoplastic disease (mainly somatic disturbances), neurosis (mainly psychosocial disturbances) and healthy people. Based on it we proposed the following hypothesis: (1) the assessment of global quality of life (QoL) depends on somatic, psychological and spiritual dimensions, (2) persons with a positive attitude towards the existential values have a higher assessment of their QoL and (3) the correlation between QoL and the somatic, psychological and spiritual dimensions exists in cancer and neurotic patients as well as in healthy people. Sixty terminally ill cancer patients, 30 neurotic patients and 30 healthy individuals were examined. The following methods were used: (1) the Rotterdam Symptom Check List, (2) the Checklist of Attitudes towards the Existential Values (assessing the spiritual dimension), (3) a semi-structured interview (including sociodemographic data) and (4) medical examination and documentation. Statistical analysis of the results received confirmed our hypothesis.

83. PSYCHOMETRIC PROPERTIES AND CLINICAL USEFULNESS OF CANADIAN EDITIONS OF THE WISCONSIN QUALITY OF LIFE QUESTIONNAIRES
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The Wisconsin Quality of Life Questionnaires are the only scales currently available which solicit information about a patient/client from several perspectives; those of a professional care-giver and a family member or friend in addition to that of the patient/client. Canadian editions (French and English) have been developed to fit Canada’s health care and social services environment and an ongoing multicentred study is evaluating them to assess their validity and reliability. Their suitability for clinical practice and research in Canada is also being assessed.

This study focuses on individuals with a diagnosis of DSM-IV schizophrenia who are receiving out-patient psychiatric services. The initial phase involves 160 persons from urban settings: 80 from Montreal, Quebec whose first language is French and 80 from Halifax, Nova Scotia whose first language is English. The validity and reliability (internal consistency and inter-rater) of the questionnaires are being tested. The study also evaluates the test–retest reliability of the patient/client questionnaire through restesting two randomized subsamples of 40 persons each, one from each language group. The perceived usefulness of the Wisconsin instruments from the perspective of care givers involved in the research will also be assessed.

The presentation will communicate the findings regarding the psychometric properties with particular reference to the results from the patient/client and care giver questionnaires. The discussion will also address the psychometric properties utilized in the Canadian editions compared with the original American forms of the questionnaires.

84. YEARS OF LIFE OR YEARS OF HEALTHY LIFE: WHICH IS THE BETTER STUDY ENDPOINT?
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Clinical studies increasingly measure years of healthy life as well as survival, but the former is rarely used as the principal study end-point, in part because of a lack of knowledge about the performance of this end-point. We used data from a longitudinal study of older adults to compare the statistical power of trials using the two end-points.

The Cardiovascular Health Study (CHS) collected data on a variety of self-reported and clinical health factors for a random sample of 5,000 older adults and followed them over time. We calculated each person’s years of life (YoL) and years of healthy life (YoHL) in the 5 years following baseline. We then calculated the effect size of both YoL and YoHL with respect to 263 different health-related baseline attributes. The calculations were performed with and without controlling for baseline health status, to provide an assessment of both the discriminative and the evaluative power of YoL and YoHL.

The effect size for YoHL was found to be greater than the effect size for YoL for 82 of the 263 health-related variables studied and approximately the same for 178 variables. YoHL had a lower effect size than YoL in only three cases. After control for baseline health, YoHL had a greater effect size for 35 of the 263 variables and YoL was better for six.

Future clinical studies could be based on YoL, instead of on survival with no decrease (and often an increase) in statistical power. In clinical trials whose goal is to improve a patient’s health, more emphasis should be placed on YoHL as the primary end-point.

85. MEASURING QUALITY OF LIFE IN PHLEBOLOGICAL STUDIES – METHODOLOGICAL APPROACH ON THE DEVELOPMENT OF A UTILITY INDEX
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Assessment of quality of life (QoL) as an outcome measure in clinical trials has been cited as a major problem of research. Besides the basic psychometric performance, it is crucial that a single score (utility index) can be formed if use in pharmaeco-
nomic research is planned, in particular, for the calculation of QALYs (quality adjusted life years).

Based on data from 246 patients (mean age 55.1 years, 63.1% female) the present study comparatively analysed the internal consistency, discriminant validity, responsiveness over time and factorial structure of the Nottingham Health Profile (NHP) and the Freiburg Questionnaire of QoL in venous diseases (FLQA).

The NHP is regarded a generic instrument while the FLQA is a disease-specific tool. Additional instruments covered the psychological status (SCL-90) and coping (FKV). Both the NHP and FLQA were of good internal consistency (Cronbach’s α). Factor analysis confirmed the expected multidimensionality of the two instruments. Both of them were able to discriminate between patients according to their CVI stage, thus showing high discriminant validity. By contrast, patients in different stages did not differ in SCL-90 and FKV. On the other hand, the NHP as well as FLQA scores correlated with both the SCL-90 and FKV scores. When the data were analysed over time, the NHP provided little statistical differences whereas five of the seven FLQA scales showed significant changes.

In conclusion, a disease-specific tool is most appropriate in assessing QoL as an outcome parameter in clinical trials. Calculating a single utility index, it has to be considered that basically, QoL contains a genuine psychological component which is independent of the disease. Furthermore, QoL is a multi-dimensional construct even when it is assessed with a disease-specific tool, thus limiting its use as a utility index.

86. PERSONALITY, PERSONALITY DISORDERS AND QUALITY OF LIFE

Dusica Lecic-Tosevska and Sara Dimic

The complex aetiology of psychiatric disorders, as well as their comprehensive effects, are a challenge to professionals who try to assess quality of life (QoL) and the treatment efficacy. Personality and personality disorders greatly affect the clinical manifestations of most psychiatric disorders and should always be taken into account in the diagnostics and assessment of QoL as well as in the treatment planning. QoL and personality are both multidimensional concepts and in this paper various dimensions of these concepts based upon biopsychosocial theory are discussed. Our research on the co-morbidity of personality disorders and depression, which has shown that personality determines not only clinical manifestations of depression but in our view is a central determinant of QoL, is also outlined in this paper.

87. EXPERIENCE IN THE TREATMENT OF PSYCHOSIS FOR QUALITY OF LIFE OF PSYCHIATRIC PATIENTS

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The authors present the results of treatment with various therapeutic methods obtained in 65 patients suffering from psychoses of a schizophrenic and paranoid nature as well as those belonging to the cycle of affective psychoses. The therapeutic methods have been divided into three large groups: medication therapy, medication and occupational therapies combined and complex therapy. The complex therapy includes the application of no less than three or more therapeutic methods.

The analysis of the results showed that complex therapeutic methods permit a shortening of the treatment duration and remissions are considerably longer and are more stable while working capacity is re-established much more quickly.

88. THE DEVELOPMENT OF THE ALZHEIMER’S CARERS’ QUALITY OF LIFE INSTRUMENT

Lynda C. Doward

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There is a great deal of interest in the effect on care givers of caring for a chronically ill elderly relative. Most research conducted with care givers has concentrated on the dementias and, in particular, on Alzheimer’s disease (AD). Despite this, no specific measure of quality of life (QoL) is available for use with carers.

The development and testing of the Alzheimer’s Carers’ Quality of Life Instrument (ACQLI) is described. The ACQLI is designed to assess the impact of interventions with Alzheimer’s patients on the QoL of the car giver. The ACQLI has the needs-based model of QoL as its theoretical basis and was developed for use in the UK, France, Germany, Italy and Spain. The initial stages of the work were carried out in the UK alone, with later stages conducted simultaneously in all five countries.

The content of the ACQLI was derived from in-depth qualitative interviews conducted with 40 carers in the UK. Items were translated for use in each of the languages with emphasis on producing conceptual equivalence. Field-testing of the measure in each country indicated that the respondents found it acceptable, relevant and easy to complete.

Each language version of the ACQLI was tested for reliability and construct validity. Test–retest correlations showed that the reliability for all language versions is high, ranging from 0.85 (Germany) to 0.94 (Italy). The internal consistency was also assessed and all α coefficients were 0.89 or above. The validity was assessed by correlating the scores on the ACQLI with those on a comparator measure. The ACQLI was found to relate as expected with these measures.

The new instrument has good psychometric properties and it is well accepted by carers. An additional version is in preparation for the USA.

89. QUALITY OF LIFE (QOL-CZ). VALIDATION OF THE CZECH VERSION OF SQUALA

Eva Dragomirecka and Ctirad Skoda

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For severe mental disorders single medical interventions are not sufficient. When complex biopsychosocial treatment is applied, it is necessary to have complex evaluation criteria; it is in this very context where the quality of life (QoL) is considered to be an appropriate measure of course and outcome assessment. In the last decade, in psychiatry, numerous QoL scales have been used in long-term follow-up research.

Our aim was to adapt a proper QoL instrument for the Czech population which is self-assessment, subjective, covers all conventional areas of life and allows the expression of their subjective importance. We are demonstrating the psychometric characteristics of the validation of the Czech version of the SQUALA (Subjective QUality of Life Analysis) on a sample of approximately 800 psychiatric cases and 400 control subjects.

In addition, comparing the patient’s QoL profile to the QoL of a healthy person, it is shown that there is no significant differences in
the subjective importance of life areas but there is in subjective satisfaction with them which differentiate according to the diagnosis.

These results were the basis for a consequent study with the goal of determining whether QoL is a more sensitive indicator of the effects of therapeutic intervention than health status indicators and to search for the link between QoL and long-term outcome.

90. INFLUENCE OF NEUROLEPTIC MOTOR SIDE-EFFECTS ON QUALITY OF LIFE IN CHRONIC SCHIZOPHRENIC OUT-PATIENTS


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The importance of neuroleptic motor side-effects is discussed for quality of life (QoL) in schizophrenic patients. Therefore, atypical neuroleptics with few side-effects are supposed to improve QoL compared to conventional neuroleptic drugs. In the present study 20 chronic schizophrenic out-patients treated with a conventional neuroleptic depot medication were compared to 16 clozapine patients with respect to motor side-effects and QoL. The doses of neuroleptics were held as low as possible and none of the patients had to be hospitalized during the previous 2 years. Motor side-effects were measured by the Akathisia Determination Scale (ADS) and the Abnormal Involuntary Movement Scale (AIMS). QoL was assessed by the German adaption of the Lancashire Quality of Life Profile ('Berliner Lebensqualitaets-Profil', BLP). No significant differences were found concerning akathisia, involuntary movements or self-reported QoL between both groups. In the group of conventionally medicated patients the ADS scores correlated significantly with the BLP domain of social relationships ($r = -0.52$ and $p = 0.02$) and the AIMS scores correlated with the BLP items of contentment with employment ($r = -0.49$ and $p = 0.03$) and payment of work ($r = -0.46$ and $p = 0.04$). Overall, the results show that conventional neuroleptic long-term therapy with carefully measured doses must not lead to essential disadvantages concerning motor side-effects and QoL compared to atypical neuroleptic drugs.

91. QUESTIONING PREMISES: HEALTH-RELATED QUALITY OF LIFE IN KENYA

O. Egesah

Moi University, Kenya

The aim of this research is to describe the lay perceptions of health-related quality of life (QoL) and to reflect on the appropriateness of using Western-based generic instruments in the Kenyan context.

The research was conducted in Western and Eastern Kenya, using unstructured interviews and participant observation.

Information on the general perceptions of health, illness and well-being in the individual and family and general descriptions of areas such as agriculture occupations, access to water, etc. was gathered. Eight broad areas of interest were seen to relate to the lay perceptions of health-related QoL: key resources, relationships, bodily well-being, access to and confidence in therapy, expectations, time and differentiation.

This paper will summarize the principal findings and raise questions especially relating to 'health' in health-related QoL, for discussion.

92. PATTERNS OF HEALTH-SEEKING BEHAVIOUR FOR STIS IN WESTERN KENYA: IMPLICATIONS FOR STI/HIV/AIDS CONTROL

O. Egesah

Moi University, Kenya

There is strong biological and epidemiological evidence linking STIs and the spread of HIV infection. This study examines patterns of health-seeking behaviour for STIs and the implications for STI and HIV infection control strategies.

A five-guides phased key informant interview schedule, in-depth interviews and focus group discussions were used for data collection. DT searched codes were reviewed and summarized.

STIs are identified and recognised in the communities, although the distinction is not based on aetiologic agents. There is a notable link between STIs and HIV/AIDS; however, many respondents described an intense social stigma attached to STIs. The consequences of the stigma included delays and failure in seeking treatment, factors which may affect quality of life (QoL). However, a number of health care options are available; thus a linear treatment algorithm does not exist.

Multiple options exist in Western Kenya for the treatment of STIs and this multiplicity bears implications for the design of STI and potential HIV control strategies.

93. SEX, AIDS AND STIS: ANALYSING THE USE OF ETHNOGRAPHIC METHODS FOR FORMATIVE RESEARCH IN STIS CONTROL IN WESTERN KENYA

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This paper describes the design and methods used for the formative phase of an STI control and HIV/AIDS project; the data collection process, extolling the use of probes and the effectiveness of a multiple sequenced interview design used to elicit sensitive information.

Key informant interviews, focus group discussions, in-depth interviews and focused observations were used, with a combination of the methods allowing for multiple perspectives which enhances validity. Community mobilization and gathering of sensitive information were two functions achieved and upon which the subsequent project design and implementation decisions were informed.

The triangulation of research methods coupled with the extended contact with key informants led to a depth of information that could not have been captured through a design that relied primarily on survey research methods.

94. SOCIAL SUPPORT IN A SAMPLE OF 40 INCARCERATED SEX OFFENDERS: IMPACT OF SUPPORT BY SIGNIFICANT OTHERS CONCERNING VIOLENT RELAPSE

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This study investigates a sample of 40 incarcerated sexual offenders concerning social network size and social support after 6 years' incarceration and therapy. The results are set in relation to previous convictions and the amount of aggression admitted.
at the admission of the offence, as well as to DMS-IV diagnosis of paraphilia. The results strongly suggest a relationship between social support and the amount of violence admitted, as well as a relationship between the total number of previous convictions and social support. Thus, social support should be seen as a crucial ingredient in rehabilitating sexual offenders.

95. SCALE OF COHERENCE AND QUALITY OF LIFE (AS MEASURED BY THE FLIC)
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Antonovsky’s Scale of Coherence (SOC) describes an individual’s predisposition to interpreting life’s experience, including health conditions. Health-related quality of life (QoL) describes an individual’s perceived life experience while living with an illness. This study investigated the extent of the relationship between the SOC and QoL, as indicated with FLIC scores in a population recently diagnosed with cancer.

The short-form SOC and the FLIC were administered to a population of 405 people diagnosed within 4 – 8 weeks with either breast or colorectal cancer who were living in 14 communities in the North Central States (US). The analysis was done by means of Pearson’s correlations and regression analyses.

The correlation between the FLIC and SOC total scores was \( r = 0.48 \) and \( p < 0.001 \). The correlations between the subscale scores were all \( r < 0.5 \), except one. Regression analyses indicated that both scales were explained with five common variables: age, pre-existing mental illness or diabetes and performance status (number of hours out of bed in a day). However, SOC is further explained by many additional variables (education \( p = 0.001 \), rural residence \( p = 0.009 \), current employment \( p = 0.002 \) and number of people in the household \( p = 0.001 \)).

SOC and QoL represent different concepts in understanding a person’s experience with cancer. The moderate correlation between the SOC and FLIC scale scores indicates that there is a relationship between the two. The regression analyses demonstrate that SOC is a broader indicator of how a person approaches life’s experience and that the QoL/FLIC represents how life is described given the specific circumstances. This implies that the SOC may predict how a person perceives changes in their health and thus reports their QoL, consistent with the theory.

96. QUALITY OF LIFE SCORES IN PERSONS WITH CANCER AND OTHER HEALTH PROBLEMS
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This study analysed the impact of eight common chronic medical conditions on cancer patients’ quality of life (QoL) as measured by the FLIC.

The FLIC was administered to a population of 405 people residing in 14 communities in the North Central States of the US within 4 – 8 weeks of diagnosis of breast or colorectal cancer. At that time, they also self-reported any other health conditions for which they had been receiving medical treatment. The impact of the selected chronic conditions on the FLIC scores was analysed using Student’s \( t \)-tests, analysis of variance and multiple regression analyses.

The overall FLIC scale score is reduced if a person also has an existing mental illness \( (p = 0.009) \). Three FLIC subscale scores – physical well-being, psychological well-being and hardship and disruption – are also reduced by the presence of mental illness \( (physical \ p = 0.008, \ psychological \ p = 0.04 \) and hardship \( p = 0.03 \). On the other hand, the nausea subscale score is reduced with the presence of diabetes \( (p = 0.008) \). Finally, the social subscale score is increased in the presence of arthritis/joint diseases \( (p = 0.006) \).

QoL, as measured with the FLIC scale score, is reduced in the presence of mental illnesses. The subscale scores showed similar variation with two exceptions: the presence of diabetes increased the report of problems with nausea in this population and those with existing arthritis reported improved social interactions.

97. HEALTH-RELATED QUALITY OF LIFE IN EPILEPSY: QUALITATIVE ANALYSIS
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The purpose of this analysis is to describe the range of responses a large sample of people with epilepsy provided in answering open-ended questions about epilepsy’s impact on their lives.

We added three open-ended questions to a health-related quality of life (QoL) and seizure severity questionnaire administered at baseline in a national surveillance study of the anti-epileptic drug Lamotrigine. The questions asked about the best and worst aspects of epilepsy and provided an opportunity for respondents to discuss their condition. The responses were content analysed.

Eighty-two percent of the 804 study participants answered the open-ended questions. Those who answered the questions tended to be female and better educated and to have more full-time and part-time employment, higher incomes and greater variety in seizure type. Women who responded had less severe seizures compared to the women who did not respond. Analysis of the open-ended responses revealed a wide range of positive and negative aspects of epilepsy. The negative aspects included driving restrictions, restricted independence, social life disruptions, work or school complications, physical suffering, family life disruptions, personal adjustments, lack of seizure control and financial hardships. The positive aspects included personal growth, improved or new social relationships, improved family relationships, new opportunities, financial benefits and spiritual growth.

The narrative portions of the health-related QoL assessment provide a finer, yet more particular view of the way epilepsy and its treatments affect individuals’ lives. These responses reveal relationships between certain aspects, such as driving restrictions and work complications or driving restrictions and family life disruptions. Further, they show that, although the implications of epilepsy are largely negative, the value of certain aspects depends on the particular context in which they are experienced.
Due to increasing interest in cross-cultural health-related quality of life (QoL) evaluation, cross-cultural adaptation and translation have become essential to the process of measure development. Translation methodology (e.g., forward translation, reconciliation, back-translation, review and pre-testing) has been well-researched and is continually being challenged and refined with the goal of producing valid, equivalent QoL measures in different languages. However, one step in this process has received inadequate analysis: the decision whether the translation of a QoL measure should be country specific or language specific. Often taken for granted, this apparently simple decision has tremendous implications for conducting the translation and adaptation processes and for determining the quality of the resulting instruments.

This study analysed the discourse surrounding each point of view for the impact on the QoL instruments in terms of what is gained and lost with each type of focus. The issues addressed include identity, practicality and differing necessities that result from the use of one language version or country-specific versions. Spanish, French and Portuguese versions of the Functional Assessment of Cancer Therapy – General (FACT-G) were adapted using the translation methodology outlined in this study. The results from the psychometric evaluation of pre-testing show that one translation is adequate for use in countries with Spanish, French and Portuguese-speaking populations.

As the necessity for cross-cultural QoL assessment increases, this divergence in the methodology of translation and adaptation needs to be understood and taken into account by researchers interested in the cross-cultural evaluation of health-related QoL.

How does the subjective well-being of persons with epilepsy compare to that of other chronically ill persons? Will their well-being change when a diagnosis is presented to them? The present study relies on a population-based sample, that is on questionnaire data from a diabetes and hypertension screening carried out in 1984 – 1986 on the entire adult population of a medium-sized Norwegian county (total number of participants 74,977).

The questionnaire contained questions on subjective well-being, including self-reported health, life satisfaction, loneliness, etc. The data from this study have been analysed relating to the diagnoses of diabetes, cardiac infarction, angina pectoris and cerebral stroke. The data on epilepsy have been collected from the hospitals of the county and are in the process of being added to the files from 1984 – 1986, assuming that a large number of persons with a diagnosis of epilepsy answered the questionnaires in 1984 – 1986. Comparisons will be made as to subjective well-being between (1) persons with epilepsy diagnosed before 1984 and (2) persons diagnosed after 1984, that is before and after they took part in the screening study. Further, the two groups will be compared to persons with diabetes and other diseases.

In spring 1997 we will interview 20 diabetes and 20 epilepsy patients on coping strategies and perceptions of stigma.

In 1998 a new screening in the same county will add data to the study.

Missing data in clinical studies rarely occurs because of a single reason. Some individuals may drop out of the study due to mortality or morbidity of the disease or its treatment. Others may drop out because their disease symptoms have disappeared or decide they do not want to be bothered. Thus, individuals may have missing assessments for reasons both unrelated and related to treatment.

Methods for analysis of longitudinal studies with missing data generally focus on a single mechanism and do not readily accommodate this multiplicity of causes and patterns of missing data. Differing methods exist for addressing missing data, but are generally based on strong assumptions that cannot be tested since the data are missing. Further, the resulting estimates are often sensitive to violations of these assumptions.

Multiple imputation for missing data is a technique that was developed to address the issue of underestimation of the variance resulting from simple imputation methods. However, the concept of multiple imputation can be extended to longitudinal studies of quality of life (QoL) allowing the incorporation of both (1) a mixture of models accommodating the variety of causes of missing data that occurs in these studies and (2) the uncertainty associated with the underlying assumptions of the models.

We will demonstrate these extensions of multiple imputation in a longitudinal study of health-related QoL in patients receiving therapy for advanced non-small cell lung cancer.
102. DEVELOPMENT OF AN ENDOCRINE SUBSCALE FOR USE WITH THE FACT-QUESTIONNAIRE
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There are many novel hormonal treatments being offered to women with breast cancer as a preventative agent, for adjuvant therapy and to those with advanced disease. Several trials are comparing the newer endocrine therapies in the hope of increasing efficacy, decreasing toxicity and improving overall general health and well-being. Existing quality of life (QoL) instruments may not provide adequate items to measure the side-effects and putative benefits. In this paper we report data from a project in which a brief, psychometrically valid endocrine subscale has been developed to accompany the FACT-B. The 18-item scale was derived from several sources: existing databases of side-effects experienced by women taking part in chemoprevention trials, focus groups of women with advanced breast cancer on endocrine therapy and the opinions of oncologists, nurses and psychologists familiar with the area. The scale was given together with the FACT-B to 230 women with breast cancer – 93 women had advanced disease and were being treated with tamoxifen, anastrozole or megestrol acetate. Ninety-three women were either receiving adjuvant tamoxifen for early stage disease or had chemo-induced ovarian oblation and there was a control group of 41 patients with early disease who were receiving no hormonal treatment. The coefficients for all subscales on the FACT-B were calculated and were all above 0.64 representing good internal consistency and comparability with the US validation data. Cronbach’s α for the endocrine subscale was 0.79. The test – retest reliability assessed by calculating a bivariate correlation for scores from questionnaires completed twice by 54 patients, with a 3 – 5 day gap (n = 0.94 and p < 0.001) indicated good stability. Women who were disease free reported better physical, emotional and functional well-being than those with advanced breast cancer. Further results on the discriminant validity and differences between the groups will be presented.

103. A MULTIPLICATIVE MULTI-ATTRIBUTE UTILITY FUNCTION FOR THE HEALTH UTILITIES INDEX MARK 3 SYSTEM
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The objective of the study was to develop a function to generate utility scores for all health states defined by the Health Utilities Index Mark 3 (HUI3) system. The HUI3 system comprises eight attributes with five to six levels per attribute. The HUI3 system has been used extensively in population health surveys and clinical studies to provide data on health status.

Preference measurements were obtained from a random sample (modelling survey) of the general population ≥16 years of age (n = 256) using a visual analogue scale (feeling thermometer) and the standard gamble (chance board). Each respondent evaluated 22 – 24 health states.

A separate random sample (n = 249) was also drawn (direct survey). The respondents were randomized to different sets of health states. Each respondent evaluated 16 health states. Utility scores were obtained for 73 health states.

A multiplicative function was fitted to the data from the modelling survey. The resulting scoring system was used to predict mean scores from the direct survey. The intraclass correlations between the predicted and direct scores are >0.69.

The HUI3 scoring function provides a method for obtaining health-related quality of life (QoL) scores based on community preferences for health states described in the HUI3 system.

104. TOWARDS AN UNDERSTANDING OF THE FACTORS THAT AFFECT AN INDIVIDUAL’S PREFERENCES FOR HEALTH STATES
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The study investigated the factors that respondents report using when making judgements about their preferences for comprehensive health states.

Open-ended questions were included at the end of a preference measurement survey of a random sample (n = 504) of the general population (age ≥16 years). The respondents were asked to evaluate health states described in the Health Utilities Index Mark 3 (HUI3) system which comprises eight attributes. Two preference measurement instruments were used – the feeling thermometer and the standard gamble. Responses from 184 randomly selected respondents were entered into NUD*IST software for the analysis of textual data.

Fourteen of 184 considered all eight attributes to be equally important. Each of the attributes was endorsed by at least some respondents as being the most important (range 9 – 72). Pain, cognition, vision and emotion were the attributes most frequently ranked as the most important. When making preference judgements the respondents considered how the quality of their life would be affected by living in that health state and the stated probabilities (for the standard gamble).

We conclude that the open-ended questions provide useful qualitative evidence on the process of preference measurement and the nature of preferences for health states and support the instrument design.

105. QUALITY OF LIFE AND PSYCHOSOCIAL ADJUSTMENT OF YOUNG PATIENTS AFTER TREATMENT OF BONE CANCER
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The purpose of this study was to assess the psychosocial status of patients after treatment of osteo- or Ewing’s sarcoma. The selection criteria for patients were age between 15 and 30 years, tumour localization at the extremities and at least 1 year’s duration since the end of treatment. From 110 patients, 60 were willing to participate. The evaluation of psychosocial quality of life (QoL) included the assessment of psychosocial adjustment, age-appropriate achievements and identification of problems typical for this patient group. Approximately 80% of the patients
showed no or only minor psychosocial problems. They could adapt well to their new living conditions, though strong efforts were necessary to get used to problems such as restricted mobility, catching up with school or the changing of jobs or job orientation. Differences between patients and control subjects emerged in the areas of marital status, independent living and parenthood. The current status of levels of education and income was similar. Clinical data as well as physical or functional sequelae had no effect on psychosocial adjustment, with one exception: patients with diagnosis in adolescence showed significantly more problems, in particular in the dimension of social well-being, than patients diagnosed in childhood or early adulthood. Recognizing the limitations of our study, our findings suggest that survivors of bone cancer are not necessarily at risk of developing long-term emotional or social problems and are not precluded from leading active and independent lives.

106. INFLUENCE OF CHRONIC PAIN AND PAIN MEDICINE ON THE QUALITY OF LIFE
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Chronic pain and its therapy play a vital role in the quality of life (QoL). The daily activities of many patients suffering from chronic pain are limited by restricted walking or mobility and difficulties bending or lifting things. As a result, these patients are often unable to continue working and maintain social integration. The cumulative probability of developing a pain condition for people surviving to an age of 70 years is estimated as high as 85% for episodes of back pain and 40% for headache. A special problem affects cancer patients, of which as many as 70% are expected to die in unrelieved pain.

Causal therapies for the underlying disease do not exist in many categories of chronic pain. It is surprising that a speciality for the medical treatment of chronic pain has developed only within the last decades. Standards for the diagnosis and therapy of chronic pain are still rare, because many of the possible measures are not properly evaluated. The most common standard is the guideline for the treatment of cancer pain published by the World Health Organization (WHO) in 1986. Consequent use of this analgesic ladder concept with cancer patients has been shown to lead to a reduction of severe and very severe pain from 78% before treatment to 13% within the first week of treatment. Following the simple guidelines for a longer time enables a further reduction on the part of patients suffering from severe and very severe cancer pain to 7% even if these patients are cared for until death.

Patients suffering from cancer pain as well as patients suffering from non-malignant chronic pain should be treated by physicians specializing in pain medicine. Guidelines and standards can help to improve the quality of care, therefore multidisciplinary efforts for their development have to be encouraged and supported.

107. QUALITY OF LIFE OF THE DEAF IN AUSTRIA
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Despite growing scientific interest in the deaf and in sign language there are still little data available on their quality of life (QoL) as compared to the general population. This is certainly partly a consequence of the fact that the usual methods of data collection such as written questionnaires or spoken interviews cannot be applied due to communication problems.

The study to be presented is about a random choice of 387 deaf patients (from a total number of approximately 1,100). As part of their preventive medical check-up (including clinical investigation and objective medical findings) at our outpatient clinic for the deaf, they were interviewed in sign language in detail about social variables, work conditions and their somatic and psychic well-being. As a control group the data of 273 hearing patients who had undergone preventive medical check-ups with a general practitioner were analysed. The final comparison of both samples shows that the deaf suffer from a significantly higher number of somatic as well as psychic complaints. Furthermore, there are some significant differences concerning objective medical data. Finally, correlations between social (including communicative) variables and medical findings are examined and reasons for the significant differences between the deaf and the hearing sample are discussed.

Our results point to the importance of the early years of deaf children’s development, where there is usually a lack of communication in their mainly hearing families (90%). Furthermore, factors such as the present separation from hearing society, the permanent stress related to communicating with the hearing world, the exclusion from information, the lack of education and vocational training as well as work places that meet their communicative needs and the lack of a system of health care where they can make themselves fully understood are to be mentioned. Our study demonstrates that there is still an urgent need to support the deaf peoples’ fight for equal access to all human rights.

108. COMPARISON OF PATIENTS’ AND PHYSICIANS’ PERCEPTIONS OF QUALITY OF LIFE DIMENSIONS IN AN OUT-PATIENT PSYCHIATRIC CLINIC
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There is a general assumption that quality of life (QoL) information is of value in the clinical decision-making process. The aim of this study was to assess patients’ perception of their own health-related QoL and physicians’ perspectives of patients’ health-related QoL to find out whether clinicians’ judgements matched with patients’ reported health-related QoL status.

Patients attending an out-patient psychiatric clinic were invited to participate in the study. While waiting for the psychiatrist’s visit, patients were asked to fill in a set of questionnaires comprising the Portuguese versions of the MOS SF-36 and the SIP. At the end of each patient’s visit, the psychiatrists were asked to fill in a form, rating from ‘very bad’ to ‘very good’, their perspective of patients’ health-related QoL according to both questionnaires’ dimensions. The scores found for the MOS SF-36 and SIP were further compared to those obtained from psychiatrist’s forms.

Three hundred and fifty-two patients (71% females, median age 48 years, range 15 – 87 years) were sequentially recruited from April 1996 to January 1997. Patients’ physical function/physical role-related dimensions were more impaired under physicians’ views compared to patients’ perceptions, while for emotional role/emotional behaviour-related dimen-
sions, differences between patients’ perceptions and physicians’ perspectives were not found. Inversely, a trend for patients’ perceptions of an improvement on social role/social behaviour-related dimensions was found compared to physicians’ perspectives of the same related dimensions. For some other dimensions of health-related QoL the disagreements observed between patients’ perceptions and psychiatrists perspectives are mainly due to differences in their codes of reference.

These results provide evidence to assess health-related QoL perceptions in the patient care process and for further investigation in identifying the code of references of psychiatrists in valuing health-related QoL dimensions.

109. DEVELOPMENT OF A PANCREATIC CANCER MODULE TO SUPPLEMENT THE EORTC QLQ C30: A GROUNDED THEORY APPROACH
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A criticism of past quality of life (QoL) measures is that they have been expert rather than patient derived. It is well-established, however, that QoL is best described by the patients themselves. We report on an adapted methodology in the development of a pancreatic cancer module to supplement the EORTC QLQ C30.

The EORTC QoL study group published guidelines for module development were used as a framework. Phase 1 involves the generation of relevant issues using a three arm approach. However, the initial literature review was largely unproductive and no study had described QoL from the pancreatic cancer patient’s perspective. A grounded theory approach was taken to interview, firstly six health professionals and, secondly, 21 patients. A constant comparison of the data allowed concepts to be generated, linked and supported. Respondent validation by five patients of the concepts raised provided a description of QoL in pancreatic cancer. An extensive literature review of the concepts raised allowed theoretic underpinning.

There was good agreement on the content of the issues. Eighty issues were generated including symptoms, side-effects and additional QoL issues. However, when the context of such issues was examined, there were noticeable differences in perception. Health professionals took a mechanistic approach and described a direct relationship between the severity of symptoms and overall QoL perception. The patients perception of QoL was influenced by linked factors: perceived threat and maintaining control. Coping acted as a mediating process and it was the success or otherwise of coping strategies which influenced QoL perception.

Our work supports the assumption that QoL is best described by patients and that the patient’s perception should be incorporated at all stages of module development. Both qualitative and quantitative methods should be incorporated into module development. This methodology was approved by the EORTC QoL study group for phase 1 development of a pancreatic cancer module.

110. MULTILINGUAL DEVELOPMENT OF A PANCREATIC CANCER MODULE TO SUPPLEMENT THE EORTC QLQ C30
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Over 90% of patients diagnosed with pancreatic cancer will die within 1 year and for the majority of patients (> 80%) treatment is aimed at the palliation of symptoms. There is overwhelming consensus that quality of life (QoL) assessment is required yet little research has been undertaken and no disease-specific QoL measure exists. The European Quality of Life in Pancreatic Cancer Study Group (EQoLiPa) has been established in over 16 centres in ten European countries, committed to the development of a pancreatic cancer QoL module to supplement the EORTC QLQ C30.

The EORTC QoL study group guidelines for module development have been used as a framework. Phase 1 (generation of issues) involved a literature search using Embase, Medline and CINAHL in all European languages and interviews with, firstly six health professionals and, secondly, with 21 patients. A grounded theory approach was taken. Respondent validation was undertaken with a further five patients. An international review panel of 17 clinicians reviewed the concepts raised and the EORTC QoL study group undertook peer review.

Phase 1 generated a list of 80 QoL issues in pancreatic cancer. On comparison with QLQ C30, 42 issues were identified as potentially suitable for inclusion. Review and refinement by patients, specialists and the EORTC QoL study group has led to the construction of a phase 2 pancreatic cancer module comprising 26 items. This has been translated (using forward – backward translation) into ten languages. Preliminary analysis indicates that it has an adequate range of responses, has adequate content validity and internal reliability (overall Cronbach’s α 0.79). The five hypothesized multi-item scales (pain, jaundice, diet, stomatosis and body image) show Cronbach’s α between 0.5 and 0.8. Qualitative analysis suggests that it is easy for patients to complete.

The pancreatic cancer module is expected to undergo a large phase 4 cross-cultural field study to assess its validity and reliability in September 1997.

111. THE PSYCHOSOCIAL ADAPTABLEITY OF ADOLESCENTS WITH CONGENITAL HEART DISEASE
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In a previous pilot study it was shown that children with congenital heart disease of between 6 and 12 years have psychological deficits as well as distinct deficiencies with regard to their social and cognitive competence. Therefore, adolescents with congenital heart disease were examined for an evaluation of the problems concerning specific questions of puberty, in particular focusing on the patients’ self-concept. The aim of the study was to determine which preventive therapeutic measurements should be taken.

Sixty patients between 12 and 16 years of age with congenital heart disease were compared to a control group of healthy adolescents. The clinical examination included a cardiological status, a chest X-ray, an electrocardiogram and, finally, a recent echocardiography. The patients’ cardiac fitness was assessed by ergometry. In the case of cardial confinement, the patients were classified according to the Somerville Ability Index. The physical state of development was evaluated using the Puberty Development Index of Tanner as well as using the somatogram according to the development curves of Prader et al. The psychological assessment battery consisted of an intense exploration and the use of six standardized psychometric tests. The cognitive
and social competences, behavioural and apperceptive problems and patients’ self-concept as well as the differentiated comprehension of the overall personality was assessed.

The cognitive capability and the social competence of the test group was significantly different from the control group. Differences concerning the self-concept of the test group compared to the control group could also be observed in the areas of self-esteem and of the sociability with others.

The results of the study show various problems of the patients’ psychosocial adaptability and underline the importance of offering adolescent patients with congenital heart disease adequate treatment options for psychosocial rehabilitation. It is equally important that efficient programmes for out-patient treatment and long-term therapy for the prevention of psychosocial problems are developed in interdisciplinary cooperation between physicians and psychologists. Of course it would be most desirable that these strategies were integrated into clinical routines.

112. COMPARISON OF THE QUALITY OF LIFE OF CANCER PATIENTS AND ALCOHOL DEPENDENTS
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The aim of the study was twofold; firstly to compare the quality of life (QoL) in alcohol dependents and cancer patients and, secondly, to examine how the 30 variables in the cancer questionnaire cluster in a group of alcohol dependents, who were subject to alcohol detoxification. At baseline (4 – 5 days after admission) sociodemographic data were collected and three questionnaires administered; the Rotterdam Symptoms Checklist (RSCL), the Severity of Alcohol Dependency Questionnaire (SADQ) and the Alcohol Problems Questionnaire (APQ).

Alcohol dependents, as defined by DSM IV, had higher RSCL scores for both physical and psychological symptoms than cancer patients, indicating a more impaired QoL. Three factors emerged from a principal components analysis – psychological, physical pain and alcohol withdrawal symptoms. Alcohol withdrawal and physical pain symptoms were both significantly correlated to the SADQ scores (p < 0.05). These findings point to the importance of a comprehensive clinical assessment for alcohol dependents which should include an evaluation of psychological, physical pain and alcohol withdrawal symptoms.

113. QUALITY OF LIFE – THE LINK BETWEEN ABSTINENCE AND RELAPSE TO HEAVY DRINKING IN ALCOHOLICS
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The study aims to investigate the quality of life (QoL) changes between baseline and 12 weeks follow-up in 39 male and 21 female alcohol dependents undergoing detoxification as a result of relapsing/not relapsing to heavy drinking. Baseline data were taken 4 – 5 days after admission including sociodemographics, the Severity of Alcohol Dependency Questionnaire (SADQ) and the Alcohol Problems Questionnaire (APQ). Other measures collected at baseline and 12 weeks follow-up were the Rotterdam Symptoms Checklist (RSCL), Life Situation Survey (LSS), Beck Depression Inventory (BDI) and Nottingham Health Profile (NHP).

Forty-eight (97%) of subjects were successfully followed up, with 36 (62%) relapsing to heavy drinking. Alcohol dependents were scoring well above the normative values for their reference populations. Relapsers and non-relapsers differed significantly in the changes in scores during the study period in the following outcome measures: life situation (LSS), depression (BDI) and physical/psychological symptoms (RSCL). These results confirm the poor QoL in alcohol dependents and show that there are significant changes as a result of either relapse/non-relapse at 12 weeks follow-up.

114. STATE AND TRAIT COMPONENTS OF QUALITY OF LIFE IN SCHIZOPHRENIC PATIENTS: A QUASI-EXPERIMENT
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Subjective quality of life (QoL) has become increasingly important in the assessment of outcome in the mentally ill. It is, however, necessary to determine to what extent subjective QoL represents a state or a trait in mental illness. This study aims to investigate whether subjective QoL of chronic schizophrenic patients varies either spontaneously or in relation to a disturbance in everyday life.

Subjective QoL and well-being of 52 long-term schizophrenic in-patients were measured at three comparable in-patient wards during 2.5 weeks at five different points of time (t1 – t5). Psychopathology, sociodemography, compliance and current life events were measured as control variables. The daily routine on one ward was mildly disturbed and on another ward severely disturbed at t5 by a necessary renovation which was used as an external disturbing stimulus.

The results indicate that the intra-individual level of subjective QoL remains very stable over time. In contrast, interindividual differences accounted for the largest proportion of the variance. It was found that the disturbance resulted in lower levels of subjective QoL in the group with severe external disturbance.

There is evidence from our results that subjective QoL represents a trait in chronic schizophrenic patients to a significant degree. On the other hand, a disturbance in everyday life was reflected by short-time changes in subjective QoL. It is recommended that subjective QoL should be measured in groups that are matched with regard to age, environmental setting and course of illness.

115. SOCIAL COMPARISON AND QUALITY OF LIFE IN SCHIZOPHRENIC PATIENTS
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Subjective quality of life (QoL) in schizophrenic patients increases with the duration of illness. Long-stay schizophrenic patients (LPs) report a higher degree of satisfaction than acute schizophrenic in-patients (APs). This study examines the relation.
of the level of subjective QoL and accommodation to adverse circumstances in terms of social comparisons. It is hypothesized that ‘upward’ comparisons (i.e. with persons viewed as superior with regard to a specific life domain) lead to lower levels of satisfaction than comparisons with persons viewed as equivalent (‘lateral’ comparisons).

Seventy LPs, 60 APs and 65 patients of a general practitioner (GP) were examined by means of a standardized interview. Social comparison processes were assessed within the domains of friendship, family and psychiatric illness.

It could be demonstrated that LPs compared themselves significantly more often to fellow in-patients than APs. While ‘upward’ comparisons were found more often in the AP groups, ‘lateral’ comparisons were dominant in the LP group. LPs and GPs reported a significantly higher degree of satisfaction with the above-mentioned life domains than APs. Significant correlations between the direction of social comparison and level of satisfaction could be found.

The results indicate that social comparison processes and the level of schizophrenic patients’ subjective QoL are related. This interrelation ought to be taken into account in the interpretation of subjective QoL data.

116. THE UNBEARABLE LIGHTNESS OF BEING – QUALITY OF LIFE BEING A FORENSIC PSYCHIATRIST
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Research on quality of life (QoL) concentrates mainly on patients’ notions, conceptions and opinions on QoL. The present investigation is guided by the conviction that the motivations, experiences, difficulties and anxieties of the professional staff working with and for the sake of patients mirrors the problems and the lack of QoL of the latter. A particularly stressed profession is investigated: the forensic psychiatrist. The emphasis lays on the occupational situation and the extent of acceptance within society in general, within the professional community of psychiatrists and within the group of people they work with – and build up their daily relationship: the offenders. Eight forensic psychiatrists, half of them having left their job, half of them still working in forensic psychiatric institutions, were interviewed with the help of semi-structured interviews. The results show that the identity of the forensic psychiatrist is characterized by the fact that society takes note of their work, mainly when spectacular relapses of offenders are reported in the media, that they are considered an outsider in the general psychiatrists’ community, that they are suspected to be allied with the offenders and, at the same time, are seen as part of a restrictive justice system in the offender’s view. This has an important impact on their work with severely disturbed and mentally ill offenders. Furthermore, the results support the hypothesis that the forensic psychiatrists’ identity is threatened through the fact that a defined curriculum has not yet been established, only little acknowledgement from society, other psychiatrists and offender patients can be expected and unclear objectives are the basis of their work. The risk of the development of a burn-out syndrome is evident.

117. QUALITY OF LIFE AFTER RELEASE FROM PRISON INFLUENCING OFFENDERS’ RECIDIVISM
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Sixty-one men were interviewed on average 5 years after their stay in a rehabilitation house for prisoners. This rehabilitative community, a social-psychiatric-oriented initiative, offers fundamental elements characterizing quality of life (QoL), e.g. an apartment of one’s own, a job, a community with other patients and staff members, the possibility to talk to professionals 24 h a day and a social advisory board to check and solve personal problems.

The target group of this community consists of persons who are largely disintegrated and stigmatized: 85% of the sample were previously convicted and had spent on average 5 years in prison. More than 70% were living in isolated circumstances without any social network. Forty-one percent had previously been in-patients of psychiatric institutions, 76% were alcohol or drug dependent, 51% had been unemployed for more than a year, 62% had debts (on average >200,000 ATS) and 57% had been homeless. The prognosis of this target group is estimated to be hopeless regarding social rehabilitation.

The staff of the ‘Emmaus Community’ believe they have a sufficient conception of dealing with these problems, like living together, working together, community training, professional guidance and various forms of therapy. In fact, no relapse occurred in 74% of the offenders, the number of offences decreased for approximately 90% and 35% of the alcohol-dependent patients remained dry. The conditions of occupation, residence and relationship had improved markedly and problems such as homelessness, unemployment, suicidal tendencies and psychiatric relapse diminished over time.

The rehabilitation of offenders is difficult to handle and needs community-based psychiatric care. One possibility to reduce offenders’ recidivism is to establish communities intensely caring for admitted patients.

118. VALIDATION OF A SELF-ADMINISTERED VERSION OF THE QUALITY OF WELL-BEING SCALE
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The Quality of Well-Being (QWB) scale is a common health status index that requires an interviewer. This project presents early evidence on the validity of the QWB-SA, a new, expanded, self-administered version of the QWB.

Four hundred and twenty-one patients from several managed care plans associated with the University of California-San Diego completed a QWB-SA in March 1997. Patient recruitment was stratified by prior year health care utilization. The patient QWB-SA scores were then correlated, without adjusting for age or gender, with these prior fiscal year costs. Ongoing analyses will test the predictive validity of the QWB-SA by correlating the scores with current year costs.

For the analyses, the patients were placed in cost quartiles, here labelled A to D for the lowest (A) to the highest (D) cost. The
QWB-SA scores for the four quartiles showed the expected trend (A = 0.686, B = 0.661, C = 0.628 and D = 0.593). The Pearson correlation coefficient for the total (in-patient plus out-patient) costs and QWB-SA was –0.28 (p = 0.0001). The five-point general health perception question provided similar correlations to total costs.

This study provides further initial evidence of the construct validity of the new QWB-SA. We anticipate accounting for greater variance in costs after adding the QWB-SA score to a model including age and gender and when the correlated costs are from the same fiscal year as the quality of life (QoL) assessment. While the correlations in this preliminary study were similar to those of the five-point health perception question, the QWB-SA has been previously shown to also contain information useful to clinicians. The QWB-SA may also prove to be useful to QoL researchers.

119. INITIAL COMPARISON OF FOUR GENERIC HEALTH-RELATED QUALITY OF LIFE INSTRUMENTS
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Generic health-related quality of life (QoL) instruments grow in popularity, but most claims regarding one approach over another are based on limited data. This abstract presents the initial data from a prospective study designed to compare four standard QoL instruments.

The 899 ambulatory, geriatric subjects (mean age = 79 years, 40% female) came from a randomized trial (Stroke Prevention in Atrial Fibrillation, SPAF), a registry tied to that trial and an established population-based cohort. Each subject will receive two of the following QoL assessments three times over 12 months: the EuroQoL (EQ-5D), the Health Utilities Index (HUI), the Quality of Well-Being (QWB), and the SF-36. This abstract presents the initial evaluation of the baseline data. All QWB assessments and the assessments of the population-based cohort were by telephone. All other assessments were self-administered.

The self-administered assessments produced a variable but significant number of incomplete responses requiring telephone follow-up to gather remaining data (EQ-5D = 6%, HUI = 11% and SF-36 = 26%). Ceiling and floor effects significantly affected several of the SF-36 domains (68% of the subjects had the highest or lowest score for role physical, 81% for role emotional and 54% for social functioning). Thirty percent of the subjects were at the EQ-5D ceiling. The QoL scores differed by the source of subjects and by instrument. For example, of the three single-score instruments, the HUI had the highest scores, ranging from 5 – 10% higher than the EQ-5D and 20 – 25% higher than the QWB. The patients from the clinical trial registry had the highest QoL scores on two of these three scales.

Each instrument has its relative strength and comparing the different instruments will allow outcomes researchers to select instruments to meet their research needs better.

120. GENDER DIFFERENCES IN QUALITY OF LIFE IN GERIATRIC ORTHOPAEDIC PATIENTS
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Orthopaedic problems are a significant cause of morbidity in the elderly. This study presents preliminary data on gender differences in musculoskeletal morbidity.

One thousand one hundred and sixty-one participants in the Rancho Bernardo Heart and Chronic Disease Study received a quality of life (QoL) assessment with a Quality of Well-Being (QWB) interview as part of the Diabetes II visit from 1992 to 1995. All assessments were performed by a trained interviewer using standard QWB protocols. The Diabetes II visit included an extensive assessment of a variety of demographic, medical history, and physiological variables. Gender-specific, age-adjusted QWB scores were compared to evaluate how a history of any bone fracture and a history of hip replacement affect current QoL.

A history of fracture was associated with lower QWB scores, though this was significant only in women. Women with a hip replacement had lower QWB scores than women without this surgery. Of note, men with a hip replacement had higher scores, though again the results did not reach statistical significance. More women than men (22 versus 7%) had a fracture; the same proportion had hip replacement (approximately 4%).

As expected, a history of fracture adversely affects QoL in men and women. The lack of statistical significance in men may be a result of low statistical power, given that only 34 men had a history of fracture. There was a decrease in QoL in women with a hip replacement, while in men there was an increase in QWB scores, a finding that approached statistical significance with only 16 men having a hip replacement. The paper will speculate on reasons for this observation.

121. RACIAL DIFFERENCES IN QUALITY OF LIFE IN EPILEPSY
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Little attention has been paid to how racial or ethnic status affects quality of life (QoL) in chronic illness. Is there a universal response to having an illness or does having a chronic condition and being of ethnic minority status represent a double load? If the latter were true, we would expect of people of ethnic minority
status and chronic illness to exhibit more negative outcomes than ill persons of majority status. In the present study, 45 Black and 45 White participants were selected from a sample of 200 persons with epilepsy and matched on three measures of socioeconomic status (education, income and employment) and seizure frequency. QoL was measured using the Washington Psychosocial Seizure Inventory. No differences were found on scales assessing vocational, financial and medical issues or adjustment to seizures. Significant differences ($p < 0.05$) were found in family background and interpersonal adjustment, with White participants doing appreciably worse than Black participants. The reasons for these somewhat paradoxical findings will be discussed, based on a comparison with other indicators and subsequent qualitative interviews of participants.

122. IS POST-OPERATIVE QUALITY OF LIFE PREDICTABLE IN RADICAL CYSTECTOMY AND URINARY DIVERSION?
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Until recently quality of life (QoL) research in patients with urinary diversion was been set retrospectively only, lacking a pre-operative assessment of this multidimensional construct. In this prospective longitudinal study we wanted to evaluate whether there are psychosocial predictors of therapeutic success in terms of the patients' health-related QoL.

Over 16 months 41 male and seven female patients (mean age 68 years) with invasive bladder cancer had been invited to complete a questionnaire (121 items) 3 days before ($t_1$) and six months after surgery ($t_2$). The instrument encompassed generic scales concerning active search for information, coping strategies, disease-related social support, depression, general complaints, satisfaction with present life, mental well-being and leisure time activities. Post-operatively stoma-related items were added. The pre- and post-operative scores were compared and Spearman's coefficient was calculated for rank correlations.

In 29 patients all data could be obtained at $t_1$ and $t_2$ (group A), 12 patients died before $t_2$ (group B) and seven patients did not respond at $t_2$ (group C). In group A there was a significant decrease in life satisfaction after surgery with a score still above the mean. There was no change in mental well-being with high ratings at $t_1$ and $t_2$. A significant correlation between satisfaction, leisure time activities and stoma-related problems could be observed. Low scores in pre-operative well-being and cognitive coping correlated with a high frequency of stoma problems. The patients in group B disclosed a lower score in pre-operative well-being and more general complaints. No single coping strategy was correlated with a favourable score in post-operative QoL parameters. Patients expecting a strong social support showed higher post-operative leisure-time activities.

The study clearly demonstrates the correlation between QoL parameters and stoma-related issues. High post-operative scores in life satisfaction and well-being suggest that as early as 6 months after the procedure, most of the patients achieve a satisfactory degree of adaptation.

123. MEASURES OF QUALITY OF LIFE TRENDS OVER TIME
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The aim of this study was to monitor over time the use of generic quality of life (QoL) measures in clinical trials. In order to achieve this, extensive bibliographic searches of 27 QoL measures were undertaken. The Bath Information and Data Services (BIDS), EMBASE was systematically searched for UK publications for the years 1980 – 1995, inclusive, on name of the measure and/or common acronym. The frequency of each of 27 QoL measures for the years 1980 – 1995, classified by type of study and population/disease studied were recorded.

During the period studied, the number of citations of QoL measures in published literature has increased by approximately 630%. The proportion of cross-sectional surveys cited to (randomized) controlled trials appears to be constant over the 16 years at approximately 69% for both randomized and controlled trials, respectively. For individual measures, the number of cross-sectional studies conducted remains to heavily outweigh the number of clinical trials even when population norms have been established for the measure.

The results from this study emphasize the need to monitor with greater vigilance those QoL measures which are of use and have proven of value to clinicians and researchers. An area which should be addressed by research funders is the extent to which the numerous cross-sectional surveys presently being conducted can be of benefit in terms of knowledge gained rather than confirming the work of previous studies.

124 QUALITY OF LIFE IN 49 DRUG-DEPENDENT PATIENTS INTEGRATED IN A METHADONE MAINTENANCE PROGRAMME (4 YEARS) IN SPAIN
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We studied the quality of life (QoL) level of a sample of 49 severe drug-dependent patients (heroin) involved in a methadone maintenance programme in Asturias, Spain over a 4 year period.

QoL was assessed using the SF-36 (Spanish version). The severity of drug-dependence was obtained employing the Spanish version of the EuroQol and symptoms of anxiety and depression were screened using the Goldberg's Anxiety and Depression Scale. Statistical analysis was made using $\chi^2$, the Student's $t$-test and the Pearson correlation coefficient.

Patients undergoing this programme show moderate QoL levels: PF (81.4), RP (79.1), BP (76.5), GH (50), V (43.8), SF (76.6), RE (64.4) and MH (55.3). Significantly lower levels of QoL were found in HIV-positive patients ($p < 0.0001$), polyconsumers who had consumed during the 6 months prior to the interview, heroin ($p < 0.0001$), cocaine ($p < 0.05$) or high doses of alcohol ($p < 0.001$), those screening positive for anxiety or depression ($p < 0.0001$), those needing high doses of methadone ($p < 0.0001$) and those most severe in all areas of the EuroQol ($p < 0.0001$).

It can be concluded that severely drug-dependent patients show psychological domains worse than the physical ones. Consequently, these patients need more intensive and specific psychosocial support.
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125. LONG-TERM EVOLUTION OF THE SF-36 (8 MONTHS) IN A SAMPLE OF 353 SCHIZOPHRENIC PATIENTS UNDERGOING RISPERIDONE TREATMENT


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The aim of this study was to evaluate the evolution of quality of life (QoL) in patients undergoing treatment with risperidone over a period of 8 months.

A long-term prospective Spanish multicentre study was conducted involving 353 schizophrenic out-patients. The instruments employed were the BPRS for clinical assessment and the SF-36 as the generic QoL measure.

Statistical analysis was made using the Wilcoxon test, and p values of 0.05 were considered significant.

A significant improvement (p < 0.0001) was observed on all scales of the SF-36 after 8 months of treatment with risperidone. Females improved significantly more than males on the role physical (p = 0.02), general health (p = 0.02) and role emotional (p = 0.03) scales. Patients with a paranoid subtype showed a significantly better evolution than non-paranoid ones on the following scales: general health (p = 0.003), vitality (p = 0.04), social functioning (p = 0.03), role emotional (p = 0.01) and mental health (p = 0.03). Patients without use – abuse of drugs improved significantly more than those with use – abuse on the physical functioning (p = 0.05), general health (p = 0.01) and social functioning (p = 0.02) scales.

Patients undergoing long-term antipsychotic treatment with standard doses of risperidone (5 – 6 mg per day) steadily improved their QoL level. A global improvement can be seen as both the physical and psychological scale scores increase to the same degree.

Female patients, paranoid patients and those without use – abuse of drugs demonstrate greater improvement in their QoL.

126. THE SF-36 VERSUS THE WHOQOL-100 AND -26 IN SCHIZOPHRENIC PRIVATE OUT-PATIENTS

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The aim of this study was to make a comparative analysis of the performance between two new generic quality of life (QoL) instruments (the WHOQOL-100 and -26) and the SF-36 in schizophrenic out-patients. A total of 60 schizophrenic out-patients (ICD-10 criteria) undergoing maintenance treatment with different neuroleptics were interviewed when out of the acute phase as measured by the PANSS. QoL was assessed using the SF-36 and both versions of the WHOQOL, that is versions 100 and 26.

In order to determine convergent validity the Pearson correlation coefficient was employed. Differences between group means were tested using the Student’s t-test. In all cases a p value of <0.05 was considered to be statistically significant.

Significant correlation coefficients were found between all the domains of the WHOQOL-100 and the majority of the SF-36 scales, with values ranging from 0.293 (between the psychological domain and vitality scale) to 0.6008 (between overall QoL and social functioning). None of the WHOQOL-100 domains correlated with the role physical scale and, in general, these domains were more highly correlated with the mental component summary scales of the SF-36 than with the physical component scales.

All the domains of the WHOQOL-26 showed significant correlations with four of the eight SF-36 scales, namely general health, social functioning, role emotional and mental health, with values ranging from 0.2583 (between environment and mental health) to 0.6008 (between overall QoL and social functioning). No WHOQOL-26 domain correlated with the physical functioning, role physical, bodily pain and vitality scales of the SF-36.

We did not find significant differences in the QoL profiles obtained by the WHOQOL-100 and the WHOQOL-26.

Our results lend moderate support to the WHOQOL convergent validity with the SF-36.

The WHOQOL-26 appears to perform equally as well as the WHOQOL-100 in measuring QoL in schizophrenic out-patients.

127. UTILITY MEASUREMENT IN CHRONIC LOW BACK PAIN PATIENTS: A COMPARISON BETWEEN DOMAIN-SPECIFIC AND PREFERENCE-BASED INSTRUMENTS

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Quality of life (QoL) provides an important outcome measure for chronic low back pain (clbp) treatments. For a comparison with different interventions and different patient populations in cost-effectiveness studies it is preferable to use different categories of QoL measures. The objective of this study is to compare domain-specific QoL measures with preference-based measures with respect to their validity, responsiveness to change and use in cost-effectiveness studies.

In a randomized controlled trial 148 clbp patients were assigned to a combined operant programme plus cognitive/relaxation programme, an operant programme plus attention control or a waiting-list control group with a programme given as usual at a rehabilitation centre. QoL was measured at baseline, after treatment and after 6 and 12 months follow-up using several domain-specific measures (the Beck Depression Inventory, McGill Pain Questionnaire, Pain Cognition List, Behavioural Avoidance Test, Fear Survey Schedule, Maudsley Marital Questionnaire, Medical Examination and Diagnostics Information Coding System, a global assessment of change and a Maastricht Utility Measurement Questionnaire, using a description on six dimensions of health and two preference-based instruments (rating scale (RS) and standard gamble (SG) method).

Immediately after treatment there was a significant difference found on the global assessment of change between the waiting-list control group and the two treatment groups. No differences were found between the operant/cognitive programme and the operant discussion programme for six dimensions of health and two preference-based instruments (rating scale (RS) and standard gamble (SG) method).

It can be concluded that the addition of a cognitive component to an operant/discussion programme does not result in an additional improvement in QoL as compared to an operant/discussion programme. Ceiling effects and risk-averse
behaviour of the low back pain patients play an important role in the insensitivity to change of the SG scores. It can be concluded that the SG, as used in this setting, is not suitable for evaluating a therapy for clbp patients.

128. OUTCOME OF SCHIZOPHRENIA AND SCHIZOAFFECTIVE PSYCHOSIS IN ADOLESCENTS – A FOLLOW-UP STUDY
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Schizophrenic and schizoaffective diseases are frequent; their signs and symptoms are very often described. The onset and symptoms of schizophrenic and schizoaffective psychosis in adolescents are often different from those of older people. Thus we retrospectively studied the case histories of 20 patients with a diagnosis of schizophrenia (n = 9) and schizoaffective psychosis (n = 11) according to the ICD-10 classification, between the ages of 12 and 18 years, who were in-patients between 1980 and 1990. We contacted these patients and studied their psychiatric problems, symptoms and social events, using a semi-structured questionnaire. In this exploration our special attention was to study the quality of life (QoL).

The aim of this pilot study is to present the first interesting results.

129. THE IMPACT OF FATIGUE ON QUALITY OF LIFE IN BONE MARROW TRANSPLANT SURVIVORS
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Fatigue is a common and persistent symptom associated with cancer and its treatment. This paper will present the impact of fatigue on quality of life (QoL) from the perspective of bone marrow transplant (BMT) survivors. The City of Hope QoL-BMT Instrument used in this study includes forced-choice questions for demographic information, 0 – 10-point items related to QoL issues and open-ended questions. Data related to the level of fatigue over four points in time and open-ended questions about fatigue will be presented. The sample included 294 post-transplant survivors. In response to the question, ‘To what extent is fatigue a problem for you?’, fatigue varied from worst to least depending upon the time since transplant. On a scale of 0 = severe or worst fatigue to 10 = no problem or no fatigue, patients reported their current level of fatigue at a mean of 5.4. Verbatim quotes related to the impact of fatigue on patients’ QoL will be shared. The findings provide a unique perspective about the relationship of fatigue and QoL. Additionally, the study findings have implications for educating patients and health care providers about fatigue and its impact on QoL and can be used to formulate interventions for pre-, post- and long-term phases of the transplant experience.

130. ASSESSING QUALITY OF LIFE WITH THE WHOQOL-100: A COMPARISON OF PATIENTS WITH CHRONIC DISEASE AND A HEALTHY POPULATION
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The aim of the study was to compare health-related quality of life (QoL) of patients with chronic tinnitus with a random sample of university employees.

Health-related QoL was assessed using the German version of the World Health Organization Quality of Life assessment instrument (WHOQOL-100). The data from tinnitus patients were collected in an out-patient setting (n = 53) and for the healthy population via a mail survey (n = 198). The group comparison was based on the six health domains covered by the WHOQOL questionnaire. A covariance analysis was performed controlling for age, gender and education.

The results indicated that tinnitus patients showed significantly lower scores compared to healthy subjects on five out of the six health-related QoL domains assessed: the physical domain (F = 11.77 and p = 0.001), psychological domain (F = 7.37 and p = 0.007), independence domain (F = 10.30 and p = 0.002), social relationships domain (F = 19.13 and p = 0.000) and religion domain (F = 25.06 and p = 0.000). There was no statistically significant mean difference on the environment domain (F = 2.50 and p = 0.12) between the two samples.

We conclude that the health-related QoL of patients with tinnitus is severely impaired in various domains and that the WHOQOL-100 appears to be a reliable instrument for group comparisons between chronically ill patients and healthy populations.

131. QUALITY OF LIFE AFTER SEVERE BRAIN INJURY
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The purpose of this clinical study was to determine occult organic lesions and neurological as well as psychological defects after severe brain injuries. Forty-one patients with severe brain injuries requiring operation and intensive care treatment were examined after a time interval of 12–27 months (mean 21 months). The group comprised 21 men and seven women with a mean age of 46 years (18–67 years) as well as six children of ages 2, 4, 5, 8, 11 and 12 years. Most of the patients suffered from multifocal intracranial lesions. After operation the patients were mechanically ventilated for 14 days on average. Hospitalization lasted 73 days on average, including rehabilitation time. Thirty-five patients returned to their former environment and six patients needed continuing physical and intellectual assistance.

The study included a neurological examination, an EEG, CCT, MRI and psychological testing. The MRI proved to be most accurate in detecting morphologic cerebral defects. The neurological findings were summarized in the BOND Scale and the activities of daily living in the BARTHEL Index. The psychological tests examined the patients’ memory, intelligence,
executive function and functional capacities in daily living as well as their social integrity. Although most of the patients did not show neurological residuals of the trauma, disorders of integrative functions were found in many cases by psychological tests.

Patients with severe brain injury can be treated successfully with the tools of modern medicine. Even if the late results in many cases are good at a first glance, occult sequelae of the trauma can diminish quality of life (QoL) to a high extent. Disorders of functional capacities can be compensated in the case of the patients’ regular social integration or continuing medical care. Additional social, familiar or professional problems can easily start the vicious circle of social isolation.

132. LONG-TERM HEALTH-RELATED QUALITY OF LIFE OUTCOMES OF PERSONS WITH DIABETES SEEKING TRANSPLANTATION
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This report describes and compares the health-related quality of life (QoL) outcomes of persons with type 1 diabetes and renal dysfunction as related to transplant surgery. Patients seeking transplants completed health and QoL self-report questionnaires prior to transplant (baseline) and again at 1 and 3 years after transplant. A nursing examination and chart review established the diabetes severity at baseline. A comparison group of persons with diabetes not seeking a transplant (no transplant) also completed these assessments. Three groups are compared: combined pancreas/kidney transplant recipients (PK, n = 66), kidney transplant alone (K, n = 87) and the comparison group (no transplant, n = 41). At baseline the no transplant group was slightly younger and had milder disease (lower diabetes severity index (DSI) scores), but had been diagnosed with diabetes at an earlier age. Longitudinal data from no transplant and PK or K patients with functioning grafts were compared using ANCOVA to adjust for age, sex and DSI and QoL at baseline. At 1 year, SF-36 subscales, life satisfaction and affect scores for both the K and PK patients improved compared to the no transplant patients. At 3 years, the improvements from baseline within each transplant group and most improvements compared to the no transplant group were sustained. Between 1 and 3 year’s differences between the K and PK scores emerged with many PK scores higher than K. For example, from years 1 – 3, the SF-36 physical component scores (PCS) declined for the K group, but continued to improve for the PK patients. The PCS scores from baseline to 3 years’ were 46.5 to 42.6 (no transplant), 36 to 46.3 (PK) and 34.1 to 35.4 (K) (p < 0.05, ANCOVA). (The norm mean PCS = 50, SD = 10 and a sample with diabetes reported mean PCS = 39.3). This prospective study documents that differential improvements in health-related QoL associated with PK transplant compared to K transplant emerge with increased length of follow-up. Funding was provided in part, by the Diabetes Research and Education Foundation & grant M01-RR00400, NCRRNLNIH.

133. WHO CARES FOR INCARCERATED MENTALLY ILL OFFENDERS?
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The social and occupational rehabilitation of mentally ill offenders is crucial for relapse prevention. Therefore, long-term imprisonment of offenders with subsequent social disintegration might not only be of questionable impact on relapse prevention but might be a further risk factor.

Prisons providing therapeutic facilities, such as psychotherapy, social therapy and family therapy might be able to overcome the negative aspects of imprisonment. In the Justizanstalt Wien-Mittersteig, a therapeutic-orientated prison predominantly for sexual offenders, 40 offenders have been followed up concerning contact to significant others and social support by them.

The results show a shift from relatives to new friends being important for the offender concerning social support in ‘showing feelings’, ‘emotional acceptance’ and ‘solidarity’ and ‘talking about sexual issues’ after 6 years imprisonment. Professionals, furthermore, played a more important role than they did before the admission offence.

We conclude that a helping system consisting of new friends and professionals might be of greater value in terms of relapse prevention than contact with persons belonging to the old system when the offence took place.

134. A QUALITY OF LIFE STUDY IN PSYCHIATRIC PATIENTS
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The study was carried out in four countries: France, Germany, England and Portugal. All patients included (in- or out-patients) were aged 16 – 65 years. ICD-10 diagnoses were recorded according to clinical judgements. They should not have been in an active phase of a psychotic illness. Four hundred and thirty-seven patients completed the Psychological General Well-Being Schedule and the Bradley’s 22-item Well-Being Questionnaire.

The preliminary results from the PGWB will be presented: Cronbach’s α coefficients, mean scores according to the diagnosis, principal component analysis (one factor accounting for the majority of the variance) and correlations with the Bradley’s Well-Being Questionnaire global scores and subscores (depression, anxiety, energy and well-being). According to these results, the PGWB Questionnaire is clearly a unidimensional tool, highly correlated with the Bradley’s Well-Being Questionnaire in each country.
135. REDUCTION OF THE AIMS2 QUESTIONNAIRE: PROPERTIES OF THE AIMS2-SF FOR RHEUMATOID ARTHRITIS

F. Guillémin, J. Coste, J. Pouchot, M. Ghézail, C. Brégéon, J. Sany and the group 'Quality of life in Rheumatology' School of Public Health, Faculty of Medicine, Nancy, France

The objective was to develop a short form of the AIMS2 questionnaire for rheumatoid arthritis (RA) to reduce its duration of administration, in preserving content validity as a priority criterion.

The original AIMS2 contains 57 items in 12 dimensions structured in five components. A two-step reduction procedure used (1) a Delphi technique, with a panel of 12 patients and a panel of 19 experts, each panel selecting one set of items independently and (2) a nominal group process, where members of both panels reached consensus on the final item selection, preserving content validity and using supplementary information derived from item analysis. The psychometric properties of the AIMS2-SF and AIMS2 were compared using data from a cohort of 127 RA patients who completed the AIMS2 twice before and 3 months post-initiation of methotrexate treatment.

The panels reached consensus on the AIMS2-SF with 26 items (54.4% reduction). Factor analysis showed preservation of the five-component structure. The internal consistency (Cronbach’s α 0.7 – 0.8), convergent validity (higher Pearson correlation of physical and symptom components with clinical variables), test–retest reproducibility (ICC over 0.7) and sensitivity to change at 3 months (SRM 0.36 – 0.8, except social components (0.08)) were very close to the original AIMS2.

The AIMS2-SF is available in a two-page format, keeping the original content validity with similar psychometric properties.

136. SELECTION OF QUALITY OF LIFE MEASURES FOR A PREVENTION TRIAL: CONCEPTUAL AND PSYCHOMETRIC BASIS WITH AN EXAMPLE

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The objective was to select quality of life (QoL) measures for a prevention trial of vitamins and antioxidants against cardiovascular and cancer diseases.

Generic instruments considered suitable for prevention should be concise for repeated administrations in this 8-year randomized trial and available in the French cultural setting. The Duke Health Profile (DHP), Nottingham Health Profile (NHP) and SF-36 were candidates for selection. The content examination was conducted using a nominal group technique. Judgements on the items and dimensions of questionnaires were rates from 0 (none relevant) to 3 (very relevant) by four experts on whether they were (1) measuring a clear identifiable concept and (2) relevant to detect change or to remain stable if no change occurred over the trial. The instruments were administered twice, 3 months apart, to 903 subjects (pilot study) for a comparison of the internal consistency, convergent validity against overall health and presence of chronic disease, reproducibility in subjects with stable health and sensitivity to change in subjects with health change over 3 months.

The content analysis gave close mean scores (2.34 – 2.43) for the items and a higher score for the NHP (2.53 over the DHP and SF-36 (2.17 and 2.16) for the dimensions. An analysis of the relevance of the trial ranked the SF-36 and DHP over the NHP (2.06, 1.97 and 1.65) at the item level and gave close mean scores at the dimension level (1.78 – 1.85). The dimension scores correlated with overall health was high with the DHP (0.36 – 0.58), in a narrower range with the NHP (0.24 – 0.43) and broader with the SF-36 (0.20 – 0.72). The presence of a chronic disease was associated with a significantly lower score in all dimensions of all three instruments. The reproducibility in 603 subjects did not differ significantly in the main dimensions (intra-class correlation coefficient from 0.46 to 0.81 in the DHP, 0.70 to 0.79 in the NHP and 0.47 to 0.80 in the SF-36). The standardized response means for the sensitivity to change were higher in the main dimensions of the DHP (0.24 – 0.58 in 185 subjects who worsened and 0.32 – 0.54 in 123 who improved) and SF-36 (0.41 – 0.44, and 0.07 – 0.49) than the NHP (0.16 – 0.29 and 0.08 – 0.43).

Balancing the content, metric properties and relevance for this prevention trial led us to choose the DHP and SF-36. The association of expert judgement and field testing formed the basis of our strategy.

137. STRESS AND QUALITY OF LIFE: AN EMPIRICAL STUDY

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What is the quality of life (QoL) in subjects suffering from stress and registering for an antistress training course? Does learning how to cope with stress have any effect on the subjects’ QoL?

In order to answer these questions we conducted an empirical study with 114 German subjects from the normal population of adults who had registered for an 8 week antistress training course offered by a major health insurance company in several cities in the state of Baden-Württemberg, Germany.

Sociodemographic variables and QoL (Münchner Lebensqualitäts Dimensionen Liste (MLDL) and other more specific items) as well as other aspects related to health and/or stress were measured before (T1) and at the training and at follow-up (T2) 6 months later. Forty-one of the subjects reported a significant event in their life which had motivated them to register for the course. Nineteen percent had to cope with a chronic physical disease and 7% with major psychological problems. Fifty-four percent had serious concerns about their physical health status. Eighty percent of the 94 subjects completing their course were generally satisfied with their personal results. Seventy-two percent of the 65 subjects at follow-up reported that they had learned how to cope better with their daily stress. Specific items to assess QoL proved to be more sensitive to change than general measures.

Our results show that antistress courses can be effective in improving aspects of QoL related to stress.

138. GOAL ATTAINMENT AND QUALITY OF LIFE

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The purpose of this presentation is to compare (1) the level of attainment of goals in relation to quality of life (QoL) and (2) the importance of goals to be accomplished with the satisfaction of occupational activities. The data stem from a study on the psychometric qualities of the Canadian versions (English and French) of the Wisconsin Quality of Life Client Questionnaire. A semi-structured interview with adults having severe mental health problems took place in the community. Descriptive and correlational tests were the statistical analyses used. The results...
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will point out the life domains identified within the goals of the
participants interviewed as well as their level of importance and
their relationship to QoL as a whole. The conclusion will
emphasize the importance of these results in relation to
psychosocial rehabilitation.

139. TRANSLATION AND VALIDATION OF
QUALITY OF LIFE INSTRUMENTS
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The cross-cultural evaluation of health-related quality of life
(QoL) is increasing within the international research arena.
Clinical treatment trials, epidemiological studies and cost-effectiveness
research have all begun to include culturally diverse
groups of patients. Multiple language versions of QoL instruments that perform equivalently across cultures are required.

In order to meet the needs of international researchers and practitioners, we initiated a multilingual translation of the
Functional Assessment of Chronic Illness Therapy (FACT) Measurement System (Version 3). The FACT system, originally
developed in English, utilizes self-report instruments to measure multidimensional QoL. An iterative forward—backward translation methodology, followed by expert review, is used to create
translated documents suitable for initial psychometric evaluation with small groups of patients in the native countries. Semi-structured interviews conducted with each patient allow additional assessment of the content and semantic equivalence of the translation and provide information about conceptual equivalence. Larger validation studies are now under way to cross-culturally evaluate the performance of the FACT instruments. Rasch model
techniques for the assessment of item bias, confirmatory factor analysis and traditional psychometric analyses of reliability and validity will be performed for each language and the results compared to those obtained for an English-speaking group of patients with the same disease/condition.

Careful implementation of a rigorous translation methodology and pre-testing with patients in the native countries, have resulted in high-quality translations of the FACT instruments. Ongoing validation studies will evaluate the statistical equivalence of multiple language versions and will permit international
researchers to implement ‘culture-fair’ QoL assessment in clinical trials and effectiveness studies.

140. UNBIASED QUALITY OF LIFE
MEASUREMENT ACROSS LITERACY
LEVELS AND MODE OF ADMINISTRATION
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USA

In order to accommodate the needs of linguistically, culturally
and educationally diverse patients, maximum flexibility is required in administration modes for quality of life (QoL) instruments. The benefits of such flexibility, however, must not be at the expense of obtaining unbiased measurements of QoL.

One of the aims of a recently completed large multicentre
study of cancer and human immunodeficiency virus (HIV)
patients, was to test the psychometric properties and statistical
equivalence of the English and Spanish language versions of the
Functional Assessment of Cancer Therapy (FACT) subscales across literacy level (low versus high) and mode of admini-
tration (self versus interview). High-literacy patients were randomly assigned to self (n = 602) or interview (n = 625) admin-
istration of the FACT, and interviews were conducted with low-literacy patients (n = 389). The equivalence of the QoL data was assessed in terms of the item-level and subscale-level missing data, internal consistency reliability, floor and ceiling effects and multivariable analysis of variance models to compare mean subscale scores.

The two randomized groups of high-literacy patients were similar in terms of clinical and sociodemographic characteristics, while the low-literacy patients were older, had higher proportions of Hispanic and Black patients, more head and neck cancer and fewer diagnoses of HIV. Technical equivalence across mode of administration was demonstrated in the high-literacy patients; there were no differences in data quality or in mean QoL scores, after adjustment for performance status, socioeconomic status, gender and age. Low-literacy patients had slightly higher rates of missing data. The adjusted mean QoL scores were similar to those of both groups of high-literacy patients.

Literacy-fair QoL evaluation of people with cancer or HIV and
technical equivalence of the modes of administration will permit the unbiased assessment of the impact of cancer/HIV and their treatment on patients from diverse backgrounds.

141. QUALITY OF LIFE, CARE AND ATMOSPHERE
IN A RESIDENCE FOR THE CHRONICALLY
MENTALLY ILL
Horst Haltenhof 1, Meryem Kilinc 2, Axel Fischer-Walther 2
and Wielant Machleidt 2
1Department of Social Psychiatry and Psychotherapy,
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In this study quality of life (QoL), a major issue of social
psychiatry, and its associations with care and atmosphere in a
community facility are evaluated.

Twenty-eight residents (16 men and 12 women of mean age
43.9 years with a diagnosis of schizophrenia ICD-10: F20.x) were
interviewed and asked to fill in questionnaires concerning QoL
(Berliner Lebensqualitätsprofil, KBB), quality of care
(Klientenbogen zur Behandlungsbewertung, KBB) and the
atmosphere of the facility (Stationsbeurteilungsbogen, SBB). The latter instrument was also filled in by five therapists.

While there was only moderate satisfaction with nine areas of
life (BLQP), quality of care (KBB) and the atmosphere of the facility (SBB) were scored higher. QoL, in particular health and
life in general and feeling of security, was associated with some
scales of the KBB and SBB. For example, there were positive
associations with being understood by therapists, adequate
medication (KBB), social relations, personal development and
goal orientation (SBB), whereas system maintenance and change
(SBB) was inversely associated with some scales of the BLQP. The
residents’ assessment of the atmosphere of the facility (SBB) was
better than that of the therapists.

QoL of chronically mentally ill persons is associated with
different aspects of quality of care and the atmosphere of a facility.
142. SYMPTOMS AND QUALITY OF LIFE 7 – 17 MONTHS POST-MYOCARDIAL INFARCTION
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The aim of the study is to describe self-reported symptoms and quality of life (QoL) 7 – 17 months after myocardial infarction (MI) to improve the empirical basis for cardiological nursing interventions.

The study is a descriptive survey design and data are collected through mailed questionnaires. The population were all discharged from the University Hospital of Bergen during September 1994 to July 1995, of age 67 years or younger and had a main diagnosis of MI. The symptoms are assessed through questions concerning sleeplessness, chest pain, thinking about disease and experienced disturbance from disease on activities of daily life. QoL is measured with the MOS-Health Survey, short form (SF-36). The study is approved by the Regional Committee for Medical Research Health Region III.

Of the 167 eligible, 102 (61%) participated. The mean age is 57 years and 84% are men. There is no significant difference between self-reported symptoms and QoL due to the difference in time since discharge. Fifty-nine percent report sleeplessness to various degrees. Twenty-seven percent have chest pain at least once a week. Fifty-one percent have seldom or no chest pain. Sixty-five percent think about heart disease at least once a week. Fifty-five percent report that disease from some to a large extent affects activities of daily life. Within QoL, the least affected dimensions are physical function, general health, bodily pain, mental health and social functioning. The more affected functions are emotional and physical role function and vitality.

Chest pain and reduced physical function no longer appear to be the dominating sequelae post MI. This can be explained by the improved medical and surgical interventions the last 10 years in Norway, where reduced chest pain has been the main focus for interventions. The results indicate that increased psychological and emotional support due to nursing interventions may enhance the QoL post-MI, complementary to medical and surgical reduction of chest pain.

143. HEALTH-RELATED QUALITY OF LIFE IN COPD PATIENTS WITH HOME VENTILATION
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Patients with COPD, who need chronic mechanical ventilatory support, are suffering from hypoxic respiratory failure and are in the late stage of the disease. There is much controversy about the functional improvement of these patients caused by mechanical ventilation. The quality of life (QoL) is supposed to be bad.

We looked at disease-specific QoL using the St. George Questionnaire of Respiratory Diseases. Comparing a group of patients with COPD and long-term oxygen therapy (LTOT), COPD on non-invasive positive pressure ventilation (NIPPV), and patients with restrictive lung disease on NIPPV, we found that COPD-LTOT and COPD-NIPPV groups have no difference in QoL, although the NIPPV group showed more severe functional impairment (FEV1, RV, PImax, PI/PI max Wob). Dyspnoea was evaluated using the Dyspnoea Index of Mahler. The change in dyspnoea was evaluated at the beginning of the home ventilation and after 1 year showed significant relief in dyspnoea sensation ($\bar{x} = 3.7 \to \bar{x} = 5.8$). The 6-minute walking distance was improved from a mean value of 227 m to 288 m.

Eighty-six percent of the ventilated individuals agreed that ventilation contributed a great deal to managing their underlying disease. Sixty percent said that they were more active since being ventilated.

We evaluated the factors influencing anxiety: >60% of the patients were anxious about what to expect in the future and qualified this as the most important problem they had. In this context the fear of losing independence and being a burden to the family were the most frequent answers.

Finally, we looked at discomfort induced by ventilatory interfaces: the most frequent patients were concerned with dryness, while some had sleep disruption.

In conclusion ventilated COPD-patients have worse QoL than restrictive patients. Compared to COPD-LTOT patients they are similar in QoL, even though having worse function. It appears that mechanical ventilation does produce some relief of the symptoms, in particular dyspnoea. There is no evidence that home mechanical ventilation per se does impair QoL.

144. THE ROLE OF NOVEL ANTIPSYCHOTICS IN IMPROVING THE QUALITY OF LIFE OF SCHIZOPHRENIC PATIENTS
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The purpose of this study is to look at the objective and subjective improvement in quality of life (QoL) of schizophrenic patients, who have been poor responders to typical antipsychotics. Poor responders are categorized as (1) patients who continue to demonstrate positive psychotic symptoms when they receive adequate trial of antipsychotics, (2) patients who are distressed or unable to tolerate the side-effects of antipsychotics and (3) patients who have persistent negative symptoms when they are treated with antipsychotics.

The subjects self-assessed their QoL with the WHO-BREF questionnaire and were assessed with PANNS before the initiation of risperidone. The assessments were repeated after 1, 3 and 6 months therapy with risperidone.

The results showed improvement in the objective as well as subjective assessments with risperidone therapy. The results from this study offer justification for increasing the expenditure on the drug budget for schizophrenic patients. Schizophrenia, unlike other chronic medical illnesses such as coronary insufficiency and renal failure, does not need costly procedures, operations or machines to improve QoL. Denying schizophrenic patients a novel antipsychotic that has been proven to improve their QoL should be considered as inhumane as the use of strait-jackets.
145. RELIABILITY AND VALIDITY OF THE SEXUAL LIFE QUALITY QUESTIONNAIRE
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This study assessed the reliability and validity of a questionnaire measuring sexual quality of life (QoL) and treatment satisfaction amongst men with erectile dysfunction and their partners. All items were constructed as nine-point Likert scales, with the sexual QoL items asking respondents to compare their current experience with the period of time prior to impotence. Evaluative questionnaires were obtained from 88 males under treatment for erectile dysfunction and 28 females (23 of whom were sexual partners of the male respondents). Cronbach’s $\alpha$ for the ten-item sexual QoL subscale was 0.97. The interrater reliability for these items ranged from 0.27 to 0.76, reaching statistical significance for seven items (frequency, duration, penis insertion, performance anxiety, feelings during love making, overall pleasure and partner pleasure). Items not reaching significance (achieving orgasm, lovemaking anticipation and orgasmic pleasure) were related to more personal rather than mutual experience. Factor analysis yielded one factor which accounted for 77% of the variance. In the analysis of the treatment subscale, after removal of one item (effect on conception), a Cronbach’s $\alpha$ of 0.82 was obtained. The interrater reliability correlations ranged from 0.31 to 0.72 and were statistically significant for all but two items (effect on love making pleasure and disruption of love making). Factor analysis yielded one factor which accounted for 45% of the variance. Statistically significant differences were found in a comparison of patients on hormone versus injection therapy ($n = 16$ and $n = 68$) on two items (disruption of love making and effectiveness). Visual comparisons fulfilled expectations regarding the direction of the score differences on the remaining 12 items where one could be hypothesized. The respondents also scored the importance of the aspects measured by each of the items. These scores were used to weight the contribution of each item when computing composite scores for the sexual and treatment satisfaction subscales. This analysis provides evidence of appropriate measurement characteristics for this new QoL measure for use in studies of erectile dysfunction.

146. THE AUSTRALIAN QUALITY OF LIFE PROJECT
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The Australian Quality of Life (AQoL) project was to construct and validate a health-related quality of life (QoL) instrument which would (1) be a psychometrically sound instrument for use in the evaluation of acute technologies, pharmaceuticals and health promotion and (2) enable the economic evaluation of programme through utilities (Quality of life years (QALYs)).

The construction of the AQoL followed conventional psychometric procedures and resulted in a five-dimensional instrument with 15 items. Preliminary tests of the coverage, reliability, sensitivity and validity are described. These show the AQoL to possess a strong factorial structure which has been confirmed through structural equation modelling (CFI = 0.90), to be sensitive to different health states, to correlate well with criterion instruments and to provide excellent health-related QoL coverage.

Based on population random sampling, utility values have been attached to the instrument enabling its use in cost-utility analyses. The AQoL covers over 1 billion health state combinations.

The AQoL can be administered by interview, mail or telephone. It takes 5 – 10 min to complete.

This paper describes some of our findings from studies which have used the AQoL and demonstrated its use as an outcome measure in health programme evaluation.

147. PROSPECTIVE AND RETROSPECTIVE REPORTS OF CHANGE IN HEALTH-RELATED QUALITY OF LIFE IN A SAMPLE OF PERSONS WITH HIV
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The sensitivity of health-related quality of life (QoL) measures to change over time is critically important in efforts to monitor the course of functioning and well-being and assess the impact of therapeutic interventions in HIV. This study compares the change in prospectively measured health-related QoL over a 1 month time interval with retrospectively reported change in a sample of 225 persons with symptomatic HIV disease. The data were collected at two public hospitals: a county-run facility and a VA hospital.

The patients in the study had a mean age of 37 years, 95% were male, 26% Black, 28% Latino and 40% White; 66% had homosexual contact, 16% had heterosexual contact and 13% had IDU as their most likely mode of HIV transmission. For each person we administered by interview a 56-item measure of health-related QoL.

Physical health and mental health composite scores were derived as weighted combinations of the scale scores and the reliability estimates were 0.93 and 0.96 respectively. In the 1 month follow-up interview, we also included retrospective change items. Multiple regression analyses revealed a significant main effect of baseline health-related QoL on the changes in physical health ($t = 2.80$ and $p < 0.01$) and mental health ($t = 2.46$ and $p < 0.05$), with lower baseline scores related to greater improvement. Those reporting at follow-up that they were a lot more limited now than 1 month ago had a significant decrease in physical health, but the decrease was significantly greater for those with a better baseline health-related QoL (25 point decrease) than for those with a worse baseline health-related QoL (six point decrease). Among those reporting at follow-up that they were a lot less limited now, the prospectively measured physical health improved for those with a better baseline health-related QoL (5 point increase), but decreased for those with a worse baseline health-related QoL (12 point decrease). Those reporting at follow-up that they felt anxious, depressed or irritable a lot more often now compared to 1 month ago had a significant decrease in their prospectively measured mental health ($t = 3.90$ and $p < 0.0001$). The results of this study reveal that the amount of change in prospective reports of physical health depends on the baseline level of health-related QoL for those reporting ‘a lot’ of change on retrospective items.
148. MEASURING QUALITY OF LIFE IN CHILDREN WITH CYSTIC FIBROSIS: THE CYSTIC FIBROSIS QUESTIONNAIRE (CFQ)
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Cystic fibrosis (CF) is a condition that adversely affects patients’ quality of life (QoL) from infancy through to adult age. Health-related QoL measures applicable to children and adults are required to assess the multidimensional impact of the disease and treatment over time.

We developed two questionnaires in parallel for evaluating CF patients aged 8 – 13 years, one exhaustive parent version concentrating on behaviour, performance and symptoms and a shorter child version focusing on subjective perceptions and emotions. The items were generated from the analysis of 22 interviews conducted separately with 6 – 13 year old CF patients and parents. Two preliminary versions were fielded in a cross-sectional survey and completed by 141 young patients and 141 parents enrolled in 24 French sites. The questionnaires were analysed using description statistics and factorial and multitrait analysis. The parent questionnaire was reduced to 46 items exploring seven QoL domains: ‘physical functioning’, ‘psychic interpersonal relations’, ‘energy/fatigue/mood’, ‘eating disturbances’, ‘body image’, ‘school performance’ and ‘treatment burden’. Two separate modules assess the intensity of the symptoms and general health perception. All of the item-scale correlations were superior to 0.4; the test of item discriminant validity achieved success rates of 85 – 100%. The Cronbach α coefficients were all above 0.7. All scales could discriminate between severity groups, except two: school performance and social/interpersonal relations. A 29-item child questionnaire was fielded in a longitudinal study. The comprehension and acceptability were excellent. Intermediate analysis on 56 children showed significant correlations across the children scales, except ‘body image’. The agreement between the parent and child reports were particularly good for physical functioning, eating disturbances, school attendance, psychic/emotional and body image, but poor on fatigue/energy, treatment burden and general health perception. Test – retest among 25 stable young patients showed good reproducibility (ICC = 0.95). The final results on the factorial structure, responsiveness and clinical validity will be discussed. A third CFQ version is concurrently being developed for the assessment of adolescents and adults. This comprehensive version of the CFQ will provide measures of health status and will facilitate the treatment of adolescents and adults. The CFQ version for adolescents and adults is currently being tested in several European countries.

150. LINGUISTIC VALIDATION OF A DAILY QUALITY OF LIFE QUESTIONNAIRE FOR MULTINATIONAL CLINICAL TRIALS
David U. Himmelberger and Joel D. Kallich
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We illustrate the challenges and pitfalls of developing a patient self-administered daily quality of life (QoL) questionnaire (‘Daily Diary’) in American–English for use in multinational clinical trials. The Daily Diary consists of 27 questions originally developed in the USA to evaluate the impact of chemotherapy-induced mucositis and diarrhoea on several QoL domains. In this paper we report on the following methodological issues: translation, including assuring the quality of the results of forward and backward translations, linguistic validation, including the practical issues and the qualitative assessment of conceptual equivalence. After using the standard duplicate forward and backward translation process, we linguistically validated the translation with a sample of four to ten patients in each of the seven countries where it is now being used in a clinical trial. The linguistic validation consisted of having each patient complete the questionnaire in one of three modes: self-administered, self-administered with help or face-to-face interview and then a personal interview was conducted with each patient. The personal interview was essential to determine whether patients in the local setting understood the translation in a manner that was functionally equivalent to that of patients in the source language in the USA. We found that hospital policy and the authoritative control of physicians in Europe made certain questions ‘not applicable’ in many countries, e.g. the question...
that asks whether the patient ate certain foods for diarrhoea (patients in Europe viewed these decisions as being made by the medical staff and not within their scope of decision making). The linguistic validation also identified problems associated with the semantic equivalence of response options between languages. Because patients associate different values with numeric labels for response options from country-to-country, the format of the questionnaire confused some patients. In addition, questions about ‘health’ were deemed inappropriate for patients who were severely ill in hospital. The qualitative methods we employed resulted in several changes to the instrument, supported the equivalence across countries and demonstrated that it is possible to create a QoL instrument that measures the same concepts across cultures.

151. ROBUSTNESS OF THE MERIT METHOD FOR REDUCING PATIENT BURDEN AND INCREASING THE EFFICIENCY OF QUALITY OF LIFE QUESTIONNAIRES

David U. Himmelberger and David W. Budd
Health Outcomes Group

Clinical studies are often overburdened by long quality of life (QoL) questionnaires that overwhelm patients. Studies with long QoL questionnaires require more time to enroll patients and have higher drop-out rates. Long QoL questionnaires also have a detrimental effect on the quality of the data. The merit method has been developed as a means of reducing the length of a questionnaire. It is easy to apply and is widely applicable. This paper describes the merit method and its statistical properties. The robustness of the statistical method is examined under a variety of circumstances that are often encountered in the clinical trial environment. The utility of the merit method in identifying ‘good’ questions to be retained in a reduced questionnaire is demonstrated. Examples are shown from several clinical trials in different therapeutic areas that yield significant reductions in the number of questions. The merit method is a simple and objective way to check the ‘goodness’ of a question. Using the Merit Reduced Questionnaire lightens the burden on the patient and improves the quality of the data without sacrificing any of the performance characteristics of the original questionnaire.

152. WHAT ‘HOW MUCH OF THE TIME’ MEANS TO PATIENTS IN DIFFERENT CULTURES

David U. Himmelberger and Louise M. Errison
Health Outcomes Group

A question often included in many quality of life (QoL) questionnaires is, ‘How much of the time?’: Although the construction of this question looks familiar and is easy for most English speakers to understand, it is artificial and awkward for many people who do not speak English. In the setting of multinational studies, great care is taken to translate questions from the source language (usually English) into the target language. The functional equivalence of understanding of translated versions of the same question is essential for pooling data for a unified statistical analysis. Although some difficulties in achieving functional equivalence are identified by the forward and backward translation process, other gaps are only identified by linguistic validation of the translation with patients. Our paper highlights the difficulties in translating the simple ‘How much of the time?’ question into many languages. The results of translation and linguistic validation of questionnaires from four different therapeutic areas into more than 40 languages are presented. Examples from linguistic validations with English-speaking patients are also presented that emphasize how patients with different diseases understand the question in dramatically different ways. When working in a cross-cultural setting where the data will be pooled for analysis, the question ‘How much of the time?’ must be reformulated in a manner that is closer to the way patients think and speak about their problem in their native language.

153. IMPACT OF PERMANENT HEARING-IMPAIRMENT ON CHILDREN

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Approximately 1,000 children are born with a permanent hearing impairment each year in the UK. We are interested in establishing the nature and extent of the impact that such hearing impairment has on children and their families. However, there are no tailor-made measures for this purpose, so we are developing a minimum set of outcome measures for routine use as indicators of service quality and effectiveness of interventions. We are particularly interested in developing measures for assessing quality of life (QoL) from the child, parent and family perspectives. Pilot interviews with parents of hearing-impaired children were conducted to identify the main issues and develop a postal questionnaire (impact questionnaire) to provide broadly based data on QoL, family history of hearing-impairment, other disability, communication, behaviour and service issues. We had previously conducted an ascertainment of all children with a permanent hearing impairment of ≥40 dB HL born between 1985 and 1993 and resident in Trent Regional Health District UK (n = 654). For stage 1 of the present study, the impact questionnaire was sent to the families of the ascertained child via their key contact in either the health or education services. There was a 63% response rate which yielded distributions comparable to the ascertainment across the main variables: chronological age, age at diagnosis, severity of hearing impairment, other disability and socioeconomic group. Over the next year, we will be conducting the second, validating stage which will involve parental interviews and psychometric test sessions with approximately 100 children. We will report on how we devised our postal questionnaire and the factors that affect the responses that were made.

154. MORBIDITY AND QUALITY OF LIFE AFTER RETROPERITONEAL LYMPHADENECTOMY FOR TESTICULAR TUMOUR – THE PATIENT’S VIEW

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The short- and long-term morbidity of open retroperitoneal lymphadenectomy (ORLA) is of major concern as is the argument to perform a ‘wait-and-see’ strategy for clinical stage 1 tumours. To avoid the addition of the morbidity of ORLA and polychemotherapy in stage II tumours, one is tempted to give a monotherapy instead, even if the efficacy of the combination is superior. This study was undertaken to investigate and compare the morbidity of laparoscopic retroperitoneal lymphadenectomy (LRLA) and ORLA and to elucidate its influence on quality of life (QoL).
A questionnaire including 39 questions on contentment with the treatment, influence of the treatment on QoL, social position, career and partnership, post-operative sexual function and morbidity was prepared by the urologists involved in the treatment of the patients and a psychiatrist. A personal interview was performed by the psychiatrist with 82 patients; ten patients answered the questionnaire by mail (January 1988 to June 1996). ORLA, 15 patients, stage I, chemotherapy plus ORLA, 32 patients stage II; August 1992: LRLA, 17 patients, stage I chemotherapy plus LRLA, 28 patients, stage II. Ninety-nine percent of the contacted patients could be evaluated.

Because of the complexity of the results only a short selection can be given here. The following questions were answered in favour of LRLA. When have you become free of complaints? How content are you with your treatment? Which treatment would you recommend to a friend? Have you been afraid about your employment? To which extent was your partner impaired as well? Only sexual activities were equally impaired by both methods.

ORLA disturbs QoL much more than LRLA and even the combination of chemotherapy and LRLA is tolerated clearly better than ORLA alone. There was no single parameter where ORLA was superior to LRLA. LRLA is preferred to all other treatment modalities and 25% would rather undergo another LRLA than another inguinal incision.

155. SOCIAL FUNCTIONING AFTER FIRST EPISODE OF PSYCHOSIS: THE IMPACT OF AN ADEQUATE DIAGNOSIS
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We studied the course of illness after the first episode of psychosis with special interest in the level of social functioning. Endogenous psychoses are not homogeneous. Therefore we tried to evaluate the impact of different diagnoses causing the psychotic syndrome in which all patients had Schneiderian first-rank symptoms.

We compared two patient groups; one with schizophrenia (n = 33, 13 females, 20 males, mean age 26.9 years) and the other group with severe psychotic mania (n = 25, 18 females, 7 males, mean age 30 years). Diagnoses were made according to ICD-10. Differentiated sociodemographic data were assessed; furthermore the PANSS, GAF, DAS, Strauss-Carpenter and Vaillant Scale were used. At first episode both patient groups were similar in seriousness of psychosis, pre-morbid social class, education or a broken-home origin. After 2 years (mean) significant differences in social class, housing, employment, PANSS, GAF and DAS were found. All data showed marked impairment in schizophrenic patients.

The results highlight the importance of an exact diagnosis of acute psychotic disorders. As a result of misdiagnosing severe psychotic mania as schizophrenia, data on social functioning and quality of life (QoL) in schizophrenia might be incorrectly influenced towards a better outcome. From a clinical point of view, the social impairment in schizophrenic patients – even 2 years after the first episode – stresses the requirement for early and sufficient treatment.

156. SUBJECTIVE HEALTH STATUS AND MAGNETIC RESONANCE IMAGING FINDINGS IN PATIENTS WITH LOW BACK PAIN
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This paper is a prospective study of the quality of life (QoL) and magnetic resonance imaging (MRI) findings in symptomatic patients. We aim to assess the relationship between the extent of disc abnormality, neural impingement and QoL.

It is known that disc herniation and nerve root compression contribute to low back pain (LBP) and poor QoL. However, significant proportions of asymptomatic subjects have been reported to have disc herniation and neural compromise. Little is known about the influence of disc abnormalities and neural compression on QoL in symptomatic patients.

Three hundred and twelve consecutive patients with LBP referred to three MRI units were studied. Before imaging, patients were asked to complete a SF-36 QoL questionnaire; a follow-up questionnaire was sent at 6 months. Each patient was placed into one of four overall categories according to the most extensive disc abnormality reported at MRI. The presence or absence of neural impingement was also noted. The relationship between disc abnormality, neural impingement and QoL was assessed. Two hundred and fifty of the 312 (80%) patients completed the initial QoL questionnaire and 194 of the 312 (62%) completed the 6 month questionnaire. One hundred and thirteen of the 312 (36%) patients had one or more herniated discs and 140 of the 312 (45%) had evidence of neural impingement. There was little relationship between radiological findings and QoL. Patients with neural impingement reported better general health perceptions (p < 0.01). QoL scores had improved at 6 months in four dimensions of the SF-36, but perceptions of general health had deteriorated (p < 0.05). Patients who had radiological evidence of neural impingement had significantly improved bodily pain scores at 6 months (p < 0.05).

The pain and dysfunction caused by disc herniation and subsequent neural compromise is not sufficiently distinct from other causes of back pain to be distinguished by the SF-36. Whilst neural compromise may be the best radiological feature distinguishing asymptomatic and symptomatic populations, it cannot predict QoL deficits in symptomatic patients attending MRI.

157. THE DEVELOPMENT OF QUALITY OF LIFE IN PATIENTS WITH DEPRESSION OVER 7 MONTHS AFTER DISCHARGE FROM HOSPITAL
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A 7 month follow-up study with three points of measurement at 1, 4 and 7 months after discharge from a psychiatric in-patient treatment was conducted for 100 patients with depression after ICD-10 including F31 – F34. The aim of the study was the analysis of the relationships between the development of psychiatric symptoms, general adaptation and subjective quality of life (QoL).
during post-in-patient treatment. Depression was measured with the SCAN-PSE 10, general adaptation was assessed with the GAS and for the measurement of subjective QoL the WHOQOL-100 was used. For the analysis of the relationships between the development of depressive symptoms and subjective QoL, patients were distributed to three groups depending on whether their diagnostic status had improved, deteriorated or remained unchanged over time. The results of the analysis show that among those patients whose diagnostic status had remained unchanged over time, QoL remained unchanged too. Among those patients whose diagnostic status improved over time, a significant improvement of QoL was found only for the psychological domain of the WHOQOL-100. In contrast, among those patients whose diagnostic status deteriorated over time, QoL decreased significantly in the physical health domain, the psychological domain, the independence domain and the spiritual domain of the WHOQOL-100. From these results it can be concluded that, for depressive patients, a deterioration of symptoms results in an overall QoL decrease whereas a reduction of symptoms has a positive effect only on psychological well-being.

158. QUALITY OF LIFE MEASURED BY EORTC QLQ-C30/BR23 IN PATIENTS WITH BREAST CANCER

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In 1990 at the university clinics in Innsbruck a special programme for the psycho-oncological treatment of cancer patients was established. A large proportion of these patients have a diagnosis of breast cancer. The aim of the study presented was to obtain indications for the improvement of the psycho-oncological treatment for this group of patients by the use of quality of life (QoL) data.

For the measurement of QoL the EORTC QLQ-C30/BR23 was applied as an internationally accepted and well-validated instrument.

The survey included 99 patients with either local, locoregional or metastatic breast cancer with a mean age of 53.4 ± 8.3 years. All patients received individual cancer therapy (mastectomy or breast conservation with or without chemotherapy, radiotherapy or hormonal therapy) – the mean period since the beginning of treatment was 5.3 ± 4.9 years.

The sample was split into two groups. The first group consisted of curatively treated patients with either local or locoregional breast cancer, while a second group was formed by patients with metastatic breast cancer.

The EORTC functioning subscales showed substantially lower scores for the patients with metastatic breast cancer in the following dimensions: physical, social and role-functioning. Significant differences were also found in the symptom subscales: pain, dyspnoea and financial impact.

The considerable implications for the psycho-oncological treatment for these groups of patients are discussed.

159. QUALITY OF LIFE IN ELDERLY SUBJECTS WITH PAIN IN THE HIP OR KNEE

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Our study examines the quality of life (QoL) of community living elderly people aged 55 – 74 years with chronic, episodic or sporadic pain in the hip or knee and of a reference group without pain (total n = 306). Firstly, it was hypothesized that the QoL experienced is lower in people with more chronic pain. Secondly, the potential mediating and moderating roles of disability and of coping with problems in general on the relationship between pain chronicity and QoL were assessed.

A visual analogue scale was used to assess global QoL. Physical as well as psychosocial disability was assessed with the Sickness Impact Profile (SIP). Coping with problems in general was assessed with the Utrecht Coping List.

As expected, a significantly lower QoL was found in people with more chronic pain (p < 0.045). The difference in QoL between the group with chronic pain and a reference group without pain was 10%. A multivariate regression model showed that physical and, in particular, psychosocial disability are mediators in the relationship between pain chronicity and QoL and that ‘seeking social support’ as a coping style is a more important predictor of the experienced QoL than either pain chronicity or physical disability. No moderating role of the style of coping with problems was found.

160. EVALUATION OF THE QUALITY OF LIFE IN PATIENTS WITH PNEUMOCONIOSIS

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This study was undertaken to assess the quality of life (QoL) of pneumoconiosis patients. A questionnaire (including physical function, mental function, social function and disease symptoms, 46 items) was used. A ‘theoretical standard’ is set on the basis of the studies of 260 pneumoconiosis patients (in a suburb of Beijing, mean age 64 years). The results indicate that the QoL of the pneumoconiosis patients is only 60% that of normal people. Health care and social services among pneumoconiosis patients should focus on following patients who are suffering from complications and suffocation, with a low income or badly in need of social care. Meanwhile, the results suggest that research into the QoL of pneumoconiosis patients should emphasize research into their mental status.
161. QUALITY OF LIFE OF MILD HYPERTENSION TREATED WITH CAPTOPRIL—A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED CLINICAL TRIAL
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The objective of the study was to determine the quality of life (QoL) of mild hypertensive patients treated with captopril as compared to placebo.

A randomized, double-blind, placebo-controlled clinical trial was used.

An out-patient clinic of Zhong Shan Hospital, a tertiary hospital in Shanghai, was the setting.

The participants were adult patients aged from 18 to 79 years old with mild hypertension defined as diastolic blood pressure from 90 to 105 mmHg, inclusively. There were 278 patients who were eligible to enter the study and only 13 were lost at follow-up.

Patients were randomized to receive captopril or placebo 25 – 50 mg twice daily for 12 weeks.

The change of QoL was compared both quantitatively and qualitatively between the captopril and placebo groups. Changes of blood pressure and side-effects were also compared.

With intention-to-treat analysis, significantly more improved QoL patients could be found in the captopril treatment (47.0 versus 24.6%, p = 0.0001 for the physical health domain, 50.0 versus 27.7%, p = 0.0005 for the mental health domain and 54.6 versus 10.9%, p = 0.0000 for the general function domain). Quantitatively, the changes of score for mental health domain and 34.6 versus 10.9%,

Further, the change of score of the physical health domain (2.90 ± 5.23 versus 1.82 ± 4.77, p = 0.000) was not significantly higher than those of the placebo group, (1.35 ± 5.12, p = 0.007, 0.25 ± 3.52, p = 0.004 and 3.42 ± 10.33, p = 0.001, respectively). However, the change of score of the physical health domain (2.90 ± 5.23 versus 1.82 ± 4.77, p = 0.079) was not significantly different. Blood pressure was lowered significantly in the captopril group than the placebo group, (p = 0.000).

Compared to placebo, captopril is not only effective in lowering blood pressure, as has been established, but is also effective in improving QoL in mild hypertensives. The quantitative change of physical health was not significant in this 3 month treatment study and it may need a longer follow-up to make it definite.

162. STATISTICAL EQUATING OF CROSS-CULTURAL INSTRUMENT
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Translating a health-related quality of life (QoL) instrument into another language for cross-cultural research necessitates the use of rigorous qualitative and quantitative methodologies to ensure the validity of translation. An instrument must show similar factor structures in different languages to be meaningful and valid in cross-cultural comparisons. If the structure of an instrument substantially changes when it is translated, it could mean one of two things. Either the instrument does not measure the same constructs in different cultural venues or the items are truly being interpreted differently despite similar constructions.

Such threats to research validity in cross-cultural comparisons have not to date been satisfactorily emphasized. In this presentation, confirmatory factor analysis and item response theory-based approaches to evaluate the psychometric properties and statistical equivalence of different language versions of a health-related QoL instrument will be presented. The use of each of the two psychometric approaches provides an opportunity for the future instrument development, refinement and modification for cross-cultural research.

163. THE IMPACT OF COMPLIANCE, PSYCHOLOGICAL VARIABLES, DYSPNOEA AND SPirometry ON THE Time Course Of health-related quality Of life IN PatIENTs WITH CHRONIC obstructive Pulmonary disease
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The purpose of this study was to investigate the effects of two different aspects of compliance with liquid oxygen therapy (LOX) on quality of life (QoL) and to explore possible pneumological and psychosocial concomitants.

The study sample consisted of 57 O2-dependent patients with chronic obstructive pulmonary disease (COPD) under LOX therapy. Compliance was defined as continuous use as prescribed and as the readiness of the patients to also use LOX outdoors. The study design encompassed one initial assessment and a follow-up examination 14 months later. QoL was assessed by the German version of the Sickness Impact Profile.

Seven (12%) patients used LOX less than the daily prescribed hours and 13 (23%) refused to use LOX away from home. Those patients who used LOX less than prescribed had a significantly lower life satisfaction than the compliants (p = 0.02). A discriminance analysis included several psychosocial variables discriminating between both groups, allowing the correct identification of 83% of the patients who used LOX as prescribed and of 83% of the non-compliants (eigenvalue = 0.71 and p = 0.01). At follow-up, the data of 25 patients were available. Of these, five refused the outdoor LOX use. Their life quality was significantly worse in almost all areas examined, (p < 0.05, respectively), except for home management and free-time activities as compared to the LOX outdoor users.

We conclude from our results that compliance is an essential prerequisite for the beneficial effects of LOX on QoL. Because psychological factors influence the adherence to the LOX regimen, the patients should receive individual psychological counselling and training before their transfer to LOX.

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Quality of life (QoL) is an important criterion for assessing disease impact and treatment outcome. On the other hand, adequate methods for the measurement of health-related QoL in brain-damaged patients are missing as of yet. Therefore, we developed the Aachen Life Quality Inventory (ALQI).

The ALQI is based on the German version of the Sickness Impact Profile which was modified for use in patients with brain damage. The ALQI consists of 11 subscales containing 117 items covering different areas of QoL, from family relations to cognitive capacity. Additionally, a parallel-version for the life companions was developed. The ALQI was psychometrically verified using the data of 231 patients with subarachnoid haemorrhage, head injury and brain tumours.

The internal consistency (Cronbach’s $\alpha$) for the subscales ranged from 0.68 to 0.91 for the subscales, while it was 0.97 for the whole instrument. Examination of the validity revealed substantial associations between the ALQI self- and proxy rating version and a wide range of related neuropsychological, psychosocial, neurological and neurosurgical variables. The sensitivity of the ALQI for the effects of neurosurgical treatment could be demonstrated. The first results underline the prognostic validity of the ALQI impairment scores for patients with malignant brain tumours. The self- and proxy rating version of the ALQI correlated with $r = 0.81$ ($p < 0.001$).

Therefore, the ALQI appears to be a valid, reliable and sensitive method for assessing QoL in patients with brain damage. Further psychometric analyses including tests for retest reliability are needed for the future.

### 165. Health-Related Quality of Life in Patients with Malignant Gliomas: Differences to Patients with Low-Grade Gliomas and the Impact of Quality of Life on the Prognosis of Survival Time

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In neuro-oncology, the Karnofsky scale is widely used for the assessment of quality of life (QoL). However, the Karnofsky rating is strictly limited to the physical functional capacity only. The Aachen Life Quality Inventory (ALQI) is a more comprehensive measure of QoL. Therefore, we analysed the prognostic capacity of the ALQI and explored differences in the health-related QoL of patients with low-grade and high-grade gliomas.

A consecutive series of 52 patients with malignant gliomas (WHO grades III – IV) and of 23 patients with low-grade gliomas (WHO grades I – II) could be included. On the date of the census (January 1997), only 30% of the patients with malignant gliomas were alive, the others had died of their illness. The patients with malignant gliomas showed not only significantly ($p < 0.01$) more impairments in their QoL but exhibited a qualitatively different profile of impairment as compared to the patients with low-grade gliomas. QoL (Karnofsky and ALQI) was significantly worse in the glioblastoma group as compared to the patients with gliomas of WHO grades III or IV ($p < 0.05$, respectively). The correlation of the ALQI with the duration of survival was $r = 0.58$ while it was $r = 0.45$ with the Karnofsky rating. Further variables of prognostic importance beyond history were age ($r = -0.33$) and the number of neurological deficits before surgery ($r = -0.41$).

The present findings suggest qualitative and quantitative differences in the QoL of patients with low-grade or highly malignant gliomas. Furthermore, the ALQI proved to be prognostically valid and highly sensitive in patients with malignant brain tumours. Beyond histology, the initial QoL appears to be the most important predictor of the duration of survival in patients with malignant gliomas.

### 166. Quality of Life Outcome for People with Schizophrenia Before and After the Introduction of Medicaid Capitation

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The purpose of this study was to investigate the effect of Medicaid capitation on the quality of life (QoL) satisfaction and service utilization of adults with schizophrenia and schizoaffective disorder.

One hundred patients were randomly selected 1 year before and another similar sample a year after the introduction of capitation. QoL was assessed using the Lancashire Quality of Life Profile (LQOLP), needs using the Camberwell Assessment of Need (CAN) and psychopathology assessed using the Brief Psychiatric Rating Scale (BPRS).

Psychopathology was lower after capitation, and the number of subjects admitted to hospital during a 6 month period after capitation was 57% lower than the equivalent period before capitation. The subjects reported greater QoL in the domains of work, finance and social relations. There were no significant changes in needs or satisfaction.

The conclusion of this study was that there was no evidence to suggest that Medicaid capitation had a significant adverse effect on the patient population after 1 year and there was evidence to suggest that capitation led to a more efficient use of treatment resources.

### 167. Which Global Quality of Life Scale Is Most Reliable and Most Preferred?

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Global quality of life (QoL) scales provide one kind of subjective judgement which patients can make about their health. We examined the reliability and preference of 12 scales: four category scales with end labels, four visual analogue scales and four specially designed H scales based on the principles originally developed by Borg for symptom assessment. Eighty undergraduates and 15 residents of a residential home for the elderly completed self-assessment using all 12 scales as well as completing preference ratings. As a measure of reliability, we examined the intercorrelations in a self-rating between the different types of scale. The H scales were most reliable and the
168. ACTIVITY CHECK-LISTS AS A COMPLEMENTARY METHOD OF QUALITY OF LIFE ASSESSMENT: IS THE POT HALF EMPTY OR HALF FULL?
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The purpose of this study is to determine whether ratings of what people say they cannot do is the inverse of check-lists where people indicate what they can do. This paper compares the correlates of a positive activity check-list, where people indicate activities they have carried out, with the correlates of disease-specific and global quality of life (QoL) scales. In an undergraduate sample (n = 95) the global QoL correlated with neuroticism (r = –0.42) and extraversion (r = 0.21) but a positive activity check-list did not (r = –0.10 and 0.01 respectively). The positive activity check-list correlated only with openness to experience (r = 0.33). In a sample of respiratory patients (n = 52), the activity check-list correlated with the FEV1 (r = 0.40) and FVC (r = 0.47), whereas the Chronic Respiratory Disease Questionnaire had correlations of 0.07 and 0.05, respectively. In a sample of patients with cancer of the oesophagus (n = 98), the activity check-list correlated with positive (r = 0.49) but not negative emotionally (r = 0.09) whereas global QoL correlated both with positive (r = 0.48) and negative (r = –0.37) emotionality. In a separate experimental study of pulmonary rehabilitation (n = 52), the global QoL scale and the Breathing Problems Questionnaire were both sensitive to change (p < 0.01). The positive activity check-list was not sensitive to change (p = 0.1). The positive activity check-list provides a useful complementary method of measuring QoL to quality of life (QoL) measurements.

169. QUALITY OF LIFE IN PATIENTS WITH END-STAGE KIDNEY DISEASE IN RELATION TO HAEMODIALYSIS TREATMENT
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The purpose of this study was to evaluate the quality of life (QoL) of patients with end-stage kidney disease on chronic dialysis and to research the influence of various factors related to the duration of treatment. Ninety patients participated, 52 males and 38 females with a mean age of 50.9 ± 13.4 years. The patients were separated into three groups according to the duration of haemodialysis treatment. The first group (honeymoon dialysis phase – 28 patients) had a duration of haemodialysis of less than 6 months, the second group (phase of disappointment – 32 patients) had a duration of haemodialysis of up to 2 years and the third group (adaptation phase – 30 patients) had a duration of haemodialysis of over 2 years. The evaluation of QoL was originally conceptualized along the following two dimensions: (1) emotional well-being and (2) social well-being. Within each dimension, several specific subdimensions were measured with multiple-choice questions and with scales and scores constructed from multiple-choice questions. Co-morbidity was evaluated according to the Friedman Comorbidity Index. A significant difference favouring patients in the adaptation phase was found for emotional well-being. In terms of family adjustment, assessed by the family summary variable, the patients in the adaptation stage once again scored higher. Advanced age and co-morbidity both adversely affected QoL in all haemodialysis phases. The authors indicate that long-term adequate haemodialysis stimulates the development of positive psychological defence mechanisms and a better sense of well-being.

170. QUALITY OF LIFE AS AN OUTCOME OF CARDIOSURGICAL PROCEDURES
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Since 1992, our clinic has been representing its results according to a risk stratification system (Parsonnet’s model) and according to quality of life (QoL) measurements. The clinic developed its own model for measuring QoL as an outcome of cardiosurgical procedures. The questionnaire includes five groups of questions: status of employment, physical status, mental status, social interaction and self-perception of health. Three hundred patients were interviewed before the operation and 6 and 12 months after the operation. The results showed that open heart surgery was beneficial for the patients: their physical status was improved (p = 0.001), as was their mental status (p < 0.001) and self-perception of health (p < 0.001). Social interaction was improved but not significantly, while employment remained at the same level. QoL was also analysed according to the level of operative risk and according to the type of operation. QoL improved more in groups of higher risk patients. The assessment of QoL as an outcome of cardiovascular procedures is a very valuable method that could contribute to the improvement of cardiosurgical work but could also be used for the prediction of QoL of patients according to their health status before the operation.

171. QUALITY OF LIFE AND PSYCHOLOGICAL OUTCOME OF ADVANCED HEAD AND NECK TUMOUR PATIENTS
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Recent findings suggest that patients with head and neck cancer have to cope with a high level of disease- and treatment-related symptoms. To implement a psychosocial intervention programme, the special psychological needs of advanced stage head and neck cancer patients were evaluated.
Patients answered standardized questionnaires to measure quality of life (QoL) (Short-Form-36 Health Survey, SF-36), coping (stress reaction questionnaire, SVF and Freiburg Questionnaire of Coping with Illness, FKV) and health-related control (KKG). All interviews were performed by an experienced psychologist. All patients received radiation therapy 6 months to 4 years ago within a prospective randomized trial (Vienna-CHART) either conventional fractionated (2 Gy, 5 days a week over 7 weeks up to 70 Gy) or accelerated (55.3 Gy given in 33 fractions within 17 consecutive days) with or without mitomycin C.

The analysis is based on the data of 25 patients who received primary radiation therapy for pT3 - 4 head and neck cancer. The mean age was 55 years (range 41 - 84 years). Psychosocial reactions were similar among the different therapy arms. The patients described their health (SF-36) to be generally bad (mean 23.9 and SD 10.2), but pain was not a major problem for almost all patients (mean 79.9). The preferred coping strategy (FKV) was ‘active problem-focused’ coping (mean 2.7 and SD 1.0) followed by ‘distraction and self-valourization’ (mean 2.66 and SD 0.87). ‘Positive self-instruction’ (SVF) was the most used stress coping strategy (mean 19.2 and SD 4.8). Eighty-three percent of the patients interviewed reported to suffer from severe social isolation. The subscales ‘internal control’ (KKGI; mean 28.7 and SD 10.2), ‘active problem-focused’ coping (mean 2.7 and SD 1.0) followed by ‘distraction and self-valourization’ (mean 2.66 and SD 0.87). ‘Positive self-instruction’ (SVF) was the most used stress coping strategy (mean 19.2 and SD 4.8). Eighty-three percent of the patients interviewed reported to suffer from severe social isolation. The subscales ‘internal control’ (KKGI; mean 28.7 and SD 6.8) and ‘external fatalistic control’ (KKG; mean 28.2 and SD 7.7) showed a high score compared to patients with polyarthritis (KKG; mean 23.0) or other chronic illness from the norm scale.

In our pilot project we therefore demonstrate that advanced stage head and neck cancer patients strongly believe their health to be determined by fate and luck, whereas only 2% of healthy controls do in the same way.

In summary, our results stress the need of an intervention programme which should be based on enhancing health-related control beliefs and social support.

172. GENDER IDENTITY DISORDER QUALITY OF LIFE QUESTIONNAIRE
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The objective of this study was to assess health-related impairment in quality of life (QoL) in adult patients with gender identity disorder (GID) and to develop a questionnaire for measuring QoL. Although the GID population is comparatively small (1 in 30,000) in comparison with those with other medical conditions, patients have complex issues that are generally not encountered in the general population. These include societal attitudes and the ramifications of the complex long-term psychological adjustments and medical treatment processes involved in gender change. A continual record from a QoL questionnaire would provide a means of predicting psychological, medical and surgical outcomes.

The Gender Identity Disorder Quality of Life (GIDQL) questionnaire was developed using the process described by Guyatt and others for disease-specific QoL questionnaires. Items were generated from the extensive clinical experience of the investigators, literature review and prior research with GID patients. The 127 items were reduced and categorized into domains based on interviews with 46 patients who were asked to rate each initial item for frequency and importance. Content experts analysed the responses, discarded low ranking items and reworked others. The selected items were further refined by detailed analysis done through interview with 15 target patients. Thirty items in question form were developed so that all domains were represented.

The GIDQL thus developed examines areas of impairment in sexuality, spirituality, social environment, physical health, emotional health and economic status. The questionnaire focuses on gender-specific issues such as ‘passing’ and societal acceptance as well as physical and emotional changes associated with gender transition. The validity of the questionnaire and its responsiveness to changes within individuals will be addressed as results from continuing use of the GIDQL are obtained.

173. QUALITY OF LIFE OF SCHIZOPHRENIC PATIENTS IN THREE DIFFERENT FORMS OF CARE
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Health-related quality of life (QoL) is a very important way to evaluate patients’ situations. It is influenced by many factors, among them the nature of the disease, hospital environment, therapeutic programme, family support, etc. Modern trends in psychiatric care put the emphasis on alternatives to hospitalization forms of care: day hospitals and community psychiatry. The aim of our study was to evaluate health-related QoL in patients suffering from schizophrenia, who are under various forms of psychiatric care. The severity of schizophrenia and QoL were evaluated in 90 schizophrenics (DSM-IV) from the hospital psychiatric ward (PW), from the day hospital (DH) and from the community psychiatry centre (CPC). The severity of schizophrenic symptoms was evaluated with the use of the PANSS scale. The Polish SF-36 questionnaire was used for evaluation of subjective QoL. The study revealed that schizophrenic symptoms were more severe in hospitalized patients than in subjects from the CPC or DH. Surprisingly, the global evaluation of patients’ QoL did not differ among three groups studied. The only exception was the reported health transition: hospitalized patients found the worsening of their health status in comparison to 1 year ago to be more profound than patients from the DH or CPC. Patients’ QoL did not correlate with the severity of the schizophrenic symptoms. Male patients judged their QoL better than female patients. This trend was also found for the following SF-36 subscales: physical functioning and role-emotional. Male subjects were younger and had lower educational levels than female subjects. Global QoL correlated negatively with subjects’ age, number of previous hospitalizations and with the duration of illness.

174. THE RELIABILITY AND VALIDITY OF THE QUALITY OF LIFE – RADIATION THERAPY INSTRUMENT (QOL-RTI)
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A review of the literature revealed no general quality of life (QoL) tool developed with radiotherapy patients. A 24-item, visual analogue, QoL questionnaire was developed and validated for patients receiving definitive radiation therapy. The questionnaire was then modified by adding one additional global QoL question (for a total of 25 items), rewording three questions and conversion to a Likert style.
The Quality of Life – Radiation Therapy Instrument (QOL-RTI) assesses four domains of health-related QoL including functional, emotional, family-socioeconomic and general QoL. The content and face validity was established by a multidisciplinary committee of oncology professionals. Each question was reviewed for clarity and relevance. The instrument was initially tested in the visual analogue form using 21 patients receiving primary radiotherapy for prostate cancer. Twenty-seven patients being treated for head and neck cancer were given the Likert version of the QOL-RTI. The initial pilot ($n = 21$) revealed an internal consistency of 0.87 (Cronbach’s $\alpha$) and further testing of the QOL-RTI ($n = 70$) yielded the internal consistency reliability as satisfactory (Cronbach’s $\alpha = 0.82$). Correlation analysis of the pilot yielded a correlation coefficient of 0.79 ($p < 0.0001$) and the test–retest reliability correlation coefficient of the prostate patients was 0.75 ($p < 0.0001$). To establish validity, correlation of the QOL-RTI with Ferrans and Powers QLIC Cancer Version 6 at baseline was 0.47. To establish validity of the general tool in its Likert version ($n = 27$), the QOL-RTI was compared to the FACT and the correlation was 0.87 ($p < 0.001$). The test–retest resulted in a reliability correlation coefficient of 0.90 ($p < 0.001$) and, supporting earlier findings, the internal consistency was satisfactory (Cronbach’s $\alpha = 0.83$).

Patient reported QoL and function is a necessary component of outcome evaluation in many clinical trials. The QOL-RTI is a reliable and valid tool for measuring QoL. Multi-institutional and cross-cultural testing is now in process. Used with site- and symptom-specific modules, the data derived from this QoL instrument may be used clinically to minimize discomfort, complications or other problems which impair a patient’s QoL.

175. QUALITY OF LIFE IN CHRONIC IDIOPATHIC CONSTIPATION

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Chronic idiopathic constipation (CIC) is characterized by symptoms of difficult, infrequent or seemingly incomplete defecation, which cannot be explained by definable dietary, systemic or local structural causes. Although the relationship between physical, emotional and psychological functioning and bowel habits is poorly documented, our initial patient research suggests that the symptomatology of the disease is likely to have a major impact on patients’ quality of life (QoL).

The impact of CIC and its treatment on social, psychological and physical function and well-being and the level of impairment was examined by interviewing patients from France, Sweden, the US and the UK, to ensure cross-cultural applicability. Verbatim patient comments were used both to identify condition-specific domains and as a potential source of ad hoc items not covered by published measurement instruments. Most patients with CIC reported a low level of morale, well-being and happiness. They were bothered by abdominal pain and bloating and had a poor health perception, possibly related to a perceived impairment in a normal physiological function or a psychological misperception of a normal frequency of defecation.

This research served as the basis for the development of a condition-specific QoL questionnaire, the CICQOL. The CICQOL is a 35-item self-administered questionnaire comprising 11 QoL domains: worries/concerns, satisfaction with treatment, symptoms, diet/appetite, interference with daily activities, coping/adaptation, sexual activity, psychological function, body image, sleep and social interaction. The final item development and psychometric properties of the CICQOL have been assessed in a multinational linguistic and psychometric validation study. A comparison of the different language versions of the instrument will provide information on cross-cultural variation in this patient population.

176. MALICIOUS SPIRITS: NEGLECTED CAUSES OF SICKNESS IN CROSS-CULTURAL HEALTH-RELATED QUALITY OF LIFE

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To date, instruments designed to measure lay perceptions of health-related quality of life (QoL) have tended to focus upon the existence of signs or symptoms of disease or ill-health and the impact of these on the lives of the sufferers. Instruments are being prepared for cross-cultural adaptation, implicitly suggesting that perceptions of health are universal. The purpose of this paper is to introduce a vital but so far neglected contributor to both individual and community assessment of health-related QoL which has arisen from our work in Kenya: that of affliction causality.

Our field work started in December 1994. Amongst our main aims we set out to describe lay perceptions of health-related QoL in two rural Kenyan communities and to reflect upon the appropriateness of existing health-related QoL measures in cross-cultural applicability. We have used a number of different methods including a variety of interview techniques and long-term participant observation which have enabled us to access locally sensitive issues. The material which will be presented drawings specifically upon beliefs in Eastern Kenya around pernicious spiritual forces and the variety of ways in which they impinge on community life.

The results show that the concern placed on this type of affliction causality reflects associated implications about interpersonal relationships and the potential to secure therapy. They further indicate that people without apparent symptoms of affliction may still not feel healthy if they perceive themselves to be threatened by the malevolent spirit world. Some of these findings reflect very different notions of health from those in which existing health-related QoL generic measures have been developed.

We conclude that local perceptions of affliction causality in Kenya play a vital role in the overall assessment of health. Since there is no explicit recognition of causality in existing generic health-related QoL measures, they are unable to capture lay perceptions of health in either of the rural Kenyan study communities and possibly in other non-industrialized settings.
177. PSYCHOSOCIAL PROBLEMS IN PATIENTS WITH EPILEPSY
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High rates of psychosocial problems among individuals with seizure disorders are observed. These problems oppress epileptics in addition to their neurological disease and reduce the quality of life (QoL). Therefore it is very important to have a short objective questionnaire to identify the individual problems beyond the individual care of the physicians.

In the Epilepsy Monitoring Unit of the University Clinic of Neurology, Vienna we used the German version of the 132-item WPSI (Washington Psychosocial Seizure Inventory) which covers family background, emotional adjustment, interpersonal adjustment, vocational adjustment, financial status, adjustment by seizures, medical management and, finally, overall psychosocial functioning.

There are four regions of profile elevation: (1) no significant problems, (2) possible problems, (3) distinct difficulties with definite adjustmental significance and (4) severe problems.

Thus it is possible to obtain an individual profile of each epileptic and we compare the whole profile of our investigation with published studies from other countries.

The results of our work will be represented and the usefulness of the questionnaire will be discussed.

Acknowledgement: This research was supported by FWF (project P10302 med and P11952 med) and the Jubiläumsfond der Österr. Nationalbank (project 6067).

178. QUALITY OF LIFE ASSESSMENTS AFTER ANTIREFLUX SURGERY – NISSEN FUNDOPICATION
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It has been required that quality of life (QoL) data should be included in evaluations of medical and surgical outcomes. We present our QoL data for more than 50 patients undergoing laparoscopic Nissen fundoplication at our department during the last 14 months. Therefore we used the Gastrointestinal Quality of Life Index (GLQI, German version). The GLQI collects a general QoL index but also classifies in five different dimensions: gastrointestinal symptoms, emotional status, physical function, social function and, finally, stress of medical treatment. In our analysis we found low scores in general and for all dimensions pre-operatively in spite of optimal medical treatment. All of the analysis we found low scores in general and for all dimensions social function and, finally, stress of medical treatment. In our QoL index but also classifies in five different dimensions: Life Index (GLQI, German version). The GLQI collects a general QoL index but also classifies in five different dimensions:

Patients with morbid obesity suffer from reduced quality of life (QoL) and a lot of attendant symptoms. The aim of surgical treatment, including psychological support, of morbid obesity is to decrease the partly dangerous attendant symptoms and to increase the QoL. During the least few years 42 patients with BMI of >35 were operated on at our surgical unit. The patients had a long history of reducing their obesity differently, but without any long-term success. Therefore, in all cases the open technique of vertical banded gastroplasty was performed. Two well-established questionnaires, the German SF-36 and the Gastrointestinal Quality of Life Index (GLQI, German version) were used to raise the QoL data pre- and post-operatively. We found reduced scores in all dimensions of the SF-36 and GLQI pre-operatively. The mean scores of all dimensions became significantly better (p < 0.05 – 0.01) 1 year or more after surgical treatment. None of the dimensions was decreased during this period. The BMI also reduced to approximately a minimum of 25% of the starting point. Three patients had a second operation because of a less strong loss of weight. In spite of these operations all patients increased their QoL scores. One patient had a second operation in another department and died unexpectedly of a pulmonary embolism.

After vertical banded gastroplasty all patients increased their QoL scores and lost more than 25% of their starting BMI. We suggest that surgical and combined psychological treatment of morbid obesity is, in contrast to other treatments, effective and increases QoL, which is an important facet of surgical outcome.

179. QUALITY OF LIFE FOLLOWING SURGICAL TREATMENT OF MORBID OBESITY
T. Kamolz, H. Wykypiel and R. Pointner
Department of Surgery, A.ö.KH Zell am See, Austria

Patients with morbid obesity suffer from reduced quality of life (QoL) and a lot of attendant symptoms. The aim of surgical treatment, including psychological support, of morbid obesity is to decrease the partly dangerous attendant symptoms and to increase the QoL. During the least few years 42 patients with BMI of >35 were operated on at our surgical unit. The patients had a long history of reducing their obesity differently, but without any long-term success. Therefore, in all cases the open technique of vertical banded gastroplasty was performed. Two well-established questionnaires, the German SF-36 and the Gastrointestinal Quality of Life Index (GLQI, German version) were used to raise the QoL data pre- and post-operatively. We found reduced scores in all dimensions of the SF-36 and GLQI pre-operatively. The mean scores of all dimensions became significantly better (p < 0.05 – 0.01) 1 year or more after surgical treatment. None of the dimensions was decreased during this period. The BMI also reduced to approximately a minimum of 25% of the starting point. Three patients had a second operation because of a less strong loss of weight. In spite of these operations all patients increased their QoL scores. One patient had a second operation in another department and died unexpectedly of a pulmonary embolism.

After vertical banded gastroplasty all patients increased their QoL scores and lost more than 25% of their starting BMI. We suggest that surgical and combined psychological treatment of morbid obesity is, in contrast to other treatments, effective and increases QoL, which is an important facet of surgical outcome.

180. QOL OF WORKING WOMEN WHO ARE INFORMAL CARE GIVERS
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1Science University of Tokyo, Tokyo and 2Nagasaki University, Nagasaki, Japan

The purpose of the study is to assess the quality of life (QoL) of working women who take care of family members by taking leave of absence for family care and to assess how they are psychologically and mentally affected by providing care at home in addition to working full time. The study used the WHOQOL-26 questionnaire and a questionnaire consisting of questions about the care situation. The right to leave of absence for family care was instituted in 1995 in Japan and more than 2,000 companies or 16.3% of all the companies in Japan are now reported to provide it. The conditions and regulations of leave systems vary with the company. The target participants were 19 female care givers who had taken leave of absence for family care within the last year. They were asked to participate in the study through the personnel offices of companies which had announced to the public that they provided a system of leave of absence for family care as part of the company’s welfare package. The control subjects were 45 informal care givers who stayed at home as housewives (group a), 89 healthy people consisting of 40 working women (group b) and 49 housewives (group c). They were recruited, matching three ages to that of the target subjects, from the PTA group of a private school and the employees of a
private university and attended a couple of meetings for care giving which offered classes on how to take care of the sick at home, held in a hospital.

The study found that the mean QoL score of all groups on the WHOQOL questionnaire was 3.14; group a scored 2.94, group b 3.0 and group c 3.26. Comparisons between group a and group b and group a and group c were found to be significantly different by Tuckey multiple comparison (> 0.05). The mean length of care for both groups a and b was 14.5 h a day. No significant difference was found between the QoL scores of those who gave less than 8 h and those who gave more than 8 h of care. Of the care givers 40.3% took care of their own parents, 32.3% their children, 14.5% their partner and 12.9% their parents-in-law. A comparison of care givers, who had some conflict with other family members about how to take care of the sick and those who do not revealed mean QoL scores of 2.53 and 3.07, respectively, which was a statistically significant difference. Similarly, a significant difference was found between people who had housing problems as a result of having to provide care and those who did not. In addition, with regard to the official support system, the QoL scores of the people who lived in an area which offered night care services, telephone counselling and welfare centres and those who had not investigated whether their areas had such systems were found to be significantly different. A significant difference was also found between people who presently had problems with moving, carrying and discharging sick family members and those who used to have but no longer did.

Based on these results, it was found that women who tried to keep their jobs and take care of family members at the same time had a heavy burden compared with other women. Through finding target participants, it was found that the leave of absence system in some of the companies did not assure people posts and who had not investigated whether their areas had such systems were found to be significantly different. A significant difference was also found between people who presently had problems with moving, carrying and discharging sick family members and those who used to have but no longer did.

181. SYNTHETIC HEALTH STATUS ASSESSMENTS: MODELLING AND MAPPING BETWEEN ESTABLISHED QUALITY OF LIFE INSTRUMENTS
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Quality of life (QoL) measures have been designed for different purposes. Measures based on psychometric theory typically produce profiles of health outcomes while those derived from decision theory offer an overall summary score that can be used to estimate quality adjusted life years (QALYs). Often, investigators require QALYs but have not performed the appropriate measurement. This paper reviews several attempts to estimate QALYs on the basis of measurements not initially designed for this purpose. The following is work proposed by Erickson. Data from US National Health Interview Surveys will be presented. Scores for the Quality of Well-Being Scale (QWB) are imputed from survey responses in the US National Health Interview Survey. Analysis suggests that the imputed QWB performs as expected. It shows differences by age, race and education. Further, it produces the expected differences for self-reported chronic conditions. In addition, models for estimating the QWB scores based on the Medical Outcome Study 36 Item Short Form (SF-36) will be reviewed. The paper will consider methodological difficulties including an estimation of questionnaire responses based on diagnosis and information loss associated with imputations. Erickson’s contributions to these methodologies will be reviewed.

182. MEASURING THE EFFECTS OF WEIGHT LOSS ON QUALITY OF LIFE IN THE SEVERELY OBESE
Jan Karlsson, Lars Sjöström and Marianne Sullivan
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The aim of the present study was to evaluate the effects of weight loss on health-related quality of life (QoL) in severely obese subjects and to explore the relative efficiency of measures to detect changes in health status. The first 544 surgical cases and their conventionally treated, matched controls followed for 4 years in the study of Swedish obese subjects (SOS) were examined. A battery of generic and study-specific, self-report questionnaires on general health, mental well-being, mood disorders, social interaction and psychosocial functioning were administered prior to treatment and after 6, 12, 24, 36 and 48 months. A poor health-related QoL at baseline was dramatically improved after obesity surgery, while stable ratings over time were observed in the control group. Improvements after 6 and 12 months in the surgical group were followed by a slight to moderate decline at 2, 3 and 4 years follow-up. Health-related QoL changes were strongly related to the magnitude of weight loss; improvements were stable in patients with substantial weight loss (> 30 kg), while a regress was observed in patients with less reduction. If weight loss was minor (< 10 kg) patients tended to return to their baseline levels. The eight-item module on obesity-specific psychosocial problems (OP) in everyday life was the most responsive measure in relation to weight loss. This module includes questions on how bothered patients are by their obesity as regards private gatherings, going to restaurants or community activities, holidays away from home, trying on and buying clothes, bathing in public places and intimate relations with partner. Perceived general health was also strongly related to weight loss, while measures of mental well-being/mood disorders and social interaction were somewhat less responsive. Alternative calculations of effect sizes will be presented. In conclusion, poor health-related QoL in the severely obese is reversible if weight loss is substantial and the short OP scale seems effective in evaluating the health-related QoL effects of obesity interventions.

183. INFLUENCE OF EVERYDAY FUNCTIONING ON SUBJECTIVE QUALITY OF LIFE OF CHRONIC SCHIZOPHRENIC PATIENTS VERSUS THE NORMAL POPULATION
Beata Kasperek, Katarzyna Spiridonow and Joanna Meder
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The aim of the work was to compare subjective quality of life (QoL) of chronic schizophrenic patients to the normal population with the help of the questionnaire ‘Survey on the Contribution of Services to the Quality of Life’. The subjects were 60 patients (P) and 45 people from normal walks of life (N). As we supposed, subjective QoL in group N was significantly better than in group P. It turned out that the level of everyday functioning influenced subjective QoL in group N but not in group P. Patients’ QoL was also not influenced by global functioning and the severity of symptoms.
184. QUALITY OF LIFE AND PSYCHOSOCIAL CHARACTERISTICS OF CANCER PATIENTS
Zs. Kaszab, I. Lázár, G. Szendi, S. Szedmák, J. Lõke and M. Kopp
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We interviewed 546 cancer patients (CPs) selected from the Hungarian Nation-wide Representative Survey on 12,477 individuals. The following quality of life (QoL) and psychosocial factors differentiate the cancer and non-cancer population (N-CP) significantly.

1. Socioeconomic status (i.e. level of education, employment status, income and parent's employment). CPs showed lower socioeconomic status compared with N-CPs.

2. Personality and behaviour characteristics (i.e. depression, exhaustion, dysfunctional attitudes, hostility and working disability). CPs are more depressed and exhausted than N-CPs and they have more working disabilities. In connection with dysfunctional attitudes CPs can be characterized with a significantly higher level of need of approval and need to be loved. However, their achievement and hostility attitudes do not differ from that of N-CPs.

3. The quality of individual-social environment interactions (i.e. social support, sense of control and coping skills). CPs perceive a significantly lower level of social support. They feel the lack of control in connection with their work, social environment and the health care system and they can be characterized with passive ways of coping.

The coincidence and the mutual interactions between the above factors increase the risks of CPs.

According to the cancer literature, we take an assumption that some of these factors (mainly socioeconomic status) might have characterized patients before contracting illness and we can also suppose that having cancer strengthens these traits and makes the QoL lower.

185. THE DEPRESSION AND QUALITY OF LIFE CONUNDRUM
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Most instruments used for assessing quality of life (QoL) in medical disorders contain depression items. One reason for this is probably that the whole QoL movement in medicine was triggered by consumer dissatisfaction with the neglect of subjective well-being of its patients by medicine. For too long medicine exclusively focused on the treatment of symptoms and the prolongation of life. This subjective well-being approach, while beneficial for medical patients in general, is of doubtful value in psychiatric disorders, in particular in depression, which in itself is characterized by a lack of well-being. It is shown that such QoL assessments reflect to a large degree the severity of depression and not an independent QoL dimension. It is argued that in assessing QoL in psychiatric patients, a three-part model should be used, which includes the assessment of social functioning and of environmental living conditions (social and material) in addition to social well-being. Because of the negative cognitive set of depressed patients--they view themselves, the world and the future negatively--their assessment should always be complemented by proxies' and professionals' evaluations. It has, for instance, been shown that depressed patients regard the social support available to them as smaller than it in fact is and also that they evaluate their QoL, while they are depressed, as worse than they do for the same time period after they have recovered. It is concluded that QoL in depression cannot be measured by well-being indices alone, but should be assessed as a profile of different life domains, by the patients themselves, proxies and professionals and, finally, by considering psychological well-being/satisfaction as well as functioning in social roles and environmental living conditions.

186. QUALITY OF LIFE OF MENTAL ILL HOMELESS MEN BEFORE AND AFTER PSYCHIATRIC TREATMENT
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Münster, Germany

There is a prevalence of up to 70% of addiction illnesses among people without a fixed abode. According to this finding psychiatrically ill homeless people form a relevant and difficult group of patients in psychiatric hospitals. Data relating to their state of health and efficacy of treatment are not yet available in Germany.

This study examines the objective as well as the subjectively reported mental and physical state of health in a representative group of homeless men (n = 50) at the time of admission into psychiatric in-patient treatment and compares the results with a control group of non-homeless men. The SF-12 Health Survey was used for the self-estimation and the BPRS and a neglect index were used to document the investigators' estimation.

On admission (n = 50) the BPRS as well as the neglect index showed markedly worse results in the group of homeless people than in the control group (p = 0.001). However, self-estimation in the SF-12 did not differ significantly in both groups.

Shortly before discharge, 32 of the homeless group were re-examined with both modules. The results showed a statistically significant improvement in the psychopathological status (p = 0.01) as well as in the self-reported quality of life (QoL). Treatment therefore was perceived to be successful both objectively and subjectively.

187. QUALITY OF LIFE IN PSYCHIATRIC OUT-PATIENTS UNDER REHABILITATION: COMPARISON OF SELF-ASSESSMENT AND ASSESSMENT THROUGH CARE GIVERS
G. Kemmler1,2, G. Gruber1, H. Meller2, B. Holzner1 and U. Meise1
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The success of psychiatric rehabilitation strongly depends on the cooperation between the patient and the caregiver(s). However, the two sides may have different views concerning the patient's quality of life (QoL) and this may affect the therapeutic relation. The aim of the present investigation was to study this in some detail by comparing the views of the patient and his/her case manager.

The study included a total of 60 psychiatric patients attending various rehabilitation programmes (day centre, occupational therapeutic centre or sociopsychiatric unit). The Lancashire QOL Profile was used for assessing both the patients' and the case managers' view of the patients' QoL. Case managers also provided information on the therapeutic relation to the patient.
The preliminary results (based on the data of 29 patients) show that case managers tend to rate the patients’ QoL lower than the patients themselves. Moreover, the correlations between the patients’ and case managers’ ratings tend to be higher for work, finances and housing \((r \geq 0.5)\) than for the social domain and leisure time activities \((r \leq 0.3)\). Further results and a discussion of the findings will be given.

188. HOW IS THE ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE INFLUENCED BY THE PSYCHOLOGICAL STATE OF THE RESPONDENT? THE EXAMPLE OF THE WHOQOL-BREF
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The potential influence of the psychological state on the subjective evaluation of health-related quality of life (QoL) is a general problem with regard to the validity of measurement techniques. Testing the capability of a measurement instrument in order to differentiate between subjective QoL and psychological state is therefore a necessary prerequisite for judgements about its psychometric properties. In the framework of the field test of the German version of the WHOQOL-BREF, a representative study of 2,000 persons from the general population was conducted. Beyond objective living conditions and subjective health-related QoL, the psychological state of the respondents was assessed by using the demoralization scale, developed by Dohrenwendt as a short form of the Psychiatric Epidemiology Research Interview (PERI-D). By use of multivariate regression analysis, the respondents’ psychological state was found to be strongly associated with an assessment of their subjective QoL for all four domains of the WHOQOL-BREF. Twenty-three to 46\% of the variance of the domain scores could be explained by demoralization. Regardless of this effect of psychological state, all domains of the WHOQOL-BREF are also influenced by objective living conditions in a very plausible manner. Health status has its strongest effect on the physical domain, demoralization has its strongest effect on the psychological domain, living arrangements has its strongest effect on the social relationship domain and region has its strongest effect on the environment domain. At the same time, most of the implausible effects disappeared and the influence structure of the models became clearer when demoralization was controlled for.

189. QUALITY OF LIFE MEASUREMENT–RELIGION OR SCIENCE?
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Nearly a quarter of a century has passed since social scientists met to collectively agree upon a definition of quality of life (QoL). In independent and at the time unrelated work Fanshel and Bush launched their formative ideas on health status measurement. Over the intervening decades the two streams of ideas and associated research have coalesced. But how much of what we now term QoL measurement is based on scientific principles and what part might be better described as being the relics of personal or collective belief systems?

The paper begins by reviewing definitions of QoL, distinguishing clearly between the universal concept found in the general sociology literature and the more specific subset of health-related QoL, within which health status measurement is nested. The measurement of health status has been encouraged by the demand for instruments capable of generating outcome data for use in the clinical and economic evaluation of health care. If we accept the dominance of this type of application, then our definitions become both simpler and less opaque and have practical implications for the design and construction of instruments. Practical usefulness may yet be an antidote for theoretical purity--witness the continued usage of the Karnofsky and Apgar Indexes.

This paper challenges the traditional mantra of the psychometrician—the high priests of the new religion. The vocabulary of QoL measurement includes several terms that need to be used with particular care. ‘Valid’, ‘reliable’, ‘precise’ and ‘sensitive’ reflect the subjective value judgement of instrument developers and users, rather than revealing any fundamental truths. The concepts themselves are made more difficult, since they depend critically upon belief systems—as evidenced by statements such as ‘sensitivity refers to the ability of the measurement to reflect true changes’. What is a ‘true’ change? Who determines its truth or otherwise? How closely is ‘truth’ approximated? In the area of the personal preference measurement, truth cannot be established as an absolute concept. In practice, we need to steer a balanced course between the acceptable standards of measurement that can reasonably be expected for any instrument (another value judgement) and an absolutist approach that represents a quasi-scientific extremism. Finally, the paper exemplifies the double standards to be found in clinical practice and reviews the comparative performance of blood pressure measurement with that reported for four generic measures of health-related QoL (the SF-36, HUI, EQ-5D and QWB). If such measures do indeed herald a new religion, then why do we worship the old gods?

190. MEASURING OUTCOME IN THE TREATMENT OF HIV/AIDS: TESTING THE RELIABILITY AND SENSITIVITY OF EQ-5D
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The measurement of outcomes is crucial to the clinical and economic evaluation of health care. Measures of health-related quality of life (QoL) that incorporate patient preferences enable us to record outcome data which would not otherwise be included in any evaluation. Generic measures of this type, such as the QWB, SIP and HUI, have been developed for use in a wide range of settings. The need to assess the performance of such measure in the evaluation of health care has been given recent emphasis.

The object of this analytic study was to test the performance of EQ-5D as a measure of health status in the treatment of patients with HIV/AIDS. The EQ-5D is a generic measure that can be used both as a profile and as an index. It captures information on health-related QoL in terms of five dimensions–mobility, self-care, usual activity, pain/discomfort and anxiety/depression. These data can be aggregated using a standard set of dimension weights to produce a single index measure of health status. Respondents also rate their own health status using a 0–100 visual analogue scale (‘thermometer’). In two clinical trials of a new pharmaceutical in the treatment of
HIV/AIDS, the EQ-5D was administered weekly. A total of some 1,500 patients took part in the two studies. The reliability of the EQ-5D was examined within the subgroup of patients with asymptomatic disease. Comparison of the EQ-5D data at 1 week after entry to the study was compared with each patient’s baseline record. Intraclass correlation coefficients were computed for the weighted index and thermometer scores. Within asymptomatic patients, with CD4 counts below 100, significant differences were found between the experimental and control groups, with patients who received Ritonavir demonstrating gains in their health-related QoL as measured by the EQ-5D. Standardized response means were computed for patients with improved CD4 counts. A strong correlation was found between the pharmacokinetic profile of the drug and observations on the EQ-5D.

Coefficients of reliability and sensitivity indicate that the EQ-5D behaves well in terms of conventional psychometric measures of performance.

191. QUALITY ADJUSTED LIFE EXPECTANCY–THE POLICY POTENTIAL OF HEALTH-RELATED QUALITY OF LIFE DATA

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Health care may affect the quality and/or the quantity of life enjoyed by individuals, and by society as a whole. Traditional measures of the population health status have relied upon a simple binary classification–alive/dead. Death remains a significant outcome for certain specific purposes, but as life expectancy increases, it becomes less easy to justify the notion that all life years count (or should count) equally. The problem that we must resolve, therefore, is to determine weights that will enable us to adjust the value of life years to take account of their quality.

Population surveys conducted in the UK during 1993 and 1995 included the EQ-5D as a measure of health-related quality of life (QoL). Some 9,500 individuals took part in the two surveys. The EQ-5D records problems on five health status domains (mobility, self-care, usual activity, pain/discomfort and anxiety/depression) and responses are converted into a single index number using a standard set of weights. The data from the two national surveys were analysed separately to generate mean values of health-related Qol. for five year age bands, for both men and women. These values were then applied to crude life expectancy tables, to produce a quality-adjusted life expectancy for each age band. By plotting the quality-adjusted profiles, it was possible to compute a total index based on the area under the curve. As an example of how such information might contribute to the evaluation of mental health policy, the quality-adjusted life expectancy for each disability weight was calculated, making different assumptions about the effectiveness of health care programmes designed to improve mental health. Linking information on quality of life with the costs of such programmes, it was possible to compare their cost-effectiveness with that of breast cancer screening—a ‘gold-standard’ programme within the UK.

The national survey data included further data relating to smoking behaviour, housing tenure and educational attainment. The potential health gains resulting from programmes designed to impact on these health-related factors has also been estimated.
The daily record of general well-being resulted in worse ratings of well-being for the interferon group at weeks 5–8. Furthermore, the patients treated with interferon experienced specific fluctuations of QoL with positive peaks registered on those days without preceding interferon application. QoL assessment at 3 month intervals resulted in significantly worse QoL for interferon patients at 3 months, whereas differences at 6, 9 and 12 months could not be detected. Analysis of variance for repeated measures revealed a significant interaction effect for the subscale fatigue. Patients of the control group experienced a deterioration of fatigue within the observation period, while the level of fatigue remained stable for the patients treated with interferon.

The results suggest that the negative effect of interferon on QoL is limited to the first 3 months of treatment and interferon affects mainly the level of fatigue and energy.

194. QUALITY OF LIFE BEFORE AND AFTER TOTAL HIP ARTHROPLASTY
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A prospective Total Hip Arthroplasty Outcome Evaluation was performed including patients admitted to our department during 1993.

The physician-derived method for evaluation was the Harris Hip Score (HHS) and the patient-derived measure of outcome was achieved using the Nottingham Health Profile (NHP) and the function questionnaire Hannover (F Fb H-R).

One hundred and one patients who underwent primary THA agreed to clinical and psychological evaluation pre-operatively and 1 year post-operatively.

The pre-operative HHS with 44.7 points (range 20–81) was significantly improved after 1 year to 87.6 points (range 52–100).

The comparison of the pre- and 1 year post-operative NHP data demonstrates a significant improvement in quality of life (QoL) in five dimensions (pain, energy, mobility, emotions and sleep). Only the social isolation scale remained unchanged.

Likewise, the total score of functional capacity (F Fb H-R) also improved significantly from 57.92 points pre-operatively to 39.79 points at follow-up 1 year after surgery.

195. A LONG-TERM COMMUNITY FOLLOW-UP STUDY OF PEOPLE WITH SEVERE MENTAL DISORDER IN THE UK
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The purpose of the study is to investigate the changes in the quality of life (QoL) of people with a severe mental illness when they are discharged into the community and their health and social care status in the community after 4 years.

Two groups of patients, old long-stay patients who had been in mental hospital for more than 1 year continuously (n = 98; eight refusals) and new long-stay patients who had been in contact with community psychiatric services for more than 3 years (n = 168; 22 refusals), were assessed at the beginning of the study in 1992 (total n = 266; 30 refusals). The assessments were made using the Lancashire Quality of Life Profile (LQOLP). Four years later 218 patients (31 deaths, 8 refusals and 9 not traced; 82% of the time 1 assessment total) were reassessed using the LQOLP. In addition, the services used by the patients, and whether they received organized after-care and their use of physical health care resources were all assessed.

This paper presents the results concerning the use of services and physical health status of the patients. In general, very few were receiving comprehensive care and many were unaware that they had been the subject of care planning. In line with other studies approximately half of the subjects had physical health problems. A small group of patients consumed a disproportionate amount of health care resources with high costs to general hospital services. For example, in one extreme instance a patient made more than two dozen visits by emergency ambulance (costing several hundred pounds sterling each time) to the hospital A & E department. In conclusion, the results are discussed in respect of both the new and old long-stay patients, the costs to general health care services, the implications for the integration of health and social care services and attempts to maintain or improve QoL for these patients in future.

196. HEALTH-RELATED QUALITY OF LIFE OF CHILDREN WITH JUVENILE CHRONIC ARTHRITIS
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The concept of health-related quality of life (QoL) is defined as children’s affective evaluation of different aspects of their daily functioning. Few attempts have been made to develop reliable health-related QoL assessment instruments for children with a chronic disease. In order to meet this need, the DUCATQOL, a generic 32-item self-report questionnaire, was constructed. The items cover four domains: physical, emotional, social and school functioning. Data were collected from different groups of children with a chronic disease. In this study 50 children with juvenile chronic arthritis (JCA) (mean age 10.5 years, SD 4.5 years, 68% pauciarticular) receiving clinical care in the Leiden University Medical Centre completed the questionnaire.

The DUCATQOL proved to be understandable, internally consistent (α = 0.91) and reproducible (r = 0.90). The four eight-item subscales showed homogeneity (α ranging from 0.68 to 0.77). In comparison with the reference group of 1,092 healthy peers, children with JCA reported significantly lower scores on the physical (F = 13.19 and p < 0.001) and emotional scale (F = 5.62 and p = 0.02). Girls evaluated their physical condition lower than boys (F = 5.79 and p = 0.01). Early onset of JCA (before age 5 years) resulted in a lower score on the social scale (F = 5.78 and p = 0.02). Disease type (pauciarticular or polyarticular) did not influence the subjective evaluation of health-related QoL.

It can be stated that children with JCA reported a lower health-related QoL on different domains of their daily functioning.
197. INTERNATIONAL PERSPECTIVES ON QUALITY OF LIFE ASSESSMENT IN CHILDREN AND ADOLESCENTS. AN INTRODUCTION.
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Major progress in the diagnosis and treatment of a number of severe and chronic diseases in childhood has drastically increased the rate of survivors. Along with this progress in medical therapy, the psychological and social task of children and adolescents and their families has become one of adapting to and coping with frequently uncertain survival, the impact of chronic disease and the costs of treatment. In recent years, this has led to efforts to assess the impact of disease on quality of life (QoL) in children and adolescents from the viewpoint of paediatrics, psychology and public health administration.

This introduction to the symposium provides an overview of conceptual and methodological issues concerning QoL measurements amongst children and youths, of the impact of life-threatening and chronic disease and treatment on the QoL of children and of the results of recent efforts to develop QoL instruments for this age group.

To reach a balanced overview, three main areas are addressed: (1) the conceptual basis of different approaches to QoL assessment, (2) the impact of the most prevalent and disabling chronic conditions on the QoL of children and adolescents and (3) recent efforts and methodological issues in the development of appropriate QoL measures for this age group.

The symposium will continue with presentations on two well-developed generic QoL measures for this age group, including efforts of cross-cultural validation and an overview of European studies on QoL issues in one specific disease, i.e. childhood cancer.

198. COMPARISON OF TWO INSTRUMENTS FOR THE MEASUREMENT OF QUALITY OF LIFE IN BONE MARROW TRANSPLANTATION: EORTC-QLQ-C30 VERSUS FACT-BMT
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Quality of life (QoL) was investigated in 56 bone marrow transplant (BMT) recipients. The objective of the study was to compare two different QoL instruments, namely the EORTC QLQ C30, developed by the QoL study group of the European organization for Research and Treatment of Cancer and the FACT-BMT scale, which was developed especially for use in BMT patients. Our main question was which instrument is more effective for the investigation of QoL in BMT patients? Our results show that the FACT-BMT is able to give a more comprehensive overview regarding a multidimensional construct of QoL than the EORTC QLQ C30. On the other hand the EORTC C30 gives more insight into the physical aspects of QoL and offers the advantage of identifying somatic symptoms which effectively decrease QoL. Our results allow a salmonic conclusion. We think that the combined use of both instruments offers the best approach for measuring QoL in BMT recipients. The two tests can be used complementarily and this procedure can be used as an internal control of QoL measures. As the total time for answering both questionnaires is approximately 30 min, this does not cause any logistical problems.

199. MECHANICAL HEART VALVE REPLACEMENT—LESS PROFIT FOR ELDERLY PATIENTS?
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Heart valve replacement is the second most common procedure in cardiac surgery. The increasing shortage of financial resources in the health care system raises the question of cost-effectiveness of expensive surgical interventions for elderly patients.

Within the ESCAT trial, which is a randomized prospective trial comparing patients with different types of mechanical valves and self-controlled versus conventional methods of anticoagulation therapy, a subgroup analysis was performed to determine age effects on the quality of life (QoL) after heart valve surgery. The sample consisted of 420 patients with a mean age of 61 years. The SF-36 and a disease-specific questionnaire were used as outcome measures of QoL.

A comparison of young and old patients (median-split) showed that the elderly patients reported a significantly higher improvement in QoL 6 months post-treatment concerning physical functioning, role-emotional and pain and complained less about disease-specific impairments. Comparing the patients’ QoL with the age and gender-specific German norm population it was detected that the younger patient group showed greater deviations from the QoL scores of healthy people, particularly in the subscales concerning physical and role functioning. Splitting of the sample into smaller age groups and analysis of the differences in QoL did not result in significant differences even between very young and very old patients.

The results indicate that elderly patients profit from heart valve surgery to the same extent or even more, compared with younger patients.

200. QUALITY OF LIFE OF PATIENTS AFTER HEART VALVE SURGERY—FIRST RESULTS OF THE EARLY SELF-CONTROLLED ANTICOAGULATION TRIAL (ESCAT)
H. Körtke1, R. Körfer1, I. Kirchberger1 and M. Bullinger1
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Heart valve replacement is the second most common procedure in cardiac surgery. A vast majority of the implanted heart valves are mechanical, necessitating long-term anticoagulation therapy. The outcome measurement of heart valve surgery concentrated on survival times and complication rates whereas quality of life (QoL) has not yet been studied in detail.

The ESCAT study is a randomized prospective trial comparing patients with three different types of mechanical valves (Medtronic Hall, Carbomedics and St Jude Medical) using the home prothrombin monitor versus conventional methods by the general practitioner. The main hypothesis concerning QoL was that the determination of prothrombin time by patients themselves will reduce their dependence on the health care system, reduce the rate of complications and thereby progressively improve the QoL of patients.
QoL was measured before and after surgery at 6, 12, 18 and 24 months post-operation using the SF-36 Health Survey and a newly-developed questionnaire which covers disease-specific problems of patients with mechanical heart valves.

The interim analysis of 420 patients showed a significant improvement in QoL 6 months post-treatment not depending on the type of mechanical valve received. Patients practising self-controlled anticoagulation therapy reported less uncertainty concerning determination of coagulation, felt less dependent on the physician and more integrated into working life.

The results emphasize the positive effect of mechanical heart valve replacement and self-controlled anticoagulation therapy on QoL.

201. CHANGING THE LIFE OF MENTAL PATIENTS WITH BEHAVIOUR OF PSYCHOTHERAPY IN A BIG MENTAL HOSPITAL
Tanja Kozarov and Nela Djokic
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Relentless life in a large mental hospital leads to hospitalisation. The patient cannot come back from outside and stays 20 or more years constantly in this department. We chose 16 patients from the Special Psychiatric Hospital in Goring Toponica, who passed through the behaviour psychotherapy programme for psychopaths, from September to December 1996 (operative conditioning token economy). We evaluated the results with the Montgomery–Asberg Scale for affective disorders and the Cornell Index for anxiety and muscular relaxation for emotional reaction. We used the scales before and after the programme. The results are as follows. On the Montgomery–Asberg scale at the second time point all patients had low depression of 0 to 20. At the first time point we had 64% with low depression and 36% with middle depression and none with high depression. On the Cornell Index at the second time point we had 90% with low anxiety, 10% with middle anxiety, whereas at the first time point we found 50% with low anxiety, 30% with middle anxiety and 20% with high anxiety. After 1 week’s treatment with muscular relaxation (1 h a day) we used EEG to improve small emotional reaction. Our intention was to improve the usefulness of behaviour psychotherapy in the treatment of mental disorders in a big hospital and enrich the lives of chronic patients in a short time and economically change their typical lives.

202. DETERMINANTS OF QUALITY OF LIFE AFTER TYPE III OPEN TIBIAL SHAFT FRACTURES
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One aim of this multicentre study was to examine the question of the extent to which quality of life (QoL) 4 years or more after an accident can be predicted by trauma-specific factors (such as the Gustilo subclassification and time-to-arrival at hospital after the accident), by the therapeutic course (duration of hospitalization and number of operations), by complications (amputation and infection) and by demographic factors (gender and age). One hundred and ninety-seven patients with type III open tibial shaft fractures (type IIIA 70, type IIIB 85 and type IIIC 42) from nine centres who were treated between 1989 and 1993 volunteered to participate in this study. A doctor’s questionnaire containing data relating to their therapy was prepared. The therapeutic course, pre-surgical staging and demographic data were recorded by the surgeon at the patients’ follow-up examination. The patients were asked to rate their QoL on the Nottingham Health Profile (NHP) and on a visual analogue scale. Multiple regression analysis (stepwise) identified two predictors of a reduction in overall QoL (F-test: p = 0.007): the number of operations (β-adjusted -0.21) and age (β-adjusted -0.17). None of the other factors showed any significant relationship to overall QoL or to sub-scales of the NHP. These results are indicative of the dilemma that exists between two therapeutic goals: functional outcome, which often requires a greater number of operations and QoL, which suffers from prolonged surgical treatment.

203. EVALUATION OF QUALITY OF LIFE IN ORAL CANCER PATIENTS: RESULTS OF THE DÖSAK-REHAB STUDY
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This multicentre study of the German–Austrian–Swiss Workgroup for Maxillofacial-Cancer (DÖSAK) found that quality of life (QoL) is determined by functional and psychosocial outcome in patients after radical surgery of oral cancer.

One thousand, four hundred and ninety patients (age 60.3 years, m : f 88 : 12%) from 38 centres for maxillofacial surgery volunteered to take part in the study. On average, the patients were 4.05 years after primary cancer surgery. Ninety-six percent were tumour free. They completed on the Bochum Questionnaire on Life Quality of patients with oral cancer in rehabilitation. It consists of 140 items and includes sections on demographic data, the course of the disease before and after surgery, the impact of the disease, coping, economical situation and health behaviour.

The results showed that patients’ QoL was significantly reduced when compared with healthy controls. In contrast, social support and coping strategies did not differ from healthy references. Multiple regression analysis showed that QoL ratings were determined by anxiety, low social support and high functional impairment, in particular speech comprehension and swallowing (adjusted r 0.31).

It can be concluded that rehabilitation programmes should focus on both improvement of the psychosocial situation and functional state of the patient.

204. QUALITY OF LIFE AND PSYCHOSOCIAL SITUATION OF CANCER PATIENTS UNDER TREATMENT: FIRST RESULTS OF A LONG-TERM STUDY
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Quality of life (QoL) issues and research have become a major focus of interest in the clinical course of cancer. Recent efforts have concentrated on the development of measures to address QoL and access the needs of the patients. This information will be
helpful in weighing the outcome of different primary treatment options. For this reason the University of Cologne initiated a long-term survey to evaluate the balance between cancer patients’ QoL and medical variables and to identify patients who have an actual need for psychological support. Built on the 1 year study results, a psycho-oncological support concept is to be developed for evaluation and modification in a 5-year period.

From September 1996 to the present time 164 patients with haematological malignancies were examined in an initial study according to the following parameters: medical history, EORTC QLQ-C30 (QoL), Hornheider questionnaire (which identifies the actual need for psychological support) and a psycho-oncological interview guide (containing variables of the patient’s individual psychosocial context).

From the initial 164 patients entered into the study, data from 100 patients are available for the present analysis. The first analysis of the QoL data revealed remarkable constraints and limitations in the individual subsdimensions of QoL of the treated patients in comparison to normals. On all functioning scales (physical, role, cognitive, emotional and social functioning) the patients showed 30-50% lower values than the normal controls. Furthermore, there were 40 patients who were identified by means of the Hornheider questionnaire as in need of psychosocial support and 47 patients indicated in a psycho-oncological interview a demand for psychosocial measures.

The high compliance of patients participating in the study shows the positive attitude of patients towards the approach. Altogether the results stress the patient’s general necessity for care in particular in the psychosocial area. To examine the interaction of patient’s QoL, medical variables and the psychosocial context more deeply, further systematic research will be carried out.

PIBS patients share many QoL concerns with incontinence patients, yet have a number of additional, unique concerns. Additional psychometric properties, including the responsiveness, of the PIBS-QOL deserve further study.

206. AWARENESS AND KNOWLEDGE ABOUT HYPERTENSION AND RELATED WELL-BEING IN NORMOTENSIVE AND HYPERTENSIVE VISITORS TO A CENTRE HOSPITAL: RESULTS OF A SURVEY
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Successful therapy of hypertension may reduce overall cardiovascular risk. Public information campaigns, hypertension-related knowledge and individual well-being are known to influence compliance of the patients treated. The present study was undertaken to compare the respective knowledge about hypertension in normotensive and hypertensive volunteers and to relate their statements to actual blood pressure, medication and well-being.

For this purpose, we investigated visitors entering our hospital during 1 day, who agreed to fill in a short questionnaire which dealt with the causes, consequences and therapies of hypertension. They were instructed by medical students. All had a routine blood pressure determination (the mean values of three measurements in a sitting position and relative calmness were assessed) which followed the questionnaire.

In the evaluation 199 out of 206 (98%) of the questionnaires could be used. Twenty-eight (14%) of the visitors defined themselves as hypertensive, 154 (77%) as normotensive and ten (5%) had no opinion. The visitors defining themselves as hypertensive had a significantly higher mean blood pressure than the normotensives (114 ± 9 (SD) versus 98 ± 11 mmHg), were significantly older (55 ± 18 versus 47 ± 17 years) and had significantly lower well-being, as well as more medical visits (5 ± 4 versus 3 ± 6 times a year). Additionally they responded correctly to more hypertension-related questions (47 versus 37%) (p<0.001 for all). A positive correlation was found between the reliability-controlled proportion of the correctly answered questions and the subjectively reported diastolic blood pressure (r=0.45 and p<0.05).

We conclude that hypertensive visitors are better informed about hypertension than normotensives. Moreover, disparate values of subjectively reported and measured blood pressure values may help to identify patients whose well-being is clearly compromised and who are probably prone to compliance problems.

207. IS POOR HEALTH-RELATED QUALITY OF LIFE IN HIV-POSITIVE WOMEN DUE TO HIV DISEASE OR SOCIAL DISADVANTAGE?
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Preliminary findings from recent work indicated striking differences in health-related quality of life (QoL) in HIV-positive women compared with UK population norms for women. The SF-36 scores of HIV-positive women were, on average, 10 points lower than women in the general population for both physical...
(PCS) and mental (MCS) health-related QoL. However, as the sample of HIV-positive women differed on important sociodemographic characteristics from women in the normative sample (e.g., age, ethnicity and social class), it was unclear whether the poor health-related QoL in HIV-positive women was due to HIV disease or to social disadvantage.

The objective of this study was to evaluate differences in health-related QoL between HIV-positive women and women in the UK general population, using multiple regression analyses to control for potential confounding factors. Two groups of women of 23–59 years were compared: 60 HIV-positive women attending outpatient clinics in east London (mean age 33 years, 58% ethnic minorities and 43% low social class) and 4,196 women from the general population in the UK (mean age 39 years, 3% ethnic minorities and 26% low social class). Both studies used the UK version of the SF-36 to measure PCS and MCS health-related QoL and the OPQS classification of occupations to determine social class.

Multiple regression analyses, controlling for age, ethnicity and social class, showed that health-related QoL was significantly lower in HIV-positive women compared to women in the UK general population on the SF-36 physical (PCS, p = 0.000) and mental (MCS, p = 0.000) summary scores as well as on all eight dimension scores. The results demonstrate that differences in health-related QoL between HIV-positive women and women in the general population cannot be explained by the greater social disadvantage of HIV-positive women. The fact of having a chronic, life-threatening illness, rather than social disadvantage, is the major determinant of poor health-related QoL in women with HIV infection.

208. HOW DOES BEING ELDERLY WITH A CHRONIC LIFE-THREATENING ILLNESS AND ON DIALYSIS AFFECT HEALTH-RELATED QUALITY OF LIFE?


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With the increasing number of elderly people being accepted onto dialysis and questions about the benefits of dialysis in the elderly, there is a need to evaluate the effectiveness of health care in this group. Several studies have evaluated health-related quality of life (QoL) in dialysis patients in general, but none have specifically examined health-related QoL in elderly patients using gold standard measures. The objective of this study was to compare health-related QoL in elderly dialysis patients (EDPs) with a control group of elderly people in the general UK population using the SF-36.

Two samples of elderly patients 70–74 years were compared: 69 EDPs from four renal units (24 F, 45 M, 38 haemodialysis and 31 peritoneal dialysis) and 61 elderly population controls (31 F and 31 M) from two general practices. The UK version of the SF-36 was used to measure physical (PCS) and mental (MCS) health-related QoL.

Multiple regression analyses, controlling for age and social class, showed that although physical health-related QoL in EDPs was significantly lower compared to controls (PCS 33 versus 40 and p = 0.001), there were no differences in mental health-related QoL (MCS 51 versus 52). Multiple regressions on the eight SF-36 dimension scores showed that EDPs scored significantly lower than controls on physical function (p = 0.002), general health perceptions (p = 0.02) and vitality (p = 0.000). The differences were marginally significant on role-physical (p = 0.08) and social function (p = 0.08). There were no differences between the two groups on the pain, role-emotional or mental health dimensions.

Although physical health-related QoL in elderly patients on dialysis is clearly compromised, mental health-related QoL is comparable to elderly patients in the general population. Therefore, despite older age and having a chronic life-threatening illness, mental health-related QoL remains remarkably intact in elderly dialysis patients.

209. WHEN IS A NORM A NORM? THE REPRESENTATIVENESS OF POPULATION NORMS FOR THE UK VERSION OF THE SF-36

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This paper addresses conceptual and methodological problems related to the development, use and interpretation of normative data for the UK version of the SF-36. A comparison of sampling strategies used in the US and UK to develop normative samples and an examination of the representativeness of normative samples of the general US and UK populations, respectively, reveal important differences which may limit the validity of current UK norms.

US norms were developed on the basis of a representative sample of 2,474 non-institutionalized adults in the general population. This sample was drawn from the sampling frame used in a national survey which stratified sampling by region, age, ethnicity and income. UK norms, on the other hand, were developed on the basis of two separate large samples of respondents drawn from two general practices in Sheffield (n = 1,582) and from four health districts in central England (n = 9,332).

A comparison of the sociodemographic characteristics of both UK normative samples with estimates obtained from the General Household Survey reveals marked differences in social class, with higher (non-manual) social classes being overrepresented in both normative samples (GHS 47%, Brazier et al. 53% and Jenkinson et al. 65%). In terms of ethnicity, whereas 5% of the general UK population are from minority ethnic groups, neither normative sample provides data for respondents from minority ethnic groups.

Whereas SF-36 norms developed for use in the US have been shown to be representative of the general population, there is little evidence that the samples used to generate UK norms are representative of the general population in terms of social class and ethnicity. As these two factors are known to be related to health-related quality of life (QoL), it is essential that SF-36 norms which are representative of the general population be developed in the UK.
210. QUALITY OF LIFE IN EPILEPSY.
PERSPECTIVES OF PATIENTS AND THEIR RELATIVES

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Our study investigated the quality of life (QoL) among 175 patients with chronic epilepsy.

The QoL measurement we used was based on the Washington Psychosocial Seizure Inventory (WPSI). There were two main differences compared to the WPSI. One was that our questionnaire showed one more dimension than the WPSI—the determinant ‘information’. The other distinction was that our questionnaire had a parallel form for relatives. The results showed that QoL of people with epilepsy was evident in two main areas: the overall psychosocial functioning and vocational adjustment. Relatives viewed the factor adjustment to seizures with concern.

The results will be discussed in synopsis with the literature.

QoL research in epilepsy is in its infancy. In the future, such research will play an important role in assessing patient suffering, demonstrating the efficacy of treatments and interventions and influencing medical economic decisions.

211. QUALITY OF LIFE AFTER INTRA-OCULAR OPERATIONS

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After a comprehensive retrospective study that was completed in 1995 and after reviewing different publications, we developed our own method for assessment of quality of life (QoL) related to visual function.

Our method is based on objective measurement (visual acuity) and on patients’ opinion of their visual functions in daily life activities. QoL is improved if both criteria are positively changed.

The method was implemented in a prospective study carried out from March 1996 to February 1997.

The study included 442 patients operated on between March and August 1996. The analysis of 300 patients with cataract operation is already completed.

Visual acuity was measured and a questionnaire completed for all patients before the operation and 1 month and 6 months after the operation.

The questionnaire consists of 40 questions related to visual function in daily life activities.

A risk stratification system was also developed. Each risk factor is expressed with a number of points. Patients are categorized into five risk groups according to the number and level of risk factors. For each risk group the expected visual acuity and visual function is calculated and is observed after 1 and 6 months. The difference between the expected and observed values is also a measure of the quality of surgical treatment.

The mean QoL index before the operation was 58.13, 86.42 1 month after the operation and 95.83 6 months after the operation ($p < 0.001$).

212. QUALITY OF LIFE OF PSYCHIATRIC PATIENTS: A SURVEY OF A DIFFERENTIATING SCENERY OF RESEARCH

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First, the historical development of quality of life (QoL) research in psychiatry is described. This is followed by critical remarks on the theory and methodology in the areas of definition of QoL, theoretical concepts and models of life quality, assessments of QoL (instruments and self-versus observer report), samples and designs. The main results of empirical research on QoL in psychiatry are summarized with regard to 12 topics: (1) comparison with the normal population and chronically somatically ill, (2) community care and QoL, (3) ongoing therapy and rehabilitation, (4) gender differences, (5) psychopathology and relapse, (6) side-effects of psychotropic drugs, (7) additional psychotherapy, (8) self-esteem, (9) social support, (10) coping, (11) QoL of relatives and (12) victimization. Finally, proposals for future questions of research and studies are submitted.

213. QUANTITATIVE ASSESSMENT OF RESPONSE SHIFT IN QUALITY OF LIFE RESEARCH

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Two assumptions which characterize the measurement of quality of life (QoL) studies, are questioned. First, the assumption that QoL is the same thing for all subjects and is related to health problems and can be easily measured across subjects. Second, when this assumption is given up by introducing subjective base rates in an intrasubject (before–after) design, researchers still tend to assume that no response shift occurs on the QoL scale, i.e. that these scales maintain the same meaning and values for the subjects over time and interventions. In our previous studies we found that QoL had different subjective interpretations. While for some certain issues in their family life determined their QoL, for others these were issues at their workplace or in their health conditions. Second, when QoL was tested against a subjective baseline (for each individual according to their choices of domains), approximately 11% of hypertensives and normotensives showed a clear response shift of scale calibration over a period of 1 year. When the scores of these subjects were excluded, the significance of certain previously reported results changed. For example, the significance difference between normotensives and hypertensives concerning the change in their subjective evaluation of QoL over the year and their initial depression became more significant, while similar changes in their evaluation of sexual impairment and control at their workplace became insignificant. These results suggest that response shifts have to be traced and quantified before one can claim results (or lack of results) in before–after designs, concerning subjective meaningful events such as QoL.
214. IMPACT OF TREATMENT BY CONTINUOUS POSITIVE AIRWAY PRESSURE ON QUALITY OF LIFE OF PATIENTS WITH THE OBSTRUCTIVE SLEEP APNOEA SYNDROME

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We have measured by means of the Nottingham Health Profile (NHP) the impact of nasal continuous positive airway pressure (CPAP) on the perceived health of 547 patients with obstructive sleep apnoea syndrome (OSAS). Measurements were made at the time of diagnosis (m0) and after 3 months (m1), 6 months (m2) and 1 year’s treatment (m3). Obesity was a factor of negative perception in patients whose body mass index (BMI) was greater than 29 kg m⁻² as regards the dimensions of energy, physical mobility and pain (p < 0.01). The Apnoea/Hypopnoea Index (AHI) did not have any influence. At m0, there was a significant improvement in all dimensions which reached up to 60%. However, 22.6% of the patients had a worse score at m1 than at m0 for at least two dimensions. These individuals were characterized in comparison with the rest of the patients by having a greater proportion of women (p < 0.05), a greater proportion of hypertensives (p < 0.01), a lesser percentage of symptoms greatly reduced at m1 (agitated sleep, daytime somnolence and fatigue, p < 0.01 and snoring p < 0.05), a greater proportion complaining of irritation to the eyes and a mark on the nose at m2 (p < 0.01), less time passed in apnoeas (p < 0.01) and a shorter mean duration of apnoeas (p < 0.001) at m2. Furthermore, patients who put on weight during the year of treatment had a greater probability of belonging to this group. Of the patients 15.3% had an improvement in NHP score at m2 which had deteriorated by m3. Comparing this group of patients to the others showed a tendency to gain weight with a higher BMI at m2 (p < 0.05). The improvement in symptoms was similar at m1 than at m0. The proportion of patients in whom the symptoms were greatly reduced was less (p < 0.05). In conclusion the NHP is sensitive to symptom changes. In fact the fluctuations in the main symptoms of the disorder are reflected directly in the evolution of the NHP scores and thus distinguish categories of patients.

215. MEASURING QUALITY OF LIFE IN CHILDHOOD ASTHMA

E. M. le Galès, N. Coster, C. Buron, F. Kinkor, Pr M. Mesbah1, J. Chwalow1, Pr G. Slama and the Clinical and Economic Working Groups2,5
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The McMaster Health Utility Index (HUI) 2 and 3 are multi-attribute health classification systems, for which multi-attribute preference functions have been developed in Canada. They provide a comprehensive instrument for use in economic evaluation and population health survey studies. This paper reports on the first results on the adaptation of the HUI 2 and 3 systems cross-culturally and the psychometric assessment of the French self-administered questionnaire in different patient populations.

The cross-cultural adaptation included translation, backtranslation, expert consensus meeting and pre-test with a few patients and healthy subjects in order to produce a conceptually equivalent French version. Different groups of in- and out-patients attending specialized clinics (n = 965) completed the questionnaire and another generic questionnaire (SIP or DUKE questionnaire) for validity assessment. Physicians and patients were also asked for a global subjective assessment of the patient’s health status.

The French version was well accepted by patients. The internal consistency was acceptable (Cronbach’s α = 0.80) as well as the test–retest reliability. The convergent and discriminant validity of the HUI questionnaire was assessed by a multitrait analysis. The validity of the questionnaire (correlations with the responses to the SIP or DUKE questionnaire and with the physicians’ assessment) was also satisfactory. The reproducibility was assessed on a subgroup of patients with a stable health status. The x coefficients were greater than 0.6.

These first results authorize careful use of the 15-item self-administered questionnaire in French. The assessment of the multi-attribute preference function for HUI 3 in France will be the next objective of the study.

216. CROSS-CULTURAL ADAPTATION AND VALIDATION OF THE HEALTH UTILITY INDEX MARK 2 AND 3 SYSTEMS IN FRANCE

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These first results authorize careful use of the 15-item self-administered questionnaire in French. The assessment of the multi-attribute preference function for HUI 3 in France will be the next objective of the study.
217. ASSESSMENT OF THE MULTI-ATTRIBUTE PREFERENCE FUNCTION FOR HEALTH UTILITY INDEX 3 IN FRANCE. PRELIMINARY RESULTS
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Following cross-cultural adaptation and psychometric validation of the Health Utility Index 2 and 3 systems in different patient populations in France, a pilot study has been realized in order to assess the multi-attribute preference function for HUI 3 on a French convenient sample.

Multi-attribute utility theory provides an efficient framework for determining the utility scores of the 972,000 health states of this system, as the eight attributes were deliberately selected to be structurally independent. The theory specifies alternative functional forms to be considered (additive, multiplicative and multilinear) and the condition under which each should be appropriate. However, a major consideration in choosing the appropriate form is the practicality of undertaking the measurements. Moreover, taking into account the absence of previous preference measurement experience in the French context, we decided to conduct a pilot study on a convenient sample in order to test the consistency of a multiplicative function.

Seventy face-to-face interviews were performed (January–March 1997). The respondents were recruited at their working place. The sample was extended using interviewees’ social networks. Visual analogue scale and standard gamble were used to reveal preferences on a scale running from 1 (perfect health) to 0 (all worst or death depending on the interviewee’s decision). The eight single-attribute value functions were directly revealed as well as the corner states values. Rating of particular multi-attribute health states was also done using both visual analogue scale and standard gamble.

For the first time in France, our pilot study demonstrates the feasibility of eliciting values and utilities in a French sample. Secondly, a preliminary analysis concluded that collected data allows (1) the fitting of multi-attribute value and utility functions for many individuals and (2) discussion of the appropriateness of the multiplicative functional form.

218. DEVELOPMENT OF INDICATORS FOR QUALITY OF LIFE FOR SCHOOL CHILDREN IN YUGOSLAVIA
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Ever since 1948 when the WHO definition of health introduced its three dimensions, there have been efforts for a more comprehensive approach in health assessment. Quality of life (QoL) as one of the comprehensive indicators is a result of these efforts. In the early 1990s the IQOOLA project was launched to obtain an international perspective of QoL. Similar research into the issue using child and adolescent data has yet to be conducted. Since 1996, a study that is developing in Yugoslavia has been trying to establish instruments for measuring all three dimensions of child and adolescent health and their QoL.

A hypothesis was posed that a deficit in either health dimension would affect a child’s QoL. The measurement model produced covers physical functioning, general health perceptions, bodily pain, role in society, self-esteem, mental health, general behaviour, family activities, family cohesion and change in health. The model uses multi-item scales. The scales are scored using Likert’s method of summation rating.

Besides this measurement model, some objective test of a child’s physical condition, his/her mental capacities and social adaptability will be used in the study.

The cluster sampling study design will be implemented, covering all typical regions of Yugoslavia.

A pilot investigation, planned for May 1997, will give more information on the quality of these instruments and these results will be presented.

219. HEALTH-RELATED QUALITY OF LIFE IN PRE-SURGICAL TEMPORAL LOBE EPILEPSY PATIENTS
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Epilepsy surgery is an increasingly common treatment for intractable epilepsy and quality of life (QoL) evaluation has emerged as an important instrument to assess surgical outcome. We have established an epilepsy surgery programme with an extensive pre-surgical epilepsy evaluation including health-related QoL assessment at our clinic. The goal of this study was to evaluate subjective reports of psychosocial impairments in pre-surgical epilepsy patients and the relation of this difficulty to demographic, clinical and cognitive variables. We used the Bonner Psychosoziale Skalen für Epilepsie (BPSE) as an instrument for assessing health-related QoL which incorporates six scales derived from factor analysis with reported satisfactory item/scale reliability (Cronbach’s α). The six scales are as follows: physical well-being, capability/activity, relations to family, emotional well-being (mood), reduced independence and reduced coping. Additionally, all patients received the MWRT-B for IQ assessment and the Zerssen Depression Scale. We will report on the results of 70 pre-surgical TLE patients regarding the patients’ primary impairments related to epilepsy and the relationship of health-related QoL variables to seizure laterality, MRI scan, seizure onset, seizure duration, depression and MWRT-B IQ. The potential usefulness of the BPSE for QoL assessment will be discussed.

220. VALIDATION RESEARCH AND THE LIFE CYCLE OF HEALTH OUTCOME MEASURES
Nancy Kline Leidy
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The scientific utility of an instrument is directly related to its validity, the extent to which it measures what it intends to measure. Evidence of validity builds throughout the life cycle of an instrument, from conception through to maturity, with loss or lack of validity often responsible for a measure’s demise. This paper will discuss the critical role of validation research in the development and ongoing evaluation of health-related quality of life (QoL) measures for use in descriptive studies and clinical trials. Examples will be drawn from psychometric work underlying the Functional Performance Inventory, a relatively new
measure of functional status developed at the National Institutes of Health and two studies evaluating the validity of the Asthma Quality of Life Questionnaire (AQLQ) across sociodemographically diverse samples in the USA.

The paper will begin with a discussion of the use of qualitative research in the early stages of instrument development and the systematic procedures involved in content validation, including the utility of the content validity index in instrument evaluation. This will be followed by an examination of alternative methods for establishing or confirming construct and concurrent validity within and across target populations. Emphasis will be placed on clinical validation in small, intensively studied samples and psychometric validation using large sample survey methods. The paper will conclude with a discussion of the potential sources of variation in the construct validity of a measure as instruments are tested or used in varying diagnostic, cultural and socioeconomic groups, both within and across countries.

221. ADAPTATION TO THE EFFECTS OF DEPRESSION ON QUALITY OF LIFE AND ITS LIMITS: EVIDENCE FOR RESPONSE SHIFT

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An individual’s perception of the significance of a health impairment may change over time as he or she adapts to the health condition. We hypothesized that if patients with depressive illnesses adapt to their health condition, they might rate their current health as being substantially better than a similar hypothetical state. We tested this hypothesis using a set of six health states that summarized commonly seen interactions of loss of mental and physical health in depression. Health states were defined from using statistical analyses of the SF-12 mental and physical health scores of 716 patients with depressive symptoms. An independent group of 172 similar patients and 76 healthy volunteers completed an SF-12 and then rated their own quality of life (QoL) using a visual analogue scale (VAS) anchored on ‘perfect health’ and ‘death’. They then rated three of the six health states, chosen at random, which were described by ‘reversing’ SF-12 questionnaire items. Subjects’ SF-12 scores were used to determine which of the six states were most similar to their current health status. We compared subjects’ VAS ratings for the most similar hypothetical state to the VAS ratings of their current health. The patients had a mean SF-12 mental score of 40.4 and a mean physical score of 45.3, indicating substantial impairments in health. As hypothesized, the patients had significantly higher preference ratings for their current health than for the hypothetical health state (self = 0.68, hypothetical = 0.51 and p < 0.001). There was also a significant interaction between patients’ health state and the magnitude of the difference between the ratings (p < 0.012). The more severe their current health, the closer the hypothetical and self-health VAS ratings. Similar findings were seen in the healthy volunteers (p < 0.001 and 0.005, respectively). These results suggest that patients do adapt to illness and place less value on their own impairments than similar impairments in others. There are limits to this ability, however, as a more realistic view was found to pervade in those with poor QoL.

222. THE VALIDATION OF A NEW PATIENT QUESTIONNAIRE FOR DIABETIC NEUROPATHY

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The results of prospective studies indicate that diabetic patients with autonomous neuropathy have a higher mortality risk. Symptoms of neuropathy, in particular autonomous symptoms, are not easily detected and appropriately interpreted by the patient. A short questionnaire is presented for assessing the subjective symptoms of distal symmetric as well as autonomous diabetic neuropathy. The questionnaire was comprehensively validated with a large repertoire of methods and data. The self-assessing questionnaire consists of 22 items. They have to be scored pertaining to frequency and degree of averseness. The parts of the questionnaire are (1) symptoms of the periphery, (2) location of the complaints, (3) symptoms of the autonomous nervous system and (4) questions for general characteristics of the complaints e.g. at which time of the day do they occur. The questionnaire data was gathered together with objective clinical parameters of the disease (cardiovascular functioning testing with a computer-driven ECG system (ProSciCard)) and anamnestic data from 32 type-I diabetes patients with diabetic neuropathy. The parameters of cardiovascular functioning were summarized into four grades of severity. A newly developed method was used to analyse the extent of central nervous processing deficits for cardiac afferent signals.

As the main results were as follows. (1) With discriminant analysis the questionnaire data allowed a 96% correct classification of the patients into the four groups of severity. (2) High correlations between certain symptoms and the degree of severity of autonomic dysfunction indicated high validity. (3) A general test score by summing the single item scores correlated highly with the degree of severity, duration of diabetes, duration of neuropathy and HbA1c. (4) The principal component analysis reproduced two factors which correspond to the distal symmetric and autonomous dimensions of neuropathy. (5) The autonomous part of the questionnaire significantly correlated with the EEG data, whereas the sensory dimension did not.

As this short self-assessing symptom list for diabetic neuropathy proved to be highly valid, it is appropriate for the integration into quality of life (QoL) measurement. We conclude that this symptom scale is suited for the purpose of patients’ screening as well as for the evaluation of therapeutic interventions.

223. CHANGES OF QUALITY OF LIFE AND MOOD AFTER PACEMAKER IMPLANTATION

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It is reported in the literature that patients complain about emotional problems after pacemaker implantation (PMI). On the other hand, more and more often the indication ‘improvement in quality of life (QoL)’ is used for PMI. This study investigated the change of QoL and mood at three points in time: some days before PMI and 4 and 12 weeks after surgery.

Forty-two patients (mean age 63 years, 26 men and 16 women) with bradycardia or other heart conditions (n = 3), A–V block (n = 9), sinus node syndrome (n = 21) and other diseases (n = 3) participated in the study. They completed a disease-specific health related QoL questionnaire (Hacettepe Quality of Life Questionnaire) and a mood questionnaire (Profile of Mood States, POMS).
Three out of eight dimensions of the QoL questionnaire yielded significant improvements 3 months after surgery. The dimensions physical symptoms and activity, appetite and work performance represent more physical aspects of QoL. The POMS and its mood scales fatigue, depression and anger indicated an improvement immediately after surgery but this effect declined over time and only remained stable after 3 months for depression.

Subgroup analysis showed more improvements for patients with frequency adaptive systems in comparison to systems over time and only remained stable after 3 months for performance represent more physical aspects of QoL. The POMS dimensions physical symptoms and activity, appetite and work yield significant improvements 3 months after surgery. The HIV-QL31 (Kidney Disease and Quality of Life) questionnaire developed by Ron Hays and collaborators in 1994. It is a self-administered questionnaire that associates a generic module, the MOS SF-36, comprising 36 items divided into eight dimensions and a specific module adapted to renal pathologies, comprising 43 questions in 11 dimensions.

The different translation phases were in line with standard techniques. Following this, a test–retest study was carried out on 70 haemodialysis or peritoneal dialysis patients in five different centres. The results confirm the validity and reliability of the questionnaire, since the translation did not alter the psychometric properties of the instrument. The sample was too small to highlight any difference in terms of QoL between haemodialysis and peritoneal dialysis patients. However, the dimensions relations with family and friends and role of carers obtained higher scores in peritoneal dialysis. Questions relating to sex life showed a high rate of missing data, which might be related to a cultural problem.

It would now appear that the French version of the KDQoL is suitable for use in the assessment of health-related QoL in patients with chronic kidney failure. It should be implemented in strict accordance with the methodology set out.

225. MEASURING QUALITY OF LIFE FROM THE POINT OF VIEW OF HIV-POSITIVE SUBJECTS: THE HIV-QL31

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The assessment of quality of life (QoL) of HIV-infected subjects is often based on questionnaires in which the items or questions are not seen to be relevant by patients, nor by the users of the data obtained. It therefore seemed appropriate to return to the issue. The methodological and bibliographical research as well as the consultations we conducted convinced us that the elaboration of a new questionnaire was both necessary and possible. In order to do so, we adopted methodological principles based on the Impact Profile development methodology. First, a bibliographical research was conducted in order to study instruments already used for HIV infection. Then, experts concerned with HIV infection and members of patients’ associations were interviewed to assess how opportune the development of a new instrument could be. Following this, a methodology was established for the design and construction of the new instrument.

One hundred and eighteen candidate questions were generated from the analysis of the content of 20 patients’ interviews, which were subsequently submitted to 102 patients, to finally obtain a set of 31 questions from interpretation of the results obtained from classic psychometric analysis and also from non-classic methods (item response theory and Rasch model). The concept being measured is the impact of illness being experienced by HIV-infected subjects from their own perspective. The range of health states covered by this questionnaire relates to fairly mild conditions. Rasch analysis of this set of 31 questions (HIV-QL31) shows that it corresponds to one unidimensional construct. A single score can be calculated by simple summation of dichotomous response options. This score is highly reliable (Cronbach’s α = 0.93) and is also discriminant regarding the severity of clinical status.

226. TOWARDS A METHODOLOGY FOR SYNERGY BETWEEN QUALITY OF LIFE AND MEDICAL TECHNOLOGY ASSESSMENT

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Medical technology is penetrating the health care system at an accelerating pace. This urged the different policy levels to introduce assessment procedures. Today, new medical technologies (NMT) are nearly always assessed for both medical and economical consequences. Investigating the social consequences is not always done in the assessment procedures (e.g. IVF, cochlear implants, gender clinics, etc.). However, social research on the effects of technologies demonstrates that there are societal effects of NMT. Quality of life (QoL) research shows that the subjective elements are important as clearly as the Quality Assessment of Care proves that the judgement of the patient can provide substantial information. Technology assessment (TA) as a methodology urges an inclusion of all concerned parties (i.e. also the perspective of the patient) in an early stage of the technology process. In health care, however, this methodology does not get much attention.

A TA project of the Medical Social Sciences at the Free University of Brussels focuses on the way scientific and technological developments in the medical world affect the process of professional care assistance. More specifically, it will study the social consequences of NMT on the characteristics of professional care assistance occupations, the organization of work and the role and autonomy of the patient. The methodology used in this study (incorporating quality of care and QoL dimensions) and preliminary results will be presented.
227. WHAT FIGURES DO NOT TELL ABOUT QUALITY OF LIFE: A COMPARISON BETWEEN QUANTITATIVE AND QUALITATIVE ASSESSMENT OF QUALITY OF LIFE OF PEOPLE WITH CHRONIC SCHIZOPHRENIA
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Critical reviews of the theoretical background and recent empirical findings of quality of life (QoL) research in psychiatry have shown that many empirical studies in this field supply results which are hardly interpretable by the underlying theoretical models. One important reason for these difficulties results from the fact that though all existing theoretical concepts of QoL of the mentally ill emphasize the central importance of patients’ subjective assessments of their objective living conditions, they largely neglect questions concerning the dynamics and factors influencing these subjective assessment processes. Since quantitative studies do not allow us to make statements regarding the evaluation processes at the root of meanings assigned to important dimensions of people’s QoL, a qualitative approach for the assessment of QoL of the chronically mentally ill has been developed using a semi-structured interview and a computer-based content analysis. In order to understand what lies behind the life satisfaction data, i.e. what people mean by being satisfied with their living situation or not, the qualitative data from the analysis of interviews were further compared with the quantitative measurements of the German version of the Lancashire Quality of Life Profile. The sample consists of 50 chronically schizophrenic patients (ICD-9) in out-patient treatment. The comparison between the results of the quantitative assessment of life satisfaction and the results of the content analysis shows that many of the apparently perplexing results of quantitative assessment are actually explicable by means of the deeper knowledge of the patients’ particular interpretation of their perceptions and experiences obtained by qualitative analysis.

228. DEVELOPMENT AND VALIDATION OF THE GENERIC QUALITY OF LIFE INVENTORY IN CHINA
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The purpose of the study was to develop a new generic quality of life (QoL) instrument for the general population in a community. Based on the theory and methodology in developing a rating scale, a new Generic Quality of Life Inventory (GQoLI), including 112 items grouped into four dimensions of physical health, psychological health, social function and living condition and two axes objective life status and subjective life satisfaction, was designed and tested with 8,550 urban and rural subjects by stratified random-cluster sampling in Hunan Province of China. Of the 112 items, 64 items were found to be highly representative of GQoLI by means of item-scale correlation and factor analysis. Then the GQoLI with these selected 64 items was tested for its reliability, validity and sensitivity. The results showed that the test–retest reliability, interrater reliability and internal consistency reliability of the GQoLI were adequate. In addition, the outcome indicated that the construct and concurrent validities of the GQoLI were satisfactory. Factor analysis identified eight factors accounting for 67.7% of the total variance, which could be ideally grouped into four dimensions as above. Meanwhile the GQoLI was sensitive in differentiating different subpopulations. The GQoLI can be used to evaluate and analyse both objective and subjective aspects of QoL in the general population.

229. INTERPERSONAL COMMUNICATION MODEL FOR BETTER QUALITY OF LIFE
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Interpersonal communication is defined as the act of exchange of information between individuals that participate in that process. The aim of this theoretical work is to expose our concept of interpersonal communication, as a result of our experience and work inside the systemic approach in psychiatry. We made a synthesis of knowledge from the universal system theory, universal living system theory, information theory and communication theory. We highlight the fact that interpersonal communication is not only exchange of information, but involves a framework for the involvement of interpersonal exchange. From the basis of system approach in psychiatry, we made a concept of interpersonal communication that provides an adequate process of interpersonal exchange. Finally, this model maintains the possibility that different variations in behaviour in psychiatric disease could be connected with an inadequate model of interpersonal communication. In our paper this model is presented, in different forms, by diagrams.

230. CHANGE IN QUALITY OF LIFE AS A MEASURE OF TREATMENT EFFECT IN PATIENTS WITH MULTIPLE SCLEROSIS
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Determinants of change in quality of life (QoL) measured longitudinally are multifactorial and related to QoL perceptions prior to treatment, the course of disease and treatment effects. The purpose of this study is to examine the specific contribution of treatment to patients’ perceptions of their QoL. One hundred and thirty consecutive patients with a definite or probable diagnosis of multiple sclerosis (MS) initiating care at a specialty centre were followed for 1 year. Pre-treatment perceptions of QoL were measured using the SF-36, sociodemographic characteristics (age, family history of MS and duration of MS diagnosis), disease status (disease course since onset and over the past year and Expanded Disability Status Scale or EDSS (a standardized measure of impairment)), and physician assignment were obtained for each patient. At 1 year, data on the costs of care, visits to ancillary services (nursing, physical/occupational therapy, social work and psychology) and a reassessment of QoL were obtained. Differences in QoL outcomes were determined for the patients of the three treating physicians using Student’s t-tests. Multivariable models for change in specific QoL domains were created controlling for factors present before and during treatment. Pre/post-treatment QoL data were available on 74 (56.9%) individuals. This subgroup had a mean age of 43.7 years (± 10.2), a mean duration of disease of 12.3 years (± 10.8), a family history of MS in 21.6%, a median EDSS value of 3.5 indicating limited disability and 1 year mean costs of care of $1,178 (± 1,438). Group changes in QoL domains following treatment ranged from a decrease in general health (-4.03 ± 24.36) to an improvement in role physical (10.27 ± 39.71) and bodily pain (15.81 ± 25.81). Although no differences in the costs of care or ancillary service
use were noted among patient groups by the physician, the mean general health was better for patients of physician 1 compared with others (mean difference 13.78 (2.06, 25.51)) as was the mean physical functioning for those treated by physician 2 (mean difference 17.14 (0.435, 33.85)). In models using change in physical functioning (model 1) and general health (model 2) as the dependent variables, physician assignment was the most significant factor associated with both (model 1 $r^2 = 0.06$ and $p = 0.036$ and model 2 $r^2 = 0.15$ and $p = 0.002$).

QoL domains of the SF-36 may be useful as indicators of treatment effect in patients with MS. Using this approach, the effectiveness of medical care may be enhanced by directing patients to providers more successful in effecting meaningful changes in specific areas.

231. THE APPLICATION OF QUALITY OF LIFE TO GASTROENTERIC DISEASE

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This thesis was the result of research into 53 cases of patients suffering from peptic ulcer, chronic superficial gastritis, chronic atrophic gastritis, chronic colitis and reflux oesophagitis with the improved WHOQoL-100. The instrument applied in this research has deleted the repetitious items and added the contents characterized by TCM (traditional Chinese medicine). The FSJ (fuzzy synthetic judgement) and PTT (paired $t$-test) was applied to analyse the results of this thesis. The results showed that quality of life (QoL) of those patients suffering from gastroenteric diseases declines to a medium extent (medium→light→normal→heavy→very heavy). This thesis also made a comparison of QoL between out-patients and in-patients. The results of FSJ showed that the QoL of out-patients declines to a light extent and that of in-patients to a medium and heavy extent. The differences in QoL for these two groups of patients were obvious.

The QoL of 24 patients who have been treated with a traditional Chinese drug for 1 month is analysed in this thesis. The results of FSJ showed that their QoL declined to a medium extent before treatment and to a light extent after. The results of PTT also showed that the QoL was better after treatment than before (the comparison of five classes was of statistical significance, $p < 0.01$). All these proved that the traditional Chinese drug was of good curative effect in treating the gastroenteric disease being measured by the standard of QoL.

The research results also showed that the living standards and financial situation of the family were affected to a certain degree after the patients received medical care and declined gradually if the diseases were worsening and lasting. This means that an economic factor plays an important role in the course of treatment in China.

The results of the research also indicated that the suffering and treatment of the disease had no apparent effects on the patients’ habits, such as physical training, entertainment, etc. The conclusion is that individual life styles are probably determined more by temperament and habits than the suffering and treatment of illness.

232. ARE BALINT GROUPS AND PSYCHOANALYTIC GROUPS IMPORTANT FACTORS IN QUALITY OF LIFE OF NURSES IN PSYCHIATRIC HOSPITAL?–A CROATIAN EXAMPLE

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In one of the largest psychiatric hospitals in Croatia, Popovača, almost all the nurses have been included in specific groups, either Balint or psychoanalytic or both. After completing such a large task of giving such an opportunity for personal growth to psychiatric nurses in that hospital, a question posed itself almost immediately: do these nurses see their own quality of life (QoL) as higher than those nurses who have no such experience?

We compared self-measured QoL scale results in psychiatric nurses in two large psychiatric hospitals in Croatia, in Popovača, the one in which Balint groups as well as psychoanalytic therapy groups were organized and of another where they had no such groups.

The hypothesis was that those nurses who underwent specific groups estimated their own overall better QoL as higher than those who did not.

QoL was measured by specific self-measurement scales and compared. The differences in the two groups were analysed regarding the most important areas of life such as their work, family and their overall feeling of contentment. In addition, differences regarding gender were analysed as well.

233. QUALITY OF LIFE IN INSOMNIACS WITH A POST-MENOPAUSAL SYNDROME

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The aim of the study was to investigate quality of life (QoL) in post-menopausal syndrome patients with insomnia (ICD-10 G47.0 and N95.1) before and after treatment with hormonal replacement therapy (2 mg Estradiolvalerate plus 3 mg Dienogest) for 2 months as compared with normal controls.

Thirty women, aged 46–67 years (mean 57.3 years and SD 5.65 years), were investigated regarding QoL, psychological general well-being (PGWB), clinical symptomatology (Kupperman-Index, KI) and subjective quality of sleep (Pittsburgh Sleep Quality Index). The inclusion criteria were a KI > 15, post-menopausal status of over 2 years, no previous hormonal treatment for the previous 6 months, no psychopharmacological treatment and no major depression according to DSM-III-R. Noopsychic and thymopsychic function was investigated by the Grünberger Verbal Memory Test, the Alphabetical Cross-out Test (Grünberger), the Freiburger Personality Inventory and the State–Trait–Anxiety Inventory in order to correlate with QoL.

Patients with insomnia (PSQI = 11 and SD 0.4) and post-menopausal syndrome (KI = 29, and SD 0.7) demonstrated lower QoL (QoL = 57 and SD 0.18), lower psychological general well-being (PGWB = 58 and SD 0.22) than normal controls (QoL = 85, SD 0.7, PGWB = 105, KI = 15 and PSQI < 5). Correlations showed significant relationships between subjective quality of sleep and...
QoL and between clinical symptomatology and PGWB. After treatment increases in QoL (QoL = 76 and SD 16), PGWB (PGWB = 77 and SD 14), clinical symptomatology (KI = 11 and SD 5) and subjective quality of sleep (PSQI = 8 and SD 3) could be found. Moreover, anxiety levels changed highly significantly (before treatment STAI = 46 and SD 11; afterwards STAI = 39 and SD 11, p = 0.0078) and depression (FPI3 pre = 11 and SD 18, Fp13 post = 7, SD 3) and extraversion increased from FPI10 pre = 4 and SD 2) to FPI10 = 6, (SD 2, p = 0.0001).

Physical problems, emotional handicaps and subjective disability to sleep minimize QoL. After treatment with HRT, QoL, satisfaction with treatment and health care. QoL associated with ageing and other co-morbidities and patient and/or disease progression, changes over time in health-related information about the QoL associated with specific therapies. We report on the study results. The length of follow-up varies from a minimum of 3 months to up to 6 years for the more established databases. All three health-related QoL instruments have demonstrated high internal consistency reliability, test–retest reliability, validity and responsiveness to change. We report on the study results comparing disease progression and therapy for each condition.

Observational databases are useful in evaluating large amounts of data in a timely fashion and evaluating outcomes in usual care settings. The information available from the patients obtained in these databases provides practising physicians with information about the QoL associated with specific therapies and/or disease progression, changes over time in health-related QoL associated with ageing and other co-morbidities and patient satisfaction with treatment and health care.

234. INCORPORATING QUALITY OF LIFE ASSESSMENT IN OBSERVATIONAL DATABASES
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Implicit in the concept of patient outcome assessment is a shift from reliance on measures of medical process to elements of direct importance to the patient. This is especially true of chronic health conditions where treatment can profoundly alter patient well-being. This research reports on the use of health-related quality of life (QoL) measures in observational databases.

We have initiated patient self-report of health-related QoL in databases for three chronic conditions: HIV infection, risk factors for musculoskeletal disease and prostate cancer. Data are collected from the physician and patient. Clinicians complete medical histories and progress notes at each prospective office visit. Patients complete baseline and quarterly or semi-annual questionnaires covering health-related QoL, resource utilization, work loss and satisfaction with care as long as they are enrolled.

Health-related QoL instruments include both general (physical, emotional and social functioning, pain, health concern and fatigue) and disease-specific domains (severity and frequency of symptoms and problems).

Approximately 2,000 patients are enrolled in the HIV and in the musculoskeletal study and over 3,500 in the prostate cancer study. The length of follow-up varies from a minimum of 3 months to up to 6 years for the more established databases. All three health-related QoL instruments have demonstrated high internal consistency reliability, test–retest reliability, validity and responsiveness to change. We report on the study results comparing disease progression and therapy for each condition.

Observational databases are useful in evaluating large amounts of data in a timely fashion and evaluating outcomes in usual care settings. The information available from the patients obtained in these databases provides practising physicians with information about the QoL associated with specific therapies and/or disease progression, changes over time in health-related QoL associated with ageing and other co-morbidities and patient satisfaction with treatment and health care.

235. VALIDATION OF A ONE-PAGE FORMAT OF BPH-SPECIFIC HEALTH-RELATED QUALITY OF LIFE QUESTIONNAIRE 9 ITEMS (BPHQoL9)
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We developed and validated a one-page format for a validated BPHQoL9 questionnaire. As recommended by international consultation on BPH, the aim was to obtain a more practical and useful questionnaire, easy to administer without modifying the psychometric characteristics of the original format.

The original format of the BPHQoL9 is a nine-page booklet with one question per page and a 10 cm visual analogue scale (VAS) for each answer. The new format is one page with the nine questions; for answers we used a modified VAS divided into five parts, which allows an immediate scoring by a semi-quantitative method. Each part of this scale is scored from one to five. In this study, patients completed both formats of the BPHQoL9. The sequence of the questionnaires was randomly assigned. We noted the patient preferences of format. We used the Wilcoxon test (sequence of questionnaire) and intraclass correlation test (test–retest reliability).

Fifty-two patients (mean age 63.1 ± 1.7 years) were included. No difference was observed depending on the questionnaire sequence. The test–retest reliabilities between the VAS original format scores and VAS one-page format scores were global score 0.97, bothersomeness subscore (BPH–specific interferences with activities) 0.94, patients perceived sexual life subscore 0.97 and overall quality of life (QoL) subscore 0.96. The test-retest reliabilities between the VAS original format scores and semi-quantitative one-page format scores were global score 0.94, bothersomeness subscore 0.91, patients perceived sexual life subscore 0.94 and overall QoL subscore 0.93. The patient preferences of format were booklet 2 (3.8%), one-page 27 (52%) and no preference 23 (44.2%).

The scores obtained with the one-page format and the original format of BPHQoL9 were very well correlated. Immediate scoring is easy to interpret. The one-page format is preferred by patients and can be used in routine practice.

236. VALIDATION OF A SHORT-FORM QUALITY OF LIFE QUESTIONNAIRE FOR BENIGN PROSTATIC HYPERPOTRYPHY
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As recommended by the WHO, quality of life (QoL) is now a mandatory measurement in the assessment of therapeutic outcomes of benign prostatic hypertrophy (BPH) treatment. This work had two goals: (1) to obtain a short form questionnaire, BPH specific, multiaxial, practical to use, easy to administer and able to capture patients’ perceived QoL and (2) to compare the domains explored by the International Prostatic Score Severity (IPSS) and this questionnaire.

From a validated 20-item BPH-specific questionnaire (QL20) a short-form questionnaire of nine items (QL9) was derived by theoretical mathematical modelling using a multiple regression.
test and principal component analysis. For the psychometric validation of this nine-item questionnaire (QL9), a cross-sectional study (test-retest) (CS) and a longitudinal study (open cohort study) (LS) were performed: the CS enrolled 48 BPH patients and 42 controls matched by age while LS enrolled 5,551 BPH patients treated with alfuzosin in a 6 month open labelled trial.

The QL9 can derive 92% of the information on health-related QoL that can be obtained using the QL20. The QL9 was practical to use (compliance 87-100% and duration of completion at inclusion 11.6 ± 2.0 months), valid (construct validity Cronbach’s α > 0.7 and discriminant validity p = 0.0004 between patients and controls in the CS), reproducible (intraclass correlation coefficient > 0.7) and responsive (effect size index 0.9 ± 0.01 in the LS compared to 0.001 ± 0.08 in the CS). The correlation between IPSS and QL9 is very low (−0.42) and the eighth IPSS question (QoL question) had a better correlation with the dSYM (−0.61) than with the dQOL (−0.19) or dSEX (0.08).

The QL9 is a short BPH health-related QoL questionnaire, easy to administer, valid, reproducible and responsive to change under α-1 blocker treatment. The QL9 captures sexual drive. The IPSS and QL9 do not explore the same domain but are complementary.

237. CANCER PAIN RELIEF AND QUALITY OF LIFE RESEARCH IN CHINESE CANCER PATIENTS
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Quality of Life (QoL) research in particular that of cancer patients is an increasingly recognized subject. Foreign QoL research has a history of years which is the prime of human life, while that of Chinese cancer patients is now in its infancy, beginning at the end of the 1980s. During the first WHO-China Training Course for Cancer Pain Relief and Palliative Care in 1990, Professor Yan Sun, Director of the Department of Medical Oncology, Cancer Hospital (Institute), Chinese Academy of Medical Sciences (CAMS), initiated the Cancer Pain and Quality of Life Inventory and from 1991 to 1992 conducted a multicentre prospective survey among 1,543 cancer patients from 11 cancer hospitals or cancer divisions of general hospitals, which were distributed in the cities of Beijing, Nanjing and Nanchang. The preliminary results showed that the questionnaire was reliable, valid, sensitive and feasible. Since then, we have been following an exploratory and systematic approach to the subject, being the first to introduce, revise, pre-test and evaluate several famous foreign cancer-specific QoL scales with satisfactory cross-cultural comparative study results, such as the Functional Living Index – Cancer (FLIC), the Quality of Life Index (QLI), the Breast Cancer Questionnaire (BCQ), etc. On the basis of these achievements, we developed the Quality of Life Questionnaire for Chinese Cancer Patients with chemotheraphy (QLQ-CCC) in 1994 and in 1995 administered and assessed it among the cancer patients.

In addition, with Professor Yan Sun’s advice and help, we have also been conducting thorough and painstaking study in the fields of cancer pain relief and palliative care. In 1992 the Pain Clinic opened for the purpose of achieving interdisciplinary approaches to cancer pain and other symptoms. Since 1993, we have been trying to apply psychological counselling/psychotherapy to palliative care as well as routine medical practice and to carry out an economic analysis of cancer care aiming at improving patients’ quality-adjusted time without symptoms and toxicities (Q-TWiST) and quality-adjusted life years (QALYs).

Future challenges are as follows. (1) Emphasis should be placed on the role of social psychological factors in the occurrence, development and transition of cancer (psycho-oncology); (2) to strengthen and extend the QoL research among cancer patients, (3) to pay more attention to the economic analysis of cancer treatment and (4) to spread QoL-related knowledge and technology.

238. MAKING QUALITY OF LIFE A MEANINGFUL END-POINT IN CANCER CLINICAL TRIALS
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National Cancer Institute, USA

Quality of life (QoL) assessments in a phase III trial must answer whether the different treatment arms have different effects on patient well-being. In times of limited resources, investigators must determine whether QoL evaluation should be part of a trial and then how to collect QoL data effectively. In some trials, the survival, disease-free interval and toxicity may be adequate proxies for QoL. The QoL instruments chosen should be sensitive enough to detect small differences in a setting with considerable similarity between patients and the treatment regimens. When treatment outcomes are similar, QoL may become the most important end-point for a trial.

239. QUALITY OF LIFE IN CANCER CHEMOTHERAPY RANDOMIZED TRIALS
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During the past decade, there has been a rapid increase in the number of quality of life (QoL) studies reported in the cancer literature, but attempts to synthesize and describe this literature have been lacking. In an effort to examine the cancer QoL literature from 1990 to 1995, a systematic review of over 900 journal articles was undertaken. Among these are 156 that provide descriptions of QoL associated with cancer chemotherapy interventions. Of these 156, 24 (15%) are randomized treatment trials with a pre/post design that measures QoL in two or more domains. In this paper, we will characterize these 24 studies in terms of the populations studied and their overall rigour; comparisons to the larger body of cancer chemotherapy studies will be made.

The largest proportion of these studies was conducted in the UK (37.5%), followed by the US (25%) and Switzerland (12.5%). They primarily reported on interventions with breast (37.5%) or lung (37.5%) cancer patients; none of the studies reported separate results for minorities, the elderly or paediatric patients. A broad range of instruments was used in the studies; those most frequently used were some form of linear analogue scale (33%), some form of the EORTC (17%) and the RSCL (17%). Most studies (83%) employed one or more standard instruments. Keeping with the conceptualization of QoL as a multidimensional construct drawing on patient reports, the studies reported on an average of 3.6 domains (median 3.5) and the most frequently used data collection method was patient surveys.
Aggravating factors, including heat, exertion, alcohol, stress and certain food additives. Furthermore, treatment for urticaria with antihistamines frequently results in side-effects such as fatigue or sedation. Clinical measurement of urticaria is difficult and is reliant on patient self-report of weals and symptoms (such as pain, itching and frequency), thus indicating a need for a measure of overall impact of treatment on quality of life (QoL). The purpose of this study was to develop and validate a QoL questionnaire specific to urticaria. A literature search identified several dermatology-specific instruments, though none had been developed for or used in chronic urticaria. Nineteen patients in the UK, Germany, Italy and France were interviewed regarding the impact of urticaria and its treatment. The in-depth interviews confirmed that several QoL domains were impacted on to some degree by urticaria or its treatment. Based on the interviews, a battery of instruments, including the PGWBI, DLQI and MOS role, cognitive, sleep and sexual functioning scales, were compiled to assess all the relevant domains mentioned by the patients. Additional items were also developed specifically for urticaria. In a UK pilot study, 54 patients completed the questionnaire. All scales exceed the acceptable level of reliability (alpha >0.70) and 87% of subjects had no missing data. Preliminary clinical validity was also demonstrated for the DLQI, sleep, role functioning and PGWBI scales and preliminary evidence for responsiveness was demonstrated for the DLQI and the augmented urticaria-specific items. The application of the current questionnaire to clinical research and urticaria severity assessment will be discussed.

241. DEVELOPMENT AND VALIDATION OF AN URTICARIA QUESTIONNAIRE
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Approximately 15–20% of the general population experience one or more episodes of urticaria, colloquially known as hives or nettle rash. While the aetiology of chronic urticaria remains unclear, patients are often advised to avoid or minimize potential

240. THE CHQ-PF50 – A NEW HEALTH INSTRUMENT FOR ASSESSING CHILD HEALTH OUTCOME
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The Regional Health and Social Services Strategy for Northern Ireland has emphasized the importance of targeting resources towards areas of greatest health and social need. The Eastern Health and Social Services Board (EHSSB) area includes some of Northern Ireland’s most deprived and affluent areas. Against this background an assessment was undertaken of the morbidity levels of children within the EHSSB.

The objectives of this study were to generate a baseline of information relating to children’s health status and lifestyle, to determine levels of deprivation experienced by children and to identify environmental and social factors influencing the health of the child.

This was a representative sample of 2,513 children born in 1989. Three questionnaires were used to collate information on the health status of the child. They were administered by a health visitor in the child’s home. The standardized health instrument used in this study was the Child Health Questionnaire – Parent Form 50 (CHQ-PF50). This questionnaire was developed by the Medical Outcomes Institute in Boston. The instrument describes health over 15 items and is self-completed by a parent on behalf of their child. This is its first use in either Britain or Ireland.

The study was carried out in late 1996 and achieved a 64% response rate. The morbidity levels for this study were higher than national figures. The reported levels of limiting long-term illness was 17.7%, asthma 21.9%, vision problems 13.5% and hearing problems 10.8%. The CHQ-PF50 scales were found to be reliable at a population level with nine scales achieving α coefficients greater than 0.7.

The CHQ-PF50 proved valid, reliable and acceptable to respondents and provides a useful tool for assessing children’s health.

242. DEVELOPMENTS WITH THE QUALITY OF LIFE IN DEPRESSION SCALE
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The Quality of Life in Depression Scale (QLDS) was the first measure developed that employed the needs-based quality of life (QoL) model. As the measure is now widely employed in clinical trials, it is an opportune time to review its current status.

The original QLDS was developed simultaneously in the UK and The Netherlands. Nine additional versions have been developed and validated for the major European and North American countries. Each version has been shown to have excellent internal consistency, test–retest reliability and construct validity. Clinical studies have shown that the measure is highly responsive to the changes in QoL associated with improvements in the severity of depression. The measure is now included in a number of international clinical trials of antidepressant therapies.

Application of Rasch analysis to QLDS data from Spain and the UK indicates that the measure is fundamentally unidimensional. However, despite its high responsiveness, there is evidence that some respondents fall outside the QLDS’s measurement range. Thus, change scores for such individuals would not represent the true change in QoL. It is proposed to initiate a study to widen the range of the measure by identifying items representing mild and severe QoL impairment. The opportunity will also be taken to improve the efficiency of the measure by removing some items that have the same construct value as others in the scale and by removing items that demonstrate bias associated with age, gender or severity of depression.

The new version of the instrument will provide even more precise and efficient outcome measurement for clinical studies and trials. The increased responsiveness will also prove valuable in investigating the onset of action of antidepressants and for monitoring maintenance depression therapy.
243. MEDICAL AND INTERVIEW METHODS IN 200 MALIGNANT MELANOMA OUT-PATIENTS
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This study considers two objectives: a practical problem and a basic research question. These objectives were (1) to give malignant melanoma patients earlier survival predictions and (2) to study the possible relation between individual loss of well-being and the risk of death. Large scale studies on groups of patients are clearly the method of choice for clinical trials aimed at finding the most reliable forms of treatment for melanoma. However, such precise statistically based studies obtaining good group data must inevitably take years to obtain. However, even then, such group data do not have a specific answer for the patient who asks just after his/her biopsy, 'How long have I got left to live?'. Two methods were compared as regards their predictive accuracy. First of all, interviews estimated the level of well-being and symptoms. Secondly, a new medical index of metastatic spread (Mfree) was calculated, based on the number of metastases in the body.

We found that one-third of our cases had waited between 1 and 9 years after their diagnosis before metastatic spread occurred to justify a definitive fatal prognosis. The remaining two-thirds of our patients were denied this mixed blessing of any such exact predictions because the disease had no secondary spread. The value of using only interviews was confirmed. Many of the patients (80 out of 200) did well on the interviews by scoring 85% or better. Nearly all these patients who 'passed' these quality of life (QoL) interviews were survivors; the single exception was a patient who died after a borderline score of 86% (1/80 = 1%). The 120 patients who ‘failed’ the interview were much more likely to die since as many as 26 patients did not survive the study, (26/120 = 22%). The Kaplan–Meier statistical comparisons also showed that the predictions from the interviews were sufficiently accurate. They were almost but not quite as precise as the medical prognoses based on metastatic spread.

For believers in the reality of mind–body interactions this result may mean that it was the QoL losses that directly caused the extra deaths by metastatic spread. However, for the non-believers, this same result may mean that the QoL losses were measuring the greater chemotherapy side-effects from the more aggressive chemotherapy prescribed for the patients who appeared sicker or had a Breslow history of thick primary lesions. Future prospective studies more systematically controlling the chemotherapy would decide between these alternatives.

244. MEASURING WELL-BEING AND COGNITIVE LOSSES IN BRAIN TUMOUR PATIENTS
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In an ideal world, all brain tumour patients would have a 30 min evaluation every 3 months, even in a busy clinic. These quarterly neuroscientific examinations would document two symptoms: (1) loss of well-being and (2) loss of working memory to assist in prognosis.

The well-being approach is based on personal experience with two sets of interviews. The first series was on 200 brain tumour patients seen at the Department of Neurological Surgery, University of California, San Francisco. The second series was on 200 melanoma patients interviewed at the Division of Medical Oncology in the University of Colorado Health Sciences Center in Denver, Colorado. The interview now in use is a 10 min version based on Aaronson’s methodology.

Our working memory approach adopts the punch-line method. This is a new procedure we devised specifically to detect cognitive losses in brain tumour patients. The patients read 20 three-sentence stories, each of which is printed on its own page. Each such display has often altered the usual order of the sentences. The concluding punch-line is not always printed at the bottom of the page. Sometimes it appears at the top of the page, sometimes in the middle and sometimes at the bottom. The stories are shown one at a time and the patient is asked to find and point at the punch-line. The measure of their achievement is the percent accuracy with which they can do this task. Twenty brain tumour patients have been studied so far. Individual well-being and memory readings both spread over the maximum possible range from nearly 100% down to 0%. Well-being losses definitely impacted the punch-line scores in some patients. Those with low well-being scores, of 34% or less, averaged much lower punch-line scores of 77%. The punch-line needs an intact right hemisphere for success. Those with left-sided lesions had high punch-line scores of 77% before and after surgical excision. However, those with right-sided lesions had punch-line scores of only 55% before excision and 48% after surgery. The reasons for this result will be discussed in detail.

245. QUALITY OF LIFE IN PATIENTS WITH PROSTATE CANCER: A DESCRIPTIVE STUDY
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The present day study aims at the determination of the quality of life (QoL) effects of prostate cancer in relation to the various treatment modalities. It is part of the evaluation of the Rotterdam screening programme for prostate cancer and it is conducted alongside the European Randomized Study of Screening for Prostate Cancer (ERSPC). The overall evaluation of the screening programme includes standardized QoL assessments in the screening phase and the phases of primary treatment and advanced disease.

To perform the QoL study, relating to primary treatment, patients with prostate cancer were recruited from four urology departments of Rotterdam hospitals. QoL is assessed at three measuring points in time: t1, baseline (shortly after diagnosis and preceding the treatment decision), t2, 6 months later and t3, 1 year later. The questionnaire contains generic QoL measures (the SF-36, COOP/WONCA charts and EuroQol), disease-specific QoL measures (the Dutch version of the UCLA Prostate Cancer Index), domain-specific QoL measures, assessing anxiety and depression (the STAI and CES-D) and demographic questions. The t1 assessment includes retrospective items relating to the period directly after primary treatment as well as items regarding the present situation of the patient.

Since 1 June 1996, 220 patients, either screen detected or clinically diagnosed, have already been included in the QoL study. Patient inclusion will continue until n = 400 patients will be recruited. The response rate at t1 is 96%. Up to now 96% of all t2 questionnaires have been returned. The participating patients were treated by radical external beam radiotherapy (60%), radical...
prostatectomy (28%) or hormonal therapy (7%). The ‘watchful-waiting’ group consisted of 5% of all included patients. The QoL data with respect to the mentioned treatment groups are currently being processed. The first results will be presented.

In the end, the study will provide insight into the QoL effects of various treatments for prostate cancer. Moreover, it will enable the incorporation of those specific effects into the overall evaluation of a population-based screening programme for prostatic cancer.

246. THE SATISFACTION PROFILE: A NEW INSTRUMENT IN QUALITY OF LIFE ASSESSMENT
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Recently, satisfaction has received more attention and can be considered a meaningful aspect of patients’ quality of life (QoL) and so it is important to evaluate both the negative and positive aspects related to the disease. No such instruments are available in Italy. We developed a new questionnaire, the Satisfaction Profile (SAT-P), purposely designed for assessing patients subjective satisfaction.

The SAT-P is composed of 32 items related to 32 daily life aspects; the patient is asked to evaluate their own satisfaction level for each item during the previous month. Four hundred and ninety-two subjects were enrolled: 313 during rehabilitative hospitalization who were suffering from severe chronic diseases, 60 who had had a myocardial infarction 6 months before, 66 who were attending a general practitioner surgery and 53 subjects working in our institute.

The data were analysed first examining the SAT-P’s psychometric properties and then comparing disease severity, age and gender. Factor analysis indicated the presence of five factors which correspond to the hypothesized areas: psychological functioning, physical functioning, work, sleep/eating/leisure and social functioning. The test-retest reliability was satisfactory and Cronbach’s α coefficient was 0.92. Comparative data analysis showed that in chronic patients satisfaction is always negatively affected, but not in every life area: on the whole the psychological and social functioning satisfaction levels are usually quite high. Overall, the results provide concurrent, divergent and construct validity for the scale.

These results support the bidimensional impact of illness experience. Patients may focus on positive changes, such as in priorities and relationships, their hierarchy of values can be modified and personal resources can be activated to cope with the disease better.

The SAT-P helps in therapeutic interventions, focusing attention both on patients’ needs and resources.

247. QUALITY OF LIFE IN PATIENTS WITH LONG-STANDING PERIANAL CROHN’S DISEASE
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Perianal Crohn’s disease (CD) is frequently associated with multiple local operations but quality of life (QoL) assessments have not been reported so far. We therefore evaluated QoL by two different questionnaires in 36 patients with long-standing perianal CD.

Thirty-six patients with long-standing perianal CD (mean ±SD duration 11.5 ± 5 years) followed up prospectively since 1989 were included in our study. All patients had an evaluation of symptoms with proctological examination and completed two self-administered visual scale QoL questionnaires: the Rating Form of IBD Patient Concerns (RFIPC) and a five-item short form of the Inflammatory Bowel Disease Questionnaire (sIBDQ). The scales were classified from 0 (excellent) to 100 (very poor).

The mean score for the RFIPC was 40.3 ± 18. An analysis of four subgroups of the RFIPC (impact of disease, sexual intimacy, complications of disease and body stigma) did not show any variance from the RFIPC. The sIBDQ showed a good correlation with the RFIPC (mean 42.9 ± 27, r = 0.78 and p = 0.0001). Patients with a CDAI of 150 (n = 8) or with immunosuppressive therapy (prednisolone 10 mg or azathioprine 50 mg; n = 10) had higher scores for the RFIPC (p = 0.05 or 0.04) and sIBDQ (p = 0.003 or 0.04). Patients with open fistulas (n = 9) more frequently had concerns about sexual intimacy (p = 0.02) compared with patients with healed fistulas.

The RFIPC is representative in assessing QoL in patients with CD and perianal disease.

248. QUALITY OF LIFE IN MANIC DEPRESSIVE PSYCHOSIS
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In studies over the last 20 years lithium, valproic acid and carbamazepine have been shown to have an efficacy of 70–80% in clinical trials in the treatment of manic depressive psychosis as measured by symptom reduction. However, other studies of long-term follow-up using the Global Assessment Scale have shown that up to 60% are functioning only fairly or poorly. The present study was undertaken to make some measures of the quality of life (QoL) in manic depressive patients under the conditions of ordinary clinical practice. Twenty currently treated patients from the practice of one psychiatrist in a medium-sized urban population in mid-Western Canada have been interviewed to determine QoL, using the Schedule for Evaluation of Individual Quality of Life (SEIQoL). All of the most recent 20 patients with manic depressive psychosis who had had an appointment with the psychiatrist in the 6 months prior to initiation of the study were eligible. Diagnosis was confirmed in all using the Structured Clinical Interview Diagnostic (DSMIV criteria). The comparison group for the QoL was 40 staff from the Department of Psychiatry. Both the patient and comparison groups identified family most frequently as being one of the five most important areas in QoL (97%, n = 39 and 85%, n = 17). Surprisingly, health was valued higher in the comparison group than in the patient group (93%, n = 37 and 50%, n = 10). As others have found, religion or spiritual life was rated as one of the five most important areas in QoL (comparison 32%, n = 13 and patient 35%, n = 7). A future study is planned and under way to bring the total number of patients to 100 along with other measures of symptom rating, occupational functioning, SF-36, social network and QoL measurement (the SEIQoL, SEIQoL Index and EuroQoL).
249. QUALITY OF LIFE AND DISEASE ACCEPTANCE IN PATIENTS WITH HAEMODIALYSIS, CORONARY ARTERY BYPASS GRAFT SURGERY AND MAMMARY CANCER


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The purpose of this study is to evaluate and investigate the quality of life (QoL) and disease acceptance in patients with haemodialysis, coronary artery bypass graft (CABG) surgery and mammary cancer. Forty-five patients with haemodialysis, 46 patients with CABG surgery, 33 patients with mammary cancer and 50 normal subjects participated in this study. Both personal interviews and self-administered questionnaires including 168 questions (21 categories) were used. In comparison with the normal subjects and the patients with CABG surgery and mammary cancer, the QoL in patients with haemodialysis was remarkably disturbed in both the cross-sectional and the longitudinal studies. In the patients with haemodialysis and CABG surgery, the high disease acceptance indicated the possibility of producing ‘high-QoL’ clinical disease management. We should pay more attention to QoL and disease acceptance for the clinical management of the patients.

250. QUALITY OF LIFE AND DRINKING STATUS IN ALCOHOLICS 6 YEARS AFTER TREATMENT

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Subjective evaluation criteria such as quality of life (QoL) are discussed more and more in the assessment of alcoholism treatment. Nevertheless empirical QoL research has rarely been applied to alcoholics so far. A very important question for the development of specific treatment goals is whether long-term abstinent patients are really more satisfied with their QoL than patients who are drinking again.

In a prospective study, we re-examined 135 alcoholics 6 years after their initial treatment. One hundred and twenty-four agreed after their initial treatment. One hundred and twenty-four agreed to the second assessment showed a better improvement for women and discharge, men had a better QoL than women, while patients with haemodialysis, coronary artery bypass graft (CABG) surgery and mammary cancer. Forty-five patients with haemodialysis, 46 patients with CABG surgery, 33 patients with mammary cancer and 50 normal subjects participated in this study. Both personal interviews and self-administered questionnaires including 168 questions (21 categories) were used. In comparison with the normal subjects and the patients with CABG surgery and mammary cancer, the QoL in patients with haemodialysis was remarkably disturbed in both the cross-sectional and the longitudinal studies. In the patients with haemodialysis and CABG surgery, the high disease acceptance indicated the possibility of producing ‘high-QoL’ clinical disease management. We should pay more attention to QoL and disease acceptance for the clinical management of the patients.

251. QUALITY OF LIFE IN CHILDREN WITH ENURESIS

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The objective was to determine the origin of enuresis in children from 7 to 14 years of age, attending day treatment psychiatric units and to work out methods which will help the patients and their families to cope with the problem. Eleven children attending our service have undergone clinical–psycho pathological, psychological and neurological investigation.

The reasons why enuresis has been paid special attention is that among 78 patients of our day treatment unit, 11 had been referred to us due to enuresis (14.1%). Our investigation showed that nine children were from poor families (mean monthly income is US$ 10–15). Eight of them had different kinds of emotional and behavioural problems. In most families the parents were unemployed. Cases of physical abuse of the children were noted in four families. In five families the fathers had a serious problem of alcohol addiction. Most of the families were extended (approximately seven people on average living in the same house). Difficulties with education occurred in seven of them. Three of the patients had signs of organic brain damage according to neurological investigation.

According to our findings, the quality of life (QoL) of these patients related to family and environmental factors played a crucial role as an aetiological factor in enuresis. Further investigation of children with enuresis connected with family, social and environmental factors is needed.

252. IMPROVEMENT OF QUALITY OF CARE USING QUALITY OF LIFE DATA

P. Marquis, A. Marrel and Christine de la Loge

Mapi Values, Lyon, France

Quality of Life (QoL) can be considered as an indicator of the quality and rapidity of the rehabilitation of ostomy patients after surgery. It allows stomacare nurses to evaluate quality of care and the support provided to patients following hospital discharge.

Concrete examples are provided by the CORCE study which is ongoing in 16 countries. Up to November 1996, 612 stomacare nurses had asked 4,532 patients to fill out a QoL questionnaire after hospital discharge and at 3, 6 and 12 months. The questionnaire is a battery made up of a QoL index measuring different components of QoL important for ostomy patients, supplemented by a module on satisfaction with medical care and confidence in dealing with the stoma.

A logistic regression and stepwise discriminant analysis were performed. The QoL index increased after hospital discharge (p < 0.01) up to month 3 and then tended to remain stable over time. Three key factors which have an impact on the evolution of QoL were satisfaction with medical care, quality of relationship with a stomacare nurse and confidence in changing appliance. The better the satisfaction, relationship and confidence, the higher the improvement in QoL. After hospital discharge, men had a better QoL than women, while patients with ileostomy or carcinoma had lower QoL. After 3 months, the second assessment showed a better improvement for women and
ileostomy patients but the scores of patients with carcinoma remained low. Men were more fearful of odours or leakage from stoma than women and they were less satisfied with the social support they get than women.

These data, in addition to individual scores allow stomacare nurses to address specific issues with their patients. Nurses can adjust their care and provide specific support required by the patient as well as specific counselling.

This study demonstrated the usefulness of QoL data for the better management of patients and targeted counselling.

253. THE PSYCHOLOGICAL GENERAL WELLBEING (PGWB) INDEX : SCORES OF A REPRESENTATIVE SAMPLE OF THE GENERAL POPULATION IN TEN COUNTRIES  
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The Psychological General Well-being (PGWB) index is a 22-item questionnaire designed to measure feelings of general well-being or distress. This questionnaire, well known in the USA, has been translated into different languages following the forward-backward method. Although the PGWB index has been applied in specific populations in some countries, no national reference standards are available for the general population outside the USA. General population norms are required to understand and interpret the results of cross-national studies.

A population survey has been conducted in a representative sample in ten countries (USA n = 1,020, Canada n = 1,036, Denmark n = 200, Finland n = 200, Norway n = 210, Sweden n = 400, Italy n = 999, Japan n = 500, The Netherlands n = 304 and Switzerland n = 514).

The internal consistency reliability of the index was acceptable across all countries (from 0.89 to 0.96) although the factorial structure differed. The mean PGWB overall index score was consistent across countries (from 71 to 79 on a 0–100 scale). The mean scores decreased with gender (-2.1), reported health problems (-7.5), digestive symptoms in women (-10.45), the psychological general well-being of the caregivers (-3.1) and the social roles of patients with a stoma (-4.8).

No correlation was found with age.

These preliminary data may be useful for the analysis and explanation of PGWB index scores across countries. The population norms can add clinical relevance to the statistical significance of the scores. To our knowledge, this analysis provides the first international cross-cultural and criterion-based interpretation of the PGWB index.

254. ADAPTING SURVEYS FOR SPANISH-SPEAKING POPULATIONS OF MULTICULTURAL ORIGINS  
M.L. Martin1, R. Gonzalez-Vizoso1 and A Grogg2
1Health Research Associates, Inc. and 2Janssen Research Foundation, USA

The objective was to describe the impact of multi-ethnic origins on the language spoken by Hispanic populations in the USA and to propose a specific methodology for developing singular, valid adaptations of subjective outcome measures for use in these populations.

Spanish-speaking populations in the USA originate from a variety of different cultures (Caribbean, South American, Mexican and other Central American) and each have a unique impact upon the Spanish that is spoken by that group. A specific stepwise methodology was developed to integrate the multicultural and colloquial impacts of mixed US Hispanic populations into the early stages of a standardized translation process for the MSAS and the Spanish translation of the EORTC-OLO-30. This approach was further elaborated through the design of a multi-ethnic lay panel for the cross-cultural adaptation of these measures, where the process of reconciliation into a single root version understandable to all Hispanic groups was begun and confirmed by back translation.

During the translation/adaptation process, several variations surfaced between the multi-ethnic Hispanic groups which affected the cognitive quality and consistency of the measures. By using a methodology which first adds multiple cultural and colloquial differences and then harmonizing them into a single, commonly understood root version of Spanish, it is possible to develop single versions of Spanish translations which are valid for use in US Hispanic populations of multiple origins.

255. THE POLICY IMPLICATIONS OF QUALITY OF LIFE RESEARCH  
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With the current emphasis on fiscal restraint in health care, policy makers must re-evaluate their programmes and priorities. It is important that any reforms be considered effective from the perspective of both health care providers and patients.

Until quite recently, medicine has focused on strictly physiological parameters of disease and treatment, largely ignoring their psychological and social effects. Public policy, too, has been somewhat misguided insofar as it has concentrated to a large degree upon measures of resource utilization.

What we need today is a common language for health care outcomes. Quality of life (QoL) research is a candidate for this role. It is the ‘final common pathway’ which brings together the efforts of the entire health care community, from basic science to clinical care to overall health policy.

However, to be effective as an evidence-based decision-making tool, QoL must be incorporated into decision making at all levels (micro, meso and macro). This can be done in several ways: (1) Promulgate rigorous standards for assessment for both classical and health policy trials to ensure that methodologies and applications are sound. (2) Move QoL from the research/group context and bring it into the individual patient perspective – this would involve individual QoL evaluation in every day clinical care by measuring patient QoL at each visit and then evaluating it over time. (3) Where appropriate, include QoL measures as part of new drug licensing – this could be done by instituting a requirement that QoL studies be part of all phase III trials. (4) Include QoL in overall programme evaluation along with the current considerations of physiological and resource utilization measures.

Developing a rational health care system requires modelling and evaluation of both group and individual outcomes. The methodologies of QoL assessment are mature enough to form the core of such analyses and project development.
256. PSYCHOMETRIC PROPERTIES OF QUALITY OF LIFE QUESTIONNAIRES. A METHODOLOGICAL SYNTHESIS
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This study presents various means which could be used by designers in order to estimate the importance of the error term in questionnaire test results, thanks to psychometry. The study must be conceived so as to minimize systematic errors (validity) and random errors (reliability).

The methods used to test the validity of a study are very subjective, even if some of them appear to be more “scientific”, being based on the principle of correlation. However, the latter do not stand up to some theoretic weaknesses and other explicit subjective methods should be chosen instead, for instance expert consensus.

Methods of reliability evaluation have been developed under some strong hypotheses to estimate a reliability coefficient. A very commonly-used method is Cronbach’s α, but some criticisms have spread concerning the right interpretation of the coefficient.

We conclude on the incompleteness aspect of the theory of error measurement. However, it is necessary to go on justifying each study due to the means which are available, that is to say the expert consensus to validate the choice of items and the α coefficient to attest their reliability. Nevertheless, we must be careful when interpreting the empirical results.

257. USING THE SF-36 FOR CLINICAL STRATEGIC PLANNING: MODELLING AND EVALUATION
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There is limited documentation in the rehabilitation literature on indications for or benefits of physical or occupational therapy (PT or OT), psychological (PSY) or social support (SW) and drug treatment (DT) in the management of chronic illness. This preliminary study uses the results from the SF-36 to contrast physician utilization of interventions with a recommended utilization model at a multidisciplinary multiple sclerosis (MS) treatment centre. The efficacy of the actual referral patterns measured by the use of SF-36 scale scores below the group mean to indicate QoL deficit, a model of recommended interventions for patients with definite MS initiating care at the clinic completed SF-36 at their first visit and their resource utilization was monitored for 12 months. the utilization model was tested using a one-tailed Fisher’s exact test. The efficacy of the treatments reflected in the SF-36 responses at 1 year was evaluated using paired t-tests in 78 (61%) patients with follow-up data.

Deficits in PF resulted in utilization of PT (p = 0.009) and DT (p = 0.015), but not OT, deficits in BP resulted in use of PT (p = 0.041) deficits in RP resulted in referral to SW (p = 0.007) and PSY (p = 0.047); no association between resource use and QoL deficits in RP, V, SF, MH, GH or HT could be identified. Use of interventions following the proposed model was not observed in the absence of QoL deficits. In evaluating the efficacy of the actual utilization model no significant QoL gains were noted in those with pre-treatment QoL deficits except that GH increased among those with low initial PF scores receiving drug therapy (mean difference 24.4 (0.76, 48.04)).

Although a high level of congruence between the actual and proposed models was noted, a QoL benefit at 1 year could not be demonstrated. Negative findings may result from the limited power of a small sample. Alternatively, the physician threshold for referral for intervention may be too high and there is little that can be done for those severely impaired patients. The use of SF-36 in this manner provides a potentially useful method for clinical groups to evaluate and strategically modify their practices.

258. MEASURING QUALITY OF LIFE IN MULTIPLE SCLEROSIS PATIENTS WITH THE SF-36 IN FOUR COUNTRIES
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Questionnaires measuring quality of life (QoL) are increasingly used in international studies of medical effectiveness. It is important to know if the data from these instruments are comparable across countries. We initiated a collaboration between five research groups – from the USA, The Netherlands, Belgium, France and the UK – in the field of QoL in multiple sclerosis (MS). All groups used the 36-item Short Form Health Survey (SF-36), a well-known generic QoL questionnaire. The goal of our study was to make a cross-cultural comparison of the SF-36. In the five countries under study the sample size varied from 50 to 134 patients with MS. The SF-36 was completed by a total of 457 patients, who were heterogeneous in relation to age, duration of illness, disease severity and type of MS. There appeared to be major differences between the country samples for each of the eight SF-36 scales. These findings may be influenced by differences in (1) method of recruitment (2) demographic and disease related characteristics (3) SF-36 administration and (4) cultural factors. After having performed a number of analyses, it appeared that the differences were mainly attributable to sample effects. However, cultural influences could not be excluded.

259. ANXIETY AND DEPRESSION IN PATIENTS WITH LUNG CANCER BEFORE AND AFTER DIAGNOSIS
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This paper reports on the data from a prospective study
The increased recognition of quality of life (QoL) by not only those in the clinical profession but also decision makers has led to the drafting of guidelines. This paper will review the current content of each guideline and make recommendations for additional steps to ensure high-quality results. The current guidelines can be divided into guidelines from official bodies (the FDA, European Union and the Australian Government) for submission purposes and the guidelines presented in economic evaluations of pharmaceuticals.

The submission guidelines for QoL for Australia (Australian Commonwealth Department of Human Services and Health) are the most detailed. These guidelines specify that validity, reliability and responsiveness analyses and the clinical importance of differences should be evaluated and presented.

The proposals by the FDA and European Commission apply (at present) only to a select number of indications: oncology, cardiovascular disease and obesity and gastronomy (FDA only). These proposals cover the use of QoL as efficacy parameters, the use of validated instruments and the domains of daily functioning to be evaluated. The European Commission has named a questionnaire to be used in cardiac failure: the Minnesota Living with Heart Failure Questionnaire. The various committees of the FDA have identified scenarios in which QoL assessment is relevant and suggestions have been made on the analysis (dealing with missing data and providing a detailed statistical analysis plan) and interpretation of the results.

International studies must be designed to accommodate each country’s governmental guidelines. Understanding the international guidelines for QoL will ensure the applicability of a study to each country and the translation of results to others.

260. INTERNATIONAL QUALITY OF LIFE REQUIREMENTS

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The last few years have seen an enormous increase in the number of clinical trials with a quality of life (QoL) component. This expansion of QoL has also increased the number of erroneous results due to lack of knowledge about QoL during the design, implementation and analysis of clinical trials. Through our observations of ‘studies gone bad’ over the last few years, in this paper we stress the importance of the involvement of individuals knowledgeable in the field of QoL.

It is important for these people to take the time to assess the available instruments appropriately and make the correct choice for the study at hand. Once the instrument has been selected, all details regarding the study (e.g. the timing of administration) should be incorporated into the protocol, detailed instructions should be provided to the investigators, along with training and a detailed analysis plan must be completed. The analysis plan should include a full psychometric evaluation to ensure usable results.

Analysis of QoL data proves difficult for the inexperienced. Sometimes very impressive and complicated analysis plans have been produced for trials. Missing in one such plan, however, were the scoring and psychometric analysis plans, resulting in errors in scoring and complications in the interpretation of sometimes flawed results. This led to unusable data which later proved to be caused by poor instruments.

In another trial, the investigator was used as a proxy for completing the patients’ QoL. It is known that investigators do not make the best proxies and in this study it was observed that they were able to produce the completed questionnaires (totaling 50 items) on 12 patients within 10 min during a monitoring visit!

Following the simple steps cited above will help avoid many of the pitfalls seen over the past few years and will, it is hoped, lead to an increase in the quality of QoL data.
In comparison with SU, acarbose showed a better QoL than the IN patients in all main dimensions. In conclusion, acarbose has advantageous effects on QoL in non-SU-treated patients with respect to optimistic coping (ANOVA) (Bonferroni adjusted, p < 0.016). In conclusion, acarbose has advantageous effects on QoL in non-insulin-dependent diabetes mellitus (NIDDM). Patients on acarbose also reached higher scores than patients on SU in general well-being, life and health satisfaction and reported less restrictions in alimentation (statistical trends). Finally, acarbose-treated patients scored higher than SU-treated patients with respect to optimistic coping (p = 0.016).

In conclusion, acarbose has advantageous effects on QoL in non-insulin-dependent diabetes mellitus (NIDDM). Patients on acarbose showed better QoL than the IN patients in all main dimensions. In comparison with SU, acarbose showed a measurable preponderance in specific domains.

263. QUALITY OF LIFE IN FAMILIES WITH HEREDITARY BREAST CANCER
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Breast cancer gene 1 (BRCA1) is responsible for approximately 5% of all breast and ovarian cancer cases. Psychosocial counselling in families with identified BRCA1 mutations is of superior importance to keep life quality. We investigated ten Austrian families with BRCA1 mutations to determine the possible impact of molecular genetic testing in these families and to determine the influence of knowledge on life quality.

Questionnaires and telephone interviews for more delicate questions concerning four major topics were performed after learning the genetic test results and receiving education about the consequences of carrying a BRCA1 mutation: (1) level of knowledge of hereditary and sporadic breast cancer, (2) motivation of genetic testing, (3) physical and mental status, body image and sexuality and (4) extent of depression and quality of life (QoL). Almost 100% of women tested for BRCA1 mutations requested the results of the molecular genetic testing. However, only 50% of all men consented to learn their test result.

One month after counselling for carrier status, questionnaires were sent to all family members that requested the test results and the telephone interviews were performed. The compliance rate for these tests amounted to more than 90%.

The evaluation of our tests revealed a high level of knowledge concerning hereditary and sporadic breast cancer. The motivation for testing was mainly to clarify the personal genetic risk and the likelihood of heredity. Almost 70% of our patients wanted to include this knowledge into their family planning. Depression status was evaluated by using self-rating depression scales. To date only one mild depression and no moderate or severe forms could be diagnosed.

264. QUALITY OF LIFE FOLLOWING THERAPY OF ADVANCED PHARYNGEAL CARCINOMAS – RADICAL SURGERY VERSUS RADIOTHERAPY
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All therapeutic measures available to the otorhinolaryngologist working in the field of oncology have an intervening, aggressive character and are feared by patients because of the contributing factors, side-effects and after-effects.

At the Magdeburg University ENT Clinic, a stage III or IV advanced oropharyngeal or hypopharyngeal carcinoma was diagnosed in 57 patients in the 1995 – 1996 period. Thirty-six patients received radiosurgical combination therapy; pharyngeal soft tissue defects resulting from radical surgery were closed by microsurgically revascularized tissue transfer (fasciocutaneous antibrachial flap and latissimus dorsi flap). Twenty-one patients underwent sole radiotherapy. In respect of age structure, both groups of patients were comparable (surgery median age 57 years, radiotherapy median age 59 years and male sex predominance 80%). In ENT carcinoma patients, the post-therapeutical quality of life (QoL) is closely related to the functions of speech and independent oral uptake of food. Therefore, the following parameters were used to assess the quality of life: Dysphagia, degree of mucositis, voice and speed function, necessity of a permanent tracheostoma, pain, social rehabilitation and Karnowsky performance scale. The post-therapeutical result could not be measured on the normal finding. Prior to therapy, all patients exhibited severe impairment of the voice and speed function and/or stage III/IV dysphagia. A marked Foetor ex ore caused social exclusion of one-third of the patients at the time of diagnosis. Although the outer physical integrity was affected by surgical intervention (laryngectomy or glossectomy) and the associated function impairment cannot be completely eliminated by the currently available measures of plastic reconstructive surgery, radiosurgical combination therapy, even in patients’ judgement, turned out to be superior to the sole radiotherapy.

265. VALIDITY OF THE NEI VISUAL FUNCTIONING QUESTIONNAIRE IN PATIENTS WITH CHOROIDAL MELANOMA: A PILOT STUDY
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A pilot study was performed to assess validity of the 25-item National Eye Institute’s (NEI) Visual Functioning Questionnaire (VFQ), a vision-specific instrument designed to assess physical and emotional disability due to vision impairment, in an evaluation of quality of life (QoL) in choroidal melanoma patients treated with enucleation or plaque radiotherapy in the Collaborative Ocular Melanoma Study (COMS).

Patients with choroidal melanoma evaluated at three COMS clinical centres who did not enrol in the COMS were interviewed by telephone using the VFQ and SF-36 Health Survey. Additional questions were asked to assess the adequacy of the instruments.
Seventy-three patients participated (mean age 64 years and 52% male); 24 treated by enucleation, 26 by plaque radiotherapy, three by other forms of globe-sparing therapy and 15 untreated (treatment status was not reported for five). The standard deviations and Cronbach’s α for VFQ composite score and subscales were in the range of the results for the NEI VFQ reference population. Comparison according to treatment indicated that only peripheral vision differed significantly according to treatment: enucleated patients scored lowest and untreated patients highest with plaqued patients intermediate (p = 0.0065).

Patients with worse better eye vision scored lower than those with better acuity in all of the VFQ scales except ocular pain and dependency. A similar pattern was seen for vision in the worse eye. The SF-36, a generic health status measure, did not discriminate well by either treatment or level of visual acuity. The patients noted a deficiency of both instruments in terms of anxiety/depression related to the fear of melanoma recurrence.

In this series of patients, the VFQ appears to be sensitive to visual acuity and possibly expected treatment-related differences. The addition of items to measure stereopsis may increase the usefulness of the visual functioning assessment in the COMS.

Apart from co-morbidities, a comparison of health-related QoL scores between groups of patients should be adjusted for non-health-related factors.

267. HEALTH-RELATED QUALITY OF LIFE AFTER CABG – DO PATIENTS BENEFIT FROM REHABILITATION PROGRAMMES? THE ISRAELI CABG STUDY

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As very few patients in Israel participated in any rehabilitation programme after CABG, the goal of this paper is to explore the putative effect of such programmes on the quality of life (QoL) of middle-aged patients 12-18 months after the operation. QoL is reviewed as the sum of the influence of the person’s characteristics as they entered the hospital, their experience there and their post-discharge circumstances, among them whether or not they participated in rehabilitation.

This report is part of the Israeli prospective CABG study, which included 4,835 patients, 2000 of whom were aged 44–65 years. Of these, only 125 (6.2%) had any rehabilitation programme and 104 (83%) answered the QoL questionnaire. These patients and their 208 controls matched on age, sex and time of completing the QoL questionnaire, are the subject of this report. The extensive data on patients within the Israeli CABG study covered clinical and demographic information together with a telephone interview 3 months after the operation. All survivors had QoL questionnaires (the SF-36 plus a specific questionnaire) 12–18 months after the operation. Those who reported any rehabilitation activity were further interviewed by phone on the duration and content of their programme. Univariate Wilcoxon tests were used for the SF-36 scores and McNemar tests for categorical variables; conditional multivariable models assessed the effect of putative risk factors on QoL (physical and mental).

There was a higher score for rehabilitated patients versus controls in five of the eight dimensions of the QoL questionnaire. These included general health, physical functioning, role physical, vitality and social functioning. No differences were found in bodily pain. Rehabilitated patients tended to be significantly more physically active than their controls. Prior to operation a higher proportion of them were fully employed, were more satisfied with the health services and felt their general functioning was better. Significantly, there were no differences between rehabilitated patients and the controls in summary scores from the risk models for mortality.

We conclude that rehabilitated patients were not ‘healthier’ than their matched controls, but had higher QoL scores in both dimensions of the SF-36. Rehabilitated patients tended to be more active, more aware of their problems and benefits and they tended to view the medical services afforded to them in a more favourable light than their controls.

226. THE IMPACT OF NON-HEALTH-RELATED FACTORS ON HEALTH-RELATED QUALITY OF LIFE DOMAINS

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The purpose of the study was to assess the effect of non-health and health-related factors on various domains of the health-related quality of life (QoL) instrument the SF-36.

During the period 1993 – 1994 we conducted a study on an Israeli-based, national sample of persons aged between 45 and 75 years. Regression analyses were performed for each of the eight SF-36 domains. The dependent variable was each of the SF-36 domain scores. The explanatory variables included age, sex, level of education, employment and economic status, religion and the presence of disease states. Bonferroni correction was made for multiple comparisons.

The sample included 2,030 persons 47.3% were male and the overall mean age was 58 ± 9.71 years. Self-evaluation of economic status was significantly associated with all domains of the SF-36 QoL measurement. It explained only 1.85% of the variance in the body pain domain score, but 9.05% of the variance in the mental health domain score, while the disease state contribution to the explanation of variance ranged from 1.97 to 16.17% in the mental health and body pain domain scores, respectively. Disease states explained 15.93% of the variance of the general health domain score, but economic status also contributed 7.51% of the variance.

Non-health-related factors have a major impact on various domains as measured by the health-related QoL instrument.
268. CHANGES IN QUALITY OF LIFE SCHIZOPHRENIC PATIENTS DURING THE PERIOD OF ECONOMIC BLOCKADE IN FRY G. Nikolic-Balkoski, N. Laskovic, Lj. Leposavic and J. Barisic-Rojnic CCS School of Medicine, Institute for Psychiatry, Belgrade, Yugoslavia

There are very few investigations in our country about the quality of life (QoL) of schizophrenic patients under the circumstances of economic blockade and civil war (patients who are not directly involved in civil war and are not refugees).

The aim of the work was to estimate how does, if it does, QoL change in this population, under the above-mentioned circumstances.

We followed and compared indicators of QoL (working ability, income, number of hospitalizations, culture and recreation activity, etc.) during the period from 1990 (before the civil war on the territory of former Yugoslavia) to 1996. For diagnostic schizophrenia, DSM IV criteria were used.

The results showed a decreased level of QoL. That could be the consequence not only of the exhaustion of adaptive mechanisms under the circumstances of life uncertainty and political instability, but also the result of the bad social and economic situations in the country, which include, also, problems with medication procurement.

269. CHANGES IN QUALITY OF LIFE AMONG THE HEALTHY POPULATION DURING THE PERIOD OF ECONOMIC BLOCKADE IN FRY G. Nikolic-Balkoski, N. Laskovic, J. Barisic-Rojnic and Lj. Leposavic CCS School of Medicine, Institute for Psychiatry, Belgrade, Yugoslavia

There are very few investigations about psychic health and quality of life (QoL) among a healthy population who live under circumstances of economic blockade and civil war (patients who are not directly involved in civil war, nor are refugees).

The aim of the work was to estimate how does, if it does, QoL changes in this population under the circumstances described.

We followed and compared indicators of QoL (income, education, number of children, divorces, culture and recreation activity) during the period from 1990 (before the civil war on the territory of former Yugoslavia) to 1996.

The results showed a decreased level of QoL. That could be the consequence not only of the bad social and economic situations in the country, but also the result of decreasing and exhaustion of adaptive mechanisms of people under the circumstances of life uncertainty and political instability, which occur.

270. A REVIEW OF MULTI-ATTRIBUTE HEALTH STATE SCALING INSTRUMENTS
Erik Nord
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A number of instruments are available for describing patients in terms of multi-attribute health profiles and assigning index values to these profiles on a scale from 1 (healthy) to 0 (dead). The OECD is exploring the possibility of including such an instrument in standard health statistics in its member countries.

Existing instruments were reviewed with respect to their psychometric properties. This paper focuses on the meaning and validity of index values.

A questionnaire was sent to the developers of eight different instruments. Completed questionnaires were returned for the 15-D, the EuroQoL Instrument (EQ-5D), The Health Utilities Index (HUI) – Mark 1 and 2, the Quality of Life and Health Questionnaire (QLHQ) and the Australian Multi-Attribute Utility (AMU).

The developers of different instruments place quite different meanings on the index values they offer. Some claim that the values reflect some kind of trade-off. These include certainty trade-offs, time trade-offs and person trade-offs. Others claim that the values are cardinal measures of quality of life (QoL). The empirical support for the various claims is weak. The values assigned to given health states vary strongly across instruments.

There is a need for conceptual clarification of index values provided by the existing health state scaling instruments.

271. AN ASSESSMENT OF THE QUALITY OF LIFE OF PEOPLE LIVING WITH HIV/AIDS: SOME EVIDENCE FROM KENYA
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This paper seeks to make an assessment of the quality of life (QoL) of people living with HIV/AIDS in Kenya. The data used were assembled from a heterosexual sample of 29 patients who were diagnosed to be HIV positive and were presenting for treatment in four STD/HIV/AIDS specialized clinics in the city of Nairobi. The paper adopts a social constructionist approach and draws on Goffman’s ‘theories’ to make sense of the lived experiences of people living with HIV/AIDS.

Because of the host of negative symbolic meanings associated with HIV/AIDS, it is observed that people diagnosed HIV positive encounter problems with employment, health insurance and housing among others and this pressures them into managing HIV/AIDS through socially meaningful ways, but ways that only exacerbate rather than inhibit the spread of HIV.

The ensuing strategies of ‘managing appearances’, however, have profound adverse effects on the quality of their lives. It is concluded that there is a need to ‘demystify’ HIV/AIDS through socially and culturally sensitive health education campaigns, if the rapid spread of HIV/AIDS in Kenya is to be checked. Possible remedial measures are discussed and policy recommendations made.

272. COMPARING QUESTIONNAIRES FOR LEFT VENTRICULAR DYSFUNCTION
C.J. O'Leary and P.W. Jones
St George's Hospital Medical School, London, UK

This study was designed to compare three health status measures in patients with left ventricular dysfunction (LVD). The Left Ventricular 36 (LVD-36), the Minnesota Living with Heart Failure (LiHFE) and the Short Form 36 (SF-36) were presented randomly to 78 (17 female) patients with chronic LVD diagnosed by echocardiogram. The mean age was 52 years (SD 15.5), the median NYHA class was 2 and the mean ejection fraction (EF) of the left ventricle was 43% (SD 14).

The ceiling and floor effects (percentage of sample with best and worst scores) were 3% and 0% for the LVD-36 and 4% and 0% for the LiHFE. The ceiling effects for the SF-36 components ranged from 0 to 58% and the floor effects ranged from 0 to 28%.
There were no significant differences in the LVD-36 or LIhFE scores of male and female patients. There were significant gender differences for four SF-36 components (r ranged from 2.1 to 3.0, \( p < 0.05 \)). Age was not associated with the LVD-36 or LIhFE scores, but was significantly correlated with two SF-36 components (physical functioning \( r = 0.28 \) and \( p = 0.03 \) and mental health \( r = 0.31 \) and \( p = 0.01 \)).

ANOVA\'s between the questionnaire scores of the NYHA classes were significant for the LVD-36 and the LIhFE (\( F = 32.5 \) and \( p < 0.0001 \) and \( F = 24.7 \) and \( p < 0.0001 \), respectively) and for seven SF-36 components (\( F \) ranged from 22.8 to 2.9 and < 0.05). The LVD-36 and the LIhFE correlated with EF (\( r = 0.3 \) and \( p = 0.04 \) in both cases). None of the SF-36 components correlated with EF.

To conclude, four SF-36 components have large floor or ceiling effects. The SF-36 is influenced by gender and age and has lower levels of validity than the LVD-36 and the LIhFE. The LVD-36 and LIhFE perform similarly. The results of an ongoing study to compare the responsiveness of these questionnaires will be reported.

273. DEVELOPMENT OF THE WHOQOL-BREF
QUALITY OF LIFE ASSESSMENT

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This paper reports on the development of the WHOQOL-BREF, an abbreviated version of the WHOQOL-100 quality of life (QoL) assessment.

The WHOQOL-BREF was derived from data collected using the WHOQOL-100. It has now been field tested in a number of countries. It produces scores for four domains related to QoL: physical health, psychological, social relationships and environment. It also includes one facet on overall QoL and general health.

The domain scores produced by the WHOQOL-BREF correlate highly (0.89 or above) with WHOQOL-100 domain scores (calculated on a four-domain structure). The WHOQOL-BREF domain scores demonstrated good discriminant validity, content validity, internal consistency and test-retest reliability.

These data suggest that the WHOQOL-BREF provides a valid and reliable alternative to the assessment of domain profiles using the WHOQOL-100. It is envisaged that the WHOQOL-BREF will be most useful in studies requiring a brief assessment of QoL, e.g. in large epidemiological studies, clinical trials or other evaluations of treatment efficacy where QoL is of interest.

274. APPROACHES TO ASSESSING HEALTH-RELATED QUALITY OF LIFE IN CLINICAL TRIALS FOR PATIENTS WITH HIGH-GRADE RECURRENT GLIOMAS

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Assessment of health-related quality of life (QoL) in phase II or III clinical trials with an expected high attrition rate due to disease progression or death poses a problem in analysis because of potentially high proportions of missing data. We explored this dilemma using, as an example, a phase II study of 119 patients with high-grade gliomas treated with six treatment cycles of oral temozolomide. At each treatment cycle, the clinical neurological status was assessed by grading neurological symptoms and signs, while health-related QoL was assessed by the EORTC Quality of Life Questionnaire (QLQ-C30 + 3) and the Brain Cancer Module (BCM20). Radiological disease status was assessed by MRI scans at the end of every second cycle. Comparisons of health-related QoL changes were carried out in two ways. In the first approach, changes in health-related QoL status from baseline to cycle 6 scores in patients who completed all six cycles of therapy without deterioration in neurological status were compared to the last reported scores in patients with deterioration before the sixth cycle. In those without neurological deterioration at cycle 6, 13 of a total of 25 possible domains or single items showed improvement (role, emotional and social functioning, global QoL, insomnia, anorexia, future uncertainty, visual disorder, communication deficit, seizures, drowsiness, leg weakness and bladder control), while in those with clinical neurological deterioration by cycle 6, there was either no improvement or deterioration in all 24 health-related QoL scores. Although this is an expected result, it confirms that health-related QoL improved in patients whose neurological status did not deteriorate and that the treatment side-effects did not substantially impair health-related QoL. In the second approach, the scores of patients with complete or partial disease responses (CR/PR) on MRI at any time during the treatment period were compared with those of patients having stable disease (SD) or progressive disease (PD) during treatment. Seven health-related QoL domains (role and social functioning, global QoL, visual disorder, motor dysfunction, communication deficit and drowsiness) were compared. As expected, an improvement (response) in at least two of the domains was seen in the majority of CR/PR patients, but a response was also seen in 43% of patients with SD and 29% with PD. This analysis approach suggests that health-related QoL benefits can occur in the absence of improvement in standard radiological response criteria.
276. US WHOQOL INSTRUMENTS IN DEVELOPMENT AND APPLICATION
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Since 1991, the University of Washington has participated in the development of the World Health Organization quality of life instruments. This paper summarizes the results of the instrument development to date and suggests alternative uses for the long and short forms of the WHOQOL measurement system. A 236-item pilot instrument was tested for contribution to the core WHOQOL measures along with the identification of a US National Supplement, with 250 users of health services and 50 healthy adults. The US National Supplement contains items of particular importance to participating respondents, but those eliminated from the core WHOQOL instrument include personal freedom, communication and sight/hearing. The importance items showed differences between US respondents and those from other participating countries. The WHOQOL-100 has been evaluated for psychometric properties of discrimination and evaluation with 128 healthy adults and 64 childbearing women. The psychometric properties of the WHOQOL-BREF 26-item version has been evaluated using a dataset obtained from the WHOQOL-100 sample. A US supplement and importance items were tested in all datasets. The ability of the WHOQOL-100 to discriminate was consistent among healthy and chronically ill persons across all datasets. The internal consistency exceeded 0.80 for the WHOQOL-100 domains, but was lower (0.58—0.86) for the WHOQOL-BREF. The reproducibility remained high (>0.80) for domain scores across all datasets. The correlations between the WHOQOL-100/BREF domain scores and SF-36 subscales and subscales of the Subjective Quality of Life Profile were similar in pattern but the WHOQOL-100 showed higher discriminant and convergent validity. For evaluation purposes, particularly in application to persons with chronic conditions or smaller samples, the longer WHOQOL-100 is the preferred instrument. For population description and large sample evaluations, the WHOQOL-BREF performs similarly. The US national supplement and importance items should be retained for comparability with US-based studies. A user’s manual has been developed for the WHOQOL-100 and testing of the WHOQOL-BREF as a stand alone instrument is under way.

277. RELATIONSHIP BETWEEN HEALTH-RELATED QUALITY OF LIFE AND READMISSION AMONG ELDERLY PATIENTS RECENTLY DISCHARGED FROM ACUTE HOSPITAL CARE
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Among patients recently discharged to home from acute hospital care, we studied the relationship between health-related quality of life (QoL) and the incidence of subsequent unplanned readmission.

One hundred and sixty-three medical and surgical patients (mean age 67.0 ± 16.3 years), prescribed a mean of 4.8 ± 2.6 medications for more than one chronic condition, were interviewed at a median of 4 weeks following acute hospitalization to determine their health-related QoL, using the MOS 36-Item Short-Form Health Survey (SF-36). Patients were followed-up for 6 months to determine the subsequent incidence of unplanned readmission.

Health-related QoL for the entire cohort, as measured by both the physical and mental health score components of the SF-36, indicated marked impairment relative to age- and gender-matched norms for the local population (p < 0.01). During study follow-up, 47 (35%) patients had an unplanned readmission, whilst one patient died. Patients who had an unplanned readmission demonstrated both significantly lower physical (32.2 ± 9.8 versus 38.6 ± 10.1, p < 0.01) and mental health component scores (45.1 ± 12.7 versus 49.9 ± 12.3, p = 0.03) in comparison to the remainder of the cohort.

According to multiple logistic regression, the significant independent correlates of unplanned readmission were (1) the presence of formal home assistance (OR 6.4, 95% CI 1.9–21.5 and p < 0.01), (2) more than five prescribed medications (OR 2.4, 95% CI 1.1–5.4 and p = 0.04) and (3) multiple admissions in the 6 months prior to administration of the SF-36 (OR 4.3, 95% CI 1.9–4.3 and p < 0.01). Lower physical component scores were also associated with a strong trend towards unplanned readmission (OR 0.96, 95% CI 0.93–1.00 and p = 0.07). This model had a positive predictive accuracy (as regards subsequent unplanned readmission) of 67%.

Among this cohort of patients with significantly lower than average health-related QoL, relatively lower SF-36 physical health component scores was a borderline, independent predictor of subsequent unplanned readmission. These data suggest that the health-related QoL scores in this type of patient cohort are potentially useful, in conjunction with the use of conventional predictors, in identifying patients at risk of unplanned readmission.

278. EFFECT OF SYMPTOM TYPE AND SYMPTOM INTENSITY ON MULTIPLE DIMENSIONS OF QUALITY OF LIFE
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Illness- and treatment-related symptoms can have a significant effect on quality of life (QoL). In this study, the relationship between type of symptom, symptom intensity and different dimensions of QoL was examined in a large sample of cancer and
HIV/AIDS patients (n = 1,163). The patients rated the intensity of three symptoms prevalent in this population (fatigue, pain and sleep disturbance) on the symptom scales of the European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC QLQ-C30). The QoL dimensions of physical well-being (PWB), social family well-being (SFWB), emotional well-being (EWB) and functional well-being (FWB) were assessed with the Functional Assessment of Cancer Therapy-General (FACT-G). Trend analysis revealed differences in QoL effects by both type of symptom and dimension of QoL. Thus, the linear trend explained the majority of the variance in QoL effects by both type of symptom and dimension of QoL. The specific form of the relationship between symptom intensity and QoL is dependent on the type of symptom and the dimension of QoL being considered.

The purpose of this study was to describe and compare the health-related quality of life (QoL) of patients undergoing different forms of treatment for end-stage renal disease. The QoL data were obtained from the SF-36 Health Status Survey and linked with co-morbidity data and clinical data. The evaluative procedures included linear multiple regression and factor analysis, paired Student’s t-tests and Mann-Whitney criteria. Fifty adult haemodialysis (HD), 39 transplant (TR) and 40 patients under peritoneal dialysis (CAPD) (first experience in Russia) were investigated. Compared to the general population, patients experienced a lower QoL in the majority of domains, in particular in physical functioning, social activities and bodily pain. A significant difference was not found on the scales of mental health. TR recipients reported higher vitality, health and mental health than dialysis patients, but there were no other differences. When treated with HD patients demonstrated surprisingly high satisfaction with a large number of social and personal relationships and significantly less distress associated with pain. These differences remained after controlling for age and co-morbidity. Freedom from bodily pain increased under the period of TR and was expressed more among young patients. Patients under CAPD were more anxious and less depressed. Physical and social functioning and general health were better in HD than in CAPD. The length of HD before TR positively influences the social adherence of TR patients. A significant negative effect on QoL because of emotional disturbances was found in TR and CAPD. Pain was the factor of QoL in CAPD. QoL in HD is also reduced under the influence of affective disorders, anxiety and pathological types of attitude to illness. The type and duration of HD, age and weight, hypertension and such biochemical characteristics as the serum creatinine, Ca and Na of blood are of importance for QoL in HD treatment.

We can conclude that successful psychosocial and somatic adaptation can be reached in adequate HD as well as in CAPD and TR. Reduction of QoL in end-stage renal patients, treated with active methods, depends mainly on physical factors; nevertheless psychological correction is a factor of their QoL.

Multiple Sclerosis (MS) is an unpredictable neurological disease causing a variety of symptoms. Its influence on health-related quality of life (QoL) is high in comparison with other chronic diseases. The SF-36, a generic questionnaire and the Disability and Impact Profile (DIP) were examined for reliability and for differences between subgroups of MS patients (for severity of MS, illness duration, MS development in the last 6 months and sex). In total 187 MS patients completed the questionnaires. The mean age was 44.6 years (SD 10.9 years) and the mean years since diagnosis (patient-reported) was 9.4 (SD 8.5). Four of the six DIP facets and the items of the WHOQOL-100. The group discussions revealed the following. (1) The participants were ambivalent about the concept of quality of life (QoL). It was considered to be valuable and indispensable and at the same time not fitting well in our culture. (2) The patients were more strongly motivated in the discussions than the professionals, who were not convinced that the patients could provide ‘objective’ data about QoL. (3) A need to share the subjective feelings related to a disease was expressed; however, it proved to be easier to talk in terms of symptoms. (4) Some of the groups propose questions for individual coping skills to be included in the questionnaire. Others delegate the responsibility for their QoL to the institutions and the government. (5) One of the main issues raised in the discussions was the shame of being different from ‘healthy’ persons. The following conclusions were reached. (1) The patients are perceived only as passive recipients of care and the impact of the disease and the treatment upon their psychic life is not taken into consideration. That might be due to the paternalistic attitudes in our society. (2) The results lend support to the need to consider QoL assessments in treatment. (3) Including questions about stigma, goal attainment and the importance of the facets for each respondent is proposed.
scales and all SF-36 scales showed an internal consistency reliability above 0.60. The 6 month test–retest coefficients varied from 0.46 to 0.87 and were above 0.60, except three scales of the SF-36. To study the differences between subgroups one MANOVA was carried out for each questionnaire. The covariates, age and five personality traits, had a multivariate effect. For ‘role-emotional functioning’ of the SF-36 effects of (1) ‘MS development’ (2) ‘severity of MS’ and (3) ‘severity of MS by illness duration by MS development’ were found. For ‘vitality’ of the SF-36 an effect of ‘severity of MS by MS development’ was found. As concerns the DIP effects were found for the scales ‘mobility’ and ‘self-care’. ‘Sex’ had an effect on both scales, the ‘severity of MS by MS development by sex’ and ‘severity of MS by MS development’ had an effect on ‘self-care’ and the ‘severity of MS by sex’ and ‘MS development by sex’ had an effect on ‘mobility’.

The reliability of the SF-36 and DIP appear to be acceptable. The DIP and the SF-36 were affected differently. In both questionnaires ‘severity of MS’ and ‘development of the disease in the last 6 months’ had an influence on some scales. ‘Sex’ only had an influence on the DIP. An interpretation of the differences between subgroups will be given. Personality appears to play an important role in the self-assessment of health-related QoL. The impact of these results on health-related QoL research will be elaborated upon.

282. AN ASSESSMENT OF QUALITY OF LIFE IN SCHIZOPHRENIC AFRICAN–AMERICANS: WORLD HEALTH ORGANIZATION QUALITY OF LIFE ASSESSMENT SCALE (WHOQOL-100) CONCEPTS

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The overall goal of the project was to assess quality of life (QoL) of schizophrenic African–Americans with the World Health Organization Quality of Life Assessment Scale (WHOQOL-100) who were on different neuroleptics. Twenty-one African–Americans (males 18, females 3 and mean age 41.24 years) primarily diagnosed with schizophrenia (DSM IV) were recruited for the study. The patient interviewers to administer questionnaires were conducted at the Ambulatory Mental Health Clinic of Howard University Hospital. The world body’s QoL module has six domains and 24 facets – domain I (physical domain), domain II (psychological domain), domain III (level of independence), domain IV (social relationships), domain V (environment) and domain VI (spirituality/religion/personal beliefs). The overall QoL and general health components are also included in the WHOQOL module. The significant correlates of total compliance scores were overall QoL and health (r = 0.454 and p ≤ 0.0285), domain I (r = 0.661 and p ≤ 0.0004), domain II (r = 0.559 and p ≤ 0.0047), domain III (r = 0.525 and p ≤ 0.0091), domain IV (r = 0.513 and p ≤ 0.0113), domain V (r = 0.618 and p ≤ 0.0012) and domain VI (r = 0.424 and p ≤ 0.0428). The newly designed compliance scale model has a predicting power of 0.664 (R² = 0.664, F = 8.880 and p ≤ 0.0004). Among all domains, the strongest predictor of compliance was domain I (p ≤ 0.0021) which contains the pain and discomfort facet. The home environment (r = 0.820 and p ≤ 0.0001) and social support (r = 0.590 and p ≤ 0.0024) facets were the other significant correlates of the total compliance scores of SC patients. Despite the study being conducted on a limited convenient sample, the WHOQOL facets domains emerged as useful tools for assessing compliance in SC patients.

284. PHARMACIST DISCHARGE COUNSELLING: ITS IMPACT ON QUALITY OF LIFE (SF-12), COMPLIANCE AND CLINICAL OUTCOMES

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The overall goal of the project was to assess the impact of pharmacist discharge counselling on quality of life (QoL) compliance and clinical outcomes of hospital discharge patients. The study was conducted on 27 subjects (male 10, female 17 and mean age 47 years) at Howard University Hospital. In this study, patients’ QoL was assessed by the SF-12 (standard) and compliance scores were measured by a standardized compliance scale with 19 items (Cronbach’s α = 0.97). At the time of discharge, baseline (t1) measures of QoL, compliance and health status were obtained in volunteered patients. They were then exposed to well-structured patient counselling sessions of the pharmacist. To reinforce the counselling, the participant subjects were supplied with written information on drugs. After 3 weeks from the time of counselling, patients’ QoL and compliance and health status were reassessed (t2). Change scores were used as indicators of impact.
assumed of pharmacist counselling. The change scores of the Mental Component Summary Scale (MCS) ($p < 0.0001$, paired $t = 4.564$ and $df = 26$) and compliance ($p < 0.0032$, paired $t = 3.259$ and $df = 26$) were significant. The change scores of the Physical Component Summary Scale (PCS) scores were found to be not significant ($p < 0.7494$, paired $t = 0.323$ and $df = 26$). The health status of discharged subjects was improved ($p < 0.05$, paired $t = 2.054$ and $df = 26$). The results of the study from this convenient sample may not be generalized, as all of the hospital-discharged patients were African-Americans. However, the SF-12 may be a convenient QoL tool for assessing patient outcomes of discharged patients quickly, when patients are eager to leave hospital for home.

285. AN ASSESSMENT OF QUALITY OF LIFE IN SICKLE CELL PATIENTS: WORLD HEALTH ORGANIZATION QUALITY OF LIFE ASSESSMENT SCALE (WHOQOL-100)

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The main objective of the study was to assess the quality of life (QoL) of sickle cell (SC) patients who are on different treatment interventions. The study was conducted on 23 sickle cell patients (male 12, female 11 and mean age 33.91 years) recruited from the Hematology and Sickle Cell Center Clinics of Howard University Hospital. The QoL profiles were assessed by administration of the WHOQOL module and patient interviews were conducted in the above clinics. The body’s QoL profile has six domains and 24 facets – domain I (physical domain), domain II (psychological domain), domain III (level of independence), domain IV (social relationships), domain V (environment) and domain VI (spirituality/religion/personal beliefs). The overall QoL and general health components are also included in the WHOQOL module. The overall QoL and general health perceptions of SC patients were found to be highly correlated with domain I ($r = 0.534$ and $p \leq 0.0077$), domain II ($r = 0.836$ and $p \leq 0.0001$), domain III ($r = 0.682$ and $p \leq 0.00029$), domain IV ($r = 0.818$ and $p \leq 0.0001$), domain V ($r = 0.779$ and $p \leq 0.0001$) and domain VI ($r = 0.838$ and $p \leq 0.0001$). The overall QoL and general health was predicted by their level of independence ($p \leq 0.0170$), social relationships ($p \leq 0.0159$) and spirituality, religion and personal beliefs ($p \leq 0.0200$). The resultant predicting model explained 83.6% of the variance ($R^2 = 0.836$, $F = 32.371$ and $p < 0.0001$). Moreover, when other domains of the WHOQOL were not significant, only domain V of SC patients exhibited a significant ($p \leq 0.0360$) association with their social support system (living alone and with others). The coping strategies of SC patients – spirituality, religion and personal beliefs ($r = 0.838$ and $p \leq 0.0001$), positive feelings ($r = 0.872$ and $p \leq 0.0001$) and lack of negative feelings ($r = 0.824$ and $p \leq 0.0001$) – were found to be highly correlated with overall QoL of SC patients. In the absence of an effective cure so far, the assessment of QoL in SC patients is very relevant and the WHOQOL-100 is seemingly a comprehensive QoL tool for SC patients.

286. THE EFFECT OF EARLY PSYCHOTHERAPEUTIC INTERVENTIONS IN MULTIPLE TRAUMA PATIENTS WITH AND WITHOUT HEAD INJURY – INTERIM RESULTS AFTER 10 MONTHS

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Severe trauma causes pain, physical, social and psychological problems for patients. Trauma patients, with and without head injury, can develop depression and anxiety that compromise their quality of life (QoL), as evidenced in many studies. In Germany, trauma patients routinely receive medical and social services, but not psychological support. We started a randomized clinical trial to demonstrate the effects of early psychotherapeutic interventions on QoL and rehabilitation for patients with multiple injuries, with and without head injuries.

The study will include 260 patients with multiple injuries. The patients are stratified into those with and without head injury. Patients with head injury have neuropsychological testing. Patients in each strata are randomly assigned to receive psychotherapy or standard care. The therapeutic interventions are provided in five sessions during the period of acute care.

Patients complete psychological tests and medical assessments five times: on the ward, at discharge and at 6, 12 and 24 months following time of injury. The psychological test includes questionnaires for anxiety, depression social support, global QoL and trauma-specific QoL.

The study started in July 1996. By the end of April 1997, we had screened 61 patients for this study; 27 patients were excluded from the study before randomization, 30 patients were randomized, and five of them later dropped out. A part of the interim results from the first two assessments of 25 are presented in table 1.

The results suggest that patients in the intervention group show better psychological outcome than patients in the control group. There are minimal differences in the SF-36 score for ‘vitality’, ‘psychological well-being’ and ‘health perception’.

### 286. Table 1. interim results of two times of assessment (standard deviation in parentheses)

<table>
<thead>
<tr>
<th></th>
<th>With therapy</th>
<th>Without therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>On the ward</td>
<td>By patient’s</td>
</tr>
<tr>
<td></td>
<td>($n = 13$)</td>
<td>discharge</td>
</tr>
<tr>
<td>STAI</td>
<td>46.23 (12.65)</td>
<td>36.00 (7.58)</td>
</tr>
<tr>
<td>SCL9OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>67.74 (31.02)</td>
<td>38.62 (33.47)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>54.06 (37.51)</td>
<td>27.22 (28.22)</td>
</tr>
<tr>
<td>Phobic anxiety</td>
<td>54.57 (26.85)</td>
<td>25.58 (29.27)</td>
</tr>
<tr>
<td>SF-36</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health perception</td>
<td>No</td>
<td>63.36 (25.48)</td>
</tr>
<tr>
<td>Vitality</td>
<td>No</td>
<td>51.36 (20.98)</td>
</tr>
<tr>
<td>Psychological well-being</td>
<td>No</td>
<td>66.54 (14.00)</td>
</tr>
</tbody>
</table>
287. QUALITY OF LIFE IN SCHIZOPHRENIC PATIENTS  
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The aim of this study was to analyse the social functioning and quality of life (QoL) of schizophrenics to determine the necessity for their rehabilitation and social care.

One hundred and fifteen patients with the confirmed DSM-IV criteria for schizophrenia were examined. The assessment procedure included the psychopathologic rating and Global Assessment of Functioning scale.

Positive symptoms (chronic hallucinatory and paranoid disorders) were observed in 77.4% of these patients. Of the patients of this group 52.2% had expressed negative disorders (anergy, avolition, apathy, affective blunting, alogia and asociality). None of the patients had a job. Seventy-one patients were acknowledged as invalids. Of the patients 84.4% were indifferent to work and social life and 13.1% of the patients with apathetic-abulic disorders were characterized by an inability for orientation, movement, persistent inability for minimal personal hygiene and self-service.

These patients had a persistent inability for functioning practically in all spheres, such as work, behaviour control and communication.

The data of this investigation demonstrate that the QoL of schizophrenics depends on the intensity of negative disorders and the ability for work and communication.

Depending on the increasing gravity of mental disorders regularity in limiting the spheres of social functioning and decreasing QoL in the mentally diseased, was revealed.

The assessment of QoL in schizophrenics reflects a present-day necessity for treatment and social care.

288. CHANGES IN THE QUALITY OF LIFE IN SUBJECTS WITH A HISTORY OF A MYOCARDIAL INFARCTION  
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The purpose of this study was to assess the change in quality of life (QoL) in the chronic phase after a myocardial infarction.

This study is an observational study of two measurements of QoL by means of the Sickness Impact Profile, with a 1–3 year time interval between the measurements. The study population was selected from participants in the Rotterdam Study, a prospective follow-up study on chronic disabling diseases in the general population aged 55 years and over. The study population consisted of 82 subjects who had been admitted to the hospital because of a myocardial infarction in the previous 6–60 months and 92 reference subjects without a history of myocardial infarction or stroke, with the same age and gender at baseline (n = 174). Mann-Whitney tests were done to test for differences in QoL at baseline. Since there is no golden standard for what is a 'true' change in QoL separate from random error, we classified the subjects into 'improved', 'equal' and 'deteriorated' according to four definitions of 'change' namely the one point difference method and the five points difference method and two methods (the dichotomic and tertile method) using a classification at baseline and follow-up in ‘good’, ‘bad’ (or ‘moderate’) QoL. Subsequently, we calculated the proportions ‘improved’, ‘equal’ and ‘deteriorated’ for the study groups. χ² tests and logistic regression analyses were done to compare the case and reference groups with respect to the proportion of ‘improved/deteriorated’.

At baseline, the cases and referents differed with respect to sleep and rest, emotional functioning, household management, social interaction and recreation and pastimes. Both univariate and multivariate analysis showed that a higher proportion of the cases, compared to referents, improved with respect to emotional functioning and deteriorated with respect to eating.

Myocardial infarction patients in the chronic phase of the disease do not differ from reference subjects as to the change in their QoL over time, except for emotional functioning and eating. Therefore, most differences, found at baseline, were still present some years later.

289. SOME ASPECTS OF QUALITY OF LIFE OF ALCOHOLICS  
Vojin Popovic, Irena Popovic, Vojin Lilic, Suzana Totic, Ljubisa Zlatanovic and Dragan Vukic  
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The quality of life (QoL) of alcoholics has become an important issue, both in the community and in the hospital. In our study we examined 30 alcoholics from the alcoholic ward in our hospital. We used a QoL checklist, which is based on the theoretical considerations reviewed above and was developed for quick, simple recording of assessments of the various aspects of QoL: household, environment, safety services, communication, education, relationships, dependency, inner experience, medical care, leisure, work, vocational rehabilitation and religion. Moreover, we compared the results from the checklist with some characteristics of alcoholics: age, education, living place (town/village), length of drinking and number of hospitalizations. The results showed us that 55.5% of the aspects of QoL were unsatisfactory for alcoholics. Patients from towns are more satisfied than patients from villages, older patients are more satisfied than younger and patients with higher education are more satisfied than others. The conclusion is that most QoL checklist aspects are satisfactory for only 37.5% of alcoholics: most of them live in towns, are aged over 50 years and have a good education.

290. QUALITY OF LIFE OF CHRONIC SCHIZOPHRENIC PATIENTS. RELATION TO SOME SOCIAL–PSYCHIATRIC CHARACTERISTICS  
Irena Popovic, Vojin Popovic, Jelena Mladenovic, Snezana Vladejc, Vojin Lilic, and Suzana Totic  
Special Psychiatric Hospital, Gornja Toponica, Yugoslavia

In this study we examined 30 patients with chronic schizophrenia. They completed the Quality of Life Checklist (QOLC) on the basis of a 1 h semi-structured-interview. The results of the QOLC were discussed according to some social-psychiatric characteristics of the patients, such as age, education, living place (village/town), schizophrenia type, duration of illness, number of hospitalizations and the use of neuroleptic drugs. Generally, the results show that over 50% of patients signed unsatisfactory next to aspects of the QOLC: relationships, dependency, inner experience, leisure and work. Significantly ‘satisfactory’ scores were recorded for the following aspects: environment,
psychiatric care and vocational rehabilitation (in hospital). The conclusion is that better scores on the QOLC (means satisfactory) were from patients with social–psychiatric characteristics: younger patients, those living in a village, high school education, having schizoaffective disorder, shorter length of illness and low number of hospitalizations. A better quality of life was reported by patients using 'atypical' neuroleptics in the previous 3 years.

291. QUALITY OF LIFE ASSESSMENTS ARE ESSENTIAL ENDPOINTS IN CLINICAL ECONOMICS
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The allocation of resources in health care systems is based on both medical and economic considerations. Services which are beneficial to patients but not well remunerated will be provided less frequently than services which are less beneficial for patients but generously remunerated. This obstacle indicates that health care reform is mainly a cultural problem.

The allocation of resources in health care systems can be improved if the rules of evidence-based medicine (EBM) are applied and if a distinction is made between the effectiveness (from the physician’s point of view) and benefit (from the patient’s point of view) of medical services. This distinction will influence several aspects of the health care system including the economy of medical services. The term effectiveness should be used to describe a surrogate parameter (e.g. lowering blood pressure or the concentration of blood lipids) while the term benefit may indicate the ultimate goal (e.g. the reduction of strokes, heart attacks and deaths). Effectiveness is measured in the dimensions of the test system used (mmHg or mg 100 ml-1). Benefit is measured in only two dimensions: quantity (objective data) and quality of life (QoL) (subjective but hard data). Clinical economics would compare outcomes with intangible costs while the term economy of medical services. The term effectiveness should be improved if the rules of evidence-based medicine (EBM) are applied and if a distinction is made between the effectiveness (from the physician’s point of view) and benefit (from the patient’s point of view) of medical services. This distinction will influence several aspects of the health care system including the economy of medical services. The term effectiveness should be used to describe a surrogate parameter (e.g. lowering blood pressure or the concentration of blood lipids) while the term benefit may indicate the ultimate goal (e.g. the reduction of strokes, heart attacks and deaths). Effectiveness is measured in the dimensions of the test system used (mmHg or mg 100 ml-1). Benefit is measured in only two dimensions: quantity (objective data) and quality of life (QoL) (subjective but hard data). Clinical economics would compare outcomes with intangible costs while the term economy of medical services.

The change from effectiveness-oriented to benefit-oriented medicine may be useful in the assessment of legal consequences of standards for the approval of new drugs, for the selection of the best clinical trial methods, for distinction between unconventional methods and evidence-based medicine and, finally, for clinically meaningful economic analyses.

292. BASELINE ASSESSMENT OF QUALITY OF LIFE IMPROVES THE QUALITY OF CLINICAL TRIALS
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Data on quality of life (QoL) characterize the impact of disease and treatment on clinical outcomes. In addition, there are some results in the literature which indicate that the data on QoL may not only reflect but also predict clinical outcomes. To address this question in this study we investigated the prognostic value of QoL for survival in patients with advanced malignancies.

Adult patients with incurable malignancies from 12 institutes in ten countries completed the EORTC QLQ-C30 questionnaire once at study entry. The baseline characteristics were recorded. We tested whether QoL assessment is an independent predictor of survival by using a proportional hazards model stratified on diagnostic categories.

Between November 1989 and September 1995, 735 eligible patients were included. In October 1995 follow-up information was available for 656 patients of whom 411 had died. The factors predictive of worse survival were age and performance status. Several of the QoL scales were predictive of subsequent survival in univariate analyses. When allowing for performance status, age and metastatic sites (the last one in patients with solid tumours), only three single item scores, overall physical functioning, overall QoL and social functioning, remained independent prognostic factors.

Our results confirm previous reports demonstrating the independent prognostic value of QoL for survival. This result suggests that baseline QoL data should be assessed in trials which use survival as an outcome measure. Reliable QoL data will also be useful to confirm the comparability of patient groups in randomized controlled trials.

293. VICTIMIZATION OF MENTAL PATIENTS
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Mental patients have an increased capacity to become victims of crimes. Our research was devoted to this problem and was based on an examination of 100 schizophrenic in-patients.

Three patterns of psychopathological-determined victimization were studied: physical, psychical and social. The physical pattern presupposes an increased vulnerability of a person to suffer physical traumatization. Psychical victimization means an increased vulnerability of a person to psychogenic factors. Social victimization shows in numerous unfavourable social factors. We studied the victim behaviour of the patient which may be ‘aggressive provocative’ if it leads to damage to a patient as a result of the active actions of other persons trying to prevent this aggression. ‘Active provocative’ behaviour is not aggressive but the actions of patients lead to the reactions of others. ‘Passive’ behaviour occurs due to the incapacity of a person to undertake actions preventing damage to themselves.

The knowledge of victimization of mental patients and their behaviour as victims may help in the development of treatment and rehabilitation programmes as well as in prevention of violence against them.

294. QUALITY OF LIFE AFTER OPEN HEART SURGERY – A PROSPECTIVE STUDY
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The study included 390 adult patients who underwent open heart surgery between 1 September 1995 and 31 December 1996. Quality of life (QoL) was seen as one multidimensional concept which included all aspects: expected and observed mortality (Parsonnet System ’95) and QoL related functions of patients after operation.

All patients were interviewed before the operation and 6 and 12 months after the operation. The questionnaire included five...
aspects of QoL: physical status, mental status, employment, social interaction and self-perception of health.

The results showed that open heart surgery was significantly beneficial for the patient; physical status was improved ($p < 0.001$), as was mental status ($p < 0.001$) and also self-perception of health ($p < 0.001$). Social interaction was improved, but not significantly, while employment remained at the same level. The data are also analysed according to surgical procedures (coronary, valvular and combined). The study confirmed the hypothesis that (1) there was significant improvement in QoL of patients before and after operation and (2) the level achieved 6 months after the operation remained unchanged 12 months after the operation.

The study showed that patients significantly improved their maximal physical activities and were relieved from their everyday burdens (fatigue, chest pain and dyspnoea).

295. QUALITY OF LIFE IN RELATION TO THE PREOPERATIVE RISK LEVEL - 2 YEAR STUDY
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University Clinic of Cardiovascular Surgery, Novi Sad, Yugoslavia.

The aim of this study was to examine the relation between patients' pre-operative severity of illness and QoL status before and 6 and 12 months after operation.

The analysed data were taken from the project, which consisted of two major topics. The first one is Parsonnet's Risk Stratification System '95 (PRSS), for quality assessment in open heart surgery and the second part is QoL of patients after open heart surgery. For the assessment of QoL, we used a self-designed questionnaire with five aspects (physical, mental and employment status, social interaction and self-perception of health).

In the period September 1995–February 1997, 390 patients living within 100 km from our clinic, underwent open heart surgery for acquired heart diseases. All patients were interviewed (by the same physician) before and 6 and 12 months after operation. The patients were categorized into four groups according to their PRSS level (group I fair risk and group IV very high risk). The observed improvement of QoL was analysed with regard to the pre-operative PRSS groups.

The first three groups showed similar QoL status pre- as well as post-operatively. Despite the fact that patients from group IV had much worse results with regard to the other three groups, the relative improvement of their QoL status was even greater. For example, their self-perception of health reached an impressive 87.5% of patients who answered good or very good, compared to the pre-operative 15% of patients.

296. HEADACHE AND QUALITY OF LIFE: EPIDEMIOLOGY AND OUTCOMES IN PRIMARY CARE
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Many studies have demonstrated that headache has negative effects on quality of life (QoL). A study in the general German population showed, for example, that people suffering from migraine are more disturbed in QoL (SF-36) than people who are diabetics. These results demonstrate that QoL should be regarded as a relevant outcome parameter in headache therapy.

The monitoring of outcomes of treatment of chronic headache includes a comprehensive information feedback to physicians and patients. In a pilot study a model with structured information about the patient history, the treatment process and treatment outcomes was tested.

Quality indicators and measurement instruments contain information about (1) headache characteristics (clinical and anamnestic questionnaire), (2) frequency and intensity of headache attacks (headache diary), (3) pain-related restrictions in activities of daily life (pain disability questionnaire) and (4) general health status and QoL (SF-36).

Quality indicators are defined for four levels of data aggregation and evaluation. (1) the monitoring of the individual patient, (2) the evaluation of treatment processes and results within a single practice, (3) comparison between practices and (4) evaluation of interventional effects of physician qualification programmes.

The preliminary results of the application of the model will be reported.

297. ADVANTAGES OF QUALITY OF LIFE WORKSHOPS
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It is universally agreed that quality of life (QoL) is an important aspect of the clinical evaluation of cancer treatments. Obtaining such information from these patients can sometimes be difficult due to health status and it is therefore essential that procedures are adopted which will maximize the potential of gathering such information.

In order to achieve good compliance rates it is extremely important that the purpose of the QoL study and what the assessments will entail are explained thoroughly to the patient prior to receiving informed consent. This is often the role of an individual in the hospital setting other than the treating clinician and it is therefore vital that these individuals are familiar with and aware of the reasons for the trial and importance of the QoL assessments.

The Yorkshire Clinical Trials and Research Unit is responsible for coordinating and managing several cancer clinical trials which include QoL assessments. The recent implementation of QoL workshops prior to the launch of a trial has proved successful as a means of communicating information to the relevant individuals and this in turn has contributed to the achievement of high compliance rates exceeding 80% in each trial. Such pre-trial workshops have also been recommended by the MRC and EORTC as a means of improving the standard of QoL data.

The methods of setting up a QoL workshop and the information which should be communicated within these will be explained in further detail.
298. CHILD AND MATERNAL REPORTS OF HEALTH-RELATED QUALITY OF LIFE AS IT RELATES TO PULMONARY FUNCTION IN ADOLESCENTS WITH CYSTIC FIBROSIS

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An increase in lifespan for children with cystic fibrosis (CF) has resulted in the recent need for additional research on every aspect of being an adolescent with CF. Past CF research has used mothers as the preferred or primary respondent although reporter discrepancies between mothers and children with CF are well-documented for child adjustment. Few studies have examined health-related quality of life (QoL) and functional status in the CF population. This study examines health-related QoL as reported by 32 adolescents with CF and their mothers. Health-related QoL was measured using the Child Health Questionnaire (CHQ-PF98 and CHQ-CF87) self and parent reports, which measure ten domains of child health-related QoL (physical functioning, bodily pain, role-social limitations due to physical health, emotional and behavioural health, mental health, behaviour, self-esteem, general health and family activities). A measure of pulmonary function (FEV1) was also collected. While significant correlations were observed between adolescent and maternal reports of health-related QoL, mothers’ reports of health-related QoL were not related to pulmonary function on any scales. However, adolescents’ reports on their general health, physical functioning, role-social limitations due to emotional difficulties and role-social limitations due to physical health were related to FEV1. These findings have implications for the importance of using multiple reporters when examining child health-related QoL in clinical research, assessment and intervention.

299. REDUCING THE ITEMS OF THE NOTTINGHAM HEALTH PROFILE

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The Spanish version of the Nottingham Health Profile (NHP) has been used in many research studies since it was released for general use in 1987. The present study aimed to develop a short form of the NHP suitable for use in clinical practice. Data from all the Spanish studies that included the NHP since 1987 were collected in a common database. Studies were identified by searching Medline and the Spanish Medical Index from 1987 to 1995, as well as the NHP cession registry. The 38 NHP items were subject to an item analysis following standardized procedures. Corrected item-total correlation coefficients (r) (discrimination index), the proportion (p) of people choosing the ‘yes’ response alternative (endorsement index) and exploratory factor analysis (EFA) served as the criteria for the reduction of the questionnaire. Forty-five different studies were included, covering a total of 9,419 subjects from the general population to patients with different clinical pathologies. The subjects were randomly split into two different subsamples. Analyses were performed in subsample A (85%) and validated in subsample B (15%). The NHP items showing a low r (< 0.4) and low p (< 0.20) were excluded first (ten items). The EFA of the remaining items revealed a four-factor structure. A secondary reduction was performed next by deleting those items showing a low portion of variance (< 0.3) associated with the variance on the four factors (three items) and those items showing the highest factor loading lower than 0.4 or similar loadings in different factors (difference ≥ 0.1) (five items). The NHP reduction resulted in a new short form containing 20 items covering four different health dimensions or scales: physical, emotional, pain and sleep disturbances. The standards of internal consistency reliability were well satisfied (α range 0.82–0.84). EFA was additionally used to determine whether the four NHP-20 dimensions could be reduced to a unique general dimension or score. The results indicated one principal component was an optimal solution (loadings range 0.77–0.85), accounting for 67% of the total variance in the four scales of the NHP-20. These results support the calculation of a summary measure of the NHP-20 as a simple addition of its four components.

300. EPIDEMIOLOGICAL ANALYSIS OF SOCIAL STRESS DISORDERS IN REFUGEES FROM CHECHNYA

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The psychopathological analysis of 800 refugees with social stress disorder (SSD), term of Y. Alexandrovsky) from Chechnya was carried out for 3 years to improve their quality of life (QoL). All of these refugees voluntarily asked for psychological-psychotherapeutical, psychopharmacological help from the psychiatrist of ‘Civic Promotion’ – a public committee for helping refugees and forced migrants. There are a number of reasons for SSD in Russia: the consequences of a long period of totalitarianism, economic and political difficulties and local civil wars which caused the appearance of hundreds of thousands of refugees and forced migrants. All these causes the specific psychopathological manifestation due to macro-social psychogenic traumatization with profound changes of living standards.

It was shown by means of phenomenological methods that 10% of refugees suffered from pre-disease conditions with emotional tension and insomnia, 20% had affective-shock reactions, 30% had psycho-adaptive states with neurasthenic, hysterical, anxious and phobic reactions and 40% had pathological personality development or psychosomatic disorders or reactions of social protest. Nosologically all the above mentioned groups of patients may be determined as having SSD, a variant of post-traumatic stress disorder when enormous groups of the civil population are involved. In the treatment of patients with SSD combinations of different kinds of psychotherapy (rational and suggestive, behavioural) with varied psychopharmacotherapy (anxiolytics, hypnotics and mild neuroleptics: alimemazin–teralen, thiordaniz–melleril, and periciazin–neuleptil) were used. The combination of psychotherapy with psychopharmacotherapy was the most effective.

301. APPROACHES TO CONSTRUCT VALIDATION OF QUALITY OF LIFE IN HEALTHY AND MENTALLY DISORDERED INDIVIDUALS

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Although there exists a vast number of instruments for measuring quality of life (QoL) as a multidimensional outcome
Diabetic patients showed high scores in the areas of sexuality and socialization. Significant differences were observed in the incidence and seriousness of anxiety and depression symptoms between males and females. The occurrence of complications was associated with a lower quality of life (QoL) and worsened the scores of all SAS areas. Psychological disturbances appeared to be more prevalent in patients requiring an insulin regimen. Both the duration of disease and glycaemic control correlated positively with the depression, anxiety and socialization scores.

In our experience, anxiety, depression and other indexes of psychological problems reflect the difficulties of adjusting to chronic illness.

304. DERMATOLOGY-SPECIFIC QUALITY OF LIFE AN INSTRUMENT VALIDATED FOR USE IN PSORIASIS SUBJECTS
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A dermatology-specific quality of life (QoL) instrument has been previously tested and validated for use in patients with other cutaneous diseases such as acne and contact dermatitis. The purpose of this three-step study was to adapt the dermatology-specific QoL instrument for use in psoriasis subjects. A psoriasis dermatology-specific QoL prototype was created using a literature review and consultation with dermatologists specialized in psoriasis and including ideas from a diverse focus group. A first pilot study tested the items in the prototype for psychometric performance such as internal consistency, reliability and validity by correlating the data with PASI (Psoriasis Area and Severity Index) and SAPASI (Self-assessed PASI) scores. As suggested by these tests, items were omitted and/or reworded as necessary. A second pilot study administering the modified version of the dermatology-specific QoL prototype instrument on 60 psoriasis subjects (20 patients each with mild, moderate and severe psoriasis as classified by a clinician) was performed to monitor the improvement in psychometric performance and finalize the instrument ready for use in clinical trials. The dermatology-specific QoL instrument, as a result of these study processes, has 40 items. The results also show the psoriasis dermatology-specific QoL scales have good to excellent internal consistency and respond to increasing severity of PASI and SAPASI scores and good correspondence with physicians global rating of severity. The most important scale content areas, in terms of disease severity, appear to be symptoms, social functioning and work.

305. COMPARATIVE STUDY OF THE QUALITY OF LIFE OF PHYSICALLY MALTRATED AND SEXUALLY ABUSED FILIPINO CHILDREN
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The objective of this study was to assess and compare the quality of life (QoL) of physically maltreated (PM) children, sexually abused (SA) children and children with no reported history of abuse (NA).

Two hundred and twenty-four children aged 6–14 years were purposely chosen from schools, hospitals and social welfare institutions in Metro Manila. Through institutional records, 80
Psoriasis is a chronic skin disorder affecting 1–2% of the population. It produces swollen, red, scaly lesions on the skin that can appear anywhere on the body. Disease-specific measures of psoriasis-related quality of life (QoL) have documented a negative impact on physical, psychological and social functioning. This study describes predictors of health-related QoL in psoriasis and compares it to the health-related QoL of five other chronic conditions.

A biopsychosocial model of the impact of psoriasis was developed that included both disease-specific measures of QoL and generic measures (Short Form 36). A survey of 317 psoriasis patients was used to test the model. The results from the SF-36 were examined to (1) compare psoriasis to depression, myocardial infarction, hypertension, congestive heart failure and type II diabetes and (2) examine the association between 19 specific biopsychosocial aspects of psoriasis (e.g. itching, pain, scaling, self-consciousness, etc.) and health-related QoL.

The results revealed that disease severity was significantly associated with all dimensions of health-related QoL. Compared to the other chronic conditions, psoriasis had a particularly negative impact on mental health. Regarding physical health functioning, psoriatics fared worse than hypertensives and diabetics. Lastly, all 19 aspects of psoriasis were associated with QoL, but multiple regression analyses revealed that different aspects are related to physical and mental health functioning.

These results support earlier findings that health-related QoL is often adversely and broadly affected by this disease. Moreover, they point out the need for multidimensional treatment programmes that address psychosocial as well as physical aspects.
The results indicate significant associations between seizure severity and QoL, but only for some dimensions. The results from separate multiple regressions analyses will be presented showing significant predictors of global epilepsy-related QoL, life satisfaction, positive mood, negative mood and income. Positive drug side-effects, negative drug side-effects and patients' sense of mastery emerged as consistent predictors of epilepsy-related QoL.

These results show that refractory epilepsy can have broad negative impact on the lives of patients. They also reveal that the relationship between seizure severity and epilepsy-related QoL is complex. While Baker et al.'s conceptualization of epilepsy-related QoL is supported, further development is needed to capture the complexity of this disorder.

309. DOCUMENTATION OF QUALITY OF LIFE WITHIN QUALITY ASSURANCE MEASURES–CARRYING OUT FIELD STUDIES ON THE REGIONAL CARE OF CANCER PATIENTS

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In field studies, which have been sponsored by the Federal Ministry of Health (BMG), Germany, the structural requirements, the procedures and the results of treating cancer patients ('tracer diagnoses', breast cancer, cancer of the rectum and lung cancer) are being evaluated by nine selected tumour centres on the basis of guidelines for diagnosis, treatment and after-care. A key aspect of the studies is the direct questionning of patients, focusing particularly on documenting their quality of life (QoL) (subjective well-being) and psychosocial situation. Complete registration would mean a prospective total of approximately 6,000 patients for the tracer diagnoses.

The patients' QoL is registered using (1) patient self-assessment and (2) external assessment by physicians, by means of biannual mailed questionnaires over a period of 5 years. For the patients, the QoL measure developed by the EORTC was chosen, namely the EORTC-QLQ-C30 together with the specific modules for the respective diagnoses. For the measurement of QoL by the physicians it was decided to use the SPLITZER Index. A key aspect of the methodology used in the field studies is supervision by two centres (the Institute for Psychosomatic Medicine of the Munich Technical University and the Institute for Biometrics and Epidemiology of the Ludwig-Maximilians University Munich), which coordinate and match the details of the QoL evaluation and documentation with the individual centres and supervise the analysis of the QoL data. Already it is obvious that the QoL questionnaires meet with a high level of acceptance with the physicians and patients involved and it appears as though the registration of QoL can be integrated into the overall schedule of regular treatment.

The findings of the evaluation will have to be individualized in communication between patients and their physicians. The application of the results on an individual basis represents one of the big challenges for implementation for general practitioners.

310. QUALITY OF LIFE IN CHRONICALLY ILL CHILDREN AND THEIR PARENTS—PSYCHOMETRIC AND CONTENT-ANALYTICAL RESULTS USING THE GERMAN KINDL

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The literature on quality of life (QoL) and children shows (1) that there is substantial need for scientific research in this field and (2) that no instrument for measuring QoL for children is available in the German language which can be used in epidemiology or medical care for assessing QoL. This paper presents the results from the empirical evaluation of the KINDL, a German questionnaire consisting of 40 items assessing emotional, physical, social and functional aspects of QoL.

A group of 90 children aged 10–16 years (45 children suffering from chronic conditions (diabetes and asthma) and 45 healthy controls) were recruited from the files of German rehabilitation clinics. The questionnaires were mailed. In addition to the children, their parents were also interviewed with regard to their own well-being and QoL as well as with regard to their perception of their children's well-being and function.

The main findings are as follows. (1) The KINDL appears to be a reliable and feasible measure (internal consistency beyond α = 0.80. (2) Children suffering from a disease tend not to differ from healthy controls with regard to the KINDL dimensions. (3) Sociodemographic factors do not impact on the perceived QoL of children with chronic diseases. (4) Relationships between ‘health locus of control’, ‘social support’, ‘stress’ and QoL are existent. (5) In addition, answers to open questions showed that specific concerns and problems of children and parents have to be addressed in such a questionnaire. (6) Parents’ perceptions of their children’s QoL differ from the children’s perceived QoL.

The results encourage us to make use of and examine KINDL in further studies and show that the instrument is economic and promising but needs further work in terms of the independence of subscales as well as modular supplements grasping the specific problems and limitations in QoL due to health conditions.

311. HEALTH-RELATED QUALITY OF LIFE IN END-STAGE RENAL DISEASE PATIENTS OVER 65 YEARS

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The objective was to evaluate health-related quality of life (QoL) of aged end-stage renal disease (ESRD) patients and to find associations between QoL and sociodemographic and clinical variables.

One hundred and twenty-four ESRD patients over 65 years on renal replacement therapy (RRT) were evaluated with the Sickness Impact Profile (SIP) and SF-36 Health Survey. Karnofsky Scale (KS), co-morbidity index (CI), sociodemographic and clinical data were collected.

(1)Description of studied sample. Age 71.36 ± 4.78 years and 55.6% male, Diagnostic of renal disease = others (30.8%) nephroangiosclerosis (23.3%), glomerulonephritis (15%), diabetes mellitus (10.8%), polycystic renal disease (10%) and...
interstitial nephropathy (10%). Transplanted patients 19.8% Haemoglobin = 10.49 ± 2.03 g dl⁻¹. Creatinine = 8.63 ± 4.31 g dl⁻¹. Albumin = 3.87 ± 0.50 g dl⁻¹. CI = 3.78 ± 4.13 diseases. KS = 70.32 ± 11.47.

(2) Scores of health-related QoL evaluation instruments. SIP: physical dimension (PHY) = 13.34 ± 12.31, psychosocial dimension (PSY) = 17.56 ± 14.83 and total (TOT) = 17.83 ± 11.38. SF-36: physical functioning (PF) = 53.14 ± 26.43, role physical = 67.13 ± 49.98, bodily pain (BP) = 68.89 ± 30.03, general health (GH) = 42.55 ± 23.06, vitality (V) = 53.30 ± 23.40, social functioning (SF) = 82.55 ± 24.21, role emotional (RE) = 77.68 ± 40.92 and mental health = 77.82 ± 79.75.

(3) Significant associations (unpaired samples t test: p ≤0.05). The female sex was associated with worse health-related QoL. SIP’s PHY, PSY and TOT and SF-36’s PF, BP, GH, V and SF). Transplanted patients had better health-related QoL on the SF-36 (PF, BP, GH, V and SF) and SIP (PHY, PSY and TOT). A higher economic level is associated with better health-related QoL (SIP’s PHY and TOT and SF-36’s PF) as well as a higher educational level (ISP’s PSY and TOT and SF-36’s BP and GH).

(4) ANOVA for diagnosis of renal disease. The only significant difference (p < 0.05) found was the highest punctuation on SIP’s E category in ‘diabetes mellitus’.

(5) Associations with Pearson’s correlation (p < 0.05). The KS score, haemoglobin and serum albumin had a positive correlation with the SF-36 and a negative correlation with the SIP. Serum creatinine and the co-morbidity index had a negative correlation with the SF-36 and positive one with the SIP. ESRD patients over 65 years on RRT show damaged areas in health-related QoL, mainly physical and general health. There are differences in health-related QoL due to sex, renal transplant, functional status, serum haemoglobin, albumin and creatinine, CI and economic and educational levels.

312. QUALITY OF LIFE IN KIDNEY-TRANSPLANTED PATIENTS

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The aim of this study was to evaluate quality of life (QoL) levels in kidney-transplanted patients and its relationship with sociodemographic and clinical parameters.

One hundred and eighty-six kidney-transplanted patients of age less than 65 years and without cognitive impairment were assessed using the Sickness Impact Profile (SIP), the SF-36 and the Karnofsky Functional Scale (K).

The mean age was 47.3 years (SD 10.9 years) and 65% were males. The differential subdiagnosis was as follows: nephroangiosclerosis (8.6%), diabetes (8.1%), glomerulonephritis (36.2%), interstitial nephropathy (17.3%), polycystosis (11.9%) and others (17.8%). The mean time in prior haemodialysis was 26.5 (SD 33.1) months and the mean months since transplant was 55.5 (SD 43.2) and 76% were not admitted to hospital during the previous year. The haemoglobin, creatinine and albumin levels were 13.4 (SD 2.1), 2.1 (SD 1.6) and 6.3 (SD 8.5) respectively. The co-morbidity index was 1.6 (SD 1.1). The mean scores on the different instruments were SIP physical 3 (SD 5.5), psychosocial 6.3 (SD 8.5) and total 8.2 (SD 6.1) and SF-36 PF 84.3 (SD 11.8), RP 88.1 (SD 28.3), BP 80.3 (SD 24.7), GH 64.7 (SD 21.6), V 74.4 (SD 17.5), SF 93.4 (SD 14.5), RE 86.7 (SD 31.4) and MH 79 (SD 16.6).

Greater age was associated with a worse functional state (K) and a worse QoL (PF).

(1) Females showed a worse functional status (K) and worse QoL levels on the following domains.

(2) Greater time on the haemodialysis was associated with lower QoL as measured by the SIP.

The functional status and QoL level can be considered as moderate in this group of patients.

313. CONTENT ANALYSIS OF ITEMS IDENTIFIED AS CONFUSING ON THREE QUALITY OF LIFE MEASURES

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Quality of life (QoL) measures are frequently used with adults who may have deficits in attention, memory or other cognitive abilities. Other than anecdotal comments, no assessment of items found confusing by cognitively impaired individuals has been reported. Therefore, to determine what items on the Sickness Impact Profile (SIP), Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) and the Comprehensive Quality of Life Scale: Intellectual Disability Version (Com-QoL-ID) are confusing to adults with mild to moderate impairment, a content analysis was done of questions and comments recorded during interviewer administration of the three measures.

The sample consisted of 153 non-institutionalized subjects, aged 18–59 years, with some cognitive impairment secondary to traumatic brain injury, multiple sclerosis, schizophrenia or severe obstructive sleep apnoea. All subjects were categorized into one of four levels of impairment by testing with the Neurobehavioral Cognitive Status Examination (NCSE). Most subjects were interviewed twice at an interval of 2 months as part of a larger study. All questions, requests for clarification and comments were recorded during the interview. Each interview included 228 QoL items, the SIP 136 items in 12 categories, the SF-36 36 items in eight categories and the Com-QoL-ID 56 items in seven categories. Out of 394 interviews and approximately 85,000 item responses, approximately 3% or 2,550 item responses included a question or comment.

The method was that of quantitative content analysis. All recorded comments were entered into a word processor on an item by item basis. Counts were done on the queries per item. The types of queries were categorized through a process of constant comparison within the data and between the two investigators.

The preliminary results suggest certain types of items are more problematic than other items. As expected, unfamiliar and more colloquial terms generated queries as did items which included double negatives. There were numerous queries about items which implied comparison but for which the basis of comparison was not clearly specified. The tendency of these subjects to think concretely and the careful recording of their comments may provide insights into how other respondents may interpret items. This information may help researchers and clinicians in choosing measures and aid developers in the refinement of new items.
314. HEALTH-RELATED QUALITY OF LIFE ASSESSMENT VIA TELEPHONE: A VIABLE ALTERNATIVE?
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Self-completed questionnaires and in-person interviews are the most frequently used methods for gathering data on health-related quality of life (QoL). In-person interviews can be expensive and the requirement for a clinic or home visit can be burdensome to patients. Self-completed questionnaires have disadvantages as well, including low response rates, unmonitored completion and a higher frequency of missing data. This paper will discuss the use of the telephone interview as a viable alternative for the evaluation of health-related QoL in patient surveys and clinical trials.

Following a brief overview of the principles and practices underlying telephone surveys, the discussion will turn to three health-related QoL measures whose psychometric properties have been evaluated across the method of administration: the MOS SF-36, the Psychological Well-Being Index (PGWB) and the Quality of Life in Epilepsy Inventory (QOLIE-89). Published data on the SF-36 and PGWB and results from a recently completed study of the QOLIE-89 will be used to illustrate the relative internal consistency reliability, stability and construct validity of telephone versus in-person and self-completed questionnaires in the USA. The paper will conclude with a discussion of the advantages and disadvantages of telephone administration in health-related QoL research and will identify issues in need of further research.

315. QUALITY OF LIFE OUTCOMES FOR OLANZAPINE AND HALOPERIDOL TREATMENT FOR SCHIZOPHRENIA AND OTHER PSYCHOTIC DISORDERS: RESULTS OF AN INTERNATIONAL RANDOMIZED CLINICAL TRIAL.
MEDTAP International, Bethesda, MD, USA and Lilly Research Laboratories, Indianapolis, IN, USA

The effects of treatment with olanzapine (OLZ) or haloperidol (HAL) on efficacy and quality of life (QoL) outcomes were evaluated in patients with schizophrenia and other psychotic disorders. This was an international randomized double-blind clinical trial with 1,996 patients with DSM-III-R diagnosis of schizophrenia, schizophreniform disorder or schizoaffective disorder and baseline BPRS (0–6 scale) total scores of ≥18. Patients were randomized to either OLZ 5–20 mg per day or HAL 5–20 mg per day for acute (6 week) therapy and responders continued for up to 52 weeks. The patient assessments included the BPRS, PANSS, CGI severity, Quality of Life Scale (QLS) and SF-36 Health Survey scores. During the acute treatment phase, OLZ had significantly greater improvements in the BPRS total (p < 0.01), PANSS total (p < 0.05) and CGI severity (p < 0.01) scores compared with HAL. OLZ compared with HAL had statistically greater 6 week mean improvements in the QLS total, intrapsychic foundations and interpersonal relations scores and the differences in the QLS total and intrapsychic foundations scores were maintained over 52 weeks of therapy. Acute phase changes in the SF-36 mental component summary, general health perceptions, mental health and vitality scores statistically signifi- 316. IMPUTING HEALTH STATUS SCORES MISSING DUE TO MORTALITY: COMPARISON OF MULTIPLE TECHNIQUES
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MEDTAP International, Bethesda, MD, Georgetown University, Washington DC and Amgen, Inc., Thousand Oaks, CA, USA

The analysis of health status outcome data from clinical trials is complicated by missing data due to mortality. There is no standardized methodology for incorporating missing data due to mortality. A simulation study was conducted to evaluate the performance of four techniques for imputing missing values for the statistical analysis of health status data: (1) last value carried forward (LVCF), (2) arbitrary substitution (i.e. scores for patients reporting worsening health), (3) empirical Bayes inference and (4) patient-specific modelling. A set of simulated data files with SF-36 physical function scale scores was constructed assuming a control and treatment group with a varying percentage of mortality and changes in physical function scores. Simulated population characteristics were compared to the estimates derived from the four methods. The findings suggest that all four methods are comparable when there is little or comparable mortality between the groups. When there are higher rates of mortality, LVCF under-weights the impact of mortality and the empirical Bayes inference and arbitrary substitution methods best capture the true population effects. Patient-specific modelling results in intermediate findings. We will make recommendations for imputing missing data under different expected mortality and health outcomes.

317. AN ATTEMPT TO QUANTIFY QUALITY OF LIFE IN A HOSPITAL AND THE ASSOCIATED PROBLEMS OF COMMUNICATION BETWEEN PARENTS AND HOSPITAL STAFF OF A BABY WARD
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The admission of a child to hospital could be experienced by some parents as restricting their autonomy and creating doubt in their ability to offer basic care. This could encourage regressive behaviour such as dissatisfaction, aggression and helplessness. The more vulnerable mother–infant dyad can be particularly affected being of a different reality to the outside world. The parents may assume that this hospital admission could be a misunderstanding and problems in the overall handling of the situation within the ward. For quality control it is necessary to ensure a certain standard of psychosocial support. The ongoing project has the following aims.

(1) To gain information on the quality of life (QoL) of the adults at the time of their child’s admission.
(2) To assess any communication problems between parents and hospital staff.
(3) To provide a concrete basis for psychosocial intervention.
(4) To encourage hospital staff to be more sensitive to the intrafamilial relationships.

As a measure instrument we have used a modified questionnaire from Kusch on aspects of the parents’ active involvement/strain and also on the behaviour of the child. This questionnaire is distributed to parents, doctors and nursing staff alike. We are aspiring to a total of 250 hospitalized infants for our empirical evaluation. The results of the completed project will be presented.

318. LONGITUDINAL QUALITY OF LIFE ASSESSMENT IN PATIENTS WITH END-STAGE HEART FAILURE BEFORE AND AFTER CARDIAC TRANSPLANTATION

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This prospective study was designed to evaluate quality of life (QoL) and life changes before and in the first year after heart transplantation (htx).

Between February 1994 and April 1997 158 patients waiting for heart transplantation, 143 m, 15 f and 52 ± 11 years) were included. Every 6 months pre- and 1, 5, 3, 6 and 12 months post-transplantation the patients received standardized and validated questionnaires: the SF-36, Munich life quality dimension list, heart failure and specific transplant symptom list, expected/experienced life changes after transplantation. The data were analysed using SPSS and p < 0.05 was defined as the level of significance.

Up to April 1997 69 patients had been successfully transplanted, 53 were waiting and six were delisted. Thirty patients died, 15 before and 15 post-transplantation. The return rate of questionnaires was 100% before and 96% post-transplantation.

Before transplantation, QoL was rated by 90% of the patients as rather poor or miserable. Only 6 months after transplantation 84% of the patients described their QoL as fair, good or excellent. Looking at the whole group, QoL correlated best before transplantation with somatic variables (e.g. satisfaction about health r = 0.64 and physical performance r = 0.69, p < 0.01), while 6 months post-transplantation psychological variables appeared more important (e.g. psychological state r = 0.61 and self-esteem r = 0.68, p < 0.01). While the somatic changes expected before transplantation corresponded well with the experienced ones, psychological improvements were smaller than expected in many areas. When the patients were grouped into five age categories (group I age < 30, II 31–40, III 41–50, IV 51–60 and V ≥ 60 years), a clear age dependency of the patients' satisfaction about health and physical well-being was seen: while before transplantation group V patients were significantly (p < 0.04) more dissatisfied about their physical state than group I/II patients, 6 weeks post-transplantation group V patients were significantly (p < 0.04) more satisfied.

QoL parameters improve rapidly and significantly after successful transplantation. While pre-transplantation somatic variables dominate patients’ subjective well-being, psychological well-being is the most important determinant of QoL after transplantation. Thus, psychological problems and the non-fulfilled expectations, which are frequently observed, demand special attention and care. The patient’s age and the degree of pre-operative dissatisfaction about the physical state both appear to have a significant impact on post-operative satisfaction.

319. THE ROLE OF FAMILY AND FRIENDS IN MAINTAINING QUALITY OF LIFE IN BONE MARROW TRANSPLANT SURVIVORS

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Bone marrow transplantation (BMT) is a physically and psychologically demanding procedure used to treat a variety of otherwise incurable malignant and non-malignant diseases. The purpose of this paper is to discuss the pivotal role that family and friends play in maintaining quality of life (QoL) before transplantation. The City of Hope QoL-BMT instrument was mailed to a sample selected from the clinical cancer centre’s file of patients who had undergone BMT during 1976 through to December 1994 and were 18 years or older at the time of survey. Two hundred and ninety-six surveys were returned yielding a response rate of 64%. The data presented in this paper were collected with an open-ended question asking respondents to identify a particular event, experience or ‘story’ that conveys their experience as a person who has had a BMT. Content analysis was performed on the verbatim written responses to the question. Demographic data will be reported including diagnosis, gender, ethnicity and type of transplant. Verbatim quotes indicating the important role that family and friends have in maintaining QoL will be shared. The findings have several implications for (1) educating health care providers about the importance of providing psychological support for family and friends of transplant patients, (2) educating family and friends about the important role that they play in maintaining QoL for transplant patients and (3) ongoing research to describe the impact of cancer and its treatment on family and friends.

320. ADAPTATION IN FRENCH OF THE CHILD HEALTH QUESTIONNAIRE AND VALIDATION IN CHILDREN AGED 10–18 YEARS

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The aim is to provide clinicians and researchers in public health with a validated French version of the Child Health Questionnaire (CHQ) in children from 10 to 18 years of age. This generic instrument was initially developed by J. Landgraf in Boston and has already been validated in several languages.

The instrument is a self-administered questionnaire, comprising 87 questions grouped in nine dimensions: perceived health, physical activities, pain, general behaviour, self-esteem, relations with family, relations with others and general well-being. There is also a questionnaire completed by the parents, comprising 50 questions grouped in the same dimensions.

Two groups of children have been recruited.

(1) One hundred children suffering from cancer, after completion of their treatment for at least 6 months, who are free of disease. Two hospitals are participating, the Gustave Roussy Institute in Villejuif (immediate suburbs of Paris) and Hospital...
321. VALIDITY OF THE HEALTH UTILITIES INDEX IN EVALUATING THERAPIES FOR ACUTE STROKE

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Moderate to severe acute ischaemic stroke (IS) is characterized by a high mortality rate and deficits in multiple domains of health-related Quality of Life (QoL). For the first time, new therapies with the potential to treat acute IS successfully are being developed. Any scale used to evaluate the outcome of such therapies must address these issues as well as be amenable to inclusion in a clinical trial. One such scale is the Health Utilities Index (HUI) mark II, a generic multi-attribute utility measure. The purpose of this paper is to present data on the validity of the HUI when used to evaluate outcomes of acute IS in a clinical trial setting. The setting for this study was a clinical trial of a new neuroprotectant. Patients were followed from enrolment (within 6 h of onset of stroke) to 12 weeks post-stroke. Data from the control groups of two studies are presented: one conducted in North America (n = 315) and one in Europe/Australia (n = 297). The mark II/III version of the HUI was used in each trial, although only the mark II was scored. Family care givers served as primary respondents due to the high level of patient disability. It was hypothesized that the HUI at week 12 would be strongly and positively correlated with measures of neurological function (NIH Stroke Scale/European Stroke Scale), functional status (Barthel Index) and disability (Rankin), but would exhibit a much lower association with the pre-stroke HUI due to the devastating impact of the stroke. It was further hypothesized that the HUI would discriminate between older and younger stroke victims and between those identified clinically as having a mild to moderate or severe stroke. These hypotheses were supported. In the North American trial, the correlation of the week 12 HUI with the NIHSS, Barthel Index and Rankin all exceeded 0.85, while the correlation with the pre-stroke HUI was 0.25. The HUI scores for patients considered to have a severe stroke were significantly lower than those with moderate strokes (p < 0.001), while those over 75 years had significantly lower scores than those ≤75 years (p < 0.001). The results for the European/Australian trial supported these findings. We conclude that these data provide strong evidence for the validity of the HUI as a measure of health-related QoL outcomes for victims of moderate to severe acute IS in the clinical trial setting.

322. THE SHORT FORM-12: A USEFUL MEASURE OF HEALTH-RELATED QUALITY OF LIFE FOR ELDERLY PEOPLE?

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The MOS Short Form-36 (SF-36) is being increasingly used as a measure of health-related quality of life (QoL). However, unless administered by personal interview, the response and data completion rates for elderly respondents may be poor, particularly when the respondents are in ill-health. A shortened version of the SF-36, the SF-12, purports to reproduce adequately the physical and mental component scores derived from the SF-36. If this is the case, the SF-12 may provide a useful alternative to the SF-36 for elderly people.

Health status data was collected by postal survey in a Commonwealth-funded ambulatory care reform project. The data of elderly respondents (mean age = 74 years and SD 6.32 years) receiving ambulatory care for conditions including diabetes and asthma in South Australia were used. Regression analysis was employed to determine the degree to which the SF-12 items accounted for variance in the SF-36 physical and mental component scores. The analysis of 432 records indicated that the SF-12 items accounted for 92% of the variance in the physical component score (compared with 82% in previous Australian analysis) and 87% of the variance in the mental component score (compared with 56% in previous Australian analysis). These results suggest that the SF-12 merits further examination, particularly for use as an alternative to the SF-36 with elderly respondents in ill health.

323. ASSESSMENT OF THE LIFE SITUATION AND THE QUALITY OF LIFE IN LONG-TERM SURVIVORS OF HODGKIN’S DISEASE

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The treatment results in Hodgkin’s disease have improved tremendously in the last two decades. Along with this the group of long-term survivors is growing constantly. Although treatment regimens become more sophisticated, little is known of the life situation (LS) of these patients. To elucidate this field we constructed an extensive questionnaire (LSQ) adapted from the original French version including aspects of health, socioeconomic situation, sexuality, emotional status and leisure activities. The LSQ was combined with a pre-validated quality of life (QoL) self-report measure.

From September to October 1995 we contacted, with the help of the local physician 1,981 patients who were enrolled in the German Hodgkin Studies HD 1–6. All patients were treated according to the treatment protocols from the HD I–3 (1981–88) and HD 4–6 (1988–93). The patients with a current status of complete remission were asked to complete the LSQ comprising...
45 questions and the QoL questionnaire (EORTC QLQ C-30 plus additional scales and questions).

To date 768 questionnaires are available for analysis. The completeness of the forms is very high. Ongoing analysis is including the description of geographic patterns, unemployment and work circumstances as well as the current family situation, perceived health status and the correlation of these variables with regard to self-reported QoL. The analysis will focus mainly on the LS and QoL status of subgroups of patients particularly in regard to the employed medical treatment regimes and the reported late sequelae of treatment and Hodgkin’s disease.

Up to now we can state that the compliance of the patients is very high indicating a great need to express their experience of a life-threatening illness even years after the end of treatment. The method of investigation is feasible. It should be used more often to take advantage of the patients’ experience for creating better supportive care in the future.

324. QUALITY OF LIFE IN A HEALTHY POPULATION–AN EPIDEMIOLOGICAL RESEARCH

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The aim of the study was to establish standard values for a quality of life (QoL) questionnaire in healthy controls. We investigated approximately 2,000 people in Tyrol. The life satisfaction questionnaire (FLZ) from Herschbach was used to assess QoL on the following dimensions: general health, partnership and sexuality, family, housing, social support, hobbies, income and occupation. Further, the distinction between importance and satisfaction on the multidimensional construct QoL can be investigated with the help of the FLZ.

Standard values have been established separated by age, sex, education and residence. Differences in QoL could be shown between the variables gender, residence and age. In QoL research sociodemographic variables have to be taken into consideration, to make detailed declarations on specific clinical populations. Further research with tumour patients will allow us to compare a clinical population with healthy controls.

325. QUALITY OF LIFE RESEARCH–THE NEED FOR GENERALLY ACCEPTED GUIDELINES

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Scientific research under the ‘quality of life (QoL)’ banner is becoming more and more of general interest in medicine. By focusing on the amount of publications we found over 6,500 publications in medical journals over the last 4 years measuring and interpreting the effects of and on QoL. However, taking a closer look at most of those articles one can perceive that everyone uses the construct QoL in several different ways, but no-one defines the concept. So one must believe QoL is in some publications what several questionnaires measure and in others just a catchphrase. They measure it if at all to a very limited extent as well-being on a physical and/or on a psychological dimension. Until now there has been neither general agreement upon the dimensions of QoL nor agreement upon the methods for assessing QoL. From a methodological viewpoint it has to be discussed, if the assessment of QoL just with a questionnaire is not a contradiction in terms.

The demand for a generally accepted formal definition should be the primary interest in QoL research. QoL is only assessable in multidimensional space and until now only one serious attempt has been made by Levy et al. (1975). The mapping sentence of Levy et al. should be taken as a base to intensify further research. QoL is defined as cognitive and affective assessment due to at least the following dimensions: communication, economic, education, family, habits, immigration, information, physical state, psychological state, recreation, religion, security, society and work. The construct of QoL requires a combination of questionnaire and interview assessment with relation to the preferences and the individual history of a person. On the basis of the interview results an integration of the subjective perceptions of patients in the scoring of questionnaires appears possible. Scientists should be aware that a lot of effort has to be made to investigate the multidimensional facet of QoL. It is generally agreed that scientific work depends on an adequate definition of a phenomenon; the QoL concept is as yet a vast amount of loosely defined concepts. Up to now one should not neglect that we are not able to instrumentalize and investigate QoL; the authors therefore suggest the use of interviews until satisfactory screening instruments have been established.

326. HOPE AND QUALITY OF LIFE IN NEWLY DIAGNOSED CANCER PATIENTS

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The aim of this study was to evaluate the effect of a nursing intervention on hope and quality of life (QoL) in cancer patients. The study used an experimental design where patients were randomly allocated to three different groups. Group 1 was the experimental group where the members received an intervention to increase hope. The second group (attention control group) participated in the ‘I Can Cope’ programme. The last group was a control group. The hope intervention consisted of eight 2 h meetings and focused on confidence, emotional reactions, relationships to others, active involvement, possibilities in the future and spirituality. An oncology nurse led the courses.

To assess the QoL two different questionnaires were completed: the Ferrans and Powers Quality of Life Index and the Cancer Rehabilitation Evaluation System, short form (CARESF). The Nowotny Hope Scale was used to measure hope. The patients filled in the questionnaires at home twice before and 2 weeks and 6 months after the intervention.

The sample consisted of 96 newly diagnosed Norwegian cancer patients aged between 26 and 78 years; the majority were women (71%). They were suffering from different types of cancer with breast cancer being the most common type (43%). Seventy-eight percent were diagnosed within the previous 6 months. Nobody was terminally ill. The patients showed a surprisingly high level of both hope and QoL at baseline. Multiple regression analysis using dummy variables to represent group membership
was performed to measure the changes in scores after intervention. The level of hope was significantly increased ($p = 0.037$) for the members of the hope group just after the intervention, but not after 6 months. In spite of the positive patients’ evaluations of the interventions, there was no impact on QoL.

From this study there is reason to believe that the nurse can improve hope in newly diagnosed cancer patients, at least in the short-term. In order to increase hope one has to focus on different aspects. Receiving attention and meeting others in the same situation is not enough. The high level of hope and QoL before the intervention may explain the lack of long-term impact.

327. COPING WITH SEVERE OBESITY: WHAT HAPPENS AFTER SURGERY?
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One purpose of this longitudinal study was to explore well-being and coping strategies among the severely obese. Does weight reduction increase well-being and what effect does it have on coping strategies? The SOS study consists of a registry and an intervention trial. The subjects reported here are the first 500 surgical cases at their 2 year follow-up (68% were women and mean age 46.6 years). The battery of questionnaires included the Mood Adjective Check List (MACL), Rosenberg’s Self-esteem Scale and a newly developed coping measure. Two years post-surgical intervention the BMI (body mass index) had decreased and mood and self-esteem had increased significantly.

327. Table 1.

<table>
<thead>
<tr>
<th>Surgical cases at baseline</th>
<th>Surgical cases at 2 years</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Men</td>
</tr>
<tr>
<td>BMI</td>
<td>40.6</td>
</tr>
<tr>
<td>Mood</td>
<td>3.00</td>
</tr>
<tr>
<td>Self-esteem</td>
<td>31.11</td>
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</table>

Compared to 1,332 subjects from the registry, surgical cases 2 years post-intervention reported significantly lower scores on the coping factors intrusiveness and helplessness but no differences on introversion. Great weight reduction co-varies with improvement in mood and self-esteem. It also reduces feelings of life being dominated by the obesity (intrusiveness) and that impact of events is not under one’s own control (helplessness).

328. GROUP WORK WITH PARENTS–CARE GIVERS OF PATIENTS WITH CHRONIC SCHIZOPHRENIA
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It is widely known that the life of families of the mentally ill is negatively affected by the lack of useful (from the point of view of care givers) information about mental disorders, the absence of any practical advice on the management of different types of disruptive behaviour, problems of the relationships of the mentally ill and their families (care givers), deficiencies in support from the outside and many other factors. Quality of life (QoL) of such families encompasses many aspects, including access to different types of professional care and information about the rights and opportunities of the mentally ill and their families. Taking into consideration these aspects a group of researchers and psychiatrists from the Research Center on Mental Health Support Systems has been carrying out a complex group psycho-educational programme aimed at clearing up the most acute and common problems of parents-care givers of the mentally ill and at reducing their subjective burden. A total of 32 parents took part in it. The majority of the participants ($n = 26$) were mothers, ages 45–76 years, all the parents lived together with their mentally ill children and were members of different Moscow organizations of relatives of mentally ill people. The programme of meetings was worked out on the basis of a wide range of the most pressing and typical needs of relatives and included different information on the clinical and treatment aspects of schizophrenia and practical advice on the management and prevention of suicide and aggressive behaviour of schizophrenic patients, information on different societies of relatives and friends of the mentally ill, practical meetings with psychologists and training on methods of self-regulation, lectures by therapists on somatic co-morbidity, somatic complications and the side-effects of psychiatric treatment, information on religious aspects of care and attitudes to the mentally ill and musical concerts for relaxation of relatives. Care givers who participated in all meetings experienced a decrease in the subjective burden of caring for their mentally ill children, an increased understanding of their problems, a more positive relationship with them and reduced emotional tension in their families.

329. DEVELOPMENT OF A DISEASE-SPECIFIC MULTI-ATTRIBUTE SYSTEM FOR CHRONIC INSOMNIA
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1Mapi Values, UK and 2France

The utility approach to the measurement of health-related quality of life (QoL) assigns values to various health states based on the preferences elicited from patients, health care providers or members of the community. A disease-specific multi-attribute utility study comprises two elements: the development of a multi-attribute system which systematically describes the patient health status corresponding to the disease in question and a multi-attribute utility index which assigns a value to health status measured within the classification system. A health-related QoL questionnaire measuring patient health status is based on the multi-attribute system and can be implemented within clinical trials to monitor the outcomes associated with treatment or for individual patient management by assessing improvement.
of a patient’s condition over time. The main benefit of a disease-specific multi-attribute instrument compared to a generic instrument is its responsiveness to change with regard to the characteristics of the disease in question. The insomnia multi-attribute system (IMAS) was developed to assess the level of suffering caused by chronic insomnia in terms of sleep quality and daytime health-related QoL, consequences. The domains relating to the consequences of chronic insomnia and its treatment were explored through discussions with clinicians and chronic insomnia sufferers. The discussions were held in three European countries (France, Germany and the UK) for cross-cultural examination. The resulting conceptual domains of the IMAS include sleep quality, psychological and social functioning and role performance. Utilities corresponding to IMAS health states were gathered through rating scale and standard gamble techniques. The utility interviews were conducted within a sample of 180 persons recruited from the three European countries. Utility models were fitted and the predictive validity of these models were tested in the study. The data on the utilities for insomnia-related health states will inform the decision maker on the value of a ‘good night’s sleep’ as indicated by patients and members of the community. A comparison of the robustness and usefulness of the insomnia utility data and the IMAS against existing insomnia health-related QoL measures has implications on the added value of utility assessment with regard to decision making for treatment adoption and patient management.

330. PSYCHOSOCIAL DISABILITIES AND INTERPERSONAL PROBLEMS IN PANIC DISORDER
G. Sachs, P. Berger, M. Anmering, A. Holzinger, D. Maierhofer, B. Bankier and H. Katschig
Department of Social Psychiatry and Evaluation Research, Department of Psychiatry, University of Vienna, Austria

Worse psychosocial functioning and difficulties in relations with partners or friends were found to be associated with a poor prognosis in patients with panic disorder (PD). In order to clarify the role of social adaptation and interpersonal problems in the psychopathology of PD the study evaluated how the severity of illness relates to particular types of psychosocial functioning and interpersonal problems.

One hundred patients with PD according to DSM IV with and without agoraphobia who participated in a randomized study with paroxetine versus paroxetine and group psychotherapy were included. The following ratings were performed: the Inventory of Interspersonal Problems IIP (L.M. Horowitz) as a self-rating, the Disability Scale (D.V. Sheehan) and the Clinician’s Global Impression as clinicians’ ratings. Statistical analysis employed Spearman correlation coefficients.

The severity of illness was associated with social and family disabilities and specific interpersonal problems at baseline evaluation; analysing the subgroups of the IIP we found significant correlations with overly introverted, subassertive and nurturant.

Follow-up data will be analysed 1 year after the end of the treatment to investigate the prognostic ability of these variables in the course of the disease.

331. QUALITY OF LIFE IN PROCTOLOGICAL PATIENTS
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The aim of our study was to measure the quality of life (QoL) in patients with benign proctological disorders. We used the Gastrointestinal Quality of Life Index (GIQLI) developed by E. Eypasch et al. which, to date, is the only validated instrument in the German language to evaluate gastrointestinal disease. Apart from 75 healthy and proctologically asymptomatic controls, the questionnaire was completed by 325 consecutive patients (182 male, 143 female and mean age 49 years) seen at our proctological out-patient clinic. For further analysis patients were classified according to the primary diagnosis into nine subgroups: (1) haemorrhoidal disease (n = 96), (2) fissure-in-ano (n = 38), (3) fistula-in-ano (n = 22), (4) severe constipation (n = 14), (5) anal incontinence (n = 35), (6) symptomatic anterior rectocele (n = 12), (7) perianal abscess (n = 7), (8) perianal thrombosis (n = 7) and (9) miscellaneous conditions (e.g. prolapse, eczema, condylomata, etc.) (n = 92). The mean score for healthy controls was 134 (i.e. 95% of the maximum score of 144) and for all patients 113 (78.5%). Testing for discrimination between healthy subjects and patients resulted in a left factor of 0.813 and an area under the ROC curve of 0.877 in the Receiver Operating Characteristic (ROC) test. Analysis of the nine diagnostic subgroups revealed the following mean scores: (1) 120, (2) 104, (3) 119, (4) 94, (5) 93, (6) 112, (7) 115, (8) 129 and (9) 117. The U-test (Mann–Whitney) showed a significant (p < 0.05) difference between the control group and each patient subgroup, respectively. The significance level was also reached for the incontinent patients when tested against all other patient subgroups, apart from the patients with severe constipation (p = 0.85). It is concluded that the GIQLI is a valuable instrument for measuring QoL in proctological patients.

The GIQLI is a very good instrument for discriminating between healthy subjects and patients. Furthermore, our study showed that patients suffering from incontinence had the significantly lowest overall score reflecting the profound negative psychosocial impact of this disorder. Interestingly, patients suffering from severe constipation also exhibit a rather low score which probably warrants more attention by health care providers.

332. COMpendium of Quality of Life Instruments
M. S. Salek
Medicines Research Unit, Redwood Building, King Edward VII Avenue, Cardiff, CF1 3XF, UK

The Medicines Research Unit at the University of Wales, Cardiff in collaboration with the Centre for Medicines Research, has compiled a comprehensive Compendium of Quality of Life Instruments. The aim was to provide a sourcebook of original questionnaires and related information for those working and/or interested in the field of health-related quality of life (QoL). The compendium contains 160 questionnaires covering a broad spectrum of disorders, with sections devoted specifically to children and the elderly.

A total of 300 developers/authors of QoL/health status instruments worldwide were identified and invited to collaborate during the period November 1995 to March 1997. There were a total of 53 non-responders/refusals and 104 incompleters (i.e those who did not meet the deadline for first edition). These will be featured in the subsequent updates. The first edition of the compendium will contain 160 instruments and their respective cross-cultural adaptations.

The compendium will be of tremendous use for anybody
interested in this field or involved in the clinical evaluation of medical treatments (e.g. comparing treatment modalities or treatment regimes, monitoring therapeutic outcomes and assessing QoL in disease management). Information on each instrument and its cross-cultural adaptations is complimented by a relevant and comprehensive bibliography. The fact that there are such a large number of measures available shows that there is no single instrument that would satisfy all users and be appropriate for all purposes. The purpose of this compendium is to present as many instruments as possible to facilitate the selection of an instrument likely to be suitable or requiring adaptation to a specific group/area or, when the group/area in question requires a new approach, facilitate the examination of existing knowledge and experience.

This will be an ongoing research project and the compendium will be updated at regular intervals.

333. ASSESSMENT OF QUALITY OF LIFE IN RENAL PATIENTS USING THE RENAL QUALITY OF LIFE PROFILE—A VALIDATION STUDY

M. S. Salek, H. Jones and G. A. Coles

1Medicines Research Unit and 2Department of Renal Medicine, University of Wales, Cardiff, UK

End-stage renal disease (ESRD) is a chronic condition which can result in death unless renal replacement therapy (i.e. haemodialysis (HD) or continuous ambulatory peritoneal dialysis (CAPD) and transplantation) is initiated. Clearly, supplementing clinical outcomes with quality of life (QoL) outcomes in patients with ESRD is of paramount importance. The Renal Quality of Life Profile (RQLP) was developed to provide a monitoring tool in both routine clinical assessment and research situations. The aim of this study therefore was to determine the validity of the RQLP in dialysis patients.

Forty-three randomly selected haemoglobin-matched CAPD patients (28 male, 15 female, mean and median age 55 years, range 23–80 years, mean duration of treatment 25.5 months, range 6–96 months and mean duration of dialysis 33.3 months, range 6–156 months) were recruited from the renal unit at the University Hospital of Wales. Each patient completed a renal-specific QoL instrument, the RQLP and a general QoL measure, the SF-36, in the CAPD out-patient clinic, after giving informed consent.

The results for both the RQLP and SF-36 showed a substantial QoL impairment in CAPD patients, in particular for areas such as physical activity (RQLP mean score = 61, SD ± 23, and SF-36 mean score = 27.3, SD ± 23), leisure time (RQLP mean score = 69, SD ± 27) and physical role limitation (SF-36 mean score = 18.2, SD 14.2). The RQLP scores increase with more impairment, while the SF-36 scores decrease. The mental health and social functioning from the SF-36 (mean score = 57.7, SD 13.3 and mean score 47.3, SD 14, respectively) were impaired to the same degree as the psychosocial category of the RQLP (mean score 43.5, SD 23). The Spearman rank correlation coefficient showed close correlations (r < 0.01) between the common categories of the RQLP and SF-36. The correlation between the ‘general health’ score from SF-36 and ‘normal life’ score from the RQLP was significantly high (p < 0.01). These findings demonstrate the construct validity of the RQLP and should be encouraging for renal clinicians in adopting this instrument with which to monitor QoL of CAPD patients.

334. LONG-TERM CYCLOSPORIN TREATMENT IMPROVES QUALITY OF LIFE IN ECZEMA

M. S. Salek, A. Y. Finlay and M. J. Sumner

1Medicines Research Unit, 2Department of Dermatology, University of Wales, Cardiff and 3Novartis Pharmaceuticals, Camberley, UK

Previous studies have examined only short-term treatment and have demonstrated that it improves both clinical and humanistic outcomes. The aim of this study, therefore, was to investigate the impact of long-term cyclosporin treatment on patients' health-related quality of life (QoL).

Ninety patients with severe refractory atopic dermatitis (52 male, 38 female, mean age 36.6 years, median 31.5 years, range 12–68 years and mean disease duration 27 years, range 2–67 years) entered a 15 centre, 48 week, open study. During the first 8 weeks, patients received 2.5 mg kg⁻¹ per day. The dose was then adjusted to the minimum effective level with the maximum dose being 5 mg kg⁻¹ per day. Each patient completed the United Kingdom Sickness Impact Profile (UKSIP), the Eczema Disability Index (EDI), and a global rating scale of overall health at baseline and weeks 12 and 48. A follow-up assessment was made 3 months after the treatment was discontinued. The disease activity and proportion of skin affected were measured.

The results indicated a major improvement in health-related QoL and disability as measured by both the UKSIP and EDI. However, this improvement was more pronounced at week 12 (p < 0.01), compared to baseline values, than at week 48 (p < 0.05).

The improvement in health-related QoL was reflected in the disease activity scores (p < 0.01) and in the body area involvement (reduction of 20%, p < 0.01). At the end of the follow-up, the UKSIP and EDI mean scores increased (i.e. deterioration), but were still significantly lower than the baseline values (p < 0.05), suggesting a possible long-term health-related QoL benefit of cyclosporin treatment. The clinical scores also showed the same pattern. The correlation between the UKSIP and EDI scores was significantly high (p < 0.01), demonstrating the validity of the measurements. These findings indicate that long-term cyclosporin may provide a well-tolerated treatment which improves health-related QoL outcomes as well as clinical outcomes in patients with eczema.

335. IMPACT OF INTERMITTENT SHORT COURSE CYCLOSPORIN THERAPY ON QUALITY OF LIFE OF PATIENTS WITH PSORIASIS

M. S. Salek, A. Y. Finlay and M. J. Sumner

1Medicines Research Unit, 2Department of Dermatology, University of Wales, Cardiff and 3Novartis Pharmaceuticals, Camberley, UK

Strategies for optimizing cyclosporin treatment because of concern over its continuous long-term use are urgently needed. The aim of this study therefore was to investigate the quality of life (QoL) impact of intermittent therapy in chronic plaque psoriasis using a new formulation called Neoral® over a 1 year period.

A total of 41 patients with chronic plaque psoriasis (26 male, 15 female, mean age 36 years, range 18–61 years and duration of psoriasis 17.1 years, range 1.8–30.6 years) entered a nine-centre, open study in which cyclosporin was taken as an initial dose of 5 mg kg⁻¹ per day for maximum of 12 weeks for up to three cycles. Each patient completed a psoriasis-specific QoL measure (the Psoriasis Disability Index) at baseline (i.e. beginning of each treatment cycle), at the end of the treatment period in each cycle.
and at the end of the study (i.e. 4 weeks after the final treatment period, the last follow-up). Clinical parameters such as the psoriasis area assessment, severity of psoriasis lesions and PASI were measured.

The Psoriasis Disability Index scores showed a significant improvement ($p < 0.05$) between the baseline visit value and the last treatment value for all three treatment periods. Comparing the last follow-up score to baseline there was significant improvement ($p < 0.01$) between the baseline value and the last treatment value for all three scores over all three treatment periods. However, comparing the last follow-up value to baseline there was a clear indication of relapse (at no point did the values after relapse reach the baseline value). A significant improvement (more than 50%) was seen in the PASI score ($p = 0.0001$) when comparing the mean score at first baseline (12.8) to that at the end of the study (5.9). These findings suggest that a short course of intermittent therapy with cyclosporin in microemulsion formulation used at starting doses of 5 mg kg$^{-1}$ per day improves the QoL of patients with chronic plaque psoriasis–clear evidence of QoL outcomes complementing the clinical outcomes.

336. QUALITY OF LIFE IN NON-ORGANIC AND ORGANIC SLEEP DISORDERS

B. Saletu, H. Löffler, P. Anderer, K. Decker, G. Gruber, G. Klösch, L. Kircheis, M. Mandl, S. Parapatics, U. Tschida and H. Katschnig

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Quality of life (QoL) was investigated in 100 sleep laboratory patients (39 females, age 52 ± 13 years and 61 males, age 53 ± 10 years) as compared with normals. The measures included QoL (Mezzich and Cohen), the PSQI, objective (polysomnographic) and subjective sleep and awakening quality (psychometry). Statistical analysis (Mann–Whitney U-test) showed QoL to be significantly reduced in sleep disorders (SDs), and more so in non-organic than in organic SDs. Non-organic patients with hypersomnia were more disturbed than those with insomnia. Within organic SDs, apnoea patients were more disturbed than obstructive snorers. Out of ten QoL subdimensions, seven were more disturbed in SDs than in normals (no differences in social support, environment and spiritual fulfillment). Non-organic SDs were worse than organic SDs in physical and psychic well-being and general QoL. QoL was more deteriorated in affective than in anxiety disorders. QoL correlated well with subjective sleep and awakening quality and thymopsyctic measures and badly with objective sleep quality (except for latency, total sleep period and sleep stage $S_1$) and objective awakening quality and noopsychic measures. Treatment based on sleep laboratory studies improved QoL persistently for 1 year and rehospitalizations were rare (15% in non-organic and 25% in organic SDs).

337. EVALUATION OF QUALITY OF LIFE AND VISUAL IMPAIRMENT IN MALI

J. F. Schemann$^1$, A. Leplege$^2$, T. Keita$^1$, E. Ecosse$^2$ and S. Resnikoff$^3$

$^1$IOTA, Mali, $^2$INSERM U292, France and $^3$WHO, Switzerland

A cross-sectional survey on visually impaired and blind people has been conducted in the Mopti region in Mali. A sample of 10,690 people was selected at random and all those over age 40 years (2,021 people) were checked for their visual acuity.

All the blind (112) had their eyes examined and were interviewed on the following topics: their socioeconomic characteristics, their therapeutic histories and the consequences of visual loss on their work and their daily living and their quality of life (QoL). An equal number of people with low vision were submitted to the same questionnaire. This paper reports on the validation and the preliminary results of the QoL questionnaire.

Thirteen questions evaluated four subscales of QoL of visually impaired and blind people: autonomy (four), mobility (four), social life (three) and happiness (two).

We first examined the descriptive statistics for questions and subscale scores. We then performed a multivariate analysis of the data in order to check the instrument validity and reliability. The internal validity was also studied by a factorial analysis. Variations of all the subscales scores were analysed depending on the visual acuity level and then stratified on sex.

337. Table 1.

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Number of Items</th>
<th>Number of response choice</th>
<th>Cronbach's $\alpha$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autonomy</td>
<td>4</td>
<td>5</td>
<td>0.81</td>
</tr>
<tr>
<td>Mobility</td>
<td>4</td>
<td>5</td>
<td>0.88</td>
</tr>
<tr>
<td>Social life</td>
<td>3</td>
<td>3</td>
<td>0.51</td>
</tr>
<tr>
<td>Happiness</td>
<td>2</td>
<td>5</td>
<td>0.46</td>
</tr>
</tbody>
</table>

The convergent and discriminant validities are acceptable for all of the subscales of QoL, with the exception of the social score. So is the reliability estimated by Cronbach's $\alpha$ coefficient.

QoL drops dramatically when visual acuity is just below the visual threshold determining blindness as defined by the WHO (vision less than 0.05).

At the same level of visual loss the QoL of blind women is poorer than for men.

This QoL questionnaire would be valuable to have as an instrument which estimates the impact of visual loss on QoL and which is translatable into the native languages.

This instrument can be used for measuring the impact of the handicap due to visual disability. It could also be used to evaluate the effectiveness of eye care and blindness prevention interventions.

We are currently working on further analysis and data interpretation so as to develop this area of research.

338. DOES SHUNT USE FOR CAROTID ENDARTERECTOMY INFLUENCE POST-OPERATIVE COGNITIVE BRAIN FUNCTION? RESULTS OF A PROSPECTIVE RANDOMIZED TRIAL

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$^1$Institute of Psychology, Department of General and Experimental Psychology, University of Vienna and $^2$Department of Vascular Surgery, University of Vienna Medical School, Austria

Thrombendarterectomy (TEA) of the internal carotid artery (ICA) is well-accepted for preventing ischaemic events in symptomatic
and asymptomatic patients with a high grade (> 75%) ICA stenosis. So far clinical practice has mainly considered parameters of general neurological functions following surgery of the ICA. Highly advanced cognitive functions were not assessed routinely. The aim of our study was to demonstrate a possible benefit in neuropsychological outcome of patients having been operated with intraluminal temporary shunt.

Eighteen patients undergoing elective TEA of the ICA until May 1996 presenting an ICA stenosis of > 75% were randomized into surgery with or without the use of a shunt. Eleven patients were operated on using an intraluminal shunt whereas seven operations were carried out without shunt. All patients were subjected to one pre-operative and three post-operative neuropsychological testing procedures on the second and the seventh post-operative day as well as after 3 months.

Statistical evaluation by means of MANOVA (α = 5%) revealed that, with all tests carried out, the first post-operative testing showed worse results altogether compared to pre-operative testing whereas the second and third post-operative tests resulted in a significant improvement compared to the initial testing and to first post-operative testing. A comparison of the two clinical groups revealed significant improvement in favour of the shunted group.

One week and 3 month post-operative control after carotid TEA showed a significant improvement of neuropsychological basic functions. A comparison of the subgroups is in favour of shunted patients.

339. HODGKIN’S DISEASE PATIENTS AND HEALTHY SUBJECTS QOL COMPARE
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For quality of life (QoL) estimation, health, socioeconomic situation, family circumstances, professional activity, personal contacts and some other scales were measured together with goals evaluation according to B. Rabkin’s methods.

Fifty patients with Hodgkin’s disease (HD) (HD group) received treatment according to the protocols MOPP-ABVD and Stanford during the years 1996–1997 in the National Centre of Haematology. The mean age of the subjects was 41 years, with a range from 20 to 60 years, 30 patients were male and 20 female. Nine percent had completed primary school, 48% had finished high school and 43% had university degrees. The control group consisted of 25 subjects of approximately the same age and social condition and of them 15 were male and ten female. The EORTC H8-LQ, the Life Situation Questionnaire and the Personal Goals and Quality of Life of Cancer Patients Cross-Sectional Interview were used. We found that the level of QoL in the HD group was significantly higher than the control group. Only 18 subjects in the control group, less than 40%, were satisfied with QoL.

The health factor was the main one in the HD group: 55% of the patients evaluated this factor as the most important but, at the same time, 32% of the patients ignored it completely. Problems of anosognosia should be studied in this group of patients. The health factor was not important in the control group, with the exception of seven subjects who were retired.

The evaluation of QoL is closely connected with personal goals. In the control group the most important values were family and work. Dissatisfaction with these aspects of life is quite high in the control group. Only 20% of the control group have complete families, 30% are divorced and 50% have no families. The HD group basically estimated their family life positively. In the HD group 50% have complete families, but the family factor as a value is second in importance after health. Eighty-four percent of the HD group were satisfied with their family life comparing to only 25% in the control group.

Health became the most important value and life satisfaction in the HD group is higher than in the control group. This may be connected with a new disease- and treatment-formed attitude to life.

340. QUALITY OF LIFE IN GASTROINTESTINAL TUMOURS EORTC-QLQ-C-30 AND TUMOUR-SPECIFIC MODULES
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Quality of Life (QoL) has become an important issue in the modern quality management of measuring health outcomes in tumour surgery. In our department from 1 August onwards patients with gastrointestinal tumours will be assessed pre- and post-operatively for their health-related QoL in the daily clinical routine. The development of the QoL modules used in this trial takes time and is dependent on specific guidelines given by the EORTC.

In 1987–1989 in a prospective pre-study, QoL was measured in 74 patients with GI tumours at the Department of Surgery at the University Hospital of Hamburg. In open interviews, the patients were asked about their symptoms before, during and after therapy. This list of symptoms was completed by consulting experts and a literature review. All subjectively experienced symptoms were worded into simple questions and tested for clarity. These modules were used in two main studies with 500 (300 plus 200) patients in 1990–1996. The patients answered the questionnaires 1 day before surgery (t1), one day before discharge (t2) and 1 year after radical surgical treatment (t3). This main study was followed by a psychometric analysis to measure the reliability and to reduce the number of items on the questionnaire. The validity was assessed by medical criteria. The questionnaires presented show good reliability and validity and can be completed by patients in less than 20 min. The development of tumour-specific questionnaires for patients with GI tumours according to the guidelines of the EORTC are presented. The results from our prospective and retrospective studies underline the good reliability and satisfactory validity of those GI modules in combination with the EORTC-QLQ-C-30.

341. DEHOSPITALIZATION OF PSYCHIATRIC LONG-STAY PATIENTS IN UPPER AUSTRIA: DESIGN, METHODS AND FIRST RESULTS
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During the last 15 years the number of long-stay patients in the Landes-Nervenklinik Wagner Jauregg has decreased dramatically from 1,100 to approximately 200. In contrast to the first years, where patients mostly have been transferred to nursing homes, now the dehospitalization is more planned and is accompanied by a large evaluation study. The main aims are the documentation, analysis and evaluation of changes in the quality of life (QoL) of the former long-stay patients and to measure and compare costs of the different mental health care systems. As an
adequate instrument we developed LISKAL. This scale for measuring the QoL of people with chronic psychosocial problems consists of five parts and we use one subscale to predict the amount of support that people need to plan an adequate patient-oriented new living situation outside of the mental hospital. First we shall present the results on the main characteristics of the long-stay patients, describe LISKAL and the helpfulness of the subscale amount of support in daily life activities as an instrument in planning the new mental health care system of Upper Austria and will discuss the first results of the comparison of the QoL before and after discharge from the Landes-Nervenklinik Wagner Jauregg.

342. PARENTS’ COPING WITH THEIR CHILD’S CANCER AND THE PARENTS’ SATISFACTION WITH THE HOSPITAL: A RETROSPECTIVE STUDY

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Our study deals with the influence of parents’ coping with their child’s cancer, on their satisfaction with the hospital, on their anxieties and on their outlook on life after the child’s illness. The sample consisted of 632 mothers and fathers of patients who had been treated in the oncology units of the St Anna Children’s Hospital in Vienna and who survived the illness. By using a specifically designed survey parents were asked how they coped with their child’s illness, how satisfied they were with the hospital and about their anxieties and their outlook on life at the time of the investigation. The confirmatory factor analysis procedures employed in the present study supported the distinction in five active and five passive strategies of coping with cancer. By setting up a model following these factors, the influence of parents’ coping strategies on their satisfaction with the hospital, on their anxieties after the child’s illness and on their outlook on life was proved. Our results emphasize that information about the child’s illness given to parents is most important for their compliance and satisfaction with the hospital. No correlation was found between a specific diagnosis of the child and the parents’ coping style or their anxieties in the present study. The major conclusion of these findings is that some active and passive coping strategies have an impact on how satisfied parents are with the hospital and with the information given to them, as well as on their anxieties and their outlook on life at the time of the inquiry. In addition, the results showed that a ‘Damocles syndrome’ exists not only for patients but also for their parents. These results confirm the importance of psychological after-care and support for the family after the child’s illness to improve their quality of life (QoL).

343. EXAMINING COPING VARIABILITY AS A MEDIATOR OF RESPONSE SHIFT

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Research on quality of life (QoL) relies heavily on the measurement of functional status. It is founded, however, on assumptions about the stability of intra-individual referents which may not be valid. The response shift phenomenon refers to meaningful shifts in an individual’s priorities, internal standards or the meaning of QoL, both in addition to and as a result of changes in actual health state. Data are presented from a series of studies with the chronically ill to examine how intra-individual variability in coping behaviour may mediate response shift. Linear methods as well as non-linear dynamical methods are used to illustrate how this variability may reflect maladaptive or adaptive processes which influence an individual’s ability to maintain emotional homeostasis despite chronic illness. A card sort measure was used to investigate coping behaviour in 258 people with lupus, rheumatoid arthritis and multiple sclerosis, as well as the elderly. We show that unreliability in reported coping behaviour was better explained by a maladaptive behaviour pattern than by measurement artefact. This behavioural constellation may be indicative of a self-evaluation process which lacks consistency and resiliency in the face of the losses imposed by illness and appears concomitant with a lack of appropriate cognitive skills to adjust referents, priorities and comparison groups. The adaptive process will be illustrated using non-linear dynamical analyses of the above samples as compared to healthy adults (n = 66). A comparison of coping variability revealed that healthy adults exhibited more situational variability in coping behaviour than did chronically ill people or the elderly. Whereas the maladaptive component may represent a dispositional inconsistency in one’s self-evaluation, the adaptive component may represent a context-driven variability which is at the heart of an adaptive response shift. The implications of response shift for intervention research, observational outcomes research and health policy will be discussed.

344. QUALITY OF LIFE OF EPILEPTIC PATIENTS TREATED WITH CARBAMAZEPINE OR PHENYTOIN

B. Schymura1, N. V. Steinbüchel2, U. Mitzdorf2, E. Pöppel2, Th. Brandt3, M. Busch1 and E. Dühmke2
1Department of Radiotherapy and Radiooncology, 2Institute for Medical Psychology and 3Department of Neurology of the University of Munich, Germany

Contrary to cardiovascular and malignant diseases, for example, which have often been the subject of studies for measuring quality of life (QoL), in epilepsy little effort has been made. Up to now there existed no fully developed instrument for epileptic patients to assess their QoL. The focus of this study was to provide new information on various aspects of their QoL under monotherapy with carbamazepine (CBZ) or phenytoin (DPh). A multicentre study included 202 adult patients (85 female, 117 male and mean age 35 years) suffering from partial simple and complex seizures with and without secondary generalization and primary generalized seizures. One hundred and two patients were treated with CBZ and 100 patients with DPh for a minimum of 6 months prior to evaluation. Patients who presented more than one generalized seizure in this period or more than one partial seizure within the previous 4 weeks did not qualify for the study. All patients answered nine standardized open questions concerning their QoL. A special system was developed to categorize and analyse their answers. QoL of epileptic patients was related to a limited number of four dimensions: psychological, physical, social and everyday life. Specific components were permanent anxiety caused by possible seizures, required changes of their daily living and physical (fatigue, forgetfulness, headache, vertigo and affected concentration) and psychical problems (self-consciousness, acceptance and unfolding) with an effect on their profession and leisure. Both treatment groups showed clear differences in managing their disease: the group under treatment with DPh reacted
Patients with stage II–IIIB inoperable non-small cell lung cancer (NSCLC) were enrolled on six phase II and III studies from 1983 to 1995. Patients were treated with standard radiation therapy (SRT) to 60 Gy, hyperfractionated RT (HRT) to 69.6 Gy, induction chemotherapy (ICT) of cisplatin (CIS) and vinblastine (VBL), followed by SRT, ICT plus concurrent CT (CCT) plus SRT and CCT plus HRT; CCT consisted of etoposide or VBL plus CIS. The toxicities assessed were skin, mucous membrane, lung, oesophagus, heart, neurologic, renal, haematologic and upper gastrointestinal (GI). Quality-adjusted survival was calculated by weighting the time spent with a specific toxicity and local or distant tumour progression. Each toxicity was weighted with increasing severity as the toxicity increased in grade, e.g. lung toxicities were weighted as grade 0 1.0, grade 1 0.95, grade 2 0.5, grade 3 0.25 and grade 4 0.0.

### Table 1

<table>
<thead>
<tr>
<th>Event</th>
<th>Number of patients with toxicity</th>
<th>Mean days lost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>547</td>
<td>149</td>
</tr>
<tr>
<td>Oesophageal</td>
<td>367</td>
<td>62</td>
</tr>
<tr>
<td>Upper GI</td>
<td>154</td>
<td>39</td>
</tr>
<tr>
<td>Haematologic (after RT)</td>
<td>154</td>
<td>49</td>
</tr>
<tr>
<td>Neurologic</td>
<td>118</td>
<td>45</td>
</tr>
<tr>
<td>Metastasis</td>
<td>402</td>
<td>26</td>
</tr>
<tr>
<td>Tumour progression</td>
<td>411</td>
<td>158</td>
</tr>
</tbody>
</table>

### Table 2

<table>
<thead>
<tr>
<th>RT</th>
<th>n</th>
<th>MST (months)</th>
<th>QTIME</th>
<th>ASL</th>
</tr>
</thead>
<tbody>
<tr>
<td>SRT</td>
<td>154</td>
<td>11.6</td>
<td>10.7</td>
<td>0.8</td>
</tr>
<tr>
<td>HRT</td>
<td>368</td>
<td>10.5</td>
<td>9.3</td>
<td>2.9</td>
</tr>
<tr>
<td>ICT plus SRT</td>
<td>149</td>
<td>13.7</td>
<td>13.3</td>
<td>1.0</td>
</tr>
<tr>
<td>ICT plus CCT plus SRT</td>
<td>110</td>
<td>16.3</td>
<td>12.8</td>
<td>2.7</td>
</tr>
<tr>
<td>CCT plus HRT</td>
<td>200</td>
<td>15.8</td>
<td>13.7</td>
<td>2.4</td>
</tr>
</tbody>
</table>

Median survival time, MST; median quality adjusted time, QTIME; average survival time lost, ASL. MST ≠ QTIME plus ASL.

Patients receiving either ICT plus CCT plus RT or CCT plus HRT have the best overall survival, but patients with ICT plus SRT have nearly equivalent QTIME as the regimens containing CCT. CCT appears to increase the overall survival but comes at a price of increased toxicity that adversely affects the quality of the gained survival.
diagnosis. In some cases the physicians took a different view of the QoL of their patients. The qualities of the domains, leisure time, social contacts, sexuality and working situation showed an influence on QoL. However, the principal determinant of QoL was QoH ($r = 82$) being influenced itself by fatigue and malaise ($r = 79$) by pain, sleeping disorders and problems of concentration ($r = 68$) and by physical functioning ($r = 48$). In summary, the study gave better insight into the relationship between QoL, QoH and other domains. Reference values for important diagnostic subgroups are now available. Lastly, our established strategy of covering the patient’s as well as the physician’s view of QoL and related domains substantially enhanced the validity of these results.

348. QUALITY OF LIFE AFTER CABG – HOW CLOSE TO NORMALCY DO PATIENTS GET?
E. L. Shabtai, N. Gafni, Y. Zilber, D. Braun, the ISCB Consortium and E. Simchen
The School of Public Health Hebrew University and Hadassah, Jerusalem, Israel

CABG is the treatment of choice for ischaemic heart disease. Its main goal is the improvement of quality of life (QoL) by reducing angina and dyspnoea and by improving functional status. Previous studies have shown a significant improvement in various dimensions of QoL after CABG. In this study we compare the QoL of patients 12–18 months following CABG to the QoL of a sample of a normal population.

The Hebrew version of the SF-36 questionnaire was used as a QoL measure. A profile of the eight scales of the SF-36 and an additional two scores on the physical and mental components were calculated for each subject, based on self-report. Data were collected in two independent studies: the Israeli CABG study, a prospective study following patients undergoing the operation in Israel in 1994 and the Health Services Study conducted in Israel in 1993. The subjects were 2,849 patients after CABG and a representative sample of 2,030 individuals of the urban Jewish population aged 45–75 years.

The results show that a higher QoL (in every dimension) was reported by the normal sample in comparison to CABG patients matched by gender and age. Interestingly, the discrepancy between the two groups narrows very much in the older age groups (> 65 years). This trend is true of both genders and is more pronounced for the physical component (PC) than for the mental component (MC). The PC scores for CABG women versus normal (45–55 years) were 39.4 ± 11.5 and 49.6 ± 10.6, respectively and for CABG women versus normal (65–75 years) 30 ± 10.6 and 36.9 ± 13.0, respectively. Similarly, for younger men the respective scores were 45.9 ± 10.2 versus 51.7 ± 9.0 and for older men the scores were 43.2 ± 9.9 versus 42.3 ± 12.6, respectively. The two samples were found to differ in several characteristics: CABG patients had more years of schooling, a higher rate of unemployment (before surgery) and a higher rate of married people. A linear regression analysis that was performed in order to adjust for the above variables, showed that CABG surgery versus the normal population was still a significant variable in predicting QoL.

For the changing differences with age between the CABG and normal populations in QoL, we suggest that younger patients are more affected by restrictions, complications and possible side-effects caused by coronary disease and surgery and therefore report a poorer QoL compared to healthy people. These differences disappear with age as older persons expect less of themselves and are less frustrated by the results of the operation. Females after CABG tended to cope worse on the mental dimension. A possible explanation is the higher rate of women living alone (26% versus 5% of men) and the higher rate with no spouse (39% versus 8%).

349. DERIVING THE MAJOR DIMENSIONS OF QUALITY OF LIFE OF THE ELDERLY IN INDIA
S. Shanmuganandan
Madurai Kamaraj University, Madurai, Tamilnadu, India

The purpose of the present study is to analyse the disease patterns of the elderly in India, to probe into the major factors that determined the quality of life (QoL) in India and to identify the major dimensions in relation to QoL and the life expectancy rate and changing health conditions and health status. The study also attempts to bring out the regional variations with reference to sociological, socioeconomic and psychosocial variations in relation to the disease pattern.

The study was based on an analysis of secondary data collected from published and unpublished sources along with a questionnaire survey administered at random among 300 elderly population chosen from Madurai City, Tamilnadu, India. The essential variables such as sociological, social, socioeconomic, and psychosocial, epidemiological and demographic variables were selected in relation to QoL. Simple descriptive statistical techniques were used to explain the health status of the elderly in India. Multivariate statistical technique factor analysis was employed to identify the major dimensions which determined QoL among the elderly.

It was inferred from the study that environmental hazards (43%) and pitfalls have a greater effect on the health status of older men and women than on that of younger citizens. It was also found that the life expectancy rate has slowly increased from 55 to 64.5 years on average in the last decade due to the advancement of medical technology and access to medical facilities. In the majority of cases, social isolation is a predisposing factor to many diseases (31%). Hypochondriasis is a condition in which the individual becomes preoccupied with declining physical health. Approximately 30% of women over the age of 55 years and men over the age of 60 years have sufficient mineral loss to produce fractures. Diseases of the cardiovascular system (27%), diabetes mellitus (23%), hypertension (21%) and high blood pressure (17%), etc. have been seen to be increasing in recent times.

Special medical insurance schemes are essential for the elderly to keep their health fit to lead a good QoL.

350. QUALITY OF LIFE OF HIV PATIENTS IN A DEVELOPING COUNTRY: A CASE STUDY FROM TAMILNADU, INDIA
S. Shanmuganandan and R. Maniyosai
Madurai Kamaraj University, Madurai, Tamilnadu, India

The present study made an attempt to analyse the quality of life (QoL) of HIV/AIDS patients in Tamilnadu, India, to probe into the major factors that cause the functional and psychosocial impairments, the effect of different interventions, psychosocial concerns related to longevity of life, illness severity and symptom severity and to analyse the negative and positive attitudes of the patients in relation to life style variations and perceived changes in social functioning, social support, partner intimacy, sexual...
functioning and medical care. The study was based on an analysis of 450 HIV/AIDS patients collected from a questionnaire survey conducted in AIDS surveillance centres in the major metropolitan cities of Madurai and Madras. The data related to their QoL, life style variations in the event of the AIDS epidemic, their psychosocial concerns and also their perceptions related to social support, medical care, suffering due to opportunistic infections, future life functioning patterns, social status in the society and their negative attitudes to leading a positive life. The data were analysed with the help of factor analysis to identify the major dimensions and also the related variables that determine the QoL of HIV patients.

The study inferred that the HIV patients (67%) perceived their suffering due to opportunistic infections such as diarrhoea, weight loss, functional incapacity, continuous fever, etc. were high and they were very much concerned about the reduction of their suffering due to these infections. Thirty-one percent of the patients perceived that they needed moral support along with intervention strategies and essential medical care from health institutions and also health care personnel to reduce their suffering and increase their level of mental stability to improve their QoL and also reduce the symptom severity. Eleven percent of the HIV patients perceived that adequate nutritional support is necessary.

351. EPIDEMIOLOGICAL DIMENSIONS OF DIABETES: A CASE STUDY ON DIABETES AND QUALITY OF LIFE AMONG URBAN DWELLERS OF MADURAI CITY, TAMILNADU, INDIA

S. Shanmuganandan1, K. Kannan1 and R. Maniyosai1
1Madurai Kamaraj University and 1Madurai Medical College, Madurai, India

The present study was an attempt to analyse the epidemiological dimensions of diabetes mellitus and quality of life (QoL) among urban dwellers in Madurai City, Tamilnadu, India, to identify the major dimensions that determine QoL and modification of behaviour and to explain how epidemiological and behavioural dimensions invariably determined not only QoL but also the longevity of life in association with the life style variations noticed among urban dwellers.

The study was based on a field survey conducted among 400 urban dwellers of Madurai City with reported diabetes mellitus complications. The data related to personal life styles and dietary patterns and drug-consuming behaviour, their personal environment and the interaction in the internal make up. Simple descriptive and multivariate statistical techniques were employed to explain the findings of the study.

It was observed that the behaviour of the urban dwellers were subject to variation according to the seriousness of the illness (17%), their social involvement (21%) and also largely controlled by physical, mental and physiological changes (39%). Individual urban dwellers who live in diverse conditions dealing with temperature, nutrition, sanitation and other environmental influences explained inconclusive findings. The drug-taking behaviour of the urban dwellers is very much concerned with and dependent on the changing situation of their health status and consciousness towards a larger and better life. Nearly 45% of the respondents could not adjust to regular drug-taking behaviour. Although health consciousness on diabetes was widely observed, their psychological make up towards the food system is often disturbed. Abnormal behaviour was seen among 33% of the urban dwellers in their diet behaviour. The dimensions further identified confirmed this unusual behaviour very harmful to the deterioration of their QoL. Health education thus has an essential role to play in modifying behaviour and leading to a healthy life.

352. QUALITY OF LIFE, RISK-TAKING BEHAVIOUR AND HEALTHY SOCIAL WELL-BEING: AN ANALYSIS OF MAJOR DETERMINANTS FOR HEALTH PROMOTION IN INDIA

S. Shanmuganandan, R. Maniyosai and M. S. Murudimohan
Madurai Kamaraj University, Madurai, Tamilnadu, India

The purpose of the present study was to analyse the major indicators of quality of life (QoL) of the people of Madurai City, India with reference to life style variations and its impact on healthy living, to bring out the sex-wise variation in the level of perception noticed on the major concepts of QoL and to identify the major indicators that actually determined the patterns of life satisfaction in relation to health and social well-being and conceptualize the major indicators for better health management. The data was based on a primary data collection survey conducted among 1,300 citizens of Madurai City related to major indicators of QoL (physical and mental health, social security, civic amenities, leisure and recreation, education, housing, food patterns, general levels of satisfaction and so on). The data were analysed with the help of multivariate statistical tool factor analysis to identify the major dimensions and also derive a conceptual framework.

It was inferred that there is spatial variation in QoL and health and social well-being indicators from one urban tract to another and this is largely contributed to by several factors such as overcrowding, social security, infant mortality, social deprivation and basic civic amenities, etc. There was a variation in the perception level among males and females on certain indicators such as health, access to civic facilities, housing and education. Seventy-one percent of the men perceived more about the necessity of improving infrastructure facilities (such as roads, streetlights and regular bus services) whereas 51% of women perceived the essential day to day life activities mostly governed their way of life (such as access to medical services, the water supply, social security, etc.). It was also noticed that there is variation in perceptions among different age groups on the level of services.

Thus it is essential that QoL of an urban area is largely based on the provision of all essential services to meet the entire satisfaction of the different age groups and sexes of the population.

353. QUALITY OF LIFE IN PTSD PATIENTS SUFFERING FROM FIBROMYALGIA SYNDROME

R. Sharabani, M. Amir, Z. Kaplan, L. Neumann and D. Buskila
Department of Behavioral Sciences, Internal Medicine and Department of Epidemiology, Ben-Gurion University of the Negev, Beer-Sheva, Israel
The aim of the present study was to inquire into quality of life (QoL) and functional impairment in PTSD patients suffering from fibromyalgia syndrome (FS). Furthermore, the PTSD group with FS was compared to the PTSD group not suffering from this syndrome. Twenty-nine PTSD patients were compared to 37 healthy controls on a measure of QoL developed by Flanagan and the Fibromyalgia Impact Questionnaire (FIQ) by Burckhardt as well as measures of tenderness and FS. The results showed that the PTSD patients had a significantly lower QoL and FIQ than the control group. In the PTSD group, we found 21% diagnosed as suffering from fibromyalgia as compared to 0% in the control group. In comparing the two groups of PTSD patients, with and without FS, we found lower QoL, worse physical functioning, more fatigue, more pain, more sleep problems and increased tenderness in the patients suffering from both PTSD and FS. It was concluded that there is a considerable overlap between PTSD and FS and that the patients suffering from both disorders have the lowest QoL and physical impairment.

354. PSYCHOMETRIC ANALYSIS OF HEALTH STATUS MEASURES IN AN ELDERLY POPULATION SAMPLE: ELPHS
L. D. Sharples1; C. Todd1; N. Caine2; A. Martin3 and S. Tait2
1MRC Biotstatistics Unit and 2Department of Community Medicine, Institute of Public Health, University of Cambridge, UK

Whilst the SF-36 and NHP have been widely used amongst adult populations little is known about their validity and reliability amongst elderly people. We report on the internal reliability and validity of these measures for the UK population of elderly people.

A stratified (5 year age bands) random population sample of men and women aged 65–85+ years were interviewed at home. Health status using four standard instruments (the SF-36, NHP, HAD and EuroQol) was collected alongside validated performance ADL data.

Four hundred and eighty-one subjects were interviewed with a mean age of 77 years (SD 6.9 years) and 229 (48%) of them were women. Cronbach’s α for the four standard instruments was high for all subscales (α range 0.61–0.98), suggesting good consistency but redundancy within some scales. We hypothesized that all four instruments would show deterioration of scores with age and the results were consistent with this. The correlation coefficients for the physical performance items (timed walk, tandem and semitandem stands, chair stands and hand grip) with the NHP and SF-36 physical function scales were small but significant (r-b range 0.27–0.44) (p < 0.001). The correlation coefficients were good for the physical performance composite score (criterion measure) with NHP physical mobility (PM) (r-b = 0.56 and p < 0.001) and SF-36 physical functioning (PF) (r-b = 0.58 and p < 0.001). The relationship between standing tasks, NHP PM and SF-36 PF revealed a significant improvement in score with increasing standing balance ability (p < 0.0001). The NHP PM scores tended to be nearer the floor suggesting SF-36 PF is more able to discriminate between healthy subjects. The EuroQol scales were closely associated with physical performance but the pain scale was less valuable. There were good correlations between similar scales of the NHP and SF-36 (0.31–0.73). HAD correlates with NHP emotional reactions (anxiety (A) r-b = 0.45 and depression (D) r-b = 0.44) and social isolation (A 0.26 and D 0.41) and SF-36 role limitations emotional (A 0.31 and D 0.19), mental health (A 0.51 and D 0.38) and social function (A 0.26 and D 0.48).

These results provide evidence for the validity of both the NHP and SF-36 for use with an elderly population. The distribution of scores gives the SF-36 the advantage in measuring differences in healthy elderly populations.

355. DEVELOPMENT OF UTILITY SCORES FOR THE SF-12
Cathy Sherbourne, Roland Sturm and Kenneth B. Wells
RAND, Santa Monica, CA, USA

This paper presents the results of a method used to develop preference-based summary scores for the MOS 12-Item Short-Form (SF-12), which is increasingly being incorporated into clinical and effectiveness trials of new treatments and new methods for improving care. In such studies, the SF-12 allows investigators to profile different health-related quality of life (QoL) domains, but fails to integrate this information into one overall score that would be useful for cost-effectiveness analyses. The data for our analyses are from approximately 18,000 adult patients screened in 41 primary care practices in six managed care organizations in five geographic sites. Thirty-seven percent of the patients are male, 68% white, 4% American–Indian, 7% black and 18% Hispanic. The mean years of education completed is 13.9 years with mean age 44 years (range 17–96 years).

The patients in the study were asked to provide valuations for their own current health status using standard gamble and time trade-off items. We first present the results showing how preferences for health outcomes (utility) vary across patients who have different chronic disease conditions, including depression. We then show the relationship between utility and generic health-related QoL measures and derive utility weights that can be used by others to generate one overall SF-12 score for use in cost-utility analyses.

Most patients, including many who were very sick, were unwilling to give up any months of life or take any chance of death for perfect health (69.8%). Among all patients, the mean months of life that they were willing to give up was only 7.8 (out of 120) and they were willing to take only a 5.1% chance of death. Preferences for remaining in their current health state varied by disease condition and were lowest for patients with depression.

In addition to providing utility weights for SF-12 items, the results provide insight into patients’ willingness to sacrifice longevity to be relieved of illness, indicate what kinds of limitations most reduce utilities and show how people appear to weight emotional health, social health and physical health in arriving at utilities.

356. AGEING IN DEVELOPING COUNTRIES: QUALITY OF LIFE AND IMPLICATIONS FOR MENTAL HEALTH SERVICES
Ibrahim M. Shoaib
Tanta University, Tanta, Egypt

Every year the global total of people aged 60 years and over increases by 14.4 million; 80% of this increase occurs in developing countries. By the year 2000, there will be 600 million people over the age of 60 years, of whom approximately two out of three will be in countries of the Third World.

The purpose of this presentation is to highlight challenges for providing quality care mental health services for the growing numbers of elderly people in Egypt.
Awareness about the unique health problems of the elderly is lacking among both the general public and the government’s policy makers. As elderly people move from a position of independence to dependency, problems with mental health increase. Patients may be neglected, ridiculed or abused. This can result in people not seeking appropriate health and social care. Mental health services are not geared to address the growing specific needs of the elderly. Early detection and adequate management require specialist knowledge and skills as well as multidisciplinary collaboration. It is the responsibility of professionals working in the field of geriatrics to put pressure on governments to ensure that reasonable and affordable quality care is provided to elderly people with mental health illnesses. Appropriate interventions can substantially improve the quality of life (QoL) of patients and their families.

357. HEALTH-RELATED QUALITY OF LIFE IN ADOLESCENCE: CONCEPTUALIZATION OF A GENERIC SELF-ADMINISTERED INSTRUMENT

M. C. Simeoni, P. Auquier, S. Gentile, I. Eynaud-Bo, J. L. San Marco, M. Bremond and R. Sambuc
Laboratoire de Santé Publique, Faculté de Médecine, Marseille, France

While data on health-related quality of life (QoL) of adults are accumulating, very little is known about health-related QoL – and in particular the perceived health-related QoL – of children. Interest in health-related QoL of children has increased in the last years, disease-specific instruments have been developed but validated self-administered generic measures of health-related QoL for adolescents have been missing. Such an instrument is not yet available in France. This report describes the early stages in the development and testing of our instrument, for assessing the perceived health of adolescents attending school, aged 11–17 years. The purpose of the instrument is to assess health in epidemiologic surveys, to determine the existence of a systematic difference in subpopulations and to provide a basis for assessing the impact of changes in health services or health policies. The instrument was developed based on the literature, the suggestions of a panel of experts and the involvement of focus groups and semi-structured interviews with adolescents. The use of these different approaches to generate relevant components of health and a large number of candidate questionnaire items helped ensure that our instrument covered aspects that are important for adolescents and that the wording is appropriate. The questionnaire was developed and piloted to test its basic acceptability and comprehension. Data from a survey carried out with more than 1,000 adolescents of 11–17 years in eight different educational establishments in Marseille were statistically analysed to produce a shorter questionnaire, selecting the most relevant items. The results of the preliminary testing of our instrument showed several independent dimensions which appear relevant.

358. QUALITY OF LIFE IN SCHIZOPHRENIC PATIENTS: A FRENCH STUDY

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In the past two decades, a number of quality of life (QoL) instruments have been developed for persons with mental illness. Unfortunately, there is little consensus about what constitutes QoL or how to measure it. Most of the instruments for assessing QoL that are used in mental health rely on a single respondent. Either the patient or the clinician is required, but rarely both. However, self-reports and subjective judgement are key elements of QoL measurement. In our study, 60 schizophrenic patients were rated using Heinrich’s QoL scale. The patients reported their own evaluation of their QoL on visual analogue scales. The results showed that the subjective rate was correlated to the intrapsychic foundations category and to the QoL scale total score ($p < 0.01$). We did not find any correlations between the self-report of QoL and the other categories of Heinrich’s QoL scale (interpersonal relations, instrumental role and common objects and activities). On the other hand we found a significant correlation between subject ratings of QoL and negative symptoms rated by PANSS. The data obtained for this study support the idea that subjective QoL is dependent on intrapsychic elements often seen as near the core of the schizophrenic deficit.

359. SELECTING NATIONAL ITEMS FOR THE WHOQOL: CONCEPTUAL AND PSYCHOMETRIC CONSIDERATIONS

Suzanne Skevington1, Jason Bradshaw1 and Shekhar Saxena2
1School of Social Sciences, University of Bath, Bath, UK and 2All India Institute of Medical Sciences, New Delhi, India

The WHOQOL is a comprehensive, cross-cultural measure designed to assess quality of life (QoL) in health and health care. An international core of 276 items covering 29 facets of QoL and organized in six domains was established first conceptually and then in psychometric terms. The method also allowed for the inclusion of extra items to enable the concept of QoL to be complete for the language and culture in each participating centre to achieve semantic and conceptual equivalence between language versions. The present study investigates the properties of these national items using data obtained from 3,740 participants. Five statistical criteria were applied to results from 142 national items submitted by ten centres worldwide to see how well each performed when competing with international core items from its own facet and the results directed the inclusion or exclusion of items. Multidimensional scaling and cluster analysis enabled the structural relationship of items to be examined within a facet. Summarized results show that 38 (27%) national items were selected for inclusion in a national module for nine centres. Detailed examples from Bangkok, Bath and Hong Kong demonstrate the selection method used and show how entirely new facets as well as individual items may be assessed for inclusion in the WHOQOL-100.

360. THE QUALITY OF LIFE OF INDIVIDUALS DYING FROM CHRONIC OBSTRUCTIVE AIRWAYS DISEASE

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There is increasing evidence within the UK of a commitment by policy makers to the provision of palliative care across the spectrum of life-threatening diseases and conditions. In the Doncaster health district the incidence and prevalence of chronic obstructive airways disease (COAD) are among the highest in the
UK and this led to a collaborative palliative care needs assessment between Doncaster Health and the Trent Palliative Care Centre. One of the project aims was to assess the quality of life (QoL) of those dying from end-stage COAD and to validate the use of the EORTC QLQ-C30 and LC-13 for a non-cancer group in the terminal phase.

During a 6-month period, all patients aged 55 years and over who had been admitted to hospital with an acute exacerbation were recruited to the study. Sixty-three were interviewed using the EORTC QLQ-C30 and LC-13. Qualitative data from critical incidents was collected to support the questionnaire. Descriptive statistics and Spearman’s correlation coefficient were used to analyse the QoL data. The internal validity of the questionnaires in this patient group was also assessed.

Thirty-three of the sample were men and 30 women. The ages ranged from 55 to 80 years with a mean age of 71 years. Eighty-five percent of the sample perceived their QoL score to be less than 50, with a mean score of 33. A large number of physical symptoms were reported. There were positive correlations between poor QoL, psychological distress, and altered social life. This is a group of people who have non-reversible disease, who suffer with extreme breathlessness. They perceived themselves to have a poor QoL, relating to social isolation and psychological distress. These results from the EORTC questionnaire were usefully supported by the qualitative data. This offers a challenge to the health district in relation to improving services to ensure that the social and psychological needs identified are met.

361. PROGRAMMATIC AND PRAGMATIC APPROACHES FOR QUALITY OF LIFE MEASUREMENT
Jeff A. Sloan, Judith Rich O’Fallon, Vera J. Suman and Daniel J. Sargent
Mayo Clinic, Rochester, MN, USA

Quality of Life (QoL) has become an increasingly important component in oncology clinical trials. The literature is contradictory and immature with regard to the appropriate methods of incorporating QoL end-points into the design and analysis of trials. We suggest programmatic approaches to assess, choose and incorporate QoL tools for oncology research gained from experience within the North Central Cancer Treatment Group (NCCTG). We propose using phase II studies as a test platform for assessing the relative strengths and weaknesses of competing QoL instruments. We address the design issues of power and sample size considerations as well as the means and timing of tool administration.

362. DIRECT AND INDIRECT MEASUREMENT OF QUALITY OF LIFE WITHIN A CLINICAL TRIAL ON A MILD CONDITION
S. C. Smith, M. M. Gannon and M. P. Haggard
MRC Institute of Hearing Research, Nottingham, UK

Under the influence of health economics, purchasers of health care services increasingly require numerical estimates of utility such as quality of life (QoL). There is growing recognition that such estimates need to be derived from the perspective of the patient or their proxy rather than that of the health care provider. Despite the apparent ease of obtaining direct measurements, for example using visual analogue scales, it can be difficult to establish validity and reliability. Where the scale measures a multifaceted concept such as QoL, there may be no guarantee that the direct measure reflects all of these facets. Yet direct numerical estimates are relatively simple to use and yield results that are easy to communicate (e.g. a percentage scale). The current study compared two types of QoL measure within a large randomized controlled trial of treatments for otitis media with effusion (OME) (‘glue ear’). Direct estimates of QoL obtained by a single visual analogue scale were compared with an indirect QoL score derived from individual items representing various aspects of QoL. Between-groups comparisons were also made between the clinical group and a population control group. The young age of children at the beginning of the study (3.5–7 years) required that responses were made by the parent rather than by the child. The initial results show a reliable relationship between the direct visual analogue measurement of the child’s QoL and the indirect derived score. The visual analogue scale was found to be sufficiently sensitive to show a mean score difference of approximately 0.5 SD in the child’s QoL between the clinical and population groups. These results suggest that visual analogue measurement of the child’s QoL has both concurrent and discriminant validity. Concurrent validity is further being measured by the prediction of other outcome variables. Further studies of the validity and reliability of direct measures of QoL are called for. However, within certain limits it is suggested that the direct numerical ratings favoured by health care purchasers can be meaningful.

363. COMPARISON OF PATIENT AND PROXY EORTC QLQ-C30 RATINGS IN ASSESSING THE QUALITY OF LIFE OF CANCER PATIENTS
The Netherlands Cancer Institute/Antoni van Leeuwenhoek Hospital and University of Amsterdam, The Netherlands

The aim of this study was to examine whether significant others can provide useful information on health-related quality of life (QoL) of patients with cancer. Employing a comprehensive analytical framework, we addressed the following issues: (1) the agreement between patient and proxy responses to a QoL instrument frequently used in cancer clinical research, (2) the association between patient–proxy agreement and the patients’ level of QoL, (3) the reliability and responsiveness of both patient- and proxy-derived information and (4) the influence of patient and proxy characteristics on the level of agreement.

The study sample included cancer patients receiving chemotherapy and their significant others (75% spouses). During an early phase of treatment and 3 months later, patients and proxy respondents completed independently the EORTC QLQ-C30. At baseline, patient and proxy information was available for 307 of the 320 participating patients (96%). Complete follow-up data were obtained for 224 pairs.

At baseline, moderate to good agreement was found (ICC = 0.46–0.73). Multitrait–Multimethod analysis of all patient-proxy correlations showed that the mean correlation between the patient and proxy scores for corresponding domains was substantially higher than that for diverging domains. Comparison of the mean scores revealed close agreement between the patient and proxy ratings. The maximum level of disagreement was found at intermediate levels of QoL, with smaller patient-proxy differences noted for patients with either a relatively poor or good QoL. Both the patient and proxy scores on
364. THE VALUE OF CAREGIVER COOP/WONCA CHART RATINGS IN EVALUATING THE QUALITY OF LIFE OF PATIENTS WITH CANCER

The Netherlands Cancer Institute/Antoni van Leeuwenhoek Hospital and University of Amsterdam, The Netherlands

The purpose of this study was to evaluate the usefulness of care giver ratings of cancer patients’ quality of life (QoL). We examined the following: (1) the comparability of responses to a brief standardized QoL questionnaire provided by patients, physicians and informal care givers and (2) the relative validity of these ratings.

The study sample included cancer patients receiving chemotherapy, their treating physicians and significant others involved closely in the (informal) care of the patient. During an early phase of treatment and 3 months later, patients and care givers completed independently the COOP/WONCA charts, covering seven QoL domains. At baseline, all sources of information were available for 295 of the 320 participating patients (92%). Complete follow-up data were obtained for 189 patient-care giver trials.

A comparison of the mean scores on the COOP/WONCA charts revealed close agreement between the patient and care giver ratings. At the individual patient level, exact or global agreement was observed in the majority of cases (73–91%). Corrected for chance agreement, moderate intraclass correlations (ICC) were noted (0.32–0.72). The patient, physician and informal care giver COOP/WONCA scores were all responsive to changes over time in specific QoL domains, but differed in their relative performance. Relative to the patients, the physicians were more efficient in detecting changes over time in physical fitness and overall health (relative validity (RV) coefficients of 3.42 and 2.64, respectively), but less so in relation to social function (RV = 0.36) and pain (RV = 0.40).

For studies among patient populations at risk of deteriorating self-report capabilities, physicians and informal care givers can be useful as alternative or complementary sources of information on cancer patients’ QoL.

366. QUALITY OF LIFE OF RELATIVES OF THE MENTALLY ILL AS AN INTEGRAL INDEX OF PSYCHIATRIC CARE QUALITY

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In recent years one of the most actual goals in Russian psychiatry has been improvement of quality of mental health care. In connection with this it is necessary to work out objective and informative assessment criteria. The objective of this research is to assess the quality of life (QoL) of relatives, living together with their grown up mentally ill children with chronic schizophrenia, to determine possibilities of the application of this method in an integral assessment of quality of psychiatric care and to define ways of its improvement. To obtain the necessary data a standard questionnaire worked out in our centre was applied. The questionnaire embraces nine spheres of the lives of relatives. Forty relatives of the mentally ill of ages 45–76 years were examined. The results of the examination showed that all the relatives meet with serious financial and sociopsychological problems, problems connected with everyday care, etc., due to the mental disorders of their mentally ill grown up children. The majority of them assessed their QoL as “poor” or “satisfactory”; from their point of view it was connected with the impossibility of their regular professional activity, leisure and with the worsening of their own health. Problems connected with the disruptive behaviour of mentally ill relatives and with dissatisfaction with psychiatric care were also determined. From our point of view this approach can be applied to an integral assessment of psychiatric care quality, because it provides an opportunity of analysing different aspects of psychiatric care – from medical to legal and ethical aspects, which require improvement.
An important factor in assessing the usefulness of health measures is the extent to which they are responsive to evaluating different policy alternatives. This paper reviews the need for aggregate measures of health in light of HHS and State Health Department policy needs. We focus on the Years of Health Life (YHL) measure and its development. We will outline some of the challenges facing YHL and health measure research and development over the next decade.

Few studies have examined the impact of clinical events such as HIV symptoms, CD4 count, stage in disease progression on sexual functioning and sexual relations in HIV-infected patients. The objective of this study was to evaluate the association between demographic and clinical variables on measures of sexual functioning and sexual relations. A sample of 163 patients with HIV disease were recruited from three HIV clinics in the Baltimore–Washington area and were followed for 1 year. The mean age was 36.7 years and 34% were women, 65% African–American, 26% with less than high school education and 44% had AIDS. To measure sexual functioning, the MOS-HIV Sexual Functioning Scale was administered every 4 months. A Sexual Relations Scale (SRS) was also developed. Patients were administered the SF-36 Health Survey, Centers for Epidemiologic Studies Depression Scale (CESD) and an HIV-related symptoms scale. Clinical data were collected from medical records. t-tests, correlations and analysis of variance were conducted to determine the differences in scores by demographic and clinical variables. No statistically significant difference in sexual functioning was observed by gender, race or education, but differences were seen by age. Patients less than 38 years of age were more likely to score lower on the sexual relations scale. Significant differences on the sexual functioning and SRS scales were seen between depressed and non-depressed patients ($p < 0.001$). Patients with AIDS or symptomatic HIV scored lower on sexual functioning than patients with asymptomatic HIV even after controlling for age, sex, race and education. Patients with CD4 counts below 100 scored lower on the sexual function scale and SRS than patients with higher CD4 counts. The strongest correlations with sexual functioning and SRS scores were seen for social functioning, general health and energy dimensions of the SF-36. The findings suggest that sexual function and relations vary by HIV disease stage and are correlated with other measures of health status.

We evaluated the impact of 8 weeks of omeprazole (20 mg once daily) treatment compared with ranitidine (150 mg twice daily) treatment in patients with poorly responsive symptomatic gastroesophageal reflux disease (GERD) on quality of life (QoL) outcomes. A multicentre, double-blind, randomized clinical trial enrolled 533 patients and 317 patients (59%) were poorly responsive after 6 weeks of ranitidine 150 mg twice daily and were randomized to treatment with omeprazole 20 mg once daily ($n = 156$) or ranitidine 150 mg twice daily ($n = 161$) for 8 weeks. The Gastrointestinal Symptom Rating Scale (GSRS), Psychological General Well-Being (PGWB) scale and Impact with Daily Activities Scale (IDAS) were administered at randomization and after 8 weeks of treatment. The primary QoL endpoints were the GSRS reflux and PGWB total scores. After 8 weeks of treatment, statistically significant differences favouring the omeprazole-treated patients were seen in the end-point mean reflux symptom scores ($p < 0.0001$) and PGWB total scores ($p < 0.019$). Statistically significant improvements in the GSRS total ($p < 0.0001$), abdominal pain ($p < 0.003$) and indigestion scores ($p < 0.003$) and in PGWB anxiety ($p < 0.03$), positive well-being ($p < 0.015$) and general health ($p < 0.01$) and IDAS scores ($p < 0.001$) were also observed in the omeprazole compared with the ranitidine group. The changes in the GSRS and PGWB scores were correlated with physician-rated GERD symptoms. These findings indicate that omeprazole 20 mg once daily significantly improves reflux and gastrointestinal-related symptoms and psychological well-being in patients with poorly responsive symptomatic GERD compared to continued treatment with ranitidine.
measures is the physical subscale which was, on average, rated higher than all other domains. In order to explain the noteworthy discrepancies between the QLQ C30 and the FACT the correlations of the corresponding subscales were studied. All subscales of the QLQ C30 correlated more highly with the ‘physical well-being’ subscale of the FACT than with any other FACT subscale. This even applied to the domains of ‘emotional and social functioning’, as measured by the QLQ C30. These results and possible clinical implications will be discussed.

371. RESPONSE SHIFT IN LONGITUDINAL QUALITY OF LIFE RESEARCH: THEORETICAL, METHODOLOGICAL AND EMPIRICAL VANTAGE POINTS
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Department of Medical Psychology, Amsterdam, The Netherlands and Frontier Science and Harvard Medical School, Boston, MA, USA

The response shift phenomenon is ubiquitous in quality of life (QoL) research, albeit neglected frequently. We will present a working definition and theoretical model of response shift and will provide empirical data to elucidate the phenomenon. Response shift refers to a change in the meaning of one’s self-evaluation of a target construct as a result of (1) a change in the respondent’s internal standards of measurement (i.e. scale recalibration), (2) a redefinition of the target construct (i.e. concept redefinition) or (3) a change in the respondent’s values. The proposed theoretical model includes antecedents (e.g. sociodemographics, personality and expectations), mediating processes (the three components of the response shift) and QoL as an outcome measure. One approach for assessing the response shift is the ‘then-test’ method which purports to assess scale recalibration by asking patients to provide a renewed judgement about previous levels of QoL. Both quantitative and qualitative data will be presented to elucidate the response shift phenomenon as assessed with the then-test approach. These data are derived from a study with 99 cancer patients undergoing radiotherapy who were administered standardized QoL and criterion measures prior to and after radiotherapy. Patients were also interviewed about their responses. The results indicate that a response shift occurred in a subsample of patients, that the then-test approach was valid (as indicated by its association with criterion measures of change) and that patients’ verbalizations reflected the response shift and mechanisms underlying the response shift (e.g. downward comparison and reordering priorities). The response shift is of paramount importance to QoL research and merits further development. Future studies are needed that address its theoretical, methodological and empirical implications.

372. SENSITIVITY OF THE EORTC QLC C-30 TO SUBJECTIVE AND OBJECTIVE INDICATORS OF CHANGE
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Division of Psychosocial Research and Epidemiology, The Netherlands Cancer Institute, The Netherlands

In studies with quality of life (QoL) end-points, statistically significant changes in scores between measurement moments are used as indicators of change. However, statistically significant changes may not always represent relevant differences. It may be that changes in the scores on a QoL measure do not correspond to the patients’ perception of change over time, nor with changes in objective indicators of health status. Subjective relevance and more objective indicators of change may also diverge. Using subjective transition scores, Osoba obtained estimates of the differences in the EORTC QLC C-30 scores that correspond with various degrees of subjective change. In this study, we elaborate on Osoba’s findings and assess (1) whether statistically detectable changes in scores on a QoL measure correspond with subjective transitions in health status, (2) the minimal subjectively relevant change that can be detected and (3) where appropriate, whether subjective differences correspond to objective indicators of change in health status.

Two hundred and twenty-four cancer patients with varying diagnoses who received chemotherapy completed the EORTC QLC C-30 twice. At follow-up, transition questions were presented to the patients for some of the dimensions of the questionnaire to obtain estimates of the patients’ perception of change in the relevant domains. The transition questions had seven response categories. Research assistants rated, at both assessment times, the performance status of the patients using the ECOG scale. The changes in the ECOG scores are used as an objective indicator of transition. Using both objective and subjective indicators of transition to define groups, analysis of variance is applied to test for significant mean change scores between groups of patients defined by (level of ) transition.

The preliminary results show that for each QoL domain groups of patients that report subjective improvement, no change or deterioration differed significantly in scores on the corresponding EORTC QLC C-30 scale (F-values ranging from 9.51 for physical functioning to 35.28 for overall QoL; all p values <0.001). Further analyses will include establishing a minimal subjective relevant difference and a correspondence analysis between the mean score differences on the questionnaire and ranges of transition scores. Finally, where appropriate, transitions in the ECOG ratings as rated by the research assistants will also be used as criteria for transitions.

373. QUALITY OF LIFE IN PARENTS OF CHILDREN WITH CYSTIC FIBROSIS: RELATION TO SEVERITY OF DISEASE AND WAYS OF COPING
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Cystic fibrosis (CF) is the most common severe autosomal recessive genetic disease in Caucasians. With the improvement of life expectancy, in the last decades, supporting patients and their families in adapting to life with this chronic progressive disease has become increasingly important.

The present study investigated the relation between quality of life (QoL) in the parents of children with CF, the severity of disease and ways of coping. A sample of 111 mothers and 14 fathers completed a generic QoL questionnaire (‘Alltagsleben’) and a questionnaire on ways of coping with regard to the illness of their child (‘Freiburger Fragebogen zur Krankheitsverarbeitung’). Regression analysis revealed that children’s disease severity did not significantly explain variance in the parent’s QoL. However, the amount of therapy at home significantly influenced
Quality of life (QoL) of parents (7% of the variance). The most important factor in explaining the variance of QoL in parents (28% of the variance) appears to be the coping style. Control of emotions/retreat from social relations and a depressive coping style were negatively related to QoL whereas compliance/confidence in treatment and self-encouragement were positively related.

The data support the important role of cognitive factors in the adaptation of care givers to this severe chronic disease. The results call for a careful assessment of the issues of coping and professional support of families with CF patients in the early course of disease, where the main process of coping with this diagnosis is going on.

374. HEALTH-RELATED QUALITY OF LIFE OF PEOPLE REPORTING ALLERGIC SYMPTOMS IN A HUNGARIAN REPRESENTATIVE SURVEY
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Institute of Behavioural Sciences, Semmelweis Medical University, Budapest, Hungary

A national representative health survey was realized in 1995. Twelve thousand and five hundred persons representing the Hungarian population over the age of 16 years by age, sex and place of residence were interviewed. Beyond physical symptoms, past and actual diseases, social, economic and psychological characteristics were examined. Health-related quality of life (QoL) was measured with the modified method of R. Rosser, the dimensions of QoL being working disabilities and pain (OPCS Questionnaire) and depressive symptoms (Shortened Beck Depression Inventory). We found significant intragroup differences in all three dimensions in people reporting allergy symptoms limiting their daily activities. Multivariate statistical analysis was performed to analyse the socioeconomic and psychological background factors influencing health-related QoL: level of education, social support, coping strategies, purposes in life and sleep quality. The subgroup of people with allergy symptoms having lower health-related QoL could be characterized by a lower level of education, less social support, high hostility, sleep disturbances and emotional coping strategies such as eating, drinking, taking drugs and blaming other people in difficult situations. These results suggest that successful coping with a chronic disease such as allergy can prevent a considerable decrease in health-related QoL, education being the most important socioeconomic background factor.

375. QUALITY OF LIFE IN FOUR CHRONIC CONDITIONS
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Health-related quality of life (QoL) was compared in patients with different chronic diseases, using the SF-36 health status measure. The patients were drawn from hospital-based registers, with epilepsy (n = 378), angina pectoris (n = 351) and obstructive lung disease (n = 207) from the Central Hospital of Akershus and Waaler-Rose positive rheumatoid arthritis (RA) (n = 496) from the Oslo RA register. For comparison we used multiple linear regression, predicting mean scores standardized for age, education and co-morbidity (scaled from 0 – 100; 0 is poor health).

<table>
<thead>
<tr>
<th>SF-36 scale</th>
<th>Epilepsy</th>
<th>Angina Pectoris</th>
<th>Obstructive Lung Disease</th>
<th>RA</th>
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<tbody>
<tr>
<td>Men</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical function</td>
<td>78.9</td>
<td>69.9</td>
<td>57.1</td>
<td>57.4</td>
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<tr>
<td>Role physical</td>
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<td>34.3</td>
<td>33.6</td>
<td>36.0</td>
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<tr>
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<td>69.6</td>
<td>57.8</td>
<td>61.0</td>
<td>48.5</td>
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<tr>
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<td>57.3</td>
<td>42.7</td>
<td>46.6</td>
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<tr>
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<td>57.8</td>
<td>51.2</td>
<td>45.0</td>
</tr>
<tr>
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<td>92.7</td>
<td>72.8</td>
<td>68.9</td>
<td>70.7</td>
</tr>
<tr>
<td>Role emotional</td>
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<td>53.4</td>
<td>56.6</td>
<td>57.0</td>
</tr>
<tr>
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<td>75.5</td>
<td>75.4</td>
<td>72.4</td>
<td>72.4</td>
</tr>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical function</td>
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<td>67.3</td>
<td>54.5</td>
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</tr>
<tr>
<td>Role physical</td>
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<td>30.3</td>
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<td>Role emotional</td>
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<td>52.3</td>
<td>55.4</td>
<td>55.8</td>
</tr>
<tr>
<td>Mental health</td>
<td>73.8</td>
<td>73.6</td>
<td>70.6</td>
<td>70.6</td>
</tr>
</tbody>
</table>

Women scored lower on all SF-36 scales for all conditions. Patients with RA and obstructive lung disease scored lowest on the physical function scales, while RA patients had the most pain. The patients with epilepsy scored highest on most scales, reflecting that in a representative sample the majority suffer from well-controlled epilepsy.

376. SEXUAL ACTIVITY QUESTIONNAIRES IN CLINICAL TRIALS – ARE THEY ACCEPTABLE TO PATIENTS?
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Although quality of life (QoL) is now assessed in many clinical trials, most measures focus on physical and psychological aspects of QoL whilst neglecting factors such as sexual functioning, even in gynaecological studies. The Yorkshire Clinical Trials and Research Unit is coordinating two multicentre, gynaecological clinical trials, one assessing the effectiveness of maintenance interferon following chemotherapy in patients with advanced ovarian cancer and one evaluating the effectiveness of laparoscopic hysterectomy in a non-cancer population. Both trials are using the Sexual Activity Questionnaire (SAQ), a self-report questionnaire which describes sexual functioning in terms of levels of activity, pleasure and discomfort and reasons for sexual inactivity. General QoL is also being assessed in both studies. Baseline QoL questionnaires are administered before randomization by a trained research nurse or clinician. Subsequent follow-up questionnaires are sent by post at specified times following randomization.

The methods employed to increase patient compliance include an explanation of the purpose and plan of the study at baseline, the use of a covering letter providing assurance that all replies will remain confidential, the inclusion of prepaid envelopes for return of the questionnaires, follow-up letters to non-responders and thank you letters to all responders.

Although both trials are still ongoing, the early indications are
encouraging. There are 90 advanced ovarian cancer patients, with a median age of 57 years (range 34 – 78 years) and 210 patients in the hysterectomy trial, with a median age of 40 years (range 25 – 74 years). The compliance of the SAQ exceeds 80% in both studies, even with repeated administration at several time points up to 18 months after randomization. This demonstrates the acceptability of sexual activity questionnaires to patients in gynaecological clinical trials, of both a cancer and non-cancer nature.

377. REPEATED ASSESSMENT OF THE QUALITY OF LIFE OF PATIENTS IN A CLINICAL TRIAL – IS IT ALWAYS NECESSARY?
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The incorporation of quality of life (QoL) assessments in clinical trials is increasing and it is becoming widely accepted by health and medical professionals that QoL measurements are as equally important as survival measures in particular cancer research. It is generally accepted that, where possible, QoL data are collected by longitudinal methods, which provide comprehensive data indicating changes over time for individual patients. However, such studies are potentially expensive and are often subject to incomplete follow-up data as a result of patient non-compliance. An alternative method is the cross-sectional study where questionnaires are given to patients at one carefully chosen time point to ensure the patients are evenly distributed between treatment and follow-up. The advantages of a cross-sectional survey include the reduced cost and burden on the patient and the acquisition of results in a shorter time span. The major limitation of a cross-sectional survey is that the variation in an individual patient’s health status over time cannot be assessed. However, it may be that in some situations, for example in patients with advanced disease, poor prognosis or elderly patients, a cross-sectional survey within a clinical trial is more effective in terms of cost, burden on the patient and administration and analysis time, providing an adequately wide range of patients is surveyed.

A study is being carried out to compare the two methods of data collection in matched groups of patients with advanced ovarian cancer to determine whether the cross-sectional method can adequately detect differences between treatments and also individual patient’s health status over time cannot be assessed. A comparison of the compliance rates in both surveys is also being carried out.

378. ANXIETY, RESPIRATORY DISTRESS OR PAIN DURING ICU-TREATMENT OF SEVERE PULMONARY FAILURE: EFFECTS ON HEALTH-RELATED QUALITY OF LIFE IN SURVIVORS
Christian Stoll1, Mathias Haller1, Josef Briegel1, Monika Bullinger1 and Gustav Schelling1
1Institute of Anaesthesiology, Ludwig-Maximilians University, Munich and 2Institute of Medical Psychology, Eppendorf University, Hamburg, Germany

Many survivors of acute pulmonary failure describe potentially adverse experiences such as anxiety, pain, respiratory distress or nightmares during intensive care therapy. Whether this affects quality of life (QoL) outcomes of intensive care is currently unknown. We performed a longitudinal study to assess the health-related QoL of survivors of severe ARDS and to delineate the effects of traumatic experiences on health-related QoL.

Eighty patients treated at our intensive care unit for acute respiratory failure between 1985 and 1995 completed the SF-36 Health Survey. This questionnaire covers eight basic health concepts: functioning (physical and social), role (physical and emotional), mental health, pain, vitality and general health perceptions. The number of adverse experiences (anxiety, respiratory distress, pain and nightmares) during intensive care was evaluated by means of a structured questionnaire.

Patients reporting multiple (>1) adverse experiences (n = 46) described a significantly lower health-related QoL than long-term survivors with no or only one traumatic episode (n = 34). These patients showed a lower general health (48.2 versus 64.9 points, p = 0.004) and mental health (59.1 versus 73.1 points, p = 0.001) perception, reported a much higher incidence of chronic physical pain (41 versus 82 points, p = 0.002), had a lower vitality (40.7 versus 58.5 points, p = 0.002) and showed deficits in emotional role function and in social function (p < 0.042). There were, however, no significant differences with regard to physical functioning (70 versus 67.5 points, p = 0.402).

Traumatic experiences during intensive care therapy of acute respiratory failure are common. They result in significant impairments of psychosocial aspects of health-related QoL.

379. OCCUPATIONAL THERAPY WORKSHOPS AS A WAY OF IMPROVEMENT OF THE QUALITY OF LIFE
Anna Stolowska and Joanna Meder
Institute of Psychiatry and Neurology, Warsaw, Poland

The Occupational Therapy Workshop (OTW) at the Institute of Psychiatry and Neurology in Warsaw was created in August 1993. It is financed by the Governmental Funds for Rehabilitation of Handicapped People. The OTW cooperates with the day-time Rehabilitation Department but it does not depend on it and has its own programme. There are different forms of occupational therapy at the OTW the aim of which is the improvement of job qualifications. The OTW is intended for 39 persons who are categorized as the disability pension group because of mental disturbances and who cannot start normal work now. At the OTW they broaden their social and work qualifications and prepare themselves for future jobs.

In the OTW, the participants watch their own medical matters themselves (organize consultations, remember to take medicines and keep appointments with doctors) which is what they will do after taking up their future work. The OTW is treated as another stage of rehabilitation and preparation for work. Our research indicates that participation in courses in the OTW significantly influences social functioning which is connected with an an improvement in quality of life (QoL) of patients with mental disorders.

380. THE MONTREUX STUDY – QUALITY OF LIFE IN CLINICAL PRACTICE
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This study was developed to prove the essential role of the enterostomal therapist (ET) in the clinical setting and to ensure the best possible quality of life (QoL) for the ostomist.
The results at this early stage already prove the essential role the ET plays in the QoL of the ostomist. It is therefore important that the ET uses the results from the Montreux Quality Life study both to ensure that the services they offer are understood, valued, and recognised by healthcare purchasers and to provide the best quality of care to the ostomate.

This study is under way in 16 Western European countries using 13 languages and is aiming to enroll 10,000 ostomists. By providing participating ETs with guidelines on how to use this information to their own and their ostomates’ advantage, we are able to make the ET more responsible and in control of the destiny of their service.

Constant contact with participating ETs has been essential particularly in consideration of the different cultures, healthcare systems, healthcare training levels and languages. Complete understanding of the study’s benefits, efficient use of results and encouragement to participate is achieved by this constant contact. The constant monitoring provided by the study will produce the most positive outcome for ostomates by defining the best possible ET service.

This paper will outline how we have achieved these objectives and how we intend to continue with this study, the largest QoL study to date, undertaken with ostomists in the world.

This has been made possible through the ConvaTec Ostomy Resource Centre Europe project, which consists to date of seven major projects, of which the Montreux Study – Quality of Life is one of the core modules.

381. SELF-RATED HEALTH IN 70 YEAR OLD MEN AND WOMEN. CLINICAL RELEVANCE OF PROFILES AND SUMMARY SCORES OF THE SF-36 (IQOLA)

Charles Taft, Jan Karlsson, Lars-Olof Persson, Bertil Steen and Marianne Sullivan

Health Care Research Unit/Institute of Internal Medicine, Göteborg University, Department of Nursing/Göteborg College of Health Science and Department of Geriatric Medicine, Göteborg University, Sahlgrenska University Hospital, S-413 Göteborg, Sweden

The aim of this study was to explore the impact on self-rated health in the elderly of eight common diagnoses: hypertension, cancer, gastric ulcer, angina pectoris, chronic bronchitis, diabetes, myocardial infarction and rheumatoid arthritis. Important covariates included hospitalization during the previous 12 years, a doctor’s visit in the previous 3 months, major life style change due to disease or injury and physical inactivity during leisure and obesity. This paper was prepared pursuant to the IQOLA Project. The study sample comprised a cohort of 544 70 year olds (60% women) representing the general population in an urban area of 500,000 inhabitants. The SF-36 profiles comprising eight scales and summary scores of physical and mental health (PCS and MCS) did not differ significantly from a 65–69 year old norm group except the mental health and role emotional scales (lower scores among 70 year olds). The vitality scores were as high as those of 15–64 year olds. All disease-related variables except gastric ulcer, cancer and diabetes correlated highly with PCS, while only major life style change due to disease or injury and physical inactivity during leisure correlated significantly with MCS. Regression analyses showed these two variables to contribute the most to the SF-36 scores. Adding the variables of a doctor’s visit in the previous 3 months and at least one of eight somatic conditions explained 41% of the variance of the PCS scores in women versus 27% in men. The corresponding figures for the MCS scores were 6% and 7%, respectively. More of the variance was explained in the well-being scales vitality and mental health associated with the aggregate MCS (34 – 13%) suggesting the benefits of profile scores. The SF-36 is sensitive enough to be recommended in clinical studies of the elderly.

382. THE INFLUENCE OF PSYCHOPATHOLOGY ON MEASURES OF QUALITY OF LIFE IN PEOPLE WITH PSYCHOTIC ILLNESS

R.E. Taylor, G. Thornicroft, L. Loftus and M. Leese

PRiSM Team, Institute of Psychiatry, London, UK

The aim of this paper was to explore the influence of specific psychiatric symptoms on ratings of subjective and objective quality of life (QoL) in patients with psychotic disorders. The specific hypotheses tested were (1) that anxiety and depressive symptoms would reduce subject QoL ratings, but have no association with objective QoL indicators, (2) positive symptoms of psychosis would be associated with reduced subjective QoL and objective QoL and (3) negative symptoms would be associated with poorer objective QoL, but not with subjective QoL. The 205 patients studied were a random sample of prevalent cases of psychosis in south London who were interviewed as part of a larger study which was evaluating different models of mental health services. QoL was measured using the Lancashire Quality of Life Profile. Symptoms were measured using the BPRS and the Social Behaviour Schedule. The results supported all three hypotheses, though the effect was least in the case of positive symptoms. The symptoms were entered in a linear regression model with global QoL as the dependent variable. Age, sex, ethnicity and disability were included to control for these variables. The results demonstrated that depressive symptoms were the only significant contributors to global QoL. Although positive and negative symptoms did have an effect in reducing the QoL scores this was partly explained by disability. In conclusion, it appears that depressive symptoms affect a person’s subjective evaluation of QoL, but not their objective situation. In contrast, negative and, to a lesser extent, positive psychotic symptoms are associated with a poorer objective situation, but have less negative effect on the subjective QoL. These findings are important as they point to the need to control for symptoms, particularly depression, in analysing QoL data. In patients with positive and negative psychotic symptoms objective indicators should be examined, as the subjective measures may indicate a high QoL in the presence of a very poor objective situation.

383. DETERMINANTS OF QUALITY OF LIFE IN PATIENTS WITH PSYCHOSIS RECEIVING TWO CONTRASTING MODELS OF COMMUNITY MENTAL HEALTH CARE

R.E. Taylor, P. Clarkson, M. Leese, F. Holloway and G. Thornicroft

PRiSM Team, Section of Community Psychiatry, Institute of Psychiatry, London, UK

The aim was to investigate factors predicting Quality of Life (QoL) in a sample of patients with psychosis. The research formed part of a wider study which comprised a population-based controlled evaluation of two different models of community mental health care in two defined geographical areas (sectors) of South London. A random sample of prevalent cases of
384. QUALITY OF LIFE IN CHILDREN WITH ASTHMA – THE PATIENTS’ AND THE PARENTS’ VIEW
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Although Quality of Life (QoL) in asthmatic children is increasingly considered an important topic in rehabilitation medicine, studies about perceptions of well-being and function with asthma before and after in- or out-patient rehabilitation from the children’s and the parents’ perspective are still rare.

In a longitudinal study involving 150 children and their parents at entry in the rehabilitation programme and 1 year thereafter, instruments to assess the QoL from the children’s perspective (the German KINDL self-reporting form) and from the parents’ perspective (the German KINDL parent report form) were used together with medical and psychosocial variables (family climate and coping, locus of control). One hundred and twenty-three of 150 children of ages 8–18 years participated in the study as well as 66 mothers and 54 fathers.

Data analysis pertaining to the first measure point indicates a good psychometric quality of the KINDL as well as impairments in QoL as compared to a reference group of healthy children. In addition, the correlation between parents’ and patients’ perceptions of QoL was in the middle to high range, indicating a correspondence of parents’ and children’s ratings. Further results concerning the relationships between psychosocial determinants and QoL indicators at the beginning of the rehabilitation programme will be presented. The study results demonstrate the use of the multidimensional assessment approach involving children and parents in evaluating paediatric rehabilitation programmes.

385. QUALITY OF LIFE AT 1 – 4 YEARS OF AGE IN RELATION TO A MEDICAL HISTORY OF PREMATURE BIRTH OR OTHER NEONATAL PROBLEMS
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The aim was to evaluate health-related quality of life (QoL) at infancy of premature or term infants who needed neonatal intensive care treatment. Parents of 193 children aged 1 – 4 years consulting the out-patient neonatology clinic of the Leiden University Medical Center were invited to complete the TAIQOL. This instrument defined health-related QoL as health status (HS) plus affective evaluation of problems in 11 health status domains. The response to the TAIQOL was 85%. In addition, the parents were asked for permission to study their children’s medical case history. If permission was granted, the case history was evaluated by means of a specially developed medical history checklist. One hundred and forty-nine medical histories were completed. The sample consisted of 51 children born very premature (<31 completed weeks of gestation), 47 children born premature (between 31 and 36.9 weeks) and 51 infants with other neonatal problems (≥36.9 weeks). Confounding variables that were found to be associated with health-related QoL (p < 0.05) according to one-way analyses were entered into a stepwise multiple regression to assess their relative contributions to health-related QoL scales. The analyses revealed, amongst others, that only the health-related QoL appetite and aggression scales are directly related to gestational age (p < 0.05), higher gestational age, better health-related QoL. No relation was found between birth weight and health-related QoL. Hyperbilirubinaemia, sepsis, multiple birth, PDA (diagnoses) and CPAP and IPPV (treatments) each related to some health-related QoL scales (p < 0.05). Having a chronic disease related to health-related QoL, physical, stomach, lungs and communication scales, when reported by the parents (OCHR), but when reported by the medical case history (MCHR) it did not relate to health-related QoL. The correlation of OCHR with MCHR was r = 0.79 (p = 0.000). In conclusion, there appeared to be a relation between perinatal factors according to case histories and health-related QoL at infancy according to the parents. Longitudinal research will relate the stability of these effects on health-related QoL.

386. QUALITY OF LIFE OF HOMELESS PEOPLE IN LILLE, FRANCE
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The quality of life (QoL) of 270 homeless subjects has been assessed by a French QoL questionnaire (Subjective Quality of Life Profile or SQLP GERIN, DAZORD), previously validated in somatic and psychiatric diseases (3,000 subjects).

The items take into consideration health, relationships, inner life and material conditions. The measures applied to each item are degree of satisfaction, importance attributed to the item and expectations concerning the item. Satisfaction is clearly poor in domains of living situations, employment and physical pain, though relationships, self-
The importance attributed is high in almost all domains. However, subjects attribute low importance to alcohol and drugs. Expectation levels are high; subjects are optimistic in particular in the domain of material conditions.

The homeless people QoL profile appears closer to psychiatric than to somatic patients.

### 387. EFFECTS ON QUALITY OF LIFE OF GASTRIC CANCER PATIENTS

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The aim of this retrospective study was to determine the effects on quality of life (QoL) of gastric cancer patients. From 1992 to 1996 208 gastric cancer patients underwent surgery for gastric cancer at the Department of General and Thoracic Surgery of the University of Kiel. All patients who were alive on 1 July 1996 were included in the study (100 of 208, 65 men and 35 women). The mean age was 63 years. Seventy-eight of these surviving patients had been treated with gastrectomy, 22 with subtotal gastrectomy. Eight patients with advanced tumours had been resected with palliative intention. For assessing QoL the EORTC QoL questionnaire (QLQ-C30) and a validated gastric cancer module were used. The questionnaires were mailed to the patients. The response rate was 91%. Statistical analysis was done with the Stat View program.

Palliative resection and tumour stage IV were associated with poorer QoL. The morbidity rate was correlated with physical functioning. Patients with gastrectomy reported more general physical complaints than patients with subtotal gastrectomy, though the differences found were not significant. Extended gastrectomy and D2-lymphadenectomy did not influence QoL negatively. Splenectomized patients reported a significant drop in performance. After intrathoracic anastomosis the incidence of gastrointestinal complaints was markedly higher compared to intraabdominal anastomosis. Radical resection combined with D2-lymphadenectomy is also the treatment of choice for gastric cancer patients if QoL is taken into account.

### 388. PINDOLOL AUGMENTATION OF PAROXETINE AND COMPLIANCE IN THE TREATMENT OF DEPRESSION: A COST-UTILITY ANALYSIS

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This is the first cost utility analysis of continuation treatment with paroxetine after a double-blind, randomized trial of paroxetine alone versus paroxetine and pindolol.

Sixty-nine of the original 80 patients in the study agreed to be followed up for 6 months. Thirty-six of them were compliant with medication for 6 months. Direct and indirect costs were calculated.

Cost utility analysis shows that the efficacy of continued paroxetine offers a 20-fold improvement in quality of life (QoL) compared with patients who do not accept the drug. A sensitivity analysis predicts QALYs based on the probability of recovering from depression.

Economic analysis provides an enriched perspective to the evaluation of therapy. The augmentation of the antidepressant action of paroxetine with pindolol may give rise to important economic as well as clinical advantages.

### 389. QUALITY OF LIFE AMONG PATIENTS WITH CANCER

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Quality of life (QoL) was defined as an individual’s perception 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.

The purpose of this study was to characterize the QoL of patients with gynaecology cancer and to evaluate differences in reported life quality among the cancer patients and individuals from the general population.

The study group consisted of patients with gynaecological cancer and was divided into two subgroups; one (n = 30) consisted of patients who had been recently diagnosed and the second (n = 30) of cancer patients who had undergone surgery and radiotherapy. The subjects were administered the WHOQOL-100 instrument.

There were no significant differences between the patients from these two subgroups, but all of them reported significantly lower scores than individuals from the general population.

Cancer and subsequent treatment have a great deal of effect on QoL.

### 390. QUALITY OF LIFE AMONG PATIENTS WITH CHRONIC MENTAL ILLNESS

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With modern drug treatment and a therapeutically minded staff, it is usually fairly easy to reduce symptoms and get a chronically mentally ill patient out of hospital, but important things such as quality of life (QoL) remedying individual sensitivity to life events and enhancing the patient’s capacity to deal with life generally must not be forgotten.

Our study involves the assessment of QoL among chronically mentally ill patients and the differences in reported life quality among two groups, as well as the validity of a self-report methodology.

Judgements on several dimensions of QoL were collected from the two groups of patients; patients with schizophrenia (n = 30) and with bipolar disorder or major depression (n = 30), as well as from their primary clinicians, by using the WHOQOL-100 instrument. The QoL ratings of these subjects was also compared with one of patients with chronic physical illness.

The patients with mood disorders reported significantly lower scores than the patients with schizophrenia, who reported higher scores than chronically physically ill patients. The opposite trend emerged when the groups were compared with respect to the judgements from their clinicians.

The validity of self-report measures of life satisfaction is questioned, particularly for use among patients with chronic mental illness, since the scores may be influenced by psychopathology.
391. DOES REPROVISION BENEFIT ELDERLY PSYCHIATRIC PATIENTS?
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The ongoing process of running down psychiatric hospitals in Britain has generated alternative types of care environments for psychogeriatric patients. This study aims to assess the effect of the transition from hospital to community-based services on these people.

A survey of all in-patients aged 70 years or more was conducted in one of London’s mental hospitals. Baseline measurements of cognitive and behavioural disabilities were established for each of the 130 functionally ill, long-stay patients. Three years later, 71 patients were still alive, being equally distributed between hospital and community facilities.

The study examines the outcomes of patients who had left hospital in comparison with a similar group who had remained there. The results indicate that the behaviour of the patients who were settled in the community was stable and even improved slightly over time, as opposed to those remained in hospital, who had become more disabled. Direct examinations demonstrated that while those who remained in hospital markedly deteriorated in their cognitive ability, patients who left hospital had also declined, but to a much lesser extent. We conclude that new forms of milieu, which have been shown to be more stimulating and interactive than EMI wards, appear to sustain the potential of slowing down the declining course of cognitive functioning among elderly schizophrenics and preserving their existing communicative and self-care skills.

392. COLLECTING AND ANALYSING QUALITY OF LIFE DATA IN CANCER TREATMENT TRIALS
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Effective quality of life (QoL) research requires first the identification of the critical QoL issues for the specific trial. Next, the investigators must identify the appropriate instrument to capture the necessary information. Administration of the instrument should be integrated with other study evaluations. Statistical review is necessary to ensure that the QoL data collected will be sufficient to answer the study questions and to determine how to handle missing data. The elimination of unnecessary data collection will reduce the cost and potential errors associated with QoL evaluation. Special efforts may be necessary to obtain QoL data from persons with low literacy, children, the elderly and hearing-impaired or visually impaired persons.

393. PUBLIC HEALTH IN PRACTICAL TRAINING – THE SETTING OF ANAMNESIS
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Public health is an aspect of medical training and work that needs specific emphasis because of its inferior position in traditional paternalistic models of interaction in health care. The paper presents selected results of an empirical research and innovation project on structures of communication and interaction on an internal hospital ward.

A combination of five qualitative methods was applied: unstructured and structured participant observation, SYMLOG, narrative interviews and survey feedback.

For the realization of an innovative health policy it is necessary to built up a partnership between the doctor and patient that allows the consensual definition of action concerning the medical treatment as well as lifestyle concepts of patients.

The first opportunity to move in this direction within the patient’s care is anamnesis where strategies of communication with patients are developed, trained and applied. Despite the fact that effective communication is most important, training strategies for communicational and social skills are developed only to a marginal degree.

Investment in this direction can lead (1) to a higher degree of information and active involvement of the patients and (2) to a development of skills within the group of the new generation of medical practitioners that allow them to fulfill the demands of new concepts in health care.

Establishing appropriate frames for teaching, learning and working provides a basis for the development of innovative strategies of action and communication that can utilize already existing but often neglected human resources.

394. DEVELOPING A QUALITY OF LIFE QUESTIONNAIRE IN SEVERAL LANGUAGES – DIFFERENT METHODOLOGICAL APPROACHES TO MEASUREMENT COMPARABILITY
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In a series of studies including the data of over 2,000 patients with haematological diseases in eight countries, we constructed, evaluated and cross-validated a quality of life (QoL) questionnaire. The methodological approaches we have chosen to ensure homogeneity between different language versions are described in this paper.

Assessment of the patient’s subjective QoL requires questionnaires that fulfill the usual psychometric criteria. In international studies it has to be demonstrated that the different language versions measure the same dimensions, i.e. they must show interlingual homogeneity (IH).

When QoL is defined as a subjective attitude this is especially difficult to ascertain, because the measurement of attitudes is known to be very sensitive to the formulation of questions and response categories and other formal aspects which must inevitably be different in different translations. The equivalence of translations cannot be directly tested, neither can there be an external criterion to validate the questionnaire.

Structural similarities in the data therefore are the only testable criterion for IH. The comparison of psychometric characteristics, factor analysis, multidimensional scaling and probabilistic test models are methods to investigate these structural aspects which are crucial concerning IH.

We applied these methods in the evaluation of our QoL questionnaire and could satisfactorily reproduce the results in a cross-validation study.

We experienced translation and retranslation of questionnaires as an important but not an adequate method of reaching IH. Therefore, we regard the investigation of the structure of empirical data by statistical methods as a necessary additional method.
395. QUALITY OF LIFE IN PATIENTS WITH LUNG CANCER – ASSESSMENT AT THE TIME OF DIAGNOSIS, AFTER THERAPY AND DURING FIRST RESTAGING

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The prognosis of patients with lung cancer depends, among other factors, on the tumour state and the histological type of the tumour. The only curative therapy is operation. One specific of small cell carcinoma is the rapid progression of the untreated disease. Given this background we evaluated the quality of life (QoL) of 30 patients with lung cancer at time of diagnosis, immediately after treatment and during follow-up (3 months later). For the assessment of QoL we used the Quality of Life Questionnaire Core module (QLQ-C30) with the symptom-specific module for lung cancer (LC 13) ad the Spitzer Index.

The paper will demonstrate the design of the investigations as well as problems using the instruments for QoL research.

Eighteen patients received curative treatment and 12 patients only palliative therapy. Twenty-three patients suffered from non-small cell lung cancer and seven patients had small cell lung cancer.

Our results demonstrate the influence of the kind of tumour and the kind of treatment on QoL of lung cancer patients considering differences between self-rating QoL and assessment by medical professionals.

396. A COMPARISON OF QUALITY OF LIFE AS MEASURED BY THE EUROQOL WITH HEPATOLOGIST’S OPINION ON LIVER DISEASE STAGE AND ACTIVITY

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It is unclear whether health-related quality of life (QoL) as measured by the EuroQol correlates with the disease stage and activity in patients with liver disease. We made a comparison between the self-administered EuroQol instrument, the treating doctor’s opinion about the severity of illness and the histological stage and biochemical activity of the disease. In a cross-sectional study 344 consecutive liver patients attending the clinic were asked to fill in the non-disease specific EuroQol ‘thermometer’ (0 = ‘worst imaginable health state’ and 100 = ‘best imaginable health state’). In the same period the treating doctor was asked to fill in a visual analogue scale (VAS) for his opinion on the severity of illness (0 = ‘not ill’ and 10 = ‘severely ill’). The histological stage of liver disease was classified as the absence of cirrhosis (C0), compensated cirrhosis (C1) and decompensated cirrhosis (C2). Disease activity was defined by alanine transaminase (ALT) and alkalinephosphatase (AF). The population comprised 210 males and 134 females, mean age 50 (19 – 81) years; 90% of them returned the questionnaires. The disease stage was C0, C1 and C2 in 163, 83 and 98 patients, respectively. The mean EuroQol score differed significantly between C0 (69.8) and C2 (72.5) versus C1 (94.4, p < 0.001, Kruskal-Wallis). The overall mean VAS score was 3.2 and differed significantly between stages C0 (2.3) and C1 (2.8) versus C2 (5.0). No differences in ALT (overall median value 34) were found between disease stages, but in AF stage C1 (median 67) differed significantly from stages C0 (median 91.5) and C2 (median 107). The correlations of the EuroQol and VAS with the parameters of inflammation (ALT and AF) were generally low (< 0.32). In conclusion, the EuroQol instrument (patients’ subjective opinion) and VAS (doctors’ subjective opinion) were able to discriminate disease stage (advanced versus mild or no illness) but showed no clear correlation with objective disease activity parameters.

397. HEALTH-RELATED QUALITY OF LIFE EVOLUTION IN PATIENTS WITH FUNCTIONING RENAL GRAFT

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The objective was to investigate changes over the time of health-related quality of life (QoL) of patients with a functioning renal graft and to find associations between health-related QoL and different sociodemographic and clinical variables.

The project included 83 transplanted patients presenting no cognitive problems, who were evaluated twice, (samples ‘a’ and ‘b’) 1 year apart, using the SF-36 Health Survey. In addition, sociodemographic and clinical data were collected for both evaluations.

(1) Description of studied sample. Sample a: age 49.38 ± 12.21 years, male 66.26%, number of transplants = 1 (84.33%) and >1 (15.66%), months with renal graft = 54.45 ± 44.72, Hto = 40.43 ± 6.13 and creatinine clearance = 61.08 ± 22.88 ml/min. Sample b: sixty one patients (73.5%) with no hospital admission during the year of the study, Hto = 40.43 ± 6.17 and creatinine clearance = 61.57 ± 25.04 ml/min.

(2) Scores on SF-36 Health Survey. Physical functioning (PF): sample a 80.84 ± 16.00 and sample b 82.02 ± 15.43. Role physical (RP): sample a 78.91 ± 31.59 and sample b 87.95 ± 28.52. Bodily pain (BP): sample a 76.43 ± 24.86 and sample b 80.43 ± 24.50. General health (GH): sample a 64.20 ± 20.38 and sample b 63.44 ± 21.76. Vitality (V): sample a 73.61 ± 21.00 and sample b 71.92 ± 17.64. Social functioning (SF): sample a 91.24 ± 16.56 and sample b 94.57 ± 12.52. Social emotional (RE): sample a 86.74 ± 28.00 and sample b 82.33 ± 35.81. Mental health (MH): sample a 77.97 ± 18.73 and sample b 76.43 ± 17.59.

Statistical analysis of scores. The differences in the scores of both evaluations were analysed using the paired samples t-test. The only significant difference was found in the RP dimension (p < 0.05). The subsequent analysis of this difference showed no...
significant association with any other variable that could explain such difference. The relations between the SF-36 scores and the remaining variables (at times ‘a’ and ‘b’) were also studied using Pearson’s correlation. The coefficients were significant and positive for creatinine clearance (RF, GH and V) and haematocrit (V) and negative for age (PF and BP) and number of admissions (PF, RB, BF and GH).

Health-related QoL of patients having received a functioning renal graft is satisfactory and stays stable over time, as long as their clinical and analytical situation remains stable. The variables that appear to influence health-related QoL of this population are age, renal function, haematocrit and number of hospital admissions.

398. HIGH-DOSE CHEMOTHERAPY IMPAIRS COGNITIVE FUNCTIONING MORE THAN STANDARD-DOSE CHEMOTHERAPY IN WOMEN RECEIVING ADJUVANT TREATMENT FOR HIGH-RISK BREAST CANCER
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The aim of this study was to assess the prevalence of cognitive deficits in a group of high-risk breast cancer patients treated with adjuvant chemotherapy and to investigate whether high-dose chemotherapy impairs cognitive functioning more than standard-dose chemotherapy in this patient population. Cognitive functioning was assessed by means of a standard battery of 14 neuropsychological tests. Patients were also interviewed with regard to cognitive problems, health-related quality of life (QoL), anxiety and depression as experienced in daily life. Testing was carried out, on average, 2 years after completion of chemotherapy. The study sample consisted of 71 high-risk breast cancer patients who participated in a prospective randomized trial comparing high-dose chemotherapy (CTC) supported by peripheral stem cell transplantation (n = 35) to standard (FEC) chemotherapy (n = 36). The results of the high-risk breast cancer patients were compared to the results of a control group consisting of stage 1 breast cancer patients not treated with chemotherapy (n = 34). Cognitive impairment was found in 34% of the patients treated with high-dose chemotherapy, compared to 17% of the patients treated with standard-dose chemotherapy and 9% of the patients treated not treated with chemotherapy. Moreover, patients treated with high-dose chemotherapy appeared to have a 9.1 times higher risk of cognitive impairment compared to the non-treated control group and a 2.9 higher risk compared to the patients treated with standard chemotherapy. The association was not related to anxiety, depression, fatigue and time since treatment. The fact that the cognitive deficits were observed on average 2 years after the completion of therapy, makes the results of this study of particular clinical significance. We believe that central neurotoxicity might become a dose-limiting factor in high-dose chemotherapy regimes and as the demands for high-dose chemotherapy are likely to increase in the coming years, the least that can and should be done is that central neurotoxicity of specific high-dose regimes should be recognized and investigated before they are introduced into routine clinical practice.

399. THE ASSOCIATION BETWEEN QUALITY OF LIFE AND MEDICAL CONSULTATION FOR RESPIRATORY SYMPTOMS: RESULTS FROM THE DIMCA PROGRAMME
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In general practice, the diagnosis and initiation of adequate treatment of COPD are in particular hampered by underpresentation: a substantial number of subjects experiencing respiratory complaints are believed not to consult their GP. In this study, the relationship between disease-specific quality of life (QoL) and medical consultation is investigated.

The study took place in the open population: a random sample of undiagnosed subjects was screened for symptoms and objective signs of COPD (n = 1,155). A disease-specific QoL questionnaire (the Chronic Respiratory Questionnaire) was administered and clinical data were collected at the beginning of the study. Those with symptoms were questioned whether they had ever consulted their GP for respiratory complaints. The lung function of subjects with symptoms of COPD was monitored for a period of 6 months. During this period, 48 previously undiagnosed COPD patients with a persistently reduced lung function (a FEV1 less than the predicted value minus two standard deviations) were detected.

Multivariate analysis showed that QoL impairments due to dyspnoea and concomitant fatigue were related to medical consultation. Clinical parameters indicating the variability in lung function (BHR, reversibility and PEFR variability) were also associated with seeking medical help. The QoL in subjects with a persistently reduced lung function was significantly lower compared to subjects with mere respiratory symptoms (p = 0.002). Despite the differences in objective clinical characteristics, in both groups a similarly small proportion (31 and 26%, respectively) had ever consulted their GP for respiratory complaints.

It appears that the mere presence of respiratory symptoms or a reduced lung function is insufficient reason to seek medical help. Subjects are more likely to consult their GP once their quality of everyday life is affected or once they experience variability in lung function.

400. ASSESSMENT OF REHABILITATION NEEDS IN CANCER PATIENTS
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In contrast with Germany and the USA, The Netherlands are unfamiliar with oncological rehabilitation programmes. The purpose of the study is the assessment of rehabilitation needs in Dutch cancer patients.

Using theories on the development of the health care needs of chronic patients and the WHO approach of impairment, disability and handicap, a framework for a questionnaire was developed. This questionnaire used quality of life (QoL) items,
functional health items and items from specific cancer-orientated instruments. After the results of this phase were clear, a focus group approach was used to confront patients with possible rehabilitation programmes. Questions were formulated verifying the nature of prior results, inquiring about specific elements and desired outcomes and about practical aspects concerning post-cancer rehabilitation. Patients interested in a rehabilitation programme were interviewed on specific items. The study population (n = 166) consisted mostly of breast cancer (69.4%) and bowel cancer patients (23.8%). QoL scored generally moderate, not indicating large problems. Approximately 25% of all respondents wanted to receive professional help; this was largely determined by perceived QoL and level of social support. The professional help-wish concentrated significantly on role, cognition, control, family, psychological and somatic aspects. The focus group discussion revealed that patients would prefer rehabilitation programme focusing on reducing fatigue, reinforcing, capacity, coping with social aspects, dietary aspects and finding new life targets.

Although QoL was indicated as being moderate, only 25% of post-cancer patients indicated the need for rehabilitation. Related to a significant lower QoL score, improved physical capacity and psychosocial defensiveness should be the main outcomes of such a programme. From the patients’ perspectives specific elements such as dietary advice and finding new life targets should be included.

401. QUALITY OF LIFE ASSESSMENT FOR PERSONS WITH MENTAL RETARDATION: THE DEVELOPMENT OF THE VINCENTIUS QUALITY OF LIFE SCALE
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This paper describes the Vincentius Quality of Life Scale. This scale is a new global measure for individuals with mental retardation. It covers the following aspects of quality of life (QoL): physical domain, psychological domain, level of independence, social relations, environment and spirituality. In this project, human needs are seen as the foundations for QoL. The level of QoL is defined in terms of the degree of satisfaction of those needs. The scale consists of two parts: (1) a measure of needs and (2) a measure of satisfaction of those needs. The first part is intended to be administered on an individual basis involving the subjective self-reports of the interviewee. Primary carers act as interviewers. Primary carers and sometimes other carers fill in the second part of the assessment instrument that focuses on the objective life circumstances. As a first step in the construction of the scale, focus group methodology was employed for defining the domains and facets of QoL of persons with mental retardation. Second, items were written based upon these definitions. Third, this initial item pool was presented to a group of adult subjects with mental retardation who resided in a community home in Vincentius, Udenhout, The Netherlands. Then, item-total correlations and Cronbach’s α were employed to select the final set of items for the domains and facets of QoL. Principal components analysis with varimax rotation at the facet level resulted in a four-factor solution with safety and security, social relations, vitality and autonomy as components. In addition to a total of 60 items for representing these four dimensions of QoL, the Vincentius Quality of Life Scale contains four items for assessing overall QoL and emotional well-being. The assessment instrument uses three-point Likert scales and has an adequate scoring system. It is actively under development and possesses acceptable psychometric properties. It is concluded that the Vincentius Quality of Life Scale can be helpful in deepening our understanding of QoL of people with an intellectual disability.

402. A STROKE-ADAPTED 30-ITEM VERSION OF THE SICKNESS IMPACT PROFILE
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In view of the growing therapeutic options in stroke, measurement of quality of life (QoL) is increasingly relevant. The Sickness Impact Profile (SIP) is one of the most widely used measures to assess QoL. To overcome the major disadvantage of the SIP, its length, we constructed a short Stroke-Adapted SIP version (SA-SIP).

We collected SIP data on 319 communicative patients at 6 months after stroke. The 12 subscales and the 136 items of the original SIP were reduced to eight subscales with 30 items, in a three-step procedure based on relevancy and homogeneity.

The reliability of the new SA-SIP30 was evaluated by means of homogeneity (Cronbach’s α coefficient). The validity was assessed by principal component analysis (construct validity), by comparing the scores of the SA-SIP30 with those of the original SIP136 on the same cohort of patients (convergent validity) and on a different cohort of stroke patients (external validity), by comparing the scores of the SA-SIP30 and the SIP136 with other functional health measures (convergent validity) and, lastly, by comparing the SA-SIP30 scores in relation to various types of stroke lesions (clinical validity).

Cronbach’s α of the SA-SIP30 was 0.85. With principal component analysis the same two dimensions as in the original SIP were found (a physical and a psychosocial dimension). The SA-SIP30 could explain 91% of the variance in scores of the SIP136 in the same cohort of patients and 89% in a different stroke cohort. Furthermore, the SA-SIP30 was related similarly to the SIP136 to other functional health measures. Lastly, we could demonstrate that the SA-SIP30 is able to distinguish patients with lacunar infarctions from patients with (sub)cortical lesions.

We conclude that the SA-SIP30 is a promising short measure to assess QoL after stroke.

403. THE NECESSARY COMPONENTS OF A QUALITY OF LIFE END-POINT EVALUATION IN A CLINICAL TRIAL
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Quality of life (QoL) assessment should focus on actual patient experiences of symptoms and functional changes. Global QoL is less helpful than health-related QoL. In studies of treatment interventions, QoL end-points should be limited to the dimensions which are likely to be affected by the intervention or the health of the patient. Functional assessment is a critical part of QoL evaluation. Cost-utility analysis may be used to take into account the cost of a health intervention as well as its impact on QoL and survival.
404. MOTHERLAND OR HOME COUNTRY: HEALTH-RELATED QUALITY OF LIFE AMONG JEWS FROM THE FORMER SOVIET UNION WHO EMIGRATED TO ISRAEL AND JEWS IN RUSSIA AS COMPARED TO ISRAELI NON-IMMIGRANTS

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The aim of the present study was to compare quality of life (QoL) between Jews from the former Soviet Union who emigrated to Israel between 3 and 8 years ago (group 1) and Jews who currently live in Russia (group 2). Both were compared to a control group of veteran Israelis (group 3). The sample consisted of 51 subjects in group 1, 52 subjects in group 2 and 49 subjects in group 3, all between the ages of 25 and 45 years, matched for sex, age and education. The subjects were administered the SF-36 questionnaire – the first two groups in Russian and the latter in Hebrew. Both versions have been culturally adapted according to accepted norms for translation of self-report instruments. The results showed that with the exception of subscale of emotional functioning in which group 1 scored significantly higher than group 2 and the subscale of physical pain, in which group 2 showed a significant advantage over group 1, no differences were found between the two groups on all the other subscales. However, both scored significantly lower than group 3 on five of the eight subscales. It was concluded that emigration among Russian Jews did not improve QoL substantially as compared to the ones who did not emigrate and that at least 8 years are needed to reach the level of veteran Israelis who enjoy a better QoL than both Jews in Russia and former Russians who emigrated to Israel.

405. QUALITY OF LIFE MEASURES IN HEALTH CARE: WHAT MAKES A GOOD MEASURING INSTRUMENT

Babu L. Verma
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Measures of quality of life (QoL) are now becoming increasingly more relevant in health care. Several instruments, generic and specific, are available to study cross-sectional differences and longitudinal changes in QoL. However, each instrument and study approach has its own strengths and weaknesses. An appropriate instrument for a specific situation is the utmost essential to ensure actual QoL measurement. This paper elicits the requirements of a good instrument.

The discriminative and evaluative instruments need to be constructed differently. Their face validity – whether an instrument covers the full range of relevant topics and the construct validity – the pattern of relationship of QoL instrument with established measures, need to be properly investigated. The instrument should be reliable, accurate, practical, reproducible, interpretable and should have a multidimensional construct. Sensitivity to change is an important feature of such instruments. Further, these should be brief and simpler and their questions should avoid double negatives and be amenable to a rating scale.

406. THE TAIQOL: A GENERIC HEALTH-RELATED QUALITY OF LIFE MEASURE FOR 1 – 4 YEAR OLD

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The purpose was to evaluate the psychometric performance and criterion validity of the TAIQOL. The questionnaire was needed in evaluating health-related quality of life (QoL) outcome in clinical research on children with a very low birth weight (VLBW). Health-related QoL was defined as health status plus affective responses to problems in health status. Health status was defined multidimensionally to encompass 13 dimensions. The TAIQOL is completed by a parent in approximately 10 min.

Parents of 106 VLBW children, aged 1 – 4 years, completed the TAIQOL as well as parents of 363 children in the open population. The psychometric performance was evaluated by Cronbach’s α and by the percentage of items with a higher item-rest Pearson correlation coefficient (r) than item-other scale rs. The multidimensionality of health-related QoL was evaluated by factor analysis and by rs between the TAIQOL scales. The criterion validity was evaluated by analyses of variance.

The Cronbach’s αs were 0.52 – 0.89. Ninety-six percent of item-rest rs were higher than item-other scale rs. Forty-nine percent of items loaded higher on their proper factor than other factors. The rs between TAIQOL scales were 0.04 – 0.50. The percentage status of problems per scale that led to negative affective responses ranged from 21 to 86%. As expected, VLBW children, children with a chronic disease and children under medical treatment had worse health-related QoL than other children.

The psychometric performance of the TAIQOL was good. The findings support the multidimensional definition of health-related QoL. The fact that on average only 39% of health-related problems led to negative emotional consequences indicates the essential importance of assessing subjective emotional appraisal of health status. The criterion validity of the TAIQOL was good. In conclusion, the TAIQOL is a suitable instrument in assessing health-related QoL in groups of very young children.

407. COLD DRAUGHT FEELING AND QUALITY OF LIFE

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The objective was to determine whether patients suffering from cold draught feeling (CDF) have reduced quality of life (QoL). A cross-sectional study was used. All patients of the different internal medicine departments of Saratov Medical University, Russia, 20 years and older, who were not in intensive care wards participated.

A special questionnaire for detecting subjects suffering from CDF was used: subjects who suffer from CDF and who completely refuse it fill also Spielberger anxiety, Eisenk questionnaire, and physical capacity questionnaire.

Two hundred and eighty-six subjects responded to the CDF questionnaire while 36 refused to participate. A description of the CDF revealed that the subjective picture is fuzzy and variable. While age and the diagnoses of the subjects who suffer from CDF
were not different from ‘non-sufferers’, the former demonstrate higher anxiety, lower physical capacity and evaluate their health lower.

While the subjective picture of CDF is indefinite, has no physiological correlates and is possibly a ‘folk disease’, people who suffer from CDF are in worse state functionally and psychologically.

408. WELL-BEING IN OFFICE BUILDINGS – RESULTS OF MULTICENTRE STUDY INTO THE SICK BUILDING SYNDROME
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Institute for Medical Psychology, University of Munich, Germany

Impaired physical and mental well-being are voiced by one-third of employees in air-conditioned office buildings in Germany and this frequently contributes to absenteeism. These complaints, defined as ‘sick building syndrome (SBS)/ include irritations of mucosa, physical complaints, changes in mood and impairments in mental function. While the causes of these impairments remain unclear to date, a role of specific indoor climate factors as well as psychosocial factors such as stress levels, work satisfaction, perception of indoor climate and sociodemographic characteristics is assumed. In a multicentre longitudinal study related to the SBS (the ProKlimA Project), impaired mood, medical condition and performance as well as the psychosocial status of employees in 16 office buildings around Germany were measured. A statistical analysis of the questionnaire data from 8 of 16 buildings involving almost 3,000 persons showed that the prevalence of SBS related impairments varies over the buildings. Furthermore, the degree of impairments is strongly related to psychosocial factors such as perceived indoor climate, work satisfaction, work strain and general stress level, which explain, according to the regression analysis results, up to 48% of the variance of SBS complaints in the eight buildings. These findings have implications for understanding the relationship between indoor climate and well-being as well as for the planning and implementation of a healthy work environment in office buildings.

409. THE RELATION OF LIFE SATISFACTION AND QUALITY OF LIFE ASSESSED BY QLQ-C30
J. van Wietersheim and A. von Böhle
Department of Psychosomatic Medicine and Department of Urology, Medical University Lübeck, Germany

The goal of this study was to analyse the relation between life satisfaction, measured with a questionnaire (LEZU) and quality of life (QoL), assessed by the EORTC questionnaire QLQ-C30. In addition, we wanted to collect community sample data to be compared with clinical samples. Medical students distributed and recollected the questionnaires and 246 data sets were analysed. The results show that the QLQ-C30-scale QoL is correlated with life satisfaction at medium size (r = 0.64), so that these terms are similar, but not identical. The other scales of the QLQ-C30 (e.g. emotional functioning and cognitive functioning) are showing smaller correlations than life satisfaction with the QoL scale. There were no differences between men and women concerning life satisfaction and scales of the QLQ-C30. Older people showed lower values in role functioning, physical functioning, cognitive functioning and QoL. People with an acute illness or a handicap showed significant impairment in all scales of the QLQ-C30, yet only a tendency to worsened life satisfaction. In conclusion, life satisfaction – a more psychological term – could be a meaningful supplementation for QoL instruments, which are more behavioural and descriptive.

410. QUALITY OF LIFE AND UTILITY EVALUATION IN SCHIZOPHRENIA TREATMENT (QUEST)
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The study examined the feasibility issues and psychometric aspects of obtaining accurate health state descriptions and their utilities, from symptomatically stable schizophrenic patients. Using a cross-sectional case-controlled design, a study group consisting of 102 clinically stabilized schizophrenic patients and a control group of 32 treated and recovered patients with major depression were asked to provide detailed descriptions of three distinct health states associated with their illnesses and to assign utilities to these health states with the aid of a purpose-built utility evaluation protocol. The battery was repeated after a 1 week interval. Symptom severity, insight and quality of life (QoL) were assessed by independent raters. The acceptability ratings and respondent burden were also ascertained.

Schizophrenic patients, as compared to controls, were able to distinguish and describe the specified health states with an equal degree of ease and accuracy. The rating scale, time trade-off and willingness to pay techniques emerged as the favoured method of utility evaluation. The test–retest reliability of the utility ratings (r = 0.87 – 0.89, and p < 0.001) and their concurrent validity with the quality of measures (r = 0.67 – 0.73, and p < 0.001) were significantly high. The reliability and validity of patients’ appraisals were unaffected by symptom severity and insight. It is concluded that clinically stabilized patients with schizophrenia can provide accurate health state descriptions and assign utilities with a fair degree of reliability and validity. Utility evaluations based on patients’ self-appraisals could be seen as potential tools in outcome studies and clinical trials involving schizophrenic patients.

411. THE THREAT OF DISEASES IN THE MIND OF AUSTRIAN PEOPLE
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The self-perceived threat of cancer, myocardial infarction, stroke, traffic accident, diabetes mellitus, AIDS, Alzheimer’s disease and drug abuse was investigated in a representative sample of Austrian people. Cancer was named by 41% of the 2,065 interviewed persons as the most feared disease, followed by traffic accident (38%) and myocardial infarction (36%); the lowest count was 6% for drug abuse.

Significantly (p < 1%) more females fear cancer, stroke, diabetes mellitus and Alzheimer’s disease than males. Significantly (p < 1%) more males responded with ‘cannot say’ to cancer and more females to diabetes mellitus. A cluster analysis shows that respondents who perceive a higher threat by the diseases have a low level of education and are living in the countryside. The age distribution of the persons who responded...
with ‘very threatening’ corresponds well with the age-specific prevalence of diseases. Smoking habits, alcohol consumption and body mass index had no influence on the self-perceived threat of the diseases under investigation.

412. AKISWAHILI VERSION OF THE SF-36 HEALTH SURVEY FOR USE IN TANZANIA: TRANSLATION AND PSYCHOMETRIC EVALUATION

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The purpose of this study was to translate and adapt the SF-36 Health Survey for use in Tanzania and to test the psychometric properties of the translated SF-36 into Kiswahili. The translated questionnaire was administered by trained interviewers to 3,802 adults (50% women, mean (SD) age 31 (13) years, 50% married and 60% with primary education) as part of a cross-sectional household survey in 1995. Item and scale-level tests of the assumptions underlying the scoring of the SF-36 were conducted for the entire sample and separately for the least educated subgroup (n = 402), using multivariate scaling analysis.

The data quality was excellent: only 1.2% of the respondents were excluded because they answered less than half of the items for one or more scales. The median item-scale correlations ranged from 0.46 to 0.85 for the entire sample. The median scaling success rates were 100% (range 87.5 – 100.0). The median internal consistency reliability of the eight scales for the entire sample was 0.84 (range 0.70 – 0.92). The floor effects were low and ceiling effects high on five of the eight scales. The results for 402 people without formal education did not differ substantially from these of the entire sample.

The psychometric results indicate that the Kiswahili translation of the SF-36 may be useful in estimating the health of people in Dar es Salaam. To make the SF-36 a useful tool for measuring health status in Tanzania, evidence for the validity of the questionnaire needs to be accumulated.

413. THE RELATIONSHIP BETWEEN CLINICAL AND DEMOGRAPHIC VARIABLES AND THE PERCEPTION OF HEALTH-RELATED QUALITY OF LIFE IN PSORIASIS PATIENTS

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Department of Public Health and Primary Health Care, University of Bergen, Norway

Health-related quality of life (QoL) is important in evaluating patients suffering from chronic diseases such as psoriasis. There have been few studies performed to assess health-related QoL in this group of patients. Therefore, the aim of the present study was to investigate the relationship between demographic (age, gender, education and living alone/not living alone) and clinical (disease duration, in-patients/out-patients, self-reported arthritis complications, emotionally charged body regions (face, neck and head) and self-rated disease severity) variables and the perception of health-related QoL in psoriasis patients. The study design was descriptive and cross-sectional. The sample comprised 282 patients (response rate 85%) who were treated consecutively in three Norwegian dermatology departments (mean age 47 years (range 19 – 86 years), 43% women, 27% lived alone, 64% had 1 or 2 years at upper secondary school or less, 20% hospitalized, mean disease duration 19 years (range 0 – 63 years) and 28% reported arthritis complications). To measure health-related QoL, the Norwegian version of the SF-36 was used (Cronbach’s α of mental health 0.90 and physical health 0.91). Correlation (Pearson r) and regression (stepwise linear) analyses were performed to assess the relationship between different clinical and demographic variables and health-related QoL.

When comparing both clinical and demographic variables in a multiple regression analysis the results show a significant relationship between physical health and age (β - 195), education (β - 165), emotionally charged body regions (β - 140), hospital setting (β - 125), arthritic complications (β - 482) and self-assessed severity (β - 341). The adjusted r² was 0.452. With regard to mental health, age (β - 185) as well as hospital setting (β - 174) and self-assessed severity (β - 210) were found to be significant. The adjusted r² was 0.136. The results indicate that age influences both physical and mental health. Further, educational level is related to physical health. When it comes to the clinical variables, hospital setting and disease severity are related to mental and physical health. In addition, arthritis complications and body regions affected impact on physical health.

414. PROXY ASSESSMENT OF PATIENT ISSUES: COMPARISON OF DOCTORS’ AND NURSES’ VIEWS OF PATIENT PERCEPTION OF THEIR QUALITY OF LIFE AND OF SYMPTOM BOther IN A POPULATION OF PATIENTS WITH TERMINAL CANCER

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1 Department of Psychology, Royal College of Surgeons in Ireland, 2 Our Lady’s Hospice, Harold’s Cross and 3 St Luke’s Hospital, Dublin, Republic of Ireland

Improvement of quality of life (QoL) for patients is the cornerstone for delivery of good palliative care. Symptom control is seen as one aspect of care that helps towards achieving this aim. The link between QoL and symptoms, as the patient perceives it, has not been assessed to date. From the assessment of QoL in palliative care research there has been an assumption that QoL deteriorates as death approaches.

The Schedule for Evaluation of Individual QoL (SEIQoL) involves a semi-structured interview to elicit aspects of life (cues) of relevance to patient QoL, assesses current status on each cue and weights these cues using either a process called judgement analysis (JA) or direct weighting procedure (DWP).

A longitudinal study of 30 consecutive terminally ill cancer patients admitted to an in-patient hospice unit, Our Lady’s Hospice, Harold’s Cross, Dublin, Republic of Ireland, was completed to study patients’ perceptions of their QoL using the SEIQoL (JA and DWP), symptom bother and symptom interference with their overall QoL. The main palliative care doctor and nurse involved in the day-to-day care of each patient was also asked to judge what they felt the patient perceived about their QoL, symptom bother and symptom interference with
overall QoL using the same assessment measures.

The results of this study are explored with particular emphasis on the positive aspects of QoL perceived by patients and underestimated by the professional carers.

415. INDIVIDUAL QUALITY OF LIFE: SEIQoL IN PALLIATIVE CARE

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Royal College of Surgeons in Ireland, Our Lady’s Hospice, and St Luke’s Hospital, Dublin, Republic of Ireland

Health-related quality of life (QoL) measures provide valuable information on how a patient’s health is affecting his/her life but may not address issues of relevance in terms of overall QoL, especially for patients with a terminal disease. The Schedule for Evaluation of Individual QoL (SEIQoL) involves a semi-structured interview to elicit aspects of life (cues) of relevance to patient QoL, assesses current status on each cue and weights these cues using either a process called judgement analysis (JA) or direct weighting procedure (DWP). This study aimed to determine the important QoL issues for terminally ill patients and to assess the feasibility of use of SEIQoL in these patients. The sample was (n = 30) consecutive cancer patients (14 male and 16 female). All were aware their disease was palliative. Twenty-six cases were excluded in the hospice population (17 of these with a prognosis of days rather than weeks). The important QoL aspects elicited in order of frequency were family (93%), health (77%), spiritual life (47%), friendship (33%), finances (33%) and social activities (27%). The mean internal validity ($r^2$) of the SEIQoL was 0.84 (SD 0.08). SEIQoL is feasible in palliative care settings. The results indicated high internal validity, showing that patients had a very good understanding of their QoL and the factors which contributed to it.

416. SHELTERED WORK INCREASES QUALITY OF LIFE AMONG CHRONICALLY MENTALLY ILL

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University of Vienna, Department of Psychiatry, Austria

Several studies have shown that, despite participation in vocational rehabilitation programmes, between 18.5 and 68.0% of mentally ill participants are unemployed at follow-up. Only a small number of studies exist on the subjective view of those who are not able to work in the free labour market. Our study was conducted in a workshop for the chronically mentally ill in Vienna (73% suffering schizophrenia). At several census days clients were asked for their subjective experiences. A questionnaire with 43 items was distributed to those working for more than 6 months ($n = 44$). Approximately 65% reported that their self-confidence and subjective well-being had increased since beginning work. The majority reported that their social network had enlarged by contacts during work. Most clients estimated the possibility of working only a few hours per day as being appropriate to their impairments. In conclusion, our study shows that vocational activities are experienced as important for their quality of life (QoL) by those mentally ill who are not able to be employed in the free labour market.

417. TESTING THE SF-12 SUMMARY HEALTH MEASURES IN NINE COUNTRIES: RESULTS FROM THE IQOLA PROJECT

John E. Ware Jr, Barbara Gandek, Neil Aaronson, Jordi Alonso, Giovanni Apolone, Jakob Bjørner, John Brazier, Monika Bullinger, Stein Kaasa, Alain Leplège, Marianne Sullivan and the IQOLA Project Group

The Health Institute, New England Medical Center, Boston, MA, USA

Research in the USA and Europe has shown that two factors account for 80 – 85% of the reliable variance in the eight SF-36 Health Survey scales. This finding led to the development of the SF-36 Physical and Mental Component Summary scores (PCS-36 and MCS-36) and the construction of a 12-item short form, which accurately estimates the PCS-36 and MCS-36. In this study, the methods used in the USA to reproduce the SF-36 summary measures with only 12 items were tested in nine European countries.

The data came from general population surveys in Denmark, France, Germany, Italy, The Netherlands, Norway, Spain, Sweden and the UK ($n = 1,582 – 9,151$). In each country, principal components analysis was used to derive and evaluate two factors and to score the PCS-36 and MCS-36. The PCS-36 and MCS-36 scores were then estimated using 12 items, in three different ways: standard (US-derived) SF-12 items and scoring algorithms, standard items and country-specific scoring and country-specific sets of 12 items and scoring. The Standard (US) and country-specific scores for the PCS-36, MCS-36, PCS-12 and MCS-12 were compared.

Physical and mental health factors within the SF-36 were confirmed in each country. The PCS-36 and MCS-36 scores were replicated and estimated well, both by the standard SF-12 items and by country-specific sets of 12 items. Standard SF-12 items explained 87 – 94% of the variance in the PCS-36 and MCS-36 scores, as did the 12 items selected within each country. The product-moment correlations between the standard and country-specific PCS-36/PCS-12 and MCS-36/MCS-12 scores were very high (0.92 – 0.99).

Because of the high degree of correspondence between the summary physical and mental health factors estimated using the SF-12 and SF-36, it appears that the SF-12 will prove to be a more practical alternative to the SF-36 for the purposes of large group comparisons among the nine countries studied here. Whether standard or country-specific scores are used depends on whether the purpose of a study is between or within country comparisons.

418. A SUCCESSFUL GROUP QUALITY OF LIFE PROGRAMME: RADIATION THERAPY ONCOLOGY GROUP (RTOG)


RTOG Quality of Life Committee, Philadelphia, PA, USA

In 1991, the RTOG formed a quality of life (QoL) committee to establish, oversee and facilitate QoL research. QoL research has been conducted in selected phase III trials in multiple disease sites. Studies were chosen where the therapeutic options most warranted a QoL investigation and where there were economic issues. As part of the education mission, the QoL committee completed a procedure manual and a patient-oriented QoL video. Using existing QoL instruments, the RTOG started 20 QoL
studies and accumulated approximately 2,400 patients on QoL research. We have been able to increase compliance to QoL research both by patients and researchers through continuing education and reinforcement. Our compliance increased, as shown in Table 1. The overall compliance of the group at 78% is excellent. One statistician coordinates all of the RTOG QoL studies to ensure consistency of design and analysis. The principal QoL researchers at the institutions are nurse coordinators. An educational aspect of our QoL video is to encourage patients to be responsible for completeness of their own data forms. All of our QoL activities have involved patient-completed data forms. Individual studies are reported in the literature upon completion. In the past 5.5 years, we have started, conducted and published QoL research and we continue to have excellent compliance by patients and researchers. The additional cost of the group has been minimal and we look forward to refining our QoL activities in the future.

### Abstracts: 4th Annual Conference of ISOQOL

#### 418. Table 1. Initial compliance to participation on QoL end-point in treatment trials

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<th>Brain</th>
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<th>Lung</th>
<th>Oesophagus</th>
<th>Rectal</th>
<th>Prostate</th>
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<td>27/33</td>
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#### 419. MEASURING CHILD HEALTH AND WELL-BEING IN A SCHOOL-BASED SAMPLE OF AUSTRALIAN PARENTS AND CHILDREN

Elsabeth Waters and Jeanne Landgraf

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The objective was to evaluate item convergent and discriminant validity, floor and ceiling effects and scale internal consistency for the parent and child report of functional health and well-being, the CHQ-PF50 and the CHQ-CF87, in an Australian school-based setting. The preliminary evaluation of the CHQ was undertaken in preparation for the collection of normative data.

A pilot study of 249 parents and 173 students was carried out in collaboration with two primary and two secondary schools in metropolitan Melbourne. Multitrait/multi-item analysis was completed using the MAP-R software at the Health Institute. The scale internal consistency was evaluated using Cronbach’s α coefficient. The results of this and further analysis of the sociodemographic data contribute to the changes made to the parent and child questionnaires for use in the Australian context, a heterogeneous cultural mix of parents and children.

All but two items in the CHQ-PF50 for the primary school parent sample and five items in the CHQ-PF50 for the secondary school sample met the scaling criteria (> 0.40) for item convergent validity. Perfect (100%) and near perfect (> 91%) item success rates were observed for tests of item discriminant validity for the CHQ-PF50 in the primary and secondary samples (α = 83 and 166; four and 12 subjects omitted for missing data or 4.6 and 6.7%, respectively). In the child self-report, the item discriminant ranged from 94.9% for the mental health scale to 100% with an overall success rating of 97.6%. Minimal floor effects and some ceiling effects were found in all questionnaires, but no unexpected results. Cronbach’s α ranged from 0.72 to 0.93 for the CHQ scales fielded in the primary sample, 0.69 to 0.91 in the secondary sample and 0.77 to 0.90 for the child self-report sample. The results of low Pearson item scale correlations led to the removal of seven items from the child self-report.

The child self-report form has been shortened to 80 items. Following the collection of normative data and further empirical research, efforts will be made to reduce the number of items per scale and yet retain the overall comprehensiveness of the questionnaire for use in epidemiological and clinical settings.

#### 420. IMPAIRMENT OF SELF-AWARENESS AND SELF-ASSESSMENT OF QUALITY OF LIFE IN SCHIZOPHRENIA


Department of Psychiatry and Psychotherapy I, J.W. Goethe University, Frankfurt/Main, Germany

The self-assessment of psychopathological symptoms in schizophrenia is restricted by a disturbance of self-awareness. The same restriction is discussed for self-report measures of life satisfaction. In the study presented the disruption of self-awareness of negative symptoms was measured in 35 chronic schizophrenic out-patients and related to their self-reported quality of life (QoL). For this purpose the Scale for the Assessment of Negative Symptoms (SANS) was transformed to a Questionnaire for Negative Symptoms (QNS) and completed by the patients. The scale for the Bilateral Assessment of Impairment of Negative Symptoms Self-Awareness (BAINS) consisted of the item score differences of the SANS and QNS. Additionally, the German adaption of the Lancashire Quality of Life Profile (Berlin-Lebensqualitaets-Profil, BLP) was performed. The BAINS scores correlated highly significantly with SANS scores (r = 0.66 and p = 0.00001) and exclusively with the global well-being score of the BLP (r = 0.45 and p = 0.0006). These results confirm the disruption of self-awareness in chronic schizophrenic patients and show it to be caused by the objective extent of negative symptoms. It can be concluded that the impairment of negative symptoms’ self-awareness in schizophrenic patients has some influence on their self-assessment of global well-being but does not disturb the self-report of QoL in the particular life domains of the BLP.
421. SELF-ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE IN DEPRESSIVE IN-PATIENTS B. Weber, B. Schneider, J. Eckert, B. Gille, P. Fey, J. Fritze and K. Maurer Department of Psychiatry, Goethe University, Frankfurt/Main, Germany

Depressive syndromes are often dominated by body symptoms and hypochondriac fears. For that reason restrictions of quality of life (QoL) can be expected to be similar to those of body diseases.

In our study 15 depressive in-patients with a wide range of severity of depression (eight unipolar and four bipolar depressive disorders, two dysthyrmias and one double depressive) were examined by a computerized version of a universal scale for the assessment of health-related QoL, the Everyday Life Questionnaire (EDLQ). Depressive symptoms were assessed by the Beck Depression Inventory (BDI) and the Depressive Delusional Fears Questionnaire (DDFQ). States of mood were measured by a visual analogue scale (VAS), the Bright – Dark Scale (BDS) and the Profile of Mood States (POMS).

High significant correlations (p ranging from <0.01 to <0.00001) were found between the depressive state of mood and QoL scores. Subscale and single item analysis showed meaningful relations between several depressive symptoms and components of QoL. These results indicate that the EDLQ is a promising tool in assessing health-related QoL in depressive patients. Furthermore, health-related QoL in depression appears to be predominantly influenced by the (self-reported) severity of depression and states of mood, followed by depressive delusional fears. Further studies should deal with the question, if restrictions of health-related QoL remain after remission of depressive episodes.

422. TREATING CHRONICALLY ILL PATIENTS WITH TRADITIONAL CHINESE MEDICINE – ITS EFFECTS ON THEIR QUALITY OF LIFE

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The purpose of the study is to demonstrate the long-term benefit of traditional Chinese Medicine (TCM) on chronically ill patients.

The analysis is based on a total of 1,037 in-patients with various pain syndromes and other chronic diseases. The open prospective observational study – as part of a routine quality management programme – includes the assessment of quality of life (QoL) using the SF-36 health survey. The questionnaires were handed out repeatedly, at admission and discharge as well as within a follow-up up to 1 year later.

The patients (73% female), with a mean age of 53 years and a mean duration of illness of approximately 11 years, showed a marked impairment regarding all eight subscales of the SF-36. At discharge (after 4 weeks of treatment) the most distinctive improvement, in terms of the standardized mean difference, can be found on mental health and bodily pain. After 6 months the greatest increase in QoL switched to bodily pain and social functioning. Approximately 50% of the patients showed an improvement on these scales of 10 points or more compared to the initial value at admission. The rate of returns after 6 months was approximately 77%. A five-cluster solution of the patients with respect to different types of profiles of their impairment demonstrates the individual weights of physical and mental health. A higher degree of internal locus of control corresponds to greater improvements on the SF-36 scales, in particular bodily pain. The physician's global judgement of the success of the treatment correlates only with changes in physical aspects of QoL.

Against the background of a chronic and stable course of the disease we conclude from our results that the patients benefit from TCM to a clinically relevant extent with regard to their subjectively evaluated health status. This effect continues for at least 1 year after their discharge from the hospital.

423. USING A PATIENT GENERATED MEASURE OF QUALITY OF LIFE IN A LONG-TERM RANDOMIZED CONTROLLED TRIAL OF HORMONE REPLACEMENT THERAPY: A PILOT STUDY

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Most quality of life (QoL) measures impose an external value system by using standard formats, questions and weights of various pre-selected components of QoL derived from group data without assessing the relevance of these questionnaires to individuals. This pilot study has assessed the feasibility and appropriateness of using the patient-generated Schedule for the Evaluation of Individual QoL (SEIQoL) in a general practice setting in addition to several health-related measures. The aim was to inform the choice of QoL measures for a long-term randomized controlled trial of hormone replacement therapy (HRT).

Sixty-two post-menopausal women, aged 45 – 64 years, were recruited through two UK general practices. They were interviewed twice, separated by a 4 month interval, by a trained practice nurse and in addition to the SEIQoL completed several other measures including the generic SF-36.

The completeness of the data obtained and positive feedback from the nurses show the feasibility of using the SEIQoL in a general practice setting. All women indicated their enjoyment in taking part and appreciated a methodology which involved them determining what was important to their own QoL. The SF-36 scores are consistent with relevant population norms.

The study demonstrated the acceptability of SEIQoL to patients and the feasibility of using it in a long-term trial of hormone replacement therapy with clinical end-points. The information elicited by the SEIQoL interview technique provides insight into the factors influencing individual QoL in a healthy population.

424. RELATION OF DISEASE SEVERITY AND COPING TO QUALITY OF LIFE IN PATIENTS WITH CYSTIC FIBROSIS

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1Department of Ped. Pneumology and Immunology, Humboldt-University and 2Inst. of Med. Statistics, Benjamin-Franklin-Clinic, FU, Berlin, Germany

Cystic fibrosis (CF) is the most common severe autosomal recessive genetic disease in Caucasians. With the improvement of life expectancy in the last decades, supporting patients in adapting to life with this chronic progressive disease has increasingly become important.
The present study investigated the relation between quality of life (QoL) in this population, severity of disease and cognitive factors, in specific, subjective health perceptions and ways of coping. A sample of 89 adolescent and adult CF patients completed a QoL questionnaire ('Alltagsleben') and a questionnaire on ways of coping with disease ('Freiburger Fragebogen zur Krankheits-verarbeitung').

Regression analyses revealed that, after accounting for illness severity and hours of therapy per day, the subjective health perception of patients significantly explained the variance in their QoL. In addition, a more depressive coping style was associated with lower QoL, whereas looking at their own situation in more relative terms by comparing themselves with others was related to better QoL.

The data support the important role of cognitive factors in the adaptation to this severe chronic disease. In general it was surprising that overall QoL in these patients does not appear to be impaired compared with the data reported in healthy subjects. It remains open whether the instrument is sufficiently sensitive to the issues relevant to this population. Preliminary data from a disease-specific QoL questionnaire for CF patients that is currently in the validation process will be reported and discussed.

425. DETERMINING CROSS-CULTURAL VALIDITY OF QUALITY OF LIFE MEASURES
Diane Whalley
Galen Research, Manchester, UK

With the increase in international clinical trials, greater emphasis needs to be placed on the cross-cultural validity of the outcome measures used. It is generally accepted that conceptual equivalence is of more importance than linguistic equivalence. However, recent advances in or understanding of measurement theory suggest that conceptual equivalence may not be sufficient. Compatibility derives not only from items that reflect the same concepts across languages but also from those concepts having equal values on the underlying construct, that is, the items must have construct equivalence. The RGHQoL, a 20-item genital herpes (GH) specific quality of life (QoL) instrument, was developed in the UK and subsequently translated into a number of additional languages using a method designed to maximize conceptual equivalence. The aim of the current analyses was to assess the validity of combining RGHQoL data from different countries.

Data from the USA, UK, Denmark, Austria/Germany and Australia/New Zealand (n = 1,313) were taken from a clinical trial comparing suppression and episodic therapy for GH. Rasch analyses were conducted to assess the measurement properties of each language version (unidimensionality, item bias and item stability over time). Similar analyses were then employed to assess the cross-cultural validity of the scale in terms of the construct equivalence of the items.

All language versions of the RGHQoL were found to have good measurement properties. The analyses identified a 12-item version of the scale that is unidimensional, has minimal differential item functioning and has item stability over time. Construct equivalence was found between the English-language versions. However, some items in the Danish and Austrian/German versions reflected different levels of QoL impairment than in the other versions.

This study is the first to examine cross-cultural validity in terms of construct equivalence and shows that this is more problematic across countries with different languages. The consideration of cross-cultural validity is crucial, given the increasing number of multinational clinical trials. It is vital that construct equivalence is addressed in the development of new instruments if cross-cultural validity is to be achieved.

426. ASTHMATICS’ PERCEPTION OF ‘ACCEPTABLE’ HEALTH
E.A. White, P.W. Jones and K. Lowton
St George’s Hospital Medical School, London W17 ORE, UK

Health has been defined as ‘the possession of acceptable levels of mental and physical fitness’. This study was designed to examine asthmatics’ perception of ‘acceptable’ health compared to their ‘actual’ health and to test whether this perception is stable. The data are presented from the first 30 subjects (19 female) in an ongoing study. The mean age was 50 years (range 22–87 years); mean post-bronchodilator FEV1 was 71.2 ± 25.1 (SD) % predicted. The effects of asthma on patients’ lives were assessed using the St George’s Respiratory Questionnaire (SGRQ). Patients first completed this as they were that day and then assessed whether the limitations they had indicated were ‘acceptable’ to them. This procedure was repeated 2 weeks later by telephone. Follow-up data is available for 25 subjects. Mean ± SD ‘actual’ and ‘acceptable’ SGRQ scores are shown in Table 1.

426. Table 1.

<table>
<thead>
<tr>
<th>SGRQ</th>
<th>Actual</th>
<th>Actual</th>
<th>Acceptable</th>
<th>Acceptable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>base line</td>
<td>follow-up</td>
<td>baseline</td>
<td>follow-up</td>
</tr>
<tr>
<td>Symptoms</td>
<td>56.0 ± 23.4</td>
<td>54.7 ± 27.2</td>
<td>18.4 ± 16.0</td>
<td>14.5 ± 18.8</td>
</tr>
<tr>
<td>Activity</td>
<td>45.0 ± 25.4</td>
<td>46.7 ± 30.3</td>
<td>12.4 ± 17.6</td>
<td>16.1 ± 21.8</td>
</tr>
<tr>
<td>Impacts</td>
<td>28.8 ± 20.4</td>
<td>34.7 ± 23.0</td>
<td>5.9 ± 9.2</td>
<td>8.0 ± 10.2</td>
</tr>
<tr>
<td>Total</td>
<td>38.2 ± 20.1</td>
<td>41.7 ± 24.1</td>
<td>9.9 ± 11.2</td>
<td>11.5 ± 13.8</td>
</tr>
</tbody>
</table>

0, best health; 100, worst health.

Acceptable SGRQ scores were considerably lower than actual scores, but indicated an acceptance of some impairment. Repeatability was examined using the intraclass correlation coefficient (acceptable data was highly skewed and was therefore square-root transformed for this analysis).

426. Table 2.

<table>
<thead>
<tr>
<th>SGRQ</th>
<th>Symptoms</th>
<th>Activity</th>
<th>Impacts</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual</td>
<td>0.78</td>
<td>0.74</td>
<td>0.78</td>
<td>0.82</td>
</tr>
<tr>
<td>Acceptable</td>
<td>0.44</td>
<td>0.44</td>
<td>0.45</td>
<td>0.58</td>
</tr>
</tbody>
</table>

The repeatability of the ‘acceptable’ compared to the ‘actual’ health ratings was low; however, the differences in the mean acceptable scores between assessments were not significant (Wilcoxon signed rank, p > 0.05). We conclude that the ratings of acceptable health are stable within a group, but vary within individuals across time. This instability may reflect the hypothetical nature of ‘acceptable’ health ratings.
427. GINSANA G115 HAS A BENEFICIAL EFFECT ON QUALITY OF LIFE IN POST-MENOPAUSAL WOMEN: RESULTS FROM A RANDOMIZED PLACEBO-CONTROLLED STUDY

*Ingela Wiklund*, Richard Lindgren, Lars-Åke Mattsson and Costanzo Limoni

1 University of Gothenburg and Linköping, Sweden and 2 Alpha 5, Riva San Vitale, Switzerland

As many as 40% of women in Sweden use herbal compounds to relieve their symptoms during the menopause. Since many herbal preparations are poorly documented with regard to efficacy, controlled clinical trials are needed.

The impact on quality of life (QoL) of treatment with Ginsana G115, a standardized ginseng extract including minerals and vitamins, was compared with placebo during a 16 week period in a randomized, double-blind, parallel group multicentre study, in symptomatic post-menopausal women. Validated questionnaires such as the Women Health Questionnaire (WHQ), the Psychological General Well-Being (PGWB) Index and VA scales focusing on vasomotor and somatic symptoms were completed at baseline and after 16 weeks.

Out of 382 randomized patients, the QoL questionnaires were completed by 191 women on G115 and 191 on placebo, with a mean age of 53.6 (± 4.0) years. Ginsana G115 provided better overall symptomatic relief (VA scale total score, \( p < 0.03 \)), than placebo, in particular regarding other somatic symptoms (\( p < 0.02 \)). Similarly, the PGWB dimensions scores showed borderline significance indicating a better effect of G115 regarding depressed mood (\( p < 0.056 \)), general health (\( p < 0.053 \)) and well-being (\( p < 0.064 \)). The WHQ indicated a slight improvement in favour of G115 versus placebo for dimensions depicting somatic symptoms (\( p < 0.072 \)) and cognitive function (\( p < 0.083 \)). Consistently, Ginsana G115 showed greater improvement in all aspects of QoL compared with baseline than was observed for placebo.

In conclusion, Ginsana G115 is significantly superior to placebo by providing better overall symptom relief and enhancing aspects of well-being.

428. ASSESSMENT OF QUALITY OF LIFE IN PROSTATE CANCER IN THE UK

*Diane Wild, Carol Farina and Ron Cookson*

UK

The purpose of the study was to choose the best questionnaire to measure the effect of prostate cancer and its treatment on quality of life (QoL). A group of research nurses specializing in prostate cancer were brought together for a roundtable discussion. The following issues were discussed: What are the effects of prostate cancer and its treatment on the QoL of the patients? What QoL instruments are available and what are the pros and cons of each? As a result of these discussions the FACT-P was chosen as the best alternative. The FACT-P was reviewed, two questions were added and four questions were changed to make them more easily understood by a UK population. A pilot study was then conducted whereby the questionnaire was administered to a group of 30 patients.

The questionnaire was generally thought to be acceptable to patients and they found the instructions easy to follow. Many of the patients enjoyed completing the questionnaire.

There were some questions which caused particular problems for the patients.

Q3. Because of my physical condition, I have trouble meeting the needs of my family. Over a quarter of the patients had problems understanding this question and many of them felt it was referring to the sexual needs of a spouse.

Q14. Have you been sexually active in the past year? If yes I am satisfied with my sex life. The structure of this question resulted in confusion for over 25% of the patients.

Q18. I am proud of how I am coping with my illness. Over 25% of the patients did not like the use of the word proud in this context.

Q36. I am able to feel like a man. Almost 50% of the patients did not understand this question.

Although the English version of the FACT-P has been developed to be used in all English-speaking countries and it is generally accepted in a UK population there are some problems with the interpretation of some of the items. Further study is required.

429. DEVELOPING A HEALTH-RELATED QUALITY OF LIFE OUTCOME MEASURE FOR PATIENTS WITH LYMPHOEDEMA

*Angela Williams*

Optimal Healthcare Solutions Ltd, London, UK

Lymphoedema is an incurable, progressive condition characterized by chronic swelling of a limb. This causes physical problems such as reduced mobility and function and psychosocial distress impairing quality of life (QoL). It affects one in three women treated for breast cancer and has a high prevalence in other cancers. In Britain, lymphoedema is managed using a physical treatment approach. The primary aim of treatment is to reduce limb size, although treatment also aims to improve mobility, function and psychological distress. The outcome measurement used by clinicians is limb volume. This takes no account of psychological implications or other physical effects of having a swollen limb. The author suggests that a condition-specific, health-related QoL outcome measurement would complement limb volume measurement, capturing clinical effectiveness beyond change in limb size.

The first step in the measurement’s development was to devise the questions. A list of typical patient’s experiences of living with lymphoedema was obtained from 40 patients attending an outpatient clinic using the first stage of the Patient Generated Index. In this way the questionnaire was patient centred and condition focused. Having obtained a list of areas/activities affected this was summarized into themes. A questionnaire for upper and lower limb swelling was devised incorporating these themes with a choice of four responses. Finally, a pre-pilot study was conducted to assess comprehensibility, ambiguity, time taken and any other problems in completing the self-completed questionnaire. The draft was sent to 25 clinicians treating lymphoedema for comments on the validity and practicality.

The 159 areas/activities affected were listed in their frequency noted prior to summarizing into 24 themes covering behavioural functioning and emotional well-being. The pre-pilot survey indicated that only minor changes were required and the clinicians’ comments supported the questionnaire’s validity and practicality.

Although some bias may be present from its development approach, the questionnaire has been rigorously developed and at the pre-pilot stage appears valid and practical. A survey is required to continue to test the measurement for reliability, validity and responsiveness.
430. THE QUEST FOR QUALITY OF LIFE: MEANING AND QUANTIFICATION
J.I. Williams.
ICES-Institute for Clinical Evaluative Sciences, 2075 Bayview Avenue, G-260, North York, Ontario M4N 3M5, Canada

In 1714, the British Parliament announced a prize of £20,000 for a practical and useful means for measuring longitude. The criterion for success was that the method had to be accurate within 0.5° of longitude. The prize was awarded in 1773 to John Harrison for the construction of a precise and reliable clock which he and his son William developed over 40 years of work. By comparing the local time of the ship’s clock to home time, sailors could calculate the degrees of longitude between the ship and home port. King George III finally awarded Harrison after years of contestation, intrigue and conflict within the scientific community.

If the British Parliament were to set a prize for a definitive measure of quality of life (QoL) how would one set the criterion for success and organize the adjudication of the contest? During the presentation I will present the challenges and hurdles in the quest for measuring longitude and relate them to the searches for the measure of QoL, including the politics of organizing the adjudicating committee and the controversies in judging the performances of the competing methods for measurement.

431. QUALITY OF LIFE IN RELATIVES OF PANIC DISORDER PATIENTS
J. Windhaber, R. Eher, D. Maierhofer and K. Dantendorfer
Department of Psychiatry, University of Vienna, Austria

Panic disorder (PD) is, for the patients, a disabling psychiatric condition leading to poorer marital status, increased financial dependency and decreased time on hobbies. However, little is known about the relatives of those patients. The purpose of our study is to describe the burden of care in relatives of patients suffering from PD. The closest relatives of consecutive DSM-III-R PD patients were interviewed with a specially designed structured interview.

Female relatives reported significantly more psychological problems since the onset of PD in their relative than males and reported to be worried more often about their ill relative and about the future. Male relatives had to do some work themselves which actually would have to be done by their ill spouses. Male relatives felt stronger that their working activities were impaired by the disorder of their spouses. Interestingly, many of the relatives found positive consequences of PD on their lives; most of them were relatives of patients suffering from PD with agoraphobia.

Our study shows that PD strongly affects the quality of life (QoL) of PD patients’ relatives. It suggests that interpersonal relations might play a role in therapeutic interventions and should be further investigated.

432. EVALUATION OF QUALITY OF LIFE IN RHEUMATOID ARTHRITIS AND SARCOIDOSIS
R.M. Wirsberger 1, J. de Vries 2, T.L. Th.A. Jansen 3, G.L. van Heck 1, E.F.M. Wouters 2 and M. Drent 1
1Department of Pulmonology, University Hospital Maastricht, 2Department of Psychology, Tilburg University and 3Department of Rheumatology, University Hospital Nijmegen St. Radboud, The Netherlands

Rheumatoid arthritis (RA) and sarcoidosis are disorders with several similar sequelae. The aim of this study was to compare the impact of RA and sarcoidosis on quality of life (QoL). Thirty-five patients with RA, 64 sarcoidosis patients and a sex- and age-matched control group completed the World Health Organization QoL assessment instrument (WHOQOL-100). This questionnaire measures 24 facets of QoL which cover six life domains as well as the global facet overall QoL and general health. Both patient groups scored low compared to the healthy controls with respect to the facets energy and fatigue, activities of daily living and working capacity (p < 0.001). Patients with RA were significantly more impaired than sarcoidosis patients with respect to the domains physical health, level of independence and social relationships and the facets of sleep and rest, pain and discomfort, mobility and negative feelings (p < 0.001). In general, the scores of the sarcoidosis patients were in between the RA patients and the healthy controls. In contrast to sarcoidosis, in RA a significant relationship was found between fatigue and psychological health. In conclusion, both disorders have an impact on patients’ QoL. The WHOQOL-100 appeared to be an appropriate instrument to assess QoL in the disorders studied. In sarcoidosis, as well as in RA, fatigue and impairment of activities of daily living appeared to be major problems.

433. INTERDISCIPLINARY VITALITY DIAGNOSTIC AND FUNCTIONAL AGE INDEX – INTEGRATION OF MEDICINE AND PSYCHOLOGY FOR ELDERLY PEOPLE
Wolfgang Wlk 1, Dagmar Meissner-Poethig 2 and U. Michalak 3
1Vienna, Austria, 2Berlin and 3Bad Wildungen, Germany

Vitality is age-related functional capacity and subjective well-being. It is the target of an interdisciplinary diagnostic concept in which the measurable effect on the individual quality of life (QoL) in the later stages of life plays a central part. Appropriate methods of investigation for determining vitality and the pertinent Functional Age Index assume that the current functional state in many of its diverse physical, mental and emotional-social aspects has been ascertained. Scientific trials of such methods of investigation are being carried out in Japan, the USA, Australia, Finland and Germany.

The authors present an innovative (age-validated, interdisciplinary and strain-orientated) functional test design which is equally practicable for theoretical and applied science. They outline its possibilities of application, paying special attention to evaluate effects of prevention, treatment and rehabilitation in a geriatric centre in Vienna.

434. INCORPORATING UTILITY ASSESSMENTS WITH NATIONAL DATA SETS
M.C. Wolfson 1, R. Roberge 2 and J-M. Berthelot 1
1Statistics Canada, Health Analysis and Modeling Group, Ottawa and 2Canadian Institute for Advanced Research, Canada

Comprehensive measures of the health status of a nation’s population should be a central feature of the statistical system, not least for monitoring basic trends. Summary measures that go...
beyond conventional measures such as life expectancy to encompass health status and morbidity among the living, such as health-adjusted life expectancy (HALE), represent a major advance, given the large share of health problems attributable to chronic disease.

At its simplest, HALE brings together and summarizes in an accessible manner two kinds of data: mortality rates which are transformed into life expectancy and population-based summary measures of health status by age and sex. Ideally, the summary health status measure is generic and reflects the population’s health state preferences. These two sets of data can then be combined using the Sullivan technique.

In Canada, a number of population surveys have included such a generic health status measure, the McMaster Health Utility Index Mark III (HUI) – specifically, the 1990 Ontario Health Survey (n = 67,000), the 1991 General Social Survey (n = 15,500), the 1994 National Population Health Survey NPHS (n = 19,500) and, most recently, the 1996 NPHS (n = 19,500). In addition, the NPHS is longitudinal, so we can now begin to examine the dynamics of health status on a population basis.

Using such a generic health status measure in both population surveys and specific clinical intervention studies provides a vital bridge between focused health care evaluations and the broad population perspective. Moreover, HALE lends itself to becoming the focus for a coherent family of measures and health policy simulation modelling whereby notions such as cause-deleted life expectancy and attributable risk can be generalized to form measures such as the portion of HALE attributable to a given health intervention, disease or risk factor – the purpose of Statistics Canada’s POpulation HEalth Model (POHEM).

436. OPTIMAL ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE: AN EMPIRICAL ANALYSIS OF SURVEY TIMING AND SUMMARY MEASURES

J. Michael Woolley1, Martha Bayliss2, Joel D. Kallich1, John Adams3 and M. Haim Erder3  
1Amgen, Inc., Thousand Oaks, CA, 2New England Medical Center, Boston, MA and 3Rand Corporation, Santa Monica, CA, USA

The timing of health-related quality of life (QoL) assessments is usually determined arbitrarily. This paper presents an analysis that empirically identifies the optimal frequency of collection of health-related QoL data. At issue is the balance between the need for frequent assessments to ensure sensitivity and the increased patient burden and high cost of frequent assessment. Less frequent assessment is acceptable as long as there is little bias or loss of sensitivity.

Using data from a clinical trial where health-related QoL was assessed at monthly intervals over a 6 month period (seven assessments), different frequencies of collection (quarterly and semi-annually) are compared to the ‘gold standard’, monthly assessment. The accuracy of a given method is determined by regressing the monthly health-related QoL area under the curve (AUC) on a given quarterly AUC. The goodness of fit is assessed by the parameter estimates for the intercept (α) and slope (β), r2 and the root mean square error of the estimates (MSE). In addition the mean bias (DIFF) and associated p value are provided.

Using the SIP physical dimension score, Table 1 presents the results based on three methods for calculating the AUC: the simple mean (the mean of the quarterly assessments), the linear method (a linear interpolation between the quarterly assessments) and the quadratic method (a quadratic function to interpolate values between the quarterly assessments).

The results show that quarterly assessment of health-related QoL provides an accurate representation of the monthly data. These results are robust to scales from the SF-36 as well. With respect to the method for calculating AUC, the simple mean performs worst across all criteria, while there is ambiguity in the rankings between the other two methods. The linear method has the lowest MSE and the lowest bias in α, while the quadratic method shows the smallest mean bias. The implications will be discussed.

436. Table 1.

<table>
<thead>
<tr>
<th>Method</th>
<th>β</th>
<th>α</th>
<th>r²</th>
<th>MSE</th>
<th>DIFF</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple mean</td>
<td>0.91</td>
<td>0.32</td>
<td>0.978</td>
<td>2.16</td>
<td>−1.51</td>
<td>0.00</td>
</tr>
<tr>
<td>Linear</td>
<td>0.97</td>
<td>0.07</td>
<td>0.991</td>
<td>1.44</td>
<td>−0.62</td>
<td>0.02</td>
</tr>
<tr>
<td>Quadratic</td>
<td>0.97</td>
<td>0.58</td>
<td>0.984</td>
<td>1.91</td>
<td>−0.01</td>
<td>0.97</td>
</tr>
</tbody>
</table>

Abstracts: 4th Annual Conference of ISOQOL
437. SENSITIVITY AND RESPONSIVENESS OF THE MOS-HIV HEALTH SURVEY, SICKNESS IMPACT PROFILE (SIP) AND DUKE ACTIVITY STATUS INDEX (DASI) TO PEAK OXYGEN CONSUMPTION IN PERSONS WITH HIV DISEASE

Albert W. Wu, R. Clark, J. Baegis and G. Chase
Department of Health Policy and Management, Johns Hopkins University, Baltimore, MD and Georgetown University, Washington DC, USA

Interpretation of health status scores is hindered by lack of data on the responsiveness to clinical parameters. We examined the relationship of patient-reported health status to differences and changes in peak oxygen consumption in an HIV-infected sample.

Subjects were enrolled in a randomized trial of a nurse-based home exercise regimen on exercise capacity and well-being in HIV disease. The patient-reported health status measures included the MOS-HIV, a 35-item, HIV-targeted instrument with ten subscales and physical and mental health summary scores, the SIP, a 136-item generic instrument with 12 subscales scores, physical and psychosocial dimension scores and an overall score and the DASI, a 12-item instrument developed for patients with coronary artery disease with item weights based on recorded metabolic costs of each activity. The independent variable was peak oxygen consumption, assessed using $V_{O2max}$ from exercise stress testing.

The 88 study participants had a mean age of 36.7, 18% were female, 52% were Black and 9% had used injection drugs. The mean CD4 count was 356 mm$^{-3}$. The internal consistency reliability (Cronbach’s $\alpha$) was > 0.70 for all scales. At baseline, the MOS-HIV physical functioning (PF) subscale was most strongly related to $V_{O2max}$, followed by the SIP ambulation subscale and the DASI ($r = 0.35$, 0.31 and 0.20, respectively). At 16 weeks, the correlation was strongest with the SIP ambulation subscale ($r = 0.47$, 0.51 and 0.43, respectively). The correlations of changes in scores and $V_{O2max}$ from baseline to week 16 ($r = 0.69$) were weaker, and were greatest for PF, followed by the SIP physical dimension score and the DASI ($r = 0.20$, 0.18 and 0.15, respectively).

Surprisingly, the MOS-HIV PF subscale and the SIP ambulation subscale were both more sensitive to $V_{O2max}$ than the DASI, despite its calibration to peak oxygen consumption in coronary artery disease patients. The MOS-HIV PF score was also more responsive to changes in $V_{O2max}$ than was the DASI. The results highlight the importance of retesting instruments when using them in different populations than the ones for which they were developed.

438. RESPONSIVENESS OF THE EUROQOL IN A CLINICAL TRIAL IN ADVANCED HIV DISEASE

Johns Hopkins University, MEDTAP International, GlaxoWellcome Inc, University of Cincinnati, USA

There is a demand for a brief utility measure for use in multicentre clinical trials. We examined the responsiveness to clinical events and the relative precision of the EuroQol instrument in advanced HIV and compared it to the MOS-HIV.

The EuroQol has two components: full health, scored as a weighted sum of current health scores in five dimensions (range 0 – 100 score. The MOS-HIV is a brief instrument with ten domain scales that can be summarized as physical (PHS) and mental health (MHS) summary scores. AIDS patients with a CD4 < 100 cells per mm$^3$ completed both questionnaires during participation in a randomized, controlled, multinational clinical trial of prophylaxis for cytomegalovirus disease (ACTG 204). We compared the responsiveness and relative precision of the scales to adverse experiences (AEs) and opportunistic infections (OIs).

The mean age for the sample ($n = 991$) was 38 years, 94% were male, 80% White and 7% had used injection drugs. At baseline, the mean full health score was 0.80, with 28% reporting the maximum score; the mean VAS score was 76, with 4% reporting the maximum. The mean subscale scores for the MOS-HIV ranged from 55 (role function) to 84 (cognitive function); the mean PHS and MHS scores were 47.4 and 49.5, respectively. The Spearman correlations of full health and MOS-HIV scales ranged from 0.44 (role) to 0.63 (pain); for the VAS the correlations ranged from 0.33 (cognitive) to 0.66 (health perceptions). Full health was also highly correlated with the PHS and MHS scores (0.60 and 0.58, respectively), as were the VAS scores (0.57 and 0.60, respectively). The MOS-HIV pain and PHS scores showed the greatest responsiveness (effect size = 0.9 and 0.4, respectively) and relative precision (2.5 and 1) to AEs. The EuroQol VAS had the greatest relative precision (1.7 relative to PHS) development of an OI.

In advanced HIV, preliminary evidence suggests a possible ceiling effect for the EuroQol full health scale. The EuroQol was less responsive to AEs than the MOS-HIV scales. However, the EuroQol VAS score was most sensitive to the development of an OI. Further analyses are needed to demonstrate responsiveness to treatment.
the means were higher for people with higher socioeconomic status. People who reported that they were sick within the previous 2 weeks scored significantly lower on all scales compared to those who were healthy, as did people who said they had a chronic condition and those who had a disability. The results indicate that the Kiswahili translation of the SF-36 is able to differentiate – as hypothesized – between groups of adults in urban Tanzania who differ in age, education level and self-reported morbidity.

440. EMOTIONAL PROFILE OF HYPERSONSITIVE PERSONALITY: SOME IMPLICATIONS FOR QUALITY OF LIFE RESEARCH
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The basic assumption of the present paper is that low or reduced quality of life (QoL) may be a consequence of a certain type of personality disorder. Therefore, the main purpose of the current study was to explore the structure of emotional dimensions of the ‘hypersensitive’ type of paranoid personality, referring to the relationship of this personality disorder – reflected in increased emotional, behavioural and interpersonal problems – and possible powerful negative effects on its QoL. The study was conducted on a sample of 30 psychiatric male patients with paranoid-depressive syndrome, all of which are assessed as pre-morbid hypersensitive personalities. Thirty clinically healthy male individuals served as a control group. For the purpose of establishing the specific structure of emotional dimensions or traits of the hypersensitive personality the Plutchik test profile index emotion was applied. This test measures 12 personality traits organized in eight primary personality dimensions. Personality assessment has also included the MMPI test; all patients had evaluations on the scales of paranoia and depression. The indicators obtained were confirmed as statistically significant differences between the mean values of these groups within the emotional dimensions of reproduction, incorporation, deprivation and opposition. These indicators are in accordance with the general finding that the ‘hypersensitive’ type of paranoid personality possesses the personality traits and styles which make such a personality disrupted in its social surrounding. It means that characteristics such as hypersensitivity, personal vulnerability and interpretative readiness in many respects significantly interfere with everyday life, disabling occupational adjustment, personal relationships and family life. The comments and suggestions were made on the possible implications of these findings for the purpose of QoL research. In particular, the author stresses the need to establish the extent to which QoL of this personality type is affected and, related to this, to identify which aspects of QoL are impaired or considerably reduced.

441. THE ROLE OF THE PERSON’S SELF-CONCEPT IN QUALITY OF LIFE RESEARCH
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The author discusses the concept of health-related quality of life (QoL) by paying special attention to the relevance of taking into account one’s own personal self-concept. Thus, an attempt was made to indicate the great importance of the unique way in which a person summarizes their own self-concept, i.e. the way they perceive and experience themselves in relation to others and to the world in general. It implies the principal research interest in the following key question: ‘If persons (patients) are asked to summarize their own overall appreciation of themselves and their life, what would they say?’ That is the reason why the author’s presentation contains the basic assumption that in the careful research of QoL in mental and somatic disorders it is essentially not possible to ignore or even to exclude peoples’ subjective and idiosyncratic feelings, experiences, attitudes and beliefs about themselves, as well as about the various elements or sides of their own life, that differentiate them from others. Within this context, the suggestion was made that a good measurement of a person’s QoL has to include an idiographic and subjective approach – but only as an important complement to nomothetic and objective emphasis in the field of QoL research.

442. QUALITY OF LIFE AND NEED FOR PSYCHOSOCIAL SUPPORT IN PATIENTS WITH TYPE I ALLERGIES, PSEUDOALLERGIES AND CHRONIC URTICARIA

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Clinical experience indicates that there is an interaction between allergic symptoms and the emotional status of many patients; This study was designed to compare the quality of life (QoL) and the need for psychosocial support between different patient groups with type I allergies, pseudoallergies and urticaria.

Consecutively, 210 in-patients were included, having insect venom (hymenoptera) allergies \( n = 105 \), drug hypersensitivity \( n = 44 \), food allergies \( n = 23 \) or chronic urticaria \( n = 38 \). At the time of investigation, the patients were admitted to a clinic for diagnostic procedures or for hyposensitization (insect venom). Emotional status and QoL was assessed by (1) the state trait inventory (STAI), (2) the SCL-90R, (3) a general QoL questionnaire (ALLTAG), (4) a QoL inventory specifically developed and validated for allergies (TLQA-A) and (5) a questionnaire on need and motivation for psychosocial interventions (FBB).

Patients with food allergies and urticaria experienced significant reductions in most areas of QoL, as shown by all questionnaires. A great many of them were in need and motivated for psychosocial support (patient education, relaxation and psychological support). In contrast, in patients with hymenoptera allergies, there were only focused areas of reduced QoL associated with specific situations of exposure and with the hyposensitization treatment. Patients with drug hypersensitivity did not differ from healthy persons.

These data indicate that patients with allergic reactions that are unpredictable – such as urticaria and food allergies – show greater reductions in QoL and more need for psychological support than allergic patients who are able to control the triggering situation. The motivation and need for psychosocial interventions corresponds with the reductions in QoL.