



# 1201/INTEGRATION OF INTERNATIONAL INPUT INTO INSTRUMENT DESIGN: TRANSLATABILITY ASSESSMENT

Katrin Conway, Director; Isabelle Mear, Linguistic Validation Department; Julie Rowbotham, Mapi Research Institute, Lyon, France

**Aims:** The last 20 years have seen the development of numerous PRO measures mostly however within and for one culture. Based on the assumption that the original concepts are universally appropriate, instruments destined for international use are translated following a standardized procedure (linguistic validation). This process however reveals the interdependence of translation and original and the importance of integrating an international component into the design of instruments, which can be done through a Translatability Assessment. The presentation will illustrate the methodology and the advantages of this new approach. **Methods:** A Translatability Assessment can be defined as an international critical review of a pre-final original in collaboration with the developer. In the absence of international development, this may be a cost and time effective compromise between the WHO approach to instrument development and translation. The translation process usually reveals difficulties when adapting the format, instructions, concepts, idiomatic expressions, response scales or demographic items to different languages. The Translatability Assessment proposes to review these aspects and suggest re-formulations in the original considering the context and constraints of other languages/cultures. **Results:** Several examples of the impact of the Translatability Assessment on the original wording will be given. For instance, although the term 'work' in English may refer both to a paid job and voluntary work, other languages may require different expressions to convey this global notion. The reference to 'daily activities' may be an alternative facilitating international harmonization across languages and pooling of data. Similarly, reference to 'patient initials' being inappropriate for Chinese languages, replacing the original with 'patient record number' can improve international acceptability. **Conclusions:** The Translatability Assessment may be a practical and easy way to integrate an international component in the design of new measures, thereby facilitating the subsequent translation by anticipating and solving its difficulties.

# 1264/ARE ENGLISH & CHINESE SF6D VERSIONS EQUIVALENT? A COMPARISON FROM A POPULATION-BASED STUDY

Hwee-Lin Wee, Pharmacy, National University of Singapore, Singapore; Yin-Bun Cheung, Singapore; David Machin, Singapore; Nan Luo, Pharmacy, Nat. Uni. S'pore, Singapore; Kok-Yong Fong & Julian Thumboo, Rheumatology & Immunology, Singapore Gen Hosp, National University of Singapore, Singapore

**Aims:** The SF6D bridges an important gap between the widely used SF36 and requirements for economic evaluation by allowing derivation of a utility index from SF36 scores. Demonstrating equivalence of various SF6D versions is a necessary prelude to developing & pooling SF6D utility scores for these versions. We therefore assessed equivalence of English & Chinese SF6D versions, two widely used languages with very different linguistic structures, using Herdman's model of equivalence. **Methods:** We analyzed data from a cross-sectional, population-based survey of ethnic Chinese in Singapore, using linear regression models to adjust for influence of potential confounding variables. Based on equivalence clinical trial methodology, measurement & item equivalence were assessed by comparing 90% confidence intervals (90% CI) of differences in scores due to language with pre-defined equivalence margins, which corresponded to the minimum clinically important difference for SF6D utility & item scores. **Results:** English & Chinese utility scores of subjects ( $n = 2558$ , completing English: 48.8%, age 21–65 years) had similar distributions and means (SD) of 0.8 (0.12). Adjusted 90% CIs for differences in utility & item scores due to language fell completely within equivalence margins, suggesting measurement & item equivalence. The 90% CI for utility scores was  $-0.0093$  to  $0.0062$  (width (0.0154), equivalence margin [0.033]); that for items ranged from  $-0.0046$  to  $-0.0020$  (0.0026), [0.0036] for Vitality to  $-0.0025$  to  $0.0035$  (0.0060), [0.0088] for Social Functioning. Functional equivalence was supported as various aspects of equivalence proposed by Herdman were demonstrated in this & other studies. **Conclusions:** English & Chinese SF6D versions

demonstrated measurement, item & functional equivalence, suggesting that scores from both versions can be pooled, thus increasing the representativeness and power of studies using SF6D, and providing a basis for studies to obtain SF6D utility scores in Asian populations.

# 1373/ARE THERE DIFFERENT COMPONENTS FOR THE TAIWAN SF-36 COMPARED TO WESTERN VERSIONS – PHYSICAL, MENTAL AND SOCIAL?

I-Chan Huang, Health Policy and Management; Constantine Frangakis, Biostatistics; Albert Wu, Health Policy and Management, Johns Hopkins University School of Public Health, Baltimore, MD

**Aims:** The SF-36 is used worldwide. Analyses have suggested a two-factor structure with physical and mental components. However, it is not known whether this structure also applies to Asian countries. We tested the equivalence of the summary scaling assumption using the Taiwan SF-36. **Methods:** This was a cross-sectional study using a national representative sample ( $n = 17,522$ ) from the 2001 Taiwan National Health Interview Survey. Structural equation modeling was used to test the best summary scaling of 3 third-order models. Based on studies from Western countries, Model 1 includes physical and mental components (PCS/MCS). Model 2 includes PCS, MCS, and general well-being (GWB), with cross-loading of general health perceptions (GH) and vitality (VT) on GWB, and social functioning (SF) on PCS. Based on factor structure of the Taiwan SF-36, Model 3 includes PCS, MCS, and a new Social component (SCS), with cross-loading of SF and role-emotion (RE) on SCS, and GH on MCS. The second-order component scales in each model were further summarized by a third-order component (Health). The criteria for goodness of model fit were comparative fit index (CFI), goodness-of-fit index (GFI), and root-mean-square error of approximation (RMSEA). **Results:** Relationships of Taiwan SF-36 subscales to component scales differed from those observed in Western countries, but were similar to those for other Asian countries (China, Hong Kong, Japan, and Singapore). Specifically, VT was strongly correlated with MCS (not PCS), and RE was moderately correlated with PCS. Structural equation modeling showed poor goodness-of-fit of the Western models (Model 1 and 2) for the Taiwan SF-36. By contrast, Model 3 with three second-order components (PCS, MCS, and SCS) satisfied fit criteria (CFI and GFI  $> 0.9$ , and RMSEA  $< 0.1$ ). The relationship to Health was highest for PCS, followed by SCS and MCS (0.99, 0.74, and 0.63 respectively). **Conclusions:** The components of the Taiwan SF-36 are not exactly the same as in Western countries. The different component structures may reflect different conceptualizations of health in Eastern and Western cultures.

#### # 1480/THE EQUIVALENCE OF WHOQOL-BREF AMONG 13 DIFFERENT LANGUAGE/CULTURE VERSIONS

Yuantao Hao, Public Health; Jiqian Fang, Dept of Medical Statistics and Epidemiology, Sun Yat-Sen University, Guangzhou, PRC; Mick J. Power, Psychiatry, University of Edinburgh, Edinburgh, UK

**Aims:** The aim of this study is to test the equivalence of the World Health Organization WHOQOL-BREF among 13 different language/cultural versions. **Methods:** The data used to test the equivalence of WHOQOL-BREF was collected by 13 centers in their own studies. These centers included Germany, Brazil, Hungary, India, Japan, Israel, Italy, Norway, Russia, Spain, United Kingdom, United States and China. The total sample consisted of 10,262 respondents, ranging from a sample size of 159, in the United States center, to 2408, in the Germany center. The mean age of respondents was 45.7, ranging from a mean of 31.1, in Israel center, to 56.3, in China center. The gender ratio of most centers was approximately 1:1. The patients' constitution consistency varied from 8.4 to 97.6%. Internal consistency of domains was assessed using Cronbach  $\alpha$ . Multi-group confirmatory factor analysis was used to examine the equivalence of WHOQOL-BREF across 13 centers. **Results:** There were some differences among the centers in relation to age, gender, health status, and sample size. All of the Cronbach  $\alpha$  values for the domains of physical, psychological, and environmental in each center were above 0.7, ranging from 0.7 to 0.88. Most of the Cronbach  $\alpha$  values for the social relationship domain were above 0.65 except that of the United Kingdom and Norway centers, which were 0.39 and 0.51 respectively. A four-domain structure was constructed according to the WHOQOL publications. The model was fitted for the 13 centers' data, respectively. The CFI (the comparative fit index) was well above 0.8. Germany, Spain and United States were the centers where the CFI was above 0.9. Multi-sample analyses were then carried out. The CFI was 0.88 and the results indicated that not all the corresponding loadings were equal across the 13 centers but the differences were small and the factor loadings' profiles were similar. **Conclusions:** WHOQOL-BREF had the same factor structure across the 13 different centers. The differences of corresponding factor loadings were small and the factor loadings' profiles were similar. In summary, WHOQOL-BREF is equivalent across the 13 different centers.

#### # 1288/A CROSS-CULTURAL COMPARISON OF SUBJECTIVE WELLBEING USING THE PERSONAL WELLBEING INDEX: SOME MATTERS FOR CONSIDERATION

Anna L. Lau, Rehabilitation Sciences, The Hong Kong Polytechnic University, Kowloon, Hong Kong SAR, China; Robert A. Cummins Psychology, Deakin University, Melbourne, Victoria, Australia; Polly H. Yeung, Rehabilitation Sciences, The Hong Kong Polytechnic University, Kowloon, Hong Kong SAR, China

**Aims:** Empirical findings suggest that the Subjective Wellbeing (SWB), also known as Subjective Quality of Life, of Asian populations is lower than those of Western populations. This study investigated whether such differences were due to a cultural response bias, which discourages strong positive appraisals of personal life quality. **Methods:** 360 participants were recruited from Hong Kong and Australia, using a combined convenience and quota sampling method, to evenly fit three age groups (18–35, 36–64, 65+). Telephone interviews were conducted with each participant to ask them to respond to items of The

Personal Wellbeing Index, which measures SWB, and is currently being developed for cross-cultural use by 35 countries. To investigate cultural response, participants were also asked to recall an extremely happy event in their lives, and then rate their life satisfaction for that event. Those who did not select the highest rating were asked to explain why they had not done so. Data were analyzed using descriptive statistics, multivariate analysis of covariance and content analysis. **Results:** The results verified a lower level of SWB for the Hong Kong population than the Australian population. This difference was found across all age, gender, income and education groups. The difference in SWB levels between both countries was found to be attributed to differential response bias. Differences in culturally related personal beliefs were identified as a major contributing factor. **Conclusions:** The identification of cultural response bias cautions against assuming scale equivalence in the interpretation of comparisons of SWB data between non-Western and Western countries in health care. The identification of a method for adjusting such bias is recommended.

#### # 1533/ENSURING SUCCESS IN QUALITY OF LIFE STUDIES WITHIN CLINICAL TRIALS – 15 YEAR EXPERIENCE OF THE NCIC CLINICAL TRIALS GROUP

Andrea Bezjak, Radiation Oncology, Princess Margaret Hospital, University of Toronto, Toronto, ON, Canada; David Osoba, QOL Consulting, West Vancouver, BC, Canada; Michael Brundage, Radiation Oncology, Kingston Regional Cancer Center, Kingston, ON, Canada; Michael Palmer, Study Coordinator, NCIC CTG Kingston, Kingston, ON, Canada; Dongsheng Tu, Biostatistician; Joseph Pater, Director, NCIC-CTG, Kingston, ON, Canada

**Aims:** Despite the general acceptance of the importance of measuring health-related quality of life (HRQOL) in and its adoption by most clinical trials groups and challenges remain that limit the successful reporting of HRQOL assessments in clinical trials. We report our systematic approach to this problem. **Methods:** The NCIC Clinical Trials Group (CTG), whose mandate is to perform phase III trials in all aspects of treatment of cancers, has been assessing HRQOL since 1988. To date, HRQOL has been assessed in 68 phase III trials, many of which have been reported. We have identified multiple steps that are needed to ensure success in HRQOL assessment in clinical trials, as well as the individuals who are responsible for ensuring success. **Results:** The essential steps in obtaining meaningful results from HRQOL assessments in clinical trials are: (1) Have a clinical trial that is designed to answer an important question and accrues well; (2) Formulate a QOL hypothesis/research question; (3) Provide a detailed QOL protocol and educate all staff in the rationale and details of that protocol; (4) Monitor and optimize compliance to HRQOL data completion; (5) Perform robust, clinically relevant data analyses; and (6) Report HRQOL results in conjunction with clinical results. The individuals who need to be involved in ensuring success are the trial sponsor/organization (for steps 1, 3, 4), the study chair (for steps 1, 2, 6), the QOL coordinator/consultant (for steps 2, 3, 4, 5, 6), the statistician (for steps 2, 5, 6), and the study coordinators and clinical research assistants (for steps 3, 4). Examples from NCIC CTG trials will be used to illustrate these points. **Conclusions:** Multiple steps and individuals need to be involved to ensure success in HRQOL assessment in clinical trials beginning with the formulation of the study idea and culminating with the successful informing of clinical practice.

# 1465/EVALUATION OF SPIRITUAL WELL-BEING QOL IN KOREAN CANCER PATIENTS UNDER HOSPICE CARE

Sehyun Kim, Preventive Medicine; Hye J. Park & Jong E. Lee, Nursing, College of Medicine, Pochon CHA University, Sunnam, Kyonggi-Do, Republic of Korea; Myung H. Park, Hospice Center, Kangnam St Mary's Hospital, Seoul, Republic of Korea

**Aims:** Spirituality has been reported as an important aspect of QOL for cancer patients. The impact of hospice care programs on spiritual well-being, however, have never been evaluated in Korean cancer patients. The objective was to evaluate whether cancer patients under hospice care have better spirituality QOL than hospitalized cancer patients without hospice care. **Methods:** A consecutive sample of 99 cancer patients was recruited from two hospitals. Among these 15 patients (15.15%) under hospice care programs were recruited. They were at least stage IV, terminally ill, and agreed to admit hospice unit for palliative care. Spiritual well-being QOL was measured by Korean version of the Functional Assessment of Chronic Illness Therapy-Spiritual (FACIT-Sp), and compared between hospice group and those who are not under hospice care. Informed consent was obtained. **Results:** The mean (SD) age of the subjects was 52.2 (12.98) years (range 21–82). The hospice group was older ( $p = 0.0305$ ) and had lower performance (mean Karnofsky score 71.6 vs. 46;  $p < 0.0001$ ). Among various domains of QOL the hospice group had lower in physical well-being ( $p < 0.0001$ ), functional well-being ( $p = 0.0142$ ), and quality of life in general (FACT-G). The hospice group did not show significantly higher spirituality QOL (FACIT-Sp) even after adjusting for demographic and clinical characteristics, and other QOL subscale scores ( $p = 0.0837$ ). **Conclusions:** The hospice care programs may not give a significant impact to terminally ill cancer patients on spiritual well-being, partly because of a small number of subjects studied and of a great extent of family supports for both terminally ill cancer patients under hospice care and cancer patient groups without hospice care. Therefore, a further research on broader concepts of hospice care programs for a large number of cancer patients is needed.

# 1175/UROGENITAL DYSFUNCTION FOLLOWING LAPAROSCOPIC (LAP) RESECTION FOR RECTAL CANCER

David Jayne, Academic Unit of Surgery, St James's University Hospital, Leeds, UK; Julia Brown, Helen Thorpe & Joanne Walker, Clinical Trials Research Unit, Phil Quirke, Academic Unit of Pathology, University of Leeds, Leeds, UK; Pierre Guillou, Academic Unit of Surgery, St James's University Hospital, Leeds, UK

**Aims:** The randomised clinical trial of Conventional vs. Laparoscopic-Assisted Surgery In Colorectal Cancer (CLASICC) has shown that lap resection of rectal cancer can be performed with short-term results comparable to open surgery. However quality of life, including bladder and sexual function, must also be similar between lap and open surgery. This study investigated sexual and bladder function following lap rectal resection performed as part of the CLASICC Trial. **Methods:** Patients who had undergone lap rectal, open rectal or lap colonic resection for cancer were identified from CLASICC. Bladder and sexual function was assessed using 3 postal questionnaires: International Prostatic Symptom Score, International Index of Erectile Function and Female Sexual Function Index. Relevant data from the EORTC QLQ-CR38 collected in CLASICC were also assessed.

Sample size was determined by the number of patients in CLASICC. Endpoints were compared using t-tests. Ninety-five percent confidence intervals were also reported. **Results:** Of the 374 patients eligible, 247 (71%) completed questionnaires: 98 lap rectal, 50 open rectal, 99 lap colon. More patients in the lap rectal than the open rectal group underwent Total Mesorectal Excision (TME) (82% vs. 68%). Bladder function was similar between lap and open rectals. Male overall sexual function and erectile function were slightly worse in lap compared to open rectal patients. Over 40% of male lap rectal patients reported a severe change in sexual function compared to 24 and 5% of open rectal and lap colon patients. Data on female sexual function was inconclusive as compliance was low. TME resection ( $p = 0.05$ ) and conversion to open surgery ( $p = 0.04$ ) were independent predictors of male sexual dysfunction. Comparison of the results with QLQ-CR38 sexual and bladder data showed similar trends. **Conclusions:** Lap resection of rectal cancer is associated with a small increase in urogenital dysfunction, most marked for male patients. This may be explained by the tendency to perform lap TME rather than partial TME.

# 1189/QUALITY OF LIFE (QL) EFFECTS OF PROPHYLACTIC OOPHORECTOMY VERSUS SCREENING AMONG WOMEN AT HIGH RISK FOR OVARIAN CANCER

Joanna Madalinska, Judith Hollenstein & Eveline Bleiker, Div. of Psychosocial Research & Epidemiology; Heiddis Valdimarsdottir, Cancer Prevention and Control, Mount Sinai School of Medicine, New York, NY; Marc van Beurden, Gynecology, The Netherlands Cancer Institute, Amsterdam, The Netherlands; Henk Boonstra, Gynecology, UMCN, Nijmegen, The Netherlands; Neil Aaronson, Div. Psychosocial Research & Epidemiology, The Netherlands Cancer Institute, Amsterdam, The Netherlands

**Aims:** The two preventive health options for women at high risk of developing ovarian cancer are prophylactic oophorectomy (PO) or gynecologic screening (GS). The purpose of this study was to determine the long-term QL effects of PO vs. GS. **Methods:** 846 of 1044 (response 81%) high-risk women who attended 8 gynecology clinics between 1995 and 2002 participated in this cross-sectional observational study. A battery of questionnaires consisted of generic and condition-specific QL measures. The PO group ( $n = 369$ ) included significantly more BRCA1/2 mutation carriers (72% vs. 26%,  $p < 0.01$ ), and more women with a history of breast cancer (49% vs. 34%,  $p < 0.01$ ) than the GS group ( $n = 477$ ). **Results:** No statistically significant between-group differences were observed in SF-36 scale scores, with women in both groups scoring similarly to the general population. The PO group reported significantly less cancer worries and anxiety, and perceived their cancer risk as significantly lower than the GS group ( $p < 0.01$ ). Younger women (30–50 years) who used hormone replacement therapy (HRT) after PO reported significantly more endocrine symptoms (FACT-ES) and worse sexual functioning (SAQ) than did premenopausal GS women; their symptom profiles were similar to those of non-HRT users in the PO group. Eight six percent of PO women would choose the same treatment again, and 63% would recommend it to others. **Conclusions:** These results suggest that the generic QL of women who opt for PO and GS is similar, but that PO reduces cancer-specific worries and perceived cancer risk. HRT does not appear to alleviate PO-induced menopausal symptoms. An on-going, prospective observational study is investigating these issues in more detail.

# 1390/TWICE DAILY RADIATION FOR HEAD AND NECK CANCER: IMPACT OF ENTERAL FEEDING

Jolie Ringash, John Waldron, Leah Gitterman & Susanna Sellmann, Radiation Oncology; Gina Lockwood, MMath, Biostatistics; Brian O'Sullivan, Andrew J. Bayley, Bernard J. Cummings, John Kim, David Payne & Padraig Warde, Radiation Oncology, The Princess Margaret Hospital, Toronto, ON, Canada

**Aims:** Quality of life (QOL) data was collected in a prospective dose escalation study of twice daily radiotherapy for locally advanced head and neck cancer. We hypothesized that QOL and time to QOL recovery would worsen with higher dose. **Methods:** Patients with TNM stage III/IV squamous cell carcinoma of the larynx/pharynx, or any stage hypopharyngeal cancer, were accrued from new patient clinics at a Canadian quaternary care cancer centre. Participants received 40 fractions of twice daily, hyperfractionated, accelerated radiotherapy. Three dose levels were tested: (L1) 60 Gy, 1.5 Gy/fraction; (L2) 62 Gy, 1.55 Gy/fraction; (L3) 64 Gy, 1.6 Gy/fraction. QOL was measured on the FACT-H&N at baseline, 6 and 12 months. **Results:** Median follow-up is now 1.92 (SD 1.3) years. Mean QOL scores were as follows: baseline 104, 6 months 110, 12 months 115. Pairwise comparisons between dose levels and time points did not reveal any significant differences between QOL scores for L1 (n = 22), L2 (n = 26) or L3 (n = 124). We performed a mixed-model analysis of determinants of QOL, which examined time, dose level, patient age, gender, disease stage, T category, N category, and whether or not patients had feeding tubes or underwent neck dissections. No dose effect was seen. Time, T-category and feeding tube use were significant. At all time points, QOL scores were lower in patients with more advanced T-stage. Overall, QOL improved significantly with time from diagnosis, however post-treatment QOL was lower and improved more slowly in patients who had feeding tubes. Feeding tubes were used more commonly in higher dose levels (L1, 41%; L2, 54%; L3, 86%). **Conclusions:** The expected trend to worsening of QOL and time to recovery with increasing radiation dose was not observed. Baseline T-stage was predictive of QOL after treatment. Although QOL has recovered by 6 months in most patients, patients with feeding tubes recovered slowly. The acute toxicity of twice-daily head and neck radiotherapy may reach a QOL threshold; however the use of enteral feeding may have a negative effect on QOL.

# 1354/PARTICIPATION IN SOCIAL ACTIVITIES AND HRQL IN OLDER ADULTS

Laura Schwartzmann, Bettina Caporale & Adriana Suárez, Medical Psychology, University of the Republic, Montevideo, Uruguay

**Aims:** HRQL of older adults has become a health priority in Uruguay, as they account for 16% of the population. Isolation and depression have been recognized as factors largely impacting on morbidity, mortality and quality of life. Participation in social meaningful activities has been considered to counteract these effects. Present work, included in field trial of WHOQOL-OLD (OLD) Project, aims to compare HRQL, impact of depression and participation in meaningful social activities in Women living alone in the Community (CW) and Residents of the only national public institution (PI) for unsupported poor elders. **Methods:** Sample included 165 subjects (105 Residents and 60 CW), aged above 60 and cognitively intact. CW included women attending a Health Workshop of the University for the Third Age (UNI3) and a paired sample of non-participants in any social activity. Applied instruments were WHOQOL-Bref, OLD module, Geriatric Depression Scale (GDS), Edinburgh Attitudes to Ageing Scale, WHO Spirituality, Religious and Personal Belief module. ANOVA and multivariate regression were used for statistical analysis. **Results:** Results showed higher HRQL scores for community dwelling compared to institutionalized elders ( $p < 0.001$ ) in all measures. In PI, participants in 2 or more social activities showed better ratings in General QL, self-esteem and perceived social support ( $p < 0.01$ ). CW participating in UNI 3 had significant better ratings in variables showing a more proactive attitude towards life and better satisfaction, in relation to their non-participant counterparts. Multivariate Regression model explained 50% of the variance with GDS, environment and physical domains of the Bref being best predictors ( $\beta$ : -24, 0.24, 0.22 respectively). **Conclusions:** Study confirmed the importance of psychosocial inter-

ventions to treat and prevent depression and positive impact of meaningful social activities on HRQL.

# 1694/A RESULT OF QOL RESEARCH WITH JAPANESE ELDERLY PEOPLE-THE RESULTS OF WHOQOL-OLD INSTRUMENT DEVELOPMENT STUDY IN JAPAN

Miyako Tazaki, Science, Tokyo University of Science, Tokyo, Japan

**Aims:** The purpose of the study is to develop the Japanese version of WHOQOL-OLD instrument, and investigate its validity, and to figure out important values and aspects of life that influence on the QOL of the elderly in Japan. **Methods:** For qualitative study, 40 people participated in eight 6 focus groups. The participants were either healthy or patient between in their 60s and 80s and more than 80s, caregivers, and medical professionals. For quantitative study, 410 elderly (average age 70.84 years old) living in Tokyo, Shizuoka, Kobe, Okinawa, Nagasaki, Fukuoka were recruited to respond the WHOQOL-OLD preliminary questionnaire, GHQ12, socio-demographic questionnaire, importance questionnaire, and medical checklists. The average QOL scores, and correlation between QOL and socio-demographic items using distribution analysis, and the item validity using IRT with one-parameter model were obtained. **Results:** The results of focus groups indicated that value and concerns differed greatly between healthy elderly and patients. Patients concerned most with their death and dying, and they preferred to be cared at home. By contrast, healthy elderly enjoyed their life with good terms, and with others with positive towards their future. Based on the distribution analysis, the elderly who were unmarried through their life, with full time job had higher QOL. In addition, if they felt respected in the society, and could decide their own time and activities, QOL scores were higher. Based on the IRT analysis, the WHOQOL-OLD excluding the question on death and dying WHOQOL-OLD instrument showed high validity score. **Conclusions:** The QOL of the elderly differed greatly by their current health conditions, but at least our society could make their QOL higher by offering more job and learning opportunities, and by providing more social welfare supports to be taken care of at home when they were sick. In addition, the traditional value system that the elderly should be respected and treated with dignity should be revived.

# 1462/DOES PHYSICAL FUNCTIONING PREDICT 3-YEAR MORTALITY AMONG NURSING HOME RESIDENTS

Hsing-Yi Chan, Medical Quality; Cheng-Chieh Lin, Family Medicine, China Medical University Hospital, Taichung, Taiwan, ROC; Tsai-Chung Li, Chinese Medicine, China Medical University, Taichung, Taiwan, ROC

**Aims:** The major reason for admission to nursing homes for elderly is due to the loss of physical function and a lack of caregiver support at home. The objective of the current study is to examine whether physical functioning is a significant predictor of 4-year mortality among nursing home residents. **Methods:** The study sample consisted of 237 nursing home residents, randomly selected by stratified cluster sampling in 2000. Each nursing home resident was evaluated by a trained nurse with the nursing home resident assessment instrument (RAI), a set of items for comprehensive functional assessment and care screening that represent common problem areas or risk factors for nursing home residents. Physical functioning scale was measured by 14 items including eating, transferring, toileting, bathing, etc. Mortality data were collected from the national mortality register using personal identification numbers. Multivariate Cox's proportional hazard models were used data analysis. The overall 3-year mortality rate in this sample is 31.6%. Chronic diseases, medication use, mood and behavior patterns, activity pursuit patterns, psychological well-being, and physical functioning were examined to see whether they are associated with mortality. Only factors significant at 0.2 level were entered final multivariate model. **Results:** Physical functioning is significantly associated with mortality, independent of age, gender, other factors in the model. Residents in the category of bottom 25% of physical functioning had significantly increased risk compared to those in the category of top 25% (relative risk = 2.84, 95% CI: 1.48-5.45). **Conclusions:** Nursing home residents with worse physical functioning had a greater risk of mortality over 3 years of follow-up compared with those with better physical functioning. The unique contribution of physical functioning to mortality is independent of other factors significantly associated with mortality.

# 1457/PSYCHOLOGICAL WELL-BEING AND HEALTH CARE RESOURCE USE AMONG NURSING HOME RESIDENTS

Cheng-Chieh Lin, Family Medicine, China Medical University Hospital, Taichung, Taiwan, ROC; Tsai-Chung Li, Chinese Medicine, China Medical University, Taichung, Taiwan, ROC; Hsing-Yi Chan, Medical Quality, China Medical University Hospital, Taichung, Taiwan, ROC

**Aims:** The objective of the current study is to examine whether psychological well-being is significantly associated with health care resource use among nursing home residents. **Methods:** The study sample consisted of 237 nursing home residents, randomly selected by stratified cluster sampling in 2000. Each nursing home resident was evaluated by a trained nurse with the Minimum Data Set (MDS), consisting of over 350 items covering most major domains: sociodemographic data, psychosocial well-being, diagnosis and medical conditions, functionality, continence, cognitive patterns, and special treatments and service. Resource use data were collected by structured form including frequency and amount of time spent in every care service item, and amount, frequency, and cost of resource use for each care service item by each resident. All staff caring for each resident recorded their direct care in minutes for a 7-day, 24-hour/day period on the structured form. Time was classified according to staff skill level. A 'nursing' cost measure was developed by wage-weighting these times for type of staff. Multivariate linear regression models were used for data analysis with care cost and time being logarithm transformation. **Results:** After adjusting for rehabilitation service use, receipt of certain significant services, special nursing care, physical functions, impaired cognition, psychological well-being is significantly associated with care time, but not total care cost. Residents with 'bad' psychological well-being had significantly increased care time by 21% compared to those with 'good' psychological well-being ( $t = 2.49$ ,  $p < 0.05$ ). **Conclusions:** Psychological well-being is a significant factor for care time among nursing home residents. Its unique contribution is independent of other significant factors such as rehabilitation service use, receipt of high tech procedure, and physical functions.

# 1502/EFFECTIVENESS OF A COORDINATED MEDICAL AND SOCIAL SERVICE PROGRAM ON ENHANCING QUALITY OF LIFE FOR ELDERLY WITH CHRONIC ILLNESS

Ho A. Po Ying, Applied Social Sciences, The Hong Kong Polytechnic University, Hong Kong, PRC

**Aims:** In Hong Kong, the lack of effective coordination between medical and social services put chronically ill elderly at risks of unplanned hospital admission and lower quality of life. It is the goal of this research to evaluate the effects of a coordinated medical and social service program on the health-related quality of life (measured by the Chinese version of SF-36 by Lam et al., 1998) and unplanned hospital admission among the participants. **Methods:** This study recruited 295 chronically ill elderly aged 65 and above. A randomized clinical trial design was adopted. Within 1-year intervention period, participants received a baseline and three post intervention assessments. The attrition rates were over 40%. Mixed ANOVA was used to compare the four assessments in terms of major outcomes. Sub-group analysis (by age) and post-hoc analysis (Bonferroni tests) were used to identify the possible main and interaction effects between the two groups. **Results:** The percentage increase in SF-36 were larger, though not significant, than the experimental group than the control group. However, older participants (aged 75 or above) had significant improvement in 2 domains of SF-36 (role limitations due to physical problems and energy vitality) than the younger participants. Post-hoc analysis showed that the participants who had significant improvement in SF-36 (good cases) had dropped out from the study after 3 months. Compared with the older participants, the younger participants had higher ratio of severe underlying conditions. The experimental group had less unplanned hospital admission than the control group, though the difference was not significant. **Conclusions:** In this study, some improvement in health-related quality of life was observed among older participants with stable chronic conditions. The lack of significant difference between the experimental and control group could be attributed to the imprecise definition of chronic illness during recruitment, the dropping out of good cases, the lack of professional ratings, and inherent problems of using SF-36 on elderly patients, such as memory bias, low motivation to provide accurate answers to repeated measures.

# 1107/DO QALYS REFLECT PREFERENCES FOR HEALTH OUTCOMES: A DISCRETE CHOICE EXPERIMENT

Rosalie C. Viney & Elizabeth J. Savage, CHERE, University of Technology, Sydney, Sydney, NSW, Australia

**Aims:** Health resource allocation decisions increasingly use Quality Adjusted Life Years (QALYs) to value health interventions. QALYs are intended to capture strength of preference for quality of life and survival in a measure that is comparable across interventions. QALYs are consistent with underlying welfare economic theory only if strong restrictions are placed on individual utility functions. **Methods:** This paper uses a discrete choice experiment to test the restrictions implied by QALYs by investigating the utility function for health care, defined over the probability of survival, life expectancy, health state and cost of treatment. The experiment involves a choice between treatment and non-treatment for hypothetical health conditions. Treatment attributes are cost, probability of successful treatment (restoring full health) with a complementary probability of dying and life expectancy if treatment is successful. Non-treatment attributes are health state, probability of surviving in the current condition, with a complementary probability of dying, and life expectancy with the health condition. A random sample of 347 respondents from the Sydney population completed the experiment. Conditional logit models are estimated to test the QALY restrictions. **Results:** Likelihood ratio tests of the QALY and more general models demonstrate that, contrary to the QALY restrictions, preferences do not conform to expected utility, and there are significant interactions between health state and survival duration. Individual specific covariates are significant, implying substantial differences in valuations of health states across the population. Simulation results demonstrate that the utility weights implied by the QALY model do not hold when a more general model is used. **Conclusions:** The results suggest that the QALY approach distorts valuations of health outcomes. This is problematic given the widespread use of QALYs in economic evaluation for health care decision making.

# 1169/MODELING TIME TRADE OFF VALUATIONS: IN SEARCH OF A GOOD FIT

Marieke Verschuuren & Ben A. van Hout, Professor, MTA/Julius Center, University Medical Center, Utrecht, The Netherlands; Gouke J. Bonsel, Public Health Epidemiology, Amsterdam Medical Center, Amsterdam, The Netherlands

**Aims:** Conventionally, utility data are modeled using some linear regression method for describing the relationship between health state attributes and valuations, with covariates to account for defined respondent characteristics. This approach ignores the threshold phenomenon in Time Trade Off (TTO), as well as coherence between values at the respondent level. Taking these aspects into consideration, a random effects Tobit model is conceptually superior to the usual approach. We conducted a study to test whether this hypothesis is supported empirically. **Methods:** Health profiles were constructed based on empirical pain data and valued by pain patients and controls by means of TTO. Time traded off (in days) was modeled using ordinary linear least squares regression (OLS) and Tobit, both with and without respondent characteristics as covariates, and both extended to a Random Effects (RE) model. Goodness of fit was assessed through comparison of the mean absolute residual (mr), the intraclass correlation coefficient (icc) of observed and predicted values, and the percentage of correctly predicted refusals to make a trade off. **Results:** Valuations for 814 different profiles were obtained from 68 respondents. Two hundred and eighty-nine times no trade off was made. Seventy four percent of these refusals were predicted correctly by Tobit, 36% by OLS. Furthermore performance was similar (Tobit: mr 601, icc 0.51; OLS: mr 604, icc 0.48). Applying RE models did not improve results. Predictive force was enhanced considerably though by adding respondent characteristics, in particular by a quantification of trading off behavior (Tobit: mr 463, icc 0.78; OLS mr 484, icc 0.76). **Conclusions:** In contrast to conventional approaches, Tobit performs adequately modeling the considerable effect of the threshold phenomenon in TTO data. RE models are not suitable for accounting for respondent-clusters in valuation data.

# 1482/FEASIBILITY, RELIABILITY AND COMPARISON OF VALUATION SCORES BY VISUAL ANALOGUE SCALE (VAS) AND TIME TRADE-OFF (TTO) OF PEDIATRIC HEALTH STATES DEFINED BY THE HEALTH UTILITIES INDEX MARK 3 (HUI3)

Hein Raat, Public health, Erasmus MC, Rotterdam, The Netherlands; G. Bonsel, Public Health Epidemiology, Amsterdam Medical Center, Amsterdam, The Netherlands; P. Krabbe, Senior Researcher, University Medical Centre Nijmegen, Nijmegen, The Netherlands; W.C. Hoogeveen, Rotterdam, The Netherlands; R. Gemke, Amsterdam, The Netherlands; M.L. Essink-Bot, Public Health, Erasmus MC University Medical Center Rotterdam, Rotterdam, The Netherlands

**Aims:** We collected VAS and 2 different types of TTO valuations from parents for 10 Health Utilities Index mark 3 (HUI3) health states of hypothetical 8-year-old children, including perfect health, most disabled, and 8 states in between. The aims were to assess the feasibility/reliability of the 3 rating methods, and to estimate conversion (power) functions between VAS and TTO valuations. **Methods:** 153 parents of children aged 4–13 completed paper and pencil-VAS and Internet-based-TTO questionnaires. States were assumed to last 60 years. VAS anchors were most/least-desirable; the relative preference for 'being dead' was assessed on a separate VAS. In 'TTO-dead', states were traded against perfect health/being dead; in 'TTO-ph/md' against perfect health/most disabled. **Results:** Mean age of respondents was 39 (SD 6); 88% were mothers. There were few missing answers (< 3%). The VAS resulted in 1% inconsistent valuations; TTO-dead in 6%; and TTO-ph/md in 5%; being dead in 15%. Inter-rater reliability as assessed by a G-study was 0.83 for VAS, 0.58 for TTO-dead, and 0.48 for TTO-ph/md ratings. Ninety-seven percent of the respondents scored most disabled <= dead; mean for most disabled was -0.32 (SD 0.59) if dead is set to 0. All Spearman rank correlations between the 3 methods and with the original Canadian utility estimates (Med Care 2002; 40: 113–128) were >0.99 ( $p < 0.01$ ); the TTO-dead scores corresponded best with the Canadian utilities (ICC 0.92;  $p < 0.01$ ). The power function between mean VAS and mean TTO-ph/md was  $T = V0.540$  ( $R^2 = 0.99$ ); and TTO-dead  $T = V1.512$  ( $R^2 = 0.98$ ); unexpectedly, the TTO-dead ratings were somewhat lower than corresponding VAS ratings. **Conclusions:** In our setting, 2 types of TTO exercises were less feasible and yielded considerably less reliable results than the VAS. All methods, however, resulted in the same ranking order, and power functions could very well predict the person-mean TTO values from person-mean VAS scores.

# 1125/DO MARKER STATES IMPROVE MEASUREMENT PROPERTIES OF UTILITY INSTRUMENTS: A RANDOMIZED MULTI-CENTER TRIAL IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Holger J. Schunemann, Dept. of Medicine, University at Buffalo, Buffalo, NY; Roger Goldstein, Medicine, University of Toronto, Toronto, ON, Canada; M. Jeffrey Mador, Medicine, University at Buffalo, Buffalo, NY; Douglas McKim, Medicine, University of Ottawa, Ottawa, ON, Canada; Elisabeth Stahl, AstraZeneca, Lund, Sweden, Peggy Austin; Gordon Guyatt, Clinical Epi & Biostatistics, McMaster University, Hamilton, ON, Canada

**Aims:** Optimizing the validity and responsiveness of utility measures is important for utility analyses as part of a randomized trial. We evaluated the impact of clinical marker state rating prior to patients rating

their own health on two preference instruments (Feeling Thermometer, FT, and Standard Gamble, SG) in patients with chronic obstructive pulmonary disease (COPD). **Methods:** We randomized 182 patients with COPD to complete the FT (self-administered) and SG (interviewer-administered) with marker states (FT+/SG+,  $n = 91$ ) or without marker states (FT-/SG-,  $n = 91$ ) before and after undergoing respiratory rehabilitation in a multi-center trial. **Results:** Use of marker states did not influence baseline preference scores ranging from 0 (dead) to 1 (full health). Improvement after rehabilitation on the scale from 0 (dead) to 1.0 (full health) was 0.04 both in FT+ ( $p = 0.03$ ) and FT- ( $p = 0.02$ ); the difference between FT+ and FT- was 0.00,  $p = 0.83$ . Improvement on the SG was 0.05 in both SG+ ( $p = 0.08$ ) and SG- ( $p = 0.04$ ); difference between SG+ and SG- 0.00,  $p = 0.95$ . Correlations with other health related quality of life scores were highest for FT+. **Conclusions:** Administration of marker states did not improve responsiveness of the FT but improved its validity. The SG showed limited validity and responsiveness that was not influenced by marker state use.

# 1135/ARE INDIRECT UTILITY MEASURES RELIABLE AND RESPONSIVE IN RHEUMATOID ARTHRITIS PATIENTS?

Carlo A. Marra, Pharmaceutical Sciences; Amir A. Rashidi, Health Care and Epidemiology, University of British Columbia, Vancouver, BC, Canada; Daphne Guh, Centre for Health Evaluation and Outcome Sciences, St Paul's Hospital, Vancouver, BC, Canada; Kopec Jacek, Health Care and Epidemiology, University of British Columbia, Vancouver, BC, Canada; Michal Abrahamowicz, Epidemiology and Biostatistics, McGill University, Montreal, PQ, Canada; John M. Esdaile, Rheumatology; Aslam H. Anis, Health Care and Epidemiology, University of British Columbia, Vancouver, BC, Canada

**Aims:** For preference-based measures HRQL (the Health Utilities Index 2 and 3 [HUI2 and HUI3], the EuroQoL-5D [EQ-5D], and the Short Form-6D [SF-6D]), there have been few comparisons of responsiveness. Therefore, in rheumatoid arthritis (RA) patients, the responsiveness of these instruments and disease specific measures (RAQoL, HAQ) were determined. **Methods:** HRQL and clinical data were collected at baseline, 3 and 6 months thereafter. Test-retest reliability was determined 5 weeks post the 3 month assessment. Anchor based approaches were utilized for responsiveness (using both a transition question and categories of the patient global assessment of disease activity VAS). Measures included the effect size (ES), the standardized response mean (SRM), the control SRM (CSRm), and the relative efficiency statistic (RE) and a polytomous regression technique. Bootstrapping was used to determine 95% confidence intervals. **Results:** 320 patients were enrolled with 75% follow-up at 6 months. Test-retest reliability was acceptable for all except the EQ-5D. For responsiveness, using the patient transition question as the anchor, the ordinal rankings were RAQoL > HAQ > SF-6D > EQ-5D > HUI2 > HUI3. Using the patient VAS anchor, ordinal rankings were RAQoL > HUI3 > EQ-5D > HAQ > HUI2 > SF-6D. The largest and smallest absolute changes for those reporting improvement was in the HUI3 and SF-6D scores respectively. **Conclusions:** The RAQoL was the most responsive; however, the HUI3 and the SF-6D were most responsive of the preference-based instruments. However, differences in the absolute change scores have important implications for cost-effectiveness analyses in the estimation of QALYs.

# 1326/TRANSLATION PROCEDURES FOR STANDARDISED QUALITY OF LIFE QUESTIONNAIRES: THE EUROPEAN ORGANISATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC) APPROACH

Michael Koller, Theoretical Surgery, Philipps-University Marburg, Marburg, Germany; Karen West & Andrew Bottomley, Quality of Life Unit, EORTC, Brussels, Belgium; Jane Blazeby, Surgery, Bristol Royal Infirmary, Bristol, UK

**Aims:** The EORTC Quality of Life (QOL) Group has developed a modular approach to QOL measurement for use in clinical trials in cancer. Questionnaires are used in international trials and standardised translation procedures are therefore required. This abstract describes EORTC QOL Group procedures and identifies problems encountered during the process. **Methods:** Translations follow a forward-backward procedure, independently done by two native-speaking individuals. Discrepancies go to a third consultant, and solutions are reached by consensus. Translated questionnaires undergo pilot-testing. Suggestions (by patients and users) are incorporated into the final questionnaire version. Translations are performed by professional translators of a translation agency. The translation procedure is managed and supervised by the Translation Committee within the EORTC QOL Group. **Results:** As to date, the core questionnaire has been translated and validated into 47 languages, with a further 8 translations in progress. Translations include all major Western languages, East European languages, Asian languages and also remote languages, such as Xhosa (Africa). The validated symptom specific modules have been translated in up to 35 languages, depending on the module. The following major translation problems were encountered: lack of expressions for specific symptoms in various languages, the quest for formal vs. informal versions, recent spelling reforms in two European countries, different weights of social issues between Western and Eastern cultures. The EORTC measurement system is now registered for use in 8400 clinical studies in 80 countries worldwide. **Conclusions:** The abstract has identified 'translation problems' in the EORTC QOL questionnaires. Whether problems are entirely related to procedures or whether they are related to subtle cross cultural differences in concepts of health, illness and QOL, needs to be explored in further work.

# 1121/LINGUISTIC VALIDATION OF THE ASTHMA QUALITY OF LIFE QUESTIONNAIRE (AQLQ) AND THE ASTHMA CONTROL QUESTIONNAIRE (ACQ) IN 10 ASIAN LANGUAGES

Isabelle Mear, Linguistic Validation Department, Mapi Research Institute, Lyon, France; Elizabeth Juniper, QoL Technologies Ltd, Bosham, West Sussex, UK; Ann-Christin Mörk, Clinical Science, AstraZeneca R&D Lund, Lund, Sweden

**Aims:** Asthma is a disease which has a strong impact on the health-related quality of life of patients. The AQLQ measures this impact. The ACQ measures the adequacy of clinical asthma control. Both questionnaires were developed in Canadian English and have undergone linguistic validation into 79 languages, more than 10 of which are Asian languages. The aim of the process was to ensure conceptual equivalence of all versions and the maintenance of the measurement properties in order to facilitate the international comparison and pooling of data. **Methods:** The linguistic validation involved the following steps: recruitment of a QOL specialist in each country, discussion of the concepts of the instrument with the developer, 2 forward translations and reconciliation, 2 backward translations, evaluation of the interval properties of the 7-point response options and pre-testing in adults with asthma in collaboration with a local asthma specialist. **Results:** Translation issues included finding conceptual equivalents for typical English expressions such as 'to feel frustrated' and 'wheezing'. The activities in which patients are bothered had to be adapted for each country. Though the conceptual content of most items were found to be universal, some adaptation of the wording was needed in most countries in order to reflect the common way people express their experiences. **Conclusions:** Rigorous linguistic validation was essential to produce cross culturally valid language versions of the AQLQ and ACQ that are also well suited for Asia. The AQLQ and ACQ may now be used with confidence in these countries to evaluate the adequacy of asthma treatment and its impact on patients daily lives.

# 1730/HONG KONG CHINESE VERSION OF PARENT PROXY HEALTH-RELATED QUALITY OF LIFE MEASURE FOR CHILDREN WITH EPILEPSY – TRANSLATION, CROSS-CULTURAL ADAPTATION AND VALIDATION OF THE MEASURE

Winnie KL Yam, FHKCPaed, Paediatrics; Alice Ho Miu Ling Nether-sole Hospital; Tai Po, Hong Kong; Susanna MK Chow, Rehabilitation Sciences, Hong Kong Polytechnic University, Hunghom, Hong Kong SAR, China; Gabriel M. Ronen, Paediatrics, McMaster University, Toronto, Canada

**Aims:** To report the translation and validation process of the Parent Proxy Response Scale of Quality of Life measure for Children with Epilepsy (PPRS-QOLCE) for Hong Kong Chinese children. **Methods:** Phase 1: Forward and backward translations, expert panel review and a series of pilot testing, cognitive interviewing and pre-testing with parents produced a Chinese translation. Phase 2: Internal consistency and construct validity (hypothesis testing) were examined on 35 parents with children having epilepsy and aged 8- to 18-years-old. Test-retest reliability was evaluated on 28 parents. **Results:** The translation was judged to have good content validity by experts and was acceptable to parents. Internal consistency was good (Cronbach  $\alpha$  0.71 to 0.94). Test-retest reliability, examined by Intraclass correlation coefficient, ranged between 0.49 and 0.90. In terms of the hypotheses, children who had any epilepsy-related hospital stay had lower scores in the subscale of 'Future worries' and children with more close friends had higher scores in the 'Interpersonal/social' subscale. No difference was found in any of the subscales for children having different number of hospital visits, seizure frequencies, number of anticonvulsants, number of hours engaged in extracurricular activities or whether they received special education. **Conclusions:** Our data in this preliminary study showed acceptable reliability and content validity in the Chinese version of Parent Proxy Response Scale of the Quality of Life measure for Children with Epilepsy. Further study with larger sample size should be performed to confirm the construct validity of the instrument.

# 1124/DEVELOPMENT AND MULTILINGUAL VALIDATION OF THE FACT-LYMPHOMA INSTRUMENT

Sonya Eremenco & Kimberly Webster, CORE, Evanston Northwestern Healthcare, Evanston, IL; Lucie Kutikova & Lee Bowman, Global Health Outcomes Research, Eli Lilly and Company, Indianapolis, IN; David Cella, CORE, Evanston Northwestern Healthcare, Evanston, IL

**Aims:** To develop a lymphoma-specific subscale for the Functional Assessment of Cancer Therapy (FACT) and to assess the linguistic validity and reliability of the Dutch, French and German translations. **Methods:** The English version of the lymphoma-specific subscale was developed through item generation from literature review, semi-structured interviews with 16 clinical experts, and adaptation of an existing leukemia-specific subscale. The FACT-Lym was then translated using the standard FACT methodology: 2 forward translations, a reconciled version of the 2 forwards, back-translation of the reconciled version to English, and 3 independent reviews by bilingual experts. The study sample included 44 patients from 3 countries: 15 in Belgium to test the Dutch; 14 in France; 15 in Germany. Lymphoma patients completed the respective translated FACT-Lym and then participated in interviews to give their opinion on any problems with the translation or content. Statistical analyses (descriptive statistics and reliability analyses) were performed on the quantitative data, and the participant comments were analyzed qualitatively. **Results:** The lymphoma subscale had acceptable reliability with the Dutch ( $\alpha = 0.76$ ), French (0.74), and German (0.88) translations. There were no negative patient comments about the lymphoma-specific items. Four item-total score correlations were  $< 0.2$ : bother about lumps or swelling, discomfort/pain in stomach area, loss of appetite, and anxiety about treatment decision-making. The treatment decision-making item may be less relevant in other cultures, while the other 3 items were symptoms that need further analysis. Wording changes were made to the German and Dutch translations resulting from this review. **Conclusions:** The FACT-Lym has shown good reliability and linguistic validity with three language versions. These results contributed to a better understanding of how quality of life issues are perceived by lymphoma patients in different countries and supported cross-cultural comparability of instrument scores. Validity testing within and outside of international trials is underway.

# 1353/USING THE SF-36 AMONG FIRST GENERATION ETHNIC MINORITY GROUP CANCER PATIENTS IN THE NETHERLANDS: A QUANTITATIVE AND QUALITATIVE APPROACH

Martin Muller, Psychosocial Research and Epidemiology; Rianne Hoopman & Neil K. Aaronson, Psychosocial Research & Epidemiology, The Netherlands Cancer Institute, Amsterdam, The Netherlands

**Aims:** As the large communities of Turkish and Moroccan labor immigrants in the Netherlands age, they are faced with an increasing incidence of cancer. Many of the first generation Turks and Moroccans lack proficiency in Dutch and are illiterate in their own language. This paper reports on a quantitative and qualitative analysis of the SF-36 when used among these populations of patients. **Methods:** The SF36 was translated into Turkish (written and oral versions) and Moroccan (Moroccan Arabic and Rifberber, oral versions only), and its psychometric properties were examined. Qualitative data, including patients' comments on each of the SF-36 items, were collected by means of a debriefing interview. **Results:** Ninety Turkish and 79 Moroccan cancer patients were recruited into the study. The mean age was 50 years, approximately 50% was female, and the most common primary diagnoses were breast (25%) and head and neck (20%) cancer. Mean time since diagnose was 3.5 years. Forty-five percent of the Moroccan and 17% of the Turkish patients were illiterate. The internal consistency reliability and known groups validity of these versions of the SF-36 were adequate and similar to those observed for the Dutch language version. Approximately 33% of the Turkish patients and 43% of the Moroccan patients had 1 or more missing items. The mean missing percentage for a single item was 4.5 (range 2–10%) for the Turkish and 12% (range 9–17%) for the Moroccan patients. Older age and lower education were associated significantly with higher rates of missing data. The most common reason for missing item responses was difficulty in understanding the question or the response categories. Examples from the debriefing interviews will be used to illustrate the problems experienced in completing the SF-36. **Conclusions:** Although the Turkish and Moroccan versions of the SF-36 exhibit satisfactory psychometric properties, the questionnaire remains difficult to administer to patients who are poorly educated and often illiterate.

# 1714/THE IMPACT OF SEVERE ACUTE RESPIRATORY SYNDROME (SARS) ON QUALITY OF LIFE MEASURED BY SF-36 AND THE CHANGES AFTER REHABILITATION PROGRAM

Siu Pui Lam, FHKCP FHKAM & Ho Pui So, FHKCP, FHKAM, Rehabilitation & Extended Care, Wong Tai Sin Hospital, Hong Kong, PRC

**Aims:** Severe Acute Respiratory Syndrome (SARS) affected SARS survivor's daily life in different aspects such as physical, functional, psychosocial well being, financial status and family harmony. We aimed to (1) evaluate the quality of life measures in SARS recovered people and (2) examine the changes of quality of life measures with time and after rehabilitation. **Methods:** Quality of life assessment was performed using the Chinese version of the SF-36 HRQOL questionnaire (SF-36) on SARS rehabilitated people. A pre-program assessment was done in June 2003, first and third month post program assessment was performed in July and September 2003 respectively. **Results:** 116 people recovered from SARS joined a pulmonary rehabilitation program and 70 subjects attended both the first and third month follow up sessions. The SF-36 measurement in 66 subjects was valid for analysis. The group consisted of 26 male (39.4%) and 40 female (60.6%) with a mean age of 43.8. The baseline scores of SF-36 domains were significantly impaired as compared with Hong Kong population norms, particularly in physical functioning (PF mean: 64.3 vs. 91.8), role physical (RP mean: 19.3 vs. 82.4), social functioning (SF mean: 53.8 vs. 78.9) and role emotion (RE mean: 37.9 vs. 71.7). The SF-36 domain measurement improved significantly in the follow up assessment after SARS rehabilitation. Both the physical component sub-scores (mean: 62.80 vs. 47.8,  $p < 0.001$ ) and mental component sub-scores (62.5 vs. 50.5,  $p < 0.001$ ) improved significantly at the third month follow up as compared with the baseline. **Conclusions:** (1) SARS had a major impact on the quality of life of SARS victims as shown by the SF-36 (HK) measurement. (2) There was a significant improvement in most of the SF-36 domains at the follow up assessments. (3) SF-36 improved with time and after rehabilitation.

# 1081/QUALITY OF LIFE OF NEPALESE PATIENTS WITH RESPIRATORY DISEASES

Pralhad C. Bhattarai, Netherlands Institute for Health Sciences; Samir KC, BMG, Health Policy and Management, Erasmus University, Rotterdam, The Netherlands; Louis Niessen, Health Policy and Management, BMG, Erasmus University, Rotterdam, The Netherlands

**Aims:** Besides morbidity and mortality, an important outcome in clinical and intervention studies is the quality of life of individuals. However, not a single study on quality of life had been done in Nepal using generic quality of life instruments. Our main objectives are to determine the quality of life in Nepalese patients with respiratory diseases and to compare WHOQoL and EuroQoL to find out their construct validity in Nepalese context. **Methods:** The English version of two generic quality of life instruments (WHOQoL and EuroQoL) were translated into Nepalese and Bhojpuri (local language) and back translated into English as per their guideline. 2243 adult patients were eligible, out of them 1917 patients responded WHOQoL whereas 2164 patients responded EuroQoL (age 15 years or more) were interviewed in 42 primary health care facilities in a low land district (Nawalparasi) in Nepal within the period of 10 months. The data was analyzed using SPSS 11.1. Descriptive characteristics were seen, relationship of quality of life with disease severity was determined using one-way ANOVA and Spearman's correlation was calculated to see the construct validity between two instruments. **Results:** The mean WHOQoL score was  $54.34 \pm 10.46$  whereas average EuroQoL score was  $0.55 \pm 0.35$ . Worse Quality of Life was found in higher age group compare with lower ( $p < 0.001$ ). Similarly both WHOQoL and EuroQoL score were higher in unmarried followed by married and widowed ( $p < 0.001$ ). Difficulty breathing patients had worse quality of life than cough or/and fever patients ( $p < 0.001$ ). The EuroQoL score was substantially correlated with mean WHOQoL score ( $r = 0.493$ ) and physical dimension of WHOQoL ( $r = 0.536$ ) but moderately correlated with psychological dimension ( $r = 0.399$ ) and it was not significantly correlated with social (0.14) and environmental (0.283) dimension. **Conclusions:** Overall lower quality of life score was found. The correlation values give their similar construct and its appropriateness in use in Nepalese context for the patients with respiratory diseases.

# 1432/DOES PHYSICAL FUNCTIONING PREDICT 6-MONTH SURVIVAL AMONG HOSPITALIZED INPATIENTS WITH DIABETES

Chia-Ing Li, Medical Research; Cheng-Chieh Lin, Family Medicine, China Medical University Hospital, Taichung, Taiwan, ROC; Tsai-Chung Li, Chinese Medicine, China Medical University, Taichung, Taiwan, ROC

**Aims:** The objective of the current study is to examine whether the physical functioning at admission to hospital predict 6-month survival among inpatients hospitalized for diabetes. **Methods:** The study sample consisted of 110 consecutive diabetes inpatients admitted in China Medical College Hospital from July, 1998 to August, 1999. All diabetes inpatients were interviewed by a trained interviewer to collect variables such as sociodemographic factors, Barthel Index, Karnosky Scale, ADL, IADL, co-morbidity, diabetic control, complication, having catheter, naso-gastric tube, or Tracheotomy use, etc. During 6-month period, all diabetes inpatients were followed up to confirm his/her mortality status. Cox's proportional hazard model was used for statistical analysis. **Results:** Mean age of the study subjects is 66.8 years old and 62.7% of them are male. The overall survival rate in this sample is 80.0%. After considering the effects of age, gender, duration of diabetes, co-morbidity, and complications, physical functioning, measured by Karnosky Scale, significantly predicts survival probability. As the Karnosky Scale increases by one point (worse physical functioning), the probability of survival for diabetes inpatients decreases by 28%. **Conclusions:** Inpatients for diabetes with worse physical functioning had a lower probability of survival over 6-month period compared with those with better physical functioning. The unique contribution of physical functioning to survival is independent of more objective health measures such as complications.



#### # 1496/QUALITY OF LIFE IN PATIENTS WITH HEPATOCELLULAR CARCINOMA

Lukas Jyuhn-Hsiarn Lee, Neurology; Chien-Hung Chen, Internal medicine; Grace Yao, Psychology; Chih-Wen Chung, Center for Health Risk Assessment and Policy; Jin-Chuan Sheu, Internal medicine; Po-Huang Lee, Surgery; Jung-Der Wang, Internal medicine, National Taiwan University, Taipei, Taiwan, ROC

**Aims:** Hepatocellular carcinoma (HCC) may have impact both on survival and quality of life (QOL). The aim of this study was to evaluate QOL in patients with HCCs and to correlate the QOL measures with clinical and socioeconomic factors. **Methods:** A total of 161 patients with HCC who were consecutively enrolled at a university hospital were assessed with Taiwan versions of WHO-QOL-BREF, EORTC QLQ-C30 and utility measures. The WHOQOL-BREF domain scores for the HCC patients were compared to healthy normative Taiwan population, using general linear models controlling for gender and age. Multiple logistic regressions were applied to explore association between QOL and clinical/sociodemographic variables. **Results:** Compared with the healthy controls, the HCC patients had reduced QOL in physical and psychological domain, but increased in environment domain. After controlling gender, age, education, and employment, duration of HCC more than 1 year, surgery, and early tumor staging defined by the Cancer of the Liver Italian Program (CLIP) score < 2 were positively associated with perceived general health and QOL. Male gender, age below 50, and education of high school or more were correlated with a better QOL score. Advanced tumor staging was associated with financial difficulties and poor visual analogue scale utility. General linear models revealed transcatheter arterial chemoembolization (TACE) had poor QOL in terms of standard gamble utility, appetite loss, constipation, after adjusting for gender and age. **Conclusions:** Disease diagnosed over 1 year, surgery, and early tumor staging were associated with better QOL in HCC patients. QOL is an important outcome indicator that may help physicians decide more appropriate management for HCC.

#### # 1256/A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL ON EVALUATION OF THE FUNCTIONAL TRAINING PROGRAM FOR THE ELDERLY AFTER HIP SURGERY

Antonia K. Soo, Occupational Therapy, Tai Po Hospital, Tai Po, Hong Kong; Cecilia W. Li-Tsang, Department of Rehabilitation Sciences, The Hong Kong Polytechnic University, Hung Hom, China

**Aims:** Hip fracture is a leading cause of disability and mortality among the elderly. Previous studies found that effectiveness of geriatric orthopaedic rehabilitation was inconclusive. The aim of this study was to investigate the effect of the Functional Training Program (FTP) for elderly after hip surgery. **Methods:** A prospective, Randomized Controlled Trial (RCT) was conducted on a group of elderly patients with hip fractures and double-blinded. FTP was experimental group and conventional occupational therapy (OT) training was control group. FTP aimed at both functional and fall related self-efficacy enhancement, which consisted a comprehensive training on activities of daily living (ADL), ADL task modifications and behaviour adjustment. Mini-Mental State Examination (MMSE), Functional Independence Measure (FIM) and Fall Efficacy Scale (FES) were used as outcome measurement. **Results:** 60 subjects aged 65 or above, with hip surgery and intact cognitive function were recruited in this study. Mean age was 78.77. Subjects in both treatment groups shared similar baseline demographics and admission MMSE, FIM and FES scores ( $p > 0.05$ ). After intervention, the FTP group had significant higher total FIM score ( $112.71 \pm 3.87$  vs.  $105 \pm 9.55$ ), total FES score ( $81.10 \pm 10.08$  vs.  $46.27 \pm 19.97$ ), FIM change efficiency (1.00 vs. 0.60) and shorter LOS ( $21.53$  vs.  $27.87$ ) than that in conventional OT training group ( $p < 0.01$ ). High correlation was noted between total FIM score and total FES score ( $r = 0.80$ ,  $p < 0.01$ ). Upon discharge, 90% of subjects returned home. Upon third month follow-up, 90% of subjects resumed pre-morbid ADL function and 18.3% of subjects resumed pre-morbid ambulatory level. **Conclusions:** FTP was found to be effective in improving functional status and fall related self-efficacy for elderly after hip surgery. Shorter LOS and better outcome was achieved in this study. Treatment carry-over effect sustained in 3 months after discharge. Comprehensive ADL training and fall related self-efficacy

should be considered as a target for intervention of geriatric hip fractures.

#### # 1535/CROSS-CULTURAL ANALYSIS OF THE EORTC QLQ-C30

Neil W. Scott & Peter M. Fayers, Public Health, University of Aberdeen, Aberdeen, UK; Andrew Bottomley, Quality of Life Unit, EORTC Data Center, Brussels, Belgium; Neil Aaronson, Psychosocial Research and Epidemiology, Netherlands Cancer Institute, Amsterdam, The Netherlands; Andrea Bezjak, Radiation Oncology, University of Toronto, Toronto, ON, Canada; Alexander de Graeff, Internal Medicine, University Medical Centre, Utrecht, The Netherlands; Mogens Groenvold & Morten A. Petersen, Palliative Medicine, Bispebjerg Hospital, Copenhagen, Denmark; Mirjam Sprangers, Medical Psychology, University of Amsterdam, Amsterdam, The Netherlands

**Aims:** The European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 is a widely used HRQL measure that has been translated into 47 languages. This project evaluates the impact of cultural and linguistic factors on reports of HRQL, and explores the variation across countries, languages and cultures. **Methods:** The EORTC Quality of Life Group has assembled a database of over 23,000 patients from 75 studies, representing 41 countries around the world. Differential item functioning (DIF) was explored for each item and subscale of the QLQ-C30, using contingency tables, logistic and ordinal logistic regression, and item response theory (IRT). The responses to each item were compared across translations, and for cultural/geographical groupings. Both uniform and non-uniform DIF were investigated. **Results:** Statistically significant DIF was detected in a number of items for several translations and cultural groupings. The practical impact of this observed DIF is discussed. It is not always easy to differentiate whether DIF was caused by linguistic or by cultural factors, or whether this was pseudo-DIF caused by bias in other items in that scale. **Conclusions:** Some items of the QLQ-C30 behave differently in other countries, and this may be partly due to translation differences and partly due to cultural differences. This represents potential bias that has implications for comparisons across countries, and for multicentre clinical trials carrying out HRQL assessment using patients from more than one country.

#### # 1170/BUILDING CORE HRQL MEASURES: POSITIVE AND NEGATIVE PSYCHOLOGICAL IMPACT OF CANCER

Jin-shei Lai, Sarah Rosenbloom, David Cella & Lynne Wagner, CORE, ENH & NWU, Evanston, IL

**Aims:** The mental component of HRQL in cancer can be divided into general emotional distress (ED), cognitive function (CF), and illness-related psychological effects, or illness impact (II). Further understanding of the latter complex area would be aided by the use of a comprehensive, reliable and valid measurement tool that has clinical utility. The purpose of this study is to describe the development and properties of such an II assessment tool and its relationship to ED and CF. **Methods:** As part of our item banking program, 205 cancer patients (93.2% white, 59.2% female, mean age  $59.6 \pm 13.0$  years) completed 46 II items (23 negative; 23 positive), 46 ED items, and 31 CF items. Data were analyzed using factor analysis (FA) to determine dimensionality of items, and item response theory (IRT) analysis to examine item parameters and patient level on the same continuum. **Results:** FA indicated positive and negative impact items as two uncorrelated factors ( $r = 0.07$ ,  $p = 0.31$ ). We therefore analyzed factors separately using IRT analysis. Eight items (2 pos; 6 neg) were removed due to lack of fit with the underlying trait, defined as mean square > 1.4, item-total correlation < 0.3, or factor loading < 0.3 (2-tailed test,  $p < 0.01$ ). As a result, 21 and 17 items were retained in II-positive (II-pos) and II-negative (II-neg) banks, respectively. Both II-pos and II-neg had acceptable internal consistency ( $\alpha = 0.95$  and  $0.93$ , respectively), and discriminated patients by functional performance status ( $F(3,201) = 2.74$ ,  $p < 0.05$  for II-pos;  $F(3,201) = 10.03$ ,  $p < 0.001$  for II-neg). Significant correlations ( $p < 0.01$ ) between II-neg and ED ( $r = 0.77$ ) and CF ( $r = 0.47$ ), and between II-pos and ED ( $r = 0.25$ ) were found. **Conclusions:** Separate item banks were developed to measure positive and negative illness impact. Both demonstrate good psychometric properties and discriminated patients based on performance status. Plans for future refinement and potential clinical utilization of the resulting item banks will be discussed

## # 1629/DIFFERENTIAL ITEM FUNCTIONING STATUS ITEMS

Colleen A. McHorney, Regenstrief Institute, Indianapolis, IN; Patrick Monahan, Medicine, Indiana University, Indianapolis, IN; Timothy Stump & Anthony Perkins, Regenstrief Institute, Indianapolis, IN

**Aims:** The purpose of this presentation is to report on differential item functioning (DIF) in the functional status items included in the Supplement on Aging (SOA,  $n = 16,148$ ) and Longitudinal Supplement on Aging (LSOA,  $n = 7527$ ) across age, gender, race, ethnic, education, and poverty subgroups. **Methods:** We used three methods to assess DIF: the Mantel-Haenszel procedure, logistic regression, and IRT-based DIF detection. Groups used for DIF analyses consisted of: females vs. males, aged 65–74, 75–84, or 85+ vs. those aged 55–64, African-Americans vs. Whites vs. Hispanics, those with 0–8, 9–11, or 12 years of education vs. those with 13+ years of education, and in poverty or not. For all three DIF methods, we used the typical two-stage purification approach. In addition to statistical significance, we also characterized the magnitude of DIF by an effect size measures. **Results:** Definite gender DIF was identified in two items and marginal DIF in an additional six items. Two items displayed definite DIF in the 55–64 vs. 75–84 comparison, and 13 items had definite DIF in the 55–64 vs. 85+ comparisons. Two items showed definite DIF when comparing African-Americans vs. Whites. Two items had definite DIF across the education groups. After creating total test scores with and without identified DIF items, comparisons between groups showed no substantial change. **Conclusions:** These results demonstrate that functional status items are highly susceptible to DIF. Functional status tools that lack measurement equivalence across diverse subpopulations can result in flawed research and erroneous policy and clinical decisions.

## # 1313/RASCH ANALYSIS OF COMBINING PHILADELPHIA GERIATRIC CENTER MORALE SCALE AND GERIATRIC DEPRESSION SCALE TO ASSESS SUBJECTIVE QUALITY OF LIFE OF ELDERS IN HONG KONG

Eric Wong, Epidemiology and Biostatistics; Jean Woo & Susanne Ho, Community and Family Medicine; Elsie Hui, Medicine and Therapeutics, Chinese University of Hong Kong, Shatin, Hong Kong

**Aims:** To explore the factorial structure and psychometric properties of the combined item pool of the Philadelphia Geriatric Morale Scale (PGMS) and the Geriatric Depression Scale (GDS), two major scales for assessing subjective well-being among the elderly in Hong Kong. **Methods:** The study subjects consist of two cohorts: 759 subjects aged 70 years and over living in the community recruited as part of a territory wide health survey, interviewed in 1993–1994; and 388 subjects living in long term care institutions in 1995–1996. Subjects who were cognitively impaired (Abbreviated Mental Test Score < 7) or who could not answer questions for other reasons were excluded. The 15 item PGMS and 15 item GDS were administered. The Rasch dichotomous model, a one-parameter item response theory model, was used to fit the data. Data were analyzed using RUMM2020 and WINSTEPS (version 3.04). **Results:** Factor analyses using tetrachoric correlations demonstrated that the combined 30 dichotomous items of the PGMS and GDS reflected two dimensions: 'unstrained affect' and 'reconciled aging'. Rasch item calibrations identified there were 4 and 5 'misfitting' and redundant items respectively on the measurement continuum. The values of item and person separation indexes were high. In addition, more items measuring high levels of well-being were recommended. Finally, differential item functioning showed items in both constructs behaving differently for gender, age, and institutionalized and non-institutionalized older Chinese. **Conclusions:** Combining the PGMS and GDS items together would provide enhanced range and sensitivity of measurement, however the combined scale should be interpreted for institutionalized and non-institutionalized separately and also controlled for gender and age.

## # 1343/DATABASES AS INSTRUMENT BANKS: WHQ, PGWBI AND MLHF QUESTIONNAIRES – THE INTERNATIONAL HEALTH-RELATED QUALITY OF LIFE OUTCOMES DATABASE (IQOD) PROGRAMME

Leticia Lobo-Luppi & Marie-Pierre Emery, Mapi Research Institute, Lyon, France; Christine Fayol-Paget, MAPI SA, Lyon, France

**Aims:** In order to standardise the administration and scoring of PRO questionnaires, study cross cultural equivalence, better understand psychometric properties, and describe the reference values/subgroups scores, analysis of 3 questionnaires (item responses) and clinical and socio-demographic variables were performed. Instrument banks were created for: the Women's Health Questionnaire (WHQ), the Psychological General Well-Being Index (PGWBI), and the Minnesota Living with Heart Failure (MLHF) questionnaire. **Methods:** Data from multinational studies were collected, anonymised, harmonised and merged into 3 single databases. Statistical analysis/psychometric methods included: Principal Components Analysis, Multitrait Analysis, Item Response Theory methods, Reliability coefficient. For PGWBI database analysis also included Confirmatory Analyses methods. Scores comparison between subgroups used parametric and non-parametric methods. **Results:** Results relate to the WHQ ( $n = 9525$ , 11 languages), the PGWBI ( $n = 8536$ , 16 languages) and the MLHF ( $n = 3197$ , 13 languages). Cross cultural equivalence and reference values per country, subgroup or disease severity were described. The WHQ is sensitive to symptom severity: women with severe hot flushes, palpitation, irritation or insomnia have worse health status. Scoring was reviewed with the author. A shorter WHQ version was developed. The PGWBI database analysis showed results may vary according to psychometric methods used: classical methods confirm good reliability and validity, and similarity across languages whereas modern psychometrics applied to the subscales of original version suggest rewording of response choices. MLHF results showed similar psychometric properties across the studied countries. MLHFQ achieved high standards of reliability, which also allows its application at individual level for all countries studied. **Conclusions:** Comprehensive instruction manuals were developed for WHQ, PGWBI and MLHF; queries can be performed with databases created. Construction of these banks raised several points, from merging data with different inclusion criteria to usefulness and applicability of item banks.

## # 1319/HEALTH RELATED QUALITY OF LIFE: A CRITIQUE

Robert A. Cummins, Psychology, Deakin University, Melbourne, Victoria, Australia

**Aims:** The contemporary literature on quality of life (QOL) is burdened by discipline-specific notions of how to represent the construct. In particular, a schism has developed between medicine and the social sciences. Within medicine the construct is operationalised as Health Related Quality of Life. Here, excellence corresponds to the absence of patient-reported symptoms of pathology. Within the social sciences the construct is represented as Subjective QOL or Subjective Well-being. Here, excellence corresponds to a highly positive state of mind and satisfaction with life in general. This paper will consider these opposing views. **Methods:** The following issues will be discussed, all of which constitute problems for HRQOL scales: (1) Objective and subjective measures of QOL are normally independent and do not scale together. (2) Scales that reflect a preoccupation with pathology do not reflect the common understanding or the spirit of 'life quality'. (3) When QOL is conceptualised as happiness or global life satisfaction, the predictive relevance of various life domains can be tested through multiple regression. In this situation, neither medical health nor perceived health is generally considered to be a particularly relevant life area. (4) Scales that mix together symptoms of pathology are likely to be less valid than the individual scale items. (5) Scales that mix causal and indicator variables cannot be interpreted. **Results:** It will be argued that all of the above problems exist in HRQOL scales. **Conclusions:** It will be concluded that there are such serious logical and psychometric problems with HRQOL scales, that this form of measurement should be abandoned. An alternative approach will be suggested that includes the separate measurement of medical symptoms, subjective well-being, and psychological ill-being determined separately as depression, anxiety, and stress.

# 1709/CONFLICTS OF INTERESTS IN TAKING INTO ACCOUNT THE PATIENTS' POINT OF VIEW IN QUALITY OF LIFE MEASUREMENTS

Alain Leplege, Philosophy, University of Amiens, Amiens, France

*Aims:* This paper discusses the potential for conflicts of interests that arise from the complexities inherent to the project of taking into account the patients' point of view in quality of life measurements. *Methods:* The purpose of quality of life measurements instrument is undoubtedly to help physicians take patients' point of view into account. However, it should be noted that with quality of life measurements, we always find ourselves in a situation with a double point of view: the physician observes the patient, the patient is seen through the physician's point of view but this object of the physician's observation is also, from his side, a subject with his own point of view. When it comes to quality of life measurements we are, therefore, in a paradoxical situation. The paradox resides in a fundamental methodological difficulty: quality of life measurements whose objective is to reflect patients' point of view can only be developed and implemented by experts (physicians, methodologists etc.) who have their own point of view which is well known to be significantly different from patients. *Results:* Because the trust being put in the impartiality and the legitimacy of quality of life measurements depends almost exclusively on the trust being put in the judgment and integrity of the experts who developed and implement them, this goes beyond a mere technical point. This question also regards investigators' deontology and justifies an analysis in terms of conflicts of interest. *Conclusions:* The idea supported here is that a reflection on conflicts of interest should be initiated, in the clinical research field in general, and more particularly in the field of quality of life evaluations. I suggest that some institutional safeguards, similar to those implemented in order to minimize unethical consequences in clinical trials, should be considered in order to enable the development of trustworthy quality of life measurement.

# 1407/HOW HQOL MEASURES CAN BE MADE VALID: RECOGNIZING QUALITY OF LIFE IS NOT SIMPLY SUMMED EXPERIENCE

Rod E. O'Connor, Rod O'Connor & Associates P/L, Sydney, NSW, Australia

*Aims:* Reveal the increasing and compelling evidence that peoples QoL assessments are unlikely to ever be a simple summation of experience, and that HQoL measures need to be constructed to acknowledge this if they are to provide valid estimates. *Methods:* Investigates the extensive and growing body of literature spread across several research areas revealing that diverse psychological processes mediating peoples reports regarding health states. *Results:* Firstly, the evidence suggests that: – rules for estimating the HQoL of complex states are unlikely to be a simple addition of the parts; – different answers are likely to be obtained depending on whether inquiring regarding an anticipated, current, or recalled health state; – self-reported QoL may suggest a more positive state than the patient is actually experiencing. Secondly, a growing range of issues need research, including: – the factors and conditions determining the rate and extent of adaptation/augmentation whether both satisfaction and affect adapt in the same way (the evidence suggests they may not); – the relationship between affect and appraisal; – the relative value of memories vs. experiences; – whether healthcare workers also experience adaptation; – the degree to which patients ignore unpalatable information to assist their adaptation, and the complex issues relating to deception by health care personnel; – whether adaptation aids recovery, perhaps via producing positive affect; – whether adaptation plays a role in the placebo effect. Finally, current implications for HQoL measurement are: – multiple measures should be used, including objective as well as subjective indicators, carer report as well as patient report, affect as well as cognitive appraisal; – the algorithm used to calculate HQoL should not be based on simple summation, but on selected events such as peak and concluding experiences. *Conclusions:* Tests aiming to provide accurate estimates of patient QoL based on multiple domain measures need to mimic the way people estimate their own HQoL, and that is a form of abstraction quite different from simple summation.

# 1348/BRIDGING CULTURAL RELATIVITY IN QOL ASSESSMENT BY ANAMNESTIC COMPARATIVE SELF ASSESSMENT (ACSA)

Jan L. Bernheim, Human Ecology; Mehrdad Mazaheri & Peter Theuns, Psychology, Vrije Universiteit Brussel, Brussels, Belgium; Matthias Rose, Psychosomatic Medicine, Charité University Hospital, Berlin, Germany

*Aims:* Ideally, sQOL should be commensurable across cultures. The conventional question (CQ) about global sQOL uses a scale between e.g. 'perfect' and 'terrible'. However, e.g. Asians and Westerners use such scales very differently. The alternative ACSA method's singularity is having the respondent rate her sQOL relative to her memories of her best and worst periods in life as the anchors (+5 and -5) of the scale. Typically, respondents attribute +5 to periods of love experiences, births or social achievements, and typical nadirs, rated -5, are bereavements, serious disease or war experiences. Such experiential scale anchors are presumably non-cultural. Thus, the ACSA anchors are solemn, concrete and individual. We hypothesised that ACSA ratings could be more sensitive to internal changes and less sensitive to traits and cultural relativities. *Methods:* 2545 university hospital patients suffering from 10 different psychiatric and somatic diseases answered the ACSA and the CQ in writing. *Results:* The coefficients of variation of the sQOL ratings were 0.72 for ACSA and 0.66 for CQ. In patients with end-stage liver disease, the increase in mean rating after life-saving liver transplantation was 4.1 points on an 11-point scale with ACSA, vs. only 1.7 points with CQ. Contrary to CQ, ACSA was not influenced by sex, age, and marital status. *Conclusions:* Compared to the CQ, the ACSA method differentiates better, is more responsive to objective change and less sensitive to trait-like variables. It should be considered as a complement or an alternative to the conventional global question on sQOL. For inter-cultural comparisons and in longitudinal or intervention studies, ACSA may be more reliable, and may circumvent some confounders. Dedicated inter-cultural studies are needed to ascertain whether ACSA can contribute to making sQOL more commensurable worldwide.

# 1707/BALANCING EQUITY AND COST EFFECTIVENESS: A CROSS-CULTURAL COMPARISON

Ho-mun Chan, Public and Social Administration; Ada Yip, Governance in Asia Research Centre, City University of Hong Kong, Kowloon, Hong Kong, PRC

*Aims:* This paper attempts to examine the public attitude in Hong Kong regarding the moral conflicts between equity and cost-effectiveness in the allocation of healthcare resources. *Methods:* A survey using a random sample (n = 281) was conducted in Hong Kong, based on three earlier studies conducted in the US. Each interviewee was asked to make allocation decisions in three simulated scenarios that had been used by the researchers in the US studies. *Results:* The results show that the principle of cost-effectiveness is not the dominant principle adopted by Hong Kong people in allocation decisions. This finding is also indicated in the US studies. However, an important difference is that the people in Hong Kong show less inclination to be driven by dominant egalitarian considerations in allocation decisions than people in the US. *Conclusions:* Allocation decisions in the Hong Kong studies reflect a mid-way moral position between a purely utilitarian cost-benefit calculation and an absolutist single-minded egalitarian ideal. They suggest results of a balancing act between equity and cost-effectiveness in the moral reasoning of the respondents which might be partly explained in terms of the cultural influence of Confucian values.

# 1394/THE PROGNOSTIC VALUE OF QUALITY OF LIFE (QOL) RATINGS IN CANCER PATIENTS: A COMPREHENSIVE REVIEW  
Carolyn C. Gotay, Cancer Res Center of HI, U of Hawaii, Honolulu, HI

**Aims:** This paper provides a systematic review of studies that examined the relationship between cancer patient-reported QOL & length of survival. **Methods:** All published research reports with analyses of QOL ratings re: cancer patient survival time were reviewed. Date, cancer site, design, & QOL assessment method were unrestricted. A PubMed search of English language papers and abstracts referenced for cancer, (QOL & prognosis) was supplemented by reference lists, hand searches & consultation. Data were abstracted and reviewed independently by two raters. **Results:** 52 papers were found, published 1986–2004. Sample sizes ranged 19–2270 ( $M = 286$ ). Number of papers by site were: lung (12), mixed (11), breast (10), melanoma (4), head and neck (4), colorectal (3), esophageal (2), ovarian (2) & one each in bladder, lymphoma, glioma & myeloma. Most common QOL measures were QLQ-C30 (23), LASA (6) & Symptom Distress Scale (5). Most reports included univariate & multivariate analyses. All but two studies found QOL related to survival & two other papers found that the relationship varied by patient group or analysis. Specific QOL domains predicting survival were inconsistent: e.g., both better & worse appetite, and better & worse psychological functioning predicted survival in different papers. The most consistent predictor was global QOL. QOL often had a stronger relationship to survival than standard clinical predictors. Effect sizes were highly variable. **Conclusions:** The relationship between QOL & survival is remarkably consistent across cancers, QOL measures & research designs. Multiple explanations are possible: patients may perceive factors that cannot be detected by clinical indicators, higher QOL may be linked with health behaviors (e.g., healthy lifestyle, adherence to cancer care), or positive attitudes may directly affect survival by through immune parameters. QOL ratings deserve consideration in determining eligibility & stratification for clinical trials & clinical decision making.

# 1173/THE PROGNOSTIC VALUE OF MEASURING HEALTH-RELATED QUALITY OF LIFE IN HOSPICE PATIENTS  
Thomas E. Elliott & Colleen M. Renier, Research, Duluth Clinic, Duluth, MN

**Aims:** Health-related quality of life (HRQoL) instruments designed for hospice patients are available to measure outcomes of care. Use of these data in prognostication has not been studied. Improving the scientific basis for determining prognosis of patients near the end of life is sorely needed. This study measured the correlation between the Missoula–Vitas Quality of Life Index (MVQOLI) and patient survival. The research question was whether measurement of HRQoL in hospice patients using the MVQOLI provides prognostic information. **Methods:** This was a cross-sectional cohort study consisting of all hospice patients admitted to St Mary's Hospice, Duluth, MN, June 1, 2002–December 31, 2003. Data included subject age, gender, marital status, terminal diagnosis, life span from admission to death, MVQOLI scores, Karnofsky performance scale (KPS), modified activity of daily living scale (ADLS), and descriptive symptom scale (DSS). The total sample was 1047 subjects, but this analysis included only subjects who completed a baseline MVQOLI form ( $N = 220$ ). Spearman correlations were performed to evaluate the relationships between survival time and other variables of interest using 2-tailed tests of significance. **Results:** The study population was 61% male, mean age 74 years (range 19–101), terminal diagnosis 76% cancer, and mean life span 74 days (range 0–561). The MVQOLI global and total scores, symptom, function and transcendence scales were not correlated with life span. The MVQOLI interpersonal and well-being scales were correlated with life span:  $-0.224$  ( $p = 0.002$ ) and  $-0.173$  ( $p = 0.02$ ), respectively. The KPS, ADLS and DSS scores were correlated with life span:  $0.304$  ( $p < 0.001$ ),  $0.256$  ( $p < 0.001$ ), and  $0.225$  ( $p = 0.002$ ), respectively. **Conclusions:** The MVQOLI interpersonal and well-being scales were modestly correlated with life span in hospice patients, but not as strongly as the KPS, ADLS, and DSS scores. The health-related quality of life in hospice patients, as measured by the MVQOLI, has weak prognostic information.

# 1116/ICF CODING OF QUALITY OF LIFE MEASURES: VALUE IN CASE-MIX ADJUSTMENT

Nancy E. Mayo, Lyne Nadeau, Linda Levesque, Lise Poissant & Robyn Tamblin, Medicine, McGill University, Montreal, PQ, Canada; Sydney Miller, Psychology, Concordia University, Montreal, PQ, Canada

**Aims:** The cornerstone of health services research is case-mix adjustment to ensure that groups being compared are equivalent on variables that predict outcome. Adjustment has relied mainly on co-morbidity derived from diagnoses coded on administrative databases. However, medical diagnoses do not capture the full impact of a health problem and there is a recognized need to add information on functional status indicators (FSI). Given existing administrative procedures would have to be modified to accept these new indicators, we thought it prudent to first estimate the extent to which prediction of health outcomes can be improved upon by information on FSIs. **Methods:** The data for this study was generated from a clustered randomized trial to evaluate computerized decision support for drug management in the elderly. A total of 107 primary-care physicians participated and 6465 of their patients (51%) completed a generic health status measure, the SF-12. Information on prescriptions and health services were obtained for the 12 months before and after the intervention commenced. The outcomes were hospitalizations ( $n = 751$ ), emergency room visits plus hospitalizations ( $n = 1718$ ), institutionalizations ( $n = 61$ ) and death ( $n = 133$ ). C statistics were used to compare the predictive accuracy of sociodemographics, various co-morbidity indices, 11 FSI predictor variables derived from the SF-12 and coded (possible for 8) using the ICF. **Results:** Using stepwise logistic regression, FSIs, particularly limitation in stair climbing or doing moderate activities like housework, were found to be strong and independent predictors of all outcomes even after controlling for sociodemographics and co-morbidity. The Mental Health summary from the SF-12 was an independent predictor of institutionalization. **Conclusions:** The study indicates that FSIs provided as robust a prediction of health events as did complex co-morbidity indices. Additionally, the ICF coding system provides a mechanism whereby information on FSIs could be incorporated into administrative databases through the vehicle of an electronic health record that included a health or functional status measure.

# 1402/JOB STRESS AND HYPERTENSION: A CASE-CONTROL STUDY IN HONG KONG

Liying Xu, Centre for Clinical Trials; Brian Tomlinson & Juliana Chan, Medicine and Therapeutics, The Chinese University of Hong Kong, Shatin, Hong Kong, PRC

**Aims:** Hypertension is a common disease in Hong Kong. The prevalence of definite hypertension (160/95mmHg) is 10% in men and 11.1% in women. The prevalence of borderline hypertension (140–159/90–94 mmHg) is 8.3% in men and 6.3 in women (Fu, 2001). The objective of the study is to evaluate the associations between psychosocial factors and hypertension. **Methods:** This study is based on a cross-sectional self-administered questionnaire survey in a sample of 103 hypertension patients and 103 controls in Hong Kong. The information of Effort-reward imbalance, job strain, family strain, social support, perceived stress, traumatic life events, health behaviors, BP, BMI and other clinical parameters were collected. **Results:** After adjusting for potential confounding factors, no significant increases in risk of hypertension was observed for job strain and high ERI ratio however, significant increases in hypertension risk were observed for individuals working in private sector (OR = 4.95, 95% CI: 2.27–10.75) and those who had dependent children (OR = 2.33, 95% CI: 1.03–5.23) and increased BMI (OR = 1.13, 95% CI: 1.02–1.26). An employee with dependent children who is employed in the private sector had 6 times higher risk of hypertension compared to an employee without this combined exposure (OR = 5.91, 95% CI: 2.55–13.6). **Conclusions:** The findings highlight the importance of company culture and its interaction with parenting role regarding to hypertension risk in the context of a Chinese society such as Hong Kong.

# 1594/USING THE MIGRAINE TREATMENT ASSESSMENT QUESTIONNAIRE (MTAQ) TO PREDICT SUCCESS IN THE MIGRAINE THERAPEUTIC INTERCHANGE (TI) PROGRAM

Rita L. Hui & James Chan, Pharmacy Operations, Kaiser Permanente Medical Care Program, Oakland, CA

**Aims:** Kaiser Permanente implemented a program to convert selected patients on oral sumatriptan to oral rizatriptan for migraine treatment. The purpose of this therapeutic interchange (TI) program is to optimize the balance between cost and the quality of care. Patients were asked to complete the Migraine Treatment Assessment Questionnaire (MTAQ) on a voluntarily basis before and 3 months after the conversion. MTAQ is a short migraine management-screening tool with 9 dichotomous items. The objective of this study is to use the baseline MTAQ to predict whether the patient remained on oral rizatriptan 90 days after the TI. **Methods:** Patients in a large HMO who had been using sumatriptan for migraine and without prior exposure to rizatriptan were eligible for the TI program. They were asked to complete a baseline MTAQ. The success rate of TI was measured 90 days after conversion. Logistic regression was used to assess association between the success of TI using patients' responses to MTAQ and demographic variables. **Results:** One thousand three hundreds and seventy four patients have been converted from sumatriptan to rizatriptan as of April 2004. Thirty eight percent (521 patients) of them completed the baseline MTAQ. Among these, 71 patients (14%) failed the TI and switched back to sumatriptan within 90 days. Higher number of affirmative responses to either item 2, 3 or 9 of the MTAQ was found to be associated with lower likelihood of successful TI (OR: 0.57 [95% = 0.40–0.82]). These 3 items were (1) if the patient was able to return to what he/she was doing within 2 hours after taking migraine medicine; (2) if the patient has 3 or more migraines per month; and (3) if the patient missed some school, work, or other activity because of a migraine. Patients age 35–44 were found to be less likely to succeed in the TI (OR: 0.44 [95% = 0.22–0.86]). Other items in the MTAQ were not found to be predictive. **Conclusions:** Patients who had more severe or frequent migraines and were already doing well with their medication were more likely to switch back to their original medication and fail the TI program.

# 1147/PATIENT-REPORTED OUTCOME IN TOTAL HIP REPLACEMENT: A COMPARISON OF FIVE HEALTH STATUS INSTRUMENTS

Henk F. van Stel, Julius Center for Health Sciences; Marieke Ostendorf, Orthopaedics; Erik Buskens, Julius Center for Health Sciences; Wouter J. Dhert, Orthopaedics, UMC Utrecht, Utrecht, The Netherlands

**Aims:** There are several patient-reported outcome measures available to assess health status in total hip replacement (THR). We defined the minimal set of patient-reported outcome measures, aiming at comprehensiveness, minimal patient burden and maximal responsiveness. **Methods:** In 114 patients treated with THR (mean age 68 year), we compared pre- and postoperative characteristics and sensitivity to change of the Oxford Hip Score (OHS), the Western Ontario and McMaster Osteoarthritis Index (WOMAC), the SF-36, the SF-12 (derived from SF-36), and the Euroqol questionnaire (EQ-5D). We computed effect sizes, pre- and postoperative correlations between instruments and correlations between change-scores. **Results:** One year postoperatively, very large effect sizes were found for the disease-specific measures, the physical domains of the SF-12, SF-36 and the EQ-5D index (1.3 – 3.0). Patients in Charnley class A (one hip affected) showed more change in OHS, WOMAC Pain and Function, the physical domains of the SF-36 and the EQ-5DVAS compared to patients in the Charnley B/C group (two hips)(all  $p < 0.05$ ). In the last group, the effect size for the OHS more than doubled the effect sizes of WOMAC Pain and Physical Function. We found high correlations and correlations-of-change between the OHS, WOMAC, physical domains of the SF-12 and SF-36 and EQ-5Dindex. The SF-36 and EQ-5D scores 1 year postoperatively approach general population scores. There was a clear distinction in responsiveness between mental and physical scales of the SF-36, which was reflected in the SF-12. **Conclusions:** We recommend using the OHS and SF-12 in the evaluation of THR. The SF-36 might be used in circumstances when smaller changes in health status are investigated, for instance in the follow-up

of THR. The EQ-5D is useful in situations where utility values are needed.

# 1180/RESPONSIVENESS OF THE CHINESE QUALITY OF LIFE INSTRUMENT (CHQOL) IN PATIENTS WITH CONGESTIVE HEART FAILURE

Li Zhao & Kelvin Chan, School of Chinese Medicine, Hong Kong Baptist University, Hong Kong, PRC; Fengbin Liu, The First Affiliated Hospital, Guangzhou University of Traditional Chinese Medicine, Guangzhou, Guangdong, PRC; Kwok-fai Leung, PDipOT, Occupational Therapy, Queen Elizabeth Hospital, Hong Kong, PRC

**Aims:** To evaluate the responsiveness of the Chinese Quality of Life Instrument (ChQOL) in patients with congestive heart failure. **Methods:** We recruited 32 in-patients with congestive heart failure who had undergone treatment with integrative medicine. Patients were assessed by the three instruments, the ChQOL, Chinese Abbreviated version of World Health Organization Quality of Life Assessment (WHOQOL-BREF) and the Chinese version of Medical Outcome Study Short Form 36-items Health Survey (SF-36), at enrolment and after 4-week treatment. The following responsiveness indices were used: effect size (ES) and standardized response mean (SRM). All patients were classified into those with stable groups and those changed groups after 4-week treatment basing upon both the doctor's global rating of change in heart function tests, and the patient's global rating of change in overall quality of life. **Results:** At baseline and at the end of fourth week, all domains of the ChQOL showed more significant improvement than those of the WHOQOL-BREF and SF-36. The responsiveness was high for physical subscales of the ChQOL and SF-36 (ES: 0.93 – 0.95; SRM: 1.14 – 0.80), moderate for the physical subscale of the WHOQOL-BREF (0.60 and 0.93). The responsiveness was low for psychological subscales of the ChQOL (ES: 0.25; SRM: 0.38) and trivial for the SF-36 and WHOQOL-BREF (ES: 0.05 – 0.15; SRM: 0.07 – 0.18). **Conclusions:** The ChQOL was better in sensitivity and responsiveness for assessing congestive heart failure as a generic measure than the SF-36 and WHOQOL-BREF.

# 1329/SENSITIVITY TO CHANGE OF THE MINNESOTA LIVING WITH HEART FAILURE QUESTIONNAIRE

Olatz Garin, Montse Ferrer & Angels Pont, Statistician; Monserrat Rué, Anna Kotzeva & Jordi Alonso, Health Services Research Unit, Institut Municipal d'Investigació Mèdica (IMIM-IMAS), Barcelona, Spain

**Aims:** The Minnesota Living with Heart Failure Questionnaire (MLHFQ) is the most widely used Quality of Life instrument among patients suffering from this disease. The aim of this study was to assess the sensitivity to change of the MLHFQ total score. **Methods:** A systematic review with meta-analysis of evaluative longitudinal studies for any heart failure treatment was performed. The search was conducted in PubMed, together with citation tracking of identified articles. Studies reporting the change in MLHFQ total score (pre-post mean and SD of change) were eligible. Score ranges from 0 to 105 (maximum disturbance) and negative differences indicate quality of life improvement. To assess responsiveness, patients who were expected to improve (therapeutic intervention) were compared with those expected to remain stable (placebo and control), since deterioration or improvement in these group is hypothesized to be clinically irrelevant. Summary estimates were calculated for each type of treatment received, when at least primary data from 5 studies was obtained. **Results:** In total, 54 studies were identified, including 89 estimates of change. Heterogeneity across studies was significant ( $p < 0.01$ ), therefore the random-effects model was used. The mean summary estimates of change (95% CI) for each of the following groups were: -17.4 (-21.2, -13.5) for pacing device [n = 23]; -16.3 (-24.4, -8.1) for ACEI [n = 10]; -14.3 (-19.5, -9.0) for patient special management [n = 12]; -9.3 (-17.9, -0.7) for exercise [n = 6]; -6.5 (-8.7, -4.3) for beta-blockers [n = 12]; -3.4 (-6.6, -0.3) for placebo [n = 16]; and -4.6 (-9.2, -0.001) for control [n = 10]. **Conclusions:** The MLHFQ total score was able to detect significant improvements in HRQL in patients with active treatment, in contrast to the clinically irrelevant change of the placebo and control groups. The wide variation of improvement observed suggests that the MLHFQ has a good sensitivity to change between different treatments.

#### # 1697/RESPONSIVENESS OF THE OCCUPATIONAL PERFORMANCE APPRAISAL QUESTIONNAIRE

Serena S. Ng, Occupational Therapy, Kowloon Hospital, Hong Kong SAR, PRC; Kwokfai Leung, Occupational Therapy, Queen Elizabeth Hospital, Hong Kong SAR, PRC

**Aims:** The Occupational Performance Appraisal Questionnaire (OPAQ) was developed as a kind of Patient Reported Outcome instrument and used as both a screening tool and a service outcome indicator for in-patient and out-patient occupational therapy services. Psychometric properties of the OPAQ were good and were reported elsewhere. This paper reports the result of a study on responsiveness of the OPAS. **Methods:** A cohort consisting of patients refer for out-patient or day-patient occupational therapy service was recruited. Subjects were asked to complete the OPAQ before and after a series of therapy. Their therapists had rated the global improvement or deterioration of functional performance on a seven point scale (range from +3 to -3). Subjects who were rated by the therapist as improved were included in the analysis of responsiveness. Effect size (ES) and standardized response mean (SRM) for the changes in pre-and post therapy OPAS score were reported. **Results:** 450 subjects were recruited. We have included 333 subjects who were rated to have improved in functions by the therapists for the analysis. The mean increase in OPAS score was 6.61 and the corresponding ES was 0.46 and the SRM was 0.51. The sample was further divided into 3 sub-groups according to the initial OPAS scores, i.e. group 1 had OPAS score below 50, group 2 had score ranged from 50 to 75, and group 3 had score above 75. It was anticipated that those with lower initial OPAS score would have greater room for improvement. For group 1, the mean increase of OPAS score were 22.10 and the corresponding ES and SRM were 2.26 and 1.33 respectively. For group 2, the mean increase of OPAS score was 4.65 and the corresponding ES and SRM were 0.55 and 0.52 respectively. For group 3, the mean change in OPAS score was -7.14 and the corresponding ES and SRM were -1.26 and -0.69 respectively. **Conclusions:** We found that an overall change of about 6.5 OPAQ score correspond to ES and SRM of about 0.45 and 0.5 respectively. These figures can be used in the estimation of sample size in further clinical trial using the OPAS. For subgroups of various initial OPAQ scores other ES and SRM can be used.

#### # 1153/HOW TO ESTIMATE MINIMAL IMPORTANT DIFFERENCE (MID) FROM AN ANCHOR-BASED PROCEDURE BASED ON REGRESSION

Klas Svensson, Clinical Science, AstraZeneca R&D, Lund, Sweden

**Aims:** To describe a procedure where MID for a new PRO (Patient Reported Outcome) instrument is estimated by using data concurrently assessed for a validated PRO instrument as an anchor. **Methods:** Different methodological approaches for determining MID for a PRO instrument have been described in the literature. The suggestion presented here is an indirect procedure that can be used when a validated instrument with an established value for MID has been assessed together with a new instrument with an unknown MID. The procedure is based on a geometric mean regression model, where change in the new instrument is regressed on change in the established instrument. The geometric regression model is closely related to a linear regression model, but contrary to this latter model the geometric mean regression model recognizes the fact that in cases with PRO instrument the independent variable as well as the dependent variable is subject to measurement errors. This will adjust the estimates, as the simple linear regression always will underestimate the MID. **Results:** The model was applied to data from different multinational pharmaceutical clinical studies from the respiratory field, where the well-known instruments AQLQ or SGRQ served as anchor models. MID for SF-36 PCS for asthmatic patients was estimated to range between 2.47 and 3.79 for different studies and settings. For COPD patients, the values varied between 2.19 and 2.52. MID values for two new measures, ASUI and ACQ, were estimated to be around 0.10 and 0.5 respectively, using AQLQ as anchor. Data from different continents showed a consistent pattern to allow pooling of data in a global approach. **Conclusions:** The geometric mean regression model is a valid procedure to estimate the MID for a PRO measure under suitable conditions.

#### # 1315/VALUATIONS OF EQ-5D HEALTH STATES: ARE THE US AND UK DIFFERENT?

Jeffrey A. Johnson & Nan Luo, Public Health Sciences, University of Alberta, Institute of Health Economics, Edmonton, Canada; James W. Shaw & Stephen J. Coons, Pharmacy, University of Arizona, Tucson, AZ

**Aims:** To compare directly elicited valuations for EQ-5D health states between the US and UK general adult populations. **Methods:** We analyzed data from two EQ-5D valuation studies where, using the same time trade-off protocol, values for 42 common health states were elicited from representative samples of the US and UK general adult populations. First, US and UK population mean valuations were estimated and compared for each health state. Second, random-effect models were used to compare the US and UK valuations while adjusting for known predictors of EQ-5D valuations (ie, age, sex, health state descriptors) and to investigate if and how the valuations differ. **Results:** Population mean valuations of the 42 health states ranged from -0.38 to 0.88 for the US and from -0.54 to 0.88 for the UK, with the US mean scores being numerically higher than the UK for 39 health states (mean difference: 0.11; range: -0.01 to 0.25). After adjusting for the main effects of known predictors, the average difference in valuations was 0.10 ( $p < 0.001$ ). The magnitude of the difference in the US and UK valuations was not constant across EQ-5D health states; greater differences in valuations were present in health states characterized by extreme problems. **Conclusions:** Meaningful differences exist in directly elicited TTO valuations of EQ-5D health states between the US and UK general populations. Therefore, EQ-5D index scores generated using valuations from the US general population should be used for studies aiming to reflect health state preferences of the US general public.

#### # 1446/BURDEN OF DISEASE AS AN EQUITY ARGUMENT IN PRIORITY SETTING: AN EMPIRICAL ILLUSTRATION

Ely Stolk, iMTA; Jan Busschbach, Medical Psychology, Erasmus University Medical Center, Rotterdam, The Netherlands

**Aims:** The impact of economic evaluations on reimbursement decisions has been modest: results do not predict funding decisions very well. This is usually explained in terms of fairness (equity): for patients with a high burden of disease one is willing to accept higher costs per QALY than for patients with a lesser burden. The problem however is that these equity concerns often remain implicit, and therefore frustrate evidence based decision-making. To solve this problem, economic evaluations could be extended with an equity adjustment. This would involve the application of equity weights to recalculate the value of QALY gains for different patients. Because these equity weights should represent burden of disease, they should both include mortality as well as quality of life. **Methods:** This paper describes a proportionate equity concept for prioritising health care interventions: proportional shortfall in which quality of life and mortality is incorporated. This equity concept combines elements of two popular but conflicting notions of equity: fair innings and severity of illness. The paper illustrates how implementation affects resource allocation. To that end, we measured proportional shortfall for 10 real life conditions. **Results:** This paper demonstrates that equity in terms of quality of life and mortality can be measured in practice and that the integration of burden of disease (equity) with economic evaluation improves the fit with actual health care policy. **Conclusions:** Implementation of an equity adjustment procedure is applicable and a useful goal in cost-effectiveness driven health policy systems. It illustrates why burden of disease studies are so often undertaken, while in principle they add little to the study of the effects of medical intervention. The reason is that these quality of life studies moderate the outcome: they determine the perspective, and indeed this shift in perspective can be understood from health economic theory.

# 1519/A COMPARISON OF PREFERENCE-BASED MEASURES IN PATIENTS WITH AGE RELATED MACULAR DEGENERATION

C.J. Czoski Murray, J. Brazier & M. Espallargues, Sheffield Health Economics Group; N. Bansback, Operational Research, University of Sheffield, Sheffield, UK

*Aims:* There is increasing interest in evaluating the cost-effectiveness of the emergent treatments for Age Related Macular Degeneration (AMD) and a key component of this is the health state values associated with visual function. This study compares the psychometric performance of four preference-based measures of health in patients with AMD. *Methods:* This was a cross-sectional study of patients with unilateral or bilateral ARMD from a large Teaching Hospital in the UK, attending either the Ophthalmic Clinic or the Low Vision Training Unit. Patients underwent visual tests (near and distant visual acuity VA-, contrast sensitivity CS-) and completed different health status questionnaires including the Visual Function Index VF-14, a rating scale (VAS) and four preference-based measures: HUI3, EQ-5D, SF-6D and time trade-off (TTO). The preference-based measures are compared in terms of means scores, mean scores by visual acuity and contrast sensitivity group and their correlation with visual function. *Results:* Two hundred and nine (209) patients with a mean age of 80 years old were recruited. On average, AMD was diagnosed 3.7 years ago, one fifth suffered from dry-ARMD and results on visual tests were poor (mean decimal VA in Better-seeing eye: 0.2). Mean VF-14 score was 41.5, also indicating substantial loss of visual function. The mean (SD) utilities were 0.34 (0.28) for HUI3, 0.66 (0.14) for SF-6D and 0.72 (0.22) for EQ-5D. In general, there was a linear trend of decreasing utility and health status values as visual function declined except for EQ-5D. This relationship was stronger for VF-14, then CS and finally VA. HUI3 was the utility measure that showed larger and more significant correlations with VF-14 (0.51,  $p < 0.01$ ), CS (0.36,  $p < 0.01$ ) and VA (-0.34,  $p < 0.01$ ). Linear regression showed that CS and VF-14 have a significant impact on health status (HUI3 and TTO) over and above VA. *Conclusions:* AMD causes a substantial impact on patients' health status. Visual impairment is more severe than in other eye diseases. The HUI3 would seem to be better related to visual function than the other preference-based measures.

# 1498/PILOT TEST OF SF-6D VALUATION SURVEY ON CHINESE ADULTS IN HONG KONG

Cindy L. Lam, Family Medicine Unit, The University of Hong Kong, Hong Kong SAR, PRC; John Brazier, School of Health and Related Research, University of Sheffield, Sheffield, UK; Sarah M. McGhee, Department of Community Medicine, The University of Hong Kong, Hong Kong SAR, PRC

*Aims:* This paper reports on the results of a pilot valuation survey undertaken in Hong Kong (HK) to assess the feasibility, acceptability and validity of using the SF-6D to derive a utility-based algorithm for estimating a single index measure from the SF-36 for use in economic evaluation. *Methods:* The SF-6D, a six dimensional health state classification based on a selection of items from the SF-36, was translated into Chinese. A sample of 50 states defined by the SF-6D (out of 18,000) were valued by an age-sex stratified sample of 126 Chinese adults randomly selected from a family practice population in HK. The standard gamble (SG) method was used to elicit values for eight SF-6D health states per respondent. Econometric models were estimated to predict health state values for all states generated by the

SF-6D and compared to the results of a similar survey undertaken in the UK. Econometric models had to deal with the hierarchical nature of the data and skewness. *Results:* All 126 respondents completed the interviews with 3% finding the process very difficult and 21% felt bored. 907 SG valuations (90% out of 1008 observations) were suitable for analysis. Health state values range from 0.75 to 1.0. The basic mean health state model (with the constant forced though unity) achieved an excellent fit with a mean absolute error of 0.054. There was only one inconsistency between model coefficients for the dimension levels. The performance of the HK model compared very favourably with the UK survey and produced similar coefficients for all dimensions except physical functioning that were somewhat larger. *Conclusions:* This pilot study showed that it was feasible, acceptable and valid to apply the SF-6D survey methodology to a Chinese adult sample in Hong Kong.

# 1270/RACIAL/ETHNIC DIFFERENCES IN PREFERENCES FOR THE EQ-5D HEALTH STATES: RESULTS FROM THE US POPULATION VALUATION STUDY

James W. Shaw, Pharmaceutical Sciences, University of Arizona, Tucson, AZ; Jeffrey A. Johnson, Institute of Health Economics, University of Alberta, Edmonton, AB, Canada; Joel R. Levin, Educational Psychology; Stephen Joel Coons, Pharmaceutical Sciences; University of Arizona, Tucson, AZ, USA

*Aims:* The EQ-5D is a brief preference-based health status measure. We examined differences in preferences for the EQ-5D health states between the two largest minority groups in the US, Hispanics and non-Hispanic blacks, and a group consisting of non-Hispanic non-blacks. *Methods:* A multistage probability sample was selected from the adult US population. Using the time trade-off method, each respondent valued a subset of the 243 EQ-5D health states. Regression analysis was used to analyze differences in mean valuations for 13 health states among the racial/ethnic groups. First, we compared unadjusted mean valuations among the three groups. Second, we evaluated differences in mean valuations among the groups after adjusting for other sociodemographic characteristics. Third, we evaluated the impact of race/ethnicity on estimates derived from the US valuation (ie, D1) model. All statistical analyses took into account the clustering and disproportionate selection probabilities inherent in our sampling design. *Results:* Valuations differed among the racial/ethnic groups for 7 of the 13 health states, and these differences persisted after adjusting for other sociodemographic factors. In general, non-Hispanic blacks valued health states more highly than Hispanics or non-Hispanic non-blacks. Non-Hispanic blacks appeared to perceive extreme health problems to be associated with less disutility than did members of the other two groups. There was some evidence to suggest that the observed differences were due to differences in preference for time. *Conclusions:* Within the US, there exist racial/ethnic differences in the perceived desirability of the EQ-5D health states. These differences cannot be readily explained by socioeconomic disparities. Several theories are offered to explain the observed differences. We also demonstrate how application of a population-based set of preference weights might lead to inappropriate resource allocation decisions from the perspective of non-Hispanic blacks.

#### # 1393/THE EFFECT OF METHOD OF ADAPTATION ON THE ACCEPTABILITY OF QUESTIONNAIRES IN CROSS-CULTURAL RESEARCH

Peter Hagell, Nursing, Lund University, Lund, Sweden; Per-Johan Heden, Rheumatology, Central Hospital, Falun, Sweden; Stephen P. McKenna, Galen Research, Manchester, UK

**Aims:** To compare the acceptability of item wording following questionnaire adaptation according to two different protocols, forward-backward translation and the two-panel (bilingual and lay people) adaptation approach. **Methods:** The 30-item Rheumatoid Arthritis Quality of Life instrument (RAQoL) has been adapted for use in Swedish patients by two independent groups. One used the forward-backward translation approach and the other used a translation panel (bilingual Swedes) followed by linguistic review by lay panel (monolingual Swedes). The two RAQoL versions were evaluated by 6 bilingual Swedes with access to all 3 RAQoL versions (the original UK and the two Swedish versions) instructed to indicate their preferred Swedish translation for each item, considering the conceptual meaning rather than literal exactness. In addition, a panel of 6 Swedish lay people evaluated the two Swedish versions item by item regarding appropriateness, ease and ambiguity of language. **Results:** The two adaptation methods produced identical wording for 7 items. Two bilingual evaluators identified 3 non-identical items that they found equivalent. The panel-produced item versions were preferred in 58% of the remaining cases ( $p < 0.05$ ). Across the 23 non-identical item versions, a majority of the bilinguals preferred the forward-backward and panel-produced versions in 6 and 12 cases, respectively, and there was a draw in 5 instances ( $p = 0.1$ ). The lay panel preferred the forward-backward produced versions of 6 items and the panel-produced versions of the remaining 17 non-identical items ( $p < 0.05$ ). **Conclusions:** No advantages were found for the commonly used 'golden standard' forward-backward translation procedure over the two-panel adaptation approach regarding the acceptability of the resulting item versions. The data clearly indicate advantages with the panel approach. The effects of the observed differences on measurement validity and equivalence remain to be determined. Our observations discourage uncritical use of forward-backward translation procedures.

#### # 1337/CROSS-CULTURAL VALIDATION OF FACT-G IN LOW LITERATE PATIENTS

Nutjaree Pratheepawanit, Clinical Pharmacy, Khon Kaen University, Khon Kaen, Thailand; Sanguan Lerkiatbundit, Pharmacy Administration, Prince of Songkhla University, Songkhla, Thailand; Somboon Thienthong & Wimonrat Krisanaprakornkit, Anesthesiology; Chulaporn Limwattananon, Clinical Pharmacy; Ake Pakkhem, Surgery, Khon Kaen University, Khon Kaen, Thailand

**Aims:** The Functional Assessment of Cancer Therapy – General (FACT-G) version 4 has been previously validated in Thai for self-administration method. The psychometric properties of this questionnaire in low-literate patients, however, have not been tested. This study aimed at determining the reliability and validity of FACT-G in such populations. **Methods:** A total of 252 cancer patients were recruited from regional hospitals in the Northeast of Thailand. The majority were male (69%), mean age 55 (range 17–78) with highest education of primary school (87%). Most patients had advanced cancer and 54% had low performance status (ECOG score of 2 or 3). The FACT-G was completed using face-to-face interviews by two

trained interviewers. A validation using confirmatory factor analysis (CFA) was also performed. **Results:** The reliability was acceptable in most domains (Cronbach's  $\alpha$  0.59–0.82). Item-total correlations in the relevant domains were high for most items, except for items GP3 (trouble meeting the needs of family), GS7 (sex life), GE1-GE3 (sad, coping with illness, losing hope) and GF4 (accepting illness). FACT-G can differentiate patients according to ECOG scores and the level of pain ( $p < 0.05$ ). It has also demonstrated sensitivity to change over time. Results from CFA showed that the original four-factor model was not consistent with the data (RMSEA = 0.086, TLI = 0.835 and CFI = 0.851). The fit of a modified six-factor model was slightly better (RMSEA = 0.061, TLI = 0.889 and CFI = 0.903). This involved the addition of two new dimensions: satisfaction with sex life (GS7) and adjustment to illness (GF4 and GE2) and two correlated errors between two pairs of items focusing on jobs (GF1–GF2) and friends (GS1 and GS3). **Conclusions:** The findings suggest acceptable psychometric properties of FACT-G in low literate patients. The different factor structure found in this population should be cross-validated in other independent populations.

#### # 1118/PINQ: PAEDIATRIC INCONTINENCE QUALITY OF LIFE TOOL

Wendy F. Bower, Surgery; Eric M. Wong, Centre for Epidemiology and Biostatistics, Chinese University of Hong Kong; Shatin, Hong Kong; C.K. Yeung, Surgery, Chinese University of Hong Kong, Shatin, New Territories, Hong Kong

**Aims:** Until recently the paradigm 'quality of life' (QoL) has been associated more with children facing life-threatening diseases than those with organic or functional disorders. In children with bladder dysfunction the psychological impact of continence problems has been measured, but to date there has been no tool to allow evaluation of QoL. The ideal tool would be age-appropriate, child-completed, cross-culturally comparable, easy and speedy to complete, and reliably able to measure response to treatment in different diagnostic groups. The aim of this research was to develop a paediatric QoL measurement tool. **Methods:** 120 expert clinicians were asked to propose QoL domains they considered would be relevant to children with continence problems. A 28-item 4-point Likert scale questionnaire covering 6 domains was then developed and administered to 156 children in 10 countries. Factor analysis and Rasch models were used to examine the validity of the scale. The draft tool was reviewed by educationalists for age-appropriate concepts and wording prior to test retest administration with affected children. **Results:** Seven out of 28-items were removed from the originally developed scale due to significant cultural differences that were identified between European and Asian subjects. Factor analysis cast 21 items into 3 domains, which could be classified as 'intrinsic', 'extrinsic' and 'family aspects'. Rasch analysis revealed that one item was ambiguously defined and could be removed and two other items could be re-written in the 'intrinsic' domain. Item reliability was high for all domains ( $r$ : 0.96–0.99), and person reliability was fair for intrinsic and extrinsic domains ( $r$ : 0.64–0.86). The modified tool comprised 22 items presented in random order: 12 intrinsic, 7 extrinsic and 3 related to family. Each of the 3 subscales score separately and are weighted for cultural spread. **Conclusions:** A cross-cultural paediatric incontinence QoL tool has been developed and is a potentially valid scale. It is currently undergoing reliability testing for sensitivity to diagnostic groups and treatment outcome.



# 1380/THE CONTENT OF HEALTH RELATED QUALITY OF LIFE OF CHILDREN AND ADOLESCENTS IN DIFFERENT CULTURES

Symone B. Detmar & Jeanet Bruil, Quality of Life, TNO Prevention and Health, Leiden, The Netherlands; for the KIDSCREEN group, Medical Psychology, Robert Koch Institute, Berlin, Germany

**Aims:** In the European project KIDSCREEN a HRQL questionnaire for healthy children and adolescents between 8 and 18 has been developed. The instrument is a generic questionnaire for use in both healthy and chronically ill populations. To minimize cultural bias, the questionnaire was developed simultaneously in 7 European countries (Germany, United Kingdom, Spain, Austria, Switzerland, France, The Netherlands). To include the opinion of children and adolescents about what constitutes HRQL, a major step in the questionnaire construction included focus groups with children and adolescents in all countries. The aim of the current analysis is to investigate similarities and differences between children and adolescents of different countries with regard to the content of HRQL. **Methods:** In each country 6 groups were held, stratified by gender and age. Age groups included: 8–10, 11–13, 14–17 years. In each group 6 to 8 children participated. A carefully conducted protocol, similar in each country, was used. The discussions were guided by experienced moderators. Entire discussions were audiotaped, transcribed and content-analyzed. All different statements with regard to HRQL were noted. **Results:** The rating of importance and content of dimensions were quite similar between the participating countries. However, differences were seen in the frequency with which items were mentioned within dimensions. E.g. in Germany and Switzerland, more items referring to cognitive function were mentioned as in the other countries. **Conclusions:** The content and importance ranking of HRQL aspects seems to be quite similar for children and adolescents from 7 European countries. This result supports the cross-cultural validity of the questionnaire and suggests that the questionnaire can be used to compare HRQL of children and adolescents between the different countries.

# 1596/EXPLAINING WELL-BEING IN PEOPLE LIVING WITH HIV AND AIDS: ASSESSING THE CONTRIBUTION OF THE WHOQOL-HIV TO THE CHRONIC ILLNESS QUALITY OF LIFE MODEL.

Suzanne M. Skevington & Susanne Norweg, Psychology, University of Bath, Bath, BANES, UK; The WHOQOL-HIV Group, Department of Mental Health, World Health Organisation, Geneva, Switzerland

**Aims:** The purpose of this work was to utilise data collected by the WHOQOL-HIV Group, to evaluate evidence for Heckman's (2003) theoretical model of chronic illness for HIV infected people. The study arises from the need to define a sound and culturally validated quality of life model for people living with HIV and AIDS (PLWHA), within a literature where few are currently available. **Methods:** PLWHA ( $N = 1281$ ) from 7 culturally diverse centres completed the field test version of the WHOQOL-HIV in Australia, Brazil, Italy, Thailand, Ukraine, and Indian centres in New Delhi and Bangalore. The WHOQOL-HIV adds HIV-specific items to the WHOQOL-100 covering 5 facets of QOL: symptoms of HIV, social inclusion, death and dying, forgiveness and fear of the future (WHOQOL-HIV Group, 2004). Within the sample subgroups were composed of people with and without HIV symptoms, and with Aids. Quotas were applied for infection status (33%), age (50% over and under 30) and sex (50%). **Results:** Following univariate investigations and multivariate regression, Structural Equation Modelling (AMOS) was used to examine the effects within Heckman's model. Acceptable support was found for the relationships between most of his proposed components namely AIDS discrimination, social support, barriers to health care and physical well-being when predicting QOL. Psychological well-being was a better substitute for the confounding concept of coping. The inclusion of sex and several other WHOQOL facets improved the model. Different models have been explored systematically and will be presented. **Conclusions:** This cross-cultural data validates the model of quality of life proposed by Heckman. However the holistic and comprehensive multidimensional profile provided by the 30 facets of the WHOQOL-HIV field data enabled us to improve the fit of the model by refining and extending it further. These results could be of assistance in designing and targeting global interventions to improve quality of life.

# 1698/QUALITY OF LIFE OF PEOPLE WITH VENOUS LEG ULCERS: THE VENUS I STUDY

Cynthia P. Iglesias, Health Sciences/Centre for Health Economics; Yvonne F. Birks, Andrea E. Nelson & Nicky A. Cullum, Health Sciences, University of York, York, North Yorkshire, UK

**Aims:** Venous leg ulcers are an important source of morbidity to society. Measuring the impact of leg ulcers on quality of life is important within clinical and economic evaluations. In this study we report a validation study of the leg ulcer disease specific Hyland questionnaire and compare its discriminative and responsive characteristics to the general health quality of life measures: the SF12 and EQ-5D. **Methods:** In the context of the largest pragmatic randomised controlled trial of venous leg ulcers. The health related quality of life of participating individuals from 9 UK regions was measured using SF-12, EQ-5D and Hyland, at baseline and every 3 months for 1 year. Psychometric analysis was used to confirm the validity of the Hyland questionnaire. Quarterly scores for all instruments were calculated. Effect size and standardised mean difference were used to investigate the responsiveness and sensitivity of the three instruments. **Results:** 387 patients were recruited into the VenUS I study. Baseline health related quality of life data from these patients suggested a two factor solution for the Hyland. This questionnaire was associated with good discriminative properties, and moderate effect sizes according to age, mobility, initial ulcer size and ulcer duration. SF-12 and EQ-5D had good evaluative properties; both instruments were sensitive to changes in HRQoL associated with leg ulcer healing. High levels of bodily pain were detected by the SF-12 questionnaire, whilst only minor ulcer related discomfort was detected by the Hyland. **Conclusions:** SF-12 and EQ 5D are suitable for exploring dimensions of health related quality of life in people with chronic venous leg ulceration. The Hyland was designed to investigate the quality of life of patients with an open leg ulcer and therefore does not deal with the chronic nature of venous ulceration.

# 1494/QUALITY OF LIFE AMONG CHINESE PEOPLE WITH PSORIASIS IN HONG KONG

C.T. Tse, MRCP; K.M. Ho, FRCP; SHS, K. Lee, MBBS, SPP, DH, Hong Kong, PRC

**Aims:** Psoriasis is a common skin disease that may considerably impair quality of life (QOL). To characterize the QOL among local Chinese people with psoriasis, we conducted a cross-sectional multi-centre survey by a validated generic QOL questionnaire. The QOL scores were compared with HK normal population. **Methods:** Chinese people with psoriasis from 6 government dermatology clinics were asked to complete the Chinese (HK) SF-36 health survey during October 2003 to March 2004. The scales and summary measures of SF-36 were reported after age and sex specific-standardization of HK normative values (mean 50, SD 10). Higher SF-36 scores indicate better QOL. Moreover, a modified Psoriasis Activity and Severity Index (MPSAI) was used to measure the clinical severity. The index was a summation of extent and lesional severity (erythema, desquamation and induration). It scores from 0 to 27 with higher value indicating worse clinical status. **Results:** Of the 128 Chinese patients recruited, 92 were male (72%). All patients had psoriasis without other comorbidities. The mean age was 41.2 years old (SD 10.1, range 18–65 years old). The majority of patients (91%) did not suffer from psoriatic arthropathy. The most common type was chronic plaque psoriasis (94%). The mean MPAI was 4.09 (SD 2.7, range 0–14) indicating mild degree of psoriasis on clinical assessment. Both summary measures, Physical Summary Score (mean 43.26,  $p < 0.001$ ) and Mental Summary Score (mean 46.04,  $p < 0.001$ ), were significantly lower than the normal population. Indeed all eight scales of SF-36 were lower than normal controls. While the greatest impairment in the physical component was Bodily Pain (mean 40.75,  $p < 0.001$ ), the greatest impairment in mental component was Social Function (mean 36.62,  $p < 0.001$ ). **Conclusions:** Despite of mild clinical severity of psoriasis, our patients demonstrated lower than normal QOL. The impairment of QOL had both physical and mental component. Physicians should be alerted on bodily pain and impaired social functioning in these patients.

#### # 1541/PROSTATE CANCER SPECIFIC SYMPTOMS IN A GERMAN REFERENCE POPULATION

Beate S. Bestmann, Reference Center Quality of Life in Oncology, University of Kiel, Kiel, Germany; Christian Loetters & Wolfgang Weidner, Professor, Urology, University of Giessen, Giessen, Germany; Thomas Kuechler, Reference Center Quality of Life in Oncology, University of Kiel, Kiel, Germany; Volker H. Rohde, Urology, University of Giessen, Giessen, Hessen, Germany

**Aims:** Prostate cancer is one of the most common forms of cancer in Europe and the USA. Predominant symptoms in these patients are erectile dysfunctions and urinary problems. Since decreases of these functions can be attributed to disease and treatment but also to age related decreases, we conducted a study on a German reference population measuring as well general QoL as prostate specific symptoms. The data from this study can be used as control group in studies with older men treated for prostate cancer. **Methods:** In cooperation with a German health insurance 3.000 questionnaires were mailed to a randomly selected sample of men aged 45–75 years. General and disease targeted health related quality of life was measured using the EORTC QLQ-C30, a prostate specific newly validated prostate specific module, the EQ-5D and the Patient Oriented Prostate Utility Score (PORPUS). 1129 (37.6%) questionnaires were returned. We compared QoL data from this new reference population to QoL data from a historical cohort of 950 patients following prostatectomy or radio therapy, in which the same set of questionnaires was used. **Results:** Mean age was 56.8 years. In terms of general QoL (QLQ-C30), the reference population showed similar QoL scores as prostatectomy patients but better scores than radio therapy patients. On the prostate specific module, the reference sample showed better QoL but a high extend of erectile dysfunction, urinary problems and psychic strain. More than 1/3 of the patients (39.0%) from the reference population reported some degree of urinary problems, 63.2% reported a decrease of sexual activity. **Conclusions:** Taking into account the sensitive topic of this study, a response rate of 37.6% is more than satisfying. Older men in our randomly selected, population based sample do not show perfect erectile and urinary function. These findings should be kept in mind when interpreting QoL data of prostate cancer patients.

# 1528/COMPARISON OF HRQOL IN PERITONEAL DIALYSIS DURING THE FIRST YEAR OF KIDNEY REPLACEMENT THERAPY  
Carole Loos-Ayav, Clinical Epidemiology and evaluation, CEC-IN-SERM, University hospital, Nancy, France; Luc Frimat & Michèle Kessler, Nephrology, University hospital, Vandoeuvre, France; Serge Briçon, Clinical Epidemiology and evaluation, CEC-INSERM, University hospital, Nancy, France

**Aims:** Relative differences in HRQoL between hemodialysis (HD) and peritoneal dialysis (PD) are not clearly known. The aim of this study was to compare HRQoL in PD vs. HD patients in an incident cohort. **Methods:** EPIREL (Epidémiologie de l'Insuffisance Renale chronique terminale en Lorraine) was a prospective study designed to evaluate treatment of end-stage renal disease (ESRD) in a comprehensive network of Kidney Replacement Therapy (KRT). Between June 1997 and June 1999, all consecutive patients with ESRD who began KRT were included in the study. Clinical and biological data were recorded at onset of KRT, at 6 and 12 months. All patients filled in KDQOL questionnaire at 6 and 12 months. We performed a treatment-received

analysis of HRQoL. All models (variance-covariance analysis) were adjusted for age, gender, comorbidity index, first dialysis session (planned vs. unplanned), and serum albumin. **Results:** Of 508 patients enrolled in EPIREL, 387 were eligible for this analysis (284 in HD, 103 in PD). At start of KRT, PD patients were older ( $70.8 \pm 11.4$  vs.  $67.6 \pm 11.3$  years,  $p < 0.05$ ), more likely to have a planned first dialysis session (68% vs. 32.8%,  $p < 0.05$ ), less likely to start KRT in life-threatening circumstances (39.8% vs. 54.9%,  $p < 0.05$ ), and less likely to have physical impairment of ambulation (11.7% vs. 20.8%,  $p < 0.05$ ) when compared to HD patients. PD patients had statistically significant higher scores in 11 of the 17 dimensions at 6 months and in 8 dimensions at 12 months. Most important differences in HRQoL between PD and HD were observed for Role limitation due to emotional function (49.2 vs. 25.6,  $p < 0.0001$ ), Burden of kidney disease (56.5 vs. 38.0,  $p < 0.0001$ ), and Role limitation due to physical function (40.6 vs. 23.4,  $p < 0.01$ ). **Conclusions:** This prospective study tends to demonstrate a very significant benefit of PD on HRQoL even 1 year after starting KRT. Moreover, it suggests that HRQoL measurement should be an important outcome in the management of patients in KRT.

#### # 1214/GP-FOCUSED INTERVENTION IMPROVES QUALITY OF LIFE (QOL) AFTER HOSPITALISATION FOR CORONARY HEART DISEASE

Frida Cheok, Strategic Planning and Research, Dept. of Human Services, Adelaide, SA, Australia; Geoffrey Schrader, Psychiatry, University of Adelaide, Woodville, SA, Australia

**Aims:** To determine, in patients with heart disease, the impact of comorbid depression on QOL, and to examine the effect of a GP focused intervention on depression and QOL. **Methods:** The Identifying Depression as a Comorbid Condition (IDACC) study was a prospective cohort study of cardiac patients with a nested randomised controlled trial. The cohort consisted of 1541 patients aged 18–84 years, admitted to four public hospitals in Adelaide, South Australia from August 2000 to June 2002, for either myocardial infarction, angina, arrhythmia, heart failure, bypass surgery or angioplasty. Self-completion questionnaires included the Center for Epidemiological Studies Depression scale (CES-D), SF36 and AQOL. Forty three percent of patients ( $n = 669$ ) were identified as depressed and randomised to a GP-focused intervention or usual care. The intervention provided brief evidence-based guidelines for management of depression, and patient specific advice to GPs by telephone. All patients were followed-up by postal questionnaire, with a 77% response rate from survivors at 12 months. Depression outcomes were analysed by  $\chi^2$  tests, with intention-to-treat analysis of the randomised trial. QOL outcomes were compared by unpaired *t*-tests. **Results:** QOL was significantly diminished in cardiac patients with depressive symptoms, measured by the physical and mental health summary of the SF36 and AQOL utility score at baseline, 3 and 12 months. The GP-focused intervention led to a reduction in the proportion of patients with moderate to severe depression after 12 months, and a significant improvement in QOL, measured by AQOL. **Conclusions:** Quality of life is an important outcome in cardiac disease. While the association of depression with quality of life in this population has been previously reported, our findings indicate that a simple GP-focused intervention for depression in cardiac patients improves QOL. This finding has significant public health consequences in view of the high prevalence of cardiac disease and its associated morbidity.

#### # 1491/VALUE OF PATIENT-REPORTED OUTCOMES (PROS) VERSUS CLINICIAN-REPORTED OUTCOMES (CROS) IN 3 CHRONIC DISEASES

Olivier Chassany, Clinical Research, Assistance Publique, Hopitaux de Paris, Paris, France; Philippe Le Jeunne, Thales, Boulogne, France

**Aims:** Irritable bowel syndrome (IBS), chronic venous insufficiency disease (CVID), and peripheral arterial occlusive disease (PAOD) are prevalent diseases in general practice. The impact of these chronic diseases on QoL is often underestimated or minimized by clinicians. The objective of the study was to compare the assessment of patients and of their clinicians on pain and QoL using validated QoL questionnaires. **Methods:** A cross-sectional survey included patients with IBS ( $n = 239$ ), CVID ( $n = 240$ ) and PAOD ( $n = 68$ ), recruited by respectively 163, 120 and 61 general practitioners (GPs). Patients completed a specific QoL questionnaire validated in French according to their disease (FDDQL, CIVIQ or CLAU-S), and scored their pain on a 10-cm visual analog scale [0–10 (maximal pain)]. GPs were asked to estimate the pain intensity and the QoL of their patients. **Results:** Pain perception is underestimated by clinicians vs. patients in IBS and CVID (respectively  $3.0 \pm 2.1$  vs.  $3.9 \pm 2.5$  and  $3.0 \pm 2.0$  vs.  $4.2 \pm 2.5$ ) and overestimated in PAOD ( $4.3 \pm 2.1$  vs.  $3.5 \pm 2.0$ ). Similarly clinicians underestimate QoL impairment in most dimensions of the IBS questionnaire (i.e. diet, sleep, discomfort, coming, control, stress), in CVID (global score  $28 \pm 19$  vs.  $39 \pm 20$  patients, 100 = worst QoL). Clinicians overestimate the impact on QoL in PAOD (global score  $54 \pm 21$  vs.  $66 \pm 23$ , 100 = best QoL). Thus, levels of correlations between PROs and CROs are moderate (e.g.  $r = 0.47$  for pain score and  $r = 0.43$  for QoL between CVID patients and clinicians). Correlations between PROs are also not perfect (e.g.  $r = 0.63$  for pain vs. QoL in IBS patients). **Conclusions:** Clinicians' and patients' perspectives although overlapping to some extent, are not similar. Clinicians tend to underestimate the pain intensity of their patients in diseases perceived as benign, but to overestimate it in diseases perceived as more severe (i.e. obstruction of arteries). Thus, perception of pain cannot be accurately inferred from the clinician's point of view. Similarly, patient's perception of pain cannot completely reflect the impact on QoL. Grant: This study was sponsored by ALFIS (Association des Laboratoires et des Firmes de Santé)

#### # 1542/CONSTRUCT VALIDITY OF THE PROXY VERSION OF THE 36 ITEMS CHRONIC GENERIC MODULE PROXY VERSION

David Debensason & Delphine Orbicini, Public Health, University of Medicine Marseilles, Marseilles, France; Silke Schmidt, Medical Psychology, University Hospital Hamburg, Hamburg, Germany; Holger Muelhan & Monika Bullinger, Medical Psychology, University Hospital Hamburg, Hamburg, Germany; Marie Claude, Simeoni, Public Health, University Hospital of Marseille, Marseilles, France

**Aims:** Self-report questionnaires are regarded as the primary method of assessing HRQoL. Nevertheless, HRQoL proxy measures are a practical alternative to assess HRQoL of subjects presenting cognitive deficiencies. The usefulness of proxy measure has been shown when assessing HRQoL of children too young or too immature. The EU-funded DISABKIDS project aims at the cross-national understanding of children's and adolescents' HRQoL by developing European instruments for HRQoL assessment from the perspective of children, adolescents, and their parents. For the chronic generic structure issued from the children's and adolescents' answers, the field study identified a six dimension-structure including 36 items: Independence (6 items), Physical (6 items), Emotion (7 items), Social inclusion (6 items), Social Exclusion (6 items), Treatment (6 items). **Methods:** During the field study 920 proxies (parents) were asked to answer the questionnaire. The purpose of this study is to know whether the children's model fits to the parents' data using confirmatory factor analysis and IRT. **Results:** CFA showed a satisfactory fit of the parents' data on the youth's model relying on maximum likelihood (ML) methods of estimation [ML:  $\chi^2 = 2385$ ;  $df = 614$ ; RMSEA = 0.061 [0.058; 0.063] 95%; NNFI = 0.96; CFI = 0.96; IFI = 0.96]. DISABKIDS proxy instrument dimension scales correlated significantly but moderately the ones with the others (Pearson's correlations ranged from 0.26 to 0.68;  $p < 0.001$ ). The results of the Rasch analyses revealed the unidimensionality of each of the six dimensions of the DISABKIDS proxy instrument. All INFIT statistics were between 0.60 and 1.40. The most

misfitting items (INFIT > 1.40) were included in the dimensions Emotion, Physical and Social Inclusion. The internal consistency of the 6 dimensions is acceptable with a range from 0.78 to 0.90. **Conclusions:** The study of external validity of the short chronic generic module is ongoing.

#### # 1537/LIKERT OR RASCH?: WHICH CONSEQUENCES ON AGREEMENT BETWEEN YOUTH AND PROXIES HRQOL MEASURES ACROSS EUROPEAN COUNTRIES

M.C. Simeoni & S. Robitail, Public Health, University Hospital of Marseille, Marseille, France; M. Erhart, Child and Adolescent Health, Robert Koch Institute, Berlin, Germany; C Tebe, Agència d'Avaluació de Tecnologia, Barcelona, Spain; J. Bruil & S. Van Buuren, Pr, TNO, Leiden, The Netherlands; D. Debensason, Public Health, University Hospital of Marseille, Marseille, France; U. Ravens-Sieberer, Child and Adolescent Health, Robert Koch Institute, Berlin, Germany; P. Auquier, Public Health, University Hospital of Marseille, Marseille, France

**Aims:** The KIDSCREEN project aims to develop an European cross-cultural HRQoL instrument for children. The aims of this study are to assess the agreement and the discrepancies between youth and their parents across European countries whether the level of HRQoL was computed from Rasch or Likert methods. **Methods:** The KIDSCREEN field survey involved more than 22.400 children and adolescent and 16.800 parents as proxy across 13 European countries. The HRQoL instrument used was the KIDSCREEN-52 instrument. To assess agreement and discrepancies between youth and proxy report Intraclass Correlation Coefficient (ICC), paired *t*-test of the mean differences (D) and effect-size (d) were computed. Many-Facet Rasch Model has been applied to locate youth and proxies scores on the same latent trait (RUMM 2010). **Results:** For all dimensions, the agreement was satisfactory (ICC > 0.4). The scales with the higher agreement (ICC > 0.6) concerned physical well-being and school functioning. The social dimension score was underestimated by the proxy ( $d > 0.20$ ). No significant difference was found for the paired *t*-test for the dimension physical well-being and Bullying. Regression models allowed to show that the level of HRQoL effect had a greater impact on the agreement than age, gender, proxy, and country. Concerning the scoring method, Rasch based scores and Likert scores are consistent in order to assess the agreement but present different results concerning the assessment of the discrepancies. **Conclusions:** The level of HRQL is the major factor related to the agreement. The effect of age, gender and countries on the agreement depends on the dimension. To compare self and proxy report the use of the Many-Facet Rasch Model seems to be an original and relevant solution.

# 1593/QUALITY OF LIFE OF WOMEN WITH BREAST CANCER: ASSESSMENT FROM WOMEN OR THEIR PROXIES

K. Tiphratene, Public Health, University Medicine, Marseille, France; H. Roche, Toulouse, France; P. Romestaing, CLB, HCL, Lyon, France; D. Serin, Clinique, SC, Avignon, France; J.P. Auuray, LASS, Lyon, France; E. Pillet, Public Health, University Medicine, Marseille, France; P. Auquier, Public Health, University Medicine, Marseille, France; C. Brun, Novartis, Paris, France

**Aims:** Measuring the impact of breast cancer (BC), in terms of quality of life of natural caregivers allows to describe consequences of health care and social support provided to these patients. The aim of this study was to carry out the development and the validation of a specific HRQL instrument for natural caregivers of women with BC. Semi-structured audio taped interviews were performed with 15 spouses and 15 children. Content analyses led to a pool of 48 items. These items explored four major domains: disease implication, family impact, psychological/emotional impact and socio-professional/economical impact. **Methods:** The item reduction study involved 259 natural caregivers: 164 spouses and 95 children. They completed the 48 items questionnaire. Exploratory factor analysis, relying on parallel analysis has been used to investigate the number of dimensions of the underlying structure. Item reduction was conducted using Rasch analyses (Rasch Rating Scale Model, WINSTEPS) and principal component analyses (varimax rotation). Differential Item Functioning (DIF) analyses and CFA were performed to compare HRQL assessment between the two categories of natural caregivers. **Results:** A 19-item profile version, describing five dimensions, explaining 70% of the total variance was defined: Psychological Well-Being (4 items), Everyday Life (5 items), Life Alteration (4 items), Perception of Woman Care (3 items) and Social Support (3 items). Internal consistency (Cronbach's  $\alpha$ ) was good, ranging between 0.77 and 0.90 for the 5 dimensions. Confirmatory factor analyses (RMSEA = 0.054, CFI = 0.97) and MAP analyses showed good results. Rasch analyses assess unidimensionality of every dimension (INFIT: 0.7–1.3). **Conclusions:** The psychometric properties of this instrument are promising. The validation of a final instrument, comprising stability over time and sensitivity to changes assessment, is needed.

# 1591/QUALITY OF LIFE OF CAREGIVERS OF BREAST CANCER PATIENTS

Pascal Auquier, Public Health, University Medicine, Marseille, France, H. H. Roche, Toulouse, France, P. Romestaing, CLB, HCL, Lyon, France, D. Serin, Clinique, SC, Avignon, France; K. Tiphratene & E. Pillet, Public Health, University Medicine, Marseille, France; C. Brun, Novartis, Paris, France

**Aims:** Breast cancer has strong social and emotional impact not only on patients but also on natural caregivers. The aim of this study was to compare HRQoL in women with breast cancer evaluated by both women and their proxies: spouse, children. **Methods:** Two hundred and one women who completed treatment for breast cancer excluding stage IV, 164 spouses and 95 children were recruited. Patients and proxies completed the FACT-B questionnaire to measure the HRQoL of the women. To assess the agreement between self-report and proxy measure several statistics have been used: Intraclass Correlation Coefficient (ICC), paired *t*-test and effect-size (*d*). **Results:** Reliability of the FACT-B scores were satisfactory: Cronbach  $\alpha$  was good for the women (0.74–0.84) and the both proxy: children (0.67–0.89) and spouses (0.73–0.87). The relationships between the self and the proxy report of the 5 dimensions and the index scores were as followed:

Physical Well-Being: (Spouses: ICC = 0.44, *d* = 0.36; Children: ICC = 0.54, *d* = 0.60), Social/Family Well-Being (H: ICC = 0.39, *d* = 0.15; C: ICC = 0.38, *d* = 0.64), Functioning (H: ICC = 0.49, *d* = 0.34; C: ICC = 0.45, *d* = 0.44), Emotional Well-Being (H: ICC = 0.49, *d* = 0.11; C: ICC = 0.37, *d* = 0.17), Additional Concerns (H: ICC = 0.53, *d* = 0.29; C: ICC = 0.49, *d* = 0.13), FACT-B index (H: ICC = 0.53, *d* = 0.29; C: ICC = 0.49, *d* = 0.60). For all dimensions, a reasonable agreement was found. Both proxy underestimated the women report for all dimensions except the Additional concerns for spouses and children, Emotional Well-Being only for the children and Family Social dimensions only for the husbands. **Conclusions:** Child–women agreement is higher than spouse–women when assessing physical domain. Conversely, spouse–women agreement is higher for emotional dimension. As retrieved in other proxy study the social domains presented the lowest agreement between self report and proxy measure. Future research are suggested in this field, especially measuring the HRQoL of caregivers to better understand the impact of the disease on the caregivers

# 1590/OPTIMIZATION OF ITEM SELECTION IN COMPUTER ADAPTIVE TESTING

Otto B. Walter, Psychosomatics, Medical School of Humboldt/Free University Berlin, Berlin, Germany; Matthias Rose, Psychosomatic Medicine, Charité University Hospital Berlin, Berlin, Germany

**Aims:** Item selection is a crucial step in computerized adaptive testing (CAT). A commonly employed item selection rule is to choose as next item to be presented that item which has the highest item information at the current ability estimate (maximum information rule, MIR). In early stages of the testing process the ability estimate is prone to change. Therefore, an item selection rule might be advantageous that obtains item information not only from a single point of the latent trait continuum but from a range of points around the current estimate. **Methods:** We investigated differences between MIR and a modified selection rule (MIR+) which uses the highest average item information in an interval around the current ability estimate for the decision which item is to be presented next. The properties of MIR and MIR+ were compared in a simulation study with our CAT engine for two CATs for depression and anxiety. These tests were developed from responses from 3270 (Depression-CAT) and 2348 (Anxiety-CAT) psychosomatic patients. Item response curves were analyzed according to Muraki's generalized partial credit model. Item banks consisted of 64 and 50 polytomous items, respectively. For each 0.25-interval of the latent trait between -3.5 and 3.5 we generated responses of *N* = 100 fictitious patients (simulees) with known ability levels. The computation of CAT scores was based on expected a posteriori (EAP) estimation. In addition, real responses of *N* = 1010 patients were used to simulate runs of the Anxiety-CAT for both selection rules. CAT scores were compared to *N*(0,1) standardized scores achieved in the State-Trait-Anxiety-Inventory (STAI). **Results:** Simulated runs of the Anxiety-CAT based on real responses yielded differences in ability estimation for the two selection rules in almost one quarter of the cases (238 out of 1010 runs). In comparison to MIR based selection, deviation from standardized STAI values for ability levels >0.0 was significantly lower for MIR+ (*p* = 0.023). CAT scores based on simulated responses showed highest differences between the two selection rules for ability estimates >1.0. **Conclusions:** Our results suggest that our modified item selection rule MIR+ can contribute to further optimization and refinement of the CAT process.

# 1242/VALIDATION OF ELECTRONIC SGRQ DATA CAPTURE  
Makiko Meguro, Respiratory Medicine; Paul W. Jones, Respiratory Medicine, St George's Hospital Medical School, London, UK

**Aims:** Good data quality is important in any study. Errors such as missed questionnaire items by patients and data entry mistakes are almost inevitable. Computerised data entry by the patient facilitates data capture, management, secure storage and auditing as well as being time and cost effective. **Methods:** An electronic version of St George's Respiratory Questionnaire (eSGRQ) has been developed using Microsoft .NET technology. The eSGRQ is Windows based software, compatible with PCs, handheld devices and tablet PCs. The eSGRQ requires minimal training in its operation. The program guides the patient through its items then calculates the component and Total scores of the questionnaire. The raw data and calculated data are stored in an exportable spreadsheet. We compared scores obtained using the eSGRQ with those using the paper method in 30 patients (16 male) with asthma and COPD (mean age 49) who completed both versions in randomised order. They also rated their expectation, difficulties and preference for using the computer vs. the paper version. **Results:** The mean SGRQ score was 39.0 (range 5–82). The  $r^2$  values for Symptoms, Activity, Impacts and Total scores were: 0.97, 0.97, 0.96, 0.99, respectively. Bland and Altman plots showed no bias in the response to the eSGRQ across the range of SGRQ scores. Ease of use of the eSGRQ was judged excellent by 40% of subjects and 90% found it easy to complete; 77% would prefer to use it in the future. Preference was unaffected by the patient's level of previous computing experience use. **Conclusions:** Computerised completion of the SGRQ by patients provides reliable data. Patients prefer it and it facilitates data management for the researcher.

# 1548/VALIDATING THE GERMAN COMPUTERIZED ADAPTIVE TEST FOR ANXIETY ON HEALTHY SAMPLE ('A-CAT')

Janine Becker, DiplPsych; Otto B. Walter & Herbert Fliege, Internal Medicine, Charité, Humboldt-University Berlin, Berlin, Germany; Jakob B. Bjorner, Deputy Chief Science Officer, QualityMetric Incorporated, Lincoln, RI; Ruya D. Kocalevent, Dipl.-Psych; Gabi Schmid, Dipl-Psych; Burghard F. Klapp & Matthias Rose, Internal Medicine, Charité, Humboldt-University Berlin, Berlin, Germany

**Aims:** Recently a German Computerized Adaptive Test has been developed on principles of the Item Response Theory (IRT) to measure anxiety (A-CAT). First validation studies demonstrated that the underlying item bank (50 items) offers a very precise ( $SE \geq 0.32$ ) and efficient measurement of anxiety (~6 items used on average). The purpose of the current study was to examine if the results can be replicated and to investigate the validity of the developed instrument in a representative sample of healthy persons. **Methods:** The 'A-CAT' and an established psychometric instrument measuring anxiety (HADS) were administered to a sample of  $n = 200$  randomly selected healthy persons by two trained researchers in the course of a phone study taking place between 09/03 and 11/03. **Results:** The results of the study on healthy persons showed them to be less anxious (A-CAT:  $0.79 \pm 0.87$ , mean of  $\theta \pm SD$ ) than a sample of  $n = 102$  psychosomatic inpatients (A-CAT:  $0.33 \pm 0.72$ , mean of  $\theta \pm SD$ ). The A-CAT scores correlate well with the anxiety score of a conventional instrument (HADS:  $r = 0.66^{**}$ ). The mean number of items needed to measure anxiety by the A-CAT is slightly higher for the healthy sample ( $7 \pm 5$  items,  $m \pm SD$ ) than for the patients sample ( $5 \pm 2$  items,  $m \pm SD$ ). This is due to the known fact that CATs need to administer more items on extreme levels of theta to ensure the same precise level of measurement ( $SE \geq 0.32$ ). Further analysis revealed that a subgroup of healthy persons (11% mavericks) scoring on very low levels of theta ( $-3.5$  to  $1.7$ ) had to answer on average 15 items ( $Sd = \pm 12$ ), whereas most of the healthy persons (89%) needed to answer as few items ( $5.8 \pm 1.4$ ,  $m \pm SD$ ) as the patients sample. **Conclusions:** Overall this study is one of the first to examine the practicability and validity of a CAT in a healthy sample. Results stand in line with foregoing studies revealing promising psychometric properties like a high measurement precision and a substantial item reduction.

# 1589/EVALUATING A COMPUTER ADAPTIVE TEST FOR DEPRESSION (D-CAT) IN A HEALTHY SAMPLE

Matthias Rose & Otto B. Walter, Psychosomatic Medicine, Charité University Hospital, Berlin, Germany; Janine Becker, Rueya Kocalevent, Herbert Fliege, Gabi Schmid, Anne Grimm & Burghard F. Klapp, Psychosomatics, Charité, Berlin, Germany

**Aims:** Recently a German Computerized Adaptive Test has been developed on principles of the Item Response Theory (IRT) to measure depression (D-CAT). First simulation studies demonstrated that the underlying item bank (64 items) offers a very precise (standard error  $\geq 0.32$ ) and efficient measurement of depression (7 items used on average) using an EAP estimator and different computer assisted forms of item presentation. The purpose of the current study was to examine if the psychometric results can be replicated in a representative sample of healthy persons using a telephone administration. **Methods:** The D-CAT and the Hospital-Anxiety-Depression-Scale (HADS) as an established psychometric instrument were administered to a sample of  $n = 200$  randomly selected healthy persons by two trained interviewers in the course of a phone study taking place between 09/03 and 11/03. **Results:** The healthy persons showed to be less depressed (D-CAT:  $-1.39 \pm 0.84$ , mean of  $\theta \pm$  standard deviation) scoring more than one standard deviation lower than a control sample of  $n = 114$  psychosomatic patients (D-CAT:  $-0.12 \pm 0.93$ ). The D-CAT estimates correlated high with the depression score of the HADS  $r = 0.61$ , showing a better discrimination at the low extremes of the latent trait. The mean number of items needed to measure depression by the D-CAT is slightly higher for the healthy sample ( $9 \pm 8$  items, mean  $\pm SD$ ) than for the patients sample ( $7 \pm 8$  items). This is due to the fact that the D-CAT needs to administer more items on very low levels of  $\theta$  to ensure the same measurement precision. **Conclusions:** In summary we could demonstrate the practicability and validity of the D-CAT in a healthy sample using a telephone interview. The results stand in line with earlier findings revealing promising psychometric properties for CATs measuring health outcome constructs.

# 1505/PERCEIVED STRESS - MEASURED BY A COMPUTERIZED ADAPTIVE TEST (STRESS-CAT)

Rueya D. Kocalevent & Otto B. Walter, Psychosomatic Medicine; Janine Becker, DiplPsych; Psychosomatic Medicine; Herbert Fliege, Psychosomatic Medicine; Burghard F. Klapp, Psychosomatic Medicine, Charité University Berlin, Berlin, Germany; Jakob B. Bjorner, Department Chief Science Officer, QualityMetric, Lincoln, RI; Matthias Rose, Psychosomatic Medicine, Charité University Berlin, Berlin, Germany

**Aims:** The study aims to develop and validate computerized adaptive tests to measure the perception of stress in the clinical field (Stress-CAT). **Methods:** 1092 psychosomatic patients (69.7% female,  $42.4 \pm 14.5$  years of age) answered 127 items out of 4 validated stress questionnaires (PSQ, TICS, ABF, SUB) within their diagnostic routines. **Results:** 5 independent reviewers rated 39 items as representative of the 'stress expression' dimension. All items underwent six steps of analyses to check for the assumptions of unidimensionality, local independence and item discrimination, using the programs Mplus, TestGraf, SAS, and Parscale. The Generalized Partial Credit Model could be applied, showing a good model fit. The CAT scores were estimated using an 'expected a posteriori' algorithm (EAP). We could demonstrate the latent trait ('perceived stress') can be estimated with approximately 5 items  $\pm 2$  items (mean  $\pm SD$ ) on a highly precise level (reliability 0.90) with high correlation to established instruments based on classical test theory. Accordingly the absolute number of items could be substantially reduced ( $-31$  to  $-77\%$ ) without loss of major information and with improved measurement precision in high and low score ranges. **Conclusions:** Measuring stress in the clinical field can be done at the same time economically and with high precision using an individually 'tailored' computerized adaptive test.

# 1277/IMPACT OF UNTREATED PSYCHOSIS ON QUALITY OF LIFE IN FIRST-EPIISODE SCHIZOPHRENIC PATIENTS  
Chi-wing Law, Psychiatry, Queen Mary Hospital, Hong Kong, PRC

*Aims:* In this study, we assessed the QOL of young people in the period of untreated psychosis when they suffered from their first episode of schizophrenia. A comparison with normal young people of similar age and background was also made. *Methods:* 117 patients (aged 14 – 28 years) with the ICD-10 diagnosis of schizophrenia who entered the Early Assessment Services for Young People with Psychosis (EASY) program from June 2001 to January 2004 were assessed with the MOS 36 item Short Form Health Survey (SF-36) and the World Health Organization Quality of Life Measure, abbreviated Hong Kong version (WHOQOL-BREF (HK)). We compared their SF-36 scores with controls from the normal population matched with age, sex, educational level and marital status. Normative data of controls were obtained from the results a large-scale study conducted in 1998 using a cross-sectional telephone survey. Clinical assessment with the Positive and Negative Syndrome Scale (PANSS), Scale for Assessment of Negative Symptoms (SANS), and the Montgomery and Asberg Depression Rating Scale (MADRS) were also carried out in 83 of these patients. *Results:* We found that our first-episode schizophrenic patients had significantly poorer scores in all of the eight scales of the SF-36 ( $p \leq 0.001$ ) when compared with their normal counterparts in the community. Correlations between various QOL domain scores and clinical parameter scores were assessed. No significant correlations between QOL domain scores and PANSS or SANS scores could be identified. On the other hand, significant inverse correlations between the MADRS and various QOL domain scores were found ( $p < 0.01$  in physical health, psychological health and environmental domains of the WHOQOL-BREF(HK), and role-physical scale of the SF-36 ( $r = -0.29$  to  $-0.33$ );  $p < 0.05$  in general health, vitality and role-emotional scales of the SF-36 ( $r = -0.22$  to  $-0.27$ )). *Conclusions:* Our findings suggest that young people suffering from their first-episode of schizophrenia, when compared with people in the general population with similar age and background, experienced significantly lower scores in all domains of QOL during the period of untreated psychosis when active symptoms were prominent.

# 1228/QUALITY OF LIFE ASSESSMENT OF CARERS OF PERSONS WITH SCHIZOPHRENIA  
Tinku Thomas & Sekar Kasi, Psychiatric Social Work; Kishore Kumar, Psychiatry, NIMHANS, Bangalore, Karnataka, India

*Aims:* Assess the quality of life in different domains of primary carers of persons with schizophrenia and to determine the characteristics of the patients and carers that can be significant predictors of the quality of life. *Methods:* The data for the study was obtained from primary carers of 84 persons with schizophrenia residing in the rural parts of Karnataka state, India. The respondents were contacted mostly at their residence by a trained Social worker. The WHO Quality of Life Schedule Bref version was used. The psychological morbidity and disability of the carers were also assessed. Tests of significance such as Chi-square, t-test and Anova were used. *Results:* The mean qol scores and their standard deviations in the different domains were obtained and the environmental domain having the highest and the physical domain having least scores. Social qol was better for those whose wards were drug naïve and had come for the first time to the care facility as compared to the old cases. They physical and psychological qol were higher for younger carers. The environmental qol did not differ between the age groups. The lowest qol was for the age group 50+. The environmental qol was better for male carers and for literate persons as compared to illiterates. The psychological and social qol were higher for carers who were working. All the domains of qol were significantly higher for persons who did not have any psychological morbidity as obtained from the SRQ and the qol was significantly higher for those with lesser disability. There was a significant negative correlation between family burden and the cost of providing medical care for the ward. *Conclusions:* The psychological morbidity status and disability of the carer and the cost of medical care were determining factors of qol, the ill persons having lower qol. Older carers had significantly lower qol. The level of disability of the patient, symptomatology etc did not affect the qol of the carers.

# 1172/THE BURDEN OF DISEASE IN LONG-TERM PSYCHOTHERAPY PATIENTS WITH PERSONALITY DISORDER: THE FALSIFICATION OF THE YAVIS-ARGUMENT  
Djøra Soeteman, VISPD, De Viersprong, Halsteren, The Netherlands; Jan Busschbach, Medical Psychology, Erasmus University Medical Center, Rotterdam, The Netherlands

*Aims:* Reimbursement of long-term psychotherapy in patients with personality disorder is controversial: in many countries reimbursement is denied or limited. An important argument in this restriction is an assumed low burden of disease. Patients with personality disorder are said to be YAVIS-patients: Young, Attractive, Verbal, Intelligent, and Successful. This discussion is a typical example of a health policy debate in which quality of life arguments play a decisive roll. Notwithstanding the continuous use of this argument, empirical evidence is lacking to support it. This is because quality of life has only been measured with disease specific questionnaires, making it impossible to compare the burden of disease in personality disorder with the burden of disease in other (i.e. mental and somatic) illnesses. *Methods:* 1334 patients from 19 different institutes with personality disorder were included during the intake for long-term psychotherapy. The generic EuroQol EQ-5D questionnaire was used to measure the burden of disease. *Results:* The EQ-5D revealed a severe suffering in these patients. The burden of disease was comparable with patients with severe (somatic) illnesses, like Parkinson's disease or chronic fatigue syndrome. The burden of disease depended on diagnostic variables and the intended dose of therapy (in terms of setting, duration and intensity). *Conclusions:* Our findings are the first formal falsification of the YAVIS-argument in patients with personality disorder indicated for long-term psychotherapy. The policy implication is that any cost-effective treatment of personality disorder must be seen as necessary care for a serious illness. This finding favours the reimbursement of long term psychotherapy and is an example how quality of life measurements can play an important role in health care policy.

# 1705/RELATIONSHIP BETWEEN PERCEIVED QUALITY OF LIFE AND SOCIAL FUNCTIONING OF PATIENTS WITH CHRONIC PSYCHIATRIC CONDITIONS IN A LONG STAY CARE HOME  
Deborah L. Wan & Kenneth K. Law, Hong Kong SAR, PRC

*Aims:* During the past decade, many patients with chronic psychiatric conditions have transferred to live in long stay care homes in Hong Kong. Few studies on how these patients adjusted in the community are available. This study aimed to investigate the change of the quality of life and social functioning of patients residing in such facility. *Methods:* 140 residents of a long stay care home were followed up for 4 years to examine the change of their quality of life and social functioning level. Data were collected in every 6 months by using a set of instruments including the Hong Kong Chinese Version of the WHO Quality of Life Measure and the WHO Psychiatric Disability Assessment Schedule. Data gathered were analyzed using Statistical Package for Social Sciences (SPSS) version 10. *Results:* The residents had high perceived quality of life and low level of social disability. The perceived quality of life increased in the first 1 year of the study and maintained in a stable level for the next 3 years. There was no difference between male and female residents but the male residents had greater change in their perceived quality of life. The residents had maintained within a minimum dysfunctional level in their overall behaviour over the 4 years period. There was a descendent in self-care and social withdrawal but improvements in their slowness in carrying out daily activities. Throughout the 4 years period, female residents had a higher functioning level. Quality of life of the residents was not correlated with social disability. *Conclusions:* The findings suggest that living in a long stay care home may help to maintain the social behaviour of the residents in a minimum dysfunctional level. In addition, the residents enjoy the life in such facility.

# 1530/IMPACT OF MENTAL DISORDERS ON QUALITY OF LIFE: THE EUROPEAN STUDY OF THE EPIDEMIOLOGY OF MENTAL DISORDERS (ESEMED)

G. Vilagut, M. Martinez-Alonso & J. Alonso, Health Services Research, Institut Municipal d'Investigació Mèdica, Barcelona, Spain; M.C. Angermeyer, Psychiatry, University of Leipzig, Leipzig, Germany; S. Bernert, Leipzig, Germany; R. Bruffaerts & K. Demyttenaere, Luven, Belgium; T.S. Brugha, Leicester, UK; G. de Girolamo, Bologna, Italy; R. de Graaf, Utrecht, The Netherlands; I. Gasquet, Villejuif, France; J.M. Haro, Sant Boi de Li, Spain; V. Kovess & J.P. Lépine, Paris, France; J. Ormel, Groningen, The Netherlands; G. Polidori, Roma, Italy

**Aims:** To assess the impact of mental disorders on health-related quality of life (HRQL) among the European general population and to evaluate differences across countries. **Methods:** Data come from the ESEMeD project, a cross-sectional, personal, home interview survey of a representative sample of non-institutionalized adults, 18+, in Belgium, France, Germany, Italy, the Netherlands and Spain. A total of 21,425 individuals were administered the WHO version of the CIDI (WMH-CIDI) by computer-assisted interviews. The SF-12 Health Survey and socio-demographic characteristics were included in the questionnaire. The SF-12 physical (PCS) and mental (MCS) summary measures were estimated according to 12-month broad diagnostic groups (i.e. mood, anxiety and alcohol disorders) using multivariate linear regression. Adjustments were made for socio-demographic variables and the presence of physical chronic conditions. Interactions between diagnostic groups and countries were tested. **Results:** 51% were females and 70% had at least one chronic condition. The mean age was 47 years (SD = 24.9). 9.7% had at least one 12-month mental disorder (4.6% pure anxiety, 2.5% pure mood, 0.7% pure alcohol). The impact of pure mood and pure anxiety disorders on MCS was statistically significant (mean difference -12.4 and -2.8, respectively). For pure alcohol and mental comorbidity impact varied by country, from -9.8 to -0.7 and from -18.1 to -10.2 respectively. Impact on PCS was smaller (the strongest was comorbidity, -4.4) without differences among countries. **Conclusions:** Pure mood and comorbid disorders have a high impact on mental HRQL. Influence of mental disorders on the mental component of HRQL is not homogeneous across countries in contrast with their impact on the physical one.

# 1451/QL-DIAGNOSTICS AND QL-ENHANCING THERAPY FOR BREAST CANCER PATIENTS: IMPLEMENTATION OF A CLINICAL PATH IN THE TUMORCENTER REGENSBURG

Monika Klinkhammer-Schalke, Tumorcenter, University of Regensburg, Regensburg, Germany; M. Koller, Theoretical Surgery, Philipps-University Marburg, Marburg, Germany; C. Jakob, B. Steinger, B. Ernst, F. Hofstädter & W. Lorenz, Tumorcenter, University of Regensburg, Regensburg, Germany

**Aims:** Improving cancer patients' quality of life (QL) requires that QL-diagnostics, the availability of QL-enhancing treatment options and treatment decisions are being integrated into a clinical path. This abstract describes the development and implementation of such a clinical path in the Tumorcenter Regensburg. **Methods:** The acting persons and institutions in this clinical path are the breast cancer patients, the hospitals, the family doctors or gynaecologists, and a QL-study team. Starting point is the QL-assessment either in the hospital or in doctors' practice (EORTC QLQ-C30 plus BR-23). The caring physician documents the patients' health status. Based on these two pieces of information, the QL-study team writes up a medical/QL-opinion plus therapy recommendation. This report is sent to the caring physician. The effectiveness of the therapy recommendation is assessed in the following QL-assessment. This clinical path is implemented via three interrelated methods of implementation: local opinion leaders, outreach visits, and quality circle. **Results:** 32 of 33 physicians were made familiar with QL-diagnostics through outreach visits, and 12 opinion leaders were identified and convinced to support this project. The quality circle provided regular CME meetings on QL-enhancing therapy options (pain control, psychotherapy, physiotherapy, nutrition, social rehabilitation). A total of 106 QL-reports were sent to physicians. 32 of 33 doctors found the QL-profiles comprehensible and the therapy recommendations clinically relevant. The most common QL-problems

were emotional functioning, fatigue, and arm/shoulder problems. **Conclusions:** QL-diagnostics is a new way to individualise and to rationalise patient care. It transforms the QL-concept into a decision-relevant, integral part of a clinical path that aims to provide high quality patient care.

# 1164/MAKING SENSE OF PATIENTS' PREFERENCES FOR ADJUVANT CHEMOTHERAPY (ACT) IN EARLY BREAST CANCER (EBC): WHAT MAKES IT WORTHWHILE, WHO DECIDES AND WHY?

Vlatka Duric & Martin Stockler, NHMRC Clinical Trials Centre; Phyllis Butow & Louise Sharpe, Psychology, University of Sydney, Sydney, Australia

**Aims:** To determine how individuals trade off the benefits, harms and uncertainties of ACT for EBC, we sought preferences of women who had ACT, predictors of their preferences, and their partners' preferences. **Methods:** 83 consecutive consenting women who completed ACT 3 to 34 months previously, and 46 of their partners, were presented 4 hypothetical scenarios based on known survival times (5 and 15 years) and rates (65 and 85% at 5 years) with and without ACT. Data was collected on demographics, disease, treatment, anxiety, depression, optimism, impact and perceptions of breast cancer. Associations between preferences and predictors were assessed with linear regression after normal score transformation. Agreement between patients and their partners was assessed with the intraclass correlation coefficient (ICC). **Results:** Mean patient age was 55 years (25-73), 57% had a partner, 48% had tertiary education, 66% were employed, 79% had children, 45% had dependants, and 6% lived alone. Mean partner age was 60 (40-74). Improvements of 0.1% in 5 year survival rates or an additional 1 day in life expectancy were judged sufficient to make ACT worthwhile by 52-61% of patients, and 50-59% of their partners. During a preliminary example, 26 of 66 women responded that chemotherapy would be worthwhile even if it conferred no survival benefit. Patients judging smaller benefits sufficient were more likely to have: dependants, lower depression scores, more intrusive thoughts about EBC, fewer perceived consequences of EBC, and fewer non-specific symptoms (all  $p < 0.05$ ). Agreement between patients and their partners was poor (mean ICC = 0.3), but their preferences did not differ systematically. Agreement was greater for couples with dependant children ( $p = 0.001$ ). **Conclusions:** Preferences were highly variable, but many judged marginal benefits sufficient to make ACT worthwhile. Psychosocial factors explained only some of this variation. These issues should be considered when discussing ACT for EBC with patients.

# 1149/PREDICTORS OF HEALTH-RELATED QUALITY OF LIFE OF BREAST CANCER PATIENTS AFTER SURGERY IN JAPAN (WOMEN'S HEALTH OUTCOME STUDY [WHOS] – 01)

Kojiro Shimozuma, Healthcare and Social Services, University of Marketing and Distribution Sciences, Kobe, Hyogo, Japan; Satoshi Morita, Epidemiology and Health Care Research, Kyoto University, Kyoto, Kyoto, Japan; Shozo Ohsumi, Surgery, National Shikoku Cancer Center Hospital, Matsuyama, Ehime, Japan; Katsumasa Kuroi, Surgery, Showa University Toyosu Hospital, Tokyo, Tokyo, Japan; Yasuo Ohashi, Biostatistics/Epidemiology and Preventive Health Sci, University of Tokyo, Tokyo, Japan

**Aims:** To understand the physical and psychological rehabilitation needs of breast cancer (BC) patients after surgery, we prospectively examined the predictors of health-related quality of life (HRQOL) of BC patients after surgery. **Methods:** One-hundred and ninety-six BC patients treated at 8 different hospitals from December 1998 to March 2003 were asked to answer the Functional Assessment of Cancer Therapy scale – Breast (FACT-B) with the Hospital Anxiety and Depression Scale (HADS) at 1 (baseline), 6, and 12 months (1 year) after surgery. Response rates of the questionnaires were 96.8–97.4%. Multivariate regression analysis was performed to examine the baseline variables predictive of HRQOL (FACT-G and FACT-B scores) outcome at 1 year. In this analysis, demographic/medical characteristics and HADS subscale scores at baseline were used as independent variables. **Results:** The baseline HADS Depression subscale score was the strongest predictor of 1 year HRQOL as assessed by the FACT-G and FACT-B ( $p = 0.002$ ,  $0.003$ , respectively). In addition, greater anxiety and hospitalization at baseline had significant positive relationships to the worse HRQOL at 1 year. Positive lymph node involvement and type of surgical procedures did not predict HRQOL. **Conclusions:** The results of this study help us to determine the appropriate candidates for psychological rehabilitation, and indicate that longer hospitalization might delay amelioration of patients' HRQOL.

# 1290/THE EFFECT OF SURGERY TYPE ON THE BODY IMAGE OF WOMEN WITH PRIMARY BREAST CANCER: A QUESTION OF AGE?

Neil K. Aaronson, Psychosocial Research & Epidemiology, The Netherlands Cancer Institute, Amsterdam, The Netherlands; Nynke Frieswijk, Social and Organizational Psychology, University of Groningen, Groningen, The Netherlands; Juan Arraras, Oncology, Hospital of Navarre, Pamplona, Spain; Mirjam A. Sprangers, Medical Psychology, Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands

**Aims:** Prior studies have consistently found that the body image of women with breast cancer who have undergone lumpectomy is significantly better than that of women who have had a mastectomy. However, as the perception of physical appearance may become more stable with increasing age, we hypothesized that the positive body image effects of lumpectomy would accrue primarily to younger women; that age is a significant modifier of the effect of surgery type on body image. **Methods:** Participants were 242 women with local or loco-regional breast cancer who had undergone a lumpectomy or a mastectomy, and were to receive either radiotherapy or chemotherapy. Questionnaires were completed on two occasions: post-surgically, immediately prior to receiving radio- or chemotherapy (T1), and on the last day of the radiotherapy course or during the second cycle of chemotherapy (T2). Body image was assessed with a subscale of the EORTC breast cancer quality of life questionnaire module (QLQ-BR23). **Results:** At both T1 and T2, older women (>55 years of age) reported a significantly more positive body image than younger women (< 55 years of age). Overall, women who underwent a lumpectomy reported a significantly better body image than those who had had a mastectomy. However, as hypothesized, the relative advantage of lumpectomy over mastectomy in terms of body image was observed primarily among younger women. Among older women, no statistically significant difference in body image was observed as a function of surgery type. **Conclusions:** These findings corroborate earlier studies that have found that lumpectomy is more protective of a woman's body image than is mastectomy. However, this body image benefit appears to accrue primarily to younger women. This suggests that, for older women, body image issues may be less important in choosing among surgical treatment options.

# 1556/POSTTRAUMATIC STRESS DISORDER AND HEALTH-RELATED QUALITY OF LIFE IN A REPRESENTATIVE SAMPLE OF BREAST CANCER PATIENTS

Anja Mehnert, Inst. Medical Psychology; Uwe Koch, Inst. of Medical Psychology, Hamburg-Eppendorf University Clinic, Hamburg, Germany

**Aims:** Prevalence rates of psychiatric disorders in adult cancer patients differ a lot ranging from 0% to approximately 50% and closely depend on cancer type, disease stage, treatment, time and methods of assessment as well as applied diagnostic categories. Since life-threatening illness was included as a potentially traumatic event in the revised DSM-IV, posttraumatic stress disorder (PTSD) has been increasingly diagnosed as an additional morbidity among cancer patients. The aim of this study was to identify posttraumatic stress responses in women with breast cancer diagnosis at all stages of the disease and to analyse differences in HRQoL in patients with a diagnosis of cancer-related PTSD. **Methods:** A sample of  $n = 1083$  breast cancer survivors randomly selected by the local cancer registry (response rate 67%) filled out a questionnaire including the Impact of Events Scale-Revised (IES-R), Posttraumatic Stress Disorder Checklist-Civilian Version (PCL-C) and Short Form-8 Health Survey (SF-8), among others. Patients had an average age of 62 years ( $SD = 9.8$ , range 31–81). Mean time since cancer diagnosis was 47 months (range 18–77). 13% had a diagnosis of recurrent cancer. **Results:** According to different Cut-off-Scores, between 8 and 15% of patients met criteria for cancer-related PTSD, and significant levels of intrusive (38%), avoidant (22%) and arousal (34%) symptoms were reported. Patients with current cancer-related PTSD showed statistically and clinically significant lower HRQoL in both physical and mental health scores (each  $p < 0.001$ , effect sizes  $d = 1.2$  and  $d = 1.8$ ). Time since initial diagnosis and disease stage had no effect on HRQoL. **Conclusions:** Results indicate that slightly less than one third of breast cancer patients are likely to meet criteria for a comorbid psychiatric disorder. These patients show remarkably lower HRQoL independently of duration and severity of the disease. Results indicate that psychological comorbidity might be a strong predictor for lower HRQoL in adult cancer patients.

# 1036/RELIABILITY, VALIDITY AND FEASIBILITY OF THE MALAY MCGILL QUALITY OF LIFE QUESTIONNAIRE (MMQOL) IN MALAYSIAN CANCER POPULATION

P. L. Lua, Psychology & Social Health Research, University Malaysia Sabah, Kota Kinabalu, Sabah, Malaysia; M. S. Salek, Centre for Socioeconomic Research; I. G. Finaly, College of Medicine, Univ of Wales, Cardiff University, Cardiff, UK; A.G. I. Boay & M. S. Rahimah, Queen Elizabeth Hospital, Sabah Health Department, Kota Kinabalu, Sabah, Malaysia

**Aims:** Despite the wide recognition of health-related quality of life (HRQoL) assessment as an important outcome measure in the cancer population, its application is still limited in Malaysia. This study aimed to test the reliability, validity and feasibility of the Malay McGill Quality of Life Questionnaire (MMQOL) in Malaysian cancer population. **Methods:** The original, McGill Quality of Life Questionnaire (MQOL) (containing 17 items examining global QoL, physical symptoms, physical well-being, psychological, existential and support issues) was cross-culturally adapted into Malay and administered to a group of patients with cancer. Descriptive statistics, Mann-Whitney U-test and principal factor analysis were carried out using SPSS 10 ( $p < 0.05 =$  significant). **Results:** A total of 65 in-patients from Queen Elizabeth Hospital, Sabah completed the MMQOL (mean age = 41; range = 18–78 years; male = 31). Excellent internal consistency reliability (Cronbach's  $\alpha > 0.70$ ) was revealed by all MMQOL domains and its total score. Four major domains (physical symptoms, psychological, existential and support) were produced by factor analysis; indicating evidence of construct validity. The MMQOL's ability to significantly discriminate between patients with different haemoglobin level and white cell count provided evidence of known-group validity. The average completion time for the MMQOL was 8.0 min ( $SD = 3.08$ ). **Conclusions:** Findings showed that the MMQOL was a reliable, valid and feasible instrument in the Malaysian cancer population. Consequently, its potential as a comprehensive and practical HRQoL tool for future investigations is very promising.



# 1178/PSYCHOMETRIC PROPERTIES OF THE CHINESE QUALITY OF LIFE INSTRUMENT (CHQOL) FOR CHINESE MEDICINE

Kelvin Chan & Li Zhao, RDD, School of Chinese Medicine, Hong Kong Baptist University, Hong Kong, PRC; Kwok-fai Leung, PDipOT, Occupational Therapy, Queen Elizabeth Hospital, Hong Kong, PRC; Fengbin Liu, The First Affiliated Hospital, Guangzhou University of Traditional Chinese Medicine, Guangzhou, Guangdong, PRC; Jiqian Fang, School of Public Health, Sun Yat-Sen University, Guangzhou, Guangdong; Jianying Lang, Chinese Medicine, Guangzhou University of Traditional Chinese Medicine, Guangzhou, Guangdong

**Aims:** The Chinese Quality of Life Instrument (ChQOL) was developed as a generic measure of health-related quality of life for use in Chinese medicine and integrative medicine based on Chinese culture and the practice of Chinese medicine. The purpose of this study is to evaluate psychometric properties of the ChQOL. **Methods:** A cross-sectional survey was conducted among 193 patients and 80 healthy subjects. For convergent validity, the ChQOL was compared with the instrumental activities of the World Health Organization Quality of Life Assessment (WHOQOL-100) and the Medical Outcomes Study Short Form 36-items Health Survey (SF-36). **Results:** We completed 273 interviews and 56 retests. The psychometric properties of the ChQOL were generally good. There were no ceiling and floor effects in scaling properties. The Cronbach's  $\alpha$  coefficients were above 0.70 for all facets and domains. Retest intra-class correlations ranged from 0.67 to 0.84 in the facets and ranged from 0.83 to 0.90 in the domains. Correlation between the ChQOL and WHOQOL-100 or SF-36 was moderate, and higher in similar domains. All domain scores were statistically significant to discriminate between healthy subjects and patients so called 'known groups'. **Conclusions:** The ChQOL has satisfactory psychometric properties and appears suitable for both clinical and research purposes.

# 1487/VALIDATION OF THE KOREAN TRANSLATION OF BATH ANKYLOSING SPONDYLITIS DISEASE ACTIVITY INDEX (BASDAI)

Hye J. Park, Nursing; Sehyun Kim, Preventive Medicine; Jong E. Lee, Nursing, Pochon CHA University, SeongNam, KyunggiDo, Republic of Korea; Jae B. Jun & Sang C. Bae, Rheumatology, Hanyang University, Seoul, Republic of Korea

**Aims:** Ankylosing spondylitis (AS) is the form of rheumatoid arthritis affecting the spine. The Bath Ankylosing Spodylitis Disease Activity Index (BASDAI) is one of the most commonly used instruments to measure disease activity and functioning for AS. The objective of this study was to validate a Korean translation of BASDAI instrument. **Methods:** We have been followed rigorous international translation steps. Forward translation into Korean, reconciliation to establish the conceptual equivalence and consistency, pilot test, panel discussion and backward translation into the original English version were performed. Subjects were 50 outpatients diagnosed by the modified New York criteria for AS. The reliability of the Korean translated BASDAI was evaluated by Cronbach's  $\alpha$ . Construct validity was examined by the correlations between BASDAI scales and clinical parameters (such as ESR, CRP, Schober test, modified Schober's test, finger to ground test, C-reactive protein, ESR, and Bath ankylosing spondylitis radiologic index score). **Results:** Of the 50 subjects, 46 (92.0%) were men. The mean (SD) age was 30.0 (6.8) years. The Cronbach's  $\alpha$  of six scales (general weakness, back pain, peripheral pain, tenderness, stiff/swelling, morning stiffness) showed 0.88, 0.84, 0.86, 0.83, 0.81 and 0.86, respectively. The mean (SD) duration of morning stiffness was 79.68 ( $\pm$ 62.92) minutes. The duration of morning stiffness correlated with the scores of back pain, peripheral pain, tenderness, stiff/swelling ( $r = 0.40, p < 0.01$ ;  $r = 0.30, p < 0.05$ ;  $r = 0.54, p < 0.001$ ;  $r = 0.59; p < 0.0001$ ). The score of back pain correlated with peripheral pain, tenderness, stiffness/swelling, morning stiffness (all  $p$ 's  $< 0.05$ ). The value of CRP and ESR correlated with total score of BASDAI ( $p < 0.05$ ). **Conclusions:** These results support the applications of the Korean BASDAI in studies assessing and evaluating the AS patients.

# 1463/VALIDATION OF A CHINESE QUALITY-OF-LIFE QUESTIONNAIRE FOR PATIENTS WITH ADVANCED COPD

Hon-keung Chan & Mei-che Pang, School of Nursing, The Hong Kong Polytechnic University, Hong Kong, PRC; Kin-sang Chan, Haven of Hope Hospital; Kam-shing Lau, Ruttonjee Hospital; Chun-yan Tse, United Christian Hospital; Hospital Authority, Hong Kong, PRC

**Aims:** Criticisms are raised regarding the relevance of using existing health-related quality of life measures for patients with advanced illnesses. This study aims to validate an empirically constructed questionnaire for eliciting the quality-of-life concerns (QOLCQ) of Chinese patients with advanced COPD. **Methods:** The ethnographic interviews of 40 patients with advanced COPD and terminal cancer yielded rich descriptions of the evaluative factors regarding their life quality in the last 6 months of life. They were subsequently categorized into 36 items and 5 domains. The McGill Quality of Life Questionnaire for Palliative Care (MQOL) was used to test the concurrent validity of QOLCQ. Both QOLCQ and MQOL were administered to 20 terminal cancer patients and 101 advanced COPD patients. Construct validity was tested by analysis of variance to compare differences between groups in terms of levels of overall QOL evaluation. The reliability was established by the internal consistency. **Results:** There was significant correlation of QOLCQ and the corresponding MQOL in each domain pair (Spearman's  $r = 0.65-0.97, p = < 0.001$ ). Contrast groups comparison yielded positive and significant correlations between different levels of overall QOL evaluation (ANOVA,  $p < 0.001$ ). The reliability coefficient of QOLCQ was 0.91. Other than the emotional well-being domain, no significant difference was found in the QOLCQ scores between the cancer and COPD patients. **Conclusions:** The QOLCQ is found to be a valid and reliable instrument to elicit the QOL concerns of patients with advanced COPD. Studies reveal that the degree of suffering experienced by patients dying from chronic respiratory diseases is not less than that of patients with cancer. This study implied that palliative care provided to the advanced COPD patients should be addressed.

# 1640/DEVELOPMENT AND PSYCHOMETRIC PROPERTIES OF THE OCCUPATIONAL PERFORMANCE APPRAISAL QUESTIONNAIRE

Kwokfai Leung, Occupational therapy, Queen Elizabeth Hospital, Hong Kong SAR, PRC

**Aims:** The Occupational Performance Appraisal Questionnaire (OPAQ) was developed as a screening tool and gross service outcome indicator for in-patient and out-patient receiving occupational therapy service in public hospitals in Hong Kong SAR, China. The OPAQ is regarded as a Patient Reported Outcome (PRO) instrument. It consists of 7 questions asking subjective appraisal of occupational performance in 7 essential occupational areas, which are: self care, domestic, work, communication with people, leisure, use of public facilities and balanced use of time. **Methods:** A cohort of patient and healthy subjects was recruited from hospitals, out-patient clinics and the community. Patient subjects were suffering from either chronic pulmonary or psychiatric conditions. All the subjects were asked to complete the OPAQ twice within 7 days. **Results:** 430 subjects were recruited. The mean OPAQ total score of the whole sample was 65 (SD 13). There were no obvious floor and ceiling effect in the score. Factor analysis resulted in a two factor structure, in which, satisfaction to performance in self care, domestic activities, work and use of time form a factor accounting for 31% of the variance, and communication, leisure, and use of public facilities formed another factor accounting for 24% of the total variance. The mean OPAQ score of in-/day- patients, out-patients and health subjects were 60, 66 and 71 and were found statistically significant. The OPAQ scores have fair correlation to the domain scores of the WHOQOL-Bref, ranging from 0.40 to 0.57. This indicated that OPAQ was tapping information on occupational performance which is different from information capture by quality of life scale. The Cronbach's  $\alpha$  value was 0.747, showing good internal consistency. Both test-retest reliability and inter-rater reliability were good, with ICC value of 0.8347 (95% CI 0.759, 0.8882) and 0.8348 (95% CI 0.7590, 0.8883) respectively. **Conclusions:** The OPAQ is capturing information on subjective appraisal of the subjective on his/her own occupational performance, which is not covered by most existing PRO instruments. It shows good psychometric properties and can be recommended for use in clinical work.

## # 1474/QUALITY OF LIFE DATA: WHAT TO DO WHEN IT IS MISSING?

Shona A. Fielding & Peter M. Fayers, Public Health, University of Aberdeen, Aberdeen, UK

**Aims:** Missing data is a serious issue when analysing quality of life (QoL) data. Simulation methods previously used to explore ways to handle missing data are inherently flawed because the missing data pattern is pre-specified. A unique opportunity to compare procedures for imputing missing data arose with a large (5000+) trial dataset, since it employed a reminder system to recover data otherwise missing. This process reduced the non-response rate from 30% to 8%. The ability to recover information originally missing allows the comparison of imputation procedures on 'missing yet known' data. **Methods:** People who responded to the questionnaire after reminders were identified and treated as missing. Logistic regression was used to test the mode of missingness (missing completely at random, missing at random or missing not at random). The missing values were imputed using various existing procedures, including regression, hotdecking and multiple imputation and compared to the observed values. In addition a new imputation procedure based on an adaptation of last value carried forward (LVCF) is introduced and evaluated. Methods were compared using several accuracy measures: bias, root mean square deviation (RMSD), mean absolute deviation (MAD) and proportionate variance (PV). **Results:** Logistic regression suggested the data were most likely missing at random. Most imputation methods were biased towards estimating the QoL scores higher (better) than observed. LVCF was shown to be the most accurate. However, it is often inappropriate when patients are in an unstable condition. The new method was just as accurate as LVCF for the RMSD, MAD and PV although not quite as good for bias. **Conclusions:** In longitudinal studies involving QoL data, where QoL is assumed to be reasonably constant over time, LVCF is a suitable imputation method. The new method proposed here does not have the disadvantages that LVCF carries and may be a more robust imputation procedure for general purposes when QoL cannot be assumed to be stable over time.

## # 1291/ANALYSIS OF QUALITY OF LIFE DATA FROM A CLINICAL TRIAL ON EARLY BREAST CANCER BASED ON A NON-PARAMETRIC GLOBAL TEST FOR REPEATED MEASURES WITH INFORMATIVE CENSORING

Dongsheng Tu, NCIC Clinical Trials Group, Queen's University, Kingston, ON, Canada; Yaqing Chen & Peter X. Song, Mathematics and Statistics, York University, Toronto, ON, Canada

**Aims:** The quality of life (QOL) data from cancer clinical trials are often incomplete because of patient dropout due to various reasons. Recently, several methods have been proposed in the statistical literature for the analysis of the incomplete repeated measures with possible informative censorings. We apply a nonparametric global test developed by Sun and Song (2001, *Statist. Med.*, 20: 63-73) to reanalyze the QOL data from a clinical trial on early breast cancer conducted by the NCIC Clinical Trials Group. **Methods:** This trial compared CEF with CMF and randomized 710 eligible patients. The QOL of patients was measured using the Breast Cancer Chemotherapy Questionnaire (BCQ) every cycle during the treatment and then every 3 months until 2 years after the completion of the treatment. BCQ consists of 30 questions, each of which was answered on a 7-point Likert scale. We are interested in the comparison of two treatment groups in terms of a global scale derived as the mean of the scores on all 30 questions. At the end of the assessments, around 30% of patients in either treatment groups had complete data on the global scale. To apply the global test, the patients are first divided into 12 withdrawal groups based on the last time they had non-missing assessments. The withdrawing probability for each group is then estimated based on the data, which is used to weight the difference of QOL scores between two groups to form the global test statistic. **Results:** The analysis showed an insignificant difference between two treatment groups, which was consistent to the results obtained from the growth curve analysis and a response based analysis, partly because of the similarity in the dropout patterns between two treatment groups. **Conclusions:** This test would be a useful tool to check the sensitivity of the results from standard methods derived under the missing at random assumption.

## # 1148/THE LONGITUDINAL ANALYSIS OF THE CONSEQUENCES OF SCHIZOPHRENIA AND SCHIZOPHRENIA TREATMENT ON SUBJECTIVE QUALITY OF LIFE

Reinhold Kilian, Psychiatry II, University of Ulm, Guenzburg, Germany; Matthias C. Angermeyer, Psychiatry, University of Leipzig, Leipzig, Germany

**Aims:** The study examines the effects of interpersonal differences and transitory changes of objective living conditions, clinical characteristics and type of psychiatric treatment on the transitory change of subjective quality of life in persons with schizophrenia over a period of 2.5 years. **Methods:** A representative sample 307 patients with schizophrenia (ICD-10 F 20) was followed over a period of 2.5 years. Objective and subjective quality of life, clinical characteristics, type of neuroleptic treatment and outpatient treatment setting were assessed five times every 6 months. Propensity score method was used to control selection bias. Error-component regression models were computed to analyze cross-section (between effects), longitudinal (within effects) and combined (random effects) effects. **Results:** Objective QOL indicators and psychopathological symptoms and subjective drug side effects were revealed to have only within but no between effects on subjective QOL. For general functioning and depression within as well as between effects were obtained. Patients who received neuroleptic treatment were found to have a better subjective QOL than patients who received no neuroleptics while for type of neuroleptic medication no effect was detected. Outpatient treatment setting had no effect on subjective QOL. **Conclusions:** Change of subjective quality of life was mainly affected by the idiosyncratic changes of objective QOL indicators but not by interpersonal differences. These results may explain why most cross-sectional studies found only weak relationships between objective and subjective QOL. Weak effects of psychiatric treatment characteristics suggest that changing the medical and non-medical treatment features do not have an important impact on subjective QOL.

## # 1597/EXTENSION OF BROWN'S PROTECTIVE RESTRICTION FOR LONGITUDINAL STUDIES WITH NON-IGNORABLE DROPOUT

Diane L. Fairclough, Colorado Health Outcomes Center, University of Colorado Health Sciences Center, Denver, CO

**Aims:** Pattern mixture models are a popular method for the analysis of longitudinal studies when dropout is potentially non-ignorable. However, most restrictions actually assume that the missing data are conditionally ignorable. The aim is to extend the restriction proposed by Brown (Biometrics, 1990) from the simple bivariate case to the more general longitudinal setting with monotone dropout. **Methods:** As a first step, we simulated longitudinal data with known mean, covariance and dropout mechanism. Correlation of observations over time was assumed to be both moderate ( $\rho = 0.5$ ) and strong ( $\rho = 0.8$ ). Missing data are generated as a function of the previous estimate (conditionally ignorable) or the current estimate (non-ignorable). Missing data are multiply imputed under Brown's protective, Neighboring Case Missing Value (NCMV) and Available Case Missing Value (ACMV) restrictions in a sequential fashion over time and the resulting datasets are analyzed using standard procedures for multiply imputed data. Results are compared to the known parameters of the simulated data. **Results:** When the missing data was generated under a non-ignorable mechanism, the estimates obtained under Brown's restrictions are less biased than under the other restrictions or maximum likelihood estimation. However, when the correlation over time is moderate ( $\rho = 0.5$ ) there remains significant bias. This is substantially reduced when the correlation is strong ( $\rho = 0.8$ ), but does not disappear altogether. **Conclusions:** This approach may add another alternative to the options that can be considered as part of a sensitivity analysis for longitudinal studies with dropout. The next step will be to examine the robustness of the technique to deviations of the assumptions such as skewed non-normal distributions and mixtures of dropout mechanisms.

#### # 1330/FALSE POSITIVE ERROR IN THE ANALYSIS OF PAIRED QUALITY OF LIFE DATA

Daniel Fong, Clinical Trials Centre; K.F. Lam, Statistics & Actuarial Science; CW Kwan, Clinical Trials Centre; JST Sham, Clinical Oncology; J.P.E. Karlberg, Clinical Trials Centre; The University of Hong Kong, Hong Kong SAR, PRC

**Aims:** Virtually all quality of life measurements are discrete. Consequently, in analysis of paired quality of life data, ties (i.e. zero differences) may often occur. Unfortunately, the presence of ties may lead to false positive results. Therefore, we aimed to show how conclusions can be wrong, and to suggest appropriate methods of analysis. **Methods:** The potential problem with ties was illustrated in a clinical trial of Chinese cancer patients who underwent 6-week qigong training. The SF-36 (HK) was administered at baseline, 6 weeks, and follow-up. The paired *t*-test, ties-adjusted signed rank test, sign test, and two recently proposed modified sign test and likelihood ratio sign test that account ties, were used to examine the change of SF-36. **Results:** Totally 169 patients completed the SF-36 at baseline and 6-week. The median 6-week change of the Role Physical scale was 0 (mean = 16; 47% ties). However, the *t*-test, the ties-adjusted signed rank and the sign test all concluded a highly significant change ( $p < 0.001$ ). The modified sign test and likelihood ratio sign test concluded an insignificant difference ( $p = 1.000$  for both tests). The same problem was observed in some other scales. In the Physical Functioning scale where the median change was 0 (mean = 0), all tests gave an insignificant conclusion ( $p > 0.269$ ). In the Mental Health scale where the median change was 4 (mean = 4), all tests gave a significant conclusion ( $p < 0.020$ ). Note these results may not adequately reflect the effects of qigong since not full data were analyzed in here. **Conclusions:** For the analysis of paired quality of life data with ties, one may obtain significant *p*-value for a zero median difference due to inflated false positive error when ties are not properly handled. The modified sign test and the likelihood ratio sign test are recommended especially when the underlying distribution is asymmetric.

#### # 1209/TOWARDS AN OPTIMAL HEALTH-RELATED QUALITY OF LIFE (HRQL) MEASUREMENT STRATEGY UNDER CONDITIONS WHEN RESPONSE SHIFT IS LIKELY TO OCCUR

Sara Ahmed, Nancy E. Mayo & Sharon Wood-Dauphinee, Epidemiology and Biostatistics; Robin Cohen, Oncology and Medicine; James Hanley, Epidemiology and Biostatistics, McGill University, Montreal, PQ, Canada

**Aims:** Developing an estimator of HRQL that differentiates between the effects of an intervention or illness from response shift is essential for the interpretation of the results. The purpose of the present paper was to contrast three methodological approaches for evaluating response shift to develop a proposed set of HRQL measurement guidelines under circumstances where response shift is expected to occur. **Methods:** The three approaches compared were a structural equation modeling technique, the 'then' test, and an individualized approach using the Patient Generated Index (PGI). The data collection for these methods was incorporated into a post-stroke randomized controlled trial of 150 subjects. **Results:** The structural equation modeling technique did not show a response shift, contrary to the results of the 'then' test and the individualized approaches. There was a significant relationship between changes on the individualized measure and the average magnitude of response shift as evaluated by the 'then' test with those who 'reduced' ( $\chi^2 = -13$ ,  $se = 6$ ) or 'expanded' ( $\chi^2 = -19$ ,  $se = 8$ ) areas on the PGI had a significantly lower magnitude of response shift as compared to subjects who chose 'completely different areas'. Factors that need to be considered before selecting a methodological approach include feasibility, subjects' cognitive ability including memory and more advanced cognitive tasks, and whether the approach evaluates response shift at the group or individual level. **Conclusions:** Response shift evaluation is necessary for the interpretation of HRQL outcomes, and further development and testing of methods to assess response shift that can easily incorporated with HRQL measurement are needed.

#### # 1196/RESPONSE SHIFT IN QUALITY OF LIFE IN PATIENTS WITH SMALL CELL LUNG CANCER

Marjan J. Westerman, Social Medicine, EMGO Institute, VU University Medical Center, Amsterdam, The Netherlands; Tony Hak, Methodology, Rotterdam School of Management, Rotterdam, The Netherlands

**Aims:** To describe response shift in QOL in patients with small cell lung cancer and to interpret it against the background of their illness trajectory. **Methods:** A qualitative exploratory longitudinal multiple case study involving 31 patients (16 men and 15 women, aged 39–82 years). Multiple interviews were conducted at equivalent points of the illness trajectory starting soon after initial diagnosis. All interviews were audio taped. Each interview consisted of (a) EORTC QLQ-C30 and EORTC QLQ-LC13 applying the Three-Step Test-Interview (TSTI) protocol; (b) a then-test of the same instruments and TSTI; (c) SEIQOL-DW; and (d) a semi-structured interview. Because of attrition due to the high mortality, the number of interviews per patient varied. 6 patients were interviewed only one time. In the other 25 patients, 2–8 interviews per patient were conducted, resulting in 85 response shift episodes (i.e., comparisons between measurements in subsequent interviews). Response shift in individual patients was analysed first, followed by analysis of similarities and differences between patients. **Results:** Applying the then-test to explore changes in internal standards is hindered by recall error regarding (1) the specific point in time of the previous measurement, and (2) what patients had thought or felt at that time. SEIQOL-DW is a useful tool for assessing change in values and concepts, but only if results are interpreted with information from the transcripts of the SEIQOL-DW session. QOL scores remain stable or get better in almost all patients, despite deteriorating health. This phenomenon can be explained by changes in internal standards and values, and a reordering of life goals, which were mainly related to 'optimism about recovery' and to comparisons with even sicker patients. **Conclusions:** For a correct interpretation of QOL scores in SCLC patients, specific knowledge of their response shift as provided by this study is necessary. Because results are specific for the illness trajectory of SCLC patients, similar research in other groups of patients is necessary to make sense of their QOL scores.

#### # 1608/CAUSAL ATTRIBUTIONS AND FORGIVENESS AS MEDIATORS OF THE HEALTH-RELATED QUALITY OF LIFE OF CANCER PATIENTS

Paulomi T. Raiji & James P. Donnelly, Counseling, School & Educational Psychology, University at Buffalo/SUNY, Amherst, NY; Sukamal Saha, Surgical Oncology, Michigan State University, Flint, MI

**Aims:** This study addresses two potentially important mediating variables in HrQoL: (1) attributions about the causes of disease and (2) forgiveness of perceived causes. The study addresses the 'black box' criticism that has been directed at response shift theory by targeting specific mechanisms (attributions and forgiveness). In addition, forgiveness appears to be efficacious for a variety of issues (e.g., divorce) but has not been studied in cancer patients. **Methods:** The study employed a semi-structured interview to explore the nature of patient thinking about causes of disease and forgiveness. The sample included 45 adult cancer patients with mixed diagnoses (25 females; 20 males) who were interviewed in an outpatient clinic. The protocol included free-response items about perceived causes of cancer. The participants were also asked to discuss their thoughts about forgiveness and whether forgiveness of the perceived cause might make a significant difference in their adjustment. **Results:** All of the patients interviewed in this study made some attribution about the cause of their disease, including behavioral, environmental and fateful causes. Strikingly, all of the patients strongly endorsed the importance of forgiveness in maintaining quality of life. Sixteen patients (36%) indicated that thinking about the cause of the illness was a continuing source of struggle in their adjustment and furthermore that they would like to be able to forgive, but did not know how. **Conclusions:** The results of this study have implications for theory and practice in HrQoL. Response shift researchers should consider including causal attributions as an important mediating variable. The results also suggest that forgiveness interventions may be relevant to patients in general, and particularly important for a subset for whom meaning is a central aspect of successful adaptation.

#### # 1568/RESPONSE SHIFT MASKS THE CLINICAL IMPACT OF TREATMENT ON IQOL IN EDENTULOUS PATIENTS

Lena Ring, Psychology, RCSI, Dublin, UK; David Harris & Frank Heuston, School of Dental Science, Trinity College, Dublin, UK; Stefan Hoefler & Ciaran A. O'Boyle, Psychology, RCSI, Dublin, UK

**Aims:** A change in an individual's health state could result in a response shift (RS) i.e., changing internal standards (recalibration), values (reprioritisation) or conceptualisation (reconceptualisation) of QoL. Individualised QoL (IQoL) measures allow respondents to select the domains most important to them and determine their relative importance. IQoL measures, combined with a then test, may allow for assessment of RS in clinical trials. The aim was to assess RS using the IQoL measure SEIQoL-DW and a then-test comparing implant supported dentures and conventional dentures in edentulous patients. **Methods:** IQoL data are reported for 122 edentulous patients (mean age 64.8; 32% male) prior to and 3 months after receiving high quality conventional dentures. The Oral Health Impact Profile (OHIP) and the Denture Satisfaction Questionnaire were also administered. **Results:** Compared to baseline, dentures did not increase IQoL, using conventional scores (pre: 74.98; post: 73.37,  $p = ns$ ). However, the then- and post-test comparison showed a treatment effect (then: 69.33; post: 73.37,  $p = 0.016$ ). Recalibration was reflected in differing pre- and then-test scores and reconceptualisation by 86.1% of patients changing one or more domain. There were no changes in the relative importance of domains, indicating no reprioritisation. Improvements were seen on both OHIP and DSQ. **Conclusions:** Improvements in edentulous patients' QoL, following treatment with conventional dentures, was only apparent when RS was taken into account. The SEIQoL-DW can be used to assess reprioritisation and reconceptualisation and can be administered as a then-test to assess recalibration. When using subjective measures, an RS may mask treatment effects in clinical trials. Acknowledgement: Royal Victoria Hospital, School of Dentistry, Belfast for patient recruitment and Straumann Ltd, Switzerland for financial support.

#### # 1378/IMPACT OF MEASURING PATIENT-REPORTED OUTCOMES IN CLINICAL PRACTICE: A SYSTEMATIC REVIEW

Anna Kotzeva, Health Services Research Unit, Institut Municipal d'Investigació Mèdica (IMIM-IMAS), Barcelona, Spain; J. Alonso & M. Espallargues, Barcelona, Spain; C. Ferrans, University of Illinois, Chicago, IL; G. Guyatt, Clin. Epi. & Biostatistics, McMaster University, Hamilton, ON, Canada; M. Halyard, Mayo Clinic, Scottsdale, AZ; A. Parada, Barcelona, Spain; D. Revicki, MEDTAP International, Bethesda, MD; T. Symonds, Sandwich, Kent, UK; J.M. Valderas, Barcelona, Spain

**Aims:** There is increasing interest in using patient-reported outcome (PRO) information in clinical practice, but evaluation of its impact is inconclusive. **Objective:** To assess the usefulness of providing patients' PRO information to health care professionals in daily clinical practice. **Methods:** A systematic review of randomised clinical trials. Data sources: MEDLINE and the Cochrane Library (2nd issue of 2003) databases; reference lists of 3 previous systematic reviews; and non-systematic approaches, including the 'related articles' search in PubMed and requests to authors and experts in the field. Four pairs of reviewers assessed studies for eligibility and extracted data independently. Consensus was reached in the cases of disagreement and index of inter-rater reliability (Cohen's  $\kappa$ ) was calculated. **Results:** Out of 1446 identified publications, 33 articles corresponding to 27 original studies, published between 1978 and 2003 were considered eligible for the review. Overall agreement on study eligibility was substantial (median  $\kappa = 0.70$ , range: 0.53–1.00). The majority of trials (19) were conducted in primary care settings; were carried out in the US (21); and assessed adult patients (25). PRO information provided to professionals was: generic health status (10), mental health (13), other specific (5). Eight trials provided single feedback and the rest, multiple or additional interventions. Investigators studied a wide variety of interventions, and measured a wide variety of outcomes. In most instances, impact on PROs was unmeasured or limited. A few studies suggested a possible important impact on patient care. **Conclusions:** The number of trials assessing the effect of providing PRO information to health professionals is high, and provide clues as to how to structure interventions to result in benefits for patient care.

#### # 1128/USING PATIENT-REPORTED QUESTIONNAIRES IN ONCOLOGY CLINICAL PRACTICE: ASKING THE RIGHT QUESTIONS

Claire F. Snyder, Sydney M. Dy & Danetta E. Hendricks, Health Policy & Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD; Julie R. Brahmer, Antonio C. Wolff & Michael A. Carducci, Oncology, Johns Hopkins School of Medicine, Baltimore, MD

**Aims:** Questionnaires used in oncology practice to help manage patients need to address issues that patients find important and want help with, and for which cancer center staff can help. In this descriptive study, we asked patients and staff to rate items from 4 widely used questionnaires for this purpose. **Methods:** We surveyed 61 cancer patients (19 lung/20 breast/14 prostate/8 other; 8 new/34 on-treatment/19 follow-up; 56 with ECOG  $\leq 1$ ) and 19 staff (3 MD/12 nurse/4 social work) at Johns Hopkins. The survey included the item content from the EORTC QLQ-C30, FACT-G, Supportive Care Needs Survey-34 (SCNS), and Kingston Needs Assessment-Cancer. Patients rated the importance of each item and whether they wanted help with it; staff rated the importance of each item and whether they felt they could help patients with it. Patients and staff also indicated the questionnaire they preferred overall. Mean item ratings for patients and staff were ranked and compared qualitatively. **Results:** Patient ratings of importance and desire for help differed qualitatively from those of staff. Patients rated information about treatments (options, benefits, side effects) and care coordination as the most important issues and those for which they most wanted help from the staff. Staff rated pain and other symptom/side effect items as most important to patients and those for which they are most able to help. In general, traditional QOL domains were not rated highly. Findings were consistent across tumor type and treatment status. The SCNS was most preferred by patients overall. Staff had no clear questionnaire preference. **Conclusions:** Patients were most interested in help keeping informed about their disease/treatment and in care coordination. Staff felt most able to help manage the symptoms/side effects of disease and treatment. A needs assessment approach may be useful for managing patient QOL issues/needs in the outpatient oncology setting. More research is needed on the role of QOL measures in clinical practice.

#### # 1625/AN EVALUATION OF THE RELEVANCE OF HRQOL DISCUSSION IN OUTPATIENT CONSULTATION TO THE LEVEL OF IMPAIRMENT AS MEASURED BY THE DQLI

Sam Salek & Sophie David, Centre for Socioeconomic Research, Cardiff University, Cardiff, UK; Zahra Ahmed & Andrew Finlay, Dermatology, University of Wales College of Medicine, Cardiff, UK

**Aims:** Dermatologists supposedly take into account their estimation of how badly their patients lives are impaired when taking management decisions. This study aimed to determine if a relationship exists between a patient assessed health related quality of life (HRQoL) score and the extent of quality of life (QoL) related discussions in dermatology outpatient clinic consultations. **Methods:** This was a prospective study observing consecutive unselected dermatology patient consultations. The clinic consultations were by consultant, specialist registrar or nurse specialist. Data was recorded concerning any mention of QoL related subjects, based on the ten subject areas of the DQLI. A DQLI questionnaire was completed by patients after each clinic consultation. **Results:** 38 consultations were observed and 100 evaluable DLQI's returned. In 94 (39%) of consultations there was no mention of QoL matters. Of the 144 (61%) consultations which included QoL discussions, in 84 (35%) the clinician initiated discussion and in 60 (25%) the patient initiated discussion. In the 144 consultations in which QoL was discussed, 92% discussed 1–2 items only and 8% discussed three or more items. Of the 100 consultations for which a DQLI was returned the mean DLQI score was 5.6 ( $\pm 6.61$  SD), median of 3 and range 0–28. The mean DLQI score of the patients in whom there was no QoL discussion was 4.1 ( $\pm 4.9$ ),  $n = 39$  compared to the mean DQLI score in whom QoL was discussed (7.3 $\pm 7.61$ SD),  $n = 61$  ( $p < 0.001$ ). **Conclusions:** This study for the first time provides evidence that very little information concerning QoL is elicited in dermatology outpatient consultations.

#### # 1230/COMPUTERIZED ASSESSMENT OF QUALITY OF LIFE IN PATIENTS UNDERGOING CHEMOTHERAPY

Bernhard Holzner, Psychiatry, University Hospital Innsbruck, Innsbruck, Austria; August Zabernigg, Internal Medicine, County Hospital Kufstein, Kufstein, Austria; Georg Kemmler, Sabine Baier, Martin Kopp & Barbara Sperner-Unterweger, Psychiatry, University Hospital Innsbruck, Innsbruck, Austria

**Aims:** To study the impact of computerized Quality of Life (QoL) assessment in the daily clinical routine of an oncological outpatient unit for the treatment of chemotherapy (CT) patients. **Methods:** Cancer patients, who were receiving CT at the day clinics of the Department of Internal Medicine, Kufstein County Hospital, participated in a longitudinal study extending over 1 year. At each visit the patients were asked to fill in the EORTC QLQ-C30. The patients were randomly assigned to two groups: in the intervention group the physicians were given a chart of the course of the patients' QoL (EORTC-QLQ C30) including reference data to be used in each patient's visit; in the control group no feedback regarding QoL was provided. After each visit a patient and a doctor feedback questionnaire (including patient satisfaction) was filled in and initiated medical interventions were recorded. **Results:** 60 cancer patients (55% female; mean age  $61.5 \pm 9.5$  years; main diagnoses: 16.6% breast, 13.3% lung, 15.0% gastro-intestinal cancer) attended between 2 and 15 (median = 4) oncological visits. The routinely QoL assessment was found to be feasible and was well accepted by both the physicians and the patients. The mean duration of the visits was  $7.3 \pm 3.7$  minutes with no difference between the two groups. Patient satisfaction with care slightly improved in the intervention group while no relevant change was observed in the control group. In a fifth (17.4%) of the patient visits medical interventions were initiated as a consequence of the interpretation and discussion of the QoL profile (intervention group). The majority of these were treatment of symptoms (20% pain, 13.3% sleep disturbances, 13.3% constipation/diarrhea), followed by further examinations (20%), psychooncological treatment (13.3%) and changes of the CT procedure (6.7%). **Conclusions:** Based on the promising results of the study a computer software was developed to professionalize the assessment and processing of individualized QoL data and was implemented in the oncological outpatient unit.

#### # 1458/THE USE OF THE BRIEF FATIGUE INVENTORY IN SYSTEMIC RHEUMATIC PATIENTS

D. A. Fedorenko, A. V. Kishtovich & T. I. Ionova, Head QOL Group, Multinational Center of Quality of Life Research, St. Petersburg, Russia; A. A. Novik, National Pirogov Medical Surgical Center, Moscow, Russia; X. Shelley, S. Wang, T. R. Mendoza & C. S. Cleeland, Anderson Cancer Center, Houston, TX

**Aims:** Fatigue is a common symptom in rheumatic diseases and negatively affects health-related quality of life. At present, an instrument that assesses fatigue in rheumatologic conditions is not available in Russia. The purpose of this work was to study the relevance of using the Russian-language version of the Brief Fatigue Inventory (BFI-R) among patients with systemic rheumatologic diseases, and to assess its psychometric properties. **Methods:** We enrolled 164 patients with systemic rheumatologic diseases (systemic lupus erythematosus, rheumatoid arthritis, systemic sclerosis, mixed connective tissue diseases, dermatomyositis) into the study. The BFI-R was administered to patients upon admission to hospital with active disease. In addition, Russian-language versions of the SF-36 and a numeric pain assessment scale were used. **Results:** From 60 to 85% of patients involved in the study reported having fatigue. Fatigue was

associated with pain, sleep disorders, disease activity, rheumatoid factors, and systemic variables. The utility of the BFI-R among this group of rheumatic patients was demonstrated. All questions were easy to read and to understand. An analysis of the frequency response distribution showed that patients made choices on all responses, with only a small (0.54%) missing-data rate. The BFI-R also showed good psychometric properties. Cronbach  $\alpha$  coefficients were greater than 0.9. Construct validity, assessed by factor analysis, confirmed 1 factor composed of 3 fatigue severity items and 6 interference items. Known-group validity showed that patients with poor health performance status had pronounced fatigue. **Conclusions:** In conclusion, the BFI-R has been shown to be a reliable and valid tool for assessing fatigue in those who suffer from systemic rheumatologic disease. Implementation of the BFI-R to assess fatigue will contribute to better patient symptom management and improve quality of care for these patients.

#### # 1379/FROM THEORETICAL MODELS TO CROSS-CULTURAL COMPARABLE QUESTIONNAIRE DIMENSIONS - THE EUROPEAN HRQOL KIDSCREEN MEASURE FOR CHILDREN AND ADOLESCENTS

Jeanet Bruil & Symone Detmar, Child Health, TNO Prevention and Health, Leiden, The Netherlands; Angela Gosch, Quality of Life & Child and Adolescent Health; Ulrike Ravens-Sieberer, Child and Adolescent Health; EUROPEAN KIDSCREEN GROUP, Quality of Life & Child and Adolescent Health, Robert Koch Institute, Berlin, Germany

**Aims:** Aim of the instrument is to describe hrqol of the child/adolescent from multiple perspectives in European health surveys as well as in pediatric studies, identifying children at risk in terms of their hrqol to suggest early interventions, making cross-national comparisons possible, thereby providing information for health planning. **Methods:** Several steps were undertaken in 13 countries simultaneously: a literature review, followed by a Delphi-study among experts, focus groups among children/adolescents and parent questionnaires, a pilot study and a large validation study. RASCH analyses and conventional psychometric methods were used to assess structure, reliability and cross cultural validity. **Results:** Children and adolescents participated in 36 focus groups and 83 parents received a mailed questionnaire. Using this method, 1642 statements by children and 863 by parents were collected. Using EUROHIS rules, the number of items was reduced to 1070 (26 dimensions). Using a card sorting technique, the number of statements was further reduced to 185 statements (9 dimensions). Statements were thereafter formulated to items and translated according to international standards. Cognitive debriefing led to item reformulation for some items. The theoretical model was confirmed in the pilot study, in which a ten scale questionnaire (52 items) was identified. A validation study was conducted in 13,289 youths and 13,092 parents in 13 European countries (response rates up to 82%) in which the 52-item structure was confirmed with good scale reliabilities. Whereas the model identified was feasible for each country, significant differences in mean scores were found between countries on all scales. **Conclusions:** Conclusions are that the methods used including the cross cultural approach were valuable to obtain a hrqol questionnaire that can be used in public health as well as pediatrics cross-culturally. By using KIDSCREEN, hrqol can be assessed in a meaningful way according to the model identified by experts, parents and children/adolescents.

# 1510/CROSS-CULTURAL VALIDATION OF THE GENERIC KIDSCREEN CHILD MEASURE: RESULTS FROM REPRESENTATIVE SURVEYS IN 12 EUROPEAN COUNTRIES

Ulrike Ravens-Sieberer, Child and Adolescent Health, Robert Koch Institute, Berlin, Germany; Luis Rajmil, Catalan Agency for Health and Technology Assessment, Barcelona, Spain; Michael Erhart, Research Unit Child Health, Robert Koch Institute, Berlin, Germany; Mick Power, Psychiatry, University of Edinburgh, Edinburgh, UK; Pascal Auquier, Public Health, University of Marseilles, Marseilles, France; Michael Herdman, 3D Health Research, Barcelona, Spain, for the Kidscreen Group Europe

**Aims:** The aim of the KIDSCREEN project was to develop and validate a self-reported HRQoL instrument for children and adolescents. A former pilot study led to a 52 item questionnaire with 10 dimensions to be validated in surveys. **Methods:** A representative sample of children and adolescents 8–18 years old (total  $n = 21,804$ ) was collected in 12 European countries (A,CZ,CH,D,E,F,GB,NL,HU,PL,GR,S). Children and parents filled in mailed questionnaires. Besides Kidscreen, other measures were included in the survey (CHQ, YouthQoL, CHIP, KINDL, PedsQoL). Psychometric properties were analysed stratified by age, gender and country using Rasch Partial Credit Modelling (PCM), Differential Item Functioning (DIF: Zumbo's OLR method), MAP analyses, ICC, and CFA. ANOVA was performed to analyse construct validity controlling for SES variables. **Results:** Rasch model fit using PCM was good (PCM INFITmsq: 0.80–1.26), so was the CFA fit (CFI = 0.979, RMSEA = 0.049). MAP results were very good (scaling success > 97.5%, Reliability: Cronbach's  $\alpha$ : 0.77–0.89). DIF analyses were satisfactory by countries, age groups and gender. The correlation coefficients between other QOL measures and the Kidscreen were high in dimensions measuring similar constructs (Pearsons  $r$  0.46–0.65). The standards of psychometrics properties have been achieved across gender, age groups and countries. All Kidscreen dimensions showed a gradient according to the socio-economic status. Significant differences between healthy and ill children (CSHCN Screener) were found in most Kidscreen dimensions and between respondents categorized as Normal and Noticeable on the SDQ mental health screener (ES 0.30–0.74). **Conclusions:** The Kidscreen measure shows good validity to be used in several different European countries as a HRQL instrument for children and adolescents.

# 1514/VALIDITY OF THE EUROPEAN KIDSCREEN-52 PROXY MEASURE

Stephane Robitail, Public Health, University Hospital of Marseille, Marseille, France; U. Ravens-Sieberer, Child and Adolescent Health, Robert Koch Institute, Berlin, Germany; J. Bruil, TNO, Leiden, The Netherlands; M. Power, Psychiatry, University of Edinburgh, Edinburgh, UK; L. Rajmil, Agència d'Avaluació de Tecnologia, Barcelona, Spain; B. Cloetta, University of Bern, Bern, Switzerland; W. Duer, University of Vienna, Vienna, Austria; J. Mazur, National Research Institute, Warsaw, Poland; L. Csémy, Prague Psychiatric Centre, Praha, Czech Republic; A. Czimbalmos, Child Health Department, Budapest, Hungary; C. Dimitrakaki, University of Athens, Athens, Greece; P. Auquier, Public Health, University of Marseille, Marseille, France

**Aims:** A children European cross-cultural HRQoL instrument is being developed during the KIDSCREEN project. Concurrently, a proxy instrument is built. To assess relationships between self and proxy HRQoL report, the validity of the proxy measure has to be confirmed. The aim of this study is to assess the validity of the KIDSCREEN-52 proxy instrument. **Methods:** The European KIDSCREEN field survey involved about 22,400 youth and 16,600 parents as proxy

across 13 countries. Multidimensional construct has been assessed with MAP analysis and confirmatory factor analyses (CFA). Non-parametric IRT and Rasch analyses have been used to assess the scalability of each dimension. Zumbo's OLR method has been applied to assess the DIF between proxy: father or mother ( $n = 13,340$ ). Trait validity has been explored using CFA to test a Multi-Trait Multi Methods model (MTMM). **Results:** MAP results showed satisfactory scaling success. Confirmatory factor analyses (LISREL) indicates satisfactory fit of the children's model to the parents data (CFI = 0.967). The unidimensionality of every dimension has been confirmed (H: 0.45–0.79, INFIT: 0.74–1.31). No large DIF effect has been retrieved for all of the items ( $\Delta R^2 < 0,5\%$ ). Items with larger DIF belonged to psychological and social dimensions. Reliability was good ( $\alpha$ : 0.77–0.90). Agreement between youth and proxy report were satisfactory (ICC: 0.45–0.62). MTMM model test is satisfactory (CFI = 0.990). **Conclusions:** This promising tool enables to explore the relationships between youth and proxy HRQoL measure in European countries. DIF study between proxy is a topic for future research.

# 1552/COMPARISON OF THE FRENCH VERSION OF THREE HRQL INSTRUMENTS FOR ADOLESCENTS IN A HEALTHY SAMPLE.

Karine Barrau & M. C. Simeoni, Public Health, University Hospital of Marseille, Marseille, France; U. Ravens-Sieberer, Child and Adolescent Health, Robert Koch Institute, Berlin, Germany; V. Serra-Sutton, Agència d'Avaluació de Tecnologia, Barcelona, Spain; D. Patrick, Department of Health Services, University of Seattle, Seattle WA; S. Robitail, P. Auquier, Public Health, University Hospital of Marseille, Marseille, France

**Aims:** The French KIDSCREEN field survey was carried out during the year 2003 in a population based adolescents sample. The profile KIDSCREEN-52 items has been used with other instruments: VSP-A (39 items-France: Profile and Index), and YQOL-S (8 items-USA). **Methods:** To better understand similarities and discrepancies between these HRQoL instruments, we compare their psychometric properties, their correlations and Item Response Theory (IRT) has been used to assess their relationships through anchoring methods. Partial Credit Modelling analysis has been performed with WINSTEPS®. Responses were obtained from 679 randomised adolescents. **Results:** Acceptability was satisfactory for YQOL-S, VSP-A and KIDSCREEN research instrument: missing data were lower than 5% for the 3 instruments. Item internal consistency and item discriminant validity were satisfactory for the VSP-A and the preliminary KIDSCREEN research instrument. Internal consistency (Cronbach's  $\alpha$ ) was good for the three instruments: VSP-A: 0.73–0.91, KIDSCREEN-52: 0.70–0.85 (except for one dimension 0.61) and Y-QOLS: 0.83. Ceiling effects (> 15%) were found only for 2 out of the 21 dimensions. Divergent and convergent validity was supported by relevant correlations between YQOL-S, VSP-A and the 52 items KIDSCREEN research instrument. Rasch analyses results were good. Only very few items showed slight misfit to the data (INFIT statistic were comprised between 0.60 and 1.40 except for one item). Anchoring methods allowed to compare the calibrations of the items of the different dimensions of the instruments. **Conclusions:** This study confirmed the pilot study's promising results of reliability and validity of the three instruments in the French adolescent population. IRT enables the assessment of each instrument construct but also comparing each instrument with the others. Item banking could be a promising future step for these instruments.

# 1422/HEALTH PROFESSIONALS PERCEPTIONS OF FEEDING RELATED QUALITY OF LIFE IN CHILDREN WITH QUADRIPLEGIC CEREBRAL PALSY

A. M. Morrow, CKR, Children's Hospital at Westmead, Sydney, NSW, Australia; J. C. Craig, CKR, CHW, Sydney, NSW, Australia; M. T. King, CHERE, UTS, Sydney, NSW, Australia; E. V. O'Loughlin, Gastroenterology, CHW, Sydney, NSW, Australia

**Aims:** 90% of children with quadriplegic cerebral palsy (QCP) have difficulties with feeding due to impaired swallowing. Our aim was to examine health professionals (staff) opinions on the major determinants of feeding related quality of life (QoL) in children with QCP. **Methods:** 45 staff members took part in 5 semi-structured focus groups conducted by a trained facilitator during September and November 2003. Participants were recruited through two pediatric university teaching hospitals in Sydney and included pediatricians (n = 18), nurses (n = 15) and allied health (n = 13). The response rate was 77%. Recruitment ceased when informational redundancy was reached. N-Vivo software was used to analyse transcribed audiotapes. **Results:** Participants thought the QoL of child and parent were inseparable and that domains could not be ranked as their relative importance would vary between families. They believed physical functioning (e.g. aspiration, nutrition) and comfort (e.g. hunger, choking), parent-child interaction (e.g. provision of care, emotional impact), social participation (e.g. sharing meals, social acceptability), the child's emotional well being (e.g. happiness) and delivery of health services (e.g. access to services, interaction with staff) were contributing factors. The time impact of provision of care emerged as a strong theme. Physicians were more likely to identify physical function and comfort as being important while nursing and allied health participants were more likely to identify parent-child interaction however there was significant overlap. Overall staff were strong advocates of tube feeding and felt that the parents need to nurture and normalise their child was the greatest barrier to accepting intervention. **Conclusions:** Staff felt that parental and child QoL were inseparable in children with QCP. Physical functioning and parent-child interaction emerged as important themes. This has implications for design of QoL tools and clinical practice. Further work to identify parental perceptions is required.

# 1547/THE ROLE OF COGNITIVE DEBRIEFING IN DEVELOPING A SYMPTOMS DIARY

Elaine McColl, Cathy Stark & John Bond, Centre for Health Services Research, University of Newcastle upon Tyne, Newcastle upon Tyne, UK

**Aims:** Structured diaries are useful in capturing contemporaneous data on symptom experience and severity. For two trials of the management of chronic constipation in older adults, we needed to develop a diary to assess bowel function, symptoms of chronic constipation and the side effects of its management, and use of laxatives and other management strategies. We carried out cognitive debriefing interviews, to check on participants' understanding of the items, and to refine a draft diary. **Methods:** 16 older adults were invited to complete the draft diary for 2-4 weeks and then to participate in a cognitive interview. A total of 14 interviews were conducted by a researcher in the respondent's home, generally within 3 days of diary completion. We asked about respondents' experiences of completing the diary, and about their understanding of the terms used. Interviews were audio-taped. The completed diaries, tapes and contemporaneous field notes were reviewed and analysed to identify potential problems with questions and instructions. **Results:** A number of potential problems with the symptom diary were identified. For some respondents, the term 'bowel movement' raised queries; should the passing of a very small amount of waste be counted? Respondents highlighted problems when experiences - for example, of the need to strain - varied across a given day. Reflecting other researchers' experience, the term 'abdominal' was found to be ambiguous. **Conclusions:** Our findings indicated that some of the draft items were open to misinterpretation, posing a threat to data quality. On the basis of the findings from these cognitive debriefing interviews, we have refined the diary in a number of ways. We have added a 'glossary' of the terms used to describe the symptoms and have included a diagram to show what is meant by 'abdominal'. The techniques we have used are applicable to the development and refinement of other measures of patient-reported outcomes.

# 1362/COMPARISON OF THE CLINIMETRIC IMPACT METHOD AND THE PSYCHOMETRIC METHOD, IN THE DEVELOPMENT OF A DISEASE-SPECIFIC HRQOL MEASURE FOR ALLERGIC RHINITIS (AR)

Eva Baró, for the ESPRINT Investigators, Outcomes Research, 3D Health Research, Barcelona, Spain

**Aims:** The clinimetric impact method (CIM) and psychometric method (PM) are alternative approaches for developing HRQoL questionnaires, which have been insufficiently compared. We compared results of using CIM, and PM in selecting and organizing items for a new disease-specific HRQoL measure for allergic rhinitis (AR). **Methods:** A pool of 58 potential items was administered to 413 patients with AR. Responses to each item were assessed in terms of frequency and degree of bother. CIM analysis: an impact index (INX) for each item was calculated by multiplying the frequency and bother scores and items scoring the highest on the INX were selected. Items were then grouped into domains on the basis of expert opinion. PM analysis: redundant and unsuitable items were deleted, factor analyses were performed, and items were selected and grouped into domains using standard psychometric criteria. In both methods item-scale statistics were estimated. **Results:** Of the 58 items in the initial pool, 38 (65.5%) were retained by at least one of the methods and 16 (27.6%) were common to both methods; CIM selected 27 items distributed in 7 domains (nasal and eye symptoms, tiredness, daily activities, environment, sleep, psychological impact). Overall Cronbach's  $\alpha - CA$  - was 0.93 and ranged between 0.68 (environment) and 0.84 (sleep and tiredness). PM produced a version with 28 items, and the final factor analysis confirmed a 5-factor solution (psychological impact, tiredness/energy, social, environment and sleep/symptoms associated) which explained 56.6% of the variance. Overall CA was 0.94 and ranged between 0.70 (environment) and 0.86 (tiredness/energy). **Conclusions:** Questionnaire content varies considerably according to the approach used, but internal consistency is satisfactory in both versions. No quantitative differences between the results for the different methods were found which could aid in deciding which method to use. Determining which version performed best in clinical practice or research would provide further information to answer this question.

# 1610/AGREEMENT OF HEALTH-RELATED QUALITY OF LIFE (HRQL) DATA OBTAINED BY DIFFERENT FORMATS: DETERMINING WHEN SUBSTITUTION IS APPROPRIATE

Carol M. Moinpour, SWOG Statistical Center, FHCR, Seattle, WA; Gary W. Donaldson, Anesthesiology, U Utah, Salt Lake City, UT; Sheryl McCoy, SWOG Statistical Center, FRCHR, Seattle, WA; Patricia J. Hollen, Nursing, U Virginia, Charlottesville, VA; Richard J. Gralla, Medical Oncology, Columbia-Pres Med Ctr, New York, NY; Mark G. Kris, Medical Oncology, MSKCC, New York, NY

**Aims:** Visual analogue scale (VAS) assessment methods are common in the HRQL literature but data programs such as Teleform and DataFax cannot directly accommodate this format. We compared ratings from the Lung Cancer Symptom Scale (LCSS) VAS format with a numerical rating scale (NRS) format to see if the NRS could be substituted for the VAS in clinical trials research. **Methods:** 67 patients completed first the VAS, then the NRS, format of the LCSS on one occasion. The following methods addressed agreement: scatter plots to identify extreme discrepancies; the intraclass correlation coefficient (ICC) and Lin's concordance correlation coefficient (CCC) to examine general agreement; CCC scale and location shift values and Bland Altman (BA) plots with smoothed non-linear trends to address bias and any association between the average difference and scale position. Effect size as a method of interpreting mean differences by format was not used because a small expected denominator magnifies even a small mean difference or bias suggesting artificially large, clinically significant differences. **Results:** ICC and CCC showed excellent to good agreement for 2 summary (0.91 and 0.93) and 7 individual item (0.87 to 0.94) scores, but poor agreement for appetite and hemoptysis (0.51 and 0.66). The appetite agreement was suppressed by several apparent score reversals across the 2 formats. BA plots obscure the effect of reversed scores. **Conclusions:** The concordance measures support the near equivalence of NRS and VAS formats, particularly for the 2 summary scores, although format substitution can never occur with perfect confidence.

# 1567/DEVELOPING SHORT FORMS FROM FULL FORMS FOR DISEASE SPECIFIC MODULES IN PAEDIATRIC QUALITY OF LIFE RESEARCH: THE HAEMOQOL EXPERIENCE

Silke Schmidt, Sylvia von Mackensen, Holger Muehlan, Eva Pollak & Monika Bullinger, Medical Psychology, University Clinic of Hamburg-Eppendorf, Hamburg, Germany

**Aims:** The use of modular systems to assess Quality of Life (QoL) in specific patient population is increasingly advocated. With this approach it is possible to both assess generic and condition related components of QoL. The availability of short, psychometrically robust and clinically meaningful disease-specific modules is increasingly considered important, especially in paediatric research. **Methods:** Using the dataset from a recent study into the development and testing of an instrument to assess QoL in children with haemophilia (the HAEMO-QOL), specific psychometric approaches were used to identify a short form. The aim was to reduce the original set of 77 items and 12 subscales to minimum set of items, applicable to different age groups, representing the content of the scales and reflecting the respective scale structure. Statistical methods included classical psychometric methods, IRT (item response theory) approaches and SEM (structural equation modelling) models. The analytical strategy, developed within two pediatric European projects (DISABKIDS and KIDSCREEN), was applied to the HAEMOQOL data set, available from 339 children in three age groups. **Results:** The results showed that depending on the conceptual approach and aims of the analysis strategy, different versions of short forms could be identified, fulfilling basic psychometric properties and reflecting the properties of the full scale. These different solutions are presented and discussed with regard to criteria governing the choice of a short form in terms of reflection of the total score, representation of subscales, fulfillment of unidimensional properties or complying with the 'ruler' concept. **Conclusions:** The results of the analyses will be examined in comparison with the DISABKIDS experience in constructing short forms from full instruments in the dataset of 1606 children with different chronic conditions in Europe. Implications for the development of short forms for research and clinical practice will be discussed.

# 1627/USING ITEM RESPONSE THEORY TO DEVELOP AN EFFICIENT AND INFORMATIVE SHORT FORM OF THE CES-D

Timothy Stump & Colleen A. McHorney, Regenstrief Institute, Indianapolis, IN

**Aims:** The purpose of this presentation is to illustrate how item response theory (IRT) can be used to create an efficient short form of the Center for Epidemiological Studies-Depression (CES-D) scale. The CES-D is one of the most widely used measures of depressive symptoms. Previous CES-D short form (SF) measures have been developed largely using elderly populations and classical test theory. **Methods:** We studied the 20 polytomous CES-D items in the NHANES-I, a national probability sample of 3059 persons aged 25–74. Using MULTILOG, we obtained item difficulty and discrimination estimates for Samejima's graded response model and generated item characteristic, item information, and test information curves. To create a SF measure based on IRT information, we blinded ourselves to item content. Then, we eliminated items with low discrimination parameters and, thus, low item information. We also eliminated items where there was substantial overlap between option response categories. The resulting CES-D SF had 13 items. To reduce the number of items to half the original scale ( $k = 10$ ), we eliminated three additional items on the basis of item information. We then compared test information curves for the full 20-item version, our 13 and 10-item versions, and three previously reported CES-D SFs. **Results:** All SFs were most useful in distinguishing among persons with depression ( $\theta < 0$ ). Maximum information for the full 20-item version was 20.9 ( $\theta = -1.8$ ). Maximum information for the 13 and 10-item versions occurred at  $\theta = -1.8$  and was 19.1 and 17.5, respectively. The IRT-derived SFs reduced test length by 35 and 50%, respectively, while only losing 9 and 16% in measurement precision. In contrast, maximum information for previously reported SFs was 10.1, 11.5, and 11.8, resulting in a loss of measurement precision of 44–52%. **Conclusions:** Using IRT methods, we derived two CES-D SFs that retain maximum information and measurement precision for use in general populations.

# 1476/RELIABILITY AND VALIDITY OF THE KIDNEY DISEASE QUALITY OF LIFE INSTRUMENT (KDQOL-SFTM) FOR KOREAN KIDNEY DIALYSIS PATIENTS

Sehyun Kim, Preventive Medicine; Hye J. Park, Nursing, College of Medicine, Pochon CHA University, Sungnam, Kyonggi-Do, Republic of Korea; Jin S. Yong & Sung S. Han, Nursing, Catholic University, Seoul, Republic of Korea

**Aims:** Assessment of quality of life with end-stage renal disease will provide information to evaluate the care delivered. The objective was to validate a Korean translation of the KDQOL-SFTM instrument. **Methods:** We have been followed rigorous translation steps guided by the KDQOL Working Group. Forward translation into Korean, reconciliation to establish the conceptual equivalence and consistency, pilot test, panel discussion and backward translation into the original English version were performed. A consecutive sample of 164 dialysis patients was included. Reliability was assessed by test-retest correlation coefficients and Cronbach's  $\alpha$ . Construct validity was evaluated by examining correlations between kidney disease-targeted scales and SF-36 scales. **Results:** Test-retest correlation coefficients ( $n = 30$ ) of the kidney disease-targeted scales ranged 0.59–0.92 and those of SF-36 scales ranged 0.38–0.92. The social function scale of the SF-36 had the lowest test-retest correlations ( $r = 0.38$ ;  $p < 0.05$ ). The Cronbach's  $\alpha$  of the kidney disease-targeted scales ranged 0.45–0.93 and those of SF-36 scales ranged 0.65–0.92. Quality of social interaction scale and the sleep scale had low Cronbach's  $\alpha$  of 0.58 and 0.45, respectively. Overall health rating score was correlated with scales of symptoms/problems, effects of kidney disease, burden of kidney disease, cognitive function and quality of social interaction (all  $p$ 's  $< 0.05$ ). In addition, overall health rating score was positively correlated with all the items of SF-36 (all  $p$ 's  $< 0.05$ ). **Conclusions:** The results support the applications of the Korean KDQOL-SFTM in studies evaluating the health-related quality of life in Korean dialysis patients.

# 1177/THE CHINESE QUALITY OF LIFE INSTRUMENT: RELIABILITY AND VALIDITY OF THE HONG KONG CANTONESE VERSION (CHQOL-HK)

Li Zhao, School of Chinese Medicine; Ngar-ting Lui, School of Chinese Medicine; Kelvin Chan, School of Chinese Medicine, Hong Kong Baptist University, Hong Kong, PRC; Kwok-fai Leung, Occupational Therapy, Queen Elizabeth Hospital, Hong Kong, PRC

**Aims:** As a result of the previous geographical, political and cultural separation between Mainland China and Hong Kong for over 100 years, each region's corresponding languages and alphabetical characters have evolved and become somewhat different. We now present the result of translation and cross-validation of the Chinese Quality of Life Instrument (ChQOL) in Hong Kong. This is an extended part of the ChQOL studies following the successful development of the Mandarin version used in Mainland. The ChQOL is a scientifically developed health-related quality of life instrument based on Chinese culture and the practice of Chinese medicine. It incorporates the holistic balance model of health concept of Chinese medicine and is applied to assess the efficacy of treatment using Chinese medicine, western medicine and integrative medicine. This study aimed to evaluate the development and psychometric properties of the Hong Kong Cantonese version of the ChQOL (ChQOL-HK). **Methods:** A standard translation procedure was followed. A prospective study was carried out among 122 subjects consisting of 53 healthy subjects and 69 patients with chronic illness in Hong Kong. **Results:** The intra-class correlation between test and retest ranged from 0.76 to 0.83 in the facets and 0.89 to 0.92 in the domains. The Cronbach's  $\alpha$  coefficients were above 0.70 for all facets and domains. The correlation coefficients between indices measuring similar dimensions of the ChQOL-HK and WHOQOL-BREF (HK) ranged from 0.62 to 0.71. Healthy subjects revealed higher scores of quality of life than patients. **Conclusions:** The psychometric properties of the ChQOL-HK scale were satisfactory. It has good reliability, validity and is reliable like the source scale and sensitive cross-culturally.



# 1466/COMPARISONS AMONG THREE CHINESE VERSIONS OF THE WHOQOL QUESTIONNAIRE

Kai-Ping G. Yao, Psychology, National Taiwan University, Taipei, Taiwan, ROC

**Aims:** Currently, three Chinese versions of the WHOQOL questionnaire have been developed in the Mainland China, Hong Kong, and Taiwan. The Mainland China version was finished in 1995, the Hong Kong version in 1997, and the Taiwan version in 1999. Each version added its own unique national questions in accord with the criteria proposed by the WHOQOL Group at Geneva. The purpose of this study was to compare the quantitative and qualitative properties of these three Chinese versions in terms of their psychometric properties, national items, and population norms. **Methods:** This study was based on the analyses of the published/unpublished research papers and documents from the WHOQOL Questionnaire Development Group of the three areas. The sample sizes (male: female) were 838:816, 425:416, and 530:530 respectively. **Results:** Psychometric analyses identified the similar results in terms of their reliability and validity indices. In evaluation of cultural item selection, both Taiwan and Hong Kong versions selected 12 items while China version selected only three items. The items in the Taiwan and Hong Kong versions were fairly similar in 9 out of 12 items. However, only one item in the China version is similar to the Hong Kong version. The same two new facets ('Being respected/Accepted (Guanxi/Mientze)' and 'Eating/Food') were proposed in both Taiwan and Hong Kong versions. However, the Taiwan version classified the two facets into the 'Social Relationships' and 'Environmental' domains, respectively, while the Hong Kong version classified both facets into the 'Psychological' domain. Finally, the Mainland Chinese have better physical and psychological QOL but worse environmental QOL. The Hong Kong Chinese have better environmental and spiritual QOL but worse social QOL. The Taiwanese have better social and independent QOL but worse physical and psychological QOL. **Conclusions:** The WHOQOL questionnaire was comparable among the Mainland Chinese, Hong Kong Chinese, and Taiwanese. However, cultural differences were also found. We suggest that for broader application, the WHOQOL questionnaire should expand its cultural adaptation role in accounting not only for all individual cultures and sub-cultures, but also for various societal policies and program planning.

# 1430/FACTOR INVARIANCE OF THE WHOQOL-BREF TAIWAN VERSION ACROSS HEALTHY AND DISEASE GROUPS

Kai-Ping G. Yao & Chia-Huei Wu, Psychology, National Taiwan University, Taipei, Taiwan, ROC

**Aims:** The aim of this study was to investigate factorial invariance of the WHOQOL-BREF Taiwan version across healthy population and populations with diverse major diseases (such as cardiac disease, pulmonary disease, hypertension, diabetic mellitus, peptic ulcer, sinusitis, liver disease, and renal disease) by using the data from the 2001 National Health Interview Survey (NHIS) in Taiwan. **Methods:** The NHIS was conducted by stratified multistage systematic sampling resulting in responses from 13,083 participants aged 20 and above who also completed the WHOQOL-BREF Taiwan version. Populations with particular diseases were diagnosed by a doctor. Those who have more than one major disease were excluded in this study. Healthy population was defined as the participants without the above 8 major diseases, stroke, and blindness. In this study, both exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) on a four-factor model are conducted. To compare the EFA factor structures among population groups, factor congruence coefficient (FCC) which measures the degree of similarity between two factor structures from two independent samples was calculated for each pair of factors. To compare the CFA factor structures among population groups, two-sample analyses with unconstrained/constrained parameters were conducted to confirm the comparability of factor structures between two groups. **Results:** Both EFA and CFA results showed incomparability of factor structures among groups. **Conclusions:** Factor invariance of the WHOQOL-BREF version across health and disease groups was not supported.

# 1483/KOREAN TRANSLATION AND VALIDATION OF PARKINSON'S DISEASE QUESTIONNAIRE (PDQ-39): A PILOT TEST

Hye J. Park, Nursing; Sehyun Kim, Preventive Medicine, Pochon CHA University, SeongNam, KyunggiDo, Republic of Korea; Hyo J. Song, Nursing, Che Ju University, Che-Ju, Chejudo, Republic of Korea; Kyung A. Shong, Nursing; Kwang S. Lee, Neurology, Catholic University, Seoul, Republic of Korea

**Aims:** Tremor, rigidity, abnormally slow body movements and postural instability characterize Parkinson's disease (PD). As the disease progresses the physical symptoms may affect other aspects of daily life and create additional psychological and social problems. The PDQ is a specific quality of life scale for evaluating the dysfunction of daily living and quality of life for PD patients. The objective of this study was to validate a Korean translation of Parkinson's disease questionnaire (PDQ-39). **Methods:** To evaluate the conceptual equivalence and consistency of the items and scales, reconciliation and focus group discussions were performed. After completing forward translation, a pilot test was conducted for cognitive debriefing. In the pilot test, we compared the quality of life 14 PD outpatients with 10 normal aged matched controls using translated Korean PDQ-39. **Results:** Of the 14 patients and 10 controls, 11 (84.62%) and 6 (60.0%) were women. The mean (SD) age of patients and controls were 72.15 (5.98) and 80.10 (8.06) years. Cronbach's  $\alpha$  of eight domains (Mobility, Activities of daily living, Emotional well-being, Stigma, Social support, Cognition, Communication, Bodily discomfort) were above 0.85. The score of mobility and bodily discomfort correlated with activities of daily living, emotional well-being, stigma, cognition, communication, bodily discomfort except social support (all  $p$ 's < 0.05). The activities of daily living positively correlated with emotional well-being, social support, cognition, communication and bodily discomfort (all  $p$ 's < 0.05). There were significant differences of the score of mobility, activities of daily living, emotional well-being and stigma between patients and controls (all  $p$ 's < 0.05). **Conclusions:** These results support the applications of the Korean PDQ-39 in field test assessing and evaluating the Parkinson's disease patients.

# 1404/DEVELOPMENT AND TESTING OF THAI SMOKING CESSATION QUALITY OF LIFE ASSESSMENT INSTRUMENT

Supakit Wongwiwatthanankit, Thitiporn Naktuan & Rawadee Dhuma-Upakorn, Meng, Clinical Pharmacy, Chulalongkorn University, Bangkok, Thailand

**Aims:** To develop a reliable and valid Thai Smoking Cessation Quality of Life Assessment Instrument (TSCQoL). **Methods:** Generated items were based on literature review, SF-36 Thai version and informal interviews with smokers, ex-smokers and healthcare professionals. The initial 95-item instrument was comprised two aspects, 71 items were intended to quantify the impact of smoking cessation on perceived functioning and well-being in adults (HRQoL aspect) and 24 items were intended to assess the inherent burden associated with the use of smoking cessation pharmacotherapies (PTRQoL aspect). Following content validation by expert review panels, the instrument was pre-tested with 20 smokers and ex-smokers. Subsequently, the revised instrument was large scale-tested with 431 smokers and ex-smokers for HRQoL aspect and 78 smokers and ex-smokers receiving pharmacotherapies for PTRQoL aspect. Exploratory factor analysis (EFA), item analysis, and known-group validity were used to examine the construct validity and reliability of the instrument. **Results:** Results indicated that the instrument had content validity, construct validity and high reliability. The HRQoL aspect was revised to 36 items with overall coefficient  $\alpha$  0.93. EFA revealed four subscales for HRQoL aspect: (1) general well being, (2) satisfaction, (3) self-control, and (4) mental and emotional problems. Mann-Whitney-U test demonstrated that ex-smokers who had been abstinent for >3 months reported significantly higher QoL scores than smokers on four subscales ( $p$  < 0.02). The PTRQoL aspect was retained at 24 items and comprised two subscales: (1) psychosocial consequences and (2) negative consequences with overall coefficient  $\alpha$  0.83. Mann-Whitney-U test showed that participants receiving Bupropion SR reported significantly higher PTRQoL scores than participants receiving nicotine gum on psychosocial consequences subscale ( $p$  = 0.03). **Conclusions:** These findings provide preliminary evidence for the validity and reliability of the TSCQoL instrument.

# 1279/DEVELOPMENT AND CONSTRUCT VALIDATION OF THE KOREAN COMPETENCE SCALE (KCS)

Chang-Wan Han & Masahiro Kohzaki, Internal Medicine & Rehabilitation Science, Tohoku University Graduate School of Medicine, Sendai, Japan; Yuki Yajima, Public Health, Okayama University Graduate School of Medicine, Okayama, Japan; Eun-Joo Lee, Neuropsychology, Tohoku University Graduate School of Medicine, Sendai, Japan; Chun-Man Park, Public Health, Keimyung University Graduate School, Keimung, Korea; Kazuo Nakajima, Welfare System and Health Sciences, Okayama Prefectural University, Soja, Japan

*Aims:* Functional independence is an important factor that influences the quality of life (QOL) in older adults and, therefore, has attracted considerable researchers' attentions. The purpose of this study was to develop a comprehensive competence scale applicable for Korean older adults (called the Korean competence scale: KCS), and to evaluate its construct validity. *Methods:* The study subjects were older community residents living in the Song-ju area and Seoul, Korea. Out of 1964 people aged 65 years and over in the city, 1933 older adults were enrolled in the survey (response rate = 98.3%). The survey contents included demographic information (sex, age) and information concerning competence. The factor structure across two aged Korean samples was retested using exploratory and confirmatory factor analysis. *Results:* The factor structure of the Korean competence scale is a second-order factor structure comprised of three factors: 'Instrumental Self-maintenance', 'Intellectual Activity', and 'Social Role'. The exploratory factor analysis replicated the three-factor structure. The confirmatory factor analysis results showed that an acceptable solution could be estimated for a second-order factor model comprised of these factors. *Conclusions:* These findings provided evidence for the construct validity of the instrument and have implications for future research on factorial invariance.

# 1417/LINGUISTIC ADAPTATION AND VALIDATION OF PEDS-QLTM GENERIC CORE AND CANCER MODULE INTO CHINESE

Joseph T.K. Lau, Jing Mao, Mei Wah Chan & Ellie Pang, School of Public Health, Chinese University of Hong Kong, N.T., Hong Kong, PRC; Ming Kong Shing, Ki Wai Chik, Tai Fai Fok & Chi Kong Li, Department of Pediatrics, Prince of Wales Hospital, N.T., Hong Kong, PRC

*Aims:* The PedsQLTM is a modular instrument measuring health-related quality of life in children and adolescence. Comprised of the child's self-report and parent's proxy-report, the PedsQLTM integrates generic core scales and disease specific modules into one measurement system. The objective of the study was to adapt and validate PedsQLTM Generic Core Scales and Cancer Module into Chinese. *Methods:* Development of the Chinese version of the PedsQLTM followed the standard forward-backward method for instrument translation and pre-test step for cognitive testing. The finalized instrument was then administered to 170 pediatric cancer patients ages 2–18 and their parents to evaluate the psychometric properties of the instrument. *Results:* Internal consistency reliability of the Generic Core Scales (Cronbach  $\alpha = 0.88$  self-report, and 0.90 proxy-report) and Cancer Module Scales (Cronbach  $\alpha = 0.91$  self-report, and 0.89 proxy-report) were satisfactory. Parent/child report intercorrelation also showed consistent results comparable to the source tool. The Cancer module was further tested for construct validity using factor analysis. An eigenvalue cutoff of 1.0 resulted in a seven-factor solution for the child's self-report (accounting for 68% of the variance) and an eight-factor solution for the parent's proxy-report (accounting for 76% of the variance). The factors that emerged indicated a good fit between the structure model of the original English version and the Chinese translation. *Conclusions:* The psychometric properties of the Chinese PedsQLTM Generic Core Scales and Cancer Module were found to be satisfactory. Further work is currently being undertaken to assess the discriminant validity and test-retest reliability of the Chinese translation.

# 1396/TO DERIVE SCORING ALGORITHMS OF A PREFERENCE-BASED SINGLE INDEX OF HEALTH: FROM THE TAIWAN SF-36 HEALTH SURVEY

Yu-Hung Chang, Health and Related Research, University of Sheffield, Sheffield, UK

*Aims:* The main aim of this study is to elicit preference-based scoring algorithms, based on the general Taiwanese population, for computing a single index of health related quality of life (HRQOL) from SF36 by the rating scale method. The results were then compared with those derived from the UK survey. *Methods:* The data was from the National Health Interview Survey, pursued in Taiwan, 2002. There were 12,880 respondents, from 20 to 65 years old, completing both of the self-reported SF36 Version 1 Health Survey and a rating scale, being marked on a graduated line with the endpoints of 0 and 100, measuring the satisfaction of their own health states. The figure derived from the scale interpreted as a utility index of HRQOL was transformed to a 0-to-1 score as the same as the QALY unit. The responses to SF36 were abstracted to the SF6D classification, composed of six health dimensions, in which there are several levels reflecting severity of health problems. Regression methods were adopted to predict the utility index with the dummy variables (amount to 25) assigned to all levels in all dimensions of SF6D. A variety of models were made and the comparison between models had been done. *Results:* Firstly, all models broadly achieved consistency. Most of the coefficients of each model had the expected direction (85–100%) and followed the expected order (80–92%), and reached the significant level of 0.05 (73–96%). Secondly, the models with an estimated intercept, denoting the estimated value of perfect health, showed that the coefficients of intercepts were around 0.79–0.80, while the models where the intercept had been forced to unity had greater absolute values of coefficients than those in the models with an estimated intercept. Thirdly, up to 37% of the difference between actual and predicted values were within |0.05| and up to 65% were within |0.10|. Finally, being compared with the results of the UK survey, the Taiwan models showed similar consistency but less capacity of prediction. *Conclusions:* The algorithms derived from general population of Taiwanese provided consistent estimation for SF6D health states. More sophisticated modelling methods were suggested to improve predictive ability.

#### # 1088/DETERMINING SCALE DESCRIPTORS OF THE INTERVIEW VERSION OF WHOQOL FOR MINNAN PEOPLE

Chi-Wen Chien & Ching-Lin Hsieh, Occupational Therapy; Jung-Der Wang, Occupational Medicine and Industrial Hygiene, National Taiwan University, Taipei, Taiwan, ROC

**Aims:** This study aimed to determine appropriate scale descriptors for the interview version of World Health Organization Quality of Life questionnaire for Minnan people living in Taiwan (WHOQOL-Minnan). **Methods:** The WHOQOL consists of 4 kinds of response scales: capacity, frequency, intensity, and evaluation. Each response scale has 5 ordinal descriptors including 2 anchors for extreme levels and 3 intermediates. This study included 4 stages. (1) Two anchors were determined based on experts' opinions and the results of interviews of 67 adults. (2) More than 15 possible intermediates were compiled according to experts' suggestions. (3) A total of 61 adults were recruited to examine the test-retest reliability of these intermediates. An interviewer used a tape player to ask them to place each descriptor on a 20 cm line according to where they think each descriptor lies in relation to the 2 anchors. The unreliable descriptors were excluded and more than 10 descriptors for each response scale remained. (4) A total of 179 adults were recruited throughout Taiwan to finally determine appropriate intermediates at the 25, 50, and 75% intervals based on mean and standard deviation. **Results:** Five appropriate Minnan descriptors were completely not (oan5-choan5 boe7-sia2), a little (bo5 siaN2 e7-sai2), half (chit8-poaN3 chit8-poaN3), able (e7-sai2), and completely (oan5-choan5 e7-sai2) for capacity; never (it-tit8 long2 bo5), seldom (han2-leh u7), half (chit8-poaN3 chit8-poaN3), very often (si5-siong5 u7), and always (it-tit8 long2 u7) for frequency; completely not (oan5-choan5 boe7), slightly (bo5 siaN2 u7), half (chit8-poaN3 chit8-poaN3), mostly (tai7-pou7-hun7 u7), and extremely (oan5-choan5 u7) for intensity; and completely dissatisfied (oan5-choan5 bo5 moa2-i3), dissatisfied (bo5 kau3 moa2-i3), half (chit8-poaN3 chit8-poaN3), satisfied (moa2-i3), and completely satisfied (oan5-choan5 moa2-i3) for evaluation. **Conclusions:** These selected descriptors, as 5-point interval-like response scales, not only establish the foundation for the WHOQOL-Minnan but also have high potential to be used in any health-related questionnaires for Minnan people living in Taiwan, China or elsewhere.

#### # 1235/HEALTH-RELATED QUALITY OF LIFE IN COPD – ARE THERE ANY DIFFERENCES IN DATA FROM ASIA AND EUROPE IN CLINICAL STUDIES?

Elisabeth Ståhl, Clinical Science, AstraZeneca R&D Lund/University Hospital, Lund, Sweden; Klas Svensson, Clinical Science, AstraZeneca R&D Lund, Lund, Sweden

**Aims:** Multinational clinical studies pose important data challenges, one of which is the validity of combining data from different centres for overall analysis. The aim was to evaluate if health-related quality of life (HRQL) data from Asian and European countries can be combined to evaluate treatment effects. **Methods:** 245 patients (mean age 48 years) in Asia and 633 patients (mean age 51 years) in Europe were treated with budesonide, formoterol, the combination budesonide/formoterol or placebo for 1 year. HRQL was assessed using the Short Form 36 Physical Component Summary (SF-36 PCS) and St George's Respiratory Questionnaire (SGRQ). Baseline values and change after 1 year of treatment were compared between the continents. **Results:** There was consistency in baseline values in the 4 treatment arms using the SF-36 PCS, the Asian scores were 37–38 and the European scores 36–37. The SGRQ Total baseline scores varied between 46 and 50 in Asia and the score was 51 for all treatment arms in Europe. After treatment the changes were all small using the SF-36 PCS. These varied from 1.25 (B/F) to –1.55 (P) in Asia and the corresponding changes in Europe were –1.51 (B/F) and –3.73 (P). Using the SGRQ, the mean changes varied between –2.99 (B/F) and 2.30 (P) in Asia and between –1.85 (B/F) and 5.24 (P) in Europe. **Conclusions:** HRQL data was consistent both at baseline and after treatment between Asia and Europe. This supports the pooling of HRQL data from different continents.

#### # 1668/VALIDATION OF THE CHINESE PAIN CATASTROPHIZING SCALE (HK-PCS) IN CHRONIC PAIN PATIENTS

J.C. Yap, P.P. Chen, T. Gin, Anaesthesia, CUHK, AHNH, Hong Kong; T. J. Lau, Centre for Epidemiology & Biostatistics, School of Public Health, Faculty of Medicine, CHUK, Hong Kong, T. Wong, J. Chu, I. Chan, E. Wong, Clinical Psychology, CP COC, Hong Kong

**Aims:** Pain catastrophizing involve an exaggerated negative orientation towards a noxious stimulus. It is associated with increased pain severity, psychological distress, and disability in chronic pain patients. This study was conducted to validate and examine the psychometric properties of a Chinese version of the Pain Catastrophizing Scale (HK-PCS). **Methods:** The translation procedure involved a process of forward and backward translation, expert panel appraisal and field testing. Patients aged 18–79 with chronic non-malignant pain attending an outpatient multidisciplinary pain centre in Hong Kong participated in this cross-sectional study (n = 130). Subjects completed a set of self administered health-related instruments: HK-PCS, Numeric Pain Rating Scale, Hospital Anxiety and Depression Scale, Roland Morris Disability Questionnaire, SF-36 Health Survey, and a general demographic form. Data were analyzed for the distribution, internal consistency, reliability, and construct validity. **Results:** The internal consistency of HK-PCS was excellent (Cronbach's  $\alpha = 0.9270$ ). Item-total correlation coefficients ranged from 0.5752 to 0.7768. Test-retest reliability was good based on the intraclass correlation coefficient (ICC) for HK-PCS (ICC = 0.9693) and its subscales Helplessness (ICC = 0.9562), Magnification (ICC = 0.9446), and Rumination (ICC = 0.9101). Confirmatory factor analysis verified a second order factor structure with the Comparative Fit Index = 1.00, Root Mean Square Error of Approximation = 0.038, Normed Fit Index = 0.99 (Chi-square = 68.84 with 58 degrees of freedom,  $p = 0.16$ ). Moderate correlations were found between catastrophizing and pain intensity, disability, anxiety, depression, general health status ( $r = 0.223$ – $0.597$ ,  $p < 0.01$ ). There was minimal association between catastrophizing and gender contrary to existing literature. **Conclusions:** This study illustrated that the psychometric properties of HK-PCS were satisfactory. Our results provide preliminary evidence for the validity and reliability of the HK-PCS as an instrument for measuring pain catastrophizing in the Chinese patient with chronic pain.

#### # 1517/VALIDATION OF THE CHINESE VERSION OF PAQLQ IN HONG KONG ASTHMATIC CHILDREN

T. F. Leung, Paediatrics; Eliza L. Wong, Institute of Chinese Medicine; L. Y. Xu, Center for Epidemiology and Biostatistics; Rita Y. Sung, Paediatrics; P. C. Leung, Institute of Chinese Medicine, The Chinese University of Hong Kong, Prince of Wales Hospital, Shatin, Hong Kong

**Aims:** The Pediatric Asthma Quality of Life Questionnaire (PAQLQ) is one of the most widely accepted tools for assessing quality of life in Caucasian children. The objective of this study is to validate a Chinese translated version of PAQLQ in Hong Kong children. **Methods:** Asthmatic children aged 7–18 years were recruited from those attending pediatric clinics of a university teaching hospital in Hong Kong. These subjects participated in a 4-month observational study in which the Chinese PAQLQ was administered to them twice. Their asthma severity was assessed concurrently according to the Global Initiative for Asthma (GINA) guideline. **Results:** Two hundred and thirty-two patients were recruited. Asthma control remained stable in 140 children (Group A, 60%) and changed during follow-up in 92 patients (Group B, 40%). The Cronbach's  $\alpha$ -coefficients for the Chinese PAQLQ ranged from 0.789 to 0.902. The discriminant validity was demonstrated by significant association between the PAQLQ scores and asthma severity as classified by GINA criteria. Intraclass correlation coefficients for symptom, activity and emotion domains and overall score were 0.437, 0.559, 0.552 and 0.549 respectively. Factor analysis revealed acceptable construct validity for Chinese PAQLQ. All domains of our questionnaire were responsive to changes in asthma severity (Group B) during the study period ( $p < 0.0001$  for all). However, a significant difference was found between groups A and B in proportional mean score only for the overall score ( $p = 0.045$ ) and under its emotional domain ( $p = 0.003$ ). **Conclusions:** The Chinese PAQLQ has satisfactory internal consistency and validity but lower responsiveness to changes in asthma severity as compared to the original version following a standard cross-cultural adaptation process.

#### # 1197/CAN AQLQ(S) DATA FROM ASIA AND EUROPE BE COMBINED IN CLINICAL TRIALS?

Ann-Christin Mörk, Klas Svensson & Elisabeth Ståhl, Clinical Science, AstraZeneca R&D Lund, Lund, Sweden

**Aims:** Establishing the validity of combining patient-reported outcomes data from multinational clinical studies is a complex procedure. The conceptual equivalence of the local languages needs to be ensured by using a linguistic validation process. One important challenge from multinational clinical studies is the validity of combining data from different countries for overall analysis. The aim was to evaluate whether AQLQ(S) data from Asia and Europe can be combined to evaluate treatment effects. **Methods:** 1255 patients (mean age 36 years) in Asian and European countries were treated with either (1) budesonide/formoterol for both maintenance and relief of symptoms (B/F + B/F), or (2) a fixed maintenance dose of budesonide/formoterol plus short-acting  $\beta_2$ -agonist (SABA) as needed (B/F) or (3) a 4-fold higher maintenance dose of budesonide + SABA (B) for 1 year. The Asthma Quality of Life Questionnaire, standardised version (AQLQ(S)) was assessed at baseline, after 1, 6 and 12 months of treatment. Baseline values and change after 1 year of treatment were compared between the continents. **Results:** At baseline AQLQ(S) overall score ranged from 4.96–5.06 for Asia and 5.01–5.09 for Europe for the different treatment groups. There was no statistically significant difference in the mean of baseline values for AQLQ(S) overall score. The change from baseline after 1 year of treatment for the 3 treatment arms was 0.64/0.61 (B/F+B/F), 0.43/0.43 (B/F) and 0.52/0.44 (B) for Asia and Europe, respectively. There was no difference between the two continents with regard to change from baseline and the difference between treatment arms was similar between the two continents. **Conclusions:** The consistency in both magnitude of change after treatment and difference between treatment arms across the two continents supports the pooling of data from different continents. These data together with the linguistic validation suggest that the translations are measuring the same construct as the original and thereby support the validity of the translations.

#### # 1130/LINGUISTIC ADAPTATION AND VALIDATION OF THE GENERAL ORAL HEALTH ASSESSMENT INDEX (GOHAI) INTO JAPANESE

Mariko Naito, Health Informatics; Yoshimi Suzukamo, Epidemiology and Healthcare Research; Takeo Nakayama, Health Informatics; Shunichi Fukuhara, Epidemiology and Healthcare Research, Kyoto University School of Public Health, Kyoto, Japan

**Aims:** The General Oral Health Assessment Index (GOHAI) is a self-administrated questionnaire developed by Drs K. Atchison and T. Dolan in the USA to assess the impact of oral status on one's Quality of Life (QOL). This questionnaire consisting of 12 items was initially designed to assess the oral health of older adults but it has been used recently with people of different ages. It has been translated into languages other than English and used in many studies. The aim of the present study was to adapt the original instrument for use in Japan and assess the psychometric properties of the new version. **Methods:** Following international methodological recommendations, the GOHAI scale was translated in a standardized way consisting of forward translation, pilot studies and backward translation. Psychometric properties were assessed from 178 subjects in a community. **Results:** Pilot studies were carried out using the tentative scale amongst local residents and health professionals and, based on their results, the questionnaire was re-evaluated. Long question sentences, difficult expressions, and the mixture of negative and positive phraseology were suggested as problems. Hence, the tentative scale was revised with care in order to follow the original as closely as possible, and then the final version was completed. In a validation study, each of the 12 items on the GOHAI had response rates of more than 97%. Reliability in terms of a Cronbach's  $\alpha$  coefficient was 0.90. Construct validity was confirmed by the factor analysis and showed unidimensionality. There were correlations between the GOHAI scores and the number of missing teeth as an objective measure of oral status ( $p < 0.001$ ), and between the GOHAI scores and both the general health and physical functioning domains of the SF-36 questionnaire ( $p < 0.01$ ). **Conclusions:** The present study showed that the Japanese version of the GOHAI was psychometrically valid and conceptually equivalent. Further investigation of different kinds of validation is underway.

#### # 1381/DEVELOPMENT OF AN ITEM BANK TO MEASURE BOWEL FUNCTION IN PROSTATE CANCER

Jin-shei Lai, David Eton & David Cella, P-QOL Investigators, CORE, ENH & NWU, Evanston, IL

**Aims:** Bowel function (BF) problems may occur in men treated for prostate cancer, especially those treated with radiotherapy. Sensitive measurement can help in monitoring patient BF over time and facilitate clinician-patient communication. Modern computerized adaptive testing (CAT) can enable precise assessment of BF using a small number of items drawn from a comprehensive item bank. The purpose of this study was to develop a BF item bank. **Methods:** We included 211 early-stage prostate cancer patients, treated with surgery, radiation, and/or hormonal therapy. Mean age was 72.6 years (SD = 8.4). Most were Caucasian (68%). A computer touch-screen was used to administer 46 items measuring various aspects of BF. Psychometric properties were examined using traditional means (factor analysis and  $\alpha$  coefficients) and a single-parameter item response theory model (Rasch), in which items were determined to fit if the ratio between expected and observed item variance (MnSq) was less than 1.4. **Results:** Though factor analysis with varimax rotation uncovered 5 factors that collectively accounted for only 59.7% of the total variance; a substantial degree of content overlap across these factors was apparent with items having significant loadings across factors. Hence, further analyses were performed assuming a single factor structure (bowel function). A series of Rasch item analyses suggest removal of 8 items due to their high MnSq values (>1.4). Internal consistency among the remaining 38 items was high ( $\alpha = 0.97$ ) and item-total correlations were all greater than 0.3. **Conclusions:** These results demonstrate satisfactory psychometric properties of this comprehensive BF item bank. Future analyses comparing early- to advanced-stage patients are warranted. The final bank will be the foundation to develop a CAT platform for use with prostate cancer patients during and following treatment.

#### # 1587/COMPUTER-ASSISTED MOBILE MEASUREMENT OF MOOD

Matthias Rose, Psychosomatic Medicine, Charité University Hospital, Berlin, Germany; Otto Walter, Rueya Kocalevent, Janine Becker, Herbert Fliege & Burghard F. Klapp, Psychosomatics, Charité, Berlin, Germany

**Aims:** The use of computer-assisted data-gathering for psychometric diagnostics offers several organizational and economic advantages over paper-and-pencil questionnaires and the development of Computer Adaptive Tests promise to improve psychological assessment fundamentally. However, with regard to APA guidelines the equivalence of both administration forms must be tested for each questionnaire. We compared two administration modes of the Berlin Version of the Mood Adjective Check List (B-MACL). **Methods:** The B-MACL consisted of 30 items examining 'depressive anxiety', 'tiredness', 'apathy', 'anger', 'involvement', and 'elevated mood'. 10,547 psychosomatic patients were examined. 2892 of the patients filled out the paper-and-pencil version of the questionnaire; 7655 received a computer-assisted version on a mobile personal digital assistant (PDA). Each item was presented on the PDA screen separately. Factor analyses and structural equation models (SEM) were used for data analysis (SPSS, Mplus, AMOS). **Results:** The explorative factor structure of both versions proved to be almost identical. The confirmatory factor analysis showed an identical 6-factorial solution for both versions in a multi group design. The SEM with two super-ordinate latent variables ('negative vs. positive mood') had the best model fit (CFI 0.90, RMSEA 0.05). A comparison of matched samples showed that the administration mode had no effect on the values of most scales. However, the scale 'anger' was more sensitive using the PDA version. **Conclusions:** Six dimensions of mood could be replicated, each belonging to one of two super-ordinate mood dimensions. All six dimensions were sufficiently unidimensional to serve for the development CATs. For most of the dimensions the mode of administration had no effect for the scale values, but this was not the fact for the anger scale.

#### # 1577/COLLECTING REFERENCE DATA FOR HRQOL-INSTRUMENTS VIA THE INTERNET?

Ton Vogels, Symone Detmar, Hans Vogelaar & Erik Verrips, Child Health, TNO Prevention and Health, Leiden, The Netherlands

**Aims:** Internet based data collection is becoming an important tool in social sciences, also in the field of HRQoL. However, it is unknown whether it is suitable for collecting reference data for HRQoL instruments. Aim of this study is to gain some insight into this matter. **Methods:** We compared two different data sets. One data set was collected in a stratified sample, with mailed questionnaires (TACQOL Parent Form, by centres for Youth Health Care. The other data set was collected via the Internet. Visitors of 'Ouders online' ('Parents online') were asked to participate. After accepting the invitation, they filled in a Web-version of the TACQOL PF. First, background characteristics of respondents and children were compared (bivariate  $\chi^2$  and multiple logistic regression). Scale structure of the two data sets were assessed (Cronbach's  $\alpha$ , interscale correlation coefficients). Finally, scales scores were compared (Manova, with and without background characteristics). **Results:** Significant bivariate and multivariate differences were found for almost all background characteristics studied. Parents who replied via the internet reported significantly more chronic conditions among the children whose HRQoL status they described. Scales in the internet data set were less independent from each other.

Mean scale scores in the internet data set were significantly lower. These differences remained significant and sizeable when the differences in background characteristics were taken into account. **Conclusions:** Data collected via the internet, using procedures similar to ours, will not yield reliable reference data as such. Weighting or similar correction procedures are a possible solution. This is only possible when relevant criteria are known and measured. The standard background characteristics and chronic conditions we measured are insufficient weighting criteria. More theoretical and empirical work needs to be done to learn about factors that really affect HRQoL. Building reference data requires a careful and structured approach. The easy accessibility of respondents via the internet cannot compensate for such requirements.

#### # 1570/STATE OF THE QOL DATA BANK FOR GERMANY

Thomas Kuechler, Maria Berend, Jens-Ulrich Siebmann, Beate Bestmann & Bjoern Malchow, Reference Center Quality of Life in Oncology; Christian E. Schmidt & Bernd Kremer, General and Thoracic Surgery, University of Kiel, Kiel, Germany

**Aims:** 1998 the German Cancer Help granted 1998 the Reference Center – Quality of Life in Oncology- with the overall aim to actively support studies and activities on outcome research with focus on QoL and/or other patient-oriented measures. One of the long-term aims of this project is to establish a databank on QoL for most tumor entities and in different treatment modalities in Germany. **Methods:** After 5 years of data collection the state of the data bank can be summarized as seen in Table 1. **Results:** Beside these data on gastrointestinal cancer patients, the data bank contains QoL data of 1003 patients with lung cancer, 1357 patients with prostate cancer, 746 patients with renal cell carcinoma and QoL data of 1129 healthy controls. Beside using these data as reference values for clinical studies they may serve as well in quality management programs in Germany. For the international context we cooperate with Peter Fayers on his project-Cross-Cultural Analysis of the QLQ-C30. **Conclusions:** Based on these data it is possible to sketch 'typical' courses of QoL in different diagnostic groups. Furthermore this large number of data sets allows for assessment of effects like different surgical procedures, adjuvant regimens etc. The ongoing challenge is to combine these QoL data with relevant medical and socio-demographic data like age, gender, TNM staging or co-morbidity.

**Table 1.** QoL data bank

	Pre-operative	At discharge	3 months post	6 months post	12 months post	24 months post	Total
Colorectal	483	387	562	484	378	231	2525
Liver/ bile	131	79	136	126	101	55	628
Gastric	180	105	156	132	88	46	707
Esophageal	46	36	62	56	34	21	255
Pancreas	150	99	136	115	75	30	605
Total	990	706	1052	913	676	383	4720

# 1400/APPLICATIONS OF THE ITEM RESPONSE THEORY IN EXAMINING OPTIMAL CATEGORIZATION AND SHORTENING OUTCOME MEASURES

Eric Wong, Epidemiology and Biostatistics; Wai-Kwong Tang, Sandra Chan, Helen Chiu & Gabor S. Ungvari, Psychiatry; Ka-Sing Wong, Timothy Kwok & Vincent Mok, Medicine and Therapeutics, Chinese University of Hong Kong, Shatin, Hong Kong

**Aims:** The aim of this study is to illustrate the applications of Item Response Theory (IRT) in determining the optimal categorization and shortening of outcome measures using data gathered on the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) for Chinese stroke survivors in Hong Kong. **Methods:** The Chinese IQCODE was administered to a total of 284 stroke patients (mean age 69.4 years; 55.4% male) admitted consecutively to the Acute Stroke Unit. The Rasch rating scale model, a one-parameter IRT model, was used to fit the data. **Results:** The Rasch calibration revealed the original 26 items and 5-category IQCODE were easily endorsed with negative response by the sample. The average measures and the step calibration did not advance monotonically with category. The conversion to a 2-category version resulted in significant improvement in the matching of item difficulty to patient ability closely. Only 4 items were misfit or muted. The person and item indices were 1.95 and 4.33. In addition, the area under the ROC curves analysis indicated that there was no significant difference between the original and revised version of the IQCODE in the diagnostic performance. **Conclusions:** The IRT is a useful tool for evaluation the psychometric properties of outcome measures. The present illustration indicates the IQCODE could be improved through a reduction of categories and the removal of items, while maintaining plausible psychometric properties and having similar reliable performance as a screening instrument for poststroke dementia. Nevertheless, other vulnerable applications of IRT include differential item functioning, test equating and computerized adaptive testing.

# 1383/EXPANSION OF A PHYSICAL FUNCTION ITEM BANK AND DEVELOPMENT OF AN ABBREVIATED FORM FOR CLINICAL TRIALS

R. Bode, CORE, Northwestern University, Chicago, IL; J.S. Lai, D. Cella, J. VonRoenn, D. Shevrin & M. McGuire, CORE, Northwestern University, Evanston, IL

**Aims:** Physical functioning (PF) is a core health domain in virtually every model of health-related quality of life (HRQL). However, PF scales specifically targeting cancer patients who are the subject of many clinical trials are lacking. This has hampered the understanding of how treatments affect PF and how PF affects HRQL in people with cancer. The aim of this study is to expand an initial PF item bank and develop an abbreviated form that can be used in oncology clinical trials. **Methods:** The sample consisted of 295 patients from 4 oncology clinics who completed a 36-PF item bank. Patients were representative of the US cancer population in terms of gender and educational level. Data were analyzed using Rasch rating scale analysis to develop equal-interval measures from the entire PF item bank. Two sets of items were selected from the bank: a 5-item form, the BriefPF, and the commonly used and well-validated MOS PF-10, selected for performance comparisons. **Results:** The 36-item bank has a reliability estimate (Cronbach's  $\alpha$ ) of 0.97; the BriefPF, 0.86, and the PF-10, 0.92. The measures for all three significantly differentiate persons across ECOG PSR levels [PF bank ( $F(df = 3280) = 61.56; p < 0.001$ ); BriefPF ( $F(df = 3280) = 64.42; p < 0.001$ ); and the PF-10 ( $F(df = 3280) = 40.55; p < 0.001$ )]. While the entire bank is most precise across the entire PF continuum, the BriefPF is more precise at the lower end of function (ECOG PSR levels 2, 3, 4) and PF-10 is more precise at the higher end (ECOG PSR levels 0, 1). **Conclusions:** Both BriefPF and PF-10 are reliable and discriminate patients with different functional status. BriefPF is more sensitive than the PF-10 for lower functioning patients whereas the reverse is true for higher functioning patients. While both short forms are sufficient for clinical trial (group) comparisons, a computerized adaptive testing based on the PF item bank would more reliably measure the functioning of cancer patients across the entire continuum.

# 1524/MORE THAN 30 YEARS OF QUALITY OF LIFE RESEARCH  
L. Boyer, MD, S. Robitail, D. Debensason, D. Orbicini, A. Clément, M.C. Siméoni, P. Auquier, Public Health, University Hospital of Marseille, Marseille, France

**Aims:** During the last three decades, quality of life (QOL) has been perceived as an innovative indicator of patients self-perceived status, allowing integration of a qualitative approach in decision-making. In 1996, the Ljubljana charter on reforming health care in Europe considered QOL improvement as the principle of health care reforms. The purpose of this study is to define the current status of QOL research. **Methods:** We performed an analysis of all the abstracts related to QOL cited in Medline from 1973 to 2003. The key word used in the search was 'quality of life' as Medical Subject Headings Major Topic. **Results:** More than 17000 abstracts were identified and analyzed, 80% have been published the last 10 years and 50% the last 5 years. The language of publication is English in 83.5% of cases, German in 4.2%, French in 2.8%, Japan in 2.5% and Spanish in 1.7%. The journals which have published the largest number of articles on QOL are by descending order Quality of Life Research (3.49%), Journal of Clinical Epidemiology (0.96%), Journal of Clinical Oncology (0.95%), Medical Care (0.81%). Concerning methodological and theoretical topics, 1574 articles (9%) are related to the validation of a scale. Among these articles, 40 are devoted to item response theory (IRT) and 199 to the cross cultural adaptation. QOL in special populations are related to elderly in 55% (65–79y) and 13% (> 80y), children in 16%, Family/caregiver in 10.5%. The most frequent disease-specific applications of QOL research are oncology (21%), neurology (16%), mental health (15%), surgery (15%), cardiovascular disease (11%), urology (8%) and respiratory disease (7.5%). Specific research settings are clinical trials in 16%, epidemiological studies in 12%. **Conclusions:** Development and validation process are more and more frequent. We can note the emergence of new techniques as IRT. Clinical trials and epidemiological studies increasingly incorporate QOL measure. But QOL assessment is variable according to diseases. Challenge for tomorrow is to develop the use of QOL measures in routine medical practice and in population monitoring screening.

# 1247/COMPARISON OF A NEW QUALITY OF LIFE MEASURE, THE QOLIBRI, WITH GLOBAL AND GENERIC MEASURES IN INDIVIDUALS WITH TBI

Virginia Winter, Richard Greenwood & Jane Powell, RNRU, Homerton Hospital, London, UK; Jean-Luc Truelle, Neurologie, Hospital Foch, Suresnes, France; Nicole von Steinbuechel, Neurogerontopsychology, University Hospitals of Geneva, Chene-Bourg, Switzerland

**Aims:** The current lack of reliable and valid scales developed specifically for the assessment of quality of life (QoL) after traumatic brain injury (TBI) has meant that researchers have had to rely on global and generic measures, which may be inappropriate. As part of an international collaboration, we have developed a new multidimensional specific questionnaire, the QOLIBRI, to assess QoL after TBI. The present study aims to compare the validity of the QOLIBRI with generic and global measures that have previously been used to assess QoL after TBI. **Methods:** A subgroup of 50 outpatients from the UK aged 18–65 years old with a TBI in the previous 3months-15 years were assessed. All participants were administered the QOLIBRI along with the global Satisfaction with Life Scale (SWLS), a single item from the Quality of Life and Health Questionnaire (QLHQ) and the generic SF-36. Current cognitive and behavioural functioning was assessed by the Neurobehavioural Rating Scale. Psychological and physical functioning was assessed using the BICRO-39, the HADS and the GOS-E. **Results:** Detailed results of the psychometric properties of the QOLIBRI will be presented elsewhere. The current study will present a comparison between the convergent validity of the QOLIBRI, SWLS, QLHQ and the SF-36. Discriminant validity will be compared with regard to clinical and socio-demographic variables, and current cognitive, behavioural, psychological and physical functioning. **Conclusions:** Conclusions will be made regarding the appropriateness of the QOLIBRI for the assessment of QoL after TBI in relation to global and generic questionnaires that are currently in use. Recommendations will be made for future investigations to examine the reliability and responsiveness of the QOLIBRI compared to other QoL measures in order to identify appropriate tools for the planning and evaluation of rehabilitation programs.

# 1318/THE DECISION-MAKING OF HAND/TUBE FEEDING FOR PATIENTS WITH ADVANCED DEMENTIA AND ITS IMPACT ON THEIR QUALITY OF LIFE

Samantha M. Pang, School of Nursing, The Hong Kong Polytechnic University, Kowloon, Hong Kong, PRC; Ivan Y. Chung, Applied Biology and Chemical Technology; Betty P. Chung, School of Nursing; Peter White, Optometry and Radiography, The Hong Kong Polytechnic University, Kowloon, Hong Kong, China; Tak Y. Chiu, Geriatrics & Rehabilitation, Haven of Hope Hospital, Tseung Kwan O, Hong Kong, China, Amanda W. Leung, School of Nursing, The Hong Kong Polytechnic University, Kowloon, Hong Kong, China; Kin S. Chan, Pulmonary and Palliative Care, Haven of Hope Hospital; Tseung Kwan O, Hong Kong, China

**Aims:** To understand the factors influencing tube/hand feeding decisions for AD patients, and how the feeding mode impact on the patient's life quality. **Methods:** 20 prospective case studies of AD patients with eating difficulties were conducted at a local hospital. The patients' physical functioning, discomfort level, and nutritional status were assessed at 2 weeks interval using Bedford Alzheimer's Nursing Severity Subscale, Modified Braden Scale, Discomfort Scale, and Modified Mini-Nutritional Assessment. Clinical observations and interviews with the patient families were undertaken for an ethnographic analysis of the factors influencing tube/hand feeding decisions along the trajectory of end-stage dementia. Independent *t*-test was undertaken to examine the association of tube/hand feeding and the patient's life quality as reflected in the standard measures. **Results:** The more care providers committed to providing hand-feeding supports for the patients, the higher was the chance to have hand-feeding sustained. Only when the patient had an advance proxy directive could hand-feeding be sustained until death. Significant difference was noted in the nutritional status, discomfort level, sense of hunger and thirst between tube- and hand-feeding patients ( $p < 0.05$ ). Patients on hand-feeding showed higher comfort level. Both groups had satisfactory nutritional level but the tube-fed patients had better nutritional scores. **Conclusions:** The results showed that the burdens of tube feeding are

higher than hand feeding in AD patients. Advance proxy directive and palliative care approach in providing hand-feeding supports is proposed as being a better alternative in promoting the quality of life and safeguarding the dignity of the AD patients in end-of-life care.

# 1644/CONVERGENT AND DISCRIMINATIVE VALIDITY OF THE UKSIP AND SF-36 IN PATIENTS WITH PARKINSON'S DISEASE (PD)

Tauhid Ali, Centre for Socioeconomic Research, Cardiff University, Cardiff, UK; Russell Lane, Neurology, Ashford Hospital, Middlesex, UK; Sam Salek, Centre for Socioeconomic Research, Cardiff University, Cardiff, UK

**Aims:** A comparison of measurement properties of SF-36 and UKSIP in neurology clinic setting has not been reported in the literature. Study aimed to evaluate the convergent and discriminative validity of the UKSIP and SF-36 in PD. **Methods:** A 6-month study in out-patient neurology clinic. Patients selected from register of patients scheduled for clinic appointments & invited to participate in advance of their scheduled visit. Patients >45 years with diagnosis of stable PD but with no dementia/other neurological complications consented to participate. Following completion of SF-36 & UKSIP, patients were examined at baseline & rated on Hoehn & Yahr scale. The same procedure was repeated at no longer than 6 months. Analyses were conducted for construct validity (Spearman's correlation coefficient), discriminative validity (Kruskall-Wallis one-way ANOVA) using SPSS10. Scores expressed as% with lower UKSIP scores & higher SF-36 scores indicating better QoL. **Results:** Evaluable data were from 36 patients. Majority at baseline had Hoehn & Yahr staging of I & II (64.7%). UKSIP overall score correlated more with SF-36 physical component (baseline  $r_s = -0.767$ , follow-up  $r_s = -0.606$ ) than SF-36 mental component (baseline  $r_s = -0.392$ , follow-up  $r_s = -0.389$ ). Non-significant changes in correlation showed a high degree of reproducibility. Clinician's rating of severity of disease using Hoehn & Yahr showed statistically significant pattern of lower scores in SF-36 (indicating worse health) for physical functioning, role physical, role emotional, social functioning & mental health domains ( $p < 0.05$ ). Other SF-36 scales showed a non-significant pattern of lower scores. Clinician's rating of severity of disease using Hoehn & Yahr showed significantly higher pattern of scores in UKSIP (indicating worse health) for emotional wellbeing, body care & movement, ambulation, alertness & behaviour & communication domains as well as for the physical & psychosocial dimensions & overall score ( $p < 0.05$ ). **Conclusions:** These findings indicate that UKSIP and SF-36 exhibit good convergent and discriminative validity in measurement of HRQoL in PD.

# 1630/AN EVALUATION OF THE HUMANISTIC BURDEN OF DYSKINESIAS IN PATIENTS WITH PARKINSON'S DISEASE (PD)  
Tauhid Ali & Sam Salek, Centre for Socioeconomic Research, Cardiff University, Cardiff, UK

**Aims:** The humanistic significance of difference in severity of dyskinesias with dopamine agonist and L-dopa is unknown. This study aimed to assess impact of dyskinesias and motor fluctuations on HRQoL of PD patients. **Methods:** 12-month longitudinal cohort study in 3 centres. Patients stratified into three groups according to UPDRS ratings: (1) No dyskinesia/motor fluctuations (NDMF); (2) Motor fluctuations, but no dyskinesias (MFND) and (3) Motor fluctuations, with dyskinesias (MFD). Data on medical history, medication use and PD status information including the UPDRS collected at baseline and repeated at follow-up visits. Patients completed PDQ-39 at baseline, 6 and 12 months. Interim analysis performed on baseline and 6 months data to compare mean PDQ-39 domain scores for patients with dyskinesia to those without using Mann-Whitney statistic. Lower PDQ-39 scores indicate better QoL. **Results:** Evaluable data were from 38 NDMF, 15 MFND and 46 MFD patients. At baseline, patients with NDMF had significantly ( $p < 0.01$ ) lower PDQ-39 scores for mobility (13.5 vs 36.8), activities of daily living (15.4 vs 35.8), emotional well being (16.1 vs 36.7), stigma (15.0 vs 32.5), cognitions (18.1 vs 37.9), communication (8.3 vs 38.9), and bodily discomfort (28.3 vs 43.3) than patients with MFND. Patients with NDMF also had significantly ( $p < 0.01$ ) lower PDQ-39 scores than patients with MFD: mobility (13.5 vs 34.2), activities of daily living (15.4 vs 32.3), emotional well being (16.1 vs 30.1), stigma (15.0 vs 26.6), cognitions (18.1 vs 30.2), communication (8.3 vs 29.6), bodily discomfort (28.3 vs 40.1). However, social support scores were not significantly different in both comparisons. Results of 6-month data were similar to baseline data, where patients with NDMF had significantly lower PDQ-39 scores than patients with MFND, as well as patients with MFD on all domains except social support scores. No significant differences in PDQ-39 scores between patients with MFND, and patients with MFD. **Conclusions:** Findings suggest that PD patients who experienced motor fluctuations with or without dyskinesia had worse HRQoL compared to patients without any of these complications. Treatment options that reduce such symptoms may preserve well-being of patients.

# 1062/HEALTH-RELATED QUALITY OF LIFE IN OUTPATIENTS OF A PSYCHOSOMATIC MEDICINE CLINIC  
Tomoaki Kimura, MOA Health Science Foundation, Atami, Shizuoka, Japan

**Aims:** The objective of this study is to clarify the difference of health-related quality of life (HRQoL) profiles by disease category with a generic instrument and to examine the possibility of application for a longitudinal study. **Methods:** Subjects who were outpatients in a psychosomatic medicine clinic in Japan, completed SF-36 questionnaires, Japanese version 1.20. A medical doctor classified the subjects into categories of disease. Visiting the clinic again after more than 1 month, they completed the SF-36 for a second time. Cronbach's  $\alpha$  coefficients by domain and correlations between domains were measured. Using the scores controlled for gender and age group, the SF-36 profiles were compared among the categories of disease. Changes between the first and second SF-36 scores were analyzed in hypertension as a representative of the high HRQoL categories and in mental disorder as a representative of the low HRQoL categories. **Results:** A number of subjects was 536, specifically 127 men and 409 women, and the mean age was 55.95. For all domains, Cronbach's  $\alpha$  exceeded 0.7. Pearson's correlation coefficients between domains were distributed broadly from 0.29 to 0.77. Categories in which all of the domains were approximately equal to the national standard included hypertension, neck and shoulders syndrome, diabetes, hyperlipidemia and cardiac disease. Patients with mental disorder had lower scores in all domains. Categories in which 5-7 of the 8 domains had lower scores included arthropathy, asthma, chronic hepatitis, autonomic imbalance, chronic rheumatism and so on. No significant change was found between the first and second scores in hypertension. In mental disorder, however, 5 of the 8 domains increased significantly. **Conclusions:** For a longitudinal study, a target disease should be chosen among subjects with low HRQoL scores before an intervention to assess its effectiveness. Or subjects with high HRQoL

scores can be examined to determine whether they keep the same level of HRQoL.

# 1582/DISABILITY AND QUALITY OF LIFE IN PATIENTS WITH MIGRAINE: DETERMINING FACTORS  
Otman F. Fernandez-Concepcion, Neurology, National Institute of Neurology and Neurosurgen, La Habana, Cuba

**Aims:** The purpose of this paper is to describe the behaviour of disability and quality of life (QOL) in patients suffering from migraine and to identify the factors associated with these variables. **Methods:** Patients and methods. A non-experimental study based on observation was conducted with 116 patients diagnosed as having migraine, who were consecutively admitted to the Casualty department at the Institute of Neurology and Neurosurgery. The chief variables used in the study were disability, QOL and the overall evaluation of their state of health. The remaining variables employed included demographic variables (age, sex, skin colour) and clinical variables involved in the bouts of migraine (with or without aura, pain location, type of pain, length of the bouts, presence of associated symptoms, presence of precipitating factors and their number, intensity of the bouts and the number of days with headache). The Migraine Disability Assessment questionnaire (MIDAS) was used to evaluate disability, while QOL was measured with the Headache Needs Assessment survey (HANA). **Results:** Results. The mean total score on the MIDAS was 40.8, and 58.6% of the patients were in grade IV disability. The mean number of days with headache over a 3 month period was 32.25 and the mean headache intensity was 8.50. The mean score on the HANA was 76.37. **Conclusions:** The factors associated with disability were the number of days with headache and comorbidity with high blood pressure, whereas their QOL was linked to the number of days with headache, the intensity of the pain and to the female sex.

# 1248/A NEW PATIENT FOCUSED SCALE FOR MEASURING QUALITY OF LIFE (QOL) IN SCHIZOPHRENIC PATIENTS (SZP), THE SCHIZOPHRENIA QUALITY OF LIFE SCALE (SOL)  
P. Martin, Department of Psych, Hosp St Antoine, Paris, France; C.S. Peretti, Department of Psych, CHU, Reims, France; J.M. Azorin, Ste-Marguerite, Marseille, France; J. Dalery, Le Vinatier, Lyon, France; D. Etienne, CREST, Paris, France; M.C. Hardy-Bayle, Hosp, Richaud, Versailles, France; C. Gury, Sanofi, Synthelabo, France; D. Gerard, Sanofi-Synthelabo, France

**Aims:** QOL has been recognized as an important measure of the outcome of patients by clinicians in Mental Health. The emerging consensus in the health field that personal values and the patient's preferences are important in monitoring the quality of medical care outcomes makes it even more important to assess the patient's perspectives. Development and validation of a QOL questionnaire based on issues pertinent to patients with schizophrenia were performed. **Methods:** During a first phase, identical pattern were identified among interviews (conducted by psychologists) of SZP ( $n = 100$ ), mental health staff ( $n = 20$ ) and families ( $n = 20$ ). The data gathered in first phase were discussed and organized, by 25 experts, into a structure that made up the skeleton of the scale (133 items, 17 factors). **Results:** From a prospective epidemiological study conducted with 337 French psychiatrists, a validation analysis of structural and psychometric proprieties was performed. Finally reliability of the scale was assessed by a test/retest (D0, D7) study ( $n = 100$ ). A total of 687 SZP (DSM-IV) were included. Internal consistency analysis identified 14 factors (74 items), with a Cronbach's  $\alpha$  range 0.75 to 0.95. Construct validity was confirmed (Pearson test) using established clinical (BPRS, CGI), social (PARS) and generic QOL (RFS/FSQ) measures, correlation coefficient was significant for all factors but 2 in the BPRS (illness knowledge and coping with drugs) 3 in the CGI (The same and life satisfaction). Lastly, test/retest indicated high reliability for each factor ( $p < 0.001$ ), the lower correlation coefficient was 0.53. **Conclusions:** The SOL, based on a patient's point of view approach, is an efficient, multidimensional instrument designed for the measurement of consequences of schizophrenia on individuals' lives.



# 1102/A REVIEW OF INSTRUMENTS ASSESSING FUNCTIONAL OUTCOMES OF COGNITIVE IMPAIRMENT ASSOCIATED WITH SCHIZOPHRENIA

Yang Zhao & Lee Bowman, Global Health Outcomes Research, Eli Lilly and Company, Indianapolis, IN; Louis Matza & Manishi Prasad, MEDTAP International, Bethesda, MD

**Aims:** Cognitive dysfunction in attention, memory, executive functioning, and motor speed is a common feature of schizophrenia. Cognitive impairment associated with schizophrenia (CIAS), which has an impact on functional outcomes, is a potential target for pharmacologic treatment. An updated literature review of measures used to assess functional outcomes of CIAS was performed. **Methods:** Review of published literature was conducted to identify articles focusing on the relationship between CIAS and functional outcomes such as social functioning, work functioning, health-related quality of life (HRQL), and the ability to perform daily tasks. **Results:** Many studies have explored the relationships between cognitive deficits and measures of functional constructs such as work functioning (Work Behavior Inventory, Griffiths Work Behavior Scale), HRQL (Quality of Life Scale, Quality of Well-being Scale, Sickness Impact Profile), social functioning (Social Adjustment Scale, Social Behavior Scale), ability to perform daily tasks (Direct Assessment of Functional Status Scale), and overall functional status (Clinical Dementia Rating Scale, Scale of Functioning, Social-Adaptive Functioning Scale). Although most functional status instruments reflected impairment among patients with schizophrenia, several measurement weaknesses are apparent. Few were developed specifically for use in a schizophrenia patient population, some were not psychometrically validated, and none captured the full range of key functional outcomes (e.g., social functioning, work functioning, living status, and instrumental activities of daily living) shown to be associated with CIAS. **Conclusions:** Although most measures detected some level of functional impact, no measure appears ideal for assessing the broad functional outcomes of CIAS. Further development of an instrument to capture full range of key functional outcomes of CIAS is needed to fill the gap in the literature.

# 1409/A COMPARATIVE STUDY OF METHADONE AND BUPRENORPHINE MAINTENANCE TREATMENTS IN WESTERN AUSTRALIA

Yuan Yuan Cheng & Bruce V. Sunderland, Pharmacy, Curtin University of Technology, Perth, Western Australia, Australia

**Aims:** To compare treatment outcomes and treatment satisfaction of opioid dependents on methadone maintenance treatment (MMT) and buprenorphine maintenance treatment (BMT) in Perth, WA. **Methods:** A longitudinal cohort study was conducted. Forty-four MMT patients and eighty-one BMT patients were randomly recruited from community pharmacies in Perth metropolitan area. After a 3-month follow-up period, retention rates were compared by survival analysis with a log-rank test. Dropout predictors were investigated by logistical regression. Repeated measures ANOVA via SPSS and generalised estimating equation (GEE) with an unstructured correlation and a logit link via Stata were carried out to detect changes in – before and after – designs on normally distributed continuous variables and categorical variables respectively. Substance use was analysed with ANCOVA on differences of the usage frequency pre- and post-treatment. **Results:** At the study endpoint, 8 patients dropped out from MMT and 28 from BMT, resulting in a retention rate of 81.8% in MMT and 65.4% in BMT. No significant difference was evident between the two medications on retention rates ( $p = 0.062$ ). Age and treatment perceptions were significantly predictive of MMT dropout. Relative contact and frequency of previous opioid treatments predicted BMT dropout. The BMT program did not differ significantly from the MMT on treatment outcomes (substance use, health risk behaviours, health symptoms and personal/social functioning) and treatment satisfaction (treatment perceptions and pharmacy service appraisal), with the exception of a greater reduction in the frequency of amphetamine use ( $p = 0.009$ ) and more friend contact ( $p = 0.004$ ) in buprenorphine patients. **Conclusions:** Similar substantial improvements occurred after MMT and BMT were commenced. Patients on both treatments expressed similar treatment satisfaction levels regarding treatment regulations and pharmacy services provided. The BMT program was verified to be as effective as the MMT program.

# 1477/CORRELATION BETWEEN HANDICAP AND QUALITY OF LIFE IN 402 STROKE PATIENTS

Raymond S. Lo, Medicine & Geriatrics, Shatin Hospital, Shatin, Hong Kong; Timothy C. Kwok, Medicine and Therapeutics; Eric Wong, Centre of Epidemiology and Biostatistics; Wai Kwong TANG, Psychiatry, The Chinese University of Hong Kong, Shatin, Hong Kong

**Aims:** To investigate the relationship between the two major patient-reported outcomes post stroke in the community: handicap in affecting participation, and quality of life. **Methods:** Consecutive stroke patients admitted into Prince of Wales Hospital were interviewed in the community at 3 months after hospital discharge. Handicap was assessed using the London Handicap Scale (LHS) which had been cross-culturally validated in Hong Kong. QOL was assessed using the WHOQOL-Hong Kong brief version. Correlation between handicap and QOL was assessed using Pearson correlation coefficient. **Results:** 402 discharged stroke patients were recruited. LHS total score had significant correlation's with all the four WHOQOL domains (all with  $p = 0.000$ ), the closest being with physical and psychological ( $r = -0.67$  and  $-0.53$  respectively). The individual LHS domains were also significantly related to various QOL domains (all with  $p = 0.000$ ). Physical domain of QOL was best reflected by LHS domains of independence, followed by mobility, and occupation; psychological domain of QOL reflected best by LHS domains of mobility, followed by economic sufficiency and occupation; social domain of QOL by LHS domains of economic sufficiency and social integration; and environment domain of QOL by LHS domain of orientation. **Conclusions:** The close relationship between handicap and QOL in stroke patients is confirmed. Stroke patients' QOL in the community can be reflected by their perception of handicap severity. Assessment of patients' handicap would be useful when QOL cannot be measured.

# 1188/A PRELIMINARY STUDY OF HEALTH-RELATED QUALITY OF LIFE OF CHINESE STROKE PATIENTS

David W.K. Man & Alan Tam, Rehabilitation Sciences, The Hong Kong Polytechnic University, Hong Kong, PRC; Zu Lin Dou, Rehabilitation, The Third Affiliated Hospital, Sun Yat Sen University, Guanzhou, PRC; Y.S. Hu, Rehabilitation, The Affiliated Hospital of Fudan University, Shanghai, PRC; L. J. Ao, Rehabilitation Medicine, 2nd Affiliated Hospital of Kunming Medical College, Kunming, PRC; G. Wang, Rehabilitation Research Centre (RRC), The Affiliated Hospital of RRC – Bo Ai Hospital, Beijing, PRC

**Aims:** Studies on Quality of Life (QoL) have gained substantial attention among social science and medical researchers. Through collaboration between Hong Kong and medical institutions in Guanzhou, Shanghai, Beijing and Kunming of PR China, this project aimed to explore the objective QoL of Chinese stroke patient, from a cross-sectional perspective. **Methods:** A pilot study of 50 stroke patients from Hong Kong and 146 from PR China using Cummin's Comprehensive Quality of Life Scale-Chinese Version (ComQoL-15) and SF-36. Both quantitative and qualitative analyses were used to depict QoL and health-related factors; multiple regression was used to identify mediators of QoL, and MANOVA to test possible difference on QoL domains across different demographics and health related factors. **Results:** Preliminary results show that the overall mean quality of life score among Chinese in mainland China was slightly less than the maximum score. Among the seven QoL domains, Health and Safety received some of the highest scores, while the lowest scores were obtained in area of Material Well-being, Place in Community, and Productivity. People who had experienced a stroke relatively recently (<5 years ago) were found to have higher Intimacy QoL scores than their counterparts injured more than 5 years ago. **Conclusions:** Lower score in the ComQoL in domains of Material Well-being, Community Activities and Responsibility, and Productivity might be consequences of physical and cognitive limitations of stroke. Thus appropriate intervention to improve their life conditions, social integration would be necessary to improve their QoL. High score in other ComQoL areas such as Safety and Health may reflect good living environment.

# 1114/IMPACT OF AGE ON LIFE'S QUALITY AFTER STROKE: CROSS-SECTIONAL AND LONGITUDINAL VIEWS

Sharon Wood Dauphinee, Medicine, McGill University, Montreal, PQ, Canada; Susan Scott & Nancy Mayo, Montreal, PQ, Canada

**Aims:** Clinicians have long advocated that to evaluate the impact of age on stroke outcome one must disentangle the effects of stroke and comorbidity from those of aging. Statistical approaches incorporating time should also be considered. The objective of this presentation is to examine the congruence of cross-sectional and longitudinal analyses when assessing the impact of age on life's quality after stroke. **Methods:** Data are from the Montreal Stroke Cohort Study that estimated the impact of stroke on community-dwelling stroke survivors. Persons with first stroke admitted to 10 acute care hospitals were approached. Those consenting were interviewed by telephone within 3 months and at 6, 12 and 24 months post stroke. A population based sample of community-dwelling individuals without stroke was also recruited and followed. Subjects provided information on diseases other than stroke, functioning and quality of life. Regression analyses, including hierarchical growth models, incorporated a maximum of 612 stroke and 480 comparison subjects. **Results:** Stroke subjects had more comorbid conditions and challenges in ADL, and these increased with age. Mean Physical and Mental Component Summary (PCS & MCS) scores from the SF-36 and QOL VAS scores were lower in those with stroke than in comparisons. Cross-sectional analyses found that comorbidity had a strong association with PCS but less in those with stroke than comparisons. Age was associated with PCS in both groups but this association disappeared when comorbidity was controlled. Longitudinal analyses demonstrated that comorbidity. Affected initial levels of PCS and interacted with age over time. While the impact of comorbidity dominated when extreme, age lowered the recovery curves in those with moderate numbers of comorbid conditions. This group made up most of the stroke sample. Recovery and plateau of MCS post stroke were driven by PCS, though age raised the level of the curve. **Conclusions:** In conclusion, the impact of age is less apparent in cross-sectional analyses than when the data are viewed over time.

# 1117/ORAL HEALTH RELATED QUALITY OF LIFE AFTER STROKE

A.S. McMillan, K.C.M. Leung, Ehn Pow & M.C.M. Wong, Dentistry, University of Hong Kong, Hong Kong, PRC; L.S.W. Li, Rehabilitation Medicine; Tung Wah Hospital, Hong Kong, PRC

**Aims:** Stroke can have a significant impact on physical, psychological and social functions. Oral impairment can also be disabling as chewing, swallowing and speech problems are common stroke-related sequelae. The aim was to measure oral health-related quality of life (OHR-QoL) of stroke survivors on hospital discharge into the community. **Methods:** 43 elderly stroke survivors of mild to moderate stroke in the non-dominant hemisphere and an age/gender matched comparison group of 43 community-dwelling elderly people were recruited. The SF-36 measure, the General Oral Health Assessment Index (GOHAI) and an oral health transition scale were administered as a structured interview prior to a dental examination. Data were analysed using Chi-squared and independent *t*-tests. **Results:** Median SF-36 subscale scores were significantly different between groups ( $p < 0.05$ ). In physical function, role-physical, role-emotional and mental health domains, stroke survivors had significantly lower scores indicating poorer health. The median GOHAI score for the stroke group was 52 and 54 for the comparison group with no significant difference between groups although more stroke survivors had difficulty speaking compared with the comparison group. About 75% of stroke survivors considered their appearance to be worse, half of them felt that speech was worse and about a third had difficulty chewing hard food compared with the pre-stroke condition ( $p < 0.05$ ). Participants were partially dentate with no significant difference in dental or prosthetic status between groups ( $p > 0.05$ ). **Conclusions:** Health-related quality of life was significantly poorer after stroke even although patients were considered physically well enough to be discharged from hospital. There was some impairment of OHR-QoL. The nature of the stroke, the hospital environment including diet and coping strategies should be taken into account when interpreting measures of health status in stroke survivors. (CRCG-HKU)

# 1506/DOES PHYSICAL FUNCTIONING PREDICT 4-YEAR MORTALITY AMONG HOSPITALIZED ACUTE STROKE INPATIENTS

Cheng-Chieh Lin, Family Medicine, China Medical University Hospital, Taichung, Taiwan, ROC; Tsai-Chung Li, Chinese Medicine, China Medical University, Taichung, Taiwan, ROC; Chia-Ing Li, Medical Research, China Medical University Hospital, Taichung, Taiwan, ROC

**Aims:** Physical functioning capacity is the only domain of health-related quality of life (HRQOL) that can be measured for hospitalized acute stroke inpatient and over half of all stroke patients have continuing problems with mobility. The objective of the current study is to examine the effects of physical functioning at admission to hospital on 4-year mortality among acute stroke inpatients after adjusting for sociodemographic factors, comorbidity, medication, and supportive device use. **Methods:** The study sample consisted of 197 consecutive acute stroke inpatients admitted in China Medical College Hospital from July, 1998 to August, 1999. All acute stroke inpatients were evaluated by a trained interviewer to collect variables such as sociodemographic factors, Barthel Index, Karnosky Scale, ADL, IADL, comorbidity, having catheter, naso-gastric tube, or Tracheotomy, etc. Mortality data were collected from the national mortality register using personal identification numbers. Multivariate Cox's proportional hazard models were used data analysis. **Results:** The overall 4-year mortality rate in this sample is 48.7%. Physical functioning measured by Karnosky Scale is significantly associated with mortality, independent of age, gender, comorbidity, medication, and supportive device use (relative risk = 1.659, 95% CI: 1.001–2.75). As Karnosky Scale increases by one point, the probability of mortality for acute stroke inpatients increases by 65.9%. **Conclusions:** Acute stroke inpatients with worse physical functioning at admission had a greater risk of mortality over 4 years of follow-up compared with those with better physical functioning. The unique contribution of physical functioning to mortality is independent of comorbidity, medication, and supportive device use.

# 1146/ANALYSIS OF INFLUENCE FACTORS OF QUALITY OF LIFE AFTER STROKE

Yue lan, MS, Dongfeng Huang & Zu Lin Dou, Rehabilitation medical, Sun yat-sen, Guangzhou, Guangdong, PRC

**Aims:** To explore the influence factors of quality of life after stroke by using the SIS Chinese version. **Methods:** One hundred and eighty stroke survivors were involved in this study. Data were collected on age, sex, education, location of brain lesion, diagnostic stroke subtype and so on. We used multiple regressions analyzing to determine those factors that could predict QOL scores of stroke patients. **Results:** The multiple regression analysis of mean scores revealed that whether receiving rehabilitation therapy or not, economical status, depressions, family support, age and complications were predictors of the result of the patient's global QOL assessment. **Conclusions:** The results of the present study call for more individually tailored. QOL of stroke patients can be improve by multifaceted rehabilitative approaches including rehabilitation therapy, controlling complications, counseling and supports of community.

# 1515/SOCIAL SUPPORT AND HRQL IN PEOPLE WITH APHASIA  
Katerina Hilari & Sarah Northcott, Language and Communication  
Science, City University, London, UK

**Aims:** Social support has been associated in the literature with better health and life satisfaction. This paper aims to explore which aspects of social support most predict health-related quality of life (HRQL) for people who have aphasia. It will examine two different conceptions of social support: firstly, social networks (the different links that embed a person in a social web, e.g., marital status, number of friends and relatives, group membership); secondly, perceived social support (a person's subjective experience of social support, e.g., the extent to which they feel loved and cared for). **Methods:** The study used a cross-sectional interview based design. Cluster sampling was used to recruit participants with chronic aphasia (>1 year) due to a stroke from three community services. Measures included the Stroke and Aphasia Quality of Life Scale- 39 item version (SAQOL-39) (Hilari et al., 2003), the MOS Social Support Survey (SSS) (Sherbourne and Stewart, 1991), a social network questionnaire and measures of other variables that have been associated with HRQL in stroke survivors (e.g., emotional distress, language and daily activities). Data will be analysed using correlation and multiple regression analysis. **Results:** 95 people took part in this study and 83 of them (87%) were able to self-report on all the assessments. This paper will report the results of those able to self-report. We anticipate that different types of social support may have a different impact on HRQL. **Conclusions:** The mechanism through which the different types of social support associate with HRQL will be discussed with reference to the theoretical framework put forward by Cohen and Wills (1985). In considering the role and function of social support, the paper will also take into account the impact of factors specific to this population. For example, it will explore the various barriers to forming and maintaining social links commonly experienced by people with chronic aphasia (Parr et al., 1997).

# 1112/INFLUENCE OF THE QOL STATUS ON THE SATISFACTION FOR TREATMENTS AND HEALTH SERVICES IN THE PATIENTS WITH CHRONIC NEURAL DISEASES  
Tomohiro Matsuda & Takuya Sugie, Epidemiology, National Institute of Public Health, Wako, Saitama, Japan; Kiyomi Sakata, Public Health, Wakayama Medical College, Wakayama, Wakayama, Japan; Naoko Masaki, Fukuoka Health Center, Kurume, Fukuoka, Japan; Masumi Minowa, Epidemiology, National Institute of Public Health, Wako, Saitama, Japan

**Aims:** Japanese health ministry entitles patients with chronic neural diseases to 15 types of health services at no charge as well as to a public financial aid in order to improve their QOL. The services are: daycare service, dental check-up, helper service, bathing assistance, home repair, etc. We investigated the status of use and satisfaction of the health services in relation to their QOL. **Methods:** We collected the information on generic QOL (SF-36 and the disease-specific measure), socio-demographic and pathological information, and the status of use of the health services. The distribution of diseases among 1707 subjects were, Parkinson's disease (53.8%) spinocellebular disease (25.3%), myasthenia gravis (6.6%), ALS (5.9%), and other diseases (8.3%). **Results:** Little less than two-thirds of the patients (59.6%) were the current users of at least one of the services, and the public health nurse visit (30.1%) and the daycare service (17.6%) were most frequently used. The patients with low Activity of Daily Living tended to use them more often. Among 1017 current users, the patients showing low QOL in any sub-scales of SF-36 except SF sub-scale and in the disease specific QOL measure tended to be dissatisfied with the services and the treatments. None of the other factors, age, sex, disease kind, service type, time interval from the first diagnostic was significantly related to satisfaction. **Conclusions:** This effect of QOL status on the satisfaction of the service usage can be explained by two hypothesis: the actual health services are not appropriate for low QOL patients, or an emotional distress may cause them not to accept any detailed fault of the services. Further studies are needed in order to reflect growth on the health service policy.

#1111/GENERIC QOL PROFILE OF PATIENTS WITH SEVERE PARKINSON'S DISEASE IN A LARGE SCALE COHORT

Tomohiro Matsuda & Takuya Sugie, Epidemiology, National Institute of Public Health, Wako, Saitama, Japan; Masaki Shinjo, Public Health and Epidemiology, Okinawa Prefectural College of Nursing, Naha, Okinawa, Japan. Kazuko Mitoku, Medical Welfare, Kawasaki University of Medical Welfare, Kurashiki, Okayama, Japan; Masaki Nagai, Public Health, Saitama Medical School, Moroyama-machi, Saitama, Japan

**Aims:** Quality of Life (QOL) of patients with severe Parkinson's disease (PD) has been rarely studied in a large-scale cohort. The objectives were description of their generic QOL and investigation of the modifying factors of QOL by using SF-36. **Methods:** In cooperation with the 37 health centers all over Japan, we recruited 1197 PD patients showing the Hoehn and Yahr disease stages higher than II. Public health nurses interviewed the patients at the moment of application or renewal for the public financial aid in order to collect information. Of this number, 709 were followed-up 1 year later. **Results:** We investigated the data of 869 respondents (296 in follow-up) to the questionnaire battery (response rate 72.6%) using uni- and multivariate regression analysis. Mean age was  $69.2 \pm 8.8$  years, sex ratio was 41:59, and distribution of Hoehn and Yahr stage was stage III 59.1%, IV 31.2%, and V 9.7%. Some of the patients were showing other chronic illness, such as hypertension, diabetes, cardio-vascular disease. Daily movement and social activity ADL median scores were respectively 11 and 6 on 14. Anti-Parkinsonism drugs usage was: Anticholin 70.2%, Amantazine 66.8%, L-Dopa 95.2%, and Dopamine 74.2%. Age/sex-standardized scores (norms: mean50  $\pm$  10) of SF-36 subscales were: PF 28.2, RP 37.4, BP 40.8, GH 37.4, VT 38.0, SF 34.6, MH 37.7. Old age, high disease stage, female sex and above all low ADL were independently related to low QOL score. No relation was found with treatment type, other illness, and time interval from the first diagnostic. Follow-up study analysis showed that improvement in ADL had contributed to higher QOL. **Conclusions:** Functional disorder that was typical for neural diseases seemed to lead to the low QOL score. However, follow-up study results imply that rehabilitative therapies have the potential to ameliorate overall QOL in Parkinson's disease patients.

# 1511/PSYCHOSOCIAL VARIABLES AND HEALTH OUTCOMES IN EPILEPTIC PATIENTS

Jose L. Pais-Ribeiro, Psychology; A. Martins da Silva, Medicine, University of Porto; R. Meneses, Psychology, University F. Pessoa, Porto, Portugal; C Falco, Psychology, Hospital Sto. António, Porto, Portugal

**Aims:** Aims of the study is to identify the impact of demographic variables, disease variables, and psychosocial variables (current health perception, health expectancy, health worry, resistance to illness, sickness orientation, self-efficacy), on outcomes measures like QOL and mental and physical components of health status (SF-8). **Methods:** 200 epileptic outpatients participate age mean 39.62 years, school level mean of 8.12 years, 63% married or similar, 95% with seizures (equal or more than one per year, 70.5% with one type of seizure), 99% taking medication for seizures (49% monotherapy, 33.5 biterapy, and 16.5 polytherapy); 53.5% males, in a correlational study; They answer to a self-report questionnaire. **Results:** Correlations between demographic, psychosocial and disease variables are statistically significant for the majority of variables. A linear regression analysis, stepwise method, using each of the outcomes variables as a dependent variable, shows that, for the mental component of health status ( $R^2$ , 0.37) the variables self efficacy, resistance to illness and health worry explain the results; for the physical component of health status ( $R^2$ , 0.71) the variables self-efficacy, perception of cognitive functioning, health worry, perception of seizure control, educational level, and resistance to illness explain the results. For quality of life ( $R^2$ , 0.30) variables self-efficacy, resistance to illness, and disease orientation explaining the results. **Conclusions:** The impact of disease on physical component of outcomes is bigger than for the other outcome variables. However the magnitude of the impact on mental health and QOL is higher enough to be considered. Different psychosocial and demographic variables explain the results on the considered outcomes, suggesting that a complex web of variables account for the outcome of disease.

# 1712/QUALITY OF LIFE IMPAIRMENT IN NEUROFIBROMATOSIS TYPE 1: COMPARISON OF US AND FRENCH PATIENTS

Alain Leplege, Philosophy, University of Amiens, Amiens, France; Bruce Korf, Medical Genetics, University of Alabama in Birmingham, Birmingham, AL, USA; Pierre Wolkenstein, Dermatology, Hospital Henri Mondor, Creteil, France

**Aims:** Neurofibromatosis type 1 (NF1) impacts the quality of life (QoL) of affected people, causing both visible manifestations and, occasionally, life-threatening illness. The progressive, unpredictable nature of the condition can be a great source of anxiety for affected individuals and their families. We report a two center, cross-sectional study designed to evaluate the impact of the severity and visibility of the NF1 phenotype on QoL and to compare US and French results. **Methods:** Participants were primarily recruited in France through the National Neurofibromatosis Foundation via both an e-mail announcement and advertisement in a newsletter and in the USA with the help of the National Neurofibromatosis Foundation. A total of 176 French adults and 169 Americans with NF1 responded and filled out the study questionnaires. Severity and visibility were evaluated using, respectively, the Riccardi and Ablon scales. The US and French version of the Skindex and the SF-36 (Short Form 36 health survey) profiles were used to evaluate, respectively, both skin disease-specific and general health QoL. Data analysis used standard psychometric and statistical techniques including multiple linear regression. **Results:** The American subjects mean age was  $42.6 \pm 11.7$ , the French were  $40.4 \pm 14.1$  year old. Overall the skindex scores (emotion, functioning, symptoms) were comparable in the two population for same visibility level as were the SF-36 scores. **Conclusions:** Neurofibromatosis type 1 has a significant impact on QoL through alteration of health and appearance in both populations. The size of this impact is comparable between the two countries. The consequences of visibility and severity from the viewpoint of patients can be evaluated using both the Skindex and the SF-36. Further validation work will include the test of cross cultural differential item functioning using the Rasch model.

# 1105/DESIGN OF THE RETINOPATHY DEPENDENT QUALITY OF LIFE MEASURE AND RETINOPATHY TREATMENT SATISFACTION QUESTIONNAIRE

Alison Woodcock, Rosalind Plowright & Clare Bradley, Psychology, Royal Holloway, University of London, Surrey, UK; Tessa Kennedy-Martin, Global Economic Affairs, Lilly, Surrey, UK; Axel Hirsch, Diabetes, Bethanien-Krankenhaus, Hamburg, Germany; Timothy Ffytche, Ophthalmology, Hospital for Tropical Diseases, London, UK

**Aims:** Measures of the impact of diabetic retinopathy on quality of life (QoL) and satisfaction with diabetic retinopathy treatments are needed to evaluate current and future therapies. This study aimed to incorporate patients' views in designing measures to meet those needs. **Methods:** Qualitative and quantitative Methods were used in semi-structured interviews with 44 people with diabetic retinopathy (11 in each of 2 UK and 2 German hospitals). Interviewees described how QoL would be different if they did not have diabetic eye problems, their experiences of retinopathy treatments and views on possible new therapies. They completed and commented on a draft Retinopathy Dependent QoL measure (RetDQoL) and Retinopathy Treatment Satisfaction Questionnaire (RetTSQ), each modelled on an established diabetes measure (ADDQoL and DTSQ respectively). Drafts

were revised and translated between centres, incorporating patient views. The interviews were content analysed. **Results:** Interviewees were 26 men, 18 women; median age 60.8 (range: 28–82), with background or proliferative retinopathy ranging in severity (1 or 2 eyes); median visual acuity better eye 0.80 (range: 0.0025 (hand motion only) to 1.20 (6/5 vision)). The 26-domain individualised RetDQoL and 13-item RetTSQ have face and content validity for people with diabetic retinopathy. Visual impairment, worries and advice to restrict movement impaired many aspects of QoL. Satisfaction dimensions included treatment effectiveness, emotional and physical experiences (before, during and after treatment), information provision and influence over treatment. **Conclusions:** The RetDQoL and RetTSQ are relevant and acceptable to a wide range of people with diabetic retinopathy in two European countries. They will be useful in evaluating current and future therapies in research and clinical contexts. The next step is to use them in trials with numbers sufficient for psychometric validation.

# 1377/CONCEPTUAL ISSUES AND ASSESSMENT MEASURES FOR A MULTIDIMENSIONAL MODEL OF PATIENT REPORTED OUTCOMES IN DIABETES: PRODUCTIVITY, SYMPTOMS AND TREATMENT SATISFACTION

Meryl Brod, The BROD Group, Mill Valley, CA; Kim U. Wittrup-Jensen, Global Health Economics and Outcomes Research; Soren E. Skovlund, Global Health, Novo Nordisk, Bagsvaerd, Denmark

**Aims:** The impact of chronic illnesses such as diabetes are complex. A multidimensional approach which takes into consideration the patient reported impact on productivity, symptoms and treatment satisfaction are critical to understand the full clinical picture. This presentation will diagram a conceptual model of the roles these key patient reported outcomes play in diabetes, and 2) present a triad of new, well validated disease-specific measures assessing these concepts. **Methods:** Literature review, expert interviews and focus groups with patients were conducted to develop the model and measures. The measures were then validated in 418 type 1/11 diabetics. **Results:** All three measures were all found to be valid and reliable. Internal consistency was high (ranging from 0.81 to 0.90), factor structures were strong and conceptually relevant, response burden for the measures was low (2–4 min) and all a priori hypotheses (construct, known-groups and criterion validity) were met. For example, it was found that treatment satisfaction was significantly lower for those using higher amounts of insulin ( $p = 0.01$ ). Patients who reported fewer symptoms had significantly greater uncontrolled blood sugar ( $p = 0.01$ ) or more work loss days ( $p = 0.001$ ). Diabetics who worked had greater life impairment than work impairments ( $p = 0.0001$ ) suggesting that both work and life productivity are important independent concepts. Age, gender, type of insulin administration and general health were found to be differentially predictive of treatment satisfaction, symptoms and productivity. **Conclusions:** This well validated triad of patient reported measures should be considered appropriate for assessing the effect of interventions and disease management programs. Additionally, they are simple and short enough to be clinically useful in patient care to help practitioners understand the full impact of diabetes on patient's lives.

#### # 1327/GENERIC AND DISEASE-SPECIFIC QUALITY OF LIFE MEASURES AS PREDICTORS OF MORTALITY AMONG TYPE 2 DIABETIC PATIENTS

Tsai-Chung Li, Chinese Medicine, China Medical University, Taichung, Taiwan, ROC; Yih-Dar Lee, Eli Lilly and Company, Taipei, Taiwan, ROC; Chia-Ing Li, Medical Research, China Medical University Hospital, Taichung, Taiwan, ROC

**Aims:** To examine the predictive value of generic and disease-specific quality of life measures on mortality, independently of age, gender, and complications among diabetic patients. **Methods:** A 5-year prospective, longitudinal study with in-person interviews was conducted. There were 420 diabetic patients recruited in outpatient clinics of a medical center. At baseline, the generic measure of Short Form 36 (SF-36), disease-specific measure of Diabetes Impact Measurement Scales (DIMS), and clinical and biological marker variables were measured. DIMS domains include symptoms, diabetes-related morale, social role fulfillment, and well-being. Complications consist of stroke, heart disease, visual impairment, amputations, kidney disease, cognitive impairment, and incontinence. Mortality data were collected from the national mortality register using personal identification numbers. Multivariate Cox's proportional hazard models were used. **Results:** The overall 5-year mortality is 10.9%. SF-36 scales of physical functioning, general health, vitality, mental health, and MCS were significant predictors of mortality while DIMS scales of symptoms, well-being, and total score significantly associated with mortality, independent of age, gender, and complications. Individuals in the category of bottom 25% (worse status) had significantly increased risk compared to those in the category of top 25% (better status) (Relative risk = 2.95, 95% CI: 1.03–8.44; 2.92, 1.23–6.96; 3.83, 1.31–11.21; 3.40, 1.36–8.53; 3.65, 1.51–8.81; 2.33, 1.07–5.05; 2.60, 1.17–5.78 and 4.57, 2.05–10.19, respectively). **Conclusions:** When SF-36 and DIMS were simultaneously considered, only total score of DIMS exerted significant effect on mortality (RR = 3.60, 95% CI: 1.45–8.93). MCS exerted borderline effect on mortality (RR = 2.44, 95% CI: 0.96–6.22). The unique contribution of HRQOL to mortality is independent of more objective health measures such as complications.

#### # 1215/THE EVALUATION OF HRQOL IN DIABETIC OUTPATIENTS BY USING SF-36 AND PATIENTS' SELF-REPORTS ON DIABETES

Hisako Adachi, Adult and Gerontology Nursing, University of Gifu, Gifu, Japan

**Aims:** This study aimed to evaluate the present health state of diabetic out-patients by using SF-36 questionnaire (Japanese ver.1.2) and patient's self-reports on the effect of diabetes on their daily life. There are a few reports to compare diabetics with healthy persons. **Methods:** Eighty patients of diabetics group (Diabetic G.) consisted of 46 women and 34 men; they were recruited from the out-patient clinic in a general hospital. The average age of Diabetic G. was 54.5 ± 12.8 years old, the mean HbA1c% was 7.1 ± 1.4 and the mean duration of diabetes was 11.4 ± 10.1. Eighty-four persons of health group (Health G.) consisted of 54 women and 30 men; they were recruited from some volunteer groups. The average age of Health G. was 50.0 ± 10.1 years old. **Results:** (1) Mean scores of physical functioning, role physical functioning and general health subscale in Diabetic G. were significantly lower than those in Health G. ( $p < 0.05$ ). (2) Mean scores of six subscales without bodily pain and vitality were significantly lower in patients with negative feelings on daily life in Diabetic G. in comparison with those in Health G. ( $p < 0.05$ ). (3) Mean score of physical functioning subscale in women of Diabetic G. was significantly lower than that in women of Health G. ( $p < 0.05$ ). (4) Mean scores of physical functioning and mental health in Diabetic G. did not change significantly with aging, and those results were different from those of Health G. (5) Mean score of general health in Diabetic G. increased significantly with aging ( $r = 0.33$ ,  $p < 0.01$ ). (6) There were no significant on Pearson's correlation coefficient between each of 8 subscale's scores and the duration of diabetes, and HbA1c%. **Conclusions:** Those results showed clearly necessity to provide more supportive physical care for diabetic patients, and explain why mean score of general health subscale of SF-36 increased toward higher score gradually with aging in the diabetic patient. (Supported by a research grant from the Ministry of Education in Japan.)

#### # 1136/MISINTERPRETATION WITH NORM-BASED SCORING IN ADULTS WITH TYPE 1 DIABETES

Alison L. Supina, Public Health Sciences; David H. Feeny, Pharmacy and Pharmaceutical Sciences; Linda Carroll; Jeffrey A. Johnson, Public Health Sciences, University of Alberta, Edmonton, AB, Canada

**Aims:** To investigate the interpretation of norm-based scoring of generic health status measures in an adult type 1 diabetes population by comparing norm-based health status scores and preference-based health-related quality of life (HRQL) scores. **Methods:** Data were collected through self-complete questionnaires sent to patients with type 1 diabetes seen in diabetes clinics. The RAND-36 and the Health Utilities Index Mark 3 (HUI3) were included. Clinical and demographic information was also collected. A total of 216 (61%) questionnaires were returned. We compared descriptive statistics, distributions, and previously established norms for these generic health status measures. **Results:** The respondent sample was predominantly female (58.8%); had a mean (SD) age of 37.1 (14.3) years and a mean duration of diabetes of 20.9 (12.4) years. Comorbidities and complications were commonly reported (e.g., retinopathy – 42%, cardiovascular disease – 34%, nephropathy – 18%). Mean (SD) health status scores were: RAND-36 PHC 58.2 (11.8), RAND-36 MHC 56.9 (9.3), and HUI3 0.78 (0.23). Histograms of the scores show that scores are not normally distributed, with substantial left skew for all measures. HUI3 scores were similar to those previously reported in type 2 diabetes and lower than those reported in the general Canadian population. However, both physical and mental health summary scores of the RAND-36 (interpreted as norm-based T-scores; mean of 50, SD of 10) suggest that this population is much healthier (effect sizes of 0.7–0.8) than the general adult population. **Conclusions:** In this sample, a preference-based measure indicated poorer health, consistent with clinical evidence, whereas a norm-based measure indicated better than normal health. Norm-based scoring measures may provide misleading interpretations in populations when health status is not normally distributed.

#### # 1026/A TEST OF THE RELIABILITY AND VALIDITY OF A DIABETES SPECIFIC QUALITY OF LIFE SCALE IN A NIGERIAN HOSPITAL

Babatope A. Kolawole & Dapo Abodunde, Medicine, Obafemi Awolowo University, Ile-Ife, Osun State, Nigeria

**Aims:** The purpose of this study was to test the reliability of the well-being and diabetes treatment satisfaction questionnaires among clinic patients with type 2 diabetes as well as determine the clinical correlates of these measures. **Methods:** A cross-sectional survey was conducted using the Well-Being Questionnaire and the Diabetes Treatment Satisfaction Questionnaire. **Results:** 83 responses were analysed. Subjects were aged between 25 and 75 years, mean 55.5 ± 11.1 years. 50.6% were males while 49.4% were females. Mean diabetes duration was 4.9 ± 6.5 years. 67 (80.7%) were receiving oral agents and dietary modification while 16 (19.3%) were on insulin therapy. The internal consistency for responses to the Well-Being subscales and treatment satisfaction scale produced coefficients ranging from 0.73 to 0.88 and 0.74, respectively. Inter-item correlations ranged between 0.19 and 0.45 for depression subscale; 0.22 - 0.78 for anxiety subscale; 0.33–0.58 for energy subscale; 0.33–0.79 for positive well-being subscale; and -0.22–0.79 for the Treatment Satisfaction scale. Item-total correlations ranged between 0.39 and 0.87 across the two scales: well-being (0.59–0.87) and treatment satisfaction (0.39–0.78). Mean score scores were similar in both insulin and oral hypoglycaemic drug treated patients. Positive well-being was higher in males 13.4 ± 4.1 vs. 11.5 ± 4.3 in females  $p = 0.04$ . None of the well-being subscale scores, or treatment satisfaction correlated with age, disease duration, body mass index or glycaemic control. **Conclusions:** The well-being and treatment satisfaction scales are reliable instruments for the measurement of diabetes specific quality of life and treatment satisfaction in Nigerians although they were originally designed and developed among a UK population. It is hoped that our data would provide the basis for future comparisons and improving diabetes care.

#### # 1599/CHANGES IN HEALTH-RELATED QUALITY OF LIFE IN RESPONSE TO LIFE EVENTS AND HEALTH CARE

Donald R. Miller, Avron Spiro & Lewis E. Kazis, Center for Health Quality, Outcomes & Economic Research, Boston University School of Public Health, Bedford, MA, USA

**Aims:** Measures of health-related quality of life (HRQoL) should be sensitive to changes in health status and to the effects of health care. In longitudinal data with repeated measures, we examined the sensitivity of HRQoL instruments to life events that influence health status (e.g. new disease onset, change in pre-existing health conditions, health care use). **Methods:** We analyzed data from two longitudinal studies of older men with repeated administrations of multidimensional HRQoL measures (SF-36, MHI-38) from 1992 through 1999. Our sample included about 1400 men from the Veterans Health Study and 1000 men from the Normative Aging Study. Average age was 67 years and most men had one or more chronic diseases. Trends in scale scores, expressed as percent of baseline standard deviation (SD), were compared among groups experiencing different health events. Linear regression was used to adjust for the effects of age, education, morbidities, and other characteristics. **Results:** Overall, scores from HRQoL measures changed modestly over time, on average decreasing by 2–5% SD per year for physical and health perception scales and increasing by 1–3% SD per year for general health perception and mental health scales. In those with no evident adverse health events, scores tended to be stable or increase. In contrast, annual average declines of 6–15% SD per year in most SF-36 scales were observed in men who developed a new illness or medical condition or who were hospitalized in the past year. Declines ranged broadly and varied across the scales depending upon the specific condition or event. **Conclusions:** Self-report measures of HRQoL are responsive to changes in health and health care use. Different health events have distinct effects on domains of physical function, role function, and emotional well-being. Brief self-report HRQoL measures reflect the impact of recent health events on quality of life to varying degrees, and can be used to profile patient health.

#### # 1358/COST OF ILLNESS FOR LOCAL FISHING COMMUNITY IN COASTAL KERALA, INDIA AFFECTED BY RADIATION INDUCED POLLUTION: A STUDY OF THEIR QUALITY OF LIFE

Subodh Kandamuthan, Ecological Economics Unit, Institute for Social and Economic Change, Bangalore, Karnataka, India; Kandamuthan Murukan, Department of Community Medicine, Vinayaka Missions Medical College, Trivandrum, Kerala, India

**Aims:** The Coastal area of Kerala is abundant in radioactive minerals from which compounds like thorium can be produced and factories mine these to get profit. However it involves a social cost to local fishing community living near mining sites in terms of health effects caused by radiation. The current study tries to calculate total cost of illness for local fishing community and look into their quality of life. **Methods:** Primary data was collected on 300 households in study area and 100 households from control group without radiation. Cost of illness approach was used to measure loss of work to earning members and total cost of illness among both groups. Discriminant analysis was done to discriminate the variables between households in both groups. To study quality of life of local fishing community, contingent valuation survey was undertaken to analyse factors affecting willingness to pay for health insurance using logit model. **Results:** Morbidity condition of households in study group revealed that Cancer and downs syndrome were prevalent. Expenditure incurred on health was high among study group households. Households in study group were mostly indebted due to high health expenditure. Discriminant analysis showed that expenditure incurred by Private inpatient and outpatient care and amount of wages lost were significant variables which discriminated between two types of households. Logit analysis confirmed that factors like total income, radiation induced illnesses in family, cost of illness and indebtedness were highly significant variables, which enhanced willingness to pay for health insurance. **Conclusions:** The study substantiated that quality of life of local fishing community is poor and burden of radiation induced illnesses are so high such that there is urgent need for government intervention to reduce their burden for which they are not responsible. A health insurance or other support to these households will provide them with better quality and fast access to health care facilities and reduces financial burden.

#### # 1328/QUALITY OF LIFE OF SURVIVORS OF SUPER CYCLONE OF ORISSA, INDIA

Kasi Sekar, Psychiatric Social Work, National Institute of Mental Health and Neuro Sciences, Bangalore, Karnataka, India. Rangaswamy Srinivasa Murthy, Mental Health, WHO, Bangalore, Karnataka, India

**Aims:** Disasters leave a trail of death and devastation, striking at the very roots of human emotions and the quality of life of the survivors. More the problems and life difficulties the affected persons experience, during the recovery and rehabilitation phase, more persistent will be the emotional reactions and lower the quality of life. Those receiving psychosocial care have less emotional reactions, disability, and better quality of life than those who do not receive the same. The current work aimed at assessing the quality of life, psychological distress and disability among the survivors of the Orissa super cyclone subsequent to a community based psychosocial intervention provided by community level workers. **Methods:** The widowed women, aged, and orphaned survivors of the cyclone were provided a holistic rehabilitation service including psychosocial care on a longitudinal basis. The current study focuses on the assessment of the quality of life (WHO QOL Bref), psychological distress (WHO, SRQ) and disability (WHO DAS) among a group of survivors intervened with psychosocial care (Study group) and a group of individuals not provided with such a care (Control group) at the end of thirty months. **Results:** The mean QOL scores in the different domains and the overall total indicated better quality of life in the physical, psychological, and environmental domains for the study samples. The social quality of life was better among the control samples. The relationship between psychological distress, disability and quality of life showed significant positive relationship for the study samples. **Conclusions:** Simple psychosocial interventions by trained community level workers for the survivors of disaster increases the quality of life, functionality and decreases the psychological distress.

#### # 1144/NARRATIVE TREATMENT (KAMISHIBAI) EFFECTS ON QUALITY OF LIFE FOR ATOMIC BOMB SURVIVORS.

Kouko Hama, Michiko Kobayashi & Keiko Mutou, Siebold University of Nagasaki, Nishisonogi-gun, Nagasaki, Japan; Takashi Mandai, Japanese Society of Quality of Life Research, Kobe, Hyogo, Japan

**Aims:** The purpose of this study was to evaluate the narrative treatment (Kamishibai) effects on quality of life (QOL) for atomic bomb survivors. **Methods:** Fifty atomic bomb survivors participated in this study. Self-administered questionnaire including 37 questions divided into 14 categories with the life satisfaction index (LSI) were used. **Results:** Cronbach's  $\alpha$  coefficients of our questionnaire were high enough to accept for clinical use; 0.91 in economy, 0.90 in social participation, 0.89 in dietary problem, 0.87 in medical service, 0.86 in mental function, etc. respectively. Our questionnaire contained 7 main factors and cumulative contribution was 0.84. Pearson's correlation coefficients between our questionnaire and LSI was  $r = 0.63$  ( $p < 0.01$ ). Compared with before narrative treatment (Kamishibai), significant improvements were shown in strata of happiness, interests and sleep ( $p < 0.05$ ) after narrative treatment (Kamishibai). The more we performed narrative treatment (Kamishibai), the more significant QOL improvements this narrative treatment (Kamishibai) demonstrated. Compared with this narrative treatment (Kamishibai) effects at general nursing home, the significant more QOL improvements were indicated in strata of interest and total QOL at special nursing home. These findings indicate that our questionnaire has high enough reliability and potency of validity to use for atomic bomb survivors. Narrative treatment approach is very important and hopeful area to improve individual QOLs by qualitative technique, because wide range subjects from babies to terminal care patients are able to participate in this program. **Conclusions:** We must pay more attention to narrative treatment effects on QOL including the message of atomic bomb survivors for permanent peace in all over the world from Nagasaki Japan.

#### # 1563/QUALITY OF LIFE IN THE EMERGENCY ROOM: A FRENCH REGIONAL SURVEY

T. Iordanova, P. Jean, A. Chevalier, M. Declémy, R. Dubuisson, G. Pedrant, A. Krajevitch, H. Liauthaud, J.M. Minguet, P. Olivier, R. Rouvier, D. Debensason, S. Robitail, M.C. Siméoni, & P. Auquier, Public Health, University Hospital of Marseille, Marseille, France

**Aims:** Precariousness is a major public health issue in France and in Europe. To assess and better understand the impact of precariousness, especially for people becoming recurrent users of emergency room, HRQoL measure should provide a practical and original solution. The aim of this study is to present the *Results* of a prospective regional survey which involved ten emergency departments of the south-east of France **Methods:** The included population consisted in 634 in- and out-patients. Two different HRQoL instruments were completed by all consenting people: the Duke Health Profile (DHP: a generic tool) and the QoL-P17 (a specific instrument developed to assess the HRQoL of people living in precarious conditions). In social sciences, experts have defined the precariousness status the subjects. **Results:** Among the 634 patients, 111 (17.5%) were defined as living probably on precarious conditions and 14 (2.2%) in great exclusion. 27.2% of people living in precarious conditions have used emergency room more than 4 times during the 6 last months versus 5% for non precarious people. Both instruments results confirmed that people living in precarious conditions reported lower HRQoL. Using the QOL-P17 index score as a test to identify precarious people was assessed: Sensitivity = 80%, Specificity = 40%, Area under ROC curve = 0.68. The comparisons of DHP scores with those of French general population showed that people living in precarious conditions reported a lower HRQoL than chronically ill patients for physical, psychological and social domains. **Conclusions:** HRQoL measure within this population should help to better understand the relationships of precariousness and access to care. The assessment of perceived health to better identify people living in precarious conditions is a topic for future research. Its use in routine should be assessed, but this solution seems feasible, cheap and should help to propose these people specific social or psychological care.

#### # 1312/QUALITY OF LIFE AMONG FEMALE PRISONERS: A DESCRIPTIVE STUDY

Fariba Almasi, Mohammad Ali Heidarnia, Social Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran; Ali Montazeri, Social Medicine, Iranian Institute for Health Sciences Research, Tehran, Iran

**Aims:** Prisoners have different health needs that differ from the general population. This was a study to investigate about health related quality of life in this special population. **Methods:** A cross sectional study was conducted to measure quality of life in female prisoners in Tehran, Iran. Data were collected from a sample of prisoners and quality of life was measured using the Iranian version of the SF-36. The findings then were compared with the normative data derived from the general population for healthy females. **Results:** In all 251 female prisoners were interviewed. The mean age of the respondent was 31.4 (SD = 11.2) years, mostly less educated (75%), married (41), and were arrested for immoral behaviors (34%), and drug trafficking (18%). The findings of prisoners' scores on the SF-36 and comparison with the normative data are shown in the table. **Conclusions:** The findings

indicate that special populations such as prisoners suffer from a very poor health related quality of life. Indeed there is an urgent need to improve health in this group of population.

#### # 1665/QUALITY OF LIFE AMONG MALE PRISONERS: A DESCRIPTIVE STUDY

Iraj Esmaili, Research and Education, Tehran Province Prison Headquarters, Tehran, Iran; Abbass Vossogh Moghaddam, Social Medicine, Shahid Beheshti University, Tehran, Iran

**Aims:** Prisoners have different health needs that differ from general population. This was a study to investigate about health related quality of life in this special population. **Methods:** Across sectional study was conducted to measure the quality of life of prisoners in Tehran, Iran. Data were collected from a sample of prisoners and the quality of life was measured using the Iranian version of the SF-36 the findings then were compared with the normative data derived from the general population for healthy females. **Results:** Across sectional study was conducted to measure the quality of life of prisoners in Tehran, Iran Data were collected from a sample of prisoners and the quality of life was measured using the Iranian version of the SF-36 the findings then were compared with the normative data derived from the general population for healthy females. **Conclusions:** The finding indicates that special populations such as prisoners who suffer from poor health related quality of life. Indeed there is an urgent need to improve health in this group of population.

Eight dimensions of SF-36	Male prisoners (N = 400)		Female prisoners (N = 251)		Healthy males (N = 2504)	
	Mean	SD	Mean	SD	Mean	SD
Physical functioning	65.4	27.0	55.2	29.3	81.9	21.7
Role physical	56.3	24.3	30.4	31.4	65.4	38.6
Bodily pain	61.4	27.6	41.1	24.8	75.5	25.9
General health	51.2	14.9	45.2	19.4	64.3	19.9
Vitality	59.3	19.4	47.8	17.5	61.6	17.3
Social functioning	61.0	24.6	46.5	24.5	73.8	24.4
Role emotional	46.1	24.1	24.2	31.6	63.4	42.7
Mental health	54.1	20.2	40.2	16.6	66.5	18.9

	Prisoners (N = 251) Mean (SD)	Healthy females (N = 2166) Mean (SD)
Physical functioning	55.2 (29.3)	82.9 (22.1)
Role physical	30.4 (31.4)	66.5 (39.1)
Bodily pain	41.1 (24.8)	76.4 (26.2)
General health	45.2 (19.4)	65.0 (20.8)
Vitality	47.8 (17.5)	62.9 (17.8)
Social functioning	46.5 (24.5)	74.2 (25.1)
Role emotional	24.2 (31.6)	61.4 (42.4)
Mental health	40.2 (16.6)	65.0 (18.6)

# 1311/JOB CONTENTS, FAMILY STRAIN, PSYCHOSOMATIC SYMPTOMS AND BLOOD PRESSURE AMONG WORKING WOMEN IN BEIJING

Liying Xu, Centre for Clinical Trials, The Chinese University of Hong Kong, Shatin, Hong Kong; Weihua Cao, Epidemiology, Beijing University, Beijing; Liming Lee, Epidemiology, Peking University, Beijing; Brian Tomlinson; Medicine and Therapeutics; Jean Woo, Community and Family Medicine; Juliana Chan, Medicine and Therapeutics, The Chinese University of Hong Kong, Shatin, Hong Kong, PRC

**Aims:** Cardiovascular disease is becoming an increasingly important cause of morbidity and mortality worldwide. There is growing evidence that psychosocial factors play an important role in the aetiology of CVD. The objective of the study is: to test the psychometric properties of the 2 psychosocial stress models: 1) Job Strain Model (Karasek, 1979), 2) a self developed Family Strain Scale. **Methods:** This study is based on a cross-sectional self-administered questionnaire survey in a sample of 421 Chinese working women in Beijing: The information of job strain and family strain, social support, perceived stress, traumatic life events, health behaviors, BP, BMI and psychosomatic symptoms were collected. **Results:** The standard measurement of JCQ and Family Strain Scale show acceptable psychometric properties and criterion validity in this population of Chinese working women. Job strain and family strain were each significantly associated with increased systolic blood pressure (4.8 and 3.0 mm Hg respectively). Job strain was also significantly associated with increased diastolic blood pressure (3.1 mm Hg). Dual exposure to job strain and family stress was associated with a significant increase in both systolic (8.8 mm Hg) and diastolic blood pressure (4.1 mm Hg) in comparison with to unexposed women. Symptoms of suspected heart disease and recurrent sleeping problems were associated with majority subscales. **Conclusions:** The findings indicate reasonable psychometric properties of the Chinese version of Job Content Questionnaire and Family Strain Scale. Job strain and family strain may have independent adverse effects on psychosomatic health and BP of Chinese working women.

# 1296/HEALTH-RELATED QUALITY OF LIFE USING EQ-5D IN KOREANS

Sang-Cheol Bae, Sang-Seokg Seong & Wan-Sik Uhm, Internal Medicine, Hanyang University, Seoul, South Korea

**Aims:** There have been no data of health related quality of life (HRQOL) in general Korean population. To know factors affecting health related quality of life in Koreans is fundamental for researching HRQOL. The objective of this study is to assess HRQOL using Korean version of EQ-5D in Koreans. **Methods:** HRQOL was assessed using EQ-5D from 1044 randomly selected people representing general Korean people with telephone interview. **Results:** The mean EQ-5D utility score of the Korean was 0.878 (range: -594-1.0). Sociodemographic data showed relatively higher score in male, younger, well educated, higher income, and white color people. Among a variety of diseases, diabetes, hypertension, low back pain, gastric ulcer/gastritis, arthritis were common in Korea. The most significant chronic diseases which influence Koreans were arthritis and gastrointestinal disorder. **Conclusions:** These results suggest that HRQOL is affected by non-

Disease entity	EQ-5D score		
	EQ-5D score(mean)	Disease entity	EQ-5D score(mean)
No disease	0.91	Liver disease	0.89
Gastritis/gastric ulcer	0.63	Heart disease	0.72
Arthritis	0.57	Rhinitis	0.85
Hypertension	0.82	Bronchial asthma	0.82
Diabetes mellitus	0.80	Kidney disease	0.73
Low back pain	0.83	Enteritis	0.67

HRQOL and arthritis and gastrointestinal disease were the most influential diseases affecting Koreans HRQOL.

# 1317/COMPARISON OF EURO-QOL EQ-5D MEASURED AMONG RURAL RESIDENTS, URBAN FACTORY WORKERS, AND HEALTH CHECKUP EXAMINEES AT A HUMAN DRY DOC IN KYOTO, JAPAN

Yoshiyuki Watanabe, Mari Fujita, Kyohei Hayashi, Kotaro Ozasa, Department of Epidemiology for Community Health and Medicine, Kyoto Prefectural University of Medicine; Sanae Harada, Tadayoshi, Miyazaki, Kazuo Takeda, Kyoto Industrial Health Association, Kyoto; Chisato Hamashima, Cancer Screening Research Section, National Cancer Center, Tokyo, Japan

**Aims:** We conducted EQ-5D surveys to investigate the health status in a rural Japanese population, urban factory workers, and health checkup examinees at a human dry doc. **Methods:** We asked all the residents aged 30 years old or older in a rural area of Kyoto from June 1999 through February 2000, all the urban factory workers (age range: 18-65) in Kyoto in May 2001, and health checkup examinees (age range: 40-79) at a human dry doc in Kyoto in February - July 2003 to answer the Japanese clinical version of EQ-5D using a self-administered questionnaire. **Results:** A total of 4900 (70.0%) out of 7000 rural residents, 1368(65.1%) out of 2130 factory workers and 298 (84.9%) out of 351 examinees at a human dry doc responded. The proportion of 'no problems' decreased with age in both rural residents and factory workers for all of the five questions of EQ-5D except for 'Anxiety/Depression' among factory workers. Factory workers in their thirties showed the lowest proportion of no problems for 'Anxiety/depression' compared to other age groups. The proportion of 'no problems' decreased with age in examinees at a human dry doc only for 'usual activities'. The proportion of a high tariff-QOL score (=1) calculated using a basic tariff for Japanese was highest among examinees at a human dry doc in their 50 and 60 and higher among urban factory workers than rural residents in all age groups. **Conclusions:** These data suggest that examinees at a human dry doc are healthiest and there is a healthy worker's effect among urban factory workers.

# 1455/WHAT IS IMPORTANT FOR IMPROVING YOUR QOL?: HEALTHY PLAN 21 SURVEY IN FURUKAWA, JAPAN

Yuko Sasaki, Masahiro Kohzaki, Yoko Goto, Hitomi Kataoka & Masayuki Kanazawa, Internal Medicine and Rehabilitation Science, Tohoku University Graduate School of Medicine, Sendai; Tamae Ujiei, Furukawa Public Health Center, Furukawa; Yukie Sugawara & Sumiko Yokoe Furukawa, Public Health Center, Furukawa, Miyagi; Tokuko Yamaguti, Furukawa Public Health Center, Furukawa; Shigeyuki Sato, Furukawa Health promotion project, Furukawa, Miyagi, Japan

**Aims:** The purpose of this study was to survey important factors for residents to improve QOL, and to determine the relationship between them and the community-based programs. **Methods:** The subjective were total of 1307 men and women selected at random in Furukawa city. They were asked the following questions: What is important for improving your QOL? and What kind of community-based programs do you hope to take part in? The answers were classified into the eight fields (nutrition (NU), physical activity and physical fitness (PP), mental health and mental disorders (MM), tobacco use and alcohol intake (TA), oral health (OH), heart disease, stroke and diabetes (HS), quality of care and long-term care (QL), maternal, infant and child health (MC)) according to the classification of Healthy Japan 21 Plan. The data were compared with three groups of generation (A; 17-29y, B; 30-59y, C; 60-79y) using the path analysis. **Results:** The top three programs they hope to participate in were NU, PP, MC in A-group, NU, PP, HS in B-group, and NU, QL, PP in C-group. The fields of the important factors for improving QOL were NU, MM in A-group, NU, PP in B and C-group. By the path analysis, there is a positive relation between some factors thought to be important for improving QOL and the community-based programs. In-group A, NU, MM, TA for improving QOL was positively correlated with HS, MC, QL, OH programs. In-group B, PP for improving QOL was positively correlated with MM program, and in-group C, TA for improving QOL was positively correlated with QL program. **Conclusions:** The results indicate that the important factors for improving QOL differ in each age's groups. They also suggest that it should be considerable factors to plan for the community-based programs.



#### # 1199/THE EFFECT OF HEALTH BEHAVIOURS ON FUTURE SELF-RATINGS OF HEALTH FOR MEN AND WOMEN

Pia Svedberg, Carola Bardage, Nancy L. Pedersen Medical Epidemiology and Biostatistics, Karolinska Institutet, Stockholm, Sweden

**Aims:** Little is known about what predicts future self-rated health. In this study we focus on predictors for future good self-ratings of health. The purposes were first to explore the predictive validity of health behaviours on self-rated health. Lack of stress, marital status, being employed and not having a physically heavy work or working overtime and body mass-index (BMI) were also included in our analysis. Secondly, we investigated sex differences. **Methods:** Data were collected 30 years ago in the Swedish Twin Registry and concurrently in a recently finished study (SALT). The design of this effort was of longitudinal nature, and provides insight into long-term predictors of self-rated health in a subset of the registry sample that is currently 40 years or older ( $n = 24,452$ ). Three self-rated health items were included: (1) How would you rate your general health status?; (2) How would you rate your health status compared to 5 years ago?; and (3) Do you think your health status prevents you from doing things you would like to do?. Items were standardized separately ( $M = 0$ ,  $SD = 1$ ) and then summed. A high score indicates a more positive health rating. **Results:** Results of linear regression analysis show that people that were employed and had a work without heavy lifts generally scored higher on the self-rated health scale. Having a BMI less or equal to 25, exercising regularly, eating vegetables and being a non-smoker or former smoker generally also scored higher on the self-rated health scale. Men that were married and that had regular working hours scored higher on the scale but there was no effect for women. Low alcohol consumption is predictive for good health among women, but not for men. Subjects who experienced low perceived stress, regardless of sex, scored higher on self-rated health. Older persons generally scored lower on self-rated health while eating regular meals, fried food or not working overtime do not seem to predict self-rated health. **Conclusions:** We conclude that health behaviours and lack of stress measured 30 years ago predict future good health status. For men, also being married and having regular working hours is of importance. While low alcohol consumption is of importance for women.

#### # 1361/HEALTH RELATED QUALITY OF LIFE: IS GENDER INEQUALITY REAL?

Mariam Vahdaninia, Health Services Management; Azita Goshtasebi, Family Health, Faranak Farzadi; Health Services Management; Ali Montazeri, Social Medicine, Iranian Institute for Health Sciences Research, Tehran, Iran

**Aims:** As part of a validation study in Iran it was found that the female respondents on all the eight scales of the SF-36 significantly rated lower as compared to the male respondents ( $p$  values  $< 0.001$ ). This was to examine whether the difference between females and males was real. **Methods:** This was a reanalysis of a population-based study measuring quality of life among the general Iranian population. Data were collected from a random sample of the general population and quality of life was measured using the SF-36 Health Survey. To examine the differences in health by gender, general linear regression analysis was performed using the respondents' scores on the SF-36 as independent outcomes, gender as a fixed factor, and age and years of formal education as covariates. **Results:** In all data for 4163 healthy individuals aged 15 years and over living in Tehran (2166 women and 1997 men) were analyzed. The mean age of women was 34.1 ( $SD = 15.1$ ) and for men it was 36.1 ( $SD = 16.9$ ) years. The mean year of formal education for women was 9.6 ( $SD = 4.5$ ) and it was 10.0 ( $SD = 4.5$ ) for men. The results of regression analysis showed that gender had significant effect on all scales ( $p$  values  $< 0.05$ ). In case of covariates age showed strong association in all instances ( $p$  values  $< 0.01$ ) but education did not show significant results except for physical functioning and mental health. The findings of interaction between factor (gender) and covariates (age and education) revealed highly significant results in most scales except for general health and vitality. **Conclusion:** The findings suggest that even after adjusting for age, education and interaction between age, gender and education, the difference between males and females remain significant indicating that women have poorer health related quality of life. It seems that the gender inequality in health related quality of life is real and needs to be tackled.

#### # 1464/EXPLORING SELF-ESTEEM AS SUBJECTIVE QUALITY OF LIFE OF PEOPLE WITH DIFFERENT DISABILITY TYPES

Sing-Fai Tam, Rehabilitation Sciences, The Hong Kong Polytechnic University, Kowloon; David W.K. Man, Rehabilitation Sciences, The Hong Kong Polytechnic University, Kowloon, China; Eria Ping-ying LI Rehabilitation Sciences, The Hong Kong Polytechnic University, Hong Kong; Jenny Y.Y. Ng, Physiotherapy, Grantham Hospital, Hong Kong Hospital Authority, Hong Kong, PRC

**Aims:** Low self-esteem appears to be both a vulnerability factor and a result of disability conditions. Thus enhancing self-esteem might facilitate disability adjustment and/or help to prevent recurrence. Since self-esteem is closely related to a person's behavioural competence, positive self-experience, and sense of self-actualization, it also serves as an important gauge of subjective quality of life. **Methods:** Using a 20-item adult source of self-esteem inventory, the authors have studied the self-esteem structure of 659 persons with various disabilities and have evidenced the multidimensional hierarchical self-esteem structure among specific disability groups. **Results:** Each of the disability groups understudied showed unique self-esteem facets. Functional independence self-esteem facet was found among persons with physical disabilities; social integrity facet was found among persons with mental illness, persons with cardiac diseases perceive physical ability attributes as being important to many aspects of their lives. For persons with intellectual disability, the family self, the social self and achievement in school and work are the most important self-concept attributes to their lives. **Conclusion:** This study identified self-esteem basis of persons with different disabilities. Findings of this study suggest disability group specific strategies should be designed for self-esteem and thus quality of life enhancement.

#### # 1424/CURRENT HEALTH STATUS AND HEALTH TRANSITION: GENDER RELATED DIFFERENCES

Ali Montazeri, Social Medicine; Jila Sadighi, Family Health; Mariam Vahdaninia, Health Services Management; Azita Goshtasebi, Family Health, Iranian Institute for Health Sciences Research, Tehran, Iran

**Aims:** People perceive health and quality of life in different ways. Gender might contribute to such differences. The aim of this study was to investigate whether men and women rate their current health and health transition differently. **Methods:** A population-based study was conducted to measure quality of life among the general population in Tehran, Iran. Using a multistage sampling method a random sample of healthy individuals aged 15 and over were interviewed. Quality of life was measured using the SF-36. This paper analysis data derived from items on current health and health transition and reports on differences observed between males and females. To analyze data, raw scores on two items transformed to 0–100. **Results:** In all 4163 individuals were interviewed. The mean age of the respondents was 35.1 ( $SD = 16.0$ ), and mostly reported that their current health is good or very good (54%) and health transition (current health compared to 1 year ago) was reported to be about the same (52%). The comparison between males and females are shown in the table. The higher values show a better condition. **Conclusion:** The findings suggest that females perceived their current health poorer than males but comparing with health transition males showed much higher decrease in their health status.

Gender	Current health	Health transition
	Mean (SD)	Mean (SD)
Female ( $n = 2166$ )	55.6 (28.8)	51.8 (23.9)
Male ( $n = 1997$ )	62.2 (29.1)	52.8 (23.0)

# 1525/FIRST ADMINISTRATION OF THE SEATTLE ANGINA QUESTIONNAIRE IN IRANIAN PATIENTS WITH CORONARY ARTERY DISEASE

Hamid R. Javadi, Cardiology, Qazvin University of Medical Sciences, Qazvin, Iran; Mohsen Asade-Lari, H. Vakili & David Gray, Cardiovascular Medicine, University of Nottingham, Nottingham, UK

**Aims:** To adopt the Farsi version of the Seattle Angina Questionnaire (SAQ) for the Iranian cardiac patients and assess its psychometric properties. **Methods:** Preparing the Farsi version of the SAQ through a cautious forward and backward translation, a pilot administration to ascertain its understandability and finally employing the new version on patients with coronary artery disease admitted to a coronary care unit in Iran. Patients were assisted by two trained nurses to fill the questionnaire during their stay in hospital. **Results:** 133 patients (83% male; mean age 54.2) completed the questionnaire, of which 65% had a confirmed MI and 35% with symptoms suggestive of ischemic heart disease. Functional class was assessed using the Canadian Cardiovascular Society Classification (CCSC); 63% with class I, 31% class II, 4% class III and 2% class IV were identified. Mean scores for five dimensions of 'physical functioning', 'angina stability', 'anginal frequency', 'treatment satisfaction', and 'quality of life perception' were 65.7, 18.5, 57.7, 72.1, and 36, respectively. Trivial rates of missing data confirmed the acceptability of the tool. Physical functioning scores were strongly correlated with CCSC ( $r = 51, p < 0.001$ ). Internal reliability (Cronbach's  $\alpha$ ) was 0.93 in physical functioning domain, which is higher than similar studies, however poor reliability in SAQ-TS and SAQ-QOL remain for further investigation. **Conclusions:** The Farsi version of the SAQ is a valid and reliable tool to be administered in Iranian population and sounds acceptable to patients.

# 1325/CONCEPTUALISATION OF A FRENCH INSTRUMENT MEASURING MALE SEXUAL ANTICIPATING COGNITIONS

Mireille Bonierbale, Psychiatry and Medical Psychology, University Hospital, Marseilles, France; Audrey Clément, Karine Barrau, Anderson Loundou & M.C. Simeoni, Public Health, University Hospital of Marseille, Marseilles, France; Karim Hamidi, Pharmacology, Lilly France Laboratories, Suresnes, France; Christophe Lancon, Psychiatry and Medical Psychology, University Hospital, Marseilles, France; Pascal Auquier, Public Health, University of Medicine of Marseilles, Marseilles, France

**Aims:** The development of sexologic active drugs justifies the use of scales for the evaluation of changes induced by such therapeutics. Among the tools available for evaluating erectile dysfunction (ED), the International Index of Erectile Function (IIEF) is mainly used, but others are also currently proposed. The analysis of the literature we are detailing showed that these instruments remain primarily focused on functional aspects of ED. The vulnerability factors involved in ED are mainly based upon organic aspects, e.g. age, cardiovascular diseases or diabetes, but the psychological factors involved in the occurrence and maintenance of ED are less studied. This conclusion led us to develop a French self-administered instrument, based on patients' perception, which should evaluate 'male sexual anticipating cognitions' using the reversal theory developed by Apter. We present here the first stages of the development of this new instrument. **Methods:** We planned two kinds of semi-structured, one-to-one interviews with patients with psychogenic ED and patients with mixed ED. Interviews were driven until the information was saturated. Manual and computerized analyses of the content were performed to generate items. **Results:** Eighteen one-to-one interviews were planned in several urologic/andrologic and psychiatric sexologist services. Dimensions isolated were sexual quality of life, performance anxiety, negative anticipation, metamotivational modes and dysfunctional coping. **Conclusions:** The acceptability and the comprehension of this preliminary questionnaire will be tested by 320 patients in a multicentric study, so as to produce a shorter questionnaire by selecting the most informative items. Once validated, this multidimensional instrument will be able to assess treatment efficacy of the psychogenic ED component.

# 1349/TRANSLATION AND VALIDATION OF THE EORTC QLQ-C30 FOR USE WITH ETHNIC MINORITY GROUP CANCER PATIENTS IN THE NETHERLANDS

Martin Muller & Rianne Hoopman, Psychosocial Research and Epidemiology; Neil K. Aaronson, Psychosocial Research and Epidemiology, The Netherlands Cancer Institute, Amsterdam, The Netherlands

**Aims:** As the large communities of Turkish and Moroccan labor immigrants in the Netherlands age, they are faced with an increasing incidence of cancer. Many of the first generation Turks and Moroccans lack proficiency in Dutch. In this study, the EORTC QLQ-C30 was translated via standard procedures into Turkish (written and oral versions) and Moroccan (Moroccan Arabic and Rifberber, oral versions only), and its psychometric properties were examined. **Methods:** Ninety Turkish and 79 Moroccan patients were recruited. The mean age was 50 years, approximately 50% was female, and the most common cancers were breast (25%) and head and neck (20%) cancer. Mean time since diagnose was 3.5 years. 45% of the Moroccan and 17% of the Turkish patients were illiterate. **Results:** Standard psychometric testing supported the scale structure, reliability and validity of both language versions. Cronbach's  $\alpha$  ranged from 0.63 to 0.86 (Turkish) and 0.63 to 0.94 (Moroccan). Item internal consistency and discriminant validity was satisfactory. Significant mean differences in relevant scale scores were observed between subgroups of patients formed on the basis of performance status, comorbidity, gender and age, but not disease stage. Relatively high levels of missing data (at the individual item level) were observed, particularly for the Moroccan patients. Approximately 30% of the patients had 1 or more missing items. The mean missing percentage for a single item was 3% (range 1–12%) for the Turkish and 10% (range 6–13%) for the Moroccan patients. The most common reason for missing item responses was difficulty in understanding the question content or the response categories. **Conclusion:** Although the psychometric evidence supports the reliability and validity of versions of the QLQ-C30 developed for use among Turkish and Moroccan cancer patients in the Netherlands, there remain concerns about the feasibility of employing the questionnaire among poorly educated and/or illiterate patients from these populations.

# 1150/ASSESSING INDIVIDUAL QUALITY OF LIFE IN DEVELOPING COUNTRIES: PILOTING A GLOBAL PGI IN ETHIOPIA AND BANGLADESH

Danny A. Ruta, Public Health, University of Newcastle, Newcastle, UK; Laura Camfield & Faith Martin, Psychology, University of Bath, Bath, UK

**Aims:** To test the feasibility of combining two individualised QoL measures to produce a new global Person Generated Index of QoL appropriate for development policy and research **Methods:** The Well-being in Developing Countries (WED) programme offers an interdisciplinary approach to understanding poverty, inequality and quality of life in developing countries. Individualised approaches to QoL assessment are predicated on the belief that only the individual living a life is fit to judge its quality. These instruments allow individuals to select, rate and weight the importance of those aspects of life considered relevant to overall QoL. This paper describes how elements of the PGI and the SEIQoL were combined to produce a new instrument appropriate to QoL assessment in a development context. WED fieldworkers were given a free hand to interpret and translate a culturally relevant version of: instructions to nominate important life areas; the wording and construction of likert statements and scales; and the method of spending points. Back/re-translation methods were used. Purposive samples were identified by local fieldworkers. Qualitative content analysis was undertaken to explore the elicited life areas, and the validity of rating and weighting methods. **Results:** 22 (7 female, 15 male) respondents were interviewed in five towns and villages in Ethiopia and Bangladesh. A PGI index score was generated for all respondents. A range of life areas was generated, with similarities and differences observed between countries. Gender differences were also identified. Development focused areas were frequently mentioned in Ethiopia. Difficulties were encountered in conveying the concept of importance consistently. Likert scales including the concept of goodness generated lower PGI scores than those using satisfaction. 6-point scales consistently emerged as most acceptable. **Conclusion:** It is feasible to develop a cross-cultural global PGI, however the identity of the interviewer and translation of importance may result in a tool that assesses development related QoL rather than overall QoL. Likert statements translated as satisfaction rather than goodness seem to generate higher QoL scores.

# 1292/FEASIBILITY AND LINGUISTIC VALIDITY OF THE REVISED SWEDISH VERSION OF THE PDQ-39

Peter Hagell, Anneli Dahlberg & Mi-Young Kim Nursing, Lund University, Lund, Sweden

**Aims:** To evaluate the feasibility and linguistic validity of the revised Swedish version of the Parkinson's disease (PD) specific health status questionnaire PDQ-39. **Methods:** 13 non-demented PD patients (mean age:  $65.5 \pm 11.6$  years; median Hoehn and Yahr stage of PD [HY]: III [range: I-V]) completed the revised Swedish version of the PDQ-39. Feasibility was assessed as the time taken to complete the questionnaire. Following questionnaire completion, patients evaluated each PDQ-39 section and item regarding clarity and linguistic validity. All comments were recorded and reviewed for accuracy at the end of each interview. **Results:** Patients needed a mean (SD) of 14.2 (8.4) min to complete the PDQ-39. Patients with more advanced PD (HY IV-V) needed more time to complete the questionnaire than those with milder (HY I-II) PD (mean: 22 and 9.5 min, respectively). Three aspects of the original Swedish PDQ-39 have earlier been found problematic: anonymity of the frame question, distinction between response options, and a double negative in the wording of two out of three items in the Social Support subscale. Revisions to the Swedish PDQ-39 had eliminated the latter two problems. However, three patients still overlooked the frame question and four patients considered the response alternatives problematic due to their unpredictable motor fluctuations. No additional linguistic problems were identified. **Conclusions:** These observations support the linguistic validity of the revised Swedish version of the PDQ-39, as well as its feasibility among patients with mild to moderate PD. However, data also indicate that the frame question may be problematic and that alternative response categories may be advantageous for this patient group. The feasibility of the PDQ-39 among patients with advanced PD can be challenged.

# 1094/THE PERFORMANCE OF THE GERMAN EQ-5D IN A GENERAL PRACTICE SAMPLE AND ITS COMPARABILITY TO THE SF-12

Corina Guethlin Dipl Psy, Environmental Medicine, University Hospital, Freiburg, Germany

**Aims:** There is consistent evidence that the SF-12 is the more discriminative health status measure (Macran S, Weatherley H, Kind P. Measuring Population Health. *Med Care* 2003; 41: 218-231), at least for the English versions. Performance data on the comparability of the 2 instruments when used as a pre-treatment measurement in evaluation-settings is missing, and psychometric considerations with respect to the German version of the EQ-5D are rare. Thus, we provide data gathered pre treatment on both instruments and compare them. **Methods:** 2417 data sets of men (20.5%) and women (79.5%) who were seeking acupuncture treatment in general practice contain the SF-12 items as well as the EQ-5D items. **Results:** The 0-100 VAS of the EQ-5D (current health status) was 67 (SD = 19) for men and 65 (SD = 19) for women. Patients reported most impairment in pain (71% had moderate pain/discomfort) and least in the scale reporting problems with self-care. Despite being younger men reported significantly more pain than women. Missing data was very low for the five descriptive dimensions and for the transition question. The 0-100 VAS scale representing the current health status was not filled in by 10% of the patients, the VAS scales serving as utility measures showed up to 35% missing data. 23% gave comments and 43% rated the questionnaire as being difficult. The mode of time was 30 min. The EQ-5D showed substantial ceiling effects with 24% of the patients scoring 'no problem' t least at four out of the five dimensions, whereas for those 24% the mean value of the SF-12 PCS is still below 50 (normed mean of t-scale). Correlations of VAS with PCS and MCS reach high significance (VAS-PCS:  $r = 0.40$ , VAS-MCS:  $r = 0.62$ ), but graphic depictions of the relation reveal high variability of SF-12 scores. **Conclusions:** The German version of the EQ-5D shows acceptable performance data, at least for the ratings of the current health status. Ceiling effects are present. Further inspection of the high pain/discomfort ratings are needed, as the German translation may suggest not only discomfort from pain but also symptoms in general.

# 1598/THE CHALLENGE OF CROSS-CULTURAL INSTRUMENT DEVELOPMENT

Ulrike Ravens-Sieberer, Child and Adolescent Health, Robert Koch Institute, Berlin, Germany; Monika Bullinger, Medical Psychology, University Hospital Hamburg, Hamburg, Germany

**Aims:** Over the last decades, the demand for internationally available instruments to assess health-related quality of life has increased. Conflicting strategies have been followed to approach the issue of cross-cultural differences in developing quality of life instruments. One is to minimize crosscultural differences by identifying and eliminating culture-specific responses to items in order to achieve a culture-free assessment. The other is to explicitly attend to and enhance such differences in order to produce culturally sensitive instruments. Depending on the purpose, both approaches are useful, but have diverging implications. **Methods:** According to recent guidelines of instrument development, necessary steps include item formulation (using focus groups and item writing), response scale choice (in terms of format and time frame), translation (with forward /backward translations and international harmonization), pilottesting (with cognitive debriefing and revision) and, after fieldtesting, the test-theoretically based analysis (on the level of single countries or the combined data set, using classical or modern psychometric methods such as IRT or SEM) **Results:** Using the framework of two large European Projects on crosscultural instrument development and testing (KIDSCREEN, DI-SABKIDS), these steps will be outlined, including the psychometric methods employed to identify crosscultural differences. As the concept of differential item functioning (DIF) is essential also for understanding the implication of crosscultural differences, selected results will be presented demonstrating the implications of minimizing or enhancing crosscultural DIF. **Conclusions:** The discussion will concentrate on the implications of minimization or enhancement of crosscultural differences also taking into account available research, and will lead to a critical appraisal of current concepts, methods and applications of cultural diversity in instrument development.

# 1586/BENEFITS AND CONSEQUENCES OF USING A SINGLE PORTUGUESE LANGUAGE VERSION OF THE FUNCTIONAL ASSESSMENT OF CANCER THERAPY-GENERAL (FACT-G)

Benjamin Arnold, S. Eremenco & J.S. Lai, CORE, ENH, Evanston, IL; J.L.P. Ribeiro, Faculdade de Psicologia, U. do Porto, Porto, Portugal; Maribel Dóro, BMT Unit, University Hospital, Curitiba, Paraná, Brazil; D. Cella, CORE, ENH, Evanston, IL

**Aims:** Languages such as Spanish and Portuguese are spoken differently in different parts of the world. It is challenging to determine whether to adapt language versions to account for regional differences in vocabulary or syntax, or whether one universal translation can be applied with due attention to harmonization of differences. To evaluate our practice of creating and applying single language translations in countries where different variations of the same language are spoken we compared the psychometric properties of the Portuguese FACT-G as completed by people from Portugal versus Brazil. **Methods:** Version 4 of the FACT-G was translated into one Portuguese version for both countries using our standard methodology. In Brazil, data were collected from 143 cancer patients, 51.1% male, mean age: 57.0 years. In Portugal, data were collected from 122 cancer patients, 37.7% male, mean age: 57.2 years. We analyzed the data using classical test theory and then applied a rating scale item response theory model to examine differential item functioning (DIF). **Results:** The FACT-G performed equally well in both countries with Cronbach's  $\alpha = 0.89$  in each sample, and all subscales between 0.71 and 0.86. Among the 27 items of the FACT-G, 10 items displayed DIF between the groups ( $p < 0.01$ ). The majority of DIF was found in the social family and emotional well-being subscales as opposed to the physical and functional well-being subscales. **Conclusions:** The Portuguese patients were more homogeneous than the Brazilian sample in terms of functioning and diagnosis, but this alone did not account for the divergences observed. The results suggest cultural (rather than linguistic) differences between groups that pertain to emotional and family norms. Although it is feasible to develop one Portuguese language version of the FACT-G for use in both Portugal and Brazil, more investigation is needed to appreciate cultural differences in the way Brazilian and Portuguese patients respond to psychosocial questions. Steps aimed at addressing these needs will be discussed.

# 1206/TEST-RETEST RELIABILITY OF HEALTH UTILITIES INDEX SCORES: EVIDENCE FROM HIP FRACTURE

David H. Feeny, Pharmacy and Pharmaceutical Sciences, Institute of Health Economics; Allyson Jones, Physical Therapy, University of Alberta; Ken Eng, Institute of Health Economics, Edmonton, AB, Canada

**Aims:** There is little published evidence on the test-retest reliability of utility scores derived from multi-attribute utility measures such as the Health Utilities Index. A prospective cohort study of patients recovering from hip fracture provided an opportunity to assess test-retest reliability. Patients experienced little change in the period between 3 and 6 months post hip fracture. The aim was to estimate test-retest reliability for overall HUI Mark 2 (HUI2) and Mark 3 (HUI3) utility scores. **Methods:** An inception cohort of hip fracture patients were recruited. Patients were enrolled within 3–5 days of surgery. Baseline assessments included the Functional Independence Measure (FIM) and the HUI2/HUI3 questionnaire. Follow-up assessments at 1, 3, and 6 months also included a global change question. Two approaches were used to estimate test-retest reliability using the intraclass correlation (ICC) coefficient: by assessing agreement among scores in stable patients and with generalizability theory. Patients were classified as stable if their FIM overall scores changed by 10 points or less and if the patient classified themselves as having changed little between the 3 and 6 month assessments. Agreement for all patients at the 3 and 6-month assessments was used for generalizability theory approach. **Results:** Complete data at both the 3 and 6 months assessments were available for 195 patients; 141 patients were classified as stable. The ICCs for stable patients for HUI2 and HUI3 were 0.71 and 0.72; the ICCs derived from generalizability theory were 0.76 and 0.77. **Conclusions:** Test-retest reliability for HUI in this cohort was similar to reliability estimates for other preference-based multi-attribute and generic profile measures

of health status and health-related quality of life and in the acceptable range for making valid group-level comparisons.

# 1543/ITEM RESPONSE THEORY TO ASSESS THE FRANCE – SPAIN CROSS-CULTURAL VALIDITY OF THE VSP-A

Karine Barrau, Public Health, University Hospital of Marseille, Marseille, France; V. Serra-Sutton & L. Rajmil, Agència d'Avaluació de Tecnologia, Barcelona, Spain; P. Auquier, S. Robitail & M.C. Simeoni, Public Health, University Hospital of Marseille, Marseille, France

**Aims:** The VSP-A is a French generic, multidimensional, self-administered HRQoL tool, based on the point of view of adolescents. It comprises 34 items, exploring 9 dimensions: Friends (FR), psychological well being (PWB), vitality (VI), self perception (PH), parents (FA), teachers (TE), school work (SCH), leisure (LE) and physical well-being (PH). VSP-A has already been validated in Spanish. The aim of this study is to explore the cross-cultural properties of this instrument by the means of IRT. **Methods:** The scalability of every dimensions was assessed using both non parametric and parametric IRT: Mokken scale analysis (MSP<sup>®</sup>) and Rasch model (WINSTEPS<sup>®</sup>). The multidimensional structure was assessed through Exploratory Factor Analyses (EFA), Confirmatory Factor Analyses (LISREL) and MAP analyses. DIF was assessed through non parametric Double Monotonicity Model and Zumbo's logistic regression method. Trait validity has been assessed using Multitrait Multimethod model (CFA). Known group validity has been checked comparing age, gender and different health status groups. The study involved 1356 adolescents (France  $n = 783$ , Spain  $n = 573$ ). **Results:** LISREL CFA results were satisfactory (RMSEA = 0.074, CFI = 0.95). Non parametric IRT Loevinger H was greater than 0.40 for all of the dimensions on international and national data. MAP analyses and EFA showed good results. Partial Credit Rasch Model fit and DIF analyses were satisfactory for all of the items except one (INFIT > 1.40, Delta- $R^2 > 3\%$ ). Multitrait multimethod CFA test of fit was good (CFI > 0.90). Reliability is satisfactory on both the international sample ( $\alpha: 0.71-0.91$ ), and the national samples (France: 0.73–0.91; Spain: 0.68–0.92). Known group validity was achieved using several comparisons between age, gender groups and health status groups. **Conclusions:** These results confirm the cross-cultural validity of the Spanish and French versions of the VSP-A. The conjoint use of non parametric and parametric IRT model is useful and should be widely reported, especially when performing DIF analyses.

#### # 1527/PERSON FIT ACROSS EUROPEAN COUNTRIES: RESULTS FROM THE KIDSCREEN FIELD SURVEY

Stephane Robitail, Public Health, University Hospital of Marseille, Marseille, France; M. Erhart, Child and Adolescent Health, Robert Koch Institute, Berlin, Germany; C. Tebe, Agència d'Avaluació de Tecnologia, Barcelona, Spain; M. Power, Psychiatry, University of Edinburgh, Edinburgh, UK; D. Debensason, Public Health, University Hospital of Marseille, Marseille, France; U. Ravens-Sieberer, Child and Adolescent Health, Robert Koch Institute, Berlin, Germany; P. Auquier, Public Health, University Hospital of Marseille, Marseille, France

**Aims:** Since few years IRT based methods have been widely used in the field of HRQoL instrument development. Item fit to the Rasch model and DIF across sub-groups and especially countries are a major topic of research. Although the results of item fit are largely reported, person fit is still not widely presented. Analysing person fit across different sub-groups should be a relevant and original way to complete the Rasch analyses. The KIDSCREEN project aims at develop an European cross-cultural instrument for children and adolescents. **Methods:** To assess and compare the person fit across age groups, gender and European countries. Rasch modeling has been led through the Andrich's extended logistic Rasch model (RUMM 2010). **Results of person fit** have presented as means and standard deviations of residual fit statistics by sub-groups. These analyses have been led on the KIDSCREEN field survey data. They concerned one of the five dimensions of the KIDSCREEN-27 item instrument: Peers and Social Support (SOC). The population comprised 22481 youth. **Results:** Person Separation Index was good (PSI = 0.818). The results on the whole sample were:  $-0.41 \pm 1.17$ . The children presented a lower misfit than the adolescent. The girls' misfit was lower for the social domain than for the boys. The misfit results differed between countries. **Conclusions:** This example emphasized the problem of interpretation of person producing misfitting score patterns. Future research is needed to compare misfit concerning different HRQoL domains. In the field of educational testing, person misfit should be understood, for example, as a result of cheating or lack of motivation. Which hypotheses should be retained to explain the person misfit in the field of quality of life measure?

#### # 1137/COMPARISON OF CHANGES IN VAS SCORES AND SF-36 BASED UTILITY ESTIMATES

Michael B. Nichol, Sheng G. Shi & Tara K. Knight, Pharmaceutical Economics and Policy, USC, LA, CA

**Aims:** In cost-utility analyses, investigating change in utility scores as a result of treatment is of great interest. SF-36 based utility estimates may be used when directly elicited utilities are unavailable. The purpose of this study is to compare change in SF-36 based utility estimates with change in Visual Analogue Scale (VAS) (gold standard) in effort to show improvement in patient health-related quality of life as the result of a pharmacy intervention. **Methods:** The study population consists of a large Health Maintenance Organization (HMO) data set of 6923 patients. Change scores were calculated using SF-36 and VAS scores from baseline and follow-up surveys. Eight utility estimates were derived from SF-36 scores, including Nichol-Sengupta-Globe OLS estimate of Health Utilities Index-2 (HUI2) from SF-36, Sengupta-Globe-Nichol estimate of VAS from SF-12 (SGN SF12-VAS), Sengupta-Globe-Nichol estimate of HUI2 from SF-12, SF6D VAS OLD, OLD and NEW SF6D-SG estimate, Lundberg estimate, and Shmueli estimate. Comparisons are made on the entire data and on sub-groups defined by the general health question of SF-36. Change in each SF-36 based utility is regressed on change in VAS. **Results:** Average change scores of SF-36 based utilities ranged from  $-0.0128$  to  $0.0008$  except for SGN SF12-VAS ( $-0.0489$ ). Average change score for VAS was  $0.0125$ . Regression and sub-group results indicate that changes for SF-36 based utilities (except SGN SF12-VAS) are smaller in magnitude than that of VAS when the latter is large ( $>0.1$ ). Roughly 60% of the time, direction of change according to a SF-36 based utility is consistent with that of VAS. **Conclusions:** Average baseline to follow-up change in utility measured by VAS is rather small in this large HMO population. SF-36 based utilities produced rather small, though mostly statistically significant (due to sample size), biases in estimation of this change. If change in VAS

scores were to be large, most SF-36 based mapping utilities might underestimate the change.

#### # 1481/MODELING VALUATIONS FOR PEDIATRIC HEALTH STATES DEFINED BY THE HEALTH UTILITIES INDEX MARK 3 (HUI3)

Hein Raat & C. Looman, Public health, Erasmus MC, Rotterdam; G.J. Bonsel, Public Health Epidemiology, Amsterdam Medical Center, Amsterdam; W.C. Hoogveen, Rotterdam; P. Krabbe, University Medical Centre Nijmegen, Nijmegen; R.J. Gemke, Amsterdam; M.L. Essink-Bot, Public Health, Erasmus MC University Medical Center Rotterdam, Rotterdam, The Netherlands

**Aims:** In this study we modeled a pediatric Health Utilities Index mark 3 (HUI3) valuation function and evaluated its performance for arbitrary HUI3 health states (i.e. states not used to estimate the model). **Methods:** In 2001, a random sample of 2040 parents of schoolchildren (aged 4–13) was mailed a questionnaire. Each respondent was asked to rate 6 HUI3 health states of hypothetical 8-year old children, randomly selected from the 65 health states included in this study (among which 49 states generated by a factorial design model), on a 0–100 Visual Analogue Scale (VAS). The individual data were used to fit additive- as well as multiplicative least square models with the 8 HUI3 dimensions as categorical predictors and 'respondent' as nuisance factor. The models were evaluated by jackknife testing (fitting the model 65 times while eliminating 1 health state at a time and comparing the estimated value by each ad-hoc model with the empirical mean value for each omitted state). **Results:** Response was 70%. The multiplicative model resulted in a lower, i.e. better, residual sum of squares (RSS = 3498) than the additive model (8973); total sum of squares was 22,637. Jackknife testing resulted in 60% explained variance for the additive model and 85% for the multiplicative model. Ten of 65 jackknife-estimates of health states by the multiplicative model differed  $>10$  points from empirical mean scores. The model is expected to result in lower estimates for higher (i.e. worse) levels of each HUI3 dimension; this was violated in the multiplicative model for levels 1 and 2 of Cognition. **Conclusions:** The large number of respondents and HUI3 states permitted us to fit models on individual data and to apply jackknife testing. As in the Canadian HUI3 study, a multiplicative model outperformed the additive one. Jackknife testing, not applied before, indicated that arbitrary HUI3 health states may show  $>10$  points difference between estimated and empirical values. We intend to estimate conversions of VAS values, applied in this study, into utilities in a separate study.

# 1064/COMPARISON BETWEEN TELEPHONE INTERVIEW AND SELF-COMPLETION OF THE MACDQOL

Jan Mitchell, Psychology, Royal Holloway, University of London, Egham, Surrey, UK; Alison Woodcock, Psychology, Royal Holloway, University of London, Egham; Clare Bradley Psychology, Royal Holloway, University of London, Egham, Surrey, UK

**Aims:** The MacDQoL is an individualised measure of the impact of macular degeneration (MD), an incurable eye condition, on quality of life (QoL). If MD is severe, people may have difficulty reading and must complete the MacDQoL by interview. Self-completion is more economical. Self-completion and telephone interviews were compared to determine whether they may be used in one study. **Methods:** Participants were members of the UK MD Society (199 contacted, 45 unable to read, 14 declined, attrition = 13): n = 127, 79% women, mean age 78 years. Vision status: 17% registered blind, 38% partially sighted, 45% not registered. All could read large print, using low vision aids if necessary. They were randomised to experimental (E) or control (C) group. All completed the MacDQoL twice (mean interval 39 days). E completed once by telephone, once by self-completion (50% self-completed at time 1, 50% at time 2). C self-completed twice. MacDQoL domain scores are weighted by importance, summed and divided by the number of applicable domains to give an average weighted impact score. Scores were compared using *t*-tests and two-way mixed design ANOVA. **Results:** C scores at times 1 and 2 did not differ. E reported greater negative impact of MD on QoL when self-completing than by telephone interview ( $p < 0.001$ ). ANOVA showed main effects of completion time ( $p < 0.001$ ) and completion method ( $p = 0.012$ ). An interaction ( $p < 0.001$ ) indicated a larger difference between the methods when telephone interview was at time 1. The MacDQoL showed good reliability with both methods (Cronbach's  $\alpha > 0.94$ ). Using both methods, the MacDQoL could detect differences between the three vision status categories ( $p$ 's  $< 0.001$ ). **Conclusions:** Completion method did influence MacDQoL scores. Self-completion for those able to read and telephone interview for those more severely impaired would underestimate the impact of severe MD on QoL. Telephone interview is preferable except where all participants have only mild or unilateral MD.

# 1355/THE 'PERCEIVED STRESS QUESTIONNAIRE' (PSQ): STRUCTURAL RE-EVALUATION, VALIDATION AND REFERENCE VALUES FROM DIFFERENT CLINICAL AND HEALTHY SAMPLES

Herbert Fliege, Department of Psychosomatic Medicine; Matthias Rose, Psychosomatic Medicine; Petra Arck, Otto B. Walter, Rueya-Daniela Kocalevent, Cora Weber, Department of Psychosomatic Medicine, Charité University Hospital, Berlin, Germany; Susan Levenstein, Department of Gastroenterology, San Camillo-Forlanini Hospital, Rome, Italy; Burghard F. Klapp, Department of Psychosomatic Medicine, Charité University Hospital, Berlin, Germany;

**Aims:** The aim was to translate the Perceived Stress Questionnaire (PSQ) by Levenstein et al. (1993) into German, reanalyze its structural and psychometric properties and shorten it. The PSQ assesses subjectively experienced stress independently of a specific occasion. **Methods:** Data from a sample of 650 subjects (psychiatric (non-psychotic) patients, women after delivery, women after miscarriage, students) served for exploratory factor analyses and a structural revision. Data from a second sample of 1808 subjects (psychiatric, tinnitus, inflammatory bowel disease patients, pregnant women, healthy adults) served for confirmatory analyses and examination of structural stability across subgroups using linear structural equation modeling (SEM) and multi-sample analyses (MSA). External validation included immunological measures in women suffering from miscarriage. **Results:** A structure of four factors emerged (worries, tension, joy, demands, with five items each). Confirmatory SEM confirmed the factor structure on the second sample. MSA yielded a fair structural stability across groups. Reliability was satisfactory. three scales represent internal stress reactions, whereas the scale 'demands' relates to perceived external stressors. There is no gender difference, yet all scales are reversely age-correlated. Group differences indicate differential validity. A higher degree of immunological imbalances after miscarriage (presumably linked to pregnancy loss) was found in those women who had a higher stress score. Sensitivity to change was demonstrated in two treatment samples. **Conclusions:** We propose the revised PSQ as

a valid and economic tool for research on perceived stress. The overall score permits comparison with results from earlier studies with the original instrument.

# 1546/THE ORTHO BIRTH CONTROL SATISFACTION ASSESSMENT TOOL (ORTHO BC-SAT): RELIABILITY AND VALIDITY OF A NEW SATISFACTION QUESTIONNAIRE

Susan Mathias, Ovation Research Group, San Francisco, CA; John LoCoco & Debra Karvois, Ortho-McNeil Pharmaceutical, Inc., Raritan, NJ; Hilary Colwell, Ovation Research Group, San Francisco, CA; Tricia Cimms, Ovation Research Group, Highland Park, IL; Andrew J. Friedman, Ortho-McNeil Pharmaceutical, Inc., Raritan, NJ

**Aims:** To assess the reliability and validity of a new satisfaction questionnaire among women using 1 of 4 hormonal birth control methods. **Methods:** A convenience sample of women, ages 18–50 using their method for at least 1 month, completed the questionnaire. To our knowledge, no other comprehensive questionnaire exists to evaluate satisfaction. The ORTHO BC-SAT was developed based on a literature search, focus groups, and interviews with clinicians. In addition to the creation of scales, the psychometric properties of the questionnaire were tested. **Results:** 339 women completed the ORTHO BC-SAT. 41 completed the questionnaire a second time, approximately 30 days later (to assess test–retest reliability). Based on variable clustering, the ORTHO BC-SAT contained 42 items in 8 domains (future fertility concerns, ease of use/convenience, compliance, lifestyle impact, symptom/side effect bother, menstrual impact, assurance/confidence, overall satisfaction). Internal consistency reliability was demonstrated with Cronbach's  $\alpha$  values for all scales (0.73–0.92). In addition, all scales reported acceptable test–retest reliability (0.79–0.91). Construct validity was demonstrated based on proposed interscale correlations being borne out [e.g., ease of use/confidence was highly correlated with compliance (0.75)]. Known groups validity was demonstrated by examining the scale scores of women categorized by levels of symptom bother [e.g., women with the least amount of bother reported higher satisfaction than those with higher bother, except on future fertility concerns ( $p = 0.12$ )]. **Conclusions:** The results of this study support the reliability and validity of the ORTHO BC-SAT. It can be used with confidence in future studies to evaluate satisfaction among women using various birth control methods.

# 1585/THE TEST-RETEST RELIABILITY OF THE OVERACTIVE BLADDER QUESTIONNAIRE (OAB-Q)

L. Matza, C. Thompson & J. Brewster, MEDTAP International, Inc., Bethesda, MD; T. Zyczynski, Pfizer Inc, New York, NY; K. Coyne, MEDTAP International, Inc., Bethesda, MD, USA

**Aims:** Overactive Bladder (OAB) is characterized by symptoms of urinary urgency, which may be accompanied by urge incontinence, increased urinary frequency, and/or nocturia. The Overactive Bladder Questionnaire (OAB-q) was designed to assess symptom bother and health-related quality of life (HRQL) among patients with OAB. The purpose of this study was to further validate the OAB-q by assessing its test-retest reliability, a psychometric property that must be examined to ensure that an instrument consistently measures the construct of interest without excessive measurement error. **Methods:** Patients were recruited from urology clinics and were scheduled for two visits approximately two weeks apart. At both visits, patients completed the OAB-q, which consists of an 8-item symptom bother scale and 25 HRQL items that form 4 subscales (coping, concern, sleep, social interaction) and a total HRQL score. A demographic form was completed at Visit 1, and a treatment effect scale used to assess symptom stability was completed at Visit 2. Test-retest reliability was examined among the stable patients using intraclass correlations (ICCs), Spearman's correlations, paired *t*-tests, and Feldt's statistic. **Results:** A total of 47 patients enrolled (mean age = 66.0 years; 74.5% female) with 46 completing both visits and 35 classified as stable with regard to symptoms and drug treatment. There were statistically significant Spearman correlations between Visit 1 and Visit 2 scores for all subscales of the OAB-q ( $p < 0.001$ ;  $r = 0.80$ ) and ICCs were in the high range ( $\geq 0.83$ ). No statistically significant differences between Visits 1 and 2 were found, except on the symptom bother scale (change of 5.8 points on a 100-point scale, which is not considered clinically significant). All subscales demonstrated good internal consistency (Cronbach's  $\alpha \geq 0.88$ ), and Feldt's Statistic found no change in internal consistency between the two assessments. **Conclusions:** The OAB-q demonstrated good test-retest reliability. These findings add to previous data, suggesting that this instrument demonstrates the necessary psychometric properties for use as an outcome measure of OAB treatments.

# 1581/DEVELOPMENT OF THE OVERACTIVE BLADDER QUESTIONNAIRE SHORT FORM (OAB-Q SF): A BRIEF MEASURE OF SYMPTOM BOTHER AND HEALTH-RELATED QUALITY OF LIFE

K. Coyne, Research Scientist, MEDTAP International, Inc., Bethesda, MD; J.S. Lai, Outcomes, Research and Education, Northwestern University, Evanston, IL; L. Matza, Bethesda, MD; T. Zyczynski, Outcomes Research, Pfizer Inc, New York, NY; Z. Kopp, New York, NY; P. Abrams, Urology, Southmead Hospital, Bristol, UK

**Aims:** The Overactive Bladder Questionnaire (OAB-q) was designed to assess symptom bother and health-related quality of life (HRQL) among patients with OAB. It has been validated among diverse samples and found to be reliable, valid, and responsive. The aim of this study was to develop a short form of the OAB-q (OAB-q SF) to reduce respondent burden while retaining sound psychometric properties. **Methods:** The original OAB-q consists of an 8-item Symptom Bother scale and 25 HRQL items that form four subscales (coping, concern, sleep, social interaction). Retrospective analyses were performed on two OAB patient samples: a cross-sectional (CS) population survey ( $n = 919$ ) and a 12-week clinical trial ( $n = 865$ ). Items of OAB-q SF were selected using baseline clinical trial data and were cross-validated by analyzing CS data. Item response theory was used to ensure items represent the whole OAB continuum and possess satisfactory psychometric properties. Exploratory factor analysis was performed on the HRQL items to identify subscales of the OAB-q SF. Internal consistency was assessed using Cronbach's  $\alpha$ . Analysis of variance, *t*-tests, and effect sizes were used to assess construct validity and responsiveness. **Results:** Results suggest a 6-item Symptom Bother short form and a 13-item HRQL short form. The majority of scaled scores could be precisely estimated using these short forms (89.1% for symptom bother SF and 94.7% for HRQL SF). Factor analysis of the 13 HRQL items revealed three subscales: coping (5 items), sleep (3 items), and emotional/social (5 items). All Cronbach's alphas and effect sizes were similar to those of the original OAB-q. OAB-q SF subscales

were significantly correlated with SF-36 subscales ( $r = 0.26$  to  $0.43$ ; all  $p$  values  $< 0.0001$ ). All subscales discriminated among normal, continent, and incontinent OAB patients ( $p < 0.01$ ). **Conclusions:** The OAB-q SF captures symptom bother and HRQL while retaining reliability, validity, and responsiveness similar to the original version.

# 1495/THE ESPRINT QUESTIONNAIRE: A SPANISH MEASURE TO ASSESS THE HEALTH-RELATED QUALITY OF LIFE (HRQOL) OF ALLERGIC RHINITIS (AR) PATIENTS IN CLINICAL PRACTICE. Michael Herdman, 3D Health Research, Barcelona, Spain

**Aims:** Instruments currently used to measure HRQOL in AR in Spain have been adapted from questionnaires developed elsewhere, with little guarantee that their content is appropriate for Spain. Likewise, most AR instruments are developed for clinical research, not for clinical practice. The ESPRINT study aimed to develop a Spanish instrument to measure HRQOL in AR that would be suitable for clinical practice. **Methods:** Instrument development consisted of several stages: (1) literature review to identify the content, format, and psychometric properties of existing, relevant HRQOL instruments; (2) a metaplan consensus session with seven clinical experts and two experts in HRQOL measurement to define basic questionnaire characteristics; (3) focus groups with a total of 27 AR patients; (4) generation of initial item pool, using content analysis of transcripts from focus groups; (5) item reduction; and (6) instrument completion and validation. **Results:** We identified 11 instruments designed to measure AR or related illnesses, ranging from 14 to 31 items in length. During the metaplan session, it was decided that the instrument should contain no more than 15 items, be self-administered, easy to score, and include basic symptoms. Focus group work generated an initial pool of 69 items, after removal of duplicate, ambiguous or difficult items. Administration of the initial item pool in 413 AR patients, and further item reduction led to a 15 item version for use in clinical practice with four dimensions (symptoms, daily activities, sleep, psychological impact). A 27-item, 7 dimension (nasal, Eye, and other symptoms, tiredness, daily activities, environment, Sleep, psychological impact) version was produced for use in clinical research. **Conclusions:** The 15 item version of the new questionnaire met a priori criteria for use in clinical practice, but both versions require assessment of reliability and validity, which is currently underway.

# 1704/METHODOLOGICAL ISSUES IN DETERMINING THE DIMENSIONALITY OF COMPOSITE HEALTH MEASURES USING PRINCIPAL COMPONENT ANALYSIS. CASE ILLUSTRATION AND RECOMMENDATIONS FOR PRACTICE

Joel Coste, Stéphane Bouée & Emmanuel Ecosse, Biostatistique et Informatique Médicale, Hospital Cochin, Université de Paris V, Paris, France; Jacques Pouchot, Médecine Interne, Hôpital Louis Mourier, Colombes, France; Alain Leplege, Philosophy, University of Amiens, Amiens, France

**Aims:** During the construction of composite health measures, principal component analysis (PCA) is commonly used to identify 'latent' factors that underlie observed variables and to determine the dimensionality of the instruments. The determination of the number of components to retain is critical to PCA and may markedly influence the identified factorial model and further condition the validity of the constructed instrument. The aims of the paper are to compare the results of the application of various published rules for determining the number of components to retain in PCA applied to quality-of-life data, and to give recommendations for PCA users. **Methods:** Ten published rules for determining the number of components to retain in PCA were applied to two representative samples of the French adult population evaluated with the SF-36 questionnaire, leading to 20 potential factorial models. These models were further evaluated from both statistical and conceptual points of view. **Results:** Very different factorial models (from 2 to 35 dimensions) resulted from the application of the rules, some of them being obviously incorrect. **Conclusions:** A careful and diversified approach to the problem of identifying dimensionality of composite health measures is proposed, in contrast to the unsatisfactory 'rule-of-thumb' that many researchers have used until now. This involves (1) using several rules to generate an interval of possible values for the number of components to retain in PCA, (2) repeating the analysis across samples, (3) comprehensively assessing the models subsequently obtained using these values, and (4) considering complementary or alternative methods to PCA and especially confirmatory factor analysis.

# 1082/CONSTRUCTING CORRELATED PHYSICAL AND MENTAL HEALTH SUMMARY SCORES FOR THE SF-36 HEALTH SURVEY

Sepideh S. Farivar & Ron D. Hays, General Internal Medicine and Health Services, UCLA School of Medicine and RAND Health Sciences, Los Angeles, CA, USA

**Aims:** The standard scoring algorithm for the SF-36 physical health (PCS) and mental health (MCS) component summary scores is based on an uncorrelated (orthogonal) two factor solution. Discrepancies between results for the 8 SF-36 scale scores and the PCS and MCS have been noted in some studies because higher mental health scale scores drive the PCS down and higher physical health scale scores drive the MCS down (and vice versa). **Objective:** To estimate SF-36 summary scores from correlated (oblique) physical and mental health factor solution. **Methods:** SF-36 was administered to 6543 patients (average age = 51; range = 17–96; 65% female) who received medical care from an independent association of 48 physician groups in the western United States. An obliquely rotated two-factor solution for the SF-36 scales was obtained. PCS-36, PCS-12, MCS-36, and MCS-12 summary scores were estimated. **Results:** Estimated correlation between physical and mental health factors was 0.58. Factor scoring coefficients for PCS-36 and MCS-36 are as follows: (1) PCS-36 =  $0.20 \times \text{physical functioning} + 0.32 \times \text{role/physical} + 0.23 \times \text{bodily pain} + 0.19 \times \text{general health perceptions} + 0.12 \times \text{energy/fatigue} + 0.12 \times \text{social functioning} + 0.05 \times \text{role-emotional} + 0.06 \times \text{emotional well-being}$ ; (2) MCS-36 =  $-0.01 \times \text{physical functioning} + 0.03 \times \text{role-physical} + 0.03 \times \text{bodily pain} + 0.07 \times \text{general health perceptions} + 0.36 \times \text{energy/fatigue} + 0.10 \times \text{social functioning} + 0.14 \times \text{role-emotional} + 0.39 \times \text{emotional well-being}$ . The scoring equations for the SF-12 summary scores are available upon request. **Conclusions:** The physical and mental health summary scores for the SF-36 and SF-12 derived here from an obliquely rotated factor solution should be used along with the PCS-36, MCS-36, PCS-12, and MCS-12 summary scores.

# 1588/FROM PATIENT PROFILE ANALYSIS TO KOSKO FUZZY HYPERCUBE: COMPARISON OF TRADITIONAL AND FUZZY SET THEORY METHODS TO ASSESS THE AGREEMENT BETWEEN RATERS OF MULTIDIMENSIONAL HRQOL MEASURES AT THE INDIVIDUAL LEVEL

K. Tiphratene, Public Health, University Medicine, Marseille; H. Borson-Chazot, Toulouse; P. Romestaing, HCL, Lyon, France; D. Serin Clinique, Avignon; J.P. Auarray, Lyon E. Pillet & P. Auquier, Department Public Health, University Medicine, Marseille, France

**Aims:** This study aimed to compare two methods to assess the inter-rater (patient vs proxy) agreement at an individual level: patient profile analysis (PPA) and fuzzy set theory based method. **Methods:** 201 women and 164 patient-proxy pairs were recruited with FACT-G full-filled. For the 5 sub-scales, the reliability was good for both self-report ( $\pm 0.71-0.83$ ) and proxy ( $\pm 0.66-0.86$ ). Intraclass correlation coefficient (ICC) were comprised between 0.39 and 0.54. At an individual level, PPA provides three indicators of agreement between self-report and proxy ratings: Level (average of ratings), Scatter (variability in ratings) and Shape (ranks of ratings). Kosko introduced a geometrical interpretation of fuzzy sets as points in a hypercube. For a given patient, the pattern of five scores expressed its membership values. The fuzzy set cardinality was defined by the sum of the membership values. The degree of similarity was computed for each pair of patient-proxy. The degree of similarity ( $S$ ) should be comprised between 0 and 1 (perfect similarity). **Results:** There were no linear relationship between  $S$  and any of the three other PPA indicators. Non parametric correlations showed that  $S$  presented higher correlation with Shape. Several sensitivity analyses have been led. For example, the selection of pairs with a high degree of similarity ( $Se 0.80$ ) enables to define two subsets of patient-proxy pairs. The first with a higher  $S$  ( $n = 108$ ) presented higher scores of agreement for the three PPA indicators and ICC comprised between 0.59 and 0.77 for the five dimensions. For the latter ( $n = 56$ ), the PPA indicators indicated a lower agreement and ICC were comprised between 0.11 and 0.28. **Conclusions:** These results expressed the great challenge of applying fuzzy set theory methods in the whole field of the quality of life research.

# 1609/APPLICATION OF GENERALIZABILITY THEORY TO ASSESS RELIABILITY OF HEALTH MARKER STATES

Holger J. Schunemann, Medicine, Clin. Epi. & Biostatistics, University at Buffalo & McMaster University, Buffalo, NY; Geoff Norman, Psychology, McMaster University, Hamilton, ON, Canada; Elisabeth Stahl, R&D, AstraZeneca Lund, Sweden; Ingela Wiklund, R&D, AstraZeneca, Molndal, Sweden; Milo Puhani, Evidence Based Practice, Horten Centre, Zurich, Switzerland; Gordon Guyatt, Clin. Epi. & Biostatistics, McMaster University, Hamilton, ON, Canada

**Aims:** To assess the reliability of marker state ratings on two preference based instruments (standard gamble, SG, and feeling thermometer, FT) with the use of generalizability theory that allows to differentiate between test-retest and inter-rater reliability. **Methods:** Two studies, one in patients with chronic obstructive pulmonary disease (COPD,  $n = 91$ ) and the other in patients with gastroesophageal reflux disease (GERD,  $n = 112$ ), provided data for this analysis. In each study we evaluated test-retest and inter-rater reliability for three different health marker states rated twice several weeks apart. Using a repeated measures ANOVA that computed mean square terms for each main effect (health state, rater and time), their interactions and error terms, we calculated intra-class correlation coefficients (ICC) corresponding to test-retest and inter-rater reliability. **Results:** Test-retest reliability was higher for the FT compared to the SG (COPD: ICC 0.77 vs. 0.73; GERD: ICC 0.86 vs. 0.67). Inter-rater reliability was also higher for the FT compared to the SG (COPD: ICC 0.61 vs. 0.27; GERD: ICC 0.71 vs. 0.26). **Conclusions:** Use of generalizability theory suggests that test-retest and inter-rater reliability of marker state ratings is higher for the FT compared to the SG. This difference may explain why marker states may enhance measurement properties of the FT, but not of the SG.



#### # 1631/PREDICTIVE VALIDITY OF MOS SF-36 HEALTH SURVEY FOR MORTALITY AND LONGITUDINAL HEALTH CARE UTILIZATION

Colleen A. McHorney, Anthony J. Perkins & Joseph Kesterson, Regenstrief Institute; Linda Williams, Roudebush VAMC; William Tierney, Medicine, Indiana University, Indianapolis, IN

**Aims:** Substantial empirical evidence supports the cross-sectional construct validity of widely used patient-based quality of life measures, such as the MOS SF-36 Health Survey. However, little empirical evidence supports predictive validity. Our objective is to investigate the relative predictive validity of the eight SF-36 scales vis à vis mortality and health care utilization over a 10-year period. **Methods:** This is a longitudinal observational study in an academic primary care group practice. The SF-36 was completed in 1992. We tracked mortality for patients over an 8-year period and health care utilization over 10 years. Multivariate modeling techniques were used. **Results:** The SF-36 general health perceptions scale exhibited the best and most consistent predictive validity across our criterion variables in the short-term, intermediate-term, and long-term. The next two best performing scales were physical functioning and role-physical. The SF-36 scales that are most indicative of mental health status, as defined by clinical and psychometric tests of validity tests (role-emotional, mental health, and social functioning), performed the worse in tests of predictive validity. **Conclusions:** A single SF-36 scale (general health perceptions) and a single SF-36 item (the excellent-to-poor rating of health) may provide an efficient measure of risk at the individual and population level.

#### # 1489/THE EFFECT OF INFORMATIVE DROPOUTS ON ESTIMATED RATE OF CHANGE IN A LONGITUDINAL STUDY

Sonia Gavriel & Paul W. Jones, Respiratory Medicine, St. George's Hospital Medical School, London, UK

**Aims:** Hierarchical linear models (HLM) are often used in longitudinal studies when there is differential withdrawal between treatments (informative dropout). We modelled the pattern of informative dropout seen in a 3-year placebo controlled trial in COPD (Burge et al. Br ModJ 2000) on HLM estimates of change in SGRQ score to test the potential for bias with such models. In that study, patients who withdrew had faster decline in SGRQ score, but the treatment slowed the decline. **Methods:** Data are from 298 patients measured 6-monthly for 3 years. Patients were split into slow or fast decline groups, determined by change in SGRQ score. We compared HLM and linear regression (REG) estimates in two states: before (control) and after removing the last 4 datapoints from 50% of patients in the fast group (model). No data were removed from the slow group. **Results:** SGRQ slopes (units/year) are tabulated. In the fast group, HLM rates were significantly lower (i.e. better) than REG rates, before (control) and after data were removed (Model). In the control state of slow group, HLM estimates were significantly higher (i.e. worse) than REG estimates. As data were removed from the Fast group, Slow HLM estimates became lower and similar to REG estimates (slow model). **Conclusions:** HLM models produce conservative results in the presence of informative dropout since less ill patients remain in the study longer and contribute more data, biasing all decline estimates.

SGRQ rate	Model	HLM mean (SD)	REG mean (SD)	p-Value
Fast	Control	2.62 (2.59)	3.03 (4.35)	0.007
	Study	1.53 (1.31)	3.76 (11.87)	0.011
Slow	Control	1.23 (2.56)	0.82 (4.18)	0.004
	Study	0.97 (2.55)	0.82 (4.18)	0.289

#### # 1699/SIMPLE IMPUTATION METHODS FOR THE EQ5D AND THE SF6D

Henk F. van Stel, Mart P. Janssen & Erik Buskens, Julius Center for Health Sciences, UMC Utrecht, Utrecht, The Netherlands

**Aims:** Utility scores such as the EQ5D and the SF6D require that all necessary items are completed by the subject. This causes missing in subjects who skip one or more questions. We developed two simple methods to use the information from other items in the same questionnaire to impute the missing utility score. **Methods:** Missing in the SF6D were imputed by first replacing missing items in the SF-36 by their respective domain scores, rounding these values to the nearest integer, and then recalculating the SF6D. Missings in the EQ5D were imputed using the valuation based on visual analogue scale (VAS) scores recently published by Greiner et al. For a person with one missing domain, there are three possible states, each with a VAS-valuation. The smallest difference between the VAS-score given by the patient and the three VAS-valuation scores was computed. Then the state associated with the smallest VAS-difference was used for recalculating the EQ5D. We used these imputation methods on baseline and post-intervention measurements from cardiovascular patients from two clinical trials (ARTS (n = 1176), Octopus (n = 561)). **Results:** Original and imputed values for both EQ5D and SF6D had similar means and standard deviations up to two decimals. The percentage of all cases with an imputed value ranged from 1.7% (ARTS) to 4.3% (Octopus) for EQ5D, and 1.4–5.9% for SF6D. Imputation decreased the amount of missings by 26–74%. **Conclusions:** These simple imputation methods decrease the amount of missings substantially, thereby increasing statistical power, while preserving means and standard deviations.

#### # 1171/ANALYSIS STRATEGY FOR QUALITY OF LIFE (QL) DATA: A PRACTICAL EXAMPLE OF PATTERN MIXTURE MODELS

Helen Thorpe & Julia Brown, Clinical Trials Research Unit, University of Leeds, Leeds, UK

**Aims:** The Big Lung Trial QL Study examined the QL of 273 non-small cell lung cancer patients receiving supportive care (SC) or SC with chemotherapy, using the EORTC QLQ-C30 and LC17 at 5 time-points, and daily diary cards. The primary (global QL at 12 weeks) and highlighted endpoints (emotional/physical functioning, fatigue, dyspnea, pain at 12 weeks) were derived from the QLQ-C30. Missing data were a problem: 34% had baseline or 12-week data missing. Statistical analysis of QL data is a developing area due to the multi-dimensional repeated measures nature and frequent missing data problems (Fayers and Machin 2000). There is also debate as to optimal methods for analysing QL data. Thus the analysis strategy was to focus on the primary and highlighted scales and use a variety of approaches to analyse these data. **Methods:** Results from the preliminary analysis of the QL Study were presented at ISOQOL 2003. Further analysis has now incorporated pattern mixture models to assess the impact of missing data. Primary and highlighted endpoints were compared using pattern mixture multi-level models (allowing for time, treatment, treatment by time, adjusting for baseline QL (all fixed effects), patient, patient by time (random effects)) by grouping patients based on tumour stage, age, performance status at 12 weeks (Fairclough, 1998). Pattern mixture models for bivariate (baseline and 12-week) data were also fitted using a variety of restrictions reflecting the missing data pattern (Fairclough, 2002). **Results:** The analysis approach utilised data in different ways to encompass as much information as possible, and allowed for differing missing data assumptions to enable testing of the sensitivity of the analysis to the missing data. Study results were not substantially changed from the preliminary analysis. Potential for a large positive impact on global QL in favour of chemotherapy remained, however potential for a large detrimental effect was only apparent if missing data were assumed to be not at random. For pain and physical functioning, some analyses indicated large positive effects for chemotherapy. Other endpoint results were unchanged. **Conclusions:** Pattern mixture models can easily be applied to aid interpretation in the presence of missing data.

# 1461/CONVERTING EORTC QLQ-C30 SCORES AND FACT-G SCORES TO ONE ANOTHER: FEASIBILITY AND RELIABILITY CONSIDERATIONS

Georg W. Kemmler, Bernhard Holzner, Barbara Sperner-Unterwieser, Psychiatry, Innsbruck University Hospital, Innsbruck, Austria; David Cella, Northwestern University and Medical School, Evanston, IL, USA

**Aims:** For assessing the quality of life (QOL) of cancer patients there is no best instrument, rather several suitable instruments are available. It would thus be useful to compare study results obtained with different, albeit similar questionnaires. Although methods for this task have been derived, their practical use has rarely been explored. Here we consider this problem for two widely used questionnaires, EORTC QLQ-C30 and FACT-G. **Aims:** (1) to check the comparability of corresponding QLQ-C30 and FACT-G subscales; (2) to derive conversion tables for those subscales for which comparability holds; (3) to assess the precision of the derived QOL scores. **Methods:** A calibration sample of 737 cancer patients (mean age  $51.4 \pm 7.6$  (SD), 63% female, 25% with current chemotherapy) who filled in both QOL questionnaires was used. Classical test theory and item response theory (Rasch analysis) were applied. Tables for converting EORTC and FACT-G subscores to one another were obtained by joint calibration of the QLQ-C30 and FACT-G items and separate re-estimation using anchored item and step measures. **Results:** Three of the 4 subscales common to both instruments proved suitable for converting (high inter-correlations of corresponding subscales, large first principal component of pooled subscales, satisfactory fit of Rasch model). The conversion tables obtained for the 3 subscales all showed a certain departure from a linear relationship. The derived scores were sufficiently precise only when used for predicting the mean of fairly large samples, not for predicting scores of individuals. **Conclusions:** The conversion tables appear promising for the comparison between EORTC QLQ-C30 and FACT-G scores of patient samples (e.g., studies in which only one of the two instruments was used), provided these are sufficiently large.

# 1271/CLINICALLY ASSOCIATED CHANGES IN SELF-REPORTED VISUAL FUNCTIONING IN AGE-RELATED MACULAR DEGENERATION (AMD) PATIENTS

Denise R. Globe, Pharmaceutical Economics and Policy; Tom Chang, Doheny Retina Institute; IvyTonnou, Pharmaceutical Economics and Policy, University of Southern California, Los Angeles, CA; Jennifer Fine, Health Economics, Genentech, Inc., San Francisco, CA; Diane Fairclough, Health Science Center, University of Colorado, Denver, CO, USA

**Aims:** To assess clinically relevant changes in National Eye Institute Visual Functioning Questionnaire-25 (VFQ-25) scores, which are useful for interpreting differences in self-reported visual functioning scores in AMD patients. **Methods:** 57 patients with primary or recurrent subfoveal neovascularization (CNV) secondary to AMD who participated in a phase I/II randomized trial of Lucentis (ranibizumab; rhuFab V2) completed a standardized interview, including the 25-item VFQ-25 to measure visual functioning, and a detailed eye examination at baseline and 3 months. Visual acuity was measured as the total number of lines read correctly and converted to a log of the minimum angle of resolution (logMAR score) in both the worse eye and the better eye. To account for differences between eyes, a weighted logMAR score was used (0.25 worse eye logMAR + 0.75 better eye logMAR). To estimate the clinically relevant change in VFQ-25 scores, differences in visual acuity were used as the clinical anchor. Regression of 3-month changes in each subscale score on the logMAR scores was used to estimate the change in VFQ-25 scores associated with 3-line change in visual acuity. **Results:** A 3-line change in binocular visual acuity was associated with a statistically significant change of 5.8 points in Distance Activities and 6.7 points in Near Vision. The magnitude change in points was similar using the eye with better visual acuity. Not surprisingly, there were no significant changes in Color Vision and Ocular Pain scores associated with change in visual acuity. **Conclusions:** Clinically meaningful changes in visual acuity (3 lines) were associated with changes in VFQ-25 subscale scores reflecting central vision loss that occurs in AMD.

# 1540/QUALITY OF LIFE AFTER KIDNEY TRANSPLANTATION

Jing Huang, Nephrology, Sun Yat-Sen University, PRC; Peigen Wu, Nephrology; Yuantao Hao, Public Health, Sun Yat-Sen University, Guangzhou, Guangdong, PRC

**Aims:** The objective was to apply KDQOL-SF36 to evaluating the changes that KT induces in QOL in a group of patients with CRF, previously undergoing dialysis, and analyze factors related to QOL in transplantation recipients. **Methods:** Patients were recruited at the First Affiliated Hospital of Sun Yat-Sen University from Jul 2003 to Oct 2003. KDQOL-SF36 was used as QOL indicators. The information was collected by interview/letters and phone. SPSS11.0 were performed to process data. **Results:** During the study, 56 were transplanted, 9 were missing. This left 47 in the study. By 6 months after transplantation, all scales of the SF-36 (PF/RF/BP/GH/MH/RE/SF/VT) had improved compared to pre-transplantation. Improvement was also observed in 8 categories of the disease-specific module, such as DRS/KDE/KDB/WS/SE/SL/SS/SAT, but CF/SI/DSE had no significant changes. One-way ANOVA analysis demonstrated that the scores of SF-36 and disease-specific module were higher in group of age < 30, high education level, high economic level, numbers of comorbid < 1, receiving CsA based immunosuppression, no episode of hospitalization, and creatinine level  $d115/4\text{mol/l}$ . In multivariate stepwise regression, economic level/comorbid/length of stay after operation were independent predictors of SF-36, age/number of hospitalizations after operation-creatinine level were independent predictors of disease-specific module. **Conclusions:** By 6 months after transplantation, quality of life had significantly improved; economic level/comorbid medical condition/length of stay after operation were independent predictors of SF-36, age/number of hospitalizations after operation/creatinine level were independent predictors of disease-specific module.

# 1143/COMPARISON OF QUALITY OF LIFE IN PATIENTS WITH BETWEEN LIVING RENAL TRANSPLANTATION AND CADAVERIC RENAL TRANSPLANTATION

Kuniyasu Ikeoka, Eriko Tokuhara, Risa Kawamura, Akane Miyazaki, Chiaki Nakauchi & Hiroshi Ishii, Japanese Society of Quality of Life Research, Kobe, Hyogo, Japan; Masamichi Yano Japanese Society of Quality of Life Research, Kobe, Japan; Youichi Kakuta, Naotsugu Ichimaru, Ryouichi Imamura, Shirou Takahara, Haruyasu Fujita, Hiromi Ohashi, Kozaburo Adachi, Kanehisa Morimoto, Takashi Mandai, Japanese Society of Quality of Life Research, Kobe, Hyogo, Japan

**Aims:** The purpose of this study was to evaluate the quality of life (QOL) in patients with renal transplantation. **Methods:** 150 patients (93 patients with living renal transplantation: LRT, and 57 patients with cadaveric renal transplantation: CRT) participated in this study. Self-administered questionnaire including 40 questions divided into 15 categories with the Life Satisfaction Index (LSI) were used. **Results:** Cronbach's  $\alpha$  coefficients of our questionnaire were high enough to accept for clinical use: 0.92 in mental function, 0.87 in environmental problem, and 0.85 in medical service, etc. respectively. Our questionnaire contained 10 main factors and cumulative contribution was 0.73. Pearson's correlation coefficient between our questionnaire and the LSI was  $r = 0.72$  ( $p < 0.01$ ). After renal transplantation, 128 patients indicated the improved total QOLs, but 22 patients showed the deteriorated total QOLs. Significant improvements were shown in strata of well-being, dietary problem, sleep pattern, mental function, and work performance ( $p < 0.01$ ) etc. after renal transplantation. Furthermore compared with CRT patients, the patients with LRT demonstrated the significant excellent QOL improvements, especially in strata of mental function, physical function, sexual life, environmental problem, and economical problem ( $p < 0.01$ ) etc. **Conclusions:** Although LRT showed more excellent QOL improvement than CRT, the patients with CRT were also given the chances to restart with passion for life. These findings indicate that our questionnaire has high enough reliability and potency of validity to use for the patients with renal transplantation. We believe that renal transplantation is the best way to improve QOLs of renal failure patients, especially in younger, with more deteriorated QOLs before renal transplantation, and with longer period of hemodialysis.

#### # 1509/QUALITY OF LIFE OF ALLERGIC RHINITIS PATIENTS WITH IMMUNOTHERAPY

Po-Jen Liu, Otolaryngology, Cheng-Ching Hospital, Taichung, Taiwan ROC; Tsai-Chung Li, Chinese Medicine, China Medical University, Taichung, Taiwan, ROC

**Aims:** Allergic rhinitis is one of the common disorders in Taiwan. The treatments of allergic rhinitis include aggressive environmental control, medicine, surgery and immunotherapy. The effect of immunotherapy on quality of life (QOL) for patients with allergic rhinitis has never been explored, so the objective of the current study is to examine how QOL in allergic rhinitis patients with immunotherapy is different from allergic rhinitis patients without treatment and normal individuals. **Methods:** A cross-sectional study design with three groups was conducted. Twenty-nine patients with allergic rhinitis without treatment (group AR), 26 patients with immunotherapy (group ARIT), and 30 persons without allergic rhinitis (group normal) were recruited in a teaching hospital. The generic outcome measure is Short Form 36 (SF-36) and disease-specific outcome measure is Allergic Rhinitis Quality of Life Instrument (ARQOL). ARQOL consists of three domains: symptoms, activity restriction, and medical resource utilization. **Results:** The findings indicate that group AR has worse QOL than Taiwan norms on all SF-36 scales except for physical functioning and bodily pain (all  $p < 0.05$ ) while group ARIT has worse QOL only on general health comparing to Taiwan norms ( $p < 0.05$ ). For ARQOL, group normal has higher scores for all subscales and total scale than groups AR and ARIT ( $p < 0.05$ ). In addition, the scores of group ARIT are significantly higher than those of group AR for all subscales and total scale of ARQOL except for medical resource utilization. **Conclusions:** In general, allergic rhinitis has great impact on generic QOL but generic QOL approaches the same level after immunotherapy. Although immunotherapy improves disease-specific QOL of allergic rhinitis patients, there still exist differences between patients with immunotherapy and normal persons.

#### # 1518/RELATIONSHIPS BETWEEN URINARY INCONTINENCE, HEALTH STATUS AND SOCIAL SUPPORT PERCEPTION

Jose Pais-Ribeiro & A. Raimundo, Psychology, University of Porto, Porto, Portugal

**Aims:** The aim of the present study is to identify the relationships between perception of social support, health status and distress due to urinary incontinence and other UI disease variables. **Methods:** Participants include 93 women suffering from UI, with a mean age of 60,15 years, (varying between 35 and 81 years of age) 74.2% married. A correlational study compare social support Instruments used include the Portuguese version of the health status Questionnaire SF-8 with two components, Mental Health (Cronbach  $\alpha = 0.81$ ) and physical health (Cronbach  $\alpha = 0.84$ ); social support perception (SSP) with four dimensions (satisfaction with friends, satisfaction with intimacy, satisfaction with family, satisfaction with social activities); Urogenital Distress Inventory Questionnaire with six items (UDI-6) evaluating the level of distress due to UI (Cronbach  $\alpha = 0.73$ ); Other disease variables include duration of disease (DD) and perception of level of UI severity (UIS) (four levels- no, slight, severe, and very severe). **Results:** Results show statistically significant correlations between UDI-6 and health status ( $r = -0.25$ ,  $p < 0.05$  with mental component and  $r = -0.20$ ,  $p < 0.05$  with physical component). No statistically significant correlations were found between Health Status and UIS or DD. Statistically significant correlations were found between dimensions of SSP and DD ( $r = 0.21$   $p < 0.05$  for satisfaction with friends, and  $r = 0.23$   $p < 0.05$  satisfaction with intimacy). No statistically significant correlations were found between SSP and UDI-6, or UIS; No statistically significant correlations were found between health status and UIS or DD. **Conclusions:** An overall assessment of results suggests that various aspects of UI have different impacts on domains of life such as health status and social support with the women showing adjustment to their disease status when the DD grows, and a decreasing Health Status with increasing UDI-6 severity.

#### # 1231/QUALITY OF LIFE (QOL) RESPONSE ON THE MODEL OF TREATMENT OF RHEUMATOID ARTHRITIS (RA) PATIENTS

A.A. Novik, Moscow; T.I. Ionova, Head QOL Group & A.V. Kishitovich, Multinational Center of Quality of Life Research; S.V. Mylnikov, St. Petersburg State University; A.A. Tzepakova & D.A. Fedorenko, Multinational Center of Quality of Life Research, St. Petersburg, Russia

**Aims:** The goal of treatment of chronic diseases that do not shorten life expectancy is to improve patients QoL. Evaluation of QoL along with clinical response might be recommended for patient management. The aim of the study was to develop QoL response paradigm in clinical practice and demonstrate its application on the model of RA. **Methods:** 200 patients with RA in active phase were enrolled. Patients filled in SF-36 at baseline and in 8 weeks of treatment. According to the paradigm there are 3 types of QoL response: complete response (CR), partial response (PR) and no response (NR). CR is correspondence of QoL after treatment to population norm; PR – improvement of QoL after treatment but not attaining CR; NR – absence of PR. To assess QoL response the integral QoL index (IQLI) was calculated by integral profiles method. To evaluate CR the lower bound of population norm mean was determined by bootstrap method (Confidence level – 0.99). Significance of differences between groups was tested by Mann-Whitney or Wilcoxon tests. **Results:** In 8 weeks 14 patients (7%) had CR, 126 (63%)-PR and 60 (30%)-NR. In patients with CR significant increase of SF-36 scales and IQLI as compared with base-line ( $p < 0.01$ ) was shown. The values of IQLI in this subgroup achieved the lower bound of population norm mean and did not differ from the ones of population sample ( $p = 0.63$ ). The values of IQLI in patients with PR improved after treatment ( $p < 0.01$ ) but were lower than of population norm. Inpatients with NR worsening of IQLI after treatment was observed as compared with base-line. **Conclusions:** QoL response paradigm in clinical practice is developed. Its application to RA allowed to demonstrate the following stratification of QoL response: 7% of patients had CR; 63%-PR and 30%-NR. The further studies on the other models of chronic disorders and comparison of QoL and clinical response are worthwhile.

# 1068/A DISEASE SPECIFIC HEALTH RELATED QUALITY OF LIFE MEASURE FOR ADULTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

Kathy McElhone, Rheumatology, Blackburn Royal Infirmary, Blackburn; Janice Abbott, Faculty of Health, University of Central Lancashire, Preston; Ada Franklin-Stevens & David Isenberg, Rheumatology, Middlesex Hospital, London; Bridget Griffiths Rheumatology, Freeman Hospital, Newcastle; Caroline Gordon; Kate Peers Rheumatology, City Hospital, Birmingham; Joanna Sheldermine, Rheumatology, Manchester Royal Infirmary, Manchester; Lee-Sean Teh, Rheumatology, Blackburn Royal Infirmary, Blackburn, UK

**Aims:** The health-related quality of life (HRQoL) literature in SLE is difficult to interpret, primarily because generic measures of HRQoL have been employed. The present work marks the development of a patient-derived, fully tested and validated measure of HRQoL: The Lupus Quality of Life (LupusQoL) Questionnaire. **Methods:** Several stages of development led to the validation of the questionnaire. First, the generation of disease-specific items was informed by (a) existing HRQoL literature, (b) other HRQoL measures, (c) consultation with the rheumatology multi-disciplinary team and, (d) patient interviews and feedback. Second, 20 patients completed the initial version of the questionnaire providing critical feedback regarding face validity, structure and content of the items and response scales, leading to revision of the LupusQoL. Third, 265 patients completed the revised version of the questionnaire. **Results:** Principal components analysis with varimax rotation highlighted nine domains. The internal reliability of each domain was evaluated using Cronbach  $\alpha$  coefficients. The domains were physical functioning ( $\alpha = 0.95$ ), pain ( $\alpha = 0.89$ ), emotional functioning ( $\alpha = 0.95$ ), fatigue ( $\alpha = 0.95$ ), body image ( $\alpha = 0.90$ ), planning ( $\alpha = 0.93$ ), burden to others ( $\alpha = 0.86$ ), intimate relationships ( $\alpha = 0.60$ ) and concentration ( $\alpha = 0.86$ ). **Conclusions:** Further testing, test retest reliability, sensitivity to changes in health and concurrent validity when compared with appropriate domains of the SF-36 is ongoing. Written translations in the Gujarati, Urdu and simplified Chinese language are being undertaken. This will provide a structurally robust, valid, reliable and sensitive instrument so that the quality of life data generated will be meaningful and useful to inform patient management and care.

# 1600/PREDICTING FUNCTIONAL OUTCOMES AT 12 MONTHS FOLLOWING SUBARACHNOID HEMORRHAGE: USE OF SIGNAL DETECTION METHODS

Yookyung Kim, Health and Community Systems; Mary E. Kerr & Sheila A. Alexander, Acute and Tertiary Care, University of Pittsburgh; Howard Yonas, Medicine, University of Pittsburgh Medical Center, Pittsburgh, PA, USA

**Aims:** The purpose of this study was to identify predictors of functional outcomes and identify mutually exclusive subgroups at 12 months following subarachnoid hemorrhage (SAH). **Methods:** Data used for the present analyses were collected prospectively on 75 subjects upon admission, and at 3 months and 12 months after severe SAH. Independent variables include: age, gender, race, initial injury severity scores [Glasgow Coma Score (GCS), Hunt & Hess score (H&H), and Fisher grades] collected upon admission; Modified Rankin Score (MRS), Barthel Index (BI), and Medical Outcome Study-Short Form36-Physical Functioning subscale (MOS-SF36-PF) assessed at 3 months after SAH. Dependent variable was the Glasgow Outcome Score (GOS) at 12 months post injury. Signal detection methods (SDM) evaluated the predictive values of the independent variables in predicting 12-month functional outcomes. Good outcomes were defined as a GOS<sup>2-4</sup>, and poor outcomes as a GOS<sup>1-3</sup>. SDM identified significant variables for predicting HRQoL outcomes. **Results:** SDM revealed that a grade of 3 on the Fisher and score of 8 on the BI provided optimal levels of sensitivity, specificity, and overall correct classification in predicting good vs. poor 12-month outcomes. Using signal detection analysis, three mutually exclusive groups at high and low probability of having good vs. poor outcomes were identified. Almost all (97.5%) patients with an admission Fisher grade < 3 and 3-month BI score > 8 had good outcomes (Group 1). However, only 28.6% with an admission Fisher grade < 3 and 3-month BI score < 8 had good outcomes (Group 2); and 33.3% with an admission Fisher grade > 3 had good outcomes (Group 3). **Conclusions:** The Fisher grades and BI

scores were identified as significant predictors of 12-month outcomes. Signal detection analysis provides an effective means of identifying predictors and subgroups at 12 months using readily available information at admission and 3 months.

# 1701/PREDICTING HEALTH-RELATED QUALITY OF LIFE (HRQOL) AT 6 MONTHS FOLLOWING LONG-TERM MECHANICAL VENTILATION (LTMV)

Yookyung Kim, Health and Community Systems; Leslie A. Hoffman & Frederick J. Tasota, Acute and Tertiary Care, University of Pittsburgh; USA; Michael P. Donahoe, Medicine, University of Pittsburgh Medical Center, Pittsburgh, PA, USA

**Aims:** Intensive care and LTMV (>7 days) may save a life only to produce a survivor dependent on supportive care for an extended interval of time. HRQoL, an accepted approach to assign a value to morbidity effects, has been infrequently examined in survivors of critical illness. Ability to identify factors that are associated with long-term (6 month) HRQoL at the time of intensive care unit (ICU) discharge could provide healthcare professionals with information to share with their patients and families. Purpose of the study was to describe HRQoL and determine the impact of selected variables on HRQoL at 6 months after ICU discharge in patients who have undergone LTMV. **Methods:** Subjects were 55 patients (62 + 15 years, 49.5% male, 86.9% Caucasian) on LTMV for 23 ± 15 days. Variables associated with general HRQoL 6 months following ICU discharge were identified using stepwise multiple regression models. Age, gender, race, severity of illness, comorbidity, functional status, HRQoL prior to admission, total days on mechanical ventilation and discharge weaning status were included as independent variables. **Results:** HRQoL at 6 months was lower for the majority of domains in the MOS-SF36 compared to a normative data on healthy age-equivalent individuals. HRQoL for physical functioning was the lowest compared with normative data. However, HRQoL for general health and vitality was comparable to the normative data. Stepwise multiple regression analysis identified Comorbidity score at admission as a significant predictor of HRQoL at 6 months for physical functioning and vitality. Analysis on the two summary component scores showed that Comorbidity score was again a significant predictor to explain variance in physical component. **Conclusions:** HRQoL was in general lower and more variable compared to a normative data, whereas, HRQoL for general health and vitality was comparable to the healthy population. Comorbidity at admission was identified as highly predictive of HRQoL at 6 months after ICU discharge in this population.

# 1454/IMPACT OF EXCESSIVE DAYTIME SLEEPINESS ON HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH OBSTRUCTIVE SLEEP APNEA SYNDROME

Misa Takegami & Satoshi Morita, Epidemiology and Healthcare Research, Kyoto University, Kyoto, Japan; Kazuo Chin, Physical Therapeutics, Kyoto University Hospital of Medicine, Kyoto, Japan; Tsuneto Akashiba, Internal Medicine, Nihon University School of Medicine, Itabashi-ku, Tokyo, Japan; Hiroshi Kimura, Internal Medicine, Nara Medical University, Nara, Japan; Yoshimi Suzukamo & Shunichi Fukuhara, Epidemiology and Healthcare Research, Kyoto University, Kyoto, Japan

**Aims:** To test the hypothesis that excessive daytime sleepiness (EDS) lowers health-related quality of life (HRQOL) of patients with OSAS (obstructive sleep apnea syndrome), even after adjustment for physiological severity as measured with the established objective methods. **Methods:** This study analyzed data from 193 patients diagnosed with moderate or severe OSAS using polysomnography (PSG). Inclusion criteria were an apnea/hypopnea index (AHI) of 30/h or more and an arterial oxygen saturation (SaO<sub>2</sub>) of 80% or less. We performed a questionnaire survey consisting of the 36-item short-form health survey (SF-36) and the Epworth sleepiness scale (ESS) in order to assess EDS in patients. We defined EDS as ESS > 10, and used norm-based scores of SF-36 to assess HRQOL. Linear regression models were used to analyze the difference in HRQOL subscales between patients with EDS and patients without EDS, after adjustment for objective severity of OSAS (BMI, AHI, and minimum and mean SaO<sub>2</sub>) and demographic variables. **Results:** A total of 189 patients (97.9%) were included in the analyses. In all generic HRQOL subscales, patients had lower scores than population norm values in Japan. In addition, patients with EDS had lower QOL scores than patients without EDS. Three of eight subscales showed a significant correlation with EDS, physical functioning (PF) ( $p = 0.003$ ), vitality (VT) ( $p = 0.043$ ) and social functioning role (SF) ( $p = 0.032$ ). ESS score had a stronger correlation with PF and SF score than physiological indices for OSAS do. **Conclusions:** Presence and degree of EDS was inversely related to HRQOL, even with same degree of physiological severity of OSAS. Our findings suggest that EDS may be independent and modifiable predictor of perceived outcomes of patients with OSAS and specific treatment targeting EDS may further improve patient outcomes.

# 1642/FACTORS ASSOCIATED WITH THE QUALITY OF LIFE OF CHINESE HIV PATIENTS

Joseph Lau, Centre for Epidemiology and Biostatistics, The Chinese University of Hong Kong, Prince of Wales Hospital, Shatin; H.Y. Tsui, Centre for Epidemiology and Biostatistics, The Chinese University of Hong Kong, Prince of Wales Hospital; Patrick Li, Rita Chung, Department of Medicine, Queen Elizabeth Hospital, Kowloon, Hong Kong, China; Alexander Molassiotis, School of Nursing, University of Nottingham, Nottingham, UK

**Aims:** The study examined factors associated with quality of life of a Chinese HIV patient population. Similar study in Chinese populations is scant. **Methods:** The study was a cross-sectional survey. It included 242 Chinese persons infected with HIV in Hong Kong, accounting for about 25% of all Chinese HIV patients reported at around the time of implementation of the study (Jan–Apr 2000). The response rate was about 73%. Research nurses explained the study and obtained informed consent from prospective respondents during their visits to any of the two public outpatient clinics serving HIV patients. The study measured respondent's QOL (using MOSHIV), optimism, social support, perceived discrimination, disclosure of HIV infection, HIV disease stage, CD4 Count and background characteristics. Student's *t*-test and ANOVA were used to examine known group differences on QOL. Correlation coefficients (Pearson's correlation and Spearman's  $\rho$  coefficients) between QOL and studied factors were calculated. Data were analyzed using SPSS.  $p$ -Value < 0.05 was taken as statistically significant. **Results:** The mean age was 38.4 (SD = 9.8) and 87.2% was male. Education level and employment status were associated with QOL. No significant differences were observed for gender, age, marital status, and living arrangement. Optimism was associated with PHS ( $r = 0.2$ ,  $p < 0.05$ ) and MHS ( $r = 0.5$ ,  $p < 0.001$ ). Higher scores on PHS and MHS were correlated with better social support ( $r = 0.2$ –

$0.4$ ,  $p < 0.01$ ). Perceived discrimination was negatively associated with both PHS and MHS ( $r = -0.2$ ,  $p < 0.01$ ). Disclosure of HIV infection was not associated with PHS nor MHS in this study. No significant differences on QOL were observed among the three HIV disease stage and CD4 Count. **Conclusions:** The study has a relatively large sample size of Chinese HIV patients. QOL of HIV patients is not necessarily affected only by physical factors like disease stage, but other social and psychological factors such as optimism and social support are also of crucial importance.

# 1687/EFFECTS OF SUBJECTIVE AND OBJECTIVE HEALTH-RELATED QUALITY OF LIFE FOLLOWING LUNG VOLUME REDUCTION SURGERY

Yoko Goto, Occupational Therapy, School of Health Science, Sapporo Medical University, Sapporo; Hajime Kurosawa, Yuko Sasaki & Masahiro Kohzaki, Internal Medicine and Rehabilitation Science, Tohoku University Graduate School of Medicine, Sendai, Japan

**Aims:** Patients with severe chronic obstructive pulmonary disease (COPD) suffer from dyspnea, which affects routine activities of daily living and health-related quality of life (HRQOL). Lung volume reduction surgery (LVRS) has been reported that it is an effective treatment modality for selected patients with advanced emphysema to improve pulmonary function, lung mechanics, exercise tolerance, and dyspnea. In this study, we investigated whether LVRS would improve both subjective and objective HRQOL in patients with severe emphysema for 36 months. **Methods:** Nineteen patients who underwent the pulmonary rehabilitation and lung volume reduction surgery (LVRS group), 8 male patients were medically treated with the pulmonary rehabilitation program without LVRS (Medical group). Objective HRQOL was assessed with use of Sickness Impact Profile (SIP), and subjective HRQOL was assessed by visual analogue scale. **Results:** At the baseline evaluation, there were no significant differences in subjective and objective HRQOL scores, pulmonary functions, and exercise capacity between the two groups. Objective HRQOL scores by SIP have been maintained until 36 months after operation in LVRS group. In Medical group, all the SIP scores tended to improve at 3 months, but then deteriorated at 12–36 months. Subjective HRQOL scores were the best at 12 months, some scores at 36 months were worse than before LVRS. In Medical group, subjective HRQOL scores were the best at the baseline and became worse gradually. **Conclusions:** The effects of LVRS were maintained up to 36 months after LVRS in terms of objective HRQOL. The subjective HRQOL changed in different ways, suggesting the importance of those, especially, when the observation was extended to long-term.

# 1255/THE ASSESSMENT OF QUALITY OF LIFE IN PATIENTS WITH ASPIRIN TRIAD BY THE RUSSIAN VERSION OF THE SF-36®  
Sergey A. Zenokhov, Clinical Immunology, Scientific Research Institute of Chemical Medicine, Moscow, Russia

**Aims:** Patients with aspirin triad (AT) often have severe asthma and chronic rhinosinusitis which may impair social life. General scales of quality of life (QOL) are used to detect the importance of social life impairment, but the extent to which QOL scores differ in patients with AT and healthy subjects is unknown. The aim of the study: the assessment of quality of life in AT patients in comparison with healthy subjects using the Russian version of the general health status questionnaire SF-36®. **Methods:** 41 AT patients (average age  $51.2 \pm 5.4$  years) with moderate to severe asthma and rhinosinusitis and 40 healthy subjects (average age  $48.4 \pm 6.7$  years) have been included in the study. The SF-36 includes multi-item scales that assess eight health concepts. The differences in QOL scores between patients with AT and healthy subjects were studied. All AT patients were receiving anti-asthmatic basic treatment with middle and high doses of inhaled glucocorticosteroids, the patients used regular nasal decongestant for reduction of rhinitis/sinusitis and short-acting beta-agonist 'as needed' for asthma symptoms reduction. **Results:** There was a significant decrease level of six of the eight scales QOL dimensions in patients with AT in comparison with healthy subjects. The greatest reduction of QOL in AT patients has been marked in role limitations because of physical problems (role physical scale) – more than 4.3 times as compared with healthy subjects ( $p < 0.005$ ). AT patients had significantly limiting pain (bodily pain scale) and very important problems at work or in other daily activities as a result of emotional problems (role emotional scale). A significant decrease in the general health perceptions, physical and social functioning was also found in AT patients (in 2.2, 2.3, and 2.7 times more than in healthy subjects). **Conclusions:** The SF-36® has demonstrated the significant distinctions in QOL patients with AT and healthy subjects.

# 1266/HEALTH-RELATED QUALITY OF LIFE IN KOREAN PATIENTS WITH CHRONIC DISEASE  
Sang Cheol Bae, Jae Hee Yun & Wan Sik Uhm, Internal Medicine, Hanyang University, Seoul, South Korea

**Aims:** Few studies have examined the impact of chronic diseases on populations using a comprehensive health-related quality of life (HRQoL) in Korea. We assessed HRQoL of patients with 16 common chronic diseases. **Methods:** We interviewed patients with chronic diseases ( $n = 980$ ) and healthy control ( $n = 288$ ) using two HRQoL measurements: Korean 36 item Short Form Health Survey (KSF-36) and Korean EuroQoL-5 Dimensions (KEQ-5D), and questions on sociodemographic and clinical characteristics. **Results:** Each illness had a distinctive profile (see table). Patients with hypertension and diabetes mellitus registered the two highest scores in general health. Patients with fibromyalgia reported the worst health experience in general health and mental component summary. **Conclusions:** The KSF-36 and KEQ-5D allow comparison of the health status of patients suffering from different conditions. Data such as these can be used to inform better purchasing decisions on how resources might be more effectively deployed and as a bench mark to monitor the effects of multiple health care interventions by conduction serial surveys.

KSF-36 and KEQ-5D in patients with chronic disease

	KSF-36	KEQ-5D		KSF-36	KEQ-5D
Whole	58.1 ± 22.0	0.69 ± 0.28	FM	41.7 ± 19.8	0.52 ± 0.32
Control	74.8 ± 15.3	0.88 ± 0.14	Glaucoma	51.4 ± 14.3	0.67 ± 0.30
AS	53.4 ± 21	0.63 ± 0.2	HTN	71.8 ± 17.3	0.75 ± 0.29
Asthma	56.0 ± 19.5	0.71 ± 0.22	IHD	62.2 ± 22.7	0.76 ± 0.24
Cataract	49.7 ± 20.0	0.62 ± 0.25	LC	48.8 ± 25.4	0.62 ± 0.34
CVA	52.7 ± 21.9	0.57 ± 0.32	OA	48.9 ± 16.9	0.56 ± 0.26
COPD	47.3 ± 19.8	0.60 ± 0.25	PUD	60.1 ± 18.9	0.68 ± 0.39
CRF	45.1 ± 22.0	0.63 ± 0.29	RA	51.5 ± 20.6	0.58 ± 0.3
DM	72.4 ± 15.9	0.78 ± 0.25	SLE	62.3 ± 20.5	0.73 ± 0.2

# 1285/QUALITY OF LIFE AND PSYCHOLOGICAL STATUS IN ADULT PATIENTS WITH MALOCCLUSION

Mayumi Tajima, Orthodontics and Dentofacial Orthopedics, Tohoku University Graduate School of Dentistry; Masahiro Kohzaki, Internal Medicine and Rehabilitation Science, Tohoku University Graduate School of Medicine; Shiori Azuma & Shuichi Saeki, Oral Dysfunction Science, Junji Sugawara, Orthodontics and Dentofacial Orthopedics, Tohoku University Graduate School of Dentistry, Sendai, Japan

**Aims:** Malocclusion is imperfect positioning of the teeth and dentition when the jaw is closed. Although the assessment of quality of life (QOL) is important in dentistry, QOL in patients with malocclusion has not been fully elucidated. The aim of this study was to clarify QOL and psychological status in patients with malocclusion. We also explored the relationship between severity of malocclusion and QOL. **Methods:** The subjects consist of 54 patients with malocclusion and age-matched 24 persons with normal occlusion. The patients were divided into three groups based on their treatment plans; namely, subjects in need of surgical correction (SURG;  $n = 14$ ), subjects in need of non-surgical correction (NONS;  $n = 38$ ), and control subjects (CONT;  $n = 24$ ). The morphological abnormality was assessed using severity scores. Generic QOL was assessed using the SF-36 and disease-specific QOL was assessed using the Subjective Oral Health Status Indicators (SOHSI), the Orthognathic QOL Questionnaire (OQLQ), and recognition and satisfaction scores of surgical correction. Anxiety and depression were assessed using STAI and SRQ-D, respectively. **Results:** There were no significant differences in SF-36 each scale scores among the three groups. Communication/social relationship and worry/concern (SOHSI), social aspects of dentofacial deformity, facial aesthetics and oral function (OQLQ), recognition and satisfaction, STAI and SRQ-D scores both in SURG and NONS were significantly higher than those in CONT. There was a significant difference in recognition between SURG and NONS. Moreover, the patients with high score of STAI and SRQ-D tended to belong to SURG. **Conclusions:** These results indicate that disease-specific, but not generic QOL is low in patients with malocclusion. Not only morphological abnormality but also psychological status of patients may affect the decision of the treatment plan for malocclusion.

# 1080/PSYCHOMETRIC PROPERTIES OF TWO NEW MEASURES OF QUALITY OF LIFE (QOL) AND TREATMENT SATISFACTION IN HYPOTHYROIDISM: THE THYDQOL AND THYTSQ

C. McMillan & C. Bradley, Psychology, Royal Holloway, University of London, Egham; S. Razvi & J. Weaver, Endocrinology, Queen Elizabeth Hospital, Gateshead, UK

**Aims:** This study evaluated the psychometric properties of two new questionnaires: (1) the ThyDQoL, an individualised, patient-centred questionnaire measuring perceived impact of hypothyroidism on QoL; (2) the ThyTSQ measuring treatment satisfaction in hypothyroidism. **Methods:** A cross-sectional study in which adults with hypothyroidism, [mean age 55.1 (s.d. 14.3) years,  $n = 110$  (103 treated with thyroxine)], attending primary care and hospital clinics, completed the questionnaires (postal and personal approach), item completion rates > 98%. The ThyDQoL, in which respondents rate personally applicable life domains for impact of hypothyroidism and importance to their QoL, has 18 domains and 2 overview items. The 7-item ThyTSQ-Present and 4-item ThyTSQ-Past measure satisfaction with present and past treatment respectively. Reliability and principal components analyses were undertaken. **Results:** The ThyDQoL had very high internal consistency reliability [Cronbach's  $\alpha = 0.95$ , ( $n = 97$ )] and could be summed into an average weighted impact score. There were no subscales. Domains reported as most severely (and negatively) impacted by hypothyroidism were [mean weighted impact (s.d.):] motivation [-4.84 (2.79)], weight [-4.51 (2.97)], and depression [-4.36 (2.73)], (possible range -9 to +3). The majority (71%) felt that hypothyroidism had a negative impact on overall QoL. Internal consistency reliability was also high for both ThyTSQ-Present and ThyTSQ-Past [ $\alpha = 0.91$  and 0.9, respectively, ( $n = 102$  and 103)]; total scores could be calculated for both measures. **Conclusions:** The ThyDQoL and ThyTSQ are new measures of perceived impact of hypothyroidism on QoL and of treatment satisfaction. They will assist health professionals in considering psychological as well as medical outcomes when treating people with hypothyroidism, and may be used in clinical trials and routine clinical monitoring.

# 1163/HCV DIAGNOSIS: IMPACT ON PSYCHOLOGICAL STATE  
Muzaffar L. Gill, Muslim Atiq, Syma Sattar & Nasir Khokhar, Gastroenterology, Shifa International Hospital, Islamabad, Pakistan

**Aims:** To assess the psychological stress induced by HCV diagnosis amongst Pakistani patients. **Methods:** This study was conducted at the Shifa International Hospital, Islamabad between February 2004 and April 2004. All patients with recently diagnosed HCV (Anti-HCV and HCV PCR Positive) were administered a questionnaire consisting of a visual analogue scale which compared stress due to HCV infection with four other variables including death of a close family member, divorce, loss of source of income and move to another city. Also we analyzed the anxiety level amongst these patients using the Beck Anxiety Inventory. **Results:** There were a total of 86 patients. There were 32 (37.2%) females and 54 (63.8%) males. 57 patients (66.3%) patients admitted that the diagnosis of HCV affected their daily life activities in one way or the other. HCV diagnosis was significantly more stressful than loss of a source of income (53.14 vs. 70.95;  $p$ -value < 0.01) and move to another city (28.84 vs. 70.95;  $p$ -value < 0.01). It was higher but not significantly different from death of a close family member (69.56 vs. 70.95) and divorce (62.47 vs. 70.95). Using regression analysis, we found that anxiety was related to HCV related stress and self perceived severity of disease. Females reported significantly higher anxiety scores (16.92 vs. 24.37;  $p$ -value < 0.15). **Conclusions:** Hepatitis C virus causes significant stress amongst newly diagnosed patients. Taking the patients into confidence and sympathetic explanation of the disease prognosis and need of treatment would certainly help them cope with the stress and anxiety.

# 1218/VARIABLES INFLUENCING QUALITY OF LIFE IN CHRONIC LIVER DISEASES: DISEASE SEVERITY OR SOCIOECONOMIC FACTORS?

Abhasnee Sobhonslidsuk, Medicine, Chatchawan Silpakit & Ronnchai Kongsakon, Psychiatry, Patchareeya Satitpornkul & Chaleaw Sripetch, Medicine, Ramathibodi hospital, Mahidol University, Bangkok, Thailand

**Aims:** Researches of QOL in chronic liver diseases (CLD) receive little attention in Asia. Previous studies using univariate analysis showed that disease severity affected QOL in CLD. We aimed to assess for QOL in CLD and for factors independently associated with the QOL. **Methods:** CLD and normal subjects were recruited. They were asked to perform the SF-36 and Chronic Liver Disease Questionnaire (CLDQ). The SF-36 was previously validated. The original CLDQ was translated into Thai by following a guideline. Coefficient  $\alpha$  and test-retest were done for reliability analysis. One-way Anova or non-parametric test was performed for discriminant validity. Spearman rank correlation was done for convergent validity. Determinant was disease stage. Controlled variables were age, sex, educational level, employment, career type, financial burden and patient health perception. Multiple regression analysis was used to evaluate the influence of a variable on QOL while controlling others.  $p$ -Value < 0.05 was considered statistically significant. **Results:** Coefficient  $\alpha$  of overall CLDQ scores was 0.96 and of domains were above 0.93. Test-retest reliability was 0.88 for the average score and ranged from 0.68 to 0.90. The reliability and validity of the CLDQ were acceptable. A total of 300 subjects (250 CLD and 50 normal) entered the study. Mean ages and the number of low educated, unemployed, blue-collar career and poor health perception increased significantly from chronic hepatitis to Child A to Child B to Child C groups. After controlling other factors, Child B, C and chronic hepatitis decreased nearly all domains of the CLDQ and SF-36. Good health perception had positive impact on all domains. Increasing age and female reduce physical health of the SF-36. Financial burden decreased several domains of the CLDQ and SF-36. Blue-collar career and unemployment affected role-emotion. **Conclusions:** The reliability and validity of the Thai CLDQ is demonstrated. Disease stages, health perception, demographic and socioeconomic factors independently affect the QOL. Raising health perception of patients with CLD may improve their QOL.

# 1203/COMPARISON OF PATIENT AND GENERAL POPULATION VALUES: THE CASE OF VARICOSE VEINS

John E. Brazier & Julie Ratcliffe, Sheffield Health Economics Group, The University of Sheffield; Jonathan Michaels & Simon Palfreyman, The Sheffield Vascular Institute, Northern General Hospital, Sheffield, Yorkshire, UK

**Aims:** The aim of this study was to examine the size of the disparity between general population and patient values for varicose veins health states. **Methods:** As part of a randomised control trial to compare treatments for varicose veins, patients ( $n = 177$ ) were surveyed at randomisation and at 12 months to assess their health status using the standard gamble (SG) elicitation technique, alongside the EQ-5D, SF-36 and a visual analogue scale (VAS). The response to the SF-36 was converted to the SF-6D using two versions of the algorithm developed by Brazier and colleagues (1998, 2002). Both SF-6D algorithms are based on general population values and version one is based on the same variant of SG as used directly on patients. General population and patient are compared using SG and VAS baseline values. **Results:** Mean SF-6D general population values are lower on average than own health state values using (1) SG [baseline mean (SD) general population values using variant one of SF-6D was 0.909 (0.072) and using variant 2 of SF-6D 0.732 (0.119) compared to patients own value of 0.939 (0.114)] and (2) VAS [SF-6D VAS was 0.668 (0.179) compared to patients own value of 0.771 (0.162)]. These differences were significantly different at baseline and 12 months. **Conclusions:** This paper adds to the evidence that patients own health valuations tend to be higher than those of a general population sample and this has important implications for cost-effectiveness. However, the results also suggest that the variant of elicitation technique is more important than the source of values.

# 1347/RELATIONSHIP BETWEEN ERECTILE FUNCTIONING AND PSYCHOSOCIAL FUNCTIONING FOLLOWING TREATMENT WITH VIAGRA® (SILDENAFIL CITRATE): RESULTS FROM AN INTERNATIONAL TRIAL

Mineo Takei, Urology, Harasanshin Hospital, Fukuoka; Hitoshi Takamoto, Urology, Kurashiki Medical Center, Kurashiki-shi, Okayama, Japan; Sidney Glina, Sao Paulo, Brazil; Joseph C. Cappelleri, Pfizer Inc., Global Research & Development, Groton, CT; Sandeep Duttagupta, Nancy Sherman, Vera J. Stecher, Richard L. Siegel & Li-Jung Tseng, New York, NY, USA

**Aims:** We examined the association between the 14-item Self-Esteem and Relationship (SEAR) questionnaire and measures of erectile function (EF) following treatment with placebo or Viagra in men with erectile dysfunction (ED). **Methods:** This international, 12-week, double-blind study involved 300 subjects with ED (placebo, n = 149; Viagra, n = 151; flexible-dose 25, 50, 100 mg). Partial Pearson's correlation coefficients were assessed on change scores from baseline to end-of-treatment on the SEAR with corresponding change scores on the EF domain of the International Index of Erectile Function and change in percent of intercourse attempts that were successful. Correlations were assessed between SEAR scores and responses to a global efficacy question (how often were your erections satisfactory for sexual intercourse?). **Results:** Changes in SEAR scores showed moderate-to-high correlations with changes in EF domain scores and in percent of successful intercourse attempts ( $p < 0.0001$ ). SEAR scores showed moderate-to-high correlation with frequency of satisfactory erections ( $p < 0.0001$ ). **Conclusions:** Gains in efficacy correlated substantially with psychosocial gains in relationships, confidence, and self-esteem as measured by the SEAR. This association was observed regardless of how efficacy was measured.

SEAR component	EF Domain (N = 283)	% Success (N = 260)	Satisfaction (N = 282)
1. Sexual relationship	0.73	0.60	0.85
2. Confidence	0.74	0.65	0.81
a. Self-esteem	0.71	0.60	0.80
b. Overall relationship	0.65	0.60	0.71
3. Overall (total) score	0.78	0.66	0.86

# 1391/VALUE OF PATIENT-REPORTED OUTCOMES IN THE MANAGEMENT OF LIPODYSTROPHY

Martin Duracinsky, Internal Medicine, Bicetre Hospital, Le Kremlin Bicetre Cedex, France; Catherine Acquadro, MAPI Research Institute, Lyon, France; Albert Wu, Health Services Research, Johns Hopkins University, Baltimore, MD, USA; Olivier Chassany, Clinical Research, Saint-Louis Hospital, AP-HP, Paris, France

**Aims:** Lipodystrophy may greatly impair quality of life (QoL). Nevertheless, the recognition of the scientific value of QoL and more broadly the patient's perspective in evaluating therapies is questioned. It may be useful to quantify the added value of the patient's perspective, using correlations between patient-reported outcomes (PROs) and clinician-reported and biological outcomes. **Methods:** We performed a cross-sectional survey in 143 HIV French outpatients with lipodystrophy. Clinical and demographic data were collected. Patients completed a new specific lipodystrophy questionnaire 'Assessment of Body Change and Distress' (ABCD), consisting of three parts: signs of lipodystrophy (6 items), global satisfaction (n = 1) and 20 items evaluating QoL. A HIV specific (MOS-HIV) and generic (SF-12) QoL questionnaires were also filled-in. **Results:** Mean age was  $43 \pm 10$  years (71% of men), and mean duration of HAART was  $4.5 \pm 1.7$  years. ABCD QoL score is weakly or no associated with viral load ( $r = 0.03$ ), CD4 count ( $r = 0.13$ ) and CDC classification ( $p = NS$ ). Its correlation with the clinician's report of number of sites of lipodystrophy is weak ( $r = 0.17$ ). Correlations between different PROs are

logically higher. ABCD QoL score is more correlated with the patient's report of number of sites of lipodystrophy ( $r = 0.39$ ) and with satisfaction ( $r = 0.58$ ). ABCD QoL score is correlated with health distress and social dimensions of the MOS-HIV ( $r > 0.6$ ) and with mental component of the SF-12 ( $r = 0.65$ ), but not with physical dimensions of these questionnaires ( $r < 0.2$ ). **Conclusions:** PROs are weakly correlated with biological markers, and although overlapping, each one of PROs measures a distinct concept. Clinicians cannot infer the QoL of their patients neither from a viral load nor from a clinical exam. The patient's perspective is essential in medical decision making and so it is with lipodystrophy.

# 1382/ABCD LIPODYSTROPHY SPECIFIC QUALITY OF LIFE QUESTIONNAIRE: CULTURAL ADAPTATION AND PSYCHOMETRIC VALIDATION IN FRENCH

Martin Duracinsky, Internal Medicine, Bicetre Hospital, Le Kremlin Bicetre Cedex; Janine Cervoni & Valerie Vincent, Internal Medicine, Lariboisiere Hospital; Daniel Sereni, Internal Medicine; Jean Michel MOLINA, Infectious Diseases, Saint-Louis Hospital, Paris; Catherine Acquadro & Katrin Conway, MAPI Research Institute, Lyon, France; Albert Wu, Health Services Research, Johns Hopkins University, Baltimore, MD, USA; Olivier Chassany, Clinical Research, Saint-Louis Hospital, AP-HP, Paris, France

**Aims:** Lipodystrophy may have a great impact on quality of life (QoL). Current HIV specific instruments do not measure this impact. We performed a cultural adaptation and psychometric validation in French of a new lipodystrophy specific instrument "Assessment of Body Change and Distress" (ABCD). **Methods:** ABCD consists of three parts: signs of lipodystrophy (six items), global satisfaction (1 item) and 20 QoL items. Items were generated in US. Our study consisted of two parts: 1/Cultural adaptation; 2/Psychometric validation in a survey in comparison with specific (MOS-HIV) and generic (SF-12) QoL questionnaires. **Results:** The approach of French patients was to some extent different from US patients, and needed cultural adaptation of several concepts. 155 HIV French outpatients (143 with lipodystrophy) from 2 Parisian hospitals and 1 general practice were included. Mean age was  $43 \pm 10$  years. Mean duration of HAART was  $4.5 \pm 1.7$  years. Discriminant validity: QoL scores decreased according to the number of sites with lipodystrophy, ranging from  $85 \pm 16$  (none) to  $42 \pm 10$  (6 sites),  $p < 0.001$ , and according to whether patients were thinking about plastic surgery or not, from  $68 \pm 20$  (never) to  $33 \pm 13$  (always),  $p < 0.001$ . Internal consistency was high (Cronbach  $\alpha = 0.94$ ). Factorial analysis yielded a 4-factor structure. Convergent validity: the highest correlations were between ABCD QoL and health distress and social dimensions of the MOS-HIV ( $r > 0.6$ ) and with the mental component of the SF-12 ( $r = 0.65$ ). **Conclusions:** The psychological and social distress related to the body changes must be measured in clinical trials, to make sure that life is not lengthened at the expense of its quality. ABCD questionnaire is a validated questionnaire which can now be used in French



# 1411/WHAT ARE THE POTENTIAL GAINS IN HRQOL FROM GENETICALLY TAILORED ANTIHYPERTENSIVE MEDICATIONS? Gretchen A. Jacobson & Albert W. Wu, Health Policy and Management, Johns Hopkins School of Public Health, Baltimore, MD, USA

**Aims:** Although patient genotype can affect the pharmacokinetics of antihypertensive drugs, little is known about the impact of genetic differences on HRQOL. We aimed to quantify the potential gains in HRQOL that might result from genetically tailored antihypertensive medications. **Methods:** We performed a Medline search (1996–2004) of the English language literature using inclusive keywords related to HRQOL, hypertension and clinical trial. Inclusion criteria were randomized placebo-controlled trials of antihypertensive agents with outcomes including at least one of the following: depression, sleep, sexual functioning, physical functioning, anxiety, fatigue, mental health, vitality, general health, and social functioning. 571 Medline articles included information about hypertension, quality of life, and clinical trials. Ten studies met all criteria and were included in the final analysis ( $n = 12,449$  participants). We assumed that treatment side effects would be reflected in HRQOL dimensions and influenced by genetic differences in drug metabolism. Pooled differences between treatment and placebo QOL scores, and the corresponding standard errors, were calculated for each dimension. To estimate a potential effect of genetic polymorphisms, we used the prevalence of alterations in CYP2D6 (a gene that most commonly affects metabolism of antihypertensive drugs), that result in a 'poor metabolizer' phenotype (~5%). Adjusted means were calculated for the remaining 95% of the population and compared to the original means to establish a lower-bound estimate of the amount of the variation attributable to patient genotype. **Results:** The estimated attributable change in HRQOL due to alterations in CYP2D6 was 21% for sleep, 14% for depression, 7% for sexual function, 3.5% for physical health, 2% for anxiety, and <1% for fatigue, general health, mental health, social functioning, and vitality. **Conclusions:** A genetic polymorphism affecting the metabolism of antihypertensive drugs could account for substantial differences in HRQOL outcomes. Genetically tailored antihypertensive medications could decrease the incidence of drug side effects and increase patients' HRQOL.

# 1428/IMPACT OF PERCEIVED STIGMA OF PATIENTS WITH ONYCHOMYCOSIS ON QUALITY OF LIFE

Natsuko Takahashi, Clinical Trial, Institute for Health Outcomes and Process Evaluation, Tokyo, Japan, Toshihiro Idei, Dermatology, Yoshimi Suzukamo, Epidemiology and HealthCare Research, Kazumasa Morita, Miyachi Yoshiki, Dermatology, Shunichi Fukuhara, Epidemiology and HealthCare Research, Kyoto University, Kyoto, Japan

**Aims:** Onychomycosis is a common disease of nail, and causes cosmetic problem such as discoloring and/or thickening of nails. Patients with onychomycosis may carry sense of stigma because of their nail appearance, which may affect their Quality of Life (QOL). The aim of this study is to measure degree of perceived stigma ('Stigma') and its association with Quality of Life (QOL). **Methods:** Four hundreds patients, 18–70 years old, were enrolled in this cross-sectional observational study from 7 dermatology clinics, regardless of their treatment history or their current method of treatment. The patients filled out self-administered questionnaire including SF-36 and the five question items addressing 'stigma' on their nail appearance. Each of the 5 stigma items had five response choices. Clinical data, such as duration and severity of their nail conditions, were also obtained from the physicians. Logistic regression was run with norm-based score of SF-36 (50/10 score) as dependent variable and 'Stigma' score as an independent variable, adjusted for demographic and clinical variables. **Results:** Responses rate was 97% (387). The mean score of 'stigma' was 2.6 and SD was 1.4; 5 ('not at all'), 1 ('extremely'). 'Stigma' score was significantly associated with 'social functioning' (SF) and 'mental health' (MH) domain scores of SF-36. Odds ratios of having poor QOL (SF or MH) was 1.3 (95% CI: 1.1–1.6) per one point decrement of 'stigma' score. **Conclusions:** QOL of the patients with onychomycosis was associated with degree of perceived stigma on their nail appearance, rather than with clinical severity.

# 1217/QUALITY OF LIFE IN PERIMENOPAUSAL WOMEN IN INDIA Charu Gandhi, DPM, Prabha S. Chandra, MD, Psychiatry, NIMHANS, Bangalore, Karnataka, India

**Aims:** Although it seems reasonable to suggest that most women experience significant changes in quality of life (QoL) during the menopausal period, few researchers have attempted to quantify these changes, especially in the Indian context where not much importance is accorded to non-physical problems associated with this phase of life. The aims of this study were to examine the QoL in perimenopausal women in comparison to a control group of healthy younger women, to determine the differences in QoL if any, and to study the factors contributing to these differences. **Methods:** 100 women in the age group 45–55 years, randomly selected from the area of urban Bangalore, India, who gave informed consent for participation were selected for the study. They were assessed using standardised Kannada (local language) versions of Women's Health Questionnaire, General Health Questionnaire-12, and The WHOQOL-100. A sociodemographically matched control group of 100 younger women between the age group 25–35 years was selected from the same area, and assessed using The WHOQOL-100. **Results:** Our results showed that perimenopausal women had significantly lower scores compared to the control group in the following domains- physical ( $15.71 \pm 2.15$  vs.  $16.49 \pm 2.18$ ,  $p = 0.012$ ), level of independent functioning ( $16.27 \pm 2.01$  vs.  $17.33 \pm 1.72$ ,  $p = 0.000$ ) and social relationships ( $15.80 \pm 2.80$  vs.  $16.84 \pm 2.89$ ,  $p = 0.010$ ). A further analysis of the differences in individual facet scores contributing to each of the above domains was performed, which showed significant differences between the two groups in the following facets- sleep, dependence on medication, mobility, activities of daily living, and sexual activity. Scores were indicative of lower QoL among older women in all these facets. Further, within the perimenopausal group of women, higher total GHQ scores were significantly associated with a lower QoL in the physical domain, and vasomotor symptoms and sleep problems assessed in women's health questionnaire were significantly associated with lower scores in the social relationships domain. **Conclusions:** Older women reported lower QoL related to sexual functioning, mobility and sleep. Health care professionals working with women need to be aware of these factors while managing problems of perimenopausal women.

# 1160/QUALITY OF LIFE AND ITS DETERMINANTS OF MENO-PAUSAL WOMEN IN TAIWAN: ASSESSMENT BY WHOQOL-BREF QUESTIONNAIRE

Jung-Nien Lai, Chinese Medicine, Taipei Municipal Yang Ming Hospital; Jung-Der Wang, Occupational Medicine and Industrial Hygiene, National Taiwan University College of Public Health; Chen HJ, Chinese Medicine, Municipal Taipei Chinese Medicine Hospital; Chen-Miao Chen, Psychology, National Taiwan University, Taipei, Taiwan, ROC

**Aims:** The purposes of this study were to determine the impact of perimenopausal transition on health-related quality of life (QOL) among women seeking medical advice (SMA) and a general population sample. **Methods:** A total of 203 subjects who were seeking outpatient treatment for menopausal symptoms at a Municipal-based menopausal special clinic and 1263 healthy referents from a national health survey sample were included in this study. Each one was asked to fill out the questionnaire of World Health Organization Quality of Life-BREF (WHOQOL-BREF) that assesses satisfaction and importance for four domains (physical, psychological, social, and environment). In addition, SMA subjects were also inquired about 35 most common symptoms encountered during perimenopausal period. Multiple regression analysis was conducted to predict quality of life and independent variables included were age, marital status, religion, and educational level. **Results:** The result showed that the mean score overall quality of life were significantly lower than those of the referents. However, mean score for the environment domain in SMA subjects were higher than that of the referents. Symptoms of insomnia, emotion, and demographic factors including age, educational level, and religion, contributed to the prediction of quality of life (adjusted  $R^2 = 0.30$ ). **Conclusions:** In conclusion, the existence of psychosocial-related symptoms seemed to be significantly associated with QOL measured by WHOQOL-BREF in perimenopausal women after controlling other determinants. And health promotion among perimenopausal women had better taken these two symptoms into account.

# 1399/COUPLES' EDUCATIONAL LEVEL AFFECTS THE QUALITY OF LIFE OF POSTPARTUM WOMEN

Shih-Chieh Liao, Medicine; Wen-Miin Liang, Department of Public Health; Li-Jin Huang, Nursing; Yu-Hsiang Juan, Medicine, China Medical University, Taichung, Taiwan

**Aims:** The purpose of this study is to address how couples' educational level affects the postpartum women's quality of life (QOL). **Methods:** In 2003, 407 Taiwanese participants after 6 weeks labor answered the WHOQOL-BREF Taiwanese Edition to evaluate their QOL. The items of WHOQOL-BREF were categorized with standard algorithms to analyze four summary scores of QOL, which are Physiology (PH), Psychology (PS), Social (SO) and Environmental (EV). **Results:** Based on the MANOVA tests, SO and EV were affected by the couples' educational level ( $p = 0.013$  and  $0.001$ , respectively), but PH and PS were not ( $p = 0.522$  and  $0.110$ , respectively). The curves of QOL versus educational level were S-shape with consistent increment throughout, except for a valley point of a specific husband-wife combination (the husband with Master and wife with bachelor degrees). **Conclusions:** The valley point is caused by status inconsistency, which plays a major role in the decline of the women's QOL. According to the official reports announced by Taiwanese government in 2003, the average income of master degree graduates had not significantly increased since 1993, but the number of graduate students rises to approximately four times as before, which resulted in higher job competitions. Pohorila (2001) argues the effect of deprivation in the three dimensions of living conditions: income, housing and household property on psychological functioning measured as depression and fatalism, which coincide with the significant valley point noted in this study, as master and bachelor degree couples may anticipate better life quality but suffer immense reality conflict in the above three domains, and this corresponds to the greatest lost of expectation in SO and EV item groups of QOL. The stress experienced by postpartum women is exaggerated by childbirth, which worsens human ability to readjust to their social life (Homes & Rahe, 1967). As a result, the valley point can be utilized as an indicator of the possible future health risks accompanied by the level of stress received and influenced by both husband and wife.

# 1410/PERSONALITY TRAITS AND MENSTRUAL SYMPTOMS IN MEDICAL COLLEGE WOMEN

Yih-Dar Lee, Eli Lilly and Company, Taipei; Tsai-Chung Li, Chinese Medicine, China Medical University, Taichung, Taiwan, ROC

**Aims:** The most common problem for young women seeking medical attention is some disturbance in menstrual symptoms. The objective of this research was to examine whether there is an association between personality traits and menstrual symptoms among young medical college women. **Methods:** A cross-sectional study with self-administered questionnaires was performed among undergraduate freshmen female students in China Medical College. A structured questionnaire about the physical constitution, life style behaviors, personality, and menstrual symptoms related to menstrual function was administered. The personality characteristics measured were level of nervous temperament and variation in emotional mood. **Results:** Our results show that the mean age of our sample is 19.6 years old. The proportion of those who always or usually had irregular menstrual period is 34.1%. And about 30% of them had ever sought for medical care due to disturbance in menstrual symptoms. After taken adjusting for medication history for menstrual problem, age at first menstruation, and stress, psychological distress and score of nervous temperament is positively associated with number of menstrual symptoms and global severity index. **Conclusions:** Our study findings indicate that the nervous temperament is associated with more reported menstrual symptoms independent of levels of stress.

# 1456/QUALITY OF LIFE OF POSTPARTUM WOMEN IN TAIWAN

Li-Jin Huang, Department of Nursing; Wen-Miin Liang, Department of Public Health, China Medical University, Taichung; Su-Chu Wu, Yi-Shawn Shy, Disease Control Section, Public Health Bureau, Chiayi; Yu-Yin Chang, Department of Public Health, China Medical University, Taichung, Taiwan, ROC

**Aims:** The aim of this study is to assess the important factors that influence the postpartum women's quality of life. **Methods:** A total of 407 postpartum women between 15 and 44 years old responded to the 28-item Taiwanese version of WHOQOL-BREF questionnaire and other items such as postpartum women's age, education level, employment status, self-evaluated health, preference for boys, method of delivery (natural, assisted with suction cup or C-section), child's gender, weeks since birth and firstborn/non-firstborn. The range of days since birth is from 2 to 113 days. Multiple regression analysis with backward selection technique was used to determine the factors that influenced health-related quality of life (HRQOL). **Results:** The results showed postpartum women's employment status ( $p = 0.03$ ), self-evaluated health ( $p < 0.001$ ) and weeks since birth ( $p = 0.03$ ) were highly correlated with physical capacity; postpartum women's self-evaluated health ( $p < 0.001$ ) and weeks since birth ( $p = 0.027$ ) were highly correlated with psychological health; postpartum women's education level ( $p = 0.009$ ) and self-evaluated health ( $p < 0.001$ ) were highly correlated with social relationships; and postpartum women's education level ( $p = 0.019$ ), self-evaluated health ( $p < 0.001$ ) and firstborn/non-firstborn ( $p = 0.04$ ) were highly correlated with environmental health. **Conclusions:** These results can help the researchers to better understand the health-related quality of life for postpartum women and to allow the postpartum women and their caregivers to better identify and treat the factors which may result in the declining of postpartum women's QOL.

# 1538/COMPARISON BETWEEN FERTILE AND INFERTILE COUPLES FOR QUALITY OF LIFE, MARITAL SATISFACTION AND SEXUAL SATISFACTION

Isabel Leal, Psychology, Instituto Superior de Psicologia Aplicada, Lisboa, Portugal

**Aims:** In Portugal infertility is becoming an important public health problem. Couples start to have children near the age of 30's, and the modern stressful life style does not facilitate to become a parent: the result is the decreasing fertility ratio, that for the Portuguese people is one of the lowest in Europe. The aim of the present study is to compare two groups of couples-fertile and infertile couples-for quality of life (QOL, marital satisfaction and sexual satisfaction. **Methods:** The principal variable is the outcome-QOL- fertility, marital satisfaction and sexual satisfaction are secondary variables. Participants were 40 couples, 20 fertile and 20 infertile, belonging to similar age group. Inclusion condition for infertile couples is that infertility is of unknown cause. QOL was assessed with SF-36. Sexual and marital satisfaction was assessed with two specific developed questionnaires for Portuguese participants. The study was comparative and correlational. **Results:** Results show no statistically significant differences for QOL between the two groups (men-men)(women-women) for all dimensions of SF-36. We found statistically significant differences for marital satisfaction and sexual satisfaction between the two groups. For each group, correlations between QOL, and marital satisfaction, and sexual satisfaction were not statistically significant. **Conclusions:** Because infertility seems to impact the couples psychosocial functioning, it was unexpected to find that the two groups show no differences for QOL, and that differences in sexual satisfaction and marital satisfaction seems do not impact QOL. This may suggest that, because QOL is a personal based perception, other fields of everyday life can compensate the likely impact of infertility, and other related variables, on QOL. It is necessary to continue the research with bigger samples intending to identify how the web of fields of interest of infertile people interacts with QOL.

# 1168/THE EFFECTS OF HEALTH EDUCATION PROGRAM ON KNOWLEDGE, ATTITUDE, AND QUALITY OF LIFE OF WOMEN IN MENOPAUSE

Arian Rostami, Prevention, Welfare Organization; Fazlolah Ghofranipour, Health Education, Tarbiat Modarres University, Tehran, Iran

**Aims:** Menopause is one of the most important stages in women's life. Menopause is not a disease but it causes severe problems in women's health as osteoporosis, cardiovascular disease and atrophy of genitalia. There is not enough research done about the effects of health educational programs on the women's quality of life during menopause. The aim of this study was to assess the effects of a health education program on knowledge, attitude and quality of life of women during menopause **Methods:** This research is a quasi-experimental study (before and after). Data gathering tools in this research were questionnaires concerning to knowledge, attitude, nutritional ratio and menopause specific quality of life questionnaire. Fifty women, aged 45-55 years who lived in suburb of Tehran (capital of Iran) attended to this study. A health education program which was designed based on pretest analysis was performed in four sessions and post test data were gathered four weeks after the last session of the educational program. **Results:** Knowledge, attitude and nutritional habits (using milk and yogurt) improved significantly by education. Quality of life of women in three dimensions; psychological, physical and sexual had similar improvement. The only field untouched by the program was vasomotor dimension. Research results about effect of education in promoting of knowledge, attitude and quality of life show any attempt to improve women knowledge and attitude in providing effective strategy for adapting with menopause problems, has positive effects on physical, psychological and sexual dimensions. Insignificant statistically differences in vasomotor dimension may be related to effects of hormonal changes on this dimension. **Conclusions:** In attention to some negative attitudes and worries about hormone replacement therapy among many of women and some contraindications of this method, it seems that health education programs as alternative methods or beside another methods for prevention of, decreasing and coping with problems for health promotion during menopause is necessary.

# 1726/THE MANAGEMENT OF REMOVING BLOOD STASIS AND RESOLVING PHLEGM COMBINATION WITH AMINOPHYLLINE IN PATIENTS WITH COPD ON PULMONARY FUNCTION, SYMPTOMS AND QUALITY OF LIFE

Shan Linan, Liu XiaoHong, Medical, Guangzhou University of Traditional Chinese Medicine, Guangzhou, Guangdong, PRC

**Aims:** The aim of the study was to assess the effect of the management of removing blood stasis and resolving phlegm combination with aminophylline on clinical pulmonary function, symptoms and quality of life in patients with mild or moderate chronic obstructive pulmonary disease (COPD) in stable condition **Methods:** 102 patients with mild or moderate COPD were selected from the outpatient clinic and randomly assigned to the treating group (group T) or to the control group (group C) on a single-blind procedure. Group T (n = 52) was treated by Chinese herb decoction (the principle of the decoction is removing blood stasis and resolving phlegm, 150 ml, twice a day) combination with taking slow-release aminophylline orally (0.1g, q12h); group C (n = 50) was treated only by slow-release aminophylline (0.1g, q12h). Pulmonary function-FEV1, FEV1%, FEV1/FVC were tested and recorded by a professional before and after the study. Changes in symptoms and quality of life were recorded at the beginning of the study and repeated every month. The SPSS 10.0 was used in statistical analysis. **Results:** After the study period, there is no significant differences ( $p > 0.05$ ) in spirometry results in either group. But for the absolute value, FEV1 of the group T decreased 10 ml after the period, FEV1% decreased 0.1%; while FEV1 decreased 30 ml after the period, FEV1% decreased 1% in group C. Clinical symptoms had been improved significantly in group T which has significant difference after 6 months compared with group C ( $p < 0.05$ ). The quality of life-the total mean score of QOL(TMS), general activity score (F1S), social activity score (F2S), depression score (F3S) and anxiety score (F4S) had been improved significantly in group T ( $p < 0.01$ ) with significantly differences after 6 months between the two groups ( $p < 0.05$ ), except for F2S ( $p > 0.05$ ) **Conclusions:** The management of removing blood stasis and resolving phlegm combination of slow-release aminophylline improved health-related quality of life and reduced symptoms, meanwhile postponed the descending of pulmonary function in COPD patients.

# 1572/COPD COUPLE QOL

Gail Low, Nursing, University of Victoria, Victoria, BC, Canada

**Aims:** At present, there is a paucity of empirical works on proxy concordance among COPD specific groups, high variance by proxy type and differences in patient-proxy measures. The purpose of this study was to determine whether COPD patient self-reports differed from all-spouse-proxy reports. From the existing literature, it was hypothesized that spouse proxies would provide consistently lower ratings, especially for psychosocial QOL, and that differences would parallel COPD-severity and proxy gender (female). **Methods:** A cross-sectional survey of a convenience sample of older adults with COPD and their non-COPD spouses using the same two QOL measures (the SIP and the SGRQ). Study packets were distributed by homecare, home oxygen and outpatient education staff. Patients and spouses received separate study packages. 67 of the 120 packages were completed and returned by participants. Within-couple differences were explored using *t*-tests. Hierarchical linear regression was used to identify significant causal factors. **Results:** At the bivariate level, significant differences were found for physical QOL on the SIP ( $t(66) = 2.687, p < 0.05$ ) and for psychosocial QOL on the SGRQ ( $t(66) = 3.110, p < 0.05$ ). At the multivariate level, only the SGRQ model was found to be statistically significant ( $F(5,61) = 2.545, p < 0.05$ ). Patient gender ( $b = 0.48, p < 0.05$ ) and spouse age ( $b = 0.52, p < 0.05$ ) predicted perceptual differences. **Conclusions:** Direction for community nursing practice includes an awareness that discordance may be highest among older-old couples. Care should also be planned with equal regard for both partners' needs. Anticipatory guidance around the psychological impact of COPD as well as respite and peer contact for female non-COPD spouses would be beneficial. Open dialogue around couple expectations about the impact of COPD and physical resource planning could facilitate open communication and reduce friction between partners. Longitudinal research, a non-COPD group focus, and qualitative inquiry would provide added insight into the presence and meaning of COPD-specific within-couple differences.

# 1202/QUALITY OF LIFE (QOL) OF PATIENTS SUFFERED FROM CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) IN CHINESE POPULATION AND ITS CORRELATION TO PHYSIOLOGICAL PARAMETERS, FUNCTIONAL PERFORMANCE, PSYCHOLOGICAL STATUS AND SOCIAL SUPPORT  
Wai Kwan Choi, The Centre for Gerontology and Geriatrics; Chor Ming Lum, Medicine and Therapeutics, The Chinese University of Hong Kong, Hong Kong, PRC

**Aims:** This study described QOL of patients suffered from COPD in Chinese population and investigated its correlation with the clinical profiles. **Methods:** A cohort study design with convenient sampling method was adopted. 80 subjects with mean age 75 were recruited in Pulmonary Rehabilitation Unit in Shatin Hospital (Aug 2002 to Mar 2003). Chronic Respiratory Disease Questionnaire (CRQ), Spirometry, Lawton Instrumental Activities of Daily Living Checklist, Six-minute Walk Test, the Chinese version of Hospital Anxiety and Depression Scale (HADS), Geriatric Depression Rating Scale (GDS) and Lubben Social Network Scale were conducted 1 week post-admission. The data was analysed by Computer software-Statistical Package for Social Sciences (SPSS) version 11.0. The association of the clinical profiles to QOL was calculated by Pearson Product Moment Correlation Coefficients with the statistical significance set at  $p < 0.05$ . **Results:** The mean CRQ scores for dyspnea, fatigue, emotional and mastery were 3.60, 3.79, 4.90 and 4.37. Significant correlations between QOL and all clinical profiles were found. Psychological status indicated the highest and most comprehensive correlation with QOL. GDS presented the highest correlation ( $r = -0.774$ ) while anxiety score in HADS also showed moderate to high correlation ( $r$  ranged from  $-0.309$  to  $-0.520$ ). The functional performance and social support were weakly to moderately correlate with QOL. The correlation coefficients ranged from  $-0.309$  to  $-0.476$  and  $-0.262$  to  $0.399$  respectively. Physiological parameters only showed weak to moderate correlation ( $r = -0.262$  to  $0.406$ ). Moreover, the pattern of correlation between QOL and clinical profiles was varied in different COPD severity groups. **Conclusions:** Patients with COPD in Chinese population definitely had impairment in QOL. Significant correlations between QOL and clinical profiles were shown. The variation of the correlations in COPD patients with different severity implied their different needs on rehabilitation.

# 1516/ASSESSING HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH COPD

Hung-Wei Chen, Public Health, China Medical University, Taichung, Taiwan, ROC; Jian-Jung Chen, Chinese Medicine, Te-Chen Hsia, Hsin-Wen Liang, Chest Medicine, China Medical University Hospital; Yu-Yin Chang, Public Health, China Medical University, Taichung, Taiwan, ROC

**Aims:** In the recent years, there are more and more case of COPD which has become one of the leading causes of morbidity and mortality in industrialized and developing countries. The aim of this study is to assess the health-related quality of life in patients with chronic obstructive lung disease (COPD). **Methods:** We assess health-related quality of life in patients with COPD using Taiwan version of WHOQOL-BREF and St. George's Respiratory Questionnaires. A total of 105 COPD patients aged from 50 to 80 were recruited at a university hospital from 2003 to 2004. Internal consistency reliability revealed by the Cronbach's alpha coefficient ranged from 0.71 to 0.78 across four domains for WHOQOL-BREF. Correlation analysis and ANOVA analysis were used for our study. **Results:** The correlation analysis shows the physical domain of the WHOQOL-BREF correlated significantly with the symptom, activity components of the SGRQ. The physical, psychological and social domains of the WHOQOL-BREF correlated significantly with the impact component of the SGRQ. The SGRQ scores and FEV1% pred correlated significantly in patients with COPD (stages I-III and the total group). The WHOQOL-BREF scores and FEV1%pred correlated significantly in patients with COPD (stages I-III and the total group), with the highest correlation between the physical domain and FEV1 predicted. **Conclusions:** According to the results, both questionnaires show the evidence in clinical practice and the validation of assessing QOL in COPD patients. Further more, we could discuss which symptoms disturb the patients' quality of life, this could help the clinicians to improve the medical service and promote the COPD patients' quality of life.

# 1507/DOMAIN-SPECIFIC CALIBRATIONS OF WHOQOL-BREF IN COPD PATIENTS

Wen-Miin Liang, Hung-Wei Chen, Public Health, China Medical University, Taichung, Taiwan, ROC, Jian-Jung Chang, Chinese medicine, Te-Chen Hsia, Hsin-Wen Liang, Chest Medicine, China Medical University Hospital, Taichung, Taiwan, ROC

**Aims:** The aim of this study is to calibrate the items of each domain of WHOQOL-BREF for COPD patients to better understand the discriminating ability and difficulty of each item applied in COPD patients. **Methods:** From 2001 to 2004, a total of 303 COPD patients aged 45-85 years were recruited. Patients' HRQOL were assessed by WHOQOL-BREF which includes four domains: physical (PH), psychological (PS), social (SO) and environmental (EN). The 2-parameter IRT model (graded response model) was used to calibrate the items of each domain of WHOQOL-BREF on the same scale. The first and last location parameter estimates provide an indication about the extremes of ability (or difficulty) that are measured. **Results:** The results show that the most discriminating items are 'the activities of daily living' in PH, 'the enjoyment of life' in PS, 'the personal relationships' in SO, and 'the home environment' in EN. The least discriminating items are 'dependence on medication or treatment' in PH, 'negative feeling' in PS, 'sexual activity' in SO, and 'transportation' in EN. The items with the lowest location parameter are 'sleep and rest' in PH, 'the self-satisfaction' in PS, 'the sexual activity' in SO, 'the eating food' in EN. The items with the largest location parameter are 'the dependence on medication or treatment' in PH, 'the thinking and concentration' in PS, 'the sexual activity' in SO, and 'the transportation' in EN. The contents and applicability for COPD patients of poorly discriminating items and extreme items are discussed. **Conclusions:** The results can provide a useful reference for item reduction and computerized adaptive testing approaches applied in COPD patients.

# 1222/ASSESSING THE UNIDIMENSIONALITY AMONG SCALES FROM WHOQOL-BREF AND SF-36 IN CHRONIC LUNG DISEASE PATIENTS

Wen-Miin Liang, Hsin-Wen Chang & Hung-Wei Chen, Public Health, China Medical University, Taichung, Taiwan, ROC; Yih-Gian Tsai, Health, Bureau of Health Promotion, Taichung, Taiwan, ROC

**Aims:** In item response theory, unidimensionality is an important assumption. Currently, most HRQOL questionnaires are multidimensional. The aim of this study was to assess the unidimensionality among scales from WHOQOL-BREF and SF-36 in chronic lung disease patients. **Methods:** A 3-stage approach was used. In the first stage, a conceptual literature review was performed to compare the theoretical structures of these two questionnaires. In the second stage, exploratory factor analysis and correlation analysis were performed to identify groups of factors. In the third stage, the scaling and contents of each factor were discussed by experts to decide the groups of factors. A sample of 395 lung disease patients (235 males and 160 females, aged 15-66 years with a mean age of 42.8 years), identified in the 2001 National Health Bureau survey was used in our analysis. **Results:** Our results indicated the unidimensionality of the WHOQOL-BREF physical domain, SF-36 BP and SF-36 VT (all paired correlation  $> 0.50$ ), which was named 'physical' domain. There was also unidimensionality of the WHOQOL-BREF psychological domain and SF-36 MH (all paired correlation  $> 0.50$ ), which was named the 'mental' domain. Cronbach's  $\alpha$  coefficients for the two newly formed dimensions (physical and mental) are 0.90 and 0.85. Though SF-36 VT had a strong correlation with WHOQOL physical domain, VT was not included in the 'physical' domain because a dichotomous scale was used for this domain whereas the other domains in 'physical' domain used five or six scales. No correspondence could be found between the remaining five SF36 domains and the two remaining WHOQOL domains. **Conclusions:** The results may help researchers better understand the similarities and dissimilarities of WHOQOL-BREF and SF-36 and provide a basis for further IRT study.

# 1479/QUALITY OF LIFE AFTER CORONARY SURGERY IN PATIENTS WITH PREOPERATIVE ISCHEMIC HEART FAILURE

Bogoljub M. Mihajlovic, Zoran R. Potic, Marijela M. Potic, Djordje Jakovljevic, Ninoslav D. Radovanovic, Cardiovascular Surgery, University Clinic of Cardiovascular Surgery Novi Sad, Sremska Kamenica, Vojvodina, Serbia & Montenegro

**Aims:** The aim of the study is to compare quality of life (QOL) in patients with preoperative heart failure, ejection fraction (EF) lower or equal to 30% and to those with EF higher than 30%, before and during 7 year follow-up period after myocardial revascularisation. **Methods:** We analyzed 607 consecutive patients, 558 with EF > 30% (80% males, mean age 57 years) and 49 with EF<30% (76% males, mean age 59 years). QOL assessment was done using a self-designed questionnaire consisting of four domains: physical status, mental status, social interaction and self-perception of health. For statistical analysis of QOL, we used pairwise and independent samples t-test of QOLI-NS, that represents integral overall numerical value of QOL. **Results:** Table 1. **Conclusions:** QOL after myocardial revascularisation was statistically significantly better than before operation, in both groups. There was no difference in QOL between patients with preoperative heart failure and those with EF>30% during 7 year follow-up. These facts confirm benefit from myocardial revascularisation in coronary patients with preoperative heart failure.

Table 1.

Time	p preop/postop	QOLI-NS EF>30%	p between groups	QOLI-NS EF<30%	p preop/postop
Preop	–	40.7	0.356	38.4	–
After 1 years	<0.001	85.6	0.355	83.6	<0.001
After 2 years	<0.001	82.6	0.933	82.9	<0.001
After 3 years	<0.001	81.9	0.702	80.9	<0.001
After 4 years	<0.001	80.2	0.101	75.2	<0.001
After 5 years	<0.001	80.6	0.089	75.0	<0.001
After 6 years	<0.001	79.9	0.124	73.4	<0.001
After 7 years	<0.001	81.0	0.698	78.3	<0.001

# 1469/QUALITY OF LIFE AND BENEFIT FROM MYOCARDIAL REVASCULARISATION

Bogoljub B. Mihajlovic, Zoran R. Potic, Marijela M. Potic, Ksenija J. Babovic, Djordje Jakovljevic & Ninoslav D. Radovanovic, Cardiovascular Surgery, University Clinic of Cardiovascular Surgery Novi Sad, Sremska Kamenica, Vojvodina, Serbia & Montenegro

**Aims:** The purpose of this research is to compare quality of life (QOL) in patients before and during 7 years follow-up period after myocardial revascularization. **Methods:** We analyzed 525 consecutive coronary patients (81% males and 19% females) mean age 56.2 years, who underwent myocardial revascularization. There were 2.3 grafts and 0.2 coronary endarterectomy per patient. QOL assessment was done using a self-designed questionnaire. For statistical analysis of QOL, we used pair wise t-test of QOL index (QOLI-NS), that represents integral overall numerical value of QOL. By combining survival and QOL assessment with developed an objective measure 'average survival adjusted patients QOL' in certain point of time. **Results:** The average QOLI-NS index before operation was 41.3. After myocardial revascularization it was 85.6, 82.4, 80.3 and 80.7 at 1, 3, 5, 7 years respectively. The greatest benefit from operation in long-term period (7 years) is registered in males coronary patients and those with low operative risk. **Conclusions:** The QOL in patients after myocardial revascularization (average QOLI-NS) increases significantly after the operation and remains stable seven years after surgery.

# 1420/QUALITY OF LIFE AND PROGNOSTIC INFORMATION. THE IMPLICATIONS FOR MEASUREMENT IN PATIENTS WITH END STAGE HEART FAILURE

Susan Waterworth, Nursing, The University of Auckland, Auckland, New Zealand

**Aims:** This paper generates discussion about the concerns that are raised when planning a study to determine quality of life at the end of life. Patients may not be fully aware that they have reached the end of life phase in their illness, and so their views of quality may be different. In this paper the notion of quality of life as it pertains to older people with end stage heart failure is examined for the methodological issues it raises, not only for the patients themselves, but families/whanau, health care professionals and researchers. **Methods:** The importance of providing palliative care to people with non-non-malignant disease has been identified in the New Zealand Palliative Care Strategy (Ministry of Health 2001). A major group of people are those with end stage heart failure. A New Zealand pilot study, adapted from current research in the UK is used as the basis to analyse the issues for quality of life research when dealing with patients and their families/whanau who have an uncertain diagnosis and lack of prognostic information. **Results:** Awareness that patients and their families/whanau have different perceptions of their diagnosis and prognosis needs to influence the research approach. Cultural considerations are paramount when working with patients and families/whanau over longer periods when end of life occurs, and may involve attendance at funerals or tangi, particularly if follow up of families/whanau is part of the study. Support for researchers working with families is required to reduce the possibilities of over engagement with research participants. **Conclusions:** The increasing trend to promote a palliative care approach for patients with non-malignant disease may present as a number of issues for researchers. In that patients reconstructing their illness journey as end of life shifts quality measurement to a different level.

# 1283/LONG-TERM IMPROVEMENT IN QOL, PSYCHOLOGICAL AND PHYSICAL ACTIVITIES AFTER A TWO-WEEK HOSPITALIZED PHASE II CARDIAC REHABILITATION IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION

Toshiko Yoshida, Nursing, Miyagi University; Masahiro Kohzuki, Masayuki Kanazawa, Kazunori Yoshida, Naoyoshi Minami, Hajime Kurosawa, Osamu Ito, Taku Harada, Makoto Nagasaka & Nobuyoshi Mori, Internal Medicine and Rehabilitation Science, Tohoku University Graduate School of Medicine, Sendai, Japan

**Aims:** Cardiac Rehabilitation (CR) program usually consists of three stages: the acute stage (phase I), subacute stage (phase II) and maintenance stage (phase III). Recently, the period of hospitalization during phase I is becoming shorter due to advances in medical interventions and financial problems. Therefore, lifestyle modification should be acquired during phase II and maintained thereafter. We have designed a new 2-week hospitalized phase II CR program. The purpose of the present study is to clarify whether QOL, the psychological and physical status of patients with acute myocardial infarction (MI) improves after participation in the program. **Methods:** Fifty-one patients with acute MI were enrolled in the program. Another 34 patients with acute MI who did not participate in the program served as a control group. The rehabilitation program consisted of exercise training, education and counseling. QOL, the physical and psychological status of the patients was evaluated before, at 1-month after the program, and at 6- and 12-month follow-up. Quality of life (QOL) was assessed using established and validated QOL scales. The psychological status was assessed by STAI and SRQ-D. **Results:** After participation in the program, the exercise tolerance, serum lipid profiles and STAI anxiety score of the patients were improved significantly. At 6-month follow-up, these parameters remained improved and regular physical activity was maintained. QOL score was also improved significantly. Even at 12-month follow-up, lipid profiles remained improved and regular physical activity was maintained. **Conclusions:** Two-week hospitalized phase II CR program improved QOL and the management of cardiac risk factors in patients with MI. This program provides beneficial effects on QOL, psychological and physical activities in the recovery phase and may also contribute to the secondary prevention of MI.

# 1732/THE EVALUATION TO THE EFFECT OF QUALITY OF LIFE WITH INVIGORATING THE KIDNEY TO CONGESTIVE HEART FAILURE

Chen Jie, Internal Medicine, TCM University of Guangzhou, Guangzhou, Guangdong, PRC

**Aims:** the purpose of this pilot study was to value the effect of the TCM therapy that invigorates the kidney to the patient with CHF. And evaluation of the effectiveness with the change of the heart functional class by NYHA and the QOL assessment SF-36, WHOQOL-BREF and MLHFQ are applied to. **Methods:** This is a prospective, randomization, and single blind controlled trail. The patients were randomly allocated to two groups: the contrast group and the treatment group, the ratio of the number of two groups was 1:2. All the patients accept the general modern medicine and Chinese herbs treatment. And the treatment group was separated into two groups (insufficiency of kidney-yang group and deficiency of kidney-Yin group) by the differential diagnosis. The deficiency of kidney-Yang group invigorate kidney yang with pill for invigorating kidney energy, the deficiency of kidney-Yin group invigorate kidney Yin with bolus of six drugs containing rehmannine peeparatae, the dose of the both medications is 6 g, three times per day the observing cycle is about 3 weeks. Before and after the intervention, the heart functional class and the QOL instruments (including SF-36, WHOQOL-BREF, MLHF, ChQOL) take as main outcomes. **Results:** In patients with CHF, the insufficiency of kidney-Yang group the improvement of heart functional class and the dimension of the physics dimension (SF-36/WHOQOL/MLHF/ChQOL) was significantly increased compared with the contrast group  $p < 0.05$ . But other group has not shown the significant difference  $p > 0.05$ . And after the treatment, in both the insufficiency of kidney-yang group and the deficiency of kidney yin group improvement of functional class and the dimension of the physical functioning (SF-36), physical dimension (WHOQOL-BREF), physical dimension and total (MLHF) and the vitality/the taste/the sleeping/the stool and the pee dimension (ChQOL) were significantly increased than before  $p < 0.05$  while other dimension of the QOL has shown significant difference  $p < 0.05$ . **Conclusions:** The heart functional class and the physical dimension and the total QOL are improved by the treatment with invigorating the kidney (especially invigorating the kidney yang) in patients with CHF.

# 1710/DISCRIMINANT PROPERTIES OF THREE SPECIFIC AND GENERIC HEALTH-RELATED QUALITY OF LIFE QUESTIONNAIRES IN HEART FAILURE

Mohsen Asadi-Lari, Cardiovascular Medicine, University of Nottingham, Nottingham, UK; Archana Rao, Cardiology, University of Liverpool, Liverpool, UK

**Aims:** To assess health-related quality of life (HRQL) in patients with suspected heart failure (HF) using two generic questionnaires, Short Form 36 (SF-36) and EuroQol 5D (EQ-5D) and one specific, the Minnesota Living with Heart Failure (MLHF-Q) HRQL; to explore their discriminant properties and correlation with New York Heart Association (NYHA) class. **Methods:** All patients with symptoms suggestive of heart failure referred to University Hospital, Nottingham, between June 2002 and March 2003. Confirmation of left ventricular systolic dysfunction by echocardiography. **Results:** 223 patients (median age = 74) were referred. HF was confirmed in 81. Lower HRQL scores were found in older patients (SF-36 and EQ-5D:  $p < 0.001$ ; MLHF-Q:  $p = ns$ ), women ( $p < 0.001$ ;  $p < 0.05$ ;  $p < 0.05$ , respectively) and BMI  $> 30$  ( $p = ns$ ;  $p < 0.05$ ;  $p = ns$ , respectively). Among those with confirmed heart failure, lower mean scores were found in both subscales of SF-36, four of six subscales in EQ-5D and all MLHF-Q subscales, but these were not statistically significant. SF-36 mental component score (MCS) and the emotional subscale of MLHF-Q were more sensitive to depressive disorders than EQ-5D ( $p < 0.001$ ;  $p < 0.001$ ; and  $p < 0.05$ , respectively). Regression analysis indicated that only SF-36 physical component score (PCS) was able to differentiate significantly between NYHA functional classes ( $p < 0.01$ ). The validity of MLHF-Q was confirmed by correlation with various subclasses in other HRQL measures ( $p < 0.001$ ) and known group analysis with NYHA functional class ( $p < 0.001$  in both physical and emotional subscales). **Conclusions:** The specific HRQL measure, MLHF-Q, was more sensitive to functional status in

heart failure but emotional abnormalities and general affections were more readily identified by generic tools. Employing both generic and specific HRQL instruments seems necessary in suspected and confirmed heart failure. MLHF-Q showed appropriate construct validity in this sample.

# 1603/COMPARING MACNEW AND SEATTLE ANGINA QUESTIONNAIRE (SAQ) IN IRANIAN PATIENTS WITH CORONARY ARTERY DISEASE

Mohsen Asadi-Lari, Cardiovascular Medicine, University of Nottingham, Nottingham, UK; Hamid R. Javadi, Cardiology, Qazvin University of Medical Sciences, Qazvin, Iran

**Aims:** Developing various cardiac specific health-related quality of life tools bewilder researchers and cardiologists to select the tool of choice. Comparing existing tools against each other and also against standard clinical assessment methods may reveal their merits. **Methods:** We administered two cardiac specific HRQL tools (MacNew and SAQ), which were recently validated in Iranian population, in a small group of patients with coronary artery disease ( $n = 28$ ) when admitted to a coronary care unit in Iran. More than half of the patients ( $n = 16$ ) participated in retest in the clinic visit one month after discharge from hospital. **Results:** 28 patients were recruited in the first section; 91% were male, 54% with a confirmed MI and the rest with symptoms of angina, 64% with class I and 36% with class II of the Canadian Cardiovascular Society Classification, 53% were non-smoker, and similar figure with higher education. Four components out of five in the SAQ (Pearson  $r = 0.37-0.71$ ,  $p < 0.05- < 0.001$ ) were correlated with CCSC categories, however none of the MacNew components were significantly correlated with CCSC ( $r = 0.29-0.35$ ,  $p = ns$ ). In test-retest, SAQ-AS was significantly different ( $p < 0.01$ ) and SAQ-QOL was in borderline ( $p < 0.06$ ); emotional component in the MacNew, nevertheless, was able to detect changes over time ( $p < 0.05$ ). **Conclusions:** Despite significant merits of the Macnew in detecting changes in quality of life perception in cardiac patients, the Seattle Angina Questionnaire showed better construct validity -in terms of functional classification of CAD- in this group of patients.

# 1132/AN ASSESSMENT OF QUALITY OF LIFE IN PATIENTS WITH CORONARY HEART DISEASE AND IN GENERAL POPULATION: WORLD HEALTH ORGANIZATION QUALITY OF LIFE ASSESSMENT SCALE (WHOQOL-100)  
Regina Reklaitiene, Population, Kaunas University of Medicine, Kaunas; Algirdas Juozulynas, Clinical Medicine, Vilnius University, Vilnius, Lithuania

**Aims:** The main objective of the study was to assess the quality of life (QoL) and its determinants of patients with CHD and to compare with the general population. **Methods:** The study was conducted on 35–64 aged 447 men and women recruited from Cardiology Clinics of Kaunas University of Medicine. Control group consisted of randomly selected 1347 Kaunas men and women aged 35–64 and stratified by age and sex (response rate 62%). The QoL profiles were evaluated by self-administered questionnaire of the WHOQOL-100. Approval from the Ethics Committee was obtained and participants signed a written consent prior to the fill in a questionnaire. Convergent validity and inter item correlations were evaluated by Pearson's correlation coefficient and by Cronbach's  $\alpha$ . Identification of the determinants of the QoL and perceived health was accomplished by stepwise linear regression. **Results:** The measure of the WHOQOL-100 showed valid and reliable results among patients with CHD and control group. Patients with CHD scored lower overall quality of life, social and spirituality domains as compared with control group; scores of physical and level of independence domains were assessed higher than in control group. The domains having the significantly impact on ratings of QoL were psychological ( $\beta = 0.25$ ), environmental ( $\beta = 0.44$ ) and spirituality ( $\beta = 0.12$ ) domains among patients with CHD; among control group significantly impact showed physical ( $\beta = 0.07$ ), psychological ( $\beta = 0.18$ ), social relationships ( $\beta = 0.17$ ), environmental ( $\beta = 0.30$ ) and spirituality ( $\beta = 0.07$ ) domains. The results on ratings of perceived health were significantly related among CHD and control groups to the physical ( $\beta = 0.18$  and  $0.18$ ) and psychological ( $\beta = 0.22$  and  $0.11$ ) domains, respectively. The impact of environmental ( $\beta = 0.12$ ) and level of independence ( $\beta = 0.34$ ) domains were important among CHD and control groups. **Conclusions:** The ratings on QoL and on perceived health among patients with CHD and general population reveals efforts should be directed to the social and medical care.

# 1557/SUBJECTIVE WELL-BEING AND 1-YEAR MORTALITY AND OCCURRENCE OF NONFATAL STROKE AND NONFATAL MYOCARDIAL INFARCTION IN PATIENTS WITH HYPERTENSION AND CORONARY ARTERY DISEASE

L. Douglas Ried, Research Service and College of Pharmacy, Veterans Affairs and University of Florida, Gainesville, FL; Michael J. Tueth, Eileen Handberg & Pamela W. Duncan, Gainesville, FL, USA

**Aims:** Health is clearly important to an individual's subjective well-being (SWB). However, it is less clear how it is associated with adverse health outcomes and health-related quality of life (HRQoL). This pilot study investigated if a global SWB item was associated with: (1) increased risk of mortality and nonfatal myocardial infarction (MI) and nonfatal stroke and (2) HRQoL and depressive symptoms. **Methods:** 2317 consecutively randomized U.S. INVEST subjects were enrolled between April 1, 1999 and October 31, 1999. INVEST was a prospective, randomized trial in 22,576 hypertensive patients with CAD assigned to a verapamil-SR or atenolol-based strategy. Patients' self-reports of depressive symptoms (CES-D) and HRQoL (SF-36) were obtained by mail survey at baseline and 1-year. SWB was obtained at each INVEST visit. Mortality and nonfatal MI and stroke outcomes were reported within 24 h using an online adverse event reporting system. Outcome events were adjudicated by the INVEST event committee. Pearson's chi-square was used to evaluate the association between SWB and mortality and nonfatal stroke and MI. Mean scores of individuals reporting excellent SWB were compared to those rating their SWB as good, fair, or poor for each HRQoL domain and depressive symptoms using ANOVA. **Results:** Subjects suffering an adverse outcome within 1-year increased ( $p < 0.003$ ) as an individual's reported worsening SWB; excellent (3.8%), good (4.8%), poor/fair (8.3%). Mortality was highest among those who rated their SWB as poor/fair (5.2 percent) compared to those rated their SWB as good or excellent (3.0% and 3.8%;

$p = 0.02$ ). Subjects rating their SWB as poor/fair (2.1%) were more likely to suffer a nonfatal stroke (RR = 2.08, 95% CI = 1.39, 3.13). MI was not associated with SWB. In every case, persons rating their SWB as excellent had fewer depressive symptoms and more favorable HRQoL compared to persons who rated their SWB as good, fair or poor ( $p < 0.001$ ). **Conclusions:** SWB may be useful within a screening instrument to screen individuals at increased risk for adverse health outcomes.

# 1331/IMPACT OF CORONARY HEART DISEASE OCCURRENCE ON HEALTH-RELATED QUALITY OF LIFE: A LONGITUDINAL ASSESSMENT

Stephanie Boini & Serge Briançon, Ecole de Santé Publique, Francis Guillemin, Epidemiology, Université Henri Poincaré Nancy 1, Vandoeuvre; Pilar Galan & Serge Herberg, ISTNA/CNAM, Paris, France

**Aims:** Investigations focusing and implementing on the impact of CHD on HRQoL by the way of a mean comparison between patients and subjects from the general population, are usually cross-sectional. Longitudinal application of HRQoL instruments to a general, initially healthy population allows for change to be assessed as an event occurs, rather than afterwards. The aim was to investigate the impact of coronary heart disease (CHD) occurrence on health-related quality of life (HRQoL) evolution. **Methods:** The 36-item Short Form (SF-36) and 12-item General Health Questionnaire (GHQ-12) were applied to the French SU.VI.MAX cohort in 1996 and 2001. A controlled longitudinal study was used to determine the impact on HRQoL of CHD: 62 patients with CHD that occurred between the 2 HRQoL measures were compared with 310 age- and sex-matched cardiovascular-free controls. **Results:** Initial HRQoL level was similar in the two groups. Between the 2 HRQoL measures, most of HRQoL dimensions decreased in the CHD group, contrary to the cardiovascular-free group. The difference between the CHD and control groups in how much HRQoL changed was  $-10.0$ ,  $-10.6$ ,  $-4.7$  and  $-8.8$  points for SF-36 Role-physical, Role-emotional Vitality and General health, respectively. The GHQ-12 score was not affected. **Conclusions:** The negative impact of CHD on the patient's lives was assessed in terms of HRQoL. The aspects most likely to be affected were general health perceptions, particularly physical- and emotional-components. Knowledge about the specific influence of CHD on HRQoL can make practitioners more aware of their patient's suffering and needs.

# 1604/HEALTH-RELATED NEEDS AND QUALITY OF LIFE IN PATIENTS WITH ACUTE CHEST PAIN: IS GENDER IMPORTANT?

Chris Packham, DM, FFPH, Epidemiology & Public Health, Mohsen Asadi-Lari, David Gray, FRCP, Cardiovascular Medicine, University of Nottingham, Nottingham, UK

**Aims:** Inequalities in health care between men and women have been described extensively, including in coronary heart disease, with regard to access to diagnostic and therapeutic procedures. Although survival rates for men and women following a myocardial infarction differ, this does not fully explain inequity in access to health services, especially diagnostic and treatment procedures, for infarct survivors. We explored whether there was an association between perceived quality of life and gender as a possible explanatory factor in such inequality. **Methods:** A comprehensive self-administered health needs assessment (HNA) questionnaire was developed for concomitant use with generic (Short Form-12 and EuroQOL) and specific (Seattle Angina Questionnaire) health-related quality of life (HRQL) instruments on 242 patients (41% female) admitted to the Acute Cardiac Unit, Nottingham. **Results:** Overall, women expressed more dissatisfaction with services than men ( $p < 0.05$ ) and appeared to have more physical needs. Women were more likely to complain about transport, which influenced their access to healthcare facilities ( $p < 0.001$ ), to be concerned about getting help with cleaning ( $p < 0.01$ ), and request information about rehabilitation services, potential limitations on their daily activities, and nutrition and diet ( $p < 0.05$ ). Women had lower health-related quality of life scores in all the HRQL variables, which was significant in EQ-5D (usual activities, and pain/discomfort), Seattle angina questionnaire (angina stability), and both components of the Short Form-12. **Conclusions:** This survey was the first attempt to develop and apply a needs assessment tool combined with quality of life assessment for cardiac patients to identify potential gender disparities. Women reported greater health needs, greater dissatisfaction with current health services and had worse HRQL. Recognising gender disparities in health needs and HRQL would clarify areas for improvement in health care services which might allow a better quality of life for infarct survivors.

# 1257/QUALITY OF LIFE AND THE USE OF COMPLEMENTARY THERAPIES AMONG CANCER PATIENTS

Ali Montazeri, Akram Sajadian, Mandana Ebrahimi & Shahpar Haghighat, Epidemiology, Iranian Centre for Breast Cancer (ICBC), Tehran, Iran

**Aims:** The use of complementary and alternative medicine is becoming increasingly common among cancer patients. The aim of this study was to examine the association between quality of life and the use of complementary and alternative medicine. **Methods:** A cross-sectional study was conducted to investigate about factors predicting the use of complementary therapies among a sample of cancer patients in Iran. Predicting factors included were age, gender, marital status, educational level, type of diagnosis, time since diagnosis, fear of recurrence, and measures of anxiety, depression and global quality of life. Anxiety and depression was measured using the Hospital Anxiety and Depression Scale and global quality of life was assessed using the EORTC quality of life core questionnaire. **Results:** In all, 377 patients with breast (47%), gastrointestinal (41%) and hematological (12%) cancers were studied. The mean age of patients was 47.1 (SD = 15.3) years, mostly were female (71%), married (78%), less educated (72%) and 36% ( $n = 135$ ) reported that they had used or are using complementary therapies. The mean global quality of life score among users was 55.6 (SD = 14.5) whereas it was 53.7 (SD = 14.5) among nonusers (possible score ranging from 0 to 100). Performing the logistic regression analysis entering all variables into the model it was found that age (odds ratio = 1.02, 95% CI 1.00–1.04,  $p = 0.02$ ), global quality of life (odds ratio = 1.02, 95% CI = 1.00–1.04,  $p = 0.01$ ) and fear of cancer recurrence (odds ratio = 1.78, 95% CI = 1.12–2.83,  $p = 0.01$ ) were significant predicting factors while gender, marital status, educational level, anxiety, depression, type of diagnosis, and time since diagnosis were not, although the results were in the expected direction. **Conclusions:** The study findings suggest that cancer patients who seek alternative therapies are likely to be older, and suffer from uncertainties and a poorer quality of life.

# 1208/TRIAL DESIGN FOR MIND-BODY INTERVENTIONS TO IMPROVE QUALITY OF LIFE

C.R. Gross, V.G. Russas & M. Reilly-Spong, Col of Pharmacy; M.J. Kreitzer, School of Nursing, Ctr for Spirituality and Healing, University of Minnesota, Minneapolis, MN, USA

**Aims:** Emphasis on patient-reported outcomes and heightened interest in rigorous evaluation of complementary therapies have combined to provide exciting opportunities for clinical trials designed with health-related quality of life (HRQL) as the primary outcome. While researchers can select their outcomes from a long list of reliable and well-validated HRQL measures, there is a paucity of guidance on clinical trial design for complementary interventions involving non-pharmacologic therapies. **Methods:** This paper will propose design options to overcome the major challenges for these clinical trials, including formation of appropriate control conditions, compliance with random assignment, composite outcomes and blinding. **Results:** For interventions with psycho-educational content, like chronic disease self-management, meditation or yoga, non-specific effects like instructor attention, social support and outcome expectancies are uncontrolled confounders when inactive conditions, like wait-list controls are used. Alternatively, active control conditions, such as sham interventions, can pose serious ethical concerns due to high patient burden and deceptive practices. In some ways these concerns are similar to those accepted with medication placebos, differing only in degree of risk and burden. For example, equating exposure time between shams and true psycho-social-educational interventions may require an unacceptably long investment of control patient time and energy. Moreover, such shams create quasi-interventions with uncertain efficacy. Multiple control-group designs, mixtures of HRQL, economic and physiologic outcomes, and two-stage randomization schemes are proposed to address these challenges. **Conclusions:** A recently funded NIH trial of mindfulness-based stress reduction to reduce symptom distress and improve HRQL among transplant recipients is used as an example of these recommended design options. Funded by R01 NR008585.



# 1460/HEALTH-RELATED QUALITY OF LIFE (HRQOL) AND SELF-REPORTED COGNITIVE FUNCTIONING IN COGNITIVELY IMPAIRED OLDER ADULTS UNDER TREATMENT WITH GINKGO BILOBA EXTRACT EGB 761<sup>®</sup>

Corinna Petersen, Medical Psychology, University Clinic of Hamburg Eppendorf, Hamburg, Germany; Lutz Frölich, Gerontopsychiatry, University of Heidelberg, Mannheim, Germany; Ulrich Weigeldt, Bremen, Germany; Daniel Dietmar, Research & Public Relation-Beratung i.Gesundheitswesen, Burscheid, Germany; Monika Bullinger, Medical Psychology, University Clinic of Hamburg-Eppendorf, Hamburg, Germany

**Aims:** The relationship between HRQOL and cognitive functioning has been studied in terms of the assessment of cognitive function as a dimension of HRQOL, the description of the HRQOL of persons with cognitive impairment and the impact of cognitive impairment on self-reports of HRQOL. The present study explores the relationship between the self-report of cognitive functioning and HRQOL. **Methods:** Within a longitudinal study, 2009 patients (mean age 68 years, 62% female) with cognitive impairments were recruited from 234 German sentinel physician offices. After baseline assessment, patients were treated with one of two herbal extracts\* and followed up after 4–6 weeks. The majority of patients had moderate cognitive impairments, using clinical evaluations and the mini-mental state exam (MMSE). Self-reports included the Cognitive Failure Questionnaire (CFQ), the SF-12 Health Survey (SF-12) and the geriatric depression scale (GDS). **Results:** Results showed that HRQOL measured with the SF-12 was impaired with regard to the age and gender representative comparison group from the German Health Survey. The degree of HRQOL impairment was associated with the degree of cognitive impairment as measured by the MMSE. Self-reported cognitive functioning measures were psychometrically robust and correlated with low HRQOL. Improvements in HRQOL and self-reported cognitive functioning from baseline to follow up were found for Egb 761<sup>®</sup>. **Conclusions:** The study suggests that the assessment of self-reported cognitive deficits is feasible in this patient group and useful for detecting differences in cognitive functioning under treatment, here Egb 761<sup>®</sup>. \*Ginkgo biloba Extract Egb 761<sup>®</sup>; hydroalcoholic St. John's wort extract WS 5572<sup>®</sup>. The study was supported by the manufacturer: Dr. W. Schwabe GmbH & Co KG, Karlsruhe, Germany.

# 1678/EARLY EXPERIENCE OF A MULTIDISCIPLINARY PAIN MANAGEMENT PROGRAMME IN CHINESE PATIENTS WITH CHRONIC PAIN

P.P. Chen, T.C.M. Wong, M. Ma, C.T. Cheung, S.P. Cheng, S.H. Leung, K.Y. Leung, L.C. Yang, H. Lei & W. Lam, COPE Programme Team, Alice Ho Miu Ling Nethersole Hospital, Tai Po, Hong Kong

**Aims:** Chronic pain is a common condition with significant impact on functional ability, mood and quality of life. We report an early experience of a multidisciplinary pain management programme in Hong Kong. **Methods:** The Comprehensive Outpatient Pain Engagement (COPE) programme is a multidisciplinary pain management programme embracing an integrated cognitive behavioural and exercise approach. Patients were recruited into the programme in two groups from the New Territory East cluster pain clinics. Over an eight-week period, patients attended the programme two days a week on an outpatient basis. The programme consisted of pain and related education, cognitive behaviour therapy, physical exercises, occupational therapy and exercises on spiritual awareness. Evaluation before and at 0, 6 and 12 months post-programme were conducted using the Hospital Anxiety Depression Scale (HADS), MOS-Short Form 36, Pain Catastrophizing Score (PCS) and VAS pain score. In the second group, Pain Self-efficacy Questionnaire (PSEQ), Canadian Occupational Performance Measurement (COPM) and Oswestry disability index were also completed. Work status was recorded prior to and at 12 months after programme. **Results:** Seventeen patients (5 male, 12 female) were recruited but 16 completed the programme. The median (interquartile range) age and duration of pain were 45.5 (39.5–50.7) and 4.5 (3.3–6.6) years respectively. There was a trend towards improvement in pain score, depression, SF-36 bodily pain perception and social functioning, Oswestry disability index, COPM (satisfaction)

and COPM (performance) with the largest change at 12-month. There was no change in PCS and PSEQ scores in our patients. All participants except two (housework/voluntary work) were either on sick leave or unemployed before the programme. At one year nine participants were either employed full-time or involved in voluntary work/housework. **Conclusions:** Integrated multidisciplinary pain management programme may improve the quality of life and function of Chinese patients with chronic pain. A more comprehensive study is required to validate the effectiveness of such programme locally.

# 1293/A COMMUNITY NURSE-LED PROTOCOL FOR CLINICAL KNEE OSTEOARTHRITIS IN OLDER PERSONS

Kam Wing Edwin Tsang, Nursing, TWGHs Fung Yiu King Hospital, Hong Kong, PRC

**Aims:** Older persons are commonly disabled by clinical knee osteoarthritis (KOA). Community nurse-led care has been demonstrated as an effective gerontological care strategy in Western Countries. However, there is no such service in Hong Kong. Therefore, the aim of this study is to evaluate the effectiveness of a community nurse-led protocol for clinical KOA (protocol) for older persons. **Methods:** It was a non-equivalent, pre-test post-test control group study. Older persons cared for by home help teams (HH) in the Southern District of HK were recruited for the treatment group while others were recruited for the control group. HH assisted treatment group to exercise protocol as directed by the gerontological nurse specialist (GNS). The GNS follow up treatment group every 4 weeks. 23 subjects were assigned to each group. Outcome measurement included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the Medical Outcome Survey (MOS SF-36), chair-rising and timed performance test of mobility for specific physical function. The score change of WOMAC and MOS SF-36 was used to detect the treatment effect of the protocol. The normality of the distribution of the score changes was examined to determine the use of independent sample *t*-test or the Mann–Whitney U test for WOMAC and MOS SF-36. For the specific physical function performance and reported health transition in the MOS SF-36, the percentage change of study groups was analyzed by  $\chi^2$  test. **Results:** The study result demonstrates significant treatment effect of the protocol in relation to the reduction of knee pain and stiffness, enhancement of the overall disease-specific and general health status in study subjects. It also demonstrates the effectiveness of service collaboration with existing gerontological care resources in enhancing health care effectiveness. **Conclusions:** The study result indicates there is not necessary association between perception of health and physical function performance. Nurse-led protocol for KOA is effective in enhancing health status of older persons with KOA. Collaboration between GNS and HH demonstrate enhanced service effectiveness through significant effect on perception of health of older persons.

# 1185/THE CHANGES IN EX-MENTAL PATIENTS ATTENDING A PSYCHIATRIC REHABILITATION PROGRAM WITH HOLISTIC CARE

Luk L. Andrew, Nursing, Alice Ho Miu Ling Nethersole Hospital, Tai Po, Hong Kong

**Aims:** It is well documented that most patients with chronic mental illnesses suffer from severe psychosocial dysfunction. Recent studies also suggest many patients have spiritual problems. This study aimed to study the changes and the related factors in ex-mental patients attending the psychiatric rehabilitation program with holistic care organized by a Christian non-government organization. The program is characterized by a SHG approach with a holistic care content in which spiritual support is also emphasized. The research questions are (1) are there any changes in physical, psychological, social and spiritual functioning of participants in the program? (2) What are the related factors affecting the changes? **Methods:** A quasi-experimental design to measure the outcomes of the changes was used. The experimental group consisted of 109 participants in the program. They were invited to complete a self-administered questionnaire. Regarding the control group, 154 clients from a psychiatric outpatient clinic who had never attended any SHG before were recruited to fill in the same self-administered questionnaire. Voluntary bases and confidentiality were assured in both groups. The WHOQOL-BREF(HK) was one of the tools to measure the physical, psychological, social and global well-being of the respondents of both groups. Chi square test, *t*-test and ANCOVA test were used to test the different outcomes of two groups. Spearman's rho, Pearson's *r*, ANOVA and *t*-test were used to test the factors affecting the changes of functioning of participants in the program. **Results:** The findings showed that those who joined the SHG had more friends and more satisfaction socially than those without joining the group. Duration of attendance, religious and group involvement were three key factors related to the change of functioning of the participants in the program. The WHOQOL-BREF(HK) was found to be a useful tool in measuring changes in physical, psychological and social functioning. **Conclusions:** This study supported the effective use of SHG and the consistent findings that the positive functions of religion could help people cope with life stress such as having a chronic illness.

# 1346/TREATMENT OF DEMENTIA PATIENTS WITH STANDARDISED GINKGO BILOBA EXTRACT EGB 761<sup>®</sup> (TEBONIN<sup>®</sup> 120MG) IMPROVES THE QUALITY OF LIFE OF THEIR CARING PERSONS

Michael Koller, Theoretical Surgery, Philipps-University Marburg, Marburg, Germany; T. Heinen-Kammerer, IFEG, Burscheid, Germany; W. Lorenz, Theoretical Surgery, Philipps-University Marburg, Marburg, Germany; V. von den Driesch & M. Habs, Schwabe Pharmaceuticals, Karlsruhe, Germany; R. Rychlik, Burscheid, Germany

**Aims:** Dementia is a progressive disease that affects patients, as well as their families. Patients are commonly treated with EGB 761<sup>®</sup> which has proven antedementia-efficacy. The aim of this study was to explore whether the benefits of Ginkgo biloba extract pass on to the person primarily caring for the patient in the sense of improving his/her quality of life (QL). **Methods:** The trial was designed as a non-randomised, two-armed cohort study. Patients (mild to moderate dementia, MMST-score 12–24 points; home care by a family member) were recruited in 133 family doctor practices all over Germany, and it was the doctors' choice either or not to treat the patient with Ginkgo biloba extract. Primary endpoint was the caring persons' QL (PLC; Siegrist et al., 1996) 12 months after start of treatment. Patients' cognitive and functional status were assessed by the MMST and the Barthel-index. In addition, costs of treatment were calculated. **Results:** A total of *n* = 683 patients were included in the study, *n* = 281 received EGB 761<sup>®</sup> (2 × 120 mg/d) and *n* = 402 did not. At the 12-months assessment point, the caring persons' QL was significantly higher in the Ginkgo biloba group than in the control group (all six PLC scores, *p* < 0.001). In the same manner, patients' cognitive and functional status were higher (*p* < 0.001). Average total cost per patient amounted to 3.032 Euro in the Ginkgo-biloba cohort, and 3.615 Euro in the control cohort (*p* < 0.001). **Conclusions:** This study demonstrated that in the reality of family doctor patient care, Ginkgo biloba extract EGB 761<sup>®</sup> positively affects the 'system' of dementia patients, resulting in a better QL of their caring partners, a better cognitive and functional status of the patients, and lower total costs.

# 1611/THE VALUE OF EMOTIONAL SUPPORT IN THE TREATMENT OF CANCER PATIENTS WITHIN A CHINESE CULTURAL CONTEXT

Fung Ling Ho, Psychology, University of Hawaii at Manoa, Honolulu, HI; John F. Babson, General Education, Polytechnic University of Hong Kong, Hong Kong, PRC

**Aims:** Western research reports a positive effect from emotional support (ES) on psychological adjustment in female breast cancer patients. The purpose of this study is to investigate whether Chinese female and male cancer patients of different sites, nasopharyngeal (NPC) and breast cancer (BC), would similarly benefit. It is postulated that ES would exert a similar positive effect in this population. Specifically, ES is hypothesized to be negatively correlated with patients' depression and anxiety. **Methods:** Subjects aged 18 and up, with a single cancer diagnosis of NPC or BC, completed treatment, and no recurrence in the past 5 years were recruited in a Hong Kong cancer center. Data collection was conducted on a medical visit until the targeted number of subjects was reached. A total 40 male NPC, 40 female NPC, and 40 BC patients participated. One-way ANOVA was used to compare the levels of self-reported ES received, depression, and anxiety of the three groups. Results revealed no differences among the three groups with respect to these three variables. All groups were collapsed into one for further analysis. Pearson correlations examined the relationship between ES and the two psychological adjustment variables. **Results:** The hypothesis was supported. ES was found to be significantly and negatively correlated with depression (*r* = -0.402) and anxiety (*r* = -0.251). **Conclusions:** This study provides cross-cultural, cross-gender, and cross-cancer-site evidence to support the robust effect of ES on depression and anxiety. This finding highlights the clinical value of incorporating ES as a treatment component particularly for patients with low ES having a high risk in developing depressive and anxiety symptoms.

# 1727/THE STUDY ON THE APPLICATION OF QUALITY OF LIFE (QOL) TO THE SUPERFICIAL GASTRITIS TREATED WITH TRADITIONAL CHINESE MEDICINE (TCM)

Liu Fengbin, Medical, Guangzhou University of Traditional Chinese Medicine, Guangzhou, Guangdong, PRC

**Aims:** The aim of the study was to research the status of QOL of chronic superficial gastritis and to observe the effect of treating the diseases with WeiYanXiao tablet. **Methods:** 93 cases of patients suffering from chronic superficial gastritis diagnosis by endoscopies were selected from the outpatients and in-patients in the first affiliated hospital of Guangzhou University of TCM. The patients were randomly assigned to treating group (48 cases) and control group (45 cases) on single-blind basis. The cases in treating group were treated with WeiYanXiao tablet (4 tablet, Tid) made of Chinese herbs, the other with Bismuth Potassium Citrate capsule (1capsule, Qid) for 1 month. The WHOQOL-BREF and the special module developed by us were applied to in the study. The module based on TCM theory and TCM clinical practice was mainly used in gastrointestinal diseases. At same times, the validity, reliability and responsibility of the module were evaluated in the study. Patient self in the pre and post treating made all the answer of the scales. And while patients answered the scales, the doctor must accompany them to answer the questions of patients. After the course of treating, the results between two groups and between pre and post-treating were statistically analyzed. **Results:** Between the pre and post-treating, the QOL in the Phy, Psy and the whole of the WHOQOL-BREF was statistically improved (*p* < 0.01) after treating, and in the Ind (*p* < 0.05), but no change in Soc and Env (*p* > 0.05). The score of the module was also improved statistically (*p* < 0.01). Between two groups, the QOL in the Phy, Psy, Ind, and the whole of the WHOQOL-BREF was statistically improved (*p* < 0.05) after treating, also no change in Soc and Env (*p* > 0.05). The score of the module was also improved statistically (*p* < 0.01). **Conclusions:** The results showed that the Chinese herbs, WeiYanXiao tablet, had a better effect on the chronic superficial gastritis in improving the QOL and the score of module than the western medicine, Bismuth Potassium Citrate capsule. So, the application of Chinese herbs to clinical practice should be studied more broadly and scientifically in the future.

# 1439/THE RELATIONSHIPS AMONG CHARACTERISTICS OF TONGUE DIAGNOSIS IN TCM AND QUALITY OF LIFE IN COPD PATIENTS

Jian-Jung Chen, Chinese Medicine; Te-Chen Hsia, Chest Medicine, China Medical University Hospital; Liang-wen Hang, Chest Medicine, China Medical University Hospital; Wen-Miin Liang, Public Health; Min-Ling Liao, Chinese Medicine, China Medical University Hospital, Taichung, Taiwan, ROC

**Aims:** In Traditional Chinese Medicine (TCM), quality of life (QOL) is based on the consonance of 'yin' and 'yang' indicating a good QOL. TCM diagnosis stresses holistic treatment by balancing yin and yang. Tongue diagnosis is one popular method of TCM diagnoses. Patients' constitution and symptoms can be evaluated by observing tongue color, tongue fur and other tongue features. This study addresses the relationships between QOL of patients with chronic obstructive pulmonary diseases (COPD) and their tongue features based on TCM diagnosis. **Methods:** A total of 40 COPD patients recruited in 2004 were analyzed. QOL data were collected by using WHOQOL-BREF questionnaire. The characteristics of the patients' tongues were objectively determined using digital photographic images. Tongues were categorized into two groups, 'excessiveness' and 'insufficiency', which corresponded to yin and yang. Excessiveness symptom-complex (blue or purple tongue, or yellow tongue fur, or plump tongue with slimy and greasy coat) indicated excessiveness symptom. Insufficiency symptom-complex (whitish tongue, or with teeth prints at the lower borders, or paralysis of the tongue) indicated insufficiency symptom. **Results:** The results shows the patients with excessiveness symptom-complex were more significantly affected by discomfort, pain and sleeping quality. The patients with insufficiency symptom-complex had worse scores in psychological items like enjoying life, spiritual feeling, and being respected. **Conclusions:** Analysis of patients' tongue characteristics was useful in evaluating patients' QOL, and may improve the quality of holistic treatment in TCM.

# 1254/MEASURING HEALTH-RELATED QUALITY OF LIFE (HRQOL) AT AN INTEGRATIVE EAST-WEST MEDICINE CENTER  
Marc Brodsky, Michael Johnston & Ka-Kit Hui, Center for East-West Medicine, University of California Los Angeles (UCLA), Santa Monica, CA, USA

**Aims:** The University of California Los Angeles (UCLA) Center for East-West Medicine is a leader in developing and disseminating an innovative model of healthcare that combines the best of conventional and Chinese medicine. The Center is under the Department of Medicine and has over 10,000 patient visits a year. The SF36 instrument was introduced to assess the HRQOL of patients at the Center. This presentation will describe the Center's experience in developing, implementing and evaluating a program to measure HRQOL in a busy clinical setting. Preliminary data will also be discussed. **Methods:** The SF36 was completed on the first visit by all new patients beginning in December 2003. One-third of the patients were asked to complete an SF36 6 weeks after their initial visit by a process approximating random assignment. **Results:** The Center implemented a program to measure HRQOL after a series of staff meetings. Initial major areas of discussion included staff buy-in and choice of instrument. Despite the Center's troubleshooting before the project began, a number of unanticipated challenges arose to include coordination between clinic and research arms of the Center, follow-up HRQOL evaluations and data analysis. Through teamwork, a process to measure HRQOL in a busy clinical setting is being refined through continuous quality improvement. **Conclusions:** This presentation will discuss the Center's experience in developing, implementing, evaluating and improving a process to use the SF36 instrument to measure HRQOL of patients in a busy clinical setting that combines conventional and Chinese medicine. Initial results and how these results have the potential to improve clinic processes and patient outcomes will be explored.

# 1265/THE JOURNEY OF HOPE: FROM CONCEPTS TO REALITY  
Antonia K. Soo, Occupational Therapy; Simon K. Wong, Occupational Therapy Department, Tai Po Hospital, Tai Po, Hong Kong

**Aims:** The concept of hope is used as a component of occupational therapy intervention. 'Journey of Hope' was an innovative project. It was a combination of the concept of hope and the use of occupation as treatment intervention. The aim of this project was to instill hope and promote well-being of patients. **Methods:** Members of this project were recruited through poster and verbal invitation by patients. Patients were encouraged to externalize the concept of hope to something concrete so that both they and other people could share the joy of hope. Regular group meeting enhanced communication and interaction between patients. Occupational therapists acted as facilitator. Patients were fully empowered to make decision according to group consensus. **Results:** After brainstorming, five sub-projects had been identified, namely, 'Tree of Hope', 'Cartoon', 'Article', 'Lyric' and 'Photograph'. Each sub-project got its own meaning on hope. Choice and context were provided for patients in the whole process. Apart from skills learning, it was an opportunity for gaining and creating meaning through self-selected purposeful activities. To our astonishment, some patients initiated some by-product including logo, badge and bookmark for this project. Patients chose rainbow as the logo of 'Journey of Hope' as it reflected different colors of our life. They also made badge with the logo and distributed to each member of the project. Patients created slogan related to concept of hope and printed on recycled paper. It formed a bookmark and served as the souvenir of the project. Final product of this project was displayed in lobby of hospital. Self-made questionnaire reflected positive effect in promoting hope among patients. **Conclusions:** The 'Journey of Hope' project successfully instilled hope and promoted well-being of our patients. Patients moved out from sick role and make contribution to others. They experienced sense of happiness as a volunteer and attained their goals by acquiring and applying learned skills. Patients were fully empowered and they are allowed to make changes in their life situations. This project used occupation as the treatment media and demonstrated Chinese concept of hope into treatment activities.

# 1414/UNDERSTANDING CONSUMER PREFERENCES AND MEASURING UTILITY FOR GENETIC SCREENING

Jane P. Hall & Madeleine T. King, Centre for Health Economics Research and Evaluation, University of Technology; Deniz G. Fiebig, Economics, University of NSW; Ishrat Hossain, Centre for Health Economics Research and Evaluation, Jordan J. Louviere, Marketing, University of Technology, Sydney, NSW, Australia

**Aims:** Screening programs to detect carrier status for hereditary conditions are typically evaluated in terms of the number of cases prevented, thereby assuming that health outcomes only are relevant. The aim of this study was to determine what factors contribute to individual utility and therefore influence individuals' participation in genetic screening. **Methods:** These issues were explored for cystic fibrosis and Tay Sachs disease carrier status using a discrete choice experiment. The factors included carrier risk, disease severity, proportion of other people tested, rate of false negatives, cost, and doctor recommendation. The survey was administered to 461 adults in metropolitan Sydney, Australia, comprising a representative community sample (n = 261) and a high-risk group (n = 200). **Results:** Individuals were prepared to pay for testing, and to pay more for test results with a lower false negative rate. Individuals who tested for one condition were more likely to be tested for the other condition. Preferences were also sensitive to doctor's recommendation and carrier risk. **Conclusions:** This study illustrates how this approach can be used to predict uptake rates for public health programs. It also shows that, in screening programs where the immediate product is information, information may have a value which should be taken into account in measuring utility.

# 1155/RELATIVE EFFICIENCY OF THE EQ-5D, HUI2 AND HUI3 IN A US POPULATION SURVEY

Nan Luo & Jeffrey A. Johnson, Public Health Sciences, University of Alberta, Edmonton, AB, Canada; James W. Shaw & Stephen Joel Coons, Pharmaceutical Sciences, University of Arizona, Tucson, AZ, USA

**Aims:** To compare the performance of the EQ-5D, HUI2, and HUI3 in a general population sample using self-reported medical conditions as a criterion. **Methods:** Analyses were conducted using data collected for the US EQ-5D valuation study where a sample of the general adult US population, with an over-sampling of Hispanics and non-Hispanic blacks, self-completed the EQ-5D, HUI2, and HUI3 questionnaires during in-home interviews. Presence of chronic medical conditions was assessed using a standardized questionnaire. The ability of the EQ-5D, HUI2 and HUI3 classification systems to predict presence of medical conditions was examined using logistic regression analyses. Health index scores assessed by these three measures were compared between respondents with and without medical conditions using one-way ANOVA. Relative efficiency (RE) was calculated based on *F*-statistics. **Results:** Data derived from 3,435 respondents (median age: 40 years, female: 57%, Hispanic: 29%, non-Hispanic black: 27%, other: 44%) were used for this study. Odds ratios of impaired health status versus full health in predicting presence of various medical conditions ranged from 1.79 to 7.29 for the EQ-5D, 2.14 to 11.71 for the HUI2, and 1.94–10.74 for the HUI3. Prevalence of reporting one or more medical conditions among respondents assessed in full health was 48% for the EQ-5D, 33% for the HUI2, and 36% for the HUI3. In ANOVA analyses, all three health indices discriminated between respondents with and without a medical condition ( $p < 0.001$  for all). Using the EQ-5D index as a reference (RE = 1), the mean (range) RE was 0.96 (0.65–1.29) for the HUI2 and 0.90 (0.44–1.29) for the HUI3. **Conclusions:** The EQ-5D, HUI2, and HUI3 performed similarly in discriminating between respondents reporting the presence or absence of chronic medical conditions assessed in this population health survey.

# 1154/A COMPARISON OF THE EQ-5D PREFERENCE WEIGHTS PREDICTED BY THE D1 (US) AND THE N3 (UK) MODELS

Nan Luo & Jeffrey A. Johnson, Public Health Sciences, University of Alberta, Edmonton, AB, Canada; James W. Shaw & Stephen Joel Coons, Pharmaceutical Sciences, University of Arizona, Tucson, AZ, USA

**Aims:** We recently generated the EQ-5D D1 model based on TTO valuations of the US general population. As the D1 model differs substantially from the commonly used N3 model from the UK, we were interested in how these two models might perform in clinical/cost-effectiveness studies. **Methods:** Preference weights for all 243 EQ-5D states predicted by D1 and N3 models were compared and associations between differences in the weights and characteristics of corresponding health states were examined using a linear regression model. All theoretical transitions between any two EQ-5D health states were simulated to compare predicted gains and responsiveness of the models. **Results:** The mean (SD) preference weights for the 243 EQ-5D health states predicted by the D1 and N3 models were 0.37 (0.23) and 0.14 (0.31), respectively. Greater differences between D1 and N3 weights were observed in health states characterized by severe problems, particularly severe pain/discomfort and anxiety/depression. The mean (SD) health gains for all 29,403 possible transitions between EQ-5D states were 0.25 (0.19) for the D1 and 0.35 (0.27) for the N3 models. These two models were consistent in predicting gains for 93.7% of these transitions. Compared to the D1 model, the N3 model predicted greater health gains in 84.6% of those transitions where both models would predict gains. In terms of the average change in health state, effect size and standardized response mean were 1.59 and 1.42 for the D1 model, and 1.60 and 1.38 for the N3 model. **Conclusions:** The D1 and N3 models are generally consistent in predicting health gains and are equally responsive to transitions between EQ-5D health states. Differences in the preference weights predicted by these models depend on the characteristics of health states. The D1 model will likely result in smaller quality-adjusted life years gained than the N3 model.

# 1167/VIOLATIONS OF THE ADDITIVE ASSUMPTION IN THE STANDARD QALY APPROACH: EXTRA-MAXIMAL TRADE OFFS

Marieke Verschuuren & Ben A. van Hout, MTA/Julius Center, University Medical Center, Utrecht; Gouke J. Bonsel, Public Health Epidemiology, Amsterdam Medical Center, Amsterdam, The Netherlands

**Aims:** The standard QALY approach (SQA) adds up quality weighted periods of assumed constant quality of life. Conventionally, these quality-weights (*Q*'s) range from 0 (death or worst imaginable health state) to 1 (perfect health). It is questionable whether the additive assumption of SQA holds in case of health profiles containing short episodes of severe pain. While valuating such profiles by means of Time Trade Off (TTO), negative *Q*'s are given implicitly if the time traded off exceeds the duration of the pain. These extra-maximal trade offs (EMT's) imply violation of the additive rule. We established the prevalence of EMT's, and determined which profile and respondent characteristics were predictive for the occurrence of EMT. **Methods:** Non-constant annual health profiles, containing alternating short episodes of pain and periods of good health, were constructed based on empirical pain data. Respondents consisted of pain patients and controls without pain. Valuations for the profiles were obtained through face-to-face interviews. As valuation technique we used a TTO method, in which trading off more time than the duration of the pain episodes was accepted. Respondents were not aware whether they were giving implicit negative *Q*'s or not. Time trade off was modeled by means of an ordered logistic regression model. **Results:** In total 711 valuations for the same number of profiles were obtained from 68 respondents. In 229 of the 711 valuations (32%), EMT was present. Explanatory analysis revealed that, after correcting for respondent characteristics, occurrence of EMT was positively related to several variables describing severity of pain in the profiles ( $p < 0.0001$ ). **Conclusions:** EMT is a common and valid phenomenon. Therefore SQA requires adaptation for QALYs to adequately reflect respondents' preferences regarding health profiles with short periods of severe pain.

# 1174/CONSTRUCT VALIDITY OF THE HEALTH UTILITIES INDEX MARK 3 IN TYPE 2 DIABETES: EVIDENCE FROM THE CANADIAN COMMUNITY HEALTH SURVEY

Sheri L. Maddigan & Jeffrey A. Johnson, Public Health Sciences; David H. Feeny, Health Utilities Inc.; Sumit R. Majumdar, Medicine, University of Alberta, Edmonton, AB, Canada; Karen B. Farris, College of Pharmacy, University of Iowa, Iowa City, IA, USA

**Aims:** To assess the cross-sectional construct validity of the Health Utilities Index Mark 3 (HUI3) in type 2 diabetes using population-health survey data. **Methods:** Data from Cycle 1.1 (2000–2001) of the Canadian Community Health Survey (CCHS) were used. A total of 5134 adult respondents were classified as having type 2 diabetes. Analyses of covariance were used to assess differences in overall and single attribute HUI3 scores between groups hypothesized a priori to differ in HRQL. We evaluated the association between healthcare resource use (i.e., hospitalizations, physician and ER visits) and overall HUI3 scores using logistic regression models. Normalized sampling weights and bootstrap variance estimates were used. **Results:** For overall HUI3 scores, clinically important and statistically significant differences were observed between all groups. The adjusted difference between the respondents with diabetes for less than 2 years and greater than 13 years was 0.07 (95% CI: 0.04–0.09). The HUI3 score of insulin users was 0.06 (95% CI: 0.03–0.09) lower than nonusers. Depression was the comorbidity associated with the largest deficit (0.17, 95% CI: 0.12–0.22), followed by stroke (0.15, 95% CI: 0.09–0.21) and heart disease (0.08, 95% CI: 0.05–0.11). A gradient in overall HUI3 scores was observed across categories of self-rated health. Significant HRQL deficits were observed on the ambulation and pain attributes according to duration of diabetes, insulin use, stroke, total number of comorbidities and self-rated health. Deficits on the pain attribute were also observed in respondents with heart disease (0.09, 95% CI: 0.05–0.12) and depression (0.10, 95% CI: 0.05–0.15). Overall HUI3 scores were significantly predictive of all three categories of healthcare resource use. **Conclusions:** Hypothesized differences between groups for the overall HUI3 and single attributes scores were supported by these analyses. This study contributes further evidence of the construct validity of the HUI3 in type 2 diabetes from a sample representative of the Canadian population.

# 1522/PATIENT INVOLVEMENT IN VALUING HEALTH STATES FOR USE IN ECONOMIC EVALUATION

John E. Brazier, Sheffield Health Economics Group, The University of Sheffield, Sheffield, Yorkshire, UK

**Aims:** Following the recommendations of the Washington Panel on the Cost Effectiveness of Medicines, Quality-adjusted life-years (QALYs) are usually calculated using health state values obtained from samples of the general population. There is a concern that such values are poorly informed about what it is like to live in such states. This paper critically reviews the role of patient values in economic evaluation. **Methods:** There is evidence of substantial difference between patient and general population values for the same states of health. This paper is a review based on an extensive and systematic review of the literature. It examines the reasons for these differences between patient and general population values including poor descriptions of the states provided to general population samples, changing standards (including response shift) and adaptation to the health state. It considers the main arguments for using general population values, including the advocacy of the social perspective in resource allocation decisions versus arguments for patients values, that includes the view that patients know what it is like to be in a given health state. **Results:** It seems difficult to justify the exclusive use of patient values or the current practice of using the relatively uninformed members of the general population values. The paper proposes a third way the role of the societal perspective to inform resource allocation in publicly funded system, but helps respondents by providing them with more information on what the states are like for patients experiencing them. This moves the research agenda towards improving the way we describe health states, the direct elicitation of patient values and developing methods for obtaining informed general population preferences by providing more information on what it is like for patients and more time to reflect and deliberate on the states. **Conclusions:** An increased role for patients in health state valuation by members of the public has

important implications for the design and conduct of preference elicitation research.

# 1559/AGREEMENT BETWEEN YOUTH AND PARENT ACROSS SEVEN EUROPEAN COUNTRIES: THE DISABKIDS PROXY QUALITY OF LIFE RESEARCH INSTRUMENT

Marie Claude Simeoni, Public Health, University Hospital of Marseille; David Debensason & Stephane Robitail, Public Health, University of Medicine Marseilles, Marseilles, France; Mick Power, Psychiatry, Royal Edinburgh Hospital, Edinburgh, UK; Monika Bullinger, Medical Psychology, University Hospital Hamburg, Hamburg, Germany

**Aims:** The DISABKIDS project aims to develop a European cross-cultural generic self-administered HRQoL instrument for children and adolescents. Proxy measures HRQoL are a practical and useful alternative to assess children's HRQoL. The DISABKIDS field study involved 1153 youth and 920 youth-proxy paired of respondent in 7 European countries (A,CH,G,GK,F,GB,NL) and led to a final research instrument with 6 dimensions including 36 items: Independence (6 items), Physical (6 items), Emotion (7 items), Social inclusion (6 items), Social Exclusion (6 items), Treatment (6 items). The proxy measure instrument is based on the model of the DISABKIDS final instrument. The aims of this study are to assess the level of agreement and the magnitude of discrepancies between youth and their parents. **Methods:** To assess and compare agreement between youth and proxy report Intraclass Correlation Coefficient (ICC) were computed. To evaluate the magnitude of discrepancies between youth and proxy ratings, paired *t*-test of the mean differences (*D*) and effect-size (*d*) were computed. **Results:** For all dimensions, the agreement between youth and proxy was satisfactory (ICC > 0.4). Physical and social inclusion showed the major agreement between youth and proxy measure. Treatment facets presented the main discrepancies. The Emotion, Social Inclusion and Physical scores were underestimated by the proxies. No significant difference was found for the paired *t*-test for the dimensions Independence, Social Exclusion and treatment. **Conclusions:** Further analyses will be conducted to evaluate the discrepancies between youth and their parents whether these levels of agreement/discrepancy depend on the age and the gender of youth.

# 1099/THE STRUCTURE, INTERNAL RELIABILITY AND DISCRIMINANT VALIDITY OF THE 'IMPACT' QUESTIONNAIRE ON BRITISH CHILDREN WITH INFLAMMATORY BOWEL DISEASE

Cassandra A. Davies & Janice Abbott, Faculty of Health, University of Central Lancashire, Preston; Adrian G. Thomas, Gastroenterology, Booth Hall Children's Hospital, Manchester, UK

**Aims:** Inflammatory Bowel Disease (IBD) is a chronic disease of the digestive system that can affect children of any age. Measures of quality of life for IBD patients are available for adult populations but not for British Children. A disease specific measure of quality of life in childhood IBD (IMPACT) has been developed in Canada and modified and translated in the Netherlands. This work aimed to validate the English translation of IMPACT on British children. The instrument consists of six domains and employed visual analogue response scales. The domains were IBD symptoms, systemic symptoms, emotional functioning, social functioning, body image and treatments/interventions. **Methods:** Pilot work was undertaken to assess the feasibility of the language, format and response scales of the instrument. Subsequently, the initial validation of IMPACT was undertaken with 100 children (aged from 8 to 17 years). As a marker of disease activity (inactive/mild, moderate, severe) the IBD Symptom Checklist was administered. Principle component analysis (PCA) with varimax rotation was performed to generate the factor structure of the instrument. Cronbach  $\alpha$  coefficients were computed to ascertain internal reliability. **Results:** 20 children took part in the pilot study. Changes in phraseology were implemented to aid comprehension. The response scales were changed from a visual analogue format to a Likert scale format as a result of child preference and ease of completion. The most clinically meaningful and statistically robust solution of the PCA highlighted five factors. These were; concerns about IBD ( $\alpha$  0.88), body image ( $\alpha$  0.79), embarrassment ( $\alpha$  0.79), IBD symptoms ( $\alpha$  0.83) and energy ( $\alpha$  0.74). The instrument showed good discriminant validity between stages of disease activity. **Conclusions:** The Dutch factor structure was not fully replicated using the English translation of IMPACT on British children. However, the English version has a clinically relevant structure with good psychometric properties. Test-retest reliability and sensitivity analysis are currently being evaluated.

# 1157/NEW QUALITY OF LIFE (QOL) QUESTIONNAIRE FOR ADOLESCENCE

Kana Takesue, Erina Kawaguchi & Michiko Kobayashi, Siebold University of Nagasaki, Nishisonogi-gun, Nagasaki; Takashi Mandai, Japanese Society of Quality of Life Research, Kobe, Hyogo, Japan

**Aims:** The purpose of this study was to develop the desirable QOL questionnaire for adolescence. **Methods:** 158 junior high school students participated in this study. Our new original self-administered questionnaire consisted of 47 questions divided into 12 categories. **Results:** Cronbach's  $\alpha$  coefficients of our new questionnaire were high enough to accept for clinical use: 0.91 in interest in the other sex, 0.88 in vision for future, 0.87 in love, 0.83 in sexual desire, 0.81 in family life, 0.80 in school life, and 0.76 in sexual information, etc. respectively. Our new questionnaire contained 12 main factors and cumulative contribution was 0.70. Compared with the male students, the female students indicated the significantly excellent total QOL scores and sexuality related scores ( $p < 0.05$ ). Significant positive correlations were shown between sexuality and school life, sexuality and family life, sexuality and vision for future ( $p < 0.05$ ), respectively. These findings indicate that our questionnaire has high enough reliability and potency of validity to use for adolescence. Excellent sexuality QOL level is an indispensable factor to keep high adolescent QOL. Right information and knowledge for sexuality are essential, so sexuality education is most important. Adolescent students have many kinds of problems in school life, family life, and private life etc. **Conclusions:** We believe that QOL evaluation plays very important roles to improve the daily life of adolescent student both in school and home, so our new questionnaire will demonstrate the valuable abilities satisfactorily. We must pay more attention for the QOL of adolescence.

# 1225/A NEW SCALE FOR MEASURING QUALITY OF LIFE (QOL) IN CHILDREN WITHOUT OR WITH GROWTH HORMONE DEFICIENCY (GHD): THE PEDIAQUALVIE SCALE

Patrick Martin, Department of Psych. Research Unit, Hosp. St. Antoine, Paris, France, Jacques Massol, Endocrinology, Hosp. Minjoz, Besançon; Sophie Harrois, Hosp. R Debré, CHU, Reims; Maria-Laura Alvarez, Novo Nordisk; Etienne Delphine, CREST; Michèle Garabedian, St. Vincent de Paul, Paris, France

**Aims:** Generic and disease specific tools to assess QOL in children are developed and applied in clinical and public health. This project aims to develop the generic self-report QOL questionnaires (quest.) for healthy and ill children valid for different age groups: 6–<10 years and 10–<15 years. **Methods:** In a first phase, identical patterns were identified in interviews of children, ( $n = 121$ ) conducted by psychologists (1 h). More questions were asked concerning at least 54 sub-domains. In the second stage, scale development aimed to construct a psychometrically sound QOL measure by using literature researches, expert consulting and Delphi method. Items ( $n = 283$ ) were developed by conducting interviews with children (6–14 years) to identify relevant QOL domains and acceptable wording. 4 quest. rounds were administered to a multidisciplinary group of 20 experts. The first Delphi round mainly consisted of open questions and answers to this round, providing the basis for later versions. Consensus was reached when at least 80% of experts either agreed or disagreed with a given item. Responses were received from 20 respondents in the 4 rounds. **Results:** There was agreement that each new scale should be a multidimensional, profile measure with 30–45 items covering 4–8 domains, taking 10–15 min to complete. Consensus was generally against having an individualised quest, except for 6–9 years where assistance is required. **Conclusions:** Finally in the third stage (validation study: 500–600 children) the 6–9 year-scale included less than 36 items. The four major domains were role, social, family-friends relations, sports and leisure, psychological well-being/general health and coping/school activities. The 10–14 year-scale included less than 58 items. The four major domains were family activities, sports and leisure/social relation; school, life perceptions.

# 1703/RELATIONSHIP BETWEEN CHILD HRQL AND PARENT HEALTH IN A SAMPLE OF CHILDREN WITH ADHD

Anne F. Klassen & Anton Miller, Pediatrics; Stuart Fine, Psychiatry, University of British Columbia, Vancouver, BC, Canada

**Aims:** The presence of ADHD in children is associated with increased levels of parenting stress and parental psychopathology. Since there is little research on the physical health of parents, our aim was to examine the relationship between parental health and child HRQL. **Methods:** We conducted a cross-sectional survey in the province of British Columbia (BC), Canada. The study population included 165 children (63.7% response rate) referred to the ADHD Clinic in BC between November '01 and October '02. The parent was sent a questionnaire booklet that contained the CHQ-PF50 and the global health item from the SF-36. We performed a series of ANOVAs to explore the relationship between parent health and child HRQL and computed effect sizes to interpret our results. **Results:** ADHD was diagnosed in 131 children. Parents rated their health as follows: 15% excellent; 33% very good; 36% good; and 16% fair/poor. Table 1 shows parent health by CHQ Psychosocial Summary Score (PSS). Significant findings were also noted for role emotional/behavioral; role physical; behaviour; mental health; self-esteem; general health; parental impact time; family activities; family cohesion. Effect sizes ranged from 0.68 to 1.16. **Conclusions:** There is a strong association between parental health and child QoL. It is possible that parents with health concerns may have fewer resources to cope with ADHD resulting in more difficulties parenting and poorer HRQL in children.

Parental health	PSS (95% CI)
Excellent	42.2 (38.0, 46.4)
Very good	34.2 (30.6, 37.7)
Good	31.6 (28.0, 35.1)
Fair/poor	26.2 (20.0, 32.3)
p-Value	0.0004
Eect size	1.33

# 1067/AGREEMENT BETWEEN SELF-REPORT AND PARENT-REPORT OF QUALITY OF LIFE IN A SAMPLE OF CHILDREN DIAGNOSED WITH ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

Anne Klassen, Pediatrics; Stuart Fine, Psychiatry; Anton Miller, Pediatrics, University of British Columbia, Vancouver, BC, Canada

**Aims:** To determine whether parent and child concordance is greater for some domains of quality of life (QoL) than others; whether parents rate their child's QoL to be better or poorer than their child's own ratings; and whether the degree of concordance is related to demographic, socioeconomic or clinical factors. **Methods:** Of 259 eligible children referred to the ADHD Clinic in the province of British Columbia (Canada) between November 2001 and October 2002, 134 were aged 10 or older and could be included in this analysis of parent-child agreement. Before the child's appointment, the parents were sent a package of questionnaires to complete. We included the 50-item parent (CHQ-PF50) and 87-item child (CHQ-CF87) version of the Child Health Questionnaire. There were eight domains and one item that could be compared. Each child received a comprehensive psychiatric assessment. Clinical data were extracted from hospital notes. **Results:** 71 questionnaires were completed by parent and child. ADHD was diagnosed in 58 children. Cronbach's  $\alpha$  coefficients for seven domains of the CHQ-PF50 were  $>0.70$  and for eight domains of the CHQ-CF87 were  $>0.80$ . ICCs were moderate for behavior, mental health, self-esteem, general health and family activities (range 0.40–0.51), and good for physical function, role physical, bodily pain, and family cohesion (range 0.60–0.70). Children rated their QoL better than their parents for behavior, self-esteem, mental health, family cohesion and worse for physical function. Standardised response means indicated important differences in parent-child ratings for behavior (1.16) and self-esteem (0.62). Compared with a population sample, in most domains of health, children with ADHD reported similar QoL. Discrepancies between parent and child were related to whether or not the child had a comorbid oppositional/defiant disorder, a psychosocial stressor, and high parent-rated ADHD symptom scores. **Conclusions:** The QoL reported by children with ADHD contrasts with what is known clinically about ADHD. Although self-report is an important means of eliciting QoL data, reliance only on the child's perspective would underestimate the impact of ADHD on their QoL.

# 1526/SHORTENING THE PRELIMINARY VERSION OF THE EUROPEAN DISABKIDS CHRONIC GENERIC MODULE

David Debensason, Public Health, University of Medicine Marseilles, Marseilles, France; Silke Schmidt, Medical Psychology, University Hospital Hamburg, Hamburg, Germany; Stephane Robitail, Public Health, University of Medicine Marseilles, Marseilles, France; Mick Power, Psychiatry; Clare Atherton, Psychiatry University, Royal Edinburgh Hospital, Edinburgh, UK; Monika Bullinger, Medical Psychology, University Hospital Hamburg, Hamburg, Germany; Marie Claude Simeoni, Public Health, University Hospital of Marseilles, Marseilles, France

**Aims:** The DISABKIDS project aims at simultaneously developing a HRQOL chronic generic inventory as well as condition-specific questionnaire modules in seven European countries. For the chronic generic module issued from children's and adolescents' answers, the pilot study identified a six dimension-structure including 56 items: independence (7 items), physical (6 items), emotion (12 items), social inclusion (9 items), social exclusion (13 items), treatment (9 items). Although this instrument may offer satisfactory results, its length often limits the extent to which it is actually applied in clinical practice. In deed, short-form outcomes measures are becoming common in response to demands for increased efficiency in health care. This study examines Rasch measurement and DIF analysis as an aid to selecting items for short-form tests. The focus of this study is on maintaining test quality while reducing items. The analyses were made on a sample of 1153 adolescents (aged between 8 and 16) which corresponds to the field study. **Methods:** Missing data, ceiling and floor effects were analysed in a first time with the intraclass correlation coefficient and the item discriminant validity. Within each dimension, INFIT were calculated for each item on the whole sample, by age group and by gender. Items were deleted, using an iterative process, when the INFIT was above 1.2. DIF analyses were performed by age, severity and

gender. The internal consistency was assessed computing Cronbach's  $\alpha$ . **Results:** At the end, 20 items were deleted. Looking at the conceptual meaning, the questionnaire remained satisfactory. The final structure still has satisfactory internal consistency with a range from 0.7 to 0.87. **Conclusions:** The study of external validity of the short chronic generic module is ongoing.

# 1335/EFFECTS OF EARLY INTERVENTION ON DEVELOPMENT AND HEALTH-RELATED QUALITY OF LIFE OF CHILDREN WITH DOWN'S SYNDROME

Jeanette Bruil, Minne Fekkes, Ko van Wouwe & Erik Verrips, Child Health, TNO Prevention and Health, Leiden, The Netherlands

**Aims:** Aim of the study was to evaluate the long term effects of early intervention performed by parents at home on the development, behaviour, autonomy, and health-related quality of life (hrqol) of 8-year old children with Down's syndrome. **Methods:** All children known by the Dutch Down Syndrome Foundation (SDS) born in the years 1992–1994 were included in the study. In 1992–1994, parents were asked whether they used an Early Intervention program (EI) and the health and hrqol of the children were assessed. In 2000–2003, the parents were asked to fill out a questionnaire on the use of EI, hrqol (TAC-QOL), behaviour problems (CBCL), autonomy, school participation and parenting stress. Children's development was assessed with the McCarthy Development Scales (MOS 2.5–8.5). **Results:** Parents of 337 children (175 boys and 164 girls) were included in the study (response rate 89%). Mean age of the children was 8.1 years (7.8–9.1). Parents of 254 children (75%) used a formal EI at home, most of them the Macquarie program. Comparison of means of children who received EI and children who did not, revealed no significant differences on autonomy, cognitive development, participation in regular primary schools, and parenting stress. On hrqol, children who received EI had significantly lower scores on the scales measuring autonomy, cognitive and social functioning, indicating a lower hrqol. Additionally, children who received EI had significantly more internalizing and externalizing behaviour problems. Within comparisons in the group of children who received EI revealed that children performed significantly better on most domains if parents used the program intensively. Comparing children who received EI intensively and children of parents who practised intensively with their child without using EI, revealed no significant results, except on the hrqol scale cognitive functioning. On this scale, children who received EI had a significantly lower score on cognitive functioning. **Conclusions:** It was concluded, that the use of EI had no significant positive effects on most domains. Intensive practicing, however, seems to be related to better outcome, regardless of receiving a formal EI or not.

# 1162/A QUALITY OF LIFE SCALE FOR CHILDREN WITH CEREBRAL PALSY: PARENTS AND CHILDREN'S VIEWS OF THE SCALE  
Elizabeth B. Waters & Elise C. Maher, Centre for Community Child Health, Murdoch Childrens Research Institute, Parkville, Victoria, Australia; Dinah Reddihough, Child Development and Rehabilitation; Kerr Graham, Orthopaedic surgery, Royal Children's Hospital, Parkville, Victoria, Australia; Andrew Mackinnon, Biostatistics and Psychometrics Unit, Mental Health Research Institute, Parkville, Victoria, Australia; Roslyn Boyd, Neonatal Neurology, Royal Children's Hospital, Parkville, Victoria, Australia

**Aims:** An international condition-specific QOL scale is being developed for children with cerebral palsy. This scale is essential to evaluate the effectiveness and impact of treatment interventions in clinical trials for children with cerebral palsy. This study aims to test the acceptability and appropriateness of the questionnaire for children with cerebral palsy and their parents. The content of this questionnaire was initially informed by qualitative interviews with children with cerebral palsy and their parents. **Methods:** A range of domains were included in the QOL scale such as physical health, daily living tasks, emotional wellbeing, and family health. Items were developed to measure each domain, and two versions of the scale were developed. Parents of children with cerebral palsy were given a parent-proxy scale (4–12 years) and children aged 9–12 years were given a self-report version (9–12 years). The children were selected from the Victorian Cerebral Palsy Register to ensure that they covered a broad range of ages and severity (using GMFCS levels). Qualitative interviews were conducted until saturation point was reached. **Results:** Recommendations for scale improvement were suggested by parents and children in terms of both the domains and items included in the scale. These changes are relevant in terms of the scale development, but also in our general understanding of QOL. **Conclusions:** In conclusion, using the comments from parents and children, a revised scale of QOL for children with cerebral palsy is presented. Following psychometric testing, the scale may be useful to evaluate interventions in clinical trials.

# 1352/HEALTH UTILITIES INDEX (HUI) CONSTRUCT VALIDITY FOR OSTEOPENIA AMONG SURVIVORS OF BRAIN TUMORS IN CHILDHOOD

William J. Furlong, Clinical Epidemiology and Biostatistics; Isaac Odame, Pediatrics, McMaster University; JoAnn Duckworth, Pediatrics; Lesley Beaumont, Nuclear Medicine, Hamilton Health Sciences; Danielle Talsma, Clinical Epidemiology and Biostatistics, McMaster University; Colin Webber, Nuclear Medicine, Hamilton Health Sciences; Ronald D. Barr, Pediatrics, McMaster University, Hamilton, ON, Canada

**Aims:** To investigate HUI Mark 2 (HUI2) and Mark 3 (HUI3) construct validity by examining relationships with bone mineral density (BMD) among survivors of brain tumors in childhood. It was hypothesized that osteopenia would be associated with lower health-related quality of life (HRQL), and pain and ambulation problems. **Methods:** Subjects were survivors of cerebellar astrocytoma or medulloblastoma or optic glioma, <18 years of age at diagnosis and >1 year post-treatment. BMD of the lumbar spine (BMD-LS) and whole body (BMD-WB) were measured by dual energy X-ray absorptiometry (DXA) expressed as z-scores of Canadian population. Severe osteopenia was defined as z-scores <-2. HUI utility scores were calculated from parental responses to a standard 15-item questionnaire. Relationships between DXA and HUI scores were assessed by linear regression. Differences in mean scores were assessed by t-test. **Results:** Of 40 eligible survivors, 24 (60%) had both HUI and DXA measurements. Mean age at time of study was 15.3 years (SD = 4.93). Prevalence of severe osteopenia was 20.8% for BMD-LS and 16.7% for BMD-WB. Positive correlations were observed between: BMD-LS and HUI2 mobility ( $r = 0.414$ ,  $p = 0.044$ ), HUI3 ambulation ( $r = 0.414$ ,  $p = 0.044$ ), and HUI3 overall HRQL ( $r = 0.586$ ,  $p = 0.003$ ); BMD-WB and HUI3 pain ( $r = 0.492$ ,  $p = 0.015$ ), and HUI3 overall HRQL ( $r = 0.429$ ,  $p = 0.036$ ). Mean HUI3 overall HRQL was lower ( $p = 0.010$ ) for severely osteopenic patients (0.468) than for the other patients (0.814). **Conclusions:** Results support HUI construct validity in osteopenia. The study demonstrates the usefulness of combining HRQL and clinical measures. Among survivors of childhood brain tumors, HRQL is lower, ambulation more limited, and pain more severe in those with

depressed BMD scores. A larger multi-centre study is needed to confirm these results.

# 1323/EVALUATION OF COST OF DISEASE: ASSESSING THE BURDEN TO SOCIETY OF ASTHMA IN CHILDREN IN THE EUROPEAN UNION

Symone B. Detmar & Jeanet Bruil, Quality of Life; Elske M. van den Akker-van Marle, Youth, TNO Prevention and Health, Leiden, The Netherlands

**Aims:** Asthma and allergies have become increasingly prevalent over the last few decades throughout the European Region. Childhood asthma is a major global health problem, which exerts a substantial burden on family, health care, and society as a whole. In decision-making on interventions to reduce the burden of childhood asthma an overview of the cost-of-illness of childhood asthma is an essential first step. This study investigated the costs of childhood asthma in terms of economic and quality of life costs in the European Union. **Methods:** To investigate the economic costs, a literature search in MEDLINE (1985–2004) was conducted using the following MeSH terms: (Asthma/Economics) AND (Child, Preschool OR Child OR Adolescent) AND (Cost and Cost Analysis). The search resulted in 176 articles. From this literature search result articles were selected on cost-of-illness of asthma in children. To investigate the quality of life, a MEDLINE search was conducted with the keywords child, asthma and health-related quality of life. Furthermore, own databases of the authors were analysed. In addition, (yet unpublished) data from the KIDSCREEN study were used. **Results:** This study showed that childhood asthma is a common disease in the European Union. The mean prevalence of wheeze is 12.3% and of self-reported asthma 7.2%, indicating a total of 9.3 million children with wheeze and 5.5 million children with self-reported asthma. The total costs of asthma for the 25 countries of the European Union are estimated at EUR 3000 million. The results on quality of life indicated that children with asthma had significantly lower scores on physical well-being, psychological well-being, moods and emotions, self-perception, peers and social support and being bullied. **Conclusions:** Effort is needed to develop strategies for better prevention and management of childhood asthma.



# 1345/AGE AND GENDER DIFFERENCES ON HEALTH-RELATED QUALITY OF LIFE AMONG HONG KONG CHINESE SCHOOL CHILDREN (PARENT-PROXY REPORTS)

Yuen-Yee J. Ng, Physiotherapy; Shui Wah Chiu, Cardio-thoracic Surgery; Yiu Fai Cheung, Paediatrics, Grantham Hospital, Hong Kong, PRC

**Aims:** The developmental speed, tasks and goals of boys and girls, younger and older children are different. These differences in understanding, valuing, and identifying factors that contribute to or detract from health-related quality of life represent significant concerns. The purpose of this paper was to have a deeper understanding and comparison of the health-related quality of life among various developmental age groups pupils. Gender differences were also explored. **Methods:** Chinese Child Health Questionnaires, parent-proxy report (CHQ-PF50) was used. Totally, 1098 parents participated in this study. Their children were divided into five developmental age groups: 5–7 ( $n = 131$ ), 8–10 ( $n = 372$ ), 11–12 ( $n = 252$ ), 13–15 ( $n = 188$ ), >16 ( $n = 155$ ); with totally 541 boys and 557 girls. **Results:** The results of ANOVA showed that there were statistically significant age effect on nine life domains: physical function ( $F = 6.22$ ,  $p < 0.001$ ), role physical ( $F = 5.16$ ,  $p < 0.001$ ), role emotion/behavior ( $F = 9.13$ ,  $p < 0.001$ ), general behavior ( $F = 3.77$ ,  $p < 0.001$ ), self-esteem ( $F = 3.37$ ,  $p < 0.001$ ), emotional impact on parent ( $F = 3.24$ ,  $p < 0.01$ ), time impact on parent ( $F = 14.69$ ,  $p < 0.001$ ), family activities ( $F = 5.59$ ,  $p < 0.001$ ) and family cohesion ( $F = 2.52$ ,  $p < 0.05$ ). Pupils aged 16–18 were evidenced to have the highest health-related quality of life except self-esteem and family cohesion which were the lowest. Pupils aged 8–10 were evidenced to have the lowest health-related quality of life on six domains. Pupils aged 5–7 showed highest self-esteem, family cohesion, but lowest time impact on parent. Girls aged 5–7 showed better general behavior than boys ( $F = 5.79$ ,  $p < 0.05$ ). Girls aged 13–15 showed worse self-esteem and pain than boys ( $F = 6.28$  and  $3.92$  respectively; both with  $p < 0.05$ ). Girls aged >13 had lower family cohesion than boys ( $F = 9.95$ ,  $p < 0.01$  for those aged 13–15;  $F = 5.9$ ,  $p < 0.05$  for those aged >16). **Conclusions:** It was concluded that various developmental stages in boys and girls have effect on parents' perception of their children's health-related quality of life. Gender effect was found to be most obvious among age 13–15 adolescents.

# 1614/PSYCHOSOCIAL IMPACT OF BEREAVEMENT ON CHILDREN

Candace Ho, Clinical Oncology, Tuen Mun Hospital; Hin Man Mak, MappSc, Applied Math, Hong Kong Polytechnic University; Wing Kin Sze, Clinical Oncology, Tuen Mun Hospital; John F. Babson, General Education, Hong Kong Polytechnic University, Hong Kong, PRC

**Aims:** Grieving children suffer silently, often neglected in the process of care. We review the findings on child grief and the impact of bereavement on psychosocial, behavioral and academic performance. **Methods:** No existing Chinese bereavement scale for children was available. The Childhood Bereavement Questionnaire (CBQ) developed by the authors explores children's grief experiences in three factors including problem, support, and life perception. Three major hospitals within the Hong Kong Hospital Authority were involved in the study. Bereaved families were contacted to identify bereaved children aged 4–14. The CBQ was administered through individual interviews to a total of 235 bereaved children consisting of 131 girls and 104 boys. **Results:** Suicidal ideation was identified in over 8% of this sample. Problem factor consists of questions concerning depressive mood, anxiety, physical symptoms, cognitive difficulties, and academic problems. Support factor deals with family and school support. Life perception factor examines the child's perception of the world and of life in general influenced by the trauma of having lost a parent. Cluster analysis separated groups with high, moderate, and low risks in the three factors. Overall, about 40% of children suffer from moderate to high levels of problems while 60% without adequate support fell into the moderate to high-risk range. A pessimistic attitude is developed after the trauma of loss. **Conclusions:** An alarming finding of almost 10% of all bereaved children in our study thought of suicide. While support is not adequate for this group of children, the devastating consequences can be foreseeable. There is an urgent need in the health care system to acknowledge the problems of child bereavement and to begin helping this vulnerable group of children.

# 1403/DO PARENTS KNOW THEIR CHILDRENS ORAL HEALTH? Colman McGrath, Edward C.M. Lo & Harry Pang, Dentistry, University of Hong Kong, Sai Ying Pun, Hong Kong, China

**Aims:** To compare the agreement between parents and children regarding the child's oral health related quality of life. **Methods:** A random sample of 549 Hong Kong 12-year-old children and their parents (either father or mother) completed components of the child oral health related quality of life measure (Jokovic et al., 2002). Agreement between child and parent scores derived from the questionnaires were assessed in comparison and correlation analysis. **Results:** Comparisons analysis identified that a group level, absolute agreement between parent and children was rare, only 3% (16) of overall scores were in agreement. Evidence of bias in parents' reports were evident; particularly, on reports of emotional well-being ( $p < 0.001$ ). Mean absolute differences in overall scores constituted 9% of possible range of scores (7–14% among domains). Correlation analysis identified that agreement between parent and child pairs was poor ( $ICC < 0.3$ ). **Conclusions:** There is disagreement between parents and children's reports regarding the child's oral health related quality of life. Exact agreement is rare, and there is evidence that parents overestimate the emotional-well-being effects. Agreement between parent and child pairs was poor.

# 1433/PARENTAL PERCEPTIONS OF FEEDING RELATED QUALITY OF LIFE OF CHILDREN WITH QUADRIPLEGIC CEREBRAL PALSY

A. M. Morrow, FRACP, CKR, Children's Hospital at Westmead; J. C. Craig, CKR, CHW; M. T. King, CHERE, UTS; E. V. O'Loughlin, Gastroenterology, CHW, Sydney, NSW, Australia

**Aims:** Up to 90% of children with quadriplegic cerebral palsy (QCP) have feeding problems due to impaired swallowing, most commonly treated with gastrostomy tube feeding. Our aim was to identify parents' opinions on the major determinants of feeding related quality of life (QoL) in children with QCP. **Methods:** Participants were recruited from parents of children attending a specialised feeding clinic in a pediatric teaching hospital in Sydney. Twenty-four parents participated in four semi-structured focus groups conducted by a trained facilitator. Recruitment ceased when informational redundancy was reached. Transcribed audiotapes were analyzed using N-Vivo software. **Results:** Parents felt that the QoL of child and parent were inseparable. They identified parent-child interaction (provision of care, emotional impact), social participation (family, peers, school, society), the child's emotional well being (e.g. happiness, enjoyment of food), physical functioning (e.g. difficulty eating), comfort (e.g. hunger) and delivery of health services (e.g. access, interaction with staff) as contributing to their child's QoL. Aspects of provision of care included impact of time, duty to protect and competency of care. Social participation emerged as a strong theme. Parents of children with and without gastrostomy differed in their perceptions. For example parents who favoured gastrostomy believed they had mistaken hunger for enjoyment of food and saw reduction in time spent feeding as the most positive outcome of gastrostomy. Some of those who did not favour gastrostomy saw it as 'giving up' or were unhappy with side effects. Communication difficulties with health professionals (e.g. feeling they were not being listened to) impacted on decisions regarding intervention. **Conclusions:** Social participation and parent-child interaction emerged as strong themes. The perceptions of parents of children with and without gastrostomy differed. These findings have implications for the design of a feeding related QoL instrument.

# 1536/REPRESENTATIVITY OF 12 NATIONAL SURVEYS OF CHILDREN AND ADOLESCENTS 8–18 YEARS OLD INCLUDED IN THE KIDSCREEN HRQOL STUDY

L. Rajmil, Catalan Agency for Health and Technology Assessment; S. Berra, Barcelona, Spain; U. von-Rueden, Berlin, Germany; C. Tebe, Agència d'Avaluació de Tecnologia, Barcelona, Spain; M. Erhart, Child and Adolescent Health, Robert Koch Institute; A. Gosh, Berlin, Germany; J. Alonso, Municipal Institute of Medical Research, Barcelona, Spain; C. Biseger, Bern, Switzerland; U. Ravens-Sieberer, Child and Adolescent Health, Robert Koch Institute, Berlin, Germany

**Aims:** To assess the representativity of the national samples of the Kidscreen fieldwork. **Methods:** A representative sample of 8–18 years old children and adolescents was collected in 12 European countries (A, CH, D, E, F, GB, NL, HU, PL, GR, S) following two approaches: one was conducted via computer assisted telephone interviews and the questionnaires were sent by post to families who had agreed to participate; in the second the sample was obtained in schools which were representative for the country in terms of type of school (private vs. public, rural vs. urban, etc.). Population values from Eurostat were used to assess representativity. Also, Eurostat data were obtained on women and men with at least one child from 8 to 18 years old in the household, in order to compare the highest educational level of mothers and fathers included in the national Kidscreen samples. One sample binomial test allowed to test whether the proportion of successes on a categorical dependent variable significantly differs from a hypothesized population value. A  $\chi^2$  goodness of fit test was used to test whether the observed proportions for Kidscreen sample's categorical variable differed from a hypothesized proportion. **Results:** The most of the national surveys achieved proportions of children and adolescents by sex similar to the European reference population, and two countries got unbalanced survey ( $p < 0.05$ ). The proportion of children was higher than the population values. Girls participated more than boys in several countries. The main difference was found in the Greek male adolescents (Eurostat percentage = 51.4%, vs. Kidscreen survey = 40.3%). When comparing the Kidscreen mothers and fathers with women and men from Eurostat, the most of national Kidscreen surveys included more educated parents ( $p < 0.05$ ). **Conclusions:** The figures found were promising at the national level. Some differences within-countries were found. They could be solved using weights. Future tasks include within-country comparisons of weighted and unweighted data.

# 1544/A LIFE-SPAN APPROACH TO HEALTH-RELATED QUALITY OF LIFE, SEVERITY OF ILLNESS AND FUNCTIONAL STATUS IN YOUTH WITH SPINA BIFIDA

Robin R. Leger, General Clinical Research Center, University of Connecticut, Farmington, CT

**Aims:** Youth with chronic conditions and disability are at risk for secondary health conditions a loss in function as they age. As they age out of pediatrics, they often have difficulty transferring care to providers who are often ill prepared and untrained in 'historically' pediatric conditions. A life-span approach for clinical research in health status, functional status and quality of life is needed in pediatric onset chronic conditions. **Methods:** A descriptive study of 60 youth (15–25 years old) with spina bifida, from a convenience sample in the north-eastern United States examines the relationship among severity of illness, functional status (FIM) and health-related quality of life (Parkin et al., 1997). The research collaborated with a regional nursing consortium, clinics, consumer associations, and websites and surveyed/assessed participants in their home, community, or college settings. Descriptive statistics of central tendencies, bi-variate, and factor analyses were utilized. **Results:** The findings indicate that 28% ( $n = 17$ ) of the youth were 'healthy', 72% ( $n = 43$ ) reported secondary conditions and 32% ( $n = 19$ ) reported additional co-morbidity. The types and frequency of conditions are described. The sample had a high level of functional status (FIM; mean = 116.8, SD = 7.07,  $r = 90$ –126). However, incontinence, inability to traverse stairs and memory deficits were identified limitations. A high level of HRQOL was reported (mean = 200.8, SD = 19.5,  $r = 155$ –232). A factor analysis identified three sub-domains: peer/self concept, skills at ADLs/work/recreation, and thoughts and hopes for the future. A correlation model of the variables illustrates a number of statistically significant relationships for future research.

**Conclusions:** In this study it was realized that youth with spina bifida report a high HRQOL, are in college, participate in recreation, sports, and other aspects of young adult life but they experience a number of secondary conditions and have concerns for their future.

# 1226/QUALITY OF LIFE IN CHILDREN WITH ACUTE LYMPHOBLASTIC LEUKEMIA IN LONG-TERM REMISSION

T. Nikitina, A. Kishtovich, A. Sabirova & A. Novik, Pediatrics, Multinational Center of Quality of Life Research, St. Petersburg, Russia

**Aims:** Health status of cancer survivors in children population is often underestimated by physicians. The goal of study was to compare HRQoL parameters in children with acute lymphoblastic leukemia (ALL) in remission and in healthy children. **Methods:** ALL survivors aged 8–12 ( $n = 20$ ), 13–18 ( $n = 34$ ) in 5-years and longer remission and healthy children of the same age ( $n$  total = 54) were involved in the study. Routine medical examination showed marked physical impairment in ALL survivors. Pediatric HRQoL was assessed using the Russian version of PedsQL Generic Core Scales (children self-report, parent proxy-report). Its validation was performed earlier in collaboration with author J. Varni. Statistical analysis was performed using unpaired Student's *t*-test with Welch correction. **Results:** As a result, survivors reported significantly lower physical, role functioning and total scale score as compared to healthy children (Means accordingly, 75.9 vs. 85.5, 68.5 vs. 82.3, 74.2 vs. 83.1 for 8–12 years; 73.8 vs. 86.3, 61.2 vs. 78.5, 72.2 vs. 82.8 for 13–18 years;  $p < 0.05$ ). Parents of survivors reported significantly lower physical, social functioning, psychosocial health summary score and total scale score in children as compared to parents of healthy children (Means accordingly, 69.4 vs. 80, 73.8 vs. 84.8, 66.9 vs. 76, 67.8 vs. 77.4 for 8–12 years, and 64.4 vs. 84, 76.3 vs. 86, 67.6 vs. 76.9 and 66.5 vs. 79.4 for 13–18 years;  $p < 0.05$ ). Furthermore, children assessed their HRQoL higher than their parents did (Means for 8–12 years: social functioning – 84 vs. 73.8; Means for 13–18 years: physical functioning – 73.8 vs. 64.4, social functioning – 85.2 vs. 76.3;  $p < 0.05$ ). **Conclusions:** Thus, HRQoL parameters are lower in ALL survivors as compared to healthy children. All findings confirm the importance of HRQoL monitoring along with traditional medical examination in children with cancer in remission and in doing so contribute to the improvement of quality of care in cancer survivors.

#### # 1595/QUALITY OF LIFE IN CHILDREN WITH A VISION IMPAIRMENT AND THEIR PARENTS

Mary G. Boulton, Social Sciences and Law, Oxford Brookes, Oxford, UK; Sue Clegg & Eleanor McDonald, Social Sciences and Law, Oxford Brookes University, Oxford, England; Alistair R. Fielder, Department of Ophthalmology, Imperial College London, London, UK

**Aims:** In the UK, one child in a thousand has a vision impairment (VI). The aim of this study was to investigate HRQL in young children with a VI and their main carer and to examine the impact of the child's vision condition, additional disabilities and behaviour problems. **Methods:** Parents of children aged 3–9 with a VI were contacted through health, education and social services and voluntary organisations in four areas of England. The parent with main caring responsibilities was asked to complete a questionnaire on their child's HRQL (HUI2 and HUI3), behaviour problems (Richman's Behaviour Checklist), vision condition and other disabilities and on their own HRQL (SF-36v2). **Results:** Parents of 79 children (31 girls, 48 boys) completed the questionnaire. The mean age of children was 6.2 years and the mean age of parents was 37.0 years. For 31 children, their VI derived from an eye condition, for 34 from a visual pathway condition and for 14 from nystagmus alone. Forty-five children had an additional severe movement, communication or learning disorder. Children with a visual pathway condition were significantly more likely to have an additional severe disorder and to have a behaviour problem as identified by the Behaviour Checklist. The mean utility scores for children were markedly low on the HUI2 Sensation and Self Care Attributes but high on the HUI2 Emotion and Pain Attributes. Children with a visual pathway condition and children with an additional severe disorder had significantly lower utility scores. Compared to norms for the UK, parents' scores on the SF36 were markedly low on the role emotional, mental health and vitality dimensions. Parents whose child had a behaviour problem and those with severe additional disorders had significantly lower scores on these three dimensions. **Conclusions:** Vision impairment affects the HRQL of children and parents, and the additional disabilities and behaviour problems associated with visual pathway conditions have particularly negative affects. Health and social care resources should be targeted appropriately.

#### # 1250/WHEN THERE'S NO QUALITY OF LIFE LEFT IT IS TIME TO DIE

Barbara A. Elliott, Family Medicine, School of Medicine Duluth; Charles E. Gessert, Research and Education, SMDC; Cynthia Peden-McAlpine, Nursing, University of Minnesota, Minneapolis, MN, USA

**Aims:** This qualitative study investigated end-of-life decision-making by family members on behalf of institutionalized elders with severe dementia. **Methods:** Eight 2-h focus groups were conducted with 39 family caregivers in urban and rural Minnesota nursing home settings. The groups were guided through discussions addressing (1) dementia and caregiving, (2) planning for end-of-life experiences, (3) making decisions, (4) preferences, (5) goals, (6) beliefs, and (7) values. The sessions were recorded and transcribed; data was analyzed using qualitative research methods. Four of the participants were of the same generations as the impaired elder (spouses, sibling); the remainder were of the next generation (children, their spouses). The elders' average age was 88; focus group participants' average age was 62. **Results:** Three themes emerged from the data regarding QOL in the setting of severe dementia: (1) Caregivers perceived dementia as a process of diminishing QOL ('He definitely was not enjoying his life. There was nothing that he was enjoying anymore. He didn't enjoy seeing my mother, he didn't enjoy food, it was all gloom. It was all non-response and that was it'). (2) They described death as appropriate when QOL had sufficiently eroded ('And I wish that she would die, tomorrow, because she has no quality of life. It's awful. I think it's terrible and I wish it would be over, and I don't see any purpose'). (3) They also perceived a threshold beyond which there was no QOL ('Because life really has no meaning anymore. When I see that with my mother, that will tell me that if there's any health problems beyond that. I'll be far less aggressive in treating [them]'). **Conclusions:** These findings have implications for the definition, theory and measurement of QOL.

#### # 1438/AN ETHNOGRAPHIC ANALYSIS OF EVERYDAY ETHICAL COMPORIMENT AND ITS IMPACT ON COPD PATIENTS' SENSE OF WELLBEING NEAR THEIR END OF LIFE

Betty P. Chung & Samantha M. Pang, School of Nursing, The Hong Kong Polytechnic University; Chun Y. Tse, Hospital Management, United Christian Hospital; Stanley K. Ko, School of Nursing, The Hong Kong Polytechnic University; Kin S. Chan, Pulmonary and Palliative Care, Haven of Hope Hospital; Man F. Leung, Medicine and Geriatrics, United Christian Hospital, Hong Kong SAR, PRC

**Aims:** To explicate the way in which salient everyday ethical comportment can impact on COPD patients' sense of wellbeing near their end of life. **Methods:** Twenty patients with advanced COPD were recruited for ethnographic case studies till the patient's death. Information sources included observation notes, patient, relative, nurse and physician interviews. Ethnographic analysis was undertaken to identify COPD patients' quality of life concerns, and how everyday practices and concerns positively/negatively impact on the patient's sense of wellbeing. **Results:** Three factors clusters constituting patients' sense of wellbeing were delineated. They are (1) prognostic factors for describing the patient's disease severity; (2) quality of life factors for evaluating the treatment burdens; and (3) existential factors for understanding the patient's treatment preference and attitude towards death. Concerns in everyday practices evolve around three constellations of issues. They are (1) learning the limits of therapeutic measures; (2) making moral decisions based on the embodied knowing of the patient's responses; and (3) negotiating the best possible actions between care provider and patients in day-to-day care. In addressing these issues, everyday ethical comportment on the part of nurses play a significant role in enhancing the patient's sense of wellbeing, and finally, peaceful death. **Conclusions:** The findings highlight the importance of salient ethical comportment in ordinary day-to-day caring practices. The main feature is sensitivity and responsiveness to patients' quality of life concerns, which is crucial in providing an ethical environment for dignified death and dying.

#### # 1601/PREDICTION SURVIVAL IN A REGIONAL HOSPICE: THE MISSOULA-VITAS QUALITY OF LIFE INDEX (MVQOLI)

Colleen M. Renier, Thomas E. Elliott & Jeanette A. Palcher, Research, Duluth Clinic, Duluth, MN

**Aims:** Quality of life instruments for hospice patients are in use, but the data is rarely used to predict length of patient survival. This evaluation was designed to look at predictive factors of hospice patient survival, including the added value of MVQOLI assessment within 30 days of admission to hospice. **Methods:** Data was collected on all 1047 patients entering a regional hospice between June 1, 2002 and December 31, 2003. Survival status and weeks of survival were evaluated through April 15, 2004. Data included age, gender, marital status, diagnoses, performance status (PS), activities of daily living scale (ADLS), and descriptive symptom scale (DSS). 254 patients had a total of 301 MVQOLI assessments within 30 days, including days since admission (DAYS), global, total, symptom (SYMP), function (FUNC), interpersonal (INTP), well-being, and/or transcendent scores. This subset of patients and MVQOLI assessments was used in the analysis. Spearman's correlations were used to evaluate relationships with weeks of survival to identify covariates for survival analysis (Cox regression), which was performed as follows: Level 1 – enter DAYS; Level 2 – forward stepwise inclusion of remaining covariates except MVQOLI scores; Level 3 – forward stepwise inclusion of MVQOLI covariates. **Results:** The population was 59% male, mean age 74 (26–94), 79% had cancer, mean survival 15 weeks (0–92), and mean days from admission to MVQOLI assessment was 8 (0–30). Significant correlations were found between weeks of survival and DAYS, cancer, PS, ADLS, DSS, and FUNC, at  $p < 0.01$ , and with age, SYMP and INTP, at  $p < 0.05$ . Survival analysis identified a predictive model containing DAYS (not sig.), DSS, cancer, ADLS and FUNC (O.R. = ns, 0.93, 2.187, 0.95 and 0.99, respectively). **Conclusions:** Hospice patient survival was associated with factors well documented in the literature; of interest is that the MVQOLI Function score, which is greatly impacted by acceptance of loss, provided additional predictive value.

#### # 1534/OCCUPATIONAL THERAPY PROMOTED FEEDING INDEPENDENCE OF CANCER PATIENTS IN PALLIATIVE CARE

Chan Hung Fai, PDOT, Occupational Therapy, Tung Wah Hospital; T.K. Warren Lee, Orthopaedics and Traumatology; Eric Wong, Centre for Epidemiology and Biostatistics, The Chinese University of Hong Kong, Hong Kong, PRC

**Aims:** Independence in feeding is important to improve quality of life (QOL) of patients receiving palliative care. Studies on feeding independence among cancer patients under palliative care are limited. This study aimed to evaluate the effectiveness of occupational therapy in promoting feeding independence of cancer patients in palliative care. **Methods:** Thirty-six end-of-life cancer patients with feeding difficulties induced by improper position (58.3%), one-handed problem (22.2%) and upper limb impairment (11.1%) were recruited from Nam Long Hospital and Grantham Hospital in Hong Kong. Feeding independence (level1: >50% assistance; level 2: <50% assistance) of patients during mealtime in hospital were assessed before and after receiving occupational therapy including positioning (58.3%), use of feeding aids (25%) and upper limb support (8.3%). Re-assessments of feeding independence were carried out at 1, 2 and 3 weeks after the initial feeding assessment. Mix-effects models were used for comparing feeding independence levels between initial assessment (baseline) and the corresponding levels in 1-, 2-, and 3-weeks. The models were also used to assess the association between patient characteristics and feeding independence levels. **Results:** Feeding independence levels showed significant improvements between initial level and their subsequent levels in 1-week ( $p = 0.035$ ), 2-week ( $p = 0.034$ ) and 3-week ( $p = 0.049$ ). Age, sex and initial ADL score (BI) did not associate with feeding independence across time. **Conclusions:** Enhancement in feeding independence improved morale and QOL of cancer patients in palliative care. It merits enhancement of occupational therapy service and in cooperation with ward staff to promote feeding independence and thus QOL of cancer patients in palliative care.

#### # 1079/CLOSENESS TO DEATH AND QUALITY OF LIFE (QL) IN ADVANCED LUNG CANCER PATIENTS

Sarah Croft, Helen Thorpe, Vicky Napp & Julia Brown, Clinical Trials Research Unit, University of Leeds, Leeds, UK

**Aims:** The aim of this work was to assess whether QL in patients with advanced non-small cell lung cancer is affected by closeness to death, i.e. time from assessment to death, and previous QL scores. We aimed to confirm Jordhoy's (2001) findings that closeness to death is predictive of QL. **Methods:** Our study sample originated from patients in the Big Lung Trial QL Study, in which QL was assessed using the EORTC QLQ-C30. Baseline and week 12 QL data, and patient characteristics (sex, WHO performance status (PS), histology, age, closeness to death, marital status, tumour stage, treatment) were used for this work. To assess the impact of closeness to death and previous QL, only patients who had died and completed baseline and week 12 questionnaires were analysed: 107 patients. Univariate analyses compared week 12 QL for each characteristic using analysis of variance. Multivariate analysis (linear regression) used backward and forward stepwise selection to investigate the independent effect of each characteristic, using a 1% significance level for variable inclusion. **Results:** Univariate analyses showed significantly different week 12 QL according to closeness to death for all functioning scales (except emotional), global QL, appetite loss, constipation, fatigue and nausea. Baseline QL was also statistically significantly associated with all week 12 scales except diarrhoea. Multivariate analyses showed PS, baseline QL and closeness to death to be the only significant predictive factors of QL. Worse PS was associated with worse functioning (except emotional), global QL, fatigue, dyspnoea and appetite loss. Better baseline QL indicated better week 12 QL for all scales except global QL, nausea, dyspnoea and diarrhoea. Being closer to death was associated with worse physical and social functioning and pain. **Conclusions:** Unlike Jordhoy, closeness to death was found not to be a major predictive factor of QL when adjusting for other prognostic factors. PS and baseline QL were however found to be significantly associated with QL. We conclude that while closeness to death may be predictive of QL when previous scores are unavailable, QL may be more dependent on patients' previous scores, which can be easily measured unlike closeness to death.

#### # 1098/QUALITY OF LIFE AMONG ELDERLY CAREGIVERS VS NON-CAREGIVERS (WHOQOL-OLD PROJECT)

Ramona Lucas, Roser Vega, Merce Aisa, J.C. Rovira, J.M. Perez-Castejon & Antoni Salva, Barcelona, Spain

**Aims:** It is well known that caregivers present more physical, psychological and social impairment than non-caregivers. Little attention has been paid to their quality of life and almost no research has compared different types of caregiving. Our objective is to compare quality of life (QoL) between elder carers and non-carers and between carers of patients with schizophrenia and dementia. This study is part of the WHOQOL-OLD Project. **Methods:** More than two hundred adults 60 and older from Community Centres (non-caregivers) and Family Associations for the Mentally Ill and Alzheimer disease (caregivers) participated on the study. Participants completed the following measures: the WHOQOL-BREF (a generic quality of life measure which contains four domains: physical, psychological, social and environmental and two general questions about quality of life and satisfaction with health), a module specific for the elderly – WHOQOL-OLD-, the Geriatric Depression Scale, the SF-12, a list of co-morbid conditions and sociodemographic information including perception of health. Caregivers completed the Carer Burden Scale. **Results:** Nearly two third were women, mean age was 70.1, 66.3% were married, 52% had primary school or less and 74.5% reported being healthy. Compared to non-caregivers, caregivers rated their QoL and their satisfaction with health significantly lower. They scored significantly lower in all QoL domains and facets. Carers had more depressive symptoms (GDS 12 vs. GDS 8.7), and reported more health conditions affecting their QoL. Caregivers of patients with dementia compared to caregivers of patients with schizophrenia, were significantly older (73.6 vs. 67.7), scored significantly lower on the physical and social domains of the WHOQOL-BREF and in both components on the SF12, and had higher depressive symptoms (GDS 15.7 vs. GDS 10.6). **Conclusions:** Caregivers had worst outcomes, including quality of life, compared to non-caregivers. Among caregivers those caring for patients with dementia had the worst outcomes. Special attention should be given to the different types and needs of caregivers and QoL should be integrated and emphasized as an outcome measure.

#### # 1097/QUALITY OF LIFE AND DEPRESSIVE SYMPTOMS AMONG SPANISH ELDERLY (WHOQOL-OLD PROJECT)

Ramona Lucas, Rosa Monteserin & Antoni Salva, Barcelona, Spain

**Aims:** Depressive symptoms are prevalent among elderly people; its association with higher number of health conditions and lower levels of functioning and quality of life is well known. The aim of this study is to present quality of life among a sample of elderly people in relation to depressive symptoms. This study is part of the WHOQOL-OLD Project. **Methods:** We studied 271 older adults from Primary Care and Community Centres, Family Associations (for the mentally ill and Alzheimer disease) and Residential Facilities in Barcelona (Spain). All participants completed the following questionnaires: the WHOQOL-BREF (a generic quality of life measure), the WHOQOL-OLD module (developed for the elderly), the SF-12, the Geriatric Depression Scale, and a list of co-morbid conditions. The sociodemographic questionnaire included information about health perception. Analyses was performed between those people had a GDS score 0–10 and more than 11. All analysis were performed using SPSS software package. **Results:** Mean age was 72 y.o.; 60% were women, 64% were married, 55% had primary school or less, 68.6% were living at home unsupported, 67.2% reported being healthy, 97% reported 1 or more health conditions but only 46.5% reported the condition affected their quality of life. Nearly fifty percent had a GDS score greater than 10. Higher depressive symptoms were found among female, the oldest group (80+), people living in residential facilities, perceiving themselves as unhealthy, with higher number of comorbid conditions and with heart problems (differences were statistically significant  $p < 0.01$ ). Subjects with higher depressive symptoms scored lower in all the WHOQOL-BREF domains, in most of the OLD facets and in the MCS12. **Conclusions:** Attention should be paid to different elderly populations in order to provide adequate treatments and/or programs to treat depressive symptoms, thus, improving their quality of life.

# 1431/THE FAMILY CAREGIVER'S EXPERIENCES OF CARING COPD (CHRONIC OBSTRUCTIVE PULMONARY DISEASE) ELDERLY RELATIVES

Polly Po Wan Chan, Occupational Therapy, Shatin Hospital, Hong Kong, HKSAR, PRC

**Aims:** COPD is one of the major diseases in elderly and the incidence of COPD is increasing both in Hong Kong and worldwide. The progressively disabling course of COPD results in social isolation and other lifestyle changes for patients and their family caregivers. Unfortunately, the experiences of caregivers of COPD patients have only been superficially examined. Most of the studies assumed a negative effect of family caregiving on family caregivers and the whole caregiving experiences were not explored in depth. This qualitative study was designed to increase understanding in the family caregivers' experiences of caring COPD elderly relatives and identify their needs. **Methods:** Qualitative method was utilized in the data collection and analysis. A semi-structured interview was carried out in Cantonese with each informant for data collection. The data was analysed using content analysis. Six family caregivers of elderly patients diagnosed with COPD were selected varying in kinship ties, age and gender through purposeful sampling. **Results:** Family caregiving of a COPD elderly relative was described as a lonely and unhappy journey. Family caregivers found helplessness towards the breathlessness and exacerbation of the COPD elderly relative. They felt vulnerable in the process of caregiving while the disease was progressively worsening. Taking care of a COPD elderly patient required a lot of supervisory care that made the caregivers felt sense of constraint. The caregiving tasks were not laborious but meticulous that caused stress to the family caregiver and also made the role difficult to be shared. Caregivers expressed that they had little knowledge on disease management, communication skills and handling of patients' emotion. The focus of formal and informal network are mainly on the care recipients. The caregivers are often neglected. **Conclusions:** There is a need to increase the awareness among family members, healthcare, and social work professionals on the care of family caregivers. Rehabilitation program should involve family caregivers and they should be better prepared and support on the role of caregiving.

# 1239/SELF-RATINGS OF HEALTH AMONG NORWEGIAN ELDERLY

Mary Kalfoss, Nursing Research; Liv Halvorsrud, Nursing Research, Menighetsøsterhjemmet University College; Svein Alve, Faculty of Business, Public Adm and Social Work, Oslo University College, Oslo, Norway

**Aims:** The aim of this study was to investigate the importance of medical, sociodemographic and psychological factors influencing the elderly's self-assessed health. **Methods:** As part of the WHOQOL OLD Pilot Project, healthy elderly participated in a postal survey where they were recruited from a nursing college, a community center, and a political committee (N 671 – response rate 43%). Unhealthy elderly participated in face-to-face interviews and were recruited from five hospital medical wards and an outpatient clinic (N 95 – response rate 98%). The total sample consisted of 286 healthy (mean age 73, range 60–90, 86% female, 14% male) and 93 unhealthy (mean age 73, range 60–90, 44% female and 56% male). Independent variables included in the regression model were medical; health problems affecting QoL (number), diseases (number), cognitive problems, pain intensity and prescribed medications. Sociodemographic variables; marital status, education, cohabitation, living conditions, social support, and finances. Psychological variables; Hopkins Symptom Checklist (depression and anxiety) and mental health status the past 2 weeks. Self-ratings of health: 'How do you evaluate your own health in general?' was assessed on a 5-point scale where response categories ranged from 'very good' (1) to 'very poor'. (5) Bivariate analyses and stepwise multiple regressions analyses were used in selecting variables for inclusion in the regression model. The variable age (dichotomized as younger than 75 or older), gender and whether or not the respondent belonged in the healthy/unhealthy group were also included as independent variables. **Results:** The results of the multiple regressions analyses showed (in descending order of importance) that pain intensity, depression, belonging to the 'unhealthy' group, being very old, and use of prescribed medications (marginal  $p = 0.07$ ) were

statistically significantly associated with reduced self-assessed health, accounting for 44% of the variance. **Conclusions:** The allocation of health care resources for the older aged with age-specific interventions are warranted.

# 1512/SUBJECTIVE QUALITY OF LIFE AMONG NORWEGIAN ELDERLY

Mary Kalfoss & Liv Halvorsrud, Assistant Professor, Nursing Research, Menighetsøsterhjemmet University College; Svein Alve, Faculty of Business, Public Adm and Social Work, Oslo University College, Oslo, Norway

**Aims:** The aim of this study was to investigate the relative importance of medical, sociodemographic and psychological factors influencing the elderly's quality of life (QoL). **Methods:** Data was collected as part of the WHOQOL OLD Pilot Study during 2002–2003. A convenience sample was drawn with different sample fractions. Healthy elderly participated in a postal survey with self-administered questionnaires and were recruited from a nursing college, a community center, and a political advisory committee (N 671). Combined response rate for these groups was 43%. Unhealthy elderly participated in face-to-face interviews and were recruited from five hospital medical wards and an out-patient clinic (N 95) with a combined response of 98%. The total sample consisted of 286 healthy (mean age 73, range 60–90, 86% female, 14% male) and 93 unhealthy (mean age 73, range 60–90, 44% female and 56% male). Independent variables included in the regression model were medical health factors; health problems (number) affecting QoL, diseases (number), cognitive problems, pain intensity and use of prescribed medications. Sociodemographic variables; marital status, education, cohabitation, living conditions, social support, and finances. Psychological variables; Hopkins Symptom Checklist (depression and anxiety) and mental health status the past 2 weeks. The dependent variable, global quality of life (QoL), was assessed by the Overall Domain of the WHOQOL 100. Bivariate analyses and stepwise multiple regressions analyses were used in selecting variables for inclusion in the regression model. The variable age (dichotomized as younger than 75 or 75 or older), gender and whether or not the respondent belonged in the healthy/unhealthy group were also included as independent variables. **Results:** The results of the multiple regressions analyses showed (in descending order of importance) that depression, pain intensity, mental health status the past 2 weeks and being very old were statistically associated with reduced QoL accounting for 49% of the variance. **Conclusions:** The allocation of health care resources and interventions focusing on psychological support services for the frail older aged is especially warranted.

# 1216/QUALITY OF LIFE IN THE ELDERLY ATTENDING TAI CHI CHUNG PRACTICE: AN APPLICATION OF SF-36

Tsung-Jung Ho, Chinese Medical Science; Bo-Yin Chu, Environmental Health; Tso-Chiang Ma, Health Services Management; Tsai-Chung Li & Jaung-Geng Lin, Chinese Medical Science; Jim-Shoung Lai & Wen-Miin Liang, Public Health, China Medical University, Taichung, Taiwan, ROC

**Aims:** Previous studies have shown health benefits of Tai Chi Chung (TCC). TCC is a traditional form of Kung Fu (a Chinese martial art). In Taiwan, TCC is a widely practiced form of exercise that is generally performed by people in public areas especially for the elderly in the early morning. The aim of this cross-sectional study was to investigate the effect of TCC on the health-related quality of life (HRQOL) in elders. **Methods:** Subjects who regularly practiced TCC in southern Taiwan were selected by random sampling and included 140 elders (77 males and 63 females, aged 40–70 years). The questionnaire was separated into two parts; personal information such as age and sex, and the SF-36 which was used to evaluate subjects' physical and mental HRQOL based on eight domains. The results were compared with those of 714 age-matched controls from the general population (382 males and 332 females). Stratified analysis was adopted to exclude confounding effects from age and gender. Two-sample *t*-test and one-way ANOVA were used to compare the differences of QOL among groups. **Results:** The result showed that there were significant differences in role-physical ( $p = 0.018$ ), general health ( $p < 0.001$ ) and vitality ( $p = 0.007$ ) between TCC males and controls. In TCC females, there were significant differences in general health ( $p < 0.001$ ) and social functioning ( $p = 0.003$ ). The effect of the type of TCC on physical-functioning was also significant. Overall, reliability and validity were good. Cronbach's  $\alpha$  coefficient was 0.81. Convergent validity was 62.9% and discriminant validity was 75%. **Conclusions:** As a result, we find that frequently practicing TCC can not only increase general health but also improve other dimensions of HRQOL for the elderly.

# 1110/PERCEIVED QUALITY OF LIFE OF THE ELDERLY PEOPLE: EVIDENCE FROM BANGLADESH

A.K.M. Masud M. Rana, Research and Evaluation, BRAC, Dhaka, Bangladesh

**Aims:** This study explores the perceived quality of life the elderly people using a culture sensitive multi dimensional measurement tool. **Methods:** The data for this study originated from a multi-country research project "Primary Health care in Later Life: Improving Services in Bangladesh and Vietnam (PHILL) funded by European Commission. A total of 1031 elderly people of 60 and above years old from eight villages of Chandpur district in Bangladesh participated in the study, where BRAC a non-governmental Organisation has been working since 1992. In order to understand the perceived quality of life of the elderly people, 22 test items were used from different aspects of quality of life. The perceived quality of life issues were categorised into six dimensions such as physical, mental, social, spiritual, economical and environmental. The items were scored in a four-point scale where lower score indicated worse and higher score indicated better situations. **Results:** Findings reveal that out of six dimensions of quality of life elderly people were worse in economical, physical, mental and environmental aspects while relatively better in social (95%) and spiritual (99%) dimensions. The result also revealed that economic status, education, marital status and sex are important determinants of quality of life of the elderly people. The older people from the poor quintile got significant lower score compared to the richest quintile and literate people enjoyed better quality of life than illiterate ( $p < 0.001$ ). The women were in more vulnerable situation than men ( $p < 0.001$ ). The respondents who were currently married achieved higher score than widow/widowers or divorced in all the dimensions of quality of life except spiritual dimension. **Conclusions:** This study concludes that the government and non-government devilmnt organisations should take pro-elderly health and development programmes to enhance the quality of life of the elderly people.

# 1140/PROSPECTIVE 5 YEARS QOL STUDY IN ELDERLY PERSONS SUPPORTED BY MANDATORY HEALTH CARE SYSTEM

Michiko Kobayashi & Hitomi Hayashi, Siebold University of Nagasaki, Nishisonogi-gun, Nagasaki, Japan; Kouji Miura, Haruyasu Fujita & Takashi Mandai, Japanese Society of Quality of Life Research, Kobe, Hyogo, Japan

**Aims:** The purpose of this study was to evaluate the prospective quality of life (QOL) changes in elderly persons supported by the mandatory long-term care insurance for the elderly. **Methods:** Sixty-five elderly persons supported by the insurance have participated in this 5 years prospective study. Both personal interviews and our self-administered questionnaire including 40 questions divided into 15 categories with the life satisfaction index were used. **Results:** Pearson's correlation coefficients between our questionnaire and the life satisfaction index was  $r = 0.82$  ( $p < 0.01$ ). Cronbach's  $\alpha$  coefficients of our questionnaire were high enough to accept for clinical use: 0.91 in environmental problems, 0.90 in well-being and dietary problems, 0.86 in economic problems, and 0.80 in medical service etc., respectively. Our questionnaire contained 11 main factors and cumulative contribution was 0.85. After the first one year health care service, significant improvements of QOL were demonstrated in the strata of well-being, physical function, mental function, cognitive function, social participation, and environmental problems ( $p < 0.05$ ) in the improved QOLs persons. With the passage of time, average total QOL levels improved for 5 years. For the deteriorated QOL subjects whose total QOL scores were under 300 points before starting of care service, this health care system were very effective for QOL improvements. These findings indicate that our questionnaire has high enough reliability and potency of validity to use for elderly persons supported by the mandatory health care system. **Conclusions:** Judging from this 5 years prospective study, we believe that this challenge for national health care system is worth notice in all over the world and QOL assessment is the best way as scientific evaluation for this mandatory health care system. We must pay more attention for the health care system to improve the QOL in all over the world.

# 1275/CONSTRUCT VALIDITY OF THE FRENCHAY ACTIVITIES INDEX IN COMMUNITY-DWELLING ELDERLY

Masahiro Kohzuki & Chang-Wan Han, Internal Medicine and Rehabilitation Science, Tohoku University Graduate School of Medicine, Sendai, Japan; Yuki Yajima, Public Health, Okayama University Graduate School of Medicine, Okayama, Okayama; Kazuo Nakajima, Welfare System and Health Science, Okayama Prefectural University, Soja, Japan

**Aims:** Functional independence is an important factor that influences the quality of life (QOL) in older adults. It, however, is well known that ADL scales generally show ceiling effects when applied to community-dwelling elderly. In order to overcome the weakness of ADL scale, a higher-order instrumental activities of daily livings (I-ADL), such as Frenchay Activities Index (FAI) has enjoyed increased attention. The primary purpose of this study was to investigate the construct validity of the FAI with community-dwelling elderly in Japan. **Methods:** The study subjects were 1323 community older residents in Hojo city, Japan. The self-report questionnaires including gender, age, and FAI were distributed to each subject. An exploratory factor analysis (EFA) was performed to responses of the FAI for 696 subjects. Interpretation and labeling of retained factors were performed relying on factor loadings  $>0.3$  in PROMAX pattern matrix. In order to evaluate robustness of the above factor structure, a confirmatory factor analysis (CFA) was performed using structural equation modeling program AMOS version 4.0. **Results:** An exploratory and confirmatory factor analysis results demonstrated the FAI had a two-factor structure consisting of domestic chores and work and leisure factor. In addition, influences of age and gender on the domestic chores and the work and leisure factor were examined and discussed. **Conclusions:** These findings imply the FAI satisfies the assumption of construct validity, and, controlling gender, the separate FAI domains may provide important and clinically valuable information in recognizing patterns of disability in IADL and QOL.

# 1274/MEASURING PERCEIVED ENVIRONMENT BARRIER IN KOREAN COMMUNITY-DWELLING ELDERLY WITH OR WITHOUT STROKE

Masahiro Kohzuki & Chang-Wan Han, Internal Medicine and Rehabilitation Science, Tohoku University School of Medicine, Sendai; Yuki Yajima, Public Health, Okayama University Graduate School of Medicine, Okayama; Kazuo Nakajima, Welfare System and Health Science, Okayama Prefectural University, Soja, Japan

**Aims:** Perceived environmental barrier (PEB) is an important factor that influences the quality of life (QOL) in older adults. To evaluate the construct validity and utility of the Craig Hospital Inventory of Environmental Factors (CHIEF), measurement of PEB in a sample of Korean community-dwelling elderly with or without stroke. **Methods:** Three hundred older adults who participated in a day-care program and 100 older adults who attended a social education program held at the Bookbu Senior Welfare Center in Nowon Ward, Korea. Data of the subjects; individual characteristics, the CHIEF, and the Barthel Index (BI) were completed. We evaluated the construct validity of the CHIEF by testing the original five-factor structure using a confirmatory factor analysis (CFA). The utility of the CHIEF was assessed by examining the relationships between individual characteristics, Barthel Index, and PEB assessed by the CHIEF using a structural equation modeling (SEM) approach. **Results:** The CFA result demonstrated the validity of a second-order factor model of the CHIEF comprising the five factors as first-order factors, and PEB as a second-order factor when provided acceptable fit indices after two modifications. The SEM indicated that age, gender, and with or without stroke was not significantly related to PEB, whereas a lower ADL was related to higher PEB. **Conclusions:** The CHIEF is useful in Korean elderly with and without stroke. These efforts will allow us to better understand QOL, PEB and participation limitations in community-dwelling elderly with stroke.

# 1276/HEALTH RELATED QOL OF HEALTHY ELDERLY PEOPLE AND ELDERLY PATIENTS IN KOREA: DEVELOPMENT OF THE KOREAN SF-36

Chang-Wan Han & Masahiro Kohzuki, Internal Medicine and Rehabilitation Science; Eun-Joo Lee, Neuropsychology, Tohoku University Graduate School of Medicine, Sendai, Japan; Tsutomu Iwaya, Functional Training, National Rehabilitation Center for the Disabled, Tokorozawa, Japan

**Aims:** The health-related QOL (HRQOL) has been used extensively in clinical and epidemiological research and health service studies. Especially, the Medical Outcome Study Short-form 36-Item Health Survey (SF-36) is a widely used health status measure. However, a Korean version has not been developed and tested yet. The purpose of this study was to develop a Korean version of the Short-form Health Survey (SF-36) for use in health related quality of life measurements for Korean elderly people. **Methods:** SF-36 data from 90 healthy elderly people using Social Education Service and 120 elderly patients using a day care service in Seoul, Korea, were examined. We translated SF-36 version 2.0 into Korean and assessed its reliability and validity. **Results:** The content validity and discriminant validity were found to be satisfactory. Cronbach's  $\alpha$  coefficients ranged from 0.9298 to 0.9383. The test-retest reliability coefficients ranged from 0.710 to 0.895. In addition, the utility was examined by testing the correlation between the health-related QOL and related factors (sex, age, motor function, ability of daily life) among the elderly people. **Conclusions:** The present findings suggested that the Korean version of SF-36 would be useful as a measure of the health related QOL in Korean elderly people.

# 1448/QUALITY OF LIFE AMONG INSTITUTIONALIZED ELDERLY PEOPLE: A DESCRIPTIVE STUDY

Narges Rafati, Parvin Yavari & Yadolah Mehrabi, Social Medicine, Shahid Beheshti University of Medical Sciences; Ali Montazeri, Social Medicine, Iranian Institute for Health Sciences Research, Tehran, Iran

**Aims:** The objective of this study was to investigate about quality of life among institutionalized elderly people. **Methods:** A cross-sectional study was conducted to measure quality of life in elderly people living in a public elderly residence house in Tehran, Iran. Quality of life was assessed using the SF-36 Health Survey. The findings then were compared with the quality of life among a sample of elderly people with similar age living in the community (n = 247). **Results:** In all 202 institutionalized elderly people were interviewed (118 female and 84 male). The mean age of the respondents was 76.7 (SD = 7.5) years. The results of the study findings on the SF-36 and its comparison with quality of life scores in elderly people living in the community are shown in the Table. The higher scores indicate a better condition. **Conclusions:** In general the institutionalized elderly people reported a poorer health related quality of life. This was more profound for physical and social functioning and mental health.

	Institutionalized sample	Community sample
	Mean (SD)	Mean (SD)
Physical functioning	33.9 (31.4)	54.9 (29.2)
Role physical	25.6 (38.8)	34.2 (40.9)
Bodily pain	49.0 (26.8)	56.9 (30.2)
General health	42.5 (13.6)	49.0 (21.9)
Vitality	47.9 (16.5)	53.0 (20.3)
Social functioning	39.6 (23.2)	58.4 (30.4)
Role emotional	45.7 (46.5)	47.6 (44.2)
Mental health	47.8 (17.2)	62.2 (18.6)

# 1041/ELDERLY'S QUALITY OF LIFE AND HEALTH-RELATED ISSUES IN IRAN WITH A FOCUS ON TEHRAN-A SOCIOLOGICAL STUDY

Mohammad Taghi Sheykhi, Sociology, Department of Social Science, Al-Zahra University, Tehran, Iran

**Aims:** The main objectives of the paper is to find out the quality of the living standards and the sociological aspects of the life of the increasing elderly in Iran with special reference to Tehran. The paper also reflects the attitudes of society towards the population. The purpose of the study is also to investigate the health-related issues of the 'study population' including their health expectancy, social security, life satisfaction and so on. **Methods:** The researcher used a combined theoretical and empirical method of study in order to conduct the present research. For that, he first probed into the relevant sociological literature of the elderly to be well equipped to enter the empirical section to collect the necessary data. In the empirical part, centres protecting the elderly were visited and studied. Though the main technique of the study was administering questionnaires, the researcher used interview method as well where necessary. The sample size of the study was one hundred elderly of both sexes out of which 78 questionnaires were extracted. **Results:** The data collected reflects the status and the way of life of the elderly, their life satisfaction, quality of cares and services, and the resultant issues. The provision of medicine and the related services were qualitatively and quantitatively examined, and they will be followed in the complete text. **Conclusions:** In the concluding section of the study, the researcher came to identify the respondents' attitudes reflected as such: 'family care first, social security next'. As the elderly phenomenon and living in non-family institutions by the elderly is a new experience for the Iranian society, it is leading to many problems and challenges which need appropriate and harmonized planning. As a whole, the scenario needs progressive research and development.

#### # 1339/ROLE AND FUNCTION – ASPECTS OF QUALITY OF LIFE IN OLDER PEOPLE IN RURAL BANGLADESH

Jan Nilsson & Margareta Grafstrom, Neurotec, Division of Geriatric Epidemiology, Karolinska Institutet, Stockholm, Sweden; Shahaduz Zaman, Research and Evaluation, BRAC, Dhaka, Bangladesh; Zarina N. Kabir, Neurotec, Division of Geriatric Epidemiology, Karolinska Institutet, Stockholm, Sweden

**Aims:** The aim of this study is to explore the meaning of quality of life (QoL) for elderly people in a rural community in Bangladesh. **Methods:** This study was conducted in Chandpur district, a rural area 70 km south of Dhaka, Bangladesh. Data were obtained through in-depth interviews with 11 elderly persons aged 63–86 years. Interview data were analysed using content analysis to determine the conceptual meaning of elderly peoples experiences of QoL. **Results:** Two major themes emerged from the data as being of utmost importance in QoL of elderly people in rural Bangladesh. These were: (i) having a role in the family and the community and (ii) being functional, both physically and economically. Results also showed that when discussing quality of life, elderly people in rural Bangladesh prioritise being healthy, having a good social network, social support and secure financial situation in order to have good QoL. **Conclusions:** This study is a step towards a better understanding of QoL experienced by the elderly people themselves in a rural Bangladeshi context.

#### # 1342/ASSESSING HEALTH-RELATED QUALITY OF LIFE AMONG OLDER PEOPLE IN RURAL BANGLADESH

Jan Nilsson, Neurotec, Karolinska Institutet, Stockholm, Sweden; Marti G. Parker, Social Gerontology, Aging Research Center, Stockholm, Sweden; Zarina N. Kabir, Neurotec, Karolinska Institutet, Stockholm, Sweden

**Aims:** It is hypothesized in this study that in order to assess health-related quality of life of older people in a low-income country such as Bangladesh, it is important to address the following dimensions: physical, psychological, social, religious, economic and environmental. Instruments of health-related quality of life (HRQoL) were reviewed to identify an instrument appropriate for community-based elderly people in Bangladesh. The context places special demands on an instrument due to the high rates of illiteracy and extreme poverty, as well as living conditions and cultural values. **Methods:** PubMed was used to search for HRQoL instruments. The initial search yielded 76 generic instruments. Additional criteria resulted in 16 instruments for further assessment. These instruments were assessed with regards to dimensions covered and construct (items, scales, mode of administration and recall period). In addition, narratives from in-depth interviews with 11 elderly Bangladeshi respondents focusing on HRQoL were analyzed using content analyses. **Results:** Great variation was found among 16 assessed instruments and none were deemed relevant or appropriate for the described context. Content analysis of the qualitative data revealed that all six dimensions i.e. physical, psychological, social, spiritual, economic and environmental dimensions are deemed important by elderly people in rural Bangladesh in the discussion of health-related quality of life. **Conclusions:** Suggestions for a new instrument for assessing health-related quality of life appropriate for elderly people in rural Bangladesh are presented.

#### # 1183/TOOTH LOSS, DENTURE WEARING AND ORAL HEALTH-RELATED QUALITY OF LIFE IN ELDERLY CHINESE PEOPLE

May C.M. Wong & Anne S. McMillan, Dentistry, University of Hong Kong, Hong Kong, PRC

**Aims:** To investigate the relationship between tooth loss, denture wearing and oral health-related quality of life (OHQoL) among community-dwelling elderly people in Hong Kong. **Methods:** A questionnaire study of elderly people aged 60–80 years who were recruited at neighborhood social centers for the elderly. The Chinese version of the General Oral Health Assessment Index (GOHAI) was used and information about natural tooth number and denture wearing were obtained. **Results:** 233 elderly subjects were recruited and interviewed. 28% (65) were edentulous and all wore conventional complete dentures to replace the missing teeth, 41% (95) were partially dentate and wore removable dentures, and 31% (73) were partially dentate and did not wear removable dentures. Around 20% of the partially dentate subjects had their last tooth loss within the previous year and a quarter within the last 5 years. Significantly fewer edentulous subjects had their last tooth loss within the previous year (3%) and within the last 5 years (12%,  $p < 0.001$ ). Twenty-two percent of the subjects had difficulty in accepting tooth loss. More edentulous subjects (69%) were satisfied with their dentures than partially dentate denture wearers (37%,  $p < 0.001$ ). Edentulous elderly subjects had a higher mean GOHAI score (53.0) than partially dentate denture wearers (49.1,  $p < 0.001$ ). Results from a multiple factor ANOVA revealed that elderly subjects who had loose teeth ( $p < 0.001$ ), difficulty in accepting tooth loss ( $p = 0.014$ ) and were not satisfied with their removable dentures ( $p = 0.003$ ) had a lower mean GOHAI score. **Conclusions:** In general, tooth loss and denture wearing did not have a major impact on OHQoL in elderly Chinese people. However, partially dentate denture wearers experienced a greater adverse impact on OHQoL than edentulous subjects most probably due to less satisfaction with their dentures and discomfort associated with loose teeth.

#### # 1289/CORRELATES OF HEALTH-RELATED QUALITY OF LIFE IN CHINESE ELDERLY RESIDENTIAL CARE HOME RESIDENTS

Linda Yin King Lee, Nursing, The Open University of Hong Kong, Hong Kong, PRC; Diana Tze Fan Lee, Nursing; Jean Woo, Community and Family Medicine, The Chinese University of Hong Kong, Shatin, Hong Kong

**Aims:** Health-related quality of life (HRQOL) is regarded as the ultimate goal of elderly residential care. Though many factors are found to be influencing HRQOL, little is known about the relative importance of these factors in determining HRQOL. Moreover, there may be cultural differences in perception of HRQOL. This study aimed to identify the demographic, physiological, psychological and social correlates of HRQOL in Chinese elderly residential care home residents. Twenty-one variables that have been theoretically or empirically justified in previous studies as relevant were investigated. **Methods:** This cross-sectional study was performed on 175 residents from six elderly residential care homes in Hong Kong. HRQOL was assessed by the Medical Outcome Study Short Form-12. Other data was collected from official records, physiological tests or questionnaires when appropriate. Correlations between the 21 variables and HRQOL were examined by Pearson correlation coefficients. Variables that showed significant bivariate correlation with HRQOL were identified and entered into the stepwise regression model. **Results:** Stepwise regression analysis demonstrated that perceived health status, balance and flexibility explained 36% of the variance in physical component of HRQOL, with  $F(3, 171) = 33.4$ ,  $p < 0.001$ . Such analysis also demonstrated that self-esteem, satisfaction with the psychological care and information received, perceived health status, number of children and heart rate explained 43% of the variance in mental component of HRQOL, with  $F(6, 168) = 23.0$ ,  $p < 0.001$ . **Conclusions:** Findings highlighted the relative importance of various factors in determining HRQOL among Chinese elderly residential care home residents. This is of utmost importance in guiding the development of effective intervention for promoting HRQOL among this population.



#### # 1447/DIFFERENCE OF HEALTH-RELATED QUALITY OF LIFE BETWEEN RURAL AND URBAN ELDERLY

Tsai-Chung Li, Chinese Medicine, China Medical University, Taichung; Yih-Dar Lee, Eli Lilly and Company, Taipei; Cheng-Chieh Lin, Family Medicine, China Medical University Hospital, Taichung, Taiwan, ROC

**Aims:** Urbanization is rapidly spreading through out Taiwan. Cities offer the lure of better employment, education, and health care, and they contribute disproportionately to national economies. However, rapid and often unplanned urban growth is often associated with a range of urban health hazards and associated health risks. There might exist a link between urbanization, a degraded environment, inaccessibility to healthcare, and a deteriorating quality of life. Therefore, the objectives of this study will examine the differences of health-related quality of life (HRQOL) between rural and urban elders in Taiwan. **Methods:** Two random samples were selected. One is from the rural community in central Taiwan, Chung-Shing-Shin-Tseun, and the other one is from the Taichung city, the largest city in central Taiwan. All residents aged 65 and over in Chung-Shing-Shin-Tseun were recruited in 1998 with an overall response rate of 89.13% (n = 921). The sample in Taichung city was randomly selected by three-stage sampling method in 1997 (n = 125). Face-to-face interview by trained interviewers was used to collect data. The Short Form 36 (SF-36) was used to measure HRQOL. **Results:** This study showed that the elders living in Taichung city reported significant lower levels of HRQOL in scales of pain (adjusted mean difference  $\pm$  SEM,  $6.67 \pm 3.01$ ), general health ( $6.26 \pm 2.98$ ), and PCS ( $3.21 \pm 1.09$ ) after taking into sociodemographic factors, chronic diseases, life style behaviors, social resources, financial resources and income adequacy. But significant higher scores of social functioning ( $49.00 \pm 1.26$ ) and MCS ( $5.61 \pm 1.16$ ) for Taichung elders were observed. **Conclusions:** Elders in urban city reported worse HRQOL of primarily physical domains but better HRQOL of social functioning and mental domain compared with those in rural community. These differences couldn't be chalked up to differences in sociodemographic factors, chronic diseases, social resources, life style behaviors, financial resources and income adequacy.

#### # 1734/THE VALIDITY OF WHO-5 AS MARKER OF DEPRESSION IN THE OLD-AGE POPULATION

Klaus Martiny, Gabriele Bech-Andersen & Per Bech, Psychiatric Research Unit, Frederiksberg General Hospital, Hilleroed, Denmark

**Aims:** While life satisfaction seems to be a concept that has different meanings for the younger and the elderly population, psychological well-being is a dimension found transferable across age. It was our aim to investigate the association between depression and psychological well-being in the elderly and to evaluate the validity of the 5-item WHO-5 Well-Being Index (WHO-5) as a marker of depression in this population. **Methods:** The international study on quality of life (QoL) in the elderly (the WHOQOL-Old study) applied QoL measures from the existing WHOQOL-100 and the newly developed WHOQOL-OLD instrument. In some centres these measures were supplemented by the WHO-5 as a measure of well-being. Our data cover the Danish part of the study. From the existing items of the WHOQOL-100 and the WHO-QOL-OLD we constructed a depression scale from which the ICD-10 diagnosis of moderate depression could be established to compare this to the WHO-5 results. Internal validity of the WHO-5 and the depression items scale was evaluated by item response theory (Mokken analysis). **Results:** In total, 685 elderly persons aged between 60 and 99 (mean 71.1 and SD 8.1) participated in the study (females: 50.5%). The WHO-5 had an adequate internal validity, with a Loevinger coefficient of 0.64, and the depression scale had an acceptable internal validity, with a Loevinger coefficient of 0.37. The prevalence of moderate depression was 2.9% (n = 20) with a corresponding WHO-5 mean score of 41.8 (100 = best possible QoL). The mean WHO-5 score for the total sample (n = 685) was 73.1, similar to that found in an earlier Danish general population study. **Conclusions:** The WHO-5 had an acceptable internal and external validity and an association between depression and psychological well-being was clearly established. This may be important as a very short instrument is easy to use and thus allows for better response rates, especially in old age.

#### # 1340/DECIDING WHAT IS IMPORTANT TO QUALITY OF LIFE

Faith A. Martin, Psychology, University of Bath, Bath, Somerset, UK

**Aims:** The subjective importance of different areas of quality of life (QoL) has been investigated far more than 'how' people make these decisions. Understanding these processes and their psychology may give insight into why things are important and how areas of life are linked, potentially leading to targets for intervention. This preliminary investigation aimed to study the use of information processing models and consideration of basic needs when making these decisions. Needs and their satisfaction are related to quality of life. Individual's goals, expectations, standards and concerns, part of the World Health Organisation definition of QoL (WHOQOL Group, 1995), may be part of this decision making process. **Methods:** Ten UK university students rated the importance of various areas of life to their QoL, narrating how they made their decisions. This is known as cognitive interviewing. Two well-known QoL instruments were used, one with participant-defined and the other with questionnaire-defined areas of life. Resulting decision making narratives underwent content analysis. **Results:** Comprehension of the task and areas of life (when given), searches and retrieval of memories, use of heuristics and response formulation took place, stages in the information processing models. Imagination was used where memories were not accessed. Imagined negative impact if the area of life was absent was linked to high importance of that area. The impact of areas of life on one-another was evident in reports. Basic needs were considered, as were goals, expectations, standards and concerns, lending further support to the WHOQOL definition. Comparisons of the participant-defined and questionnaire-defined methods revealed similar processes at play, supporting the validity of both. **Conclusions:** Results suggest that cognitive interviewing is suitable for studying decision making relating to importance. Further work is needed to support initial findings and to investigate the method's use cross-culturally and with groups of different ages and cognitive ability/educational level. Moreover this method may allow further analysis of changes in importance of areas of life, as observed in response shift.

#### # 1367/SF-36 AND WHOQOL-BREF: DO THEY MEASURE THE SAME CONSTRUCTS?

I-Chan Huang, Health Policy and Management; Constantine Frangakis, Biostatistics; Albert Wu, Health Policy and Management, Johns Hopkins University School of Public Health, Baltimore, MD

**Aims:** The SF-36 and WHOQOL instruments are available for international use, but it is not clear if they measure the same constructs. We compared the psychometric properties and factor structure of these two instruments. **Methods:** Data were collected from a national representative sample (n = 11,440) in the 2001 Taiwan National Health Interview Survey, which included Taiwanese versions of the SF-36 and Short-Form WHOQOL (WHOQOL-BREF). We examined the eight subscales of SF-36 and four subscales of WHOQOL-BREF. Cronbach's  $\alpha$  was used to estimate scale reliability. Multitrait analysis was used to evaluate convergent and discriminant validity. Exploratory factor analysis was used to determine factor structure. Relative validity (RV) was used to compare known-groups validity for clinical variables (chronic heart failure, stroke, diabetes, physician visits, and hospitalizations) and QOL (visual analog scale). Structural equation modeling was used to analyze pathways among SF-36 two component scales (PCS and MCS) and four WHOQOL subscales. **Results:** Cronbach's  $\alpha$  coefficients were acceptable ( $>0.7$ ) for all subscales of both instruments. Pearson's correlation coefficients were weak among subscales of both instruments ( $<0.3$ ). Correlations for subscales hypothesized to measure similar constructs differed little from those for heterogeneous subscales, suggesting poor convergent and discriminant validity. The confirmatory factor analysis extracted two unique factors: one for the eight SF-36 subscales and another for the four WHOQOL subscales. The RV approach suggested greater discrimination by the SF-36 of clinical known-groups, but greater discrimination by the WHOQOL of QOL known groups. Structural equation modeling suggested that the SF-36 PCS and MCS were weakly associated with WHOQOL. **Conclusions:** In this Taiwan population sample, the SF-36 and WHOQOL-BREF appear to measure different constructs. SF-36 appears to measure HRQOL, while the WHOQOL-BREF measures global QOL. Clinicians and researchers should take care in defining their research questions before selecting which instrument to use.

# 1638/A CONCEPTUAL FRAMEWORK FOR UNDERSTANDING AND INTERPRETING DIFFERENT PROXY PERSPECTIVES ON HEALTH-RELATED QUALITY OF LIFE

A. Simon Pickard, Pharmacy Practice, University of Illinois at Chicago, Chicago, IL; Sara Knight, Psychiatry and Urology, VA and University of California, San Francisco, CA, USA

**Aims:** Proxy assessment of health-related quality of life may be sought to substitute for, or to complement, patient self-assessment. The viewpoint from which the proxy is asked to assess the patient is a subtle yet important aspect of proxy assessment that has received little attention. Proxy assessments can be elicited by asking a caregiver to assess the patient as they think the patient would respond (i.e. proxy-patient perspective) or for the caregiver to provide their own perspective on the patient's HRQL (i.e. proxy-caregiver perspective). **Methods:** In this paper, we propose a conceptual framework that incorporates experience, expectation, and empathy to explain and interpret differences attributable to the elicited perspective on HRQL. **Results:** The systematic difference between patient self-assessment and the proxy-patient perspective is defined as the inter-person gap, while the systematic difference between the proxy-patient and proxy-caregiver perspective is described as the within-proxy gap. The within-proxy gap is dictated by the caregiver's health experience, the caregiver's knowledge of the patient's health experience, the caregiver's ability to understand their own and the patient's health expectations, the caregiver's ability to empathize with the patient, and the caregiver's ability to expand upon and clarify the patient's perspective. **Conclusions:** Conceptualization of proxy assessments using the proposed framework will help to guide the psychometric evaluation of the validity of proxy judgments and further develop and expand upon the application of proxy measures of HRQL in clinical trials, population health monitoring, resource allocation, and clinical management.

# 1268/IS THE INFLUENCE OF SOCIODEMOGRAPHIC FACTORS ON EQ-5D SCORES AFFECTED BY THE UNDERLYING DISEASE: A STUDY IN PATIENTS WITH CHRONIC HEPATITIS B OR DIABETES MELLITUS

Hwee-Lin Wee, Pharmacy, National University of Singapore, and Rheumatology and Immunology, Singapore Gen Hosp; Su-Yen Goh, Endocrinology, Singapore General Hospital; Shu-Chuen Li, Pharmacy, National University of Singapore; Seng-Gee Lim, Medicine, National University Hospital; Siew-Chin Ong, Pharmacy, National University of Singapore; Chee-Eng Tan, Endocrinology; Julian Thumboo, Rheumatology and Immunology, Singapore General Hospital, and Medicine, National University of Singapore, Singapore

**Aims:** Sociodemographic factors are known determinants of HRQoL, whose distribution in different diseases also varies. We therefore hypothesized that sociodemographic influences on HRQoL might be influenced by disease type, and tested this in patients with either chronic hepatitis B (CHB, more common in females and Chinese) or diabetes mellitus (DM, more common in non-Chinese). **Methods:** We studied effects of age, gender, ethnicity and education on EQ-5D utility and VAS scores in CHB and DM patients using separate multiple linear regression models. We then pooled the CHB and DM data and studied the influence of these same variables, disease type and their interactions on utility and VAS scores. **Results:** We studied 120 CHB patients (77.5% male, mean age: 42.0 ± 12.30 years) and 130 DM patients (53.8% male, mean age: 51.9 ± 12.68 years). In separate analyses, after adjusting for the influence of sociodemographic factors, ethnicity influenced utility scores in DM patients ( $p = 0.004$ ). No factors influenced utility scores in CHB patients or VAS scores in DM or CHB patients. In the pooled sample, disease type and education were significant predictors of utility scores ( $p < 0.001$  and  $p < 0.05$ ) while disease type alone was a significant predictor of VAS scores ( $p < 0.001$ ). The interaction between disease type and Chinese ethnicity was significant for both utility ( $p = 0.003$ ) and VAS ( $p < 0.001$ ) scores. **Conclusions:** The influence of sociodemographic factors on EQ-5D scores is modulated by the underlying disease in patients with CHB and DM. To avoid potential confounding due to these interactions, studies need to assess whether sociodemographic influences on HRQoL are modulated by underlying disease type.

# 1485/QUALITY OF LIFE IN PERITONEAL DIALYSIS PATIENTS: IS THERE A RELATIONSHIP WITH RESIDUAL KIDNEY FUNCTION AND DIALYSIS ADEQUACY?

Angela Y. Wang, Chinese University of Hong Kong, Hong Kong, PRC; Mandy M. Sea & Rachel W. Leung, Medicine & Therapeutics, Chinese University of Hong Kong, Prince of Wales Hos, Hong Kong, PRC; Siu-Fai Lui, Philip K. Li & Jean Woo, Medicine & Therapeutics, Chinese University of Hong Kong, Hong Kong, PRC

**Aims:** Previous studies have indicated the importance of residual renal function in predicting outcome of peritoneal dialysis (PD) patients. This study aimed to evaluate the key factors associated with QOL in PD patients. In particular, we examined the relationships between QOL and dialysis adequacy. **Methods:** The Kidney Disease Quality of Life questionnaire was administered to 251 chronic PD patients (52% men, mean age 55 years) from a single regional dialysis center together with measurement of indices of dialysis adequacy. Univariate and multivariate regression analysis were performed to identify factors associated with QOL dimension scores. **Results:** The mean (SD) QOL dimension scores for physical health (PH), mental health (MH), kidney disease issues (KDI) and patient satisfaction (PS) were 53 (18), 65 (17), 67 (17) and 67 (21), respectively with no significant difference between men and women. On univariate analysis, PH dimension scores showed significant correlations with background cardiovascular disease ( $p = 0.001$ ), dialysis duration ( $p < 0.001$ ), residual glomerular filtration rate (GFR) ( $p < 0.001$ ), total weekly urea clearance ( $Kt/V$ ) ( $p = 0.019$ ) and PD  $Kt/V$  ( $p = 0.014$ ). MH showed only marginal significance with age ( $p = 0.057$ ) and residual GFR ( $p = 0.087$ ). KDI showed significant correlations with dialysis duration ( $p = 0.003$ ) and residual GFR ( $p < 0.001$ ). No correlation was observed between diabetes or hemoglobin level with any of the QOL dimension scores. Using multivariate analysis, residual GFR [partial  $r = 0.356$ ,  $p < 0.001$ ] background cardiovascular disease [partial  $r = -0.189$ ,  $p = 0.002$ ] and dialysis duration [partial  $r = -0.185$ ,  $p = 0.005$ ] showed independent correlations with PH. Residual GFR [OR, 1.27, 95% CI, 1.04–1.55;  $p = 0.020$ ] was also independently correlated with KDI. Age was an independent correlate of MH [OR, 1.03, 95% CI, 1.00–1.05;  $p = 0.032$ ]. **Conclusions:** The strong and independent relationships between residual renal function but not PD clearance with physical health and kidney disease issues QOL dimension scores imply that the contribution of residual renal function and dialysis clearance to the well-being of PD patients cannot be considered equivalent. Our results highlight the need to focus more attention towards improving the QOL in PD patients who became anuric with time on dialysis.

# 1306/THE SHORT-FORM 36 (SF-36) AS A PREDICTOR OF MORTALITY: A 7-YEAR FOLLOW-UP STUDY OF A TAIWANESE COMMUNITY

Jim-Shoung Lai, Public Health; Tsai-Chung Li, Chinese Medicine, China Medical University, Taichung, Taiwan, ROC; Yih-Dar Lee, Eli Lilly and Company, Taipei, Taiwan, ROC; Jwo-Leun Lee, Health Services Management, China Medical University, Taichung, Taiwan, ROC; Chia-Ing Li, Medical Research, China Medical University Hospital, Taichung, Taiwan, ROC

**Aims:** The objective of the present study is to examine the predictive ability of 10 scales of Short Form 36 (SF-36) on mortality controlling for objective health measures in terms of co-morbidity in a Taiwanese, community-based sample. **Methods:** A 7-year follow-up study design was conducted in a representative sample of 2164 residents of Taichung City, and Taichung, NanTou, ChangHwan, and Yunlin Counties of Taiwan. These study subjects were drawn by a four-stage sampling design in October 1994. An in-person interview was used for data collection. The SF-36 measures eight multi-item variables: physical functioning, social functioning, role limitations due to physical and emotional problems, mental health, vitality, pain, and general perception of health. In addition, SF-36 Physical (PCS) and Mental (MCS) Component Summary scales are derived. Mortality data were collected from the national mortality register using personal identification numbers. Multivariate Cox's proportional hazard models were used. **Results:** Our study findings indicate that after adjusting for age, gender, and chronic conditions, scales of general perception of health, vitality, mental health, physical functioning, and MCS are significantly associated with mortality. Individuals in the category of bottom 25% had significantly increased risk compared to those in the category of top 25% (relative risk = 2.69, 95% CI: 1.04–6.98; 6.39, 1.51–27.06; 2.77, 1.22–6.30; 2.02, 1.18–3.47; and 2.70, 1.20–6.05, respectively). When PCS and MCS were simultaneously taken into account, only MCS exerted significant effect on mortality (RR = 2.71, 95% CI: 1.20–6.11). **Conclusions:** People who reported worse health status measured by SF-36 had a greater risk of mortality over 7 years of follow-up compared with those reported better health status. The unique contribution of health perceptions to mortality is independent of more objective health measures such as chronic conditions.

# 1574/HEALTH RELATED QUALITY OF LIFE: DOES EDUCATION MATTER?

Azita Goshtasebi, Family Health; Mariam Vahdaninia, Health Services Management; Ali Montazeri, Social Medicine, Iranian Institute for Health Sciences Research, Tehran, Iran

**Aims:** The aim of this study was to assess the relative contribution of education to variations of health related quality of life among the general population. **Methods:** A population-based study was conducted to measure quality of life among the general Iranian population. Using a multistage sampling procedure a random sample of healthy individuals aged 15 and over living in Tehran were entered into the study. Quality of life was measured using the Iranian version of the SF-36 Health Survey. Analysis of variance was performed using the respondents' scores as outcome variables, gender and educational levels as fixed factors and age as covariate (full factorial model). **Results:** In all 4163 individuals were interviewed. The mean age of the respondents was 35.1 (SD = 16.0), mostly female (52%) and had primary (19%), secondary (62%) and higher (19%) education. The results of analysis of variance showed that apart from age and gender gradients, education had a significant effect on all measures on the SF-36 except for social functioning ( $p = 0.09$ ) and role emotional ( $p = 0.10$ ). In addition the interaction between gender and education did not show any significant results except for physical functioning ( $p$  value < 0.0001). **Conclusions:** The study findings indicate that the contribution of education gradient in health related quality of life reported by healthy individuals is distinct and should not be neglected in the light of strong effect of age and gender on people's health status.

# 1715/CHANGE AND STATUS IN QUALITY OF LIFE IN NORTHERN SWEDEN

Jan Olof Hornquist, AB CQL Research, Consultancy, Södertälje, Sweden

**Aims:** The aim was to examine how the citizens in northern Sweden in 1997/1998 perceived their life changes past 6 months. How did they evaluate their situation? What was related to the change and status? **Methods:** Sixty-five percent or 14,279 of all 18+ addressees in the population responded to a broad postal public health survey within which the QLcs was inserted. Apart from a global self-rating of one's 'whole life', the respondents also rated separately their somatic health, wellbeing, cognitive functioning, social and cohabiting/family life, ability to be active, economy and the meaningful/lessness of their lives. **Results:** Perceived changes were minor on average, however, mostly significantly 'for the better'. Declared statuses were positively skewed and rated as being 'good'. Change as well as status in economy, ability to be active and somatic health exhibited somewhat lower levels. The older, the greater was the change for the worse, and the poorer the status. Females declared greater change for the better, higher social and existential status but poorer status in remaining domains. Residential enjoyment emerged as a fairly strong correlate. Weak to modest (max  $R^2 = 0.10$ ) but pervasive social network bonds were noted. The work-related patterns underlined in listed order the clear but modest significance of explicit appreciation, social contact, creativity as well as reasonable stress at work. Satisfactory sleep seemed to be favourable. Ill-health indicators were evidently negatively correlated. **Conclusions:** New intriguing regional levels and profile patterns not previously documented similarly were salient. Some differential impact of age, gender and key work site related factors was found. The overall bearing in particular of existential and family conditions, but also of one's ability to be active was underscored. Causation, reversed causation and possible criteria contamination await closer clarification. The outcome patterns resemble similar narrower ill-health-oriented findings, modify and balance but corroborate also recent Swedish National Public Health Investigations.

# 1717/PHYSICAL ACTIVITY AND QUALITY OF LIFE

Jan Olof Hornquist, AB CQL Research, Consultancy, Södertälje, Sweden

**Aims:** The aim was to analyse the correlation between self-declared frequency of physical training and change and status in quality of life (CaSinQoL). Overall hypothesis was that the higher declared frequency, the greater rated change for the better in retrospect during last 6 months and the higher status nowadays. **Methods:** The study comprised a presumably somewhat better off population-based sample in northern Sweden in 1997/1998. Of all addressees in 18+ ages 65% or 14,279 responded to a public health postal survey. The mini QLcs applied for assessing CaSinQoL was inserted. Between 94 and 82% completed the various QLcs ratings. **Results:** Consistent and pervasive weak to modest significant bonds emerged across CaSinQoL sub-modules and life domains, respectively. The more frequent exercise, the greater was the change for the better and the higher current status. Females, younger and senior citizens exhibited stronger bivariate associations. After ruling out significant background influences in stepwise multiple regression analyses, the physical activity parameter applied explained significantly typically 5% of remaining variance in CaSinQoL in a second block. **Conclusions:** The salient result accords with published studies along the same but narrower clinical or health-oriented theme. Thus, exercising may have some impact on your quality of life, although a partial reversed relationship cannot be conclusively ruled out.

#### # 1720/THE IMPACT OF AREA DEPRIVATION ON QUALITY OF LIFE AMONG ADULTS IN TAIWAN

Jung-Hua Liu, Health Policy and Management, National Taiwan University, Taipei, Taiwan, ROC; I-Chan Huang, Health Policy and Management, Johns Hopkins University School of Public Health, Baltimore, MD, USA; Tung-liang Chiang, Health Policy and Management, National Taiwan University, Taipei, Taiwan, ROC

**Aims:** To investigate the relationship of quality of life with area deprivation among adults in Taiwan. **Methods:** This is a cross-sectional study using 2001 TAIWAN National Health Interview Survey. Subjects ( $n = 11375$ ) aged 20–65 years were randomly selected from 82 towns in TAIWAN. Quality of life (QOL) was measured using Short-Form WHOQOL (WHOQOL-BREF), including domains of physical, psychological, social, and environmental QOL. The area deprivation score was an un-weighted combination of proportions of agricultural labor and no schooling prevalence of 18–21 years. Generalized estimating equation (GEE) modeling was used to adjust for clustering of subjects within town. **Results:** There is negative linear relationships between areas deprivation scores and all domains of QOL. After using GEE model and adjusting for subject's age, gender, education background, income, marriage status, number of chronic diseases, and smoking status, people living in higher deprivation areas were more likely to have poor QOL than those living in lower deprivation area ( $p < 0.01$ ), except for domain of physical QOL. **Conclusions:** The area deprivation was significantly associated with QOL. Our results suggest when evaluating QOL, we need to take the influence of community's social-economic status into account, such as area deprivation.

#### # 1539/CORRELATION BETWEEN CLINICAL SEVERITY AND QUALITY-OF-LIFE MEASUREMENT IN CHINESE PEOPLE WITH PSORIASIS

C. T. Tse, K. M. Ho, SHS, K. Lee, SPP, DH, Hong Kong, PRC

**Aims:** Both Psoriasis Activity and Severity Index and SF-36 scores are commonly used outcome measure in psoriasis. While the former measures the clinical severity, the latter captures quality of life (QOL). We conducted a cross-sectional multi-centre study to examine the relationship between the two measures in Chinese patients with psoriasis. **Methods:** During the study period, from October 2003 to March 2004, Chinese people with psoriasis attending six government dermatology clinics were invited to assess their own QOL by the Chinese (Hong Kong) SF-36 health survey. The SF-36 scores were reported after age and sex specific-standardization of HK normative value (mean 50, SD10). Higher scores represent better QOL. Simultaneously, five physicians participating the study gauged the clinical severity by a modified version of Psoriasis Activity and Severity Index (MPASI). The index was a summation of extent and lesional severity (erythema, desquamation and induration). Higher index represents greater severity in psoriasis. All physicians were blinded to the SF-36 scores. **Results:** The study recruited 128 (M 92, F 36) Chinese patients with psoriasis. Most patients (91%) did not have psoriatic arthropathy. Chronic plaque psoriasis was the most common type (94%). The association between MPASI and Physical Summary Scores was weak ( $r = -0.20$ ,  $p < 0.05$ ). Not surprisingly, there was no relation ( $r = -0.06$ ,  $p > 0.05$ ) between MPASI and Mental Summary Score. In the physical component, the strongest association with MPASI was Role Physical ( $r = -0.20$ ,  $p < 0.05$ ). In the mental component, the strongest association was Social Function ( $r = -0.21$ ,  $p < 0.05$ ). **Conclusions:** This study showed that physician-based assessment of clinical severity could not accurately predict the impact of psoriasis, in particularly the psychosocial aspect. This reinforces the need of QOL survey as one of the outcome measures, in addition to the traditional clinical assessment, in the future clinical study of psoriasis.

#### # 1046/SUBSTITUTION TO LOPINAVIR/RITONAVIR (LPV/R) IS ASSOCIATED WITH IMPROVEMENT IN PATIENT-REPORTED SEXUAL DYSFUNCTION (SD) IN HIV+ INDIVIDUALS

M. P. Luo, Y. Shen, R. Rode, F. McMillan, R. Tressler & T. Ashraf, HEOR, Abbott Laboratories, Abbott Park, IL

**Aims:** SD is a common symptom in HIV+ patients (PT). This analysis evaluates whether substitution to LPV/r, a generally well tolerated and efficacious PI, affects SD in HIV+ PT with Grade 2 side effects (SE) attributed to their PI/NNRTI. **Methods:** In the open-label PLATO trial, PT with these types of SE were randomized (4:1) to immediate substitution (IS) of their PI/NNRTI with LPV/r at baseline (BL) or deferred substitution (DS) at Week 4 (Wk4). The MOS-HIV and ACTG Symptoms Distress Module, with two additional items for nephrolithiasis (ASDM), were administered at BL, Wk4 and Wk8. ASDM specific items were used to measure the presence/bothersomeness of SE including SD, fatigue, anxiety and peripheral neuropathy (PN). The CESD survey was administered at BL and Wk8. Forward stepwise regression was used. **Results:** 827 PT previously on indinavir (IDV) or IDV/r ( $n = 352$ ), nelfinavir ( $n = 291$ ), efavirenz ( $n = 136$ ) or another PI/NNRTI ( $n = 48$ ) were analyzed (80% male, mean age 42 years, 75% with baseline HIV RNA  $< 50$  copies/ml). At BL, mean SD score was 1.16, with 38% males and 25% females rating SD as bothersome. SD scores at BL were correlated ( $p < 0.05$ ) with gender, race, baseline HIV RNA  $> 50$  copies/ml, presence of depression (CESD $> 16$ ), PN and fatigue scores. Improved SD scores were seen at Wk4 in IS vs. DS ( $-0.17$  vs.  $+0.12$ ,  $p = 0.012$ ), with PT previously on IDV or IDV/r demonstrating significant mean improvement ( $-0.31$  vs.  $+0.16$ ,  $p = 0.009$ ). At Wk8, SD improvement remained for IS PT ( $-0.19$ ,  $p < 0.001$ ), while DS PT had no change from BL ( $+0.05$ ,  $p = 0.548$ ). Improved SD scores were associated ( $p < 0.05$ ) with reduced prevalence of depression and improved fatigue score. Improvement in SD and IS were significant predictors of improved MOS-HIV physical health summary, mental health summary and QOL domain scores at Wk4 ( $p < 0.05$ ). **Conclusions:** SD was improved after substitution with LPV/r and was associated with reduced prevalence of depression and fatigue. Improvement in SD was a predictor of improvement in QOL.

#### # 1194/THE BIOLOGICAL MECHANISMS BEHIND A GOOD OR BAD SELF-RATED HEALTH

Carola Bardage, Pia Svedberg & Nancy L. Pedersen, Medical Epidemiology and Biostatistics, Karolinska Institutet, Stockholm, Sweden

**Aims:** The association between self-rated health (SRH) and morbidity and mortality is well-known. However, the biological mechanisms behind a good or bad SRH have not been studied to any great extent. The purpose of this study was to analyse the relationship between SRH and biological markers in blood. **Methods:** Data were collected in 1996 and 1997 in the Swedish Twin Registry. Three self-rated health items developed for the Older Americans Resource Survey at Duke University were included (How would you rate your general health status?, How would you rate your health status compared to 5 years ago?, Do you think your health status prevents you from doing things you would like to do?). Items were standardized separately ( $M = 0$ ,  $SD = 1$ ) and then summed. A high score indicates better health. **Results:** Results of the correlation analyses showed that higher levels of triglycerides and apo-lipoprotein B (ApoB) were associated with poorer SRH. Higher levels of high-density lipoprotein cholesterol (HDL-C) were associated with higher health ratings. Higher levels of markers associated with liver damage (aspartate aminotransferase, ASAT, alanine aminotransferase, ALAT and g-glutamyl transferase, GGT) were related to poorer SRH. Further, higher levels of immunoglobulin E (IgE) were associated with lower health ratings. Electrolytes associated with salt- and water balance were not correlated with SRH. **Conclusions:** We conclude that there is a biological mechanism behind a state of good or bad self-ratings of health. SRH is a sensitive indicator of the biological state of the organism, and reflects differences also at sub-clinical levels of the biomarkers.

#### # 1429/DETERMINANTS OF QUALITY OF LIFE OF STROKE SURVIVORS IN HONG KONG

Timothy Kwok, Medicine and Therapeutics, The Chinese University of Hong Kong; Raymond Lo, Medicine and Geriatrics, Shatin Hospital; Eric Wong, Centre for Epidemiology and Biostatistics; Wai Kwong Tang, Psychiatry, The Chinese University of Hong Kong, Shatin, Hong Kong, China

**Aims:** To investigate the determinants of quality of life (QOL) in stroke survivors in the first year. **Methods:** 303 consecutive Chinese patients with the first disabling stroke in Prince of Wales Hospital, Hong Kong, were followed-up at 3, 6 and 12 months. At follow-up, subjects were interviewed to obtain Barthel index (BI), Mini mental state examination, Geriatric depression scale (GDS), and the Hong Kong Chinese version WHO QOL questionnaire (short form). 247 subjects were able to respond to QOL questionnaire. Demographic data, physical exercise habit, soft diets or tube feeding, pain in affected limbs, dysphagia were also recorded. **Results:** The average changes of percentage QOL scores in the four domains: physical, psychological, social, environmental, due to the measured variables at the three time points were estimated from multilevel modelling. GDS was an independent factor for the QOL scores in all four domains, particularly in the psychological QOL domain. For the physical QOL domain, the other significant independent negative factors in order of importance were low BI, female sex, pain in affected limbs, social welfare financial assistance, and soft diets or tube feeding. For the psychological domain, the negative factors were social welfare financial assistance, no physical exercise, and low BI. For the social domain, the negative factors were no physical exercise and 12 months after stroke. For the environmental domain, the negative factors were 6 or 12 months after stroke and old age home residence. **Conclusions:** A small but significant decline in social and environmental QOL over the first year of stroke was observed. Apart from low mood and physical disabilities, financial status, physical exercise, diet, pain and old age home placement were important modifiable determinants of the quality of life of stroke patients in the first year.

#### # 1499/ASSESSING SYMPTOMS IN GASTROESOPHAGEAL REFLUX DISEASE: PATIENTS' VS. CLINICIANS' ASSESSMENTS

Elaine McColl, Centre for Health Services Research, University of Newcastle upon Tyne, Newcastle upon Tyne, UK; Ingela Wiklund & Ola Junghard, AstraZeneca, Mölndal, Sweden, Dennis Revicki, MEDTAP International, Bethesda, MD, USA

**Aims:** Gastro-oesophageal reflux disease (GERD) should be diagnosed and managed on the basis of symptom severity and frequency. We aimed to determine the extent of agreement between clinicians and GERD patients regarding reflux symptom severity, to inform decisions about whose assessments to use in clinical practice and in trials. **Methods:** Secondary analysis of data from four randomized trials, involving a total of 2674 patients, was carried out. The percentage agreement between clinician and patient regarding symptom severity before and after treatment, and for the absence of symptoms after treatment, and weighted  $\kappa$  values, were calculated. The degree of concordance at different levels of symptom severity was also assessed. **Results:** At baseline, clinician-patient agreement regarding symptom severity was slight to moderate to ( $\kappa$ : 0.17–0.53); the lowest levels of agreement were for epigastric pain (24–35%) and the highest were for dysphagia (63%). Poor agreement reflected clinician under-estimation of symptom severity relative to patient ratings in three studies and over-estimation in the fourth. Agreement regarding symptom severity improved at follow-up, being fair to substantial ( $\kappa$ : 0.31–0.73). After treatment, agreement was greatest for assessments of symptom absence; clinician-patient agreement in this respect was at least as good as for symptom severity, ranging from 63 to 90%. In general, concordance decreased with increasing severity of symptoms. **Conclusions:** The agreement between clinicians and patients in assessments of the severity of GERD symptoms is poor, particularly before treatment and for more severe symptoms. Improvements in clinician-patient communication may help to bridge this gap, and greater reliance on patient assessments may be appropriate in clinical trials and everyday practice.

#### # 1244/A COMPARISON OF THE EFFECTS OF GASTROESOPHAGEAL REFLUX DISEASE AND OTHER CHRONIC DISEASES ON UTILITY VALUES – RESULTS OF THE CANADIAN FEELING THERMOMETER STUDY

Ingela Wiklund R&D; Alessio degl'Innocenti, Med & Sci, AstraZeneca, Mölndal, Sweden; Gordon H. Guyatt, Medicine, McMaster University, Hamilton, ON, Canada; Samer El-Dika & Holger J. Schünemann, Medicine, University of Buffalo, SUNY, Buffalo, NY, USA

**Aims:** To compare utility values using different utility measurement instruments for patients with gastroesophageal reflux disease (GERD) with those for different reference populations. **Methods:** Outpatients (aged  $\geq 18$  years) with uninvestigated GERD (for  $\geq 3$  months) with moderate to severe symptoms were enrolled from specialist centres and general practices across Canada. Utility scores were assessed using the standard gamble (SG) and feeling thermometer (FT) instruments, which gauge patients' perceived health states from 0 = dead to 1 = full health. **Results:** 217 patients completed the study (mean age: 50 years; 53% female). For both GERD and chronic obstructive pulmonary disease (COPD), utility scores were lower using the FT than using the SG (Table 1). SG scores for patients with GERD were similar to those for patients with angina pectoris and lower than those for patients with asthma and from survivors of minor stroke (Table 1). **Conclusions:** Patients with moderate to severe GERD had substantial reductions in utility scores comparable with a range of other chronic conditions. The FT generates lower scores than the SG. **References:** 1: Schunemann HJ, et al. Med Decis Making 2003; 23: 140–149; 2: Morimoto T, et al. J Epidemiol 2002; 12: 160–178, 3: Post PN, et al. Stroke 2001; 32: 1425–1429.

Mean utility scores obtained using the SG or FT instruments

Disease	SG	FT
GERD (this study)	0.78 (0.75–0.80)	0.67 (0.64–0.70)
Moderate/severe COPD <sup>1</sup>	0.66 [SD = 0.27]	0.60 [SD=0.18]
Angina pectoris <sup>2</sup>	0.76 (0.64–0.97)	–
Previous minor stroke <sup>3</sup>	0.89 (0.81–0.95)	–
Chronic renal failure <sup>2</sup>	0.52 (0.49–0.55)	–
Asthma <sup>2</sup>	0.88 (0.82–0.91)	–

# 1237/SYMPATOM RELIEF RESULTS IN IMPROVED QUALITY OF LIFE: THE CANADIAN FEELING THERMOMETER STUDY IN PATIENTS WITH UNINVESTIGATED REFLUX DISEASE

Ingela Wiklund, R&D; Alessio degl'Innocenti, Med & Sci, AstraZeneca, Mölndal, Sweden; David Armstrong, Diane Heels-Ansdell & Gordon H. Guyatt, Medicine, McMaster University, Hamilton, ON, Canada; Holger J. Schünemann, Medicine, University of Buffalo, State University of New York, Buffalo, NY, USA

**Aims:** To evaluate how relief of reflux symptoms (clinician and patient rated) affects health-related quality of life (HRQL). **Methods:** Patients with uninvestigated reflux disease with moderate to severe symptoms were studied before and after 4 weeks' treatment with esomeprazole 40 mg once daily. Clinicians and patients evaluated symptom relief on 7-point scales. Patients completed the SF-36 at baseline and the Quality of Life in Reflux and Dyspepsia (QOLRAD) before and after treatment. **Results:** 217 patients were studied (mean age: 49.7years; 52% female; mean duration of reflux symptoms: 86 months). Before treatment, HRQL was impaired (mean SF-36 scores ~45 or lower in all dimensions; normal values: 60–90). Substantial impairment of HRQL was seen in the QOLRAD dimensions eat/drink, sleep disturbance, vitality and well-being. After treatment, the patient symptom score improved 2.8 points ( $p < 0.001$ ); QOLRAD scores improved 1.5 points in sleep disturbances, 1.3 in well being and 1.3 in eat/drink (all  $p$ -values  $< 0.001$ ). Clinician-assessed symptom changes correlated moderately with patient assessed symptoms (0.49) but weakly with QOLRAD score changes: 0.36 (Eat/drink); 0.28 (Sleep); 0.27 (well-being). The change score correlations between patient-assessed relief of heartburn, acid regurgitation and symptom severity vs. change in eat/drink was 0.56, 0.49 and 0.48, vs. sleep improvement 0.43, 0.36 and 0.35, and vs. well-being 0.50, 0.45 and 0.38, respectively. **Conclusions:** Patients with uninvestigated reflux disease have a poor HRQL. Symptom relief, following esomeprazole treatment, was associated with improvements in certain HRQL areas. The weak concordance between patient clinician ratings suggests patients should be the prime reporter of treatment outcome.

# 1241/IMPACT OF REFLUX DISEASE ON HEALTH-RELATED QUALITY OF LIFE – RESULTS FROM THE GERD FEELING THERMOMETER STUDY

Alessio degl'Innocenti, Med & Sci, AstraZeneca, Mölndal, Sweden; Gordon H. Guyatt, Clin. Epi. & Biostatistics, McMaster University, Hamilton, ON, Canada; Ingela Wiklund, R&D, AstraZeneca, Mölndal, Sweden; David Armstrong, Medicine, McMaster University, Hamilton, ON, Canada; Diane Heels-Ansdell, Naoki Chiba & Peggy Austin, Medicine, McMaster University, Hamilton, ON, Canada; Lisa Tanser, GI, AstraZeneca, Mississauga, ON, Canada; Carlo A. Fallone & Alan N. Barkun, Gastroenterology, McGill University Health Center, Montreal, PQ, Canada; Sander vanZanten, Medicine, Dalhousie University, Halifax, NS, Canada; Samer El-Dika & Holger J. Schünemann, Medicine, University at Buffalo, SUNY, Buffalo, NY, USA

**Aims:** To assess the impact of gastroesophageal reflux disease (GERD) on health-related quality of life (HRQL) in Canadian patients with GERD. **Methods:** Outpatients (aged  $\geq 18$  years) with uninvestigated GERD and moderate to severe symptoms for at least 3 months were enrolled at 13 specialist centres and 4 general practices across Canada. Patients' HRQL was assessed using the SF-36. **Results:** 217 completed the study (mean age: 50 years; 53% female). Baseline SF-36 scores and those of reference populations are shown in the table (\*\* $p < 0.01$ ; \*\*\* $p < 0.001$  compared to our GERD patients). For the GERD patients, both physical and mental components were significantly lower than those for a general US population. In addition, the mental component mean score was significantly lower than for reference populations suffering from diabetes or hypertension.<sup>1</sup> **Conclusions:** In these Canadian patients, moderate to severe GERD imparted a significant reduction in both physical and mental aspects of HRQL. **Reference:** 1: Revicki DA, et al. Am J Med 1998; 104: 252–258.

Baseline mean (standard deviation) SF-36 component scores

	Physical	Mental
GERD (this study)	45.1 (8.7) (n = 213)	47.8 (11.0) (n = 216)
US General Population (n = 2474)	50.0*** (10.0)	50.0** (10.0)
Diabetes (n = 541)	41.5*** (11.3)	51.9*** (9.6)
Hypertension (n = 2089)	44.3 (10.8)	52.2*** (9.3)

# 1243/STRATIFICATION OF DUODENAL ULCER PATIENTS BY HEALTH RELATED QUALITY OF LIFE

Andrei A. Novik, Hematology and Cell Therapy Department, National Medical Surgical Center named after Pirogov, Moscow, Russia; Tatiana I. Ionova, Head QOL Group, Vasily A. Shuvaev & Anton V. Kishtovich, Biostatistic Department, Multinational Center of Quality of Life Research, Saint Petersburg, Russia

**Aims:** Duodenal ulcer patients are heterogeneous in terms of physiologic and psychophysiological parameters. In duodenal ulcer like in most chronic diseases, that do not shorten life expectancy, patient's health related quality of life (HRQL) might be considered as the final goal of treatment. The aim of the work was to investigate the heterogeneity of duodenal ulcer patients in terms of HRQL. **Methods:** 127 patients with duodenal ulcer relapse were enrolled in the study. HRQL was assessed using Russian versions of SF-36 and GSRS that previously have been validated. Integral HRQL index was calculated using the integral profile method (Novik AA et al., 2003). Stratification was performed on the basis of integral HRQL index by cluster analysis. Clinical and HRQL monitoring was conducted during a year after baseline. **Results:** As a result of stratification five groups of duodenal ulcer patients with different integral HRQL index were determined. The first group exhibited the lowest integral HRQL index mean, the fifth group – the highest one. The gastrointestinal symptoms decreased in accordance with stratification groups. No significant difference between groups by gender, age, duration of disease, relapse frequency was found. The analysis of duration of relapse-free period by Kaplan–Meier curves demonstrated significant ( $p < 0.01$ ) differences between groups. In the first group remission median was 2 months, relapse-free period – 3.71 months; in the fifth group ones was 4 months and – 6.09 months. **Conclusions:** Duodenal ulcer patients in relapse are heterogeneous in terms of their HRQL. Five groups of duodenal ulcer patients differing by HRQL and gastrointestinal symptoms have been identified. The groups vary in relapse dynamics and relapse-free periods.

#### # 1501/LOCATION IS AN INDEPENDENT PREDICTOR OF QUALITY OF LIFE OF PATIENTS WITH ACNE

Yoshimi Suzukamo, Epidemiology and HealthCare Research, Kyoto University School of Public Health; Motonobu Nakamura & Yoshiaki Miyachi, Dermatology, Kyoto University; Shunichi Fukuhara, Epidemiology and HealthCare Research, Kyoto University School of Public Health, Kyoto, Japan

**Aims:** Acne is a one of the commonly observed skin conditions which can alter patient's appearance. Several studies report that QOL of patients with acne can be much poorer than those with other chronic conditions. The aim of this study was to (1) measure burden of acne in terms of QOL, and (2) identify clinical characteristics of acne which is associated with QOL. **Methods:** A total of 216 patients 16 years old or older were enrolled in this cross-sectional observational study from nine dermatology clinics. They filled out self-administered questionnaire consisting of the Skindex 29, as acne-specific QOL measures, and some domains of SF-36v2 as general QOL measures. Clinical variables were obtained from their physicians, such as types, location, duration, clinical severity of acne. The score of SF-36v2 of the patients with acne were compared with the Japanese norm and tested by *t*-test. The scores of Skindex 29 among three different severity categories of acne were compared and tested by ANOVA. In addition, multivariate logistic regression analysis was done to examine association between QOL and patient's clinical variables described above. **Results:** Two hundred and four patients' data were available for analysis. The mean age was 24.5 years old and female were 78.9%. The mean scores of general QOL ('mental health', 'vitality', 'role emotional', 'role physical', and 'social functioning') were significantly lower than Japanese norm. Gender (female) and clinical severity of acne was significantly correlated with the 'emotion' and 'function' domain scores of Skindex 29. Odds ratios of having poor QOL (in 'emotion' and 'function' of Skindex 29 respectively) was 1.8 (95%CI 1.1–2.7) and 1.7 (95%CI 1.1–2.7) in acne's location being at their cheeks. **Conclusions:** The result of this study showed that acne lowers patient's QOL significantly, both in emotional and functional domain of QOL. Location of acne (cheek) is a very important predictor of one's QOL, independently of gender (female) and clinical severity.

#### # 1731/PILOT STUDY ON QUALITY OF LIFE OF VITILIGO PATIENTS FROM SOUTH CHINA WITH CANTONESE VERSION OF DLQI AND A SELF-DEVELOPED QUESTIONNAIRE

Wu Liangcai, Dermatology, 1st Affiliated Hospital of Sun Yat-sen University; Lu Nianzu, Dermatology, Sun Yat-sen University, Guangzhou, Guangdong Province, PRC

**Aims:** Vitiligo is an important skin disease having major impact on quality of life (QoL) of patients. The chronic nature of disease, long term treatment, lack of uniform effective therapy and unpredictable course of disease is usually very demoralizing for patients suffering from vitiligo. We design the present study to explore the QoL of vitiligo patients from South China with two different scales, Cantonese Version of Dermatology Life Quality Index (DLQI-C) and a self-developed Vitiligo Quality of Life Questionnaire (VQOLQ). **Methods:** 100 patients with vitiligo were enrolled from dermatology clinic. A 29-item Vitiligo Quality of Life Questionnaire (VQOLQ) was developed by the core study group including four dermatologists, one psychologist. **Results:** Of those 130 vitiligo patients, who responded to the survey, 112 patients returned the questionnaires (90.8%). However, only 103 questionnaires are valid (83.3%). And of the 120 acne patients, we retrieved 88 valid questionnaires (73.3%). The total mean DLQI-C score in vitiligo patients was 8 (SD = 5.22), higher than that in acne patients (6.97 ± 5.00). The disparity in the leisure facet, work and study facet had statistical significance. Using the unidimensional concept, the internal consistency coefficient (Cronbach's  $\alpha$ ) of DLQI-C was 0.8629. The Cronbach's  $\alpha$  of four facets were: symptoms and feelings (item 1 and 2) 0.7716; daily activities (item 3 and 4) 0.8780; leisure (item 5 and 6) 0.9166; personal relationships (item 8 and 9) 0.8647. The Cronbach's  $\alpha$  of VQOLQ was 0.8088 and its five subscales' Cronbach's  $\alpha$  were: 0.3435 for subjective health perception; 0.8577 for feelings; 0.7824 for thinking; 0.8544 for human communication; and 0.7591 for other affected areas. The correlations between WHOQOL-BREF, DLQI-C and VQOLQ were significant: Pearson correlation coefficient between DLQI-C and VQOLQ was 0.86

( $p < 0.01$ ); between DLQI-C and WHOQOL-BREF was 0.431 ( $p < 0.01$ ). In VQOLQ, the mutual correlation coefficients among the four factors ranged from 0.676 to 0.918 ( $p < 0.05$ ) except that the correlation coefficient between subjective health perception factors and other factors was lower than 0.5. Using multi-variant stepwise regression method, We screened out four influencing factors: Total area of white patches ( $b = 0.227$ ), VIDA score ( $b = 0.281$ ), age ( $b = -0.292$ ), educational background ( $b = -0.223$ ). **Conclusions:** Vitiligo is a chronic depigmentation disease mainly impacts patients' quality of life. DLQI-C scores were significantly associated with the total area of white patches, disease activity, educational background and age. We find that DLQI-C as a valid, reliable and clinically useful outcome measure for quality of life in vitiligo patients in Guangdong Province of China. On the basis of the findings of this study we also believe that vitiligo should not be considered as merely a cosmetic problem, and the clinical approach toward the patients with vitiligo should be multi-dimension.

#### # 1674/THE CORRELATIVE STUDY ON QUALITY OF LIFE IN VITILIGO PATIENTS AND ITS INFLUENCING FACTORS

Wu Liangcai & Lu Nianzu, Dermatology, Sun Yat-sen University, Guangzhou, Guangdong Province, PRC

**Aims:** Vitiligo is an important skin disease having major impact on quality of life (QoL) of patients. We design the present study to explore the QoL and the influencing factors in vitiligo patients with two different scales, Chinese version of WHOQOL-BREF, Cantonese version of DLQI (DLQI-C). And we aim to assess the reliability and validity of the DLQI-C. **Methods:** 100 patients with vitiligo were enrolled from dermatology clinic. And 88 Acne patients were chose as control group. A face-to-face survey was conducted in the subjects with vitiligo and acne. The questionnaire for patients of the two groups consisted of a request for demographic information, a checklist of basic data of the diseases and the two scales: WHOQOL-BREF, DLQI-C. **Results:** The total mean DLQI-C score in vitiligo patients was 9.34 (SD = 5.22), higher than that in acne patients (7.97 ± 5.00). The disparity in the leisure facet, work and study facet had statistical significance. The internal consistency coefficient (Cronbach's  $\alpha$ ) of DLQI-C and the four facets were above 0.7. The correlation between WHOQOL-BREF and DLQI-C was significant (Pearson correlation coefficient  $r = -0.431$ ,  $p < 0.01$ ). Factor analysis was adopted to assess the construct validity of DLQI-C as a unidimensional instrument. With the default criterion of an eigenvalue above 1.0 and cumulative % being 66.88%, A three-dimensional solution is to be preferred. Using multivariate stepwise regression method, We screened out four influencing factors with DLQI-C: Total area of white patches ( $b = 0.227$ ), VIDA score ( $b = 0.281$ ), age ( $b = -0.292$ ), educational background ( $b = -0.223$ ). **Conclusions:** Vitiligo is a chronic depigmentation disease mainly impact patients QoL. Total area of white patches, disease activity of vitiligo, educational background and age were the four main factors that influence patients' QoL. DLQI-C is a very good scale to measure QoL in vitiligo patients in Guangdong Province, China. It has been proved to have a good reliability and validity. It is meaningful to apply DLQI-C as an index in routine clinic and clinical trial.

# 1504/QUALITY OF LIFE FOR CHINESE PEOPLE WITH ACNE VULGARIS IN HONG KONG

K. M. Ho, N. C. Cheng, C. T. Tse, & K. K. Lo, Hong Kong, PRC

**Aims:** To study the impact of acne vulgaris on the quality of life (QOL) of local Chinese patients attending a public dermatology specialist clinic and the factors affecting the QOL of them. **Methods:** It is a cross-sectional survey using self-administered anonymous questionnaire. During the study period from March to June 2004, all clients attending the Dermatology clinic of Fanling Integrated Treatment Centre with the diagnosis acne vulgaris will be invited to participate the study. After informed consent, they will be given a questionnaire composed of (1) WHO QOL-BREF; (2) Chinese version of Skindex-29, to be filled on site. Two doctors (investigators) will perform the physician assessment on the disease severity for the participant on a 6-point scale. **Results:** Sixty-eight subjects (34 male, 34 female) were recruited. The Cronbach  $\alpha$  of the four domains (physical, psychological, social relationship and environmental health) of the WHOQOL-BREF was 0.66, 0.80, 0.55, & 0.67 respectively. The Cronbach  $\alpha$  of the three domains (functional, emotional, and symptom) of Skindex 29 were 0.94, 0.95, and 0.79 respectively. There was correlation between the two instruments. The QOL, measured by either of the instrument, of the subjects were not significantly associated with the age, gender and disease severity. **Conclusions:** By using the WHOQOL-BREF instrument to compare the QOL scores of the studied subjects with those with other medical illness, the physical and psychological health of the studied subjects were worse than the normal subjects and was comparable to those patients with cancer, cardiac diseases, stroke, renal disease and diabetes. The scores in the environmental and social relationship were comparable to the normal subjects. Both the generic and skin specific instruments were still less than ideal to assess the impact of acne vulgaris patients with respect to their QOL. Application of other instrument such as SF-36 or acne specific instrument should be explored in future studies.

# 1372/VALIDITY OF A NEW ADAPTIVE MEASURE OF HEALTH-RELATED QUALITY OF LIFE IN ARTHRITIS

Jacques Pouchot, Jacek A. Kopec, James Latteier, Eric C. Sayre, Fayed Al-Harthy, Donald Garbuz, Nelson Greidanus & Aslam Anis, Health Care and Epidemiology; John M. Esdaile, Rheumatology, Arthritis Research Centre of Canada, Vancouver, BC, Canada

**Aims:** We developed an adaptive, Item Response Theory based questionnaire to measure health-related quality of life (HRQL) in arthritis. The instrument produces scores for five domains of HRQL and an overall utility score (ISOQOL 2003). The purpose of this study was to examine cross-sectional and longitudinal validity of this new measure. **Methods:** Data were obtained by a self-administered mailed questionnaire from patients with osteoarthritis (OA) while on the waiting list for total joint replacement surgery (Time 1) and 2 years later (Time 2). Outcome measures included the new questionnaire, WOMAC OA Index, Oxford-12, and SF-12. There were 126 patients who responded at Time 2 (70% follow-up rate). To assess cross-sectional validity, we tested hypotheses about the relationships of our measure with other outcomes, sociodemographic, and clinical variables. Longitudinal validity was measured by effect size (ES), comparing scores at two points in time. **Results:** Overall utility scores on the adaptive questionnaire correlated as expected with total WOMAC ( $r = 0.70$ ) and Oxford-12 ( $r = 0.67$ ) scores, as well as SF-12 Physical ( $r = 0.70$ ) and Mental Health Component ( $r = 0.45$ ). Ceiling effect at Time 2 was 0% for the overall score, and ranged from 0 to 7% for the domains, compared with 10% for the WOMAC total and 11% for Oxford-12. Overall scores were associated with education, medication use, co-morbidity, and having surgery. Patients with longer time after surgery tended to have better scores on most measures; however, the effect was statistically significant only for the adaptive questionnaire (walking, daily activities, and feelings domains). The ES comparing patients before and after surgery ranged from 0.5 for the handling objects domain to 1.7 for pain/discomfort. **Conclusions:** The adaptive questionnaire demonstrated both cross-sectional and longitudinal validity in patients with advanced OA of the hip and knee, had virtually no ceiling effect post-surgery, and was better able to discriminate between patients assessed at different times after surgery than standard disease-specific and generic outcome measures in OA.

# 1602/CONTENT VALIDITY OF THE OAKHQOL (OSTEOARTHRITIS KNEE HIP QUALITY OF LIFE) INSTRUMENT

Anne-Christine Rat, Epidemiology; Michèle Baumann, Sociology, University of Nancy, Vandoeuvre; Joël Coste, Biostatistiques, hôpital Cochin, Paris; Francis Guillemin, Epidemiology, University of Nancy, Vandoeuvre; Jacques Pouchot, Internal medicine, hôpital Louis Mourier, Garennes les Colombes; Nathalie Retel-Rude, Biostatistiques, University of Besançon, Besançon; Elizabeth Spitz, Psychology, University of Metz, Metz, France

**Aims:** Objective: to examine the content validity of the OAKHQOL by comparing its items with the items of instruments frequently used in OA. **Methods:** 96 patients with hip or knee OA and 32 health professionals taking care of OA patients taped interviews were transcribed and analysed by three teams of psychologists and sociologists. A total of 80 verbatims pertaining to quality of life was identified. The selection of the items was based first on the content of the 80 derived items then on the psychometric properties of the remaining 46 items tested on a sample of 263 patients. The final version of the OAKHQOL is a self-administered questionnaire of 43 items. A qualitative analysis comparing the 43 items of the definitive version of the OAKHQOL to the items of the SF36 was conducted by a panel of experts. The same analysis was made with the WOMAC and the Lequesne scales. **Results:** When comparing the OAKHQOL to the SF36 many themes were exclusive to the OAKHQOL (e.g.: social support, sleep, side effects of drugs, plan for the future, the embarrassment to be seen by people, the use of public transportation, the difficulty to move after staying in the same position and sexuality). In this regard, 24 items were OAKHQOL exclusive. On the opposite, four items of the SF36 were not in the OAKHQOL: general health and locus of control items. Among the 20 physical activity and pain items of the OAKHQOL, only 45 and 50% were part of the WOMAC and of the Lequesne indices. Four new items were raised by more than 50% of patients during interviews. **Conclusions:** The OAKHQOL is able to capture specific aspects of HRQL encountered by patients with knee and hip OA. It is easy to use, short and has the advantage to allow for the use of only one instrument instead of a battery of different scales.



# 1551/RESULTS OF THE FIELD STUDY OF AN INTERNATIONAL PATIENT-CENTERED QUALITY OF LIFE SCALE FOR MULTIPLE SCLEROSIS: MUSIQOL

Pascal Auquier, Department of Public Health, School of Medicine; A. Beresniak, Marseille, France; O. Fernandez, Neurology, Hospital, Marbella, Spain; P. Flachenecker, Neurology, Wurzburg, Germany; J. Pelletier, Neurology, School of Medicine; Marseille, France; S. Stecchi, Neurology, Hospital, Bologna, Italy; C. Constantinescu, Neurology, Hospital, Nottingham, UK; E. Pillet, Public Health, University Medicine; M.C. Siméoni, Public Health, University Hospital of Marseille, Marseille, France; D. Patrick, Department of Health Services, Washington University, Seattle, WA, USA; S. Robitail, Public Health, University Hospital of Marseille, Marseille, France

**Aims:** The MuSIQoL Questionnaire is a multidimensional self-administered specific health-related quality of life scale for multiple sclerosis (MS). It focuses on concerns identified by patients with MS and has been developed simultaneously in several languages like English, French, German, Spanish, and Italian. We conducted a validation study, in 12 countries: Argentina, Germany, UK, Spain, France, Israel, Italia, Lebanon, Turkey, Norway, Russia and South Africa, including 1428 patients with relapsing-remitting, primary progressive and secondary progressive MS and with isolated clinical syndromes. **Methods:** Patients fulfilled MuSIQoL, SF36, symptoms questionnaire at day 0 and day 21. Physicians reported socio-demographic data, clinical evaluation (history, EDSS, ambulation index, cognitive problems, CGI, treatments). **Results:** The randomly split-sample approach has been used. Several models have been considered issued from exploratory factor analyses cluster analyses, experts' point of view. For each model, psychometric properties have been tested and number of item reduced via Mokken scale analyses (MSP), Rasch Partial Credit Modelling (PCM), Differential Item Functioning (DIF: Zumbo's logistic regression method), MAP analyses and Confirmatory factor analyses (CFA). Analyses have been led by countries, clinical form, age and gender groups. Analyses, isolated a version describing six major domains: Psychological and physical well-being, social relationships, relations with caregivers, self-esteem and body image (MAP analysis, Factor Analysis, Rasch). Cronbach's  $\alpha$  are over 0.7 and ICC satisfactory. **Conclusions:** The final results will be presented.

# 1532/QUALITY OF LIFE ASSESSMENT AS A CORRECTIVE FOR PRIMARY SURGICAL TREATMENT AFTER ORTHOPAEDIC TRAUMA

Hans Josef L. Ertl, Department of Trauma Surgery; Marc Bruegmann, Institute of Medical Psychology and Sociology; Richard M. Sellei, Department of Trauma Surgery, University Hospital RWTH Aachen; Aachen; Joachim Kugler, Institute of Medical Biometry, Technical University of Dresden, Dresden, Germany

**Aims:** After having performed several QoL-trials in patient collectives after orthopaedic trauma, the question appears, which significance QoL measures can have for the medical practice in orthopaedic surgery. **Methods:** Retrospective clinical outcome trials including quality of life assessment were performed by an interdisciplinary study-group for different collectives of patients after orthopaedic trauma. Studies were performed for multiple trauma patients ( $n = 173$ ), elderly female patients after hip-fractures ( $n = 78$ ) and patients with severe knee injuries (matched pair study,  $n = 18$ ). An ongoing trial is concerned with patients after vertebral fractures. In each study clinical outcome was determined by physical and radiological investigation and application of clinical outcome scores. NHP, Spitzer-Index, ELQ, SF-36 and REALOS (a 42 item QoL-questionnaire, developed for patients after orthopaedic trauma) were used for Quality of Life assessment (REALOS). Demographic data, classification and severity of the injury, treatment data and clinical outcome were correlated with the QoL measures and screened for predictors for the long-term quality of life. **Results:** In all trials so far evaluated, we found a close correlation between clinical outcome scores and the results of the QoL measures. In all studied collectives QoL outcome is correlated to demographic, injury- and treatment related data. Calculating multiple regressions it was found, that variables were most predictive for the quality of life outcome, which were related to the quality of the primary surgical reconstruction. **Conclusions:** Clinical outcome scores were not found superior to QoL measures for patients after orthopaedic trauma in our

trials, even if those scores assess physical and radiological data. An outcome assessment with more comfort for the patient seems possible. QoL after orthopaedic trauma seems to be predicted to a high extent by variables of the primary surgical therapy allowing a quality control also of this phase of a treatment.

# 1415/CONSTRUCT VALIDITY OF THE HEALTH UTILITIES INDEX MARK 2 AND MARK 3 AND THE FUNCTIONAL INDEPENDENCE MEASURE IN PATIENTS WITH HIP FRACTURES

C. Allyson Jones, Physical Therapy; David H. Feeny, Pharmacy and Pharmaceutical Sciences, University of Alberta; Ken Eng, Institute of Health Economics, Edmonton, AB, Canada

**Aims:** The Health Utilities Index Mark 2 and Mark 3 (HUI2/3) have not been used in patients recovering after hip fractures. The objective was to examine the construct validity of the HUI2, HUI3, and FIM<sup>®</sup> within a prospective cohort of patients with hip fracture. **Methods:** Patients completed the HUI2/3 and FIM<sup>®</sup> within 3–5 days of surgery, and 1, 3, and 6 months after surgery. The expected relationships between the HUI2, HUI3 and the FIM<sup>®</sup> were identified a priori by a clinician and health economist for two periods of time; during the acute recovery (baseline and 1 month) and sub-acute recovery (3 and 6 months). Correlations were calculated for overall scores and single attribute scores at all four time periods and compared to the associations defined a priori. **Results:** Correlations were examined in 270 patients who were primarily women (71%). The mean age was 81.2 (sd 7.6) and mean number of comorbid conditions was 5.3 (sd 2.8). Overall the relationships of the HUI2 and HUI3 were consistent with the FIM<sup>®</sup> score. Forty to 53% of the a priori predictions were confirmed. When predictions were incorrect, 85% of predictions were off by only one category. Overall HUI2 and HUI3 scores were strongly correlated ( $r > 0.50$ ) with the FIM<sup>®</sup>. HUI3 ambulation and HUI2 mobility were strongly correlated with the FIM<sup>®</sup> locomotion. Correlations did not change substantially over time. **Conclusions:** In general the expected relationships were observed. The HUI2, HUI3 and FIM provide useful information for patients with hip fractures.

#### # 1184/ICF – DOES IT COMPREHENSIVELY COVER HEALTH PROBLEMS OF PATIENTS WITH MUSCULOSKELETAL CONDITIONS?

Martin Weigl, Alarcos Cieza & Gerold Stucki, ICF Research Branch of the WHO CC FIC (DIMDI), Ludwig-Maximilians-University, Munich, Germany

**Aims:** To examine whether the ICF comprehensively covers the spectrum of health problems encountered by health professionals in patients with musculoskeletal conditions. **Methods:** A world-wide Delphi exercise per e-mail was conducted. Representatives from the WHO and partner organizations were requested to name experts for rheumatoid arthritis, osteoporosis, osteoarthritis and low back pain. Condition specific questionnaires were used to ask for relevant and/or typical body functions (BF), body structures (BS), activities and participation (AP) and environmental factors (EF) in patients with one of the musculoskeletal conditions. Answers were linked to the ICF and then grouped into five categories: (1) Identical: ICF category has an identical meaning. (2) ICF less specific: ICF category encompasses the same concept, but is less specific. (3) Resp. less specific: ICF categories are more specific and the response therefore encompasses more than one ICF category. (4) ICF similar: ICF category has a similar but not identical meaning. (5) Not represented. **Results:** The 84 responders (Response rate 44%) came from four different continents. All responses could be linked to the ICF, with the exception of 67 named personal factors, that are not classified in the ICF. The table shows the precision of the linkage. **Conclusions:** The ICF comprehensively covers the spectrum of problems encountered in patients with musculoskeletal conditions by experts throughout the world. This fact strengthens the validity of the ICF in the view of the users and will encourage the use of ICF based applications such as the new developed condition specific ICF Core Sets.

ICF component	Dierent response	% ICF identical	% ICF less spec.	% Resp. less spec.	% ICF similar
BF	108	49	42	5	6
BS	134	47	40	9	1
AP	155	51	40	9	1
EF	200	32	59	5	1

#### # 1123/BODY IMAGE ENHANCEMENT PROGRAM FOR PATIENTS AFTER AMPUTATION

Frank H. Lai, Keith T. Yip, Occupational Therapy Department, Antonia K. Soo Occupational Therapy, Simon K. Wong, Occupational Therapy Department, Tai Po Hospital, Tai Po, Hong Kong

**Aims:** Body image is crucial to the successfulness of rehabilitation. Negative body image after limb amputation is a universal problem, a common struggle many amputees share. The aim of this study is to assess the effectiveness of a Body Image Enhancement Program (BIEP) for patients after amputation. **Methods:** The BIEP consists of 10 sessions, the program targeted at decreasing body dissatisfaction, to develop a sense of ownership, and control of perceptions and feelings about their own body. Techniques applied including cognitive behavioural therapy, counseling, functional training, touch therapy, relaxation training, life-style redesign. Measurement tools including Mini Mental State Examination (MMSE), Functional Independence Measure (FIM), Amputee Body Image Scale (ABIS), Personal Well-being Index (PWI). **Results:** 37 patients (20 males and 17 females) with mean age 71.48 were recruited. Admission ABIS score was 49.53 (sd + 14.58), while discharge ABIS score was 47.85 (sd + 11.70), which showed a gentle reduction in body image disturbance. Decreased anxiety and worries on body appearance in social environment was noted. Moreover, there was improvement noted in acceptance of body functioning, and less "fear" in public area. In the dimension of subjective well-being, patients showed improved satisfaction on their life as a whole. Improved satisfaction in their standard of living, and community engagement was noted. Significant correlation noted between discharge ABIS score and FIM change ( $r = -0.68$ ,  $p < 0.01$ ). Therefore, it can be connoted that change in motor function

of amputee patients was correlated to body image. Elder patients showed better acceptance in newly acquired body image than younger patients. Illiterate patients had more difficulties in handling concepts from cognitive behavioral therapy. **Conclusions:** Addressing negative body image could be a key factor to the rehabilitation of patients with amputation. By grabbing the root of the problem – negative body image, it might be easier to succeed in producing more effective and long-lasting rehabilitation outcome.

#### # 1120/ITEM RESPONSE ON MOTOR PERFORMANCE FOR GERIATRIC PATIENTS WITH HIP FRACTURES IN HONG KONG

Frank H. Lai, Occupational Therapy, Tai Po Hospital, Tai Po, Hong Kong; Eric Wong, Centre of Epidemiology and Biostatistics, The Chinese University of Hong Kong, Shatin, Hong Kong; Antonia K. Soo & Simon K. Wong, Occupational Therapy, Tai Po Hospital, Tai Po, Hong Kong

**Aims:** To compare on the Rasch-based psychometric properties of Functional Independence Measure (FIM) and Modified Barthel Index (BI) on motor performance for geriatric patients with hip fractures in Hong Kong. **Methods:** Retrospective cohort of 357 geriatric patients with hip fractures admitted consecutively to a rehabilitation hospital were recruited in this study. Both the FIM and BI were administered to the same patients at admission and discharge. Rasch analysis was conducted to test on the flooring and ceiling effects, sensitivity to change, difficulty patterns and usefulness of the two outcome measures. The masters' partial credit model was used with WINSTEPS version 3.04 software. **Results:** The results suggested similar flooring and ceiling characteristics between FIM motor subscale and BI at admission. The item characteristics between the two measures were different. The item invariance remained stable across the patient samples in admission and discharge. In addition, FIM motor subscale showed similar precision and sensitivity as BI. Sensitivity of change of both FIM motor and BI was both 0.84. Hierarchical structures of two measures were similar. The items 'eating' and 'feeding' were the easiest while 'climbing stairs' and 'bathing' were the most difficult on the measurement continuum. **Conclusions:** Rasch analysis substantiates the usefulness of both FIM motor subscale and BI in assessing motor performance, which may need further revision or shortening, for Chinese geriatric patients with hip fractures. Future studies are required to confirm these findings.

#### # 1108/COMPARISON OF THE WHOQOL-BREF AND SF-36 FOR PERSONS WITH SPINAL CORD INJURY IN TAIWAN

Mau-Roung Lin, Institute of Injury Prevention and Control, Taipei Medical University; Hei-Fen Hwang, Nursing, National Taipei College of Nursing; Chih-Yi Chen & Wen Ta Chiu, Institute of Injury Prevention and Control, Taipei Medical University, Taipei, Taiwan, ROC

**Aims:** To compare the psychometric performance of the brief version of the World Health Organization Quality of Life (WHOQOL-BREF) with the Short-Form 36 (SF-36) for people with traumatic spinal cord injury (SCI) in Taiwan. **Methods:** A total of 187 SCI subjects from a nationwide registry of traumatic SCIs were interviewed by telephone. Score distributions, internal consistency, and convergent and discriminant validities of the WHOQOL-BREF and SF-36 were compared. **Results:** Both the WHOQOL-BREF and the SF-36 exhibited good internal consistency and low missing values. Furthermore, the WHOQOL-BREF's four domain scores also had the lowest percentages of ceiling and floor values. The WHOQOL-BREF's domain scores were convergent with corresponding scores in the SF-36, and better discriminated between groups with respect to eight selected characteristics (i.e., age, gender, education, marital status, employment, time since injury, and level and cause of injury) than did the SF-36. **Conclusions:** The WHOQOL-BREF has a better psychometric performance than the SF-36 for people with traumatic SCIs.

#### # 1084/HEALTH RELATED QUALITY OF LIFE IN LOW BACK PAIN PATIENTS TREATED USING INSTRUMENTED FUSION

Signe Berit Bentsen, Department of Health and Primary Health Care, University of Bergen, Vedavagen, Norway

**Aims:** The aim of this study was to determine the health related quality of life in low back pain patients treated using instrumented fusion, based on the patients subjective responses after surgery. **Methods:** The samples consisted of 101 Norwegian adult patients treated using instrumented fusion for chronic low back pain recruited for a Swedish hospital between 1993 and 2000 (response rate 80%). The patients filled in a questionnaire consisting of (1) demographic data, (2) SF-36 Health Survey. 71% of the sample was female and the mean age was 46 years (SD8.9), age range 26–60. **Results:** SF-36 scores; Physical functioning = 64(SD26.2), role physical functioning = 39(SD44.7), bodily pain = 54(SD33.3), general health = 65(SD24.7), vitality = 53(SD23.2), social functioning = 68(SD32.2), role emotional functioning = 77(SD40.1), mental health = 78(SD20.9). The low back pain patients had 10 points lower scores than the normal Norwegian population on physical functioning, role physical functioning, bodily pain, general health and social functioning. **Conclusions:** The SF-36 scores show that the low back pain patients had less physical functioning, role physical functioning, general health and social functioning, and more bodily pain compared to the Norwegian normal population norms.

#### # 1262/WHICH DOMAINS OF HEALTH-RELATED QUALITY OF LIFE ARE IMPORTANT IN HIP AND KNEE OSTEOARTHRITIS? A QUALITATIVE SYSTEMATIC LITERATURE REVIEW

Feng Xie & Shu Chuen Li, Pharmacy, National University of Singapore Julian Thumboo; Rheumatology and Immunology, Singapore General Hospital,

**Aims:** Knee and hip osteoarthritis (OA) are among the commonest forms of arthritis worldwide and are associated with pain and reduction in physical function, leading to a significant impact on Health-related quality of life (HRQoL). However, little is known about the nature and importance of domains of HRQoL and items in these domains in patients with OA. Additionally, it is not clear if these domains are constant or vary across cultures. This study thus aimed to identify domains/items of importance in patients with hip or knee OA. **Methods:** A qualitative systematic literature review was performed using several. **Methods** (1) 2 overlapping search strategies in Medline, PsycINFO, ISI web of knowledge and Cochrane Library using relevant keywords (knee or hip OA combined with 18 other keywords; names of OA-specific instruments) (2) a manual search of relevant journals, textbooks and bibliographies. Titles and abstracts were reviewed to select potential articles for full text review using predefined criteria. **Results:** From 19,181 references, 76 articles were selected for full text review, of which 12 articles fulfilled inclusion criteria (3 specifically assessing domains/items in hip or knee OA, 9 containing such information but not directly assessing these domains/items). Studies were conducted in English (USA( $n = 4$ ), United Kingdom( $n = 2$ ), Ireland( $n = 1$ ) and Canada( $n = 1$ )), French ( $n = 2$ ) and Swedish ( $n = 2$ ). HRQoL domains of importance included pain, physical disability, mental health, and social health. Some items in the pain domain differed across countries, possibly related to actual or methodological differences. Several items common across various countries were identified in the physical disability domain (e.g. standing, housekeeping, walking). **Conclusions:** A surprisingly sparse literature exists on domains of HRQoL and items in these domains that are important in patients with knee or hip OA. Existing work has been mainly from Europe and North America. Such studies are urgently needed to confirm that OA specific measures are truly accurate & comprehensive when applied in various socio-cultural contexts.

#### # 1453/DEVELOPMENT OF DIFFERENT LANGUAGE VERSIONS OF A US BACK PAIN QUESTIONNAIRE

Katrin Conway, Laurence Chevallet, Mapi Research Institute, Lyon, France, Beth L. Barber & Sandra Gavart, Health Outcomes, Eli Lilly, Indianapolis, IN, USA; Michael C. Nevitt, Division Preventive Medicine, UCSF Coordinating Center, San Francisco, CA, USA

**Aims:** Measuring back pain for further clinical research required the linguistic validation of a 9-item questionnaire developed in US English.

Based on the assumption that the original concepts were universally appropriate, we aimed to develop language versions of a US back pain questionnaire according to a rigorous methodology to ensure the conceptual equivalence between the original and the translations. **Methods:** The process was conducted by a specialist in each target country using the following standardized methodology: (1) two forward translations by professional translators, native speakers of the target language and fluent in English; (2) comparison and reconciliation of the translations by the specialist in the target country and the translators; (3) backward translation by a native English speaker; (4) comparison of source and backward version; (5) comprehension test on five individuals suffering from back pain and review by one clinician. **Results:** Issues regarding the universal appropriateness of the original concepts emerged during the creation of the 35 language versions. Items investigating the respondent's ability to get in and out of his car had to be reformulated in countries where the ownership of cars was rare. Similarly for countries in which people did not wear socks or stockings an alternative question had to be found. **Conclusions:** The 35 language versions were established according to a rigorous translation methodology. The process ensured the conceptual equivalence of all language versions to facilitate the international comparison and pooling of data. This process also reveals that the original concepts are not necessarily universally appropriate. This indicates the necessity to integrate international feedback on concepts before the original questionnaire is finalized to facilitate the cross-cultural equivalence of concepts.

#### # 1376/SEXUAL FUNCTIONING AND LONG-TERM PROSTATE CANCER SURVIVORSHIP: COMPARISON OF ASIAN/PACIFIC ISLANDER AND WHITE SURVIVORS

Miles Y. Muraoka & Carolyn C. Gotay, Cancer Research Center of Hawaii, University of Hawaii, Honolulu, HI

**Aims:** We compared sexual functioning in long-term prostate cancer survivors of Asian/Pacific Islander (API) and Caucasian descent. Information about late effects in prostate cancer survivors is lacking, as well as information about API survivors. **Methods:** Participants were identified through a population-based statewide tumor registry and were between 5 and 11 years post-diagnosis with localized disease at time of diagnosis. The sample was comprised of 381 API and 148 White men; mean age of all participants was 77.0 years (range 49-96). Data were collected through mailed questionnaires that included standardized scales and supplemental items to address relevant outcomes. Reported here is the sexual functioning subscale of the prostate cancer module of the EORTC QLQ-C30. This composite score assessed interest, arousal, and enjoyment. Items from the Sexual Adjustment Questionnaire (SAQ), which assessed desire, satisfaction, and effects of cancer on survivors' sexual relationship, are also reported. **Results:** The results showed that White survivors had higher (poorer) QLQ-C30 composite sexual functioning scores relative to API survivors,  $t(447) = 1.79, p < 0.02$ . There was a suggestion that White survivors reported greater negative impact of cancer on their sexual relationship than API survivors,  $t(338) = 1.83, p < 0.07$ . Correlations between the composite score and global QOL ratings were significant for White ( $r = -0.36, p < 0.001$ ) but not API ( $r = -0.09, p > 0.10$ ), men. **Conclusions:** Our findings suggest that for elderly Caucasian long-term prostate cancer survivors, sexual functioning and activity are important components of their QOL, relative to API survivors. These differences were maintained in multiple regression analyses that controlled for clinical and demographic variables. Even though sexual dysfunction had a negative impact on White men's global QOL ratings, only 6% sought therapy for sexual dysfunction (less than 2% of API reported the same). Cancer care needs to incorporate long-term follow-ups for the increasing number of cancer survivors, including assistance with QOL issues such as sexuality. Services need to reflect cultural and ethnic differences in values and preferences.

# 1151/PERSONAL AND SOCIAL RESOURCES PROMOTE DIFFERENT ASPECTS OF HRQOL IN MEN AND WOMEN WITH CANCER

Sonja Boehmer & Ralf Schwarzer, Health Psychology, Free University of Berlin, Berlin, Germany

**Aims:** Personal and social resources can facilitate the adjustment to critical life events such as being diagnosed with cancer. The present study investigated gender effects on (a) the progression of different facets of subjective health-related quality of life (HRQOL) after cancer-related surgery, (b) the way self-efficacy and social support may influence the adjustment to cancer, and c) the role coping may play in this process. **Methods:** Data were collected from cancer patients 1 month (T1), 6 months (T2) and 1 year after (T3) surgery (n = 130, 60% male, aged between 24 and 86 years). The questionnaire assessed emotional, functional and social well-being, global HRQOL, general self-efficacy, received social support, and coping strategies. Repeated measures ANOVA, and multiple regression were used for data analyses. **Results:** Patients improved in all facets of HRQOL over time. Interactions with gender were observed in the progression of global HRQOL, emotional, and social well-being. Between T1 and T2, lack of support predicted depression ( $\beta = 0.23$ ), and self-efficacy predicted physical and social well-being ( $\beta = 0.26$  and  $0.28$ ) in women. In men, lack of support also predicted depression ( $\beta = 0.16$ ), but self-efficacy did not predict any facets of well-being. Between T2 and T3, lack of support did not affect any domain of well-being in both genders, whilst self-efficacy predicted future global HRQOL, physical and social well-being in male patients ( $\beta = 0.39$ ,  $0.24$ , and  $0.27$ ), and global HRQOL, physical and emotional well-being in female patients ( $\beta = 0.24$ ,  $0.19$ , and  $0.22$ ). In neither men nor women the effects of self-efficacy and received support were mediated by coping. **Conclusions:** Self-efficacy and social support promote different aspects of well-being in male and female cancer patients. Social support is more effective at the beginning, but later on in the adaptation process, optimistic self-beliefs to cope with difficult demands become more important.

# 1152/DOES PERCEIVED AGE REFLECT HEALTH-RELATED QUALITY OF LIFE IN CANCER PATIENTS?

Sonja Boehmer & Nihal E. Mohamed, Health Psychology, Free University of Berlin, Berlin, Germany

**Aims:** Many studies have found relationships between aspects of subjective ageing and health. Morbidity and functional capacity are important predictors of perceived age. The present study on post-surgical cancer patients addressed two questions: (1) Do people differ in their subjective health status, quality of life, and personal and social resources, depending on their felt age? (2) Is change in felt age associated with change in subjective health and quality of life? **Methods:** Data were collected at three times, i.e., 1 month (T1), 6 months (T2) and 1 year (T3) after cancer surgery (N = 130; 60% men, aged 24 to 86 years). The questionnaire comprised the EORTC-QLQ-C30, the General Self-Efficacy-Scale, the Berlin Social Support Scales, and an assessment of felt age. Repeated measures ANOVAS and t-tests for independent samples were used for data analyses. **Results:** In general, patients' subjective health status and quality of life improved over time. At all measurement times, almost 50% of the patients subjectively felt younger than their chronological age. In contrast, the percentage of patients subjectively feeling older increased from 18.5 to 47.2% over all points of measurement. Patients subjectively feeling younger reported better health, higher quality of life, and higher general self-efficacy than those subjectively feeling older. The groups did not differ in terms of received social support. Between T1 and T2, an increment of felt age was found in 26.2% and a decrement in 36.9% of cases, and between T2 and T3, an increment was found in 31.5% and a decrement in 44.4% of cases. Subjective health and quality of life improved also among those patients who subjectively aged over time; but improvements were found in fewer aspects and with substantially lower effect sizes than among those with a decrement of felt age. **Conclusions:** Subjective health status and quality of life are correlates of felt age. But an increment in felt age does not imply a decrease of quality of life.

# 1182/QUALITY OF LIFE IN THE TWO YEARS AFTER SURGERY FOR NON-SMALL CELL LUNG CANCER

Patricia M. Kenny, Madeleine T. King & Rosalie C. Viney, Centre for Health Economics Research & Evaluation, University of Technology Sydney, Sydney, Australia; Michael J. Boyer & Christine Pollicino, Medicine, University of Sydney, Sydney, Australia; Michael J. Fulham, Medicine, University of Sydney, Sydney, Australia; Jocelyn McLean & Brian C. McCaughan, Cardiothoracic Surgery, Royal Prince Alfred Hospital, Sydney, Australia

**Aims:** Surgery for early stage lung cancer is known to have a substantial impact on health related quality of life (HRQOL), but little is known about HRQOL in the long term. This study aims to describe the short and long term effects of treatment and disease on HRQOL. **Methods:** The sample comprised 173 adults who received surgical treatment for clinical stage I or II non-small cell lung cancer. The setting was a randomised trial of preoperative positron emission tomography (PET), which found PET had no effect on patient management and outcomes. Participants completed HRQOL questionnaires before and after surgery (94% response), one month after surgery (83% response) and then four monthly for two years (completed by 83% of 2-year survivors). HRQOL was measured with a generic cancer questionnaire (QLQ-C30) and a lung cancer specific questionnaire (QLQ-LC13). Multilevel modeling was used to examine the impact of surgery and any subsequent therapy. **Results:** Surgery significantly reduced HRQOL across all dimensions except emotional functioning. For patients who were disease-free at the end of follow-up (65%), HRQOL improved over the two years following surgery, returning to preoperative levels in most dimensions except physical and role functioning. The HRQOL of patients with disease recurrence (35%) remained poor in most dimensions including overall quality of life. The HRQOL of patients with recurrent disease was worse at all measured time points, including preoperatively. **Conclusions:** Surgery had a substantial impact on HRQOL, and only disease free survivors experienced recovery of HRQOL. Longitudinal HRQOL assessment can enhance the evidence base for treatment decision making in early stage lung cancer.

# 1392 QUALITY OF LIFE (QOL) IN LONG-TERM SURVIVORS OF *IN SITU* AND INVASIVE CERVICAL CANCER (CERV CA)

Carolyn C. Gotay, Crissy T. Kawamoto & Adela Mearig, Cancer Research Center of Hawaii, University of Hawaii, Honolulu, HI

**Aims:** This study assessed QOL in women diagnosed with *in situ* or invasive cerv ca 15–25 years before. Little is known about QOL in survivors so far post-diagnosis, or in cerv ca survivors. Most ca registries no longer track *in situ* cerv ca. The study provided a unique opportunity to describe QOL in these women and explore effects of disease severity. **Methods:** A population based ca registry identified women diagnosed with cerv ca 1975-1985. Data were collected in mailed surveys using standardized questionnaires in 99 survivors (n = 69 *in situ*, n = 30 invasive). The response rate of 34% was the same in both groups. Data analysis included descriptive statistics and regression; findings below are significant at  $p < 0.05$ . **Results:** The two survivor groups did not differ on any SF-36 scales; compared to population norms, they were comparable on mental health and better on physical functioning. Invasive survivors had worse scores than *in situ* survivors on Fear of Intimacy (FIS) and Index of Femininity scales; however, they had significantly more social ties. FIS scores for invasive survivors were significantly worse than comparative data. Almost half (48%) of invasive survivors & 20% of *in situ* survivors reported that their current QOL was directly related to their cerv ca experience. **Conclusions:** These findings illustrate the very long-term consequences of cerv ca treatment. While both groups were comparable on most functional measures, more subtle differences in self by concept were seen. Invasive cerv ca continued to be a major influence on survivor QOL a quarter of a century after diagnosis. Survivors were difficult to reach due to outdated contact information. Health care systems need to develop tracking mechanisms for long-term follow-up of the increasing numbers of ca survivors to understand their needs and implement appropriate interventions.

## # 1612/A NEGLECTED SYMPTOM OF CANCER: INSOMNIA

John F. Babson, General Education, Hong Kong Polytechnic University, Hong Kong, PRC; Candace Ho, Clinical Oncology, Tuen Mun Hospital, Hong Kong, PRC; Fung Ling Ho, Psychology, University of Hawaii at Manoa, Honolulu, HI; Kin Man Mak, Applied Math, Hong Kong Polytechnic University, Hong Kong, PRC

**Aims:** Insomnia is a common but often neglected problem in both cancer patients and medical professionals alike. It can be devastating to the patient's QOL, at times even more serious than the physical symptoms of their disease. It is the purpose of this study to investigate the clinical characteristics of sleep problems and its impact on the QOL in breast cancer (BC) and nasopharyngeal cancer (NPC) patients. **Methods:** Subjects aged 18 and up, with a single cancer diagnosis of NPC or BC, completed treatment, and no recurrence in the past 5 years were recruited in a Hong Kong cancer center. Data collection was conducted on a medical visit until the targeted number of subjects was reached. A total 40 male NPC, 40 female NPC, and 40 BC patients participated. Descriptive statistics revealed the clinical characteristics of insomnia among the subjects. Impact of cancer on the quality of sleep was examined by performing paired *t*-test for the pre- and post-cancer diagnosis. Pearson correlation was conducted to compare the relationship between insomnia and other psychological factors. **Results:** Insomnia was found to be highly correlated with anxiety, depression, and PTSD. After diagnosis, patients in all three groups suffered increased sleep problems while the male NPC patients are affected most. Fatigue (over 60%) and reduced daily functioning (40%) were reported by patients as resulting from insomnia. Common ways to handle insomnia are by doing nothing (35.8%), relaxation (38.8%), and using medication (17.9%). **Conclusions:** Findings in this study showed the neglect of insomnia in cancer care. Medical professionals should treat insomnia as another symptom. Patients should be educated on effective treatment, both pharmacological and psycho-behavioral to improve the QOL.

# 1350/INCIDENCE AND IMPACT OF CHEMOTHERAPY INDUCED NAUSEA AND VOMITING (CINV) ON THE DAILY LIFE OF PATIENTS IN TAIWAN: A PROSPECTIVE OBSERVATIONAL STUDY  
Robert R. Deuson, Outcomes Research, Merck and Co. Inc., Whitehouse Station, PO Box 100, NJ, USA; Chi-Ting Liao & Jen-Shi Chen, Division of Hematology-Oncology, Chang Gung Memorial Hospital; Hsueh-Erh Liu, School of Nursing, Chang Gung University, Taoyuan Kweishan; Nei-Min Chu, Division of Hematology and Medical Oncology, Sun Yat-sen Cancer Center; Guang-Yang Yang, Christina Lac & Jade Lien, Medical Department, Merck, Sharp & Dohme(I.A.) Corp., Taipei, Taiwan, ROC.

**Aims:** To assess the incidence of acute and delayed CINV among chemotherapy (CTx) patients and to estimate the impact of CINV on their daily life. **Methods:** In two oncology centers in Taiwan, acute (first 24 h post-CTx) and delayed (days 2-5 post-CTx) nausea (N) and vomiting (V) were assessed prospectively. CTx-naïve patients completed a 5-day N/V diary following cisplatin-based highly emetogenic (HEC) and moderately emetogenic (MEC) CTx. Nausea ratings were recorded daily on a 100 mm visual analogue scale (VAS) along with vomiting episodes. No N was VAS <5 mm. Impact of CINV on patient daily life 5 days post-CTx was estimated using the Functional Living Index Emesis (FLIE) instrument. End-point: minimal or no impact of CINV on daily life is an average item score >6 on a 100 mm, 7-point scale with anchors: 1 for a great deal to 7 for not at all. **Results:** 110 patients enrolled, 107 patients were followed through 1st cycle of CTx. Mean patient age was 49 ± 10; 76% female; 74% breast cancer. Antiemetic prophylaxis: 94% dexamethasone; 74% metoclopramide; 21% diphenhydramine; 77% a 5-HT3 antagonist. HEC patients (39%) experienced acute N/V (43/21%) and delayed N/V (64/60%). MEC patients (61%) experienced acute N/V (55/18%) and delayed N/V (73/55%). Mean FLIE scores were <6 for all items in both domains (N/V) with less than 47/52% patients reporting minimal or no impact of N/V on daily life. **Conclusions:** Despite the use of modern antiemetics, CINV continues to be a significant clinical problem in Taiwan that impacts negatively on the ability of over half of patients to enjoy daily living activities.

## # 1371/IMPACT OF NAUSEA AND VOMITING ON QUALITY OF LIFE IN PATIENTS RECEIVING MODERATELY TO HIGHLY EMETOGENIC CHEMOTHERAPY IN HONG KONG

Robert R. Deuson, Outcomes Research, Merck & Co. Inc., Whitehouse Station, NJ, USA; Benny Zee, Tony Mok, Winnie Yeo, Frankie Mo & Angel Lee, Comprehensive Cancer Trials Unit, Chinese University of Hong Kong, Shatin, Hong Kong, PRC; Grace Lau, Medical Department, Merck Sharp & Dohme (Asia) Ltd, Hong Kong, PRC

**Aims:** To measure the impact of chemotherapy-induced nausea and vomiting (CINV) on quality of life (QoL) in symptom control trials. **Methods:** Patients completed a diary to capture nausea (N) and vomiting (V) episodes and the EuroQoL Visual Analogue Scale (EQVAS) for 5 days. The EORTC QLQ-C30 and Functional Living Index for Emesis (FLIE) were completed prior to chemotherapy (CTx) and at the end of day 5. The QLQ-C30 was used to assess changes in functional and symptom scales. The FLIE was used to assess the impact of CINV on patient daily lives. A score change from baseline to day 5 was used in the analysis. For N and the EQVAS, 5-day averages were used as endpoints in the analysis. Patients with and without V episodes were compared (Wilcoxon rank-sum test). **Results:** 57 patients receiving moderately (20%) or highly emetogenic (80%) CTx enrolled in the study: 46% male, 89% received single-day chemotherapy; mean age 53. Cancer types: breast (20), lung (16), hepatocellular carcinomas (12) and others (9). 30/57 (53%) patients vomited in cycle 1, 17/43 (40%) in cycle 2, and 18/38 (47%) in cycle 3. Differences between patients without/with V were significant ( $p < 0.05$ ) across three cycles with respect to responses on the QLQ-C30 (N/V: 4 vs. 47, 3 vs. 57, 6 vs. 50; appetite loss: 13 vs. 46, 16 vs. 40, 12 vs. 41), the FLIE (5.4 vs. 45.1, 6.2 vs. 63.2, 7.9 vs. 54.3) and the EQVAS (72.4 vs. 55.1, 76.5 vs. 47.6, 74.2 vs. 52.5). In cycle 2, significant ( $p < 0.05$ ) differences were also measured with the QLQ-C30 in global health status (-14 vs. -16), emotional (-6 vs. -17) and social (-8 vs. -31) functioning, and fatigue (12 vs. 24). **Conclusions:** These results provide a basis for comprehensively assessing the impact of CINV on patients and the potential benefits of better antiemetic therapies.

## # 1057/IMPACT OF PROSTATE CANCER DIAGNOSIS AND TREATMENT ON ANXIETY AND DEPRESSION, A LONG-TERM FOLLOW-UP

Ida J. Korfaage & Harry J. de Koning, Public Health; Wim J. Kirkels, Urology; Joanna B. Madalinska & Marie-Louise Essink-Bot, Public Health, Erasmus MC University Medical Center Rotterdam, Rotterdam, The Netherlands

**Aims:** Prostate cancer diagnosis and treatment can lead to feelings of anxiety or depression, affecting patients' perceptions and reporting of their condition. In addition to disease specific and generic health, we assessed long-term consequences for anxiety and depression in localised prostate cancer patients. **Methods:** Newly diagnosed patients, recruited through four hospitals in Rotterdam, the Netherlands, completed four questionnaires, containing SF-36, CES-D and STAI. CES-D is designed to detect major and clinical depression. STAI assesses both situational or state anxiety (STAI-S) and underlying or trait anxiety (STAI-T). A STAI-T score of 34 or more defines an individual as anxiety prone. Scores of anxiety prone and non-anxiety prone patients were compared. Results were analysed using a repeated measures model. **Results:** 314 eligible men were followed for up to 58 months (median 52 months). Overall response to the four assessments was 76%. Patients were treated by radical prostatectomy ( $n = 127$ ) or external radiotherapy ( $n = 187$ ). Before treatment anxiety prone individuals reported significantly worse Mental Health (61 vs. 81), higher levels of depression (15 vs. 6) and more situational anxiety (46 vs. 30). Shortly after treatment situational anxiety decreased mainly in anxiety prone individuals (6 vs. 3 points). Average Mental Health scores and levels of depression improved in all patients. Differences between two anxiety groups remained significant at all assessments after diagnosis. **Conclusions:** If anxiety prone, prostate cancer diagnosis had significant impact on men, causing significant increase of depression and anxiety. After treatment patients regained better levels of functioning. If non-anxiety prone, levels of distress and anxiety remained at norm level. Physicians should be aware of the impact of diagnosis on (especially) anxiety-prone patients, even though prostate cancer has a comparably favourable prognosis.

#### # 1395/IMPACT OF PAIN ON PATIENTS' HEALTH-RELATED QUALITY OF LIFE

W. Krisanaprakornkit & S. Thienthong, Anesthesiology; N. Pratheep-awanit, Clinical Pharmacy, Khon Kaen University; C. Kuchaisit, Nursing, Srinagarind Hospital; C. Limwattananon, Clinical Pharmacy; A. Pakkhem, Surgery, Khon Kaen University; S. Srimongkol, Nursing, Srinagarind Hospital, Khon Kaen, Thailand

**Aims:** Pain is a common symptom reported by patients with cholangiocarcinoma. This study aimed to evaluate health-related quality of life (HRQOL) in relation to pain of those patients. **Methods:** A longitudinal study was conducted and all new patients who received care at Srinagarind Hospital, Thailand, were recruited. The FACT-Hep and Brief Pain Inventory instruments were used for assessing HRQOL and pain, respectively, at baseline and one, 3 and 6 months after diagnosis. Herein, the preliminary data of 49 patients who completed the questionnaire on the first visit, and a month later, is presented. **Results:** Almost all patients had advanced cancer (stage 3/4). The patient's mean age was 57 years, ranging from 35 to 78 years. Most patients were men (65%), occupation farmer (80%) and with highest education of primary school (88%). At baseline, 19 patients reported their level of maximum pain as mild (score 0–3), 12 reported moderate (score 4–6) and 18 reported severe (score 7–10). Patients with severe pain had poorer HRQOL scores than others, especially in physical and emotional well-being domains ( $p < 0.01$ ). Overall, patients' report of maximum pain increased after 1 month (mean 4.5, median 5 vs. mean 4.8, median 6). The group with mild pain reported an average increase of pain level 3.8 (median = 2.5, range 0–10) while the severe pain group reported decreased pain with average decrease of  $-3.4$  (median =  $-2$ , range  $-10$  to 1). Patients with mild pain at baseline had more deteriorated HRQOL scores after 1 month. The mean difference was significant for physical well-being ( $p = 0.02$ ) and total FACT-G ( $p = 0.02$ ). The deterioration of FACT-G scores (mean difference =  $-07.8$ ) greater than the minimal important difference (5–6) indicates a clinical significance of pain on patients' HRQOL. **Conclusions:** The findings emphasize the importance of pain management in these patients, especially in those presenting with less pain, as the symptom quickly develops and clearly impairs patients' HRQOL.

#### # 1280/QOL AND SPIRITUAL WELL-BEING IN ADULTS PATIENTS WITH ALLOGENIC HEMATOPOIETIC STEM CELL TRANSPLANTATION

Kumi Otsuki, Masahiro Kohzaki, Yuko Sasaki, Hitomi Kataoka & Masayuki Kabazawa, Internal Medicine & Rehabilitation Science; Takeshi Sasaki, Molecular Diagnostics, Tohoku University Graduate School of Medicine, Sendai, Japan

**Aims:** Most of the commonly used quality of life (QOL) instruments in oncology do not include spirituality as a core domain. It is suggested that spirituality might be an important aspect of QOL for cancer patients and that it may be especially salient in the context of life-threatening illness. The aim of this study was to clarify QOL and spiritual well-being (Sp) in patients following allogeneic hematopoietic stem cell transplantation (allo-HSCT). We also explored the putative relationship between Sp and QOL of allo HSCT patients. **Methods:** The subjects of this cross-sectional survey were 24 adult patients who received allo-HSCT at Tohoku University Hospital in Japan. QOL and Sp were assessed by Functional Assessment of Cancer Therapy-Bone Marrow Transplantation (FACT) and Functional Assessment of Chronic Illness Therapy-Spiritual Well-being (FACIT-Sp). Both of them have four common assistant scales: physical well-being (PWB), social/family well-being (SWB), emotional well-being (EWB) and functional well-being (FWB). A disease specific QOL of bone marrow transplantation (BMT) and Sp were added as assistant subscale to FACT and FACIT-Sp, respectively. Moreover, longitudinal survey of QOL and Sp in 11 adult patients who received allo-HSCT in was evaluated before allo-HSCT, 1, 14, 28, 56, 84 and 100 days after the allo HSCT. **Results:** In the cross-sectional study, stepwise multiple regression analysis was performed with PWB, SWB, EWB, FWB or BMT as dependent variable. In the stepwise multiple regression analysis, only Sp remained in the model as a significant predictor of EWB, FWB and BMT, respectively. Moreover, in the longitudinal study, the patients with high score of Sp showed a tendency to have high scores of EWB,

FWB and BMT. **Conclusions:** These results suggest that Sp may be an important factor for evaluating QOL for allo-HSCT patients.

#### # 1282/GENERIC AND DISEASE-SPECIFIC QUALITY OF LIFE IN JAPANESE UROSTOMATES

Hitomi Kataoka, Yuko Sasaki, Nobuyoshi Mori, Makoto Nagasaka, Taku Harada, Osamu Ito, Naoyoshi Minami, Hajime Kurosawa, Masayuki Kanazawa & Masahiro Kohzaki, Internal Medicine and Rehabilitation Science, Tohoku University Graduate School of Medicine, Sendai, Miyagi, Japan

**Aims:** Patients who underwent cystectomy with urostomy for bladder cancer face many problems, both physical and psychological. The aim of this study is to evaluate the generic and disease-specific Quality of Life in Japanese urostomates. **Methods:** The generic and disease-specific QOL were evaluated by SF-36 and Olbrisch ostomy adjustment scale (OAS), respectively. Those questionnaires were sent by mail with stoma appliances when urostomates ordered them. We were also elucidated the factors that influence the QOL of Japanese urostomates. Date analysis was performed using Student *t*-test, Pearson's correlation coefficient and step-wise multiple regressions. **Results:** Forty-nine urostomates (age:  $72.7 \pm 8.4$  years,  $8.1 \pm 5.2$  years after surgery) who underwent cystectomy replied. The SF-36 scores of urostomates were below the average scores of Japanese general population except bodily pain (BP). The mean total score of OAS were lower than that reported by Olbrisch (1983), Burckhardt (1990) and Brydolf (1994), 128.5 compared to 155.7, 168 and 178.6. The factor of 'skin irritation' may deteriorate the QOL of Japanese urostomates, however the other factors which 'sex', 'age', 'marital status', 'time after surgery', 'independence in changing of a stoma appliance', 'experiences of stoma clinic' and 'the enrollment to an ostomy association' did not affect the QOL. **Conclusions:** In the present study, the generic QOL of Japanese urostomates was lower than that of Japanese general population. The mean value of total OAS of Japanese urostomates was lower than that which has been already reported in Western countries. As skin irritation may deteriorate QOL, care to the management of skin irritation postoperatively should be carefully planned. Longitudinal prospective studies need to be done to elucidate whether the increase in physical and psychological status can improve QOL in urostomates.

## # 1284/HEALTH-RELATED QOL IN JAPANESE COLOSTOMATES

Hitomi Kataoka, Masahiro Kohzaki, Eiko Kumagai & Maki Takahashi, Internal Medicine & Rehabilitation Science, Tohoku University Graduate School of Medicine, Sendai, Japan; Minae Iguchi, Nursing, Yokohama City University Medical Center, Yokohama, Japan; Toshiko Yamana, Nursing, Kawaguchi City Medical Center, Kawaguchi, Japan; Yukiko Saito, Nursing, Fukushima University Hospital, Fukushima, Japan

**Aims:** The aim of this study is to evaluate the health-related QOL of Japanese colostomates for treatment of rectal cancer. **Methods:** Thirty-nine colostomates who visit stoma clinic periodically were evaluated by QLQ-C30 and QLQ-CR38 which was developed by the European Organisation for Research and Treatment of Cancer, and the Ostomates' QOL questionnaires (OsQOL) which was developed for Japanese ostomates. The QLQ-C30 is a cancer-specific questionnaire and QLQ-CR38 is a colorectal cancer module. Those questionnaires were handed after the stoma clinic by stoma care nurses. We also assessed if individual OsQOL domains correlated QLQ-C30 and QLQ-CR38 domains, and some factors influence the OsQOL, QLQ-C30 and QLQ-CR38. Data analysis was performed using Pearson's correlation. **Results:** The mean age of colostomates was  $65.4 \pm 10.4$  years. The mean score of the OsQOL were higher than the reference mean of the OsQOL committee except 'activity'. There were significant correlations between 'activity' 'psychological state' and 'economic aspect' of OsQOL and QLQ-C30 or QLQ-CR38. For example, 'stress' of OsQOL and 'stoma-related problem' of QLQ-CR38 had correlations of  $-0.524 (p < 0.05)$ , and 'economic aspect' of OsQOL and 'social functioning' of QLQ-C30. Only the factor of 'skin irritation' correlate 'future perspective' of QLQ-CR38 ( $r = 0.548, p < 0.05$ ). **Conclusions:** The result of OsQOL provides that the health-related QOL in colostomates who visit periodically our stoma clinic were better than that reported. Moreover, some domains of OsQOL have the significant correlations with QLQ-C30 and QLQ-CR38. Longitudinal prospective studies need to be done to elucidate whether the longer follow-up improve QOL of Japanese colostomates.

## # 1077/DEVELOPMENT AND VALIDATION OF THE FUNCTIONAL DYSPEPSIA RELATED QUALITY OF LIFE SCALE

Eun-Hyun Lee, Preventive Medicine and Public Health; Ki-Baik Hahm, Gastroenterology, Ajou University, Suwon, South Korea

**Aims:** Quality of life (QOL) is an important outcome indicator for evaluating the effect of medical treatments. Nevertheless, a study on QOL in patients with functional dyspepsia in Korea has been never conducted due to the lack of a psychometrically validated disease-specific instrument measuring QOL. Therefore, the aim of this study was to develop and validate a QOL scale for Korean patients with functional dyspepsia. **Methods:** The development and validation of the Functional Dyspepsia-related QOL (FD-QOL) took place in three steps: item generation, pilot test, and psychometric test. An expert panel to determine content validity generated a list of preliminary items. A pilot test to determine the comprehensiveness of the items was undertaken with 15 patients. A psychometric test was conducted with 220 patients with functional dyspepsia who were recruited from seven hospitals. For the psychometric test, subjects were asked to complete the preliminary item-generated FD-QOL, the SF-36, and Korean Index of Dyspepsia Symptoms to determine factorial validity, convergent and known-groups validity, and internal consistency reliability. The data were analyzed using factor analysis, Pearson correlation, ANOVA, and Cronbach  $\alpha$ . **Results:** Likert-type of 23 items was preliminary generated. Subjects completed the FD-QOL in less than five minutes without any difficulties in understanding. Factor analysis extracted a four-factor solution, and two items were deleted since they were not significantly weighted at any factor. The FD-QOL was moderately correlated with the SF-36 subscales. The FD-QOL scores were statistically different by three groups of dyspepsia symptom levels. Cronbach alpha was 0.94. **Conclusions:** The FD-QOL is a short and easily applicable instrument with excellent psychometric properties. The FD-QOL can be reliably and validly used in clinical settings and in research to measure QOL of patients with functional dyspepsia.

## # 1444/THE EFFECT OF LUNG CANCER SYMPTOMS AND ITS TREATMENT-RELATED SIDE EFFECTS ON HRQOL

Chin-Yen Wu, Environmental Health, China Medical University, Taichung; Ching-Ling Chang, Changuha; Ming-Lin Ho, Chest Medicine, Changhua Christian Hospital, Taiwan; Wen-Min Liang, Public Health, China Medical University, Taichung, Taiwan, ROC

**Aims:** Lung cancer symptoms typically worsen health-related QOL (HRQOL). The worsen symptoms of treatment-related. The aim of this study is to assess the association between lung cancer symptoms and its treatment-related side-effects with HRQOL in patients with lung cancer. **Methods:** The subject pool is from the 76 lung cancer patient (47 male and 29 female aged 41-95 with a mean age 65.46 years). The EORTC QOQ-LC13 questionnaire was used to assess the lung cancer symptoms and its treatment-related side-effects in lung cancer patients; the EORTC-QLQ-C30 and WHOQOL-BREF were used to assess patients' HRQOL. We divided the 4-point scales of EORTC QOQ-LC13 into two parts: the first group (the less serious group) combines the two answers 'not at all' and 'a little', and the second group (the serious group) combines the other two answers 'quite a lot' and 'very serious'. These groups were compared to each domain (or scale) in the HRQOL by the two-sample  $t$  test. **Results:** There were 20% of patients belonging to the serious groups for both coughing and dyspnea, followed by 17.1% for pain in other parts of the body, 13.2% for pain in chest, and 10.5% in hair loss. Except for sour mouth, hair loss and pain in arm, average scores of QOL were significantly worse in patients belonging to the serious group than the less serious group for most domains (or scales) from the WHOQOL-BREF and EORTC-QOL-C30. Especially, in the serious group patients with dysphagia and peripheral neuropathy; mean QOL scores of physical domain in WHOQOL-BREF and physical functioning scale in EORTC-QOL-C30 were much lower than those in the less serious group patients. **Conclusions:** A QOL assessment could provide important information about suitable candidate for assessment intervuitable.

# 1413/QUALITY OF LIFE AND DETERMINANTS IN PATIENTS WITH LUNG CANCER: EVALUATION WITH WHOQOL AND EORTC QLQ QUESTIONNAIRES

Chih-Wen Chung, Center for Health Risk Assessment and Policy; Cheng-Fen Yu & Jung-Der Wang, Occupational Medicine and Industrial Hygiene, National Taiwan University College of Public Health, Taipei, Taiwan, ROC

**Aims:** Malignant neoplasms are the No. 1 leading causes of death in Taiwan, and lung cancer is the top one cause of death among malignant neoplasms. This study is to evaluate the quality of life (QOL) and its determinants in patients with lung cancer. **Methods:** QOL of lung cancer patients (n = 241, 216 outpatients and 25 inpatients) were assessed at the National Taiwan University Hospital (NTUH) using two QOL measuring instruments: EORTC QLQ (QLQ-C30 and its lung cancer supplement QLQ-LC13) and WHOQOL-Bref. These patients were undergone pathological ascertainment to determine the onset date and the staging of the lung cancer. A norm, established by a nationwide survey of WHOQOL-Bref, was used as a reference, and the comparisons were conducted accordingly. **Results:** The psychometric scores for lung cancer patients with more advanced stages were found to be significantly lower than those with less severe stages in several items of physical and psychological domains of both EORTC QLQ and WHOQOL-Bref. There was no significant difference on social and environmental domains of WHOQOL among patients with different stages. Comparing to the QOL of general population, however, it does reveal significant difference on items of these two domains. Lung cancer patients have higher satisfactory scores than general populations did on item of social support (social domain) and on items of financial resources, health and social care (environmental domain). Gender differences were found in a few items of both EORTC QLQ and WHOQOL-Bref. In general, EORTC QLQ seemed to provide more information related to disease and showed better differentiability in items of financial difficulties and social functioning. **Conclusions:** Both EORTC QLQ and WHOQOL-Bref were sensitive to the QOL status of lung cancer patients with different stages and gender in the physical and psychological items. EORTC QLQ showed a better differentiability in some items. Because we had norms from general population on WHOQOL, it provided us the potential to compare QOL across different diseases or health states.

# 1401/QUALITY OF LIFE IN CANCER PATIENTS – AN INDIAN STUDY

Ashu R. Gandhi, Santosh K. Chaturvedi, Prabha S. Chandra, Psychiatry, NIMHANS, Bangalore, Karnataka, India

**Aims:** The diagnosis of cancer brings about images of pain, suffering, angst, death, which can easily be conceived to be associated with poor QoL, but specific studies assessing factors influencing it are lacking, especially from India. This study attempted to measure health related quality of life (HRQoL) in cancer patients using a brief generic scale, and to explore its relation with factors like subjective concerns, desire for death, and psychiatric diagnosis. **Methods:** 200 patients with a primary diagnosis of cancer who gave informed consent for participation were recruited from the Neurosurgical units of NIMHANS, Radiotherapy units of Manipal hospital, and from Hospice care in Bangalore, India. Patients who were cognitively impaired, weak, or too ill to complete the assessments were excluded. Patients were assessed using the Hospital anxiety and depression scale (HADS), Manchester concerns Scale, EQ-5D, FACT, and Chochinov's Desire for Death Scale. Analysis was done using SPSS 7.5. **Results:** The study found that the overall Health Related QoL is not so good in most of the patients with cancer. The domains of pain/discomfort and mobility contribute maximally to the poor HRQoL scores. Ongoing radiotherapy, active desire for death, high level of subjective concerns, and psychiatric diagnosis of depression were significantly associated with a worse QoL. **Conclusions:** Overall health related QoL is not so good in most of the patients with cancer. Better management of pain and psychiatric illness, and a higher level of awareness regarding issues of subjective concerns can guide health professionals working with cancer patients towards provision of better overall care.

# 1370/PROSPECTIVE EVALUATION OF QUALITY OF LIFE IN PATIENTS RECEIVING EITHER ABDOMINOPERINEAL RESECTION OR SPHINCTER PRESERVING PROCEDURE FOR RECTAL CANCER

Christian E. Schmidt, Surgery, Beate Bestmann, Thomas Kuchler, Reference Center QOL; Bernd Kremer, Surgery, University of Kiel, Kiel, Germany

**Aims:** Study results on the differences in quality of life (QoL) between patients receiving an anterior resection (AR) or abdominoperineal resection (APR) for rectal cancer vary greatly. A main reason is grounded in unequal and unproven methodology. The aims of this study were to assess differences in perceived QoL over time among patients treated with either an anterior resection or abdominoperineal resection using recommended study design and methodology. **Methods:** In a prospective single center study, the EORTC-QLQ-C-30 and a tumor specific module were administered to patients with a diagnosis of rectal cancer before surgery, at discharge, 3, 6 and 12 months after the operation. Comparisons were made between patients receiving an AR and those receiving an APR. **Results:** Two hundred forty-nine patients were included; 46 patients received an APR, 203 an AR. QoL data was available for 212 patients of which 112 were female and 100 male. Median age was 65.3 years. No differences in the distribution of age, gender and tumor stage were observed between both groups. EORTC function scales showed no significant differences including body image scales between patients receiving an AR and those receiving an APR. In symptom scores AR patients had more difficulty with diarrhea and constipation, while those patients with APR suffered more from impaired sexuality and pain in the anoperineal region. At discharge, patients receiving an AR were more confident about their future. **Conclusions:** Despite other studies, QoL in patients receiving an AR and those receiving an APR is not different. While patients with APR suffer more from impaired sexuality, patients receiving an AR experience decreases in QoL by impaired bowel function.

# 1366/THE IMPACT OF AGE ON QUALITY OF LIFE IN PATIENTS WITH RECTAL CANCER

Christian E. Schmidt, Surgery; Beate Bestmann, Reference Center QOL; Thomas Kuchler, Bernd Kremer, Surgery, University of Kiel, Kiel, Germany

**Aims:** Some studies indicate that age at the time of surgery has a general effect on outcomes. The impact of age on QoL in patients with rectal cancer has however not been investigated yet. The presenting study was conducted to address this issue. **Methods:** Over a 5-year, the EORTC-QLQ-C-30 and a tumor specific module were prospectively administered to patients before surgery, at discharge, 3, 6, 12 and 24 months postoperatively. Comparisons were made between different age groups. **Results:** Five hundred nineteen patients participated in the study. QoL data was available for 253 patients. Significant differences were only observed between patients aged 69 and younger (169/253) and those aged 70 years and older (85/253). Physical and role functioning were better for patients aged 69 and younger while patients aged 70 years and older suffered from increased pain and fatigue. Younger patients had more difficulties with sexual enjoyment; Furthermore, over time, sexual problems created high levels of strain in these patients. These problems tended to remain. Treatment strain was worse for patients aged 70 years and older in the early postoperative period but improved while patients aged 69 and younger had increasing levels of strain over time. **Conclusions:** The findings in this study confirm that QoL is dynamic over time and that age has an impact on QoL and sexuality. Patients aged 70 years and older are affected by impaired physical functioning, global health and fatigue while increased treatment strain in the early postoperative period improves over time. Patients aged 69 and younger experience increased strain by impaired sexual function.



# 1635/MAINTAINING COMPLIANCE IN QUALITY OF LIFE DATA COMPLETION IN CLINICAL TRIALS – THE NATIONAL CANCER INSTITUTE OF CANADA CLINICAL TRIALS GROUP (NCIC CTG) EXPERIENCE

Andrea Bezjak, Radiation Oncology, Princess Margaret Hospital, Toronto, ON, Canada; Michael Palmer, Study Coordinator, NCIC CTG, Kingston, ON, Canada; Michael Brundage, Radiation Oncology, Kingston Regional Cancer Center, Kingston, ON, Canada; David Osoba, QOL Consulting, West Vancouver, BC, Canada; Joseph L. Pater, Director, NCIC CTG, Kingston, ON, Canada

**Aims:** Among the greatest threats to interpretation of results of health related quality of life (HRQOL) data analyses are problems related to missing HRQOL data. We report our experience in ensuring high rates of compliance. **Methods:** The NCIC CTG is a Canada-wide clinical trials group, with the mandate of performing phase III oncology trials. Its HRQOL activities are coordinated by the QOL committee, which was formed in 1987. HRQOL completion is required of all patients entered on the study, unless they cannot complete questionnaires due to visual or other impairments or language problems. Compliance with HRQOL questionnaire completion has been prospectively recorded, reported and acted upon (if necessary) since 1999. **Results:** The baseline compliance of HRQOL was >95% in 20/25 studies, and >85% in 5/25 studies. Compliance with follow-up assessments ranges from 90%+ (for brief symptom control studies), 80%+ (for most studies), to 70%+ (for studies with longer follow-up). The time point that has yielded the lowest compliance rates is at relapse (50–70%). Prospective recording of questionnaire completion rates is done where possible, and electronically reported to the QOL coordinator and study coordinator on a regular basis for their review and action (letters to centres, changes in QOL protocol) with resultant improvement in compliance. A strong rationale for the inclusion of HRQOL in the protocol, explicit instructions about the logistical issues of questionnaire administration, training of clinical research associates (CRAs) in participating centers, and presence of a CRA representative in the QOL committee have been adopted by our group to ensure high levels of compliance. **Conclusions:** Ongoing prospective attention to HRQOL completion, coupled with strong support from the central office and CRA staff has helped ensure ongoing high rates of HRQOL data completion in NCIC CTG studies.

# 1351/HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH PHARYNGEAL CARCINOMA, A FIVE-YEAR FOLLOW-UP

Eva Hammerlid, Department of ENT Head and Neck Surgery, Sahlgrenska University Hospital, Göteborg, Sweden; Mats Nordgren, Magnus Jannert, ENT Department, Malmö University Hospital, Malmö, Sweden

**Aims:** To evaluate the health-related quality of life (HRQL) of patients with pharyngeal carcinoma in a prospective longitudinal multicenter study at diagnosis, after 1 and 5 years in relation to tumor location and treatment modality, and compare the HRQL of patients with reference data from a population sample. **Methods:** Eighty-nine patients (mean age 60.0 years; 76% males) with pharyngeal carcinoma were evaluated with standardized HRQL questionnaires; the European Organization for Research and Treatment of Cancer, Quality of Life Questionnaire Core-30 (EORTC QLQ-C30) and Head&Neck Cancer Module (EORTC QLQ-H&N35). **Results:** Patients reported several symptoms that deteriorated between diagnosis and the 5-year follow-up such as problems with dry mouth and problems with teeth. Some side-effects got worse between 1 and 5 years especially sticky saliva and teeth problems. Dry mouth remained a great problem even after 1 year. The HRQL at diagnosis seems to be associated with survival, especially physical functioning scale which could be regarded as a predictive factor for survival as well as low stage disease. Global quality of life scale and low stage disease at diagnosis seems to be related to HRQL after 5 years and could be regarded as predictive factors for HRQL after 5 years. Patients with oropharyngeal carcinoma had during and after treatment better HRQL than patients with hypopharyngeal carcinoma. The survivors HRQL were significantly different from the norm data for the EORTC QLQ-H&N35, whereas the results from the EORTC QLQ-C30 were not. **Conclusions:** HRQL questionnaires might be valuable instruments in the treatment planning and serve as aid in foreseeing treatment side-effects. Evaluation of HRQL

at diagnosis for patients with pharyngeal carcinoma seems to be of value for the prognosis of HRQL over time and for the prognosis of survival. It should be recognized that treatment for pharyngeal carcinoma often results in long term side-effects.

# 1055/QUALITY OF LIFE ASSESSMENT AFTER CHEMORADIATION (RADPLAT) IN LOCALLY ADVANCED, INOPERABLE STAGE IV HEAD AND NECK CANCER PATIENTS

Annemieke H. Ackerstaff, Otolaryngology, Head&Neck Oncology, Netherlands Cancer Institute, Amsterdam, The Netherlands

**Aims:** Surgical treatment of patients with advanced head and neck cancer (stage IV) often results in anatomical changes, and thus in disturbed QOL aspects. To try to prevent this, a non-surgical organ preservation approach, i.e. targeted supradose cisplatin chemoradiation treatment, was employed. The purpose of this study is to assess the effect of this treatment on the QOL of a subgroup of patients. **Methods:** Fifty patients (mean age: 53 years) participated in this clinical, non-randomised phase IIB feasibility trial. Patients were interviewed by means of the FACT questionnaire, including a special Head and Neck module, and the University of Washington (UW) questionnaire, pre-treatment, and 3, 6, and 12 months after starting treatment. Changes over time were assessed by *t*-tests and the GLM procedure for repeated measures. **Results:** During the 12 months follow-up period 16 patients died (14 DOD and 2 DIC), and 5 patients needed salvage surgery. In addition, 3 patients were lost to follow-up. This resulted in 26 evaluable patients at 12 months. The functional well-being scale and the head and neck subscale, both most affected by the tumour and treatment show a statistically significant improvement over time. After 12 months, 21 patients (80%) returned to an oral diet, while 5 patients still needed tube feeding. Xerostomia, a common consequence of radiotherapy, was frequently noted. For 23 patients (88%), the quality and the strength of the voice was more or less normal. From the 18 patients, who were employed before their treatment, 10 were able to return to their job within 12 months. **Conclusions:** Considering the fact that only patients with locally (anatomical or functional) inoperable stage IV disease were treated, the results are promising, underlining the feasibility of the RADPLAT protocol. It seemed that the impact of an organ preservation protocol such as RADPLAT is less far-reaching than a pure surgical approach in terms of QOL effects.

#### # 1032/HEALTH-RELATED QUALITY OF LIFE IN CANCER POPULATION RECEIVING DIFFERENT THERAPIES IN SABAH, MALAYSIA

P.L. Lua, Psychology & Social Health Research, University Malaysia Sabah, Kota Kinabalu, Sabah, Malaysia; M.S. Salek, Centre for Socioeconomic Research; I.G. Finlay, College of Medicine, University of Wales, Cardiff University, Cardiff, UK; A.G.I. Boay, M.S. Rahimah, Queen Elizabeth Hospital, Sabah Health Department, Kota Kinabalu, Sabah, Malaysia

**Aims:** The impact of various cancer treatments on health-related quality of life (HRQoL) is influential in medical decision-making. This study aimed to compare HRQoL profiles of cancer patients receiving various therapies and the predictor(s) of overall HRQoL for each therapy. **Methods:** A prospective, cross-sectional study recruiting in-patients with heterogeneous cancer was conducted in Queen Elizabeth Hospital, Sabah. The 17-item Malay McGill Quality of Life Questionnaire (MMQOL) was used (global QoL, physical symptoms, physical well-being, psychological, existential and support issues). Eligible patients completed MMQOL upon written consents. Statistical analysis was carried out using SPSS 10 (ANOVA, post-hoc Tukey test and stepwise regression). **Results:** Sixty-five patients (mean age = 41; male = 31) participated and were undergoing pain control (n = 8), anti-cancer therapy (n = 25), radiotherapy (n = 10) and supportive care (n = 22). Overall, significant differences were revealed by the global QoL score ( $p = 0.011$ ) and the physical symptoms domain ( $p = 0.006$ ). Patients receiving pain control reported lower score compared to patients on anti-cancer therapy ( $p_{\text{global}} = 0.04$ ;  $p_{\text{physical symptoms}} = 0.01$ ) and radiotherapy ( $p_{\text{global}} = 0.04$ ;  $p_{\text{physical symptoms}} = 0.02$ ), respectively. The psychological domain was strongly predictive for overall HRQoL for the pain control and anti-cancer therapy groups while the existential domain was important to all groups except the former. **Conclusions:** The results showed the varying HRQoL impact of cancer therapies whereby the psychological and spiritual concerns were significant predictors. Such information is useful in medical decision-making in order to improve healthcare delivery.

#### # 1733/EFFICACY OF TRANSDERMAL-FENTANYL IN RADIATION-INDUCED MUCOSITIC PAIN

Pimkhuang Kamnerdsupaphon, Vicharn Lorvidhaya, Vimol Sukthomya, Prathomporn Koopai, Anun Tonusin, Imjai Chitapanarux, Therapeutic Radiology and Oncology, Chiang Mai University, A. Muang, Chiang Mai, Thailand

**Aims:** To evaluate the analgesic efficacy and safety of transdermal-fentanyl in the treatment of pain due to mucositis in head and neck cancer during radiotherapy. **Methods:** Forty-five patients, who developed radiation-induced oral mucositis, were enrolled into the study. This study comprises of two phases. The first phase is oral morphine stabilization. Eligible patients, who meet one of the following criteria will be entered to the second treatment phase. (1). Patients must convert other opioids to the stable oral morphine dose. (2). Patients received the stable oral morphine dose for a while. (3). Patients could not wait for oral morphine titration due to intolerance to the pain severity. The second phase was open transdermal-fentanyl treatment phase. Patients complied with the previous criteria could be enrolled to this phase. Pain intensity and well being score were measured using self-assessment (numeric analog-scale everyday until completion of radiotherapy. Safety was based on clinical adverse events reported by patients or physician. **Results:** All 45 patients initial transdermal-fentanyl dose requirements were 25 mg/hour. Only 1 patient required transdermal-fentanyl 50 mg/h after administration of transdermal-fentanyl 25 mg/h for 9 days. Transdermal-fentanyl was usually well tolerated. Adverse events reported in this study were nausea/vomiting (38%) constipation (20%), itching (11%) and palpitation (2%). As the mean pain score decreasing, the mean daily well being score and global assessment score were increase. **Conclusions:** Transdermal-fentanyl is simple, safe, and effective treatment in radiation induced oral mucositis pain, which warrants further multi-center randomized trials to validate our findings.

#### # 1553/QOL AND SEXUALITY IN PATIENTS WITH RECTAL CANCER

Beate S. Bestmann, Reference Center Quality of Life in Oncology; Christian E. Schmidt, General and Thoracic Surgery; Thomas Kuechler, Reference Center Quality of Life in Oncology; Bernd Kremer, General and Thoracic Surgery, University of Kiel, Kiel, Germany

**Aims:** Little is known about how QoL changes over time in patients after surgery for rectal cancer, and whether gender of the patients is associated with a different perception of QoL. The aim of this study was to assess changes of quality of life after surgery for rectal cancer with a focus on sexuality and gender differences. **Methods:** Since 1998, the EORTC QLQ-C30 and a tumor specific module were prospectively administered to patients before surgery, at discharge, 3, 6, 12 and 24 months post-operatively. These data were combined with QoL data from a historical cohort of patients that underwent surgery between 1992 and 1997. Altogether, 541 patients with rectum and sigma carcinoma provided QoL data for at least one time point. Comparisons were made between female and male patients. Non-parametric analyses were performed. A global  $\alpha$  of  $p < 0.05$  was considered significant (adjusted for multiple tests). **Results:** Out of the 541 patients providing QoL data, 262 were female and 279 male. Both groups were comparable in terms of age ( $p > 0.05$ ), tumor stage and surgical procedure ( $p > 0.05$ ). In men as well as in women most QoL scores dropped significantly below baseline in the early postoperative period. From the third month onwards, global health, emotional and physical functioning improved. Female gender was associated with significantly worse global health and physical functioning and with higher scores on treatment strain and fatigue. Men reported difficulties with sexual enjoyment. Furthermore, over time, sexual problems created high levels of strain in men that were worse than baseline levels in the early post-operative period. **Conclusions:** The findings in this study confirm that QoL changes post-surgery and is different between men and women. Women appear to be affected by impaired physical functioning and global health. Female gender is associated with significantly higher fatigue levels and increased strain values after surgery. In terms of impaired sexual enjoyment, men are put more under strain than woman. All differences between men and women remain stable in the course of time.

# 1569/FEASIBILITY STUDY OF 'PIGGY-BACKING' INTERNATIONAL QUALITY OF LIFE QUESTIONNAIRE VALIDATION ONTO ON-GOING CLINICAL TRIALS

Kim Hawkins & Julia M. Brown, Clinical Trials Research Unit, University of Leeds, Leeds, UK, Maxine Stead, National Cancer Research Network, NCRN Co-ordinating Centre, Leeds, UK

**Aims:** An international field-testing study of a quality of life (QOL) module for multiple myeloma patients to be used alongside the European Organisation for Research and Treatment of Cancer (EORTC) core questionnaire. The study aims to determine the psychometric properties of the module including reliability, validity and cross-cultural applicability but is also piloting a new approach to questionnaire development. Generally, a study specifically for validation of a module is designed, whereas this study aims to assess the feasibility and efficiency of using a method of piggy-backing on to ongoing clinical trials already evaluating QOL within a trial. **Methods:** A prospective study to collect QOL data using the QLQ-C30 and QLQ-MY24 in patients undergoing treatment for myeloma within a clinical trial. Studies assessing QOL at baseline and during or on completion of treatment were eligible for inclusion. Demographic, clinical and QOL data were collected from approved trials for use in the validation of the QLQ-MY24 module. **Results:** The study closes in July 2004 with 340 patients. The study has been monitored to evaluate this new approach to questionnaire development. Potential issues will be discussed including:

- Impact of not being able to set the assessment times, which will be defined by each trial rather than the validation study.
- Impact of no direct control over questionnaires completion rates and data collection

- International communication to ensure compliance and quality.

- The feasibility of patient registration and data collection.

- Ethical and data protection regulations for different countries and the effect on the conduct and feasibility of the piggy-backing method.

**Conclusions:** This approach to international validation of questionnaires is an important concept with the potential to decrease costs of questionnaire development substantially. This could increase the capacity of quality of life groups to develop new quality of life instruments. The problems encountered with this novel approach will be discussed and any recommendations for change in current practice will be made.

# 1605/EVOLUTION OF THE SATISFACTION SCORE OF THE HOSPITALIZED PATIENTS. A PERMANENT MEASUREMENT

Phi Linh Nguyen Thi, Epidemiology and Clinical Evaluation, CEC-INSERM CHU Nancy, Nancy, France, Serge Briancon, School of Public Health, Epidemiology Clinical Eval., Epidemiology and Clinical Evaluation, CHU Nancy, Nancy, France, Fabienne Empereur, Sylvie Klein, Epidemiology and Clinical Evaluation, CEC-INSERM, CHU Nancy, Nancy, France, Jean-Marc Virion, Epidemiology and Clinical Evaluation, CEC-INSERM, CHU Nancy, Public Health School, Nancy, France

**Aims:** To have a reliable and precise indicator by determining the various components of the series of satisfaction scores. **Methods:** Two weeks after discharge, patients among 39 medical and surgical services of the Nancy University Hospital Center were mailed a questionnaire (PJHQ adapted in French). The satisfaction scores of dimension are standardized from 0 (poor) to 100 (excellent). The monthly evolutions of the satisfaction scores were separated into tendency, seasonal and random components (on period analysis of 51 months) by using programs X11 and ARIMA/SAS. **Results:** The response rate is 37.2%. Mean age of patients is 55.1 years; 57% are men. The mean length of stay is 7.1 days. The extent of the mean scores of satisfaction varies over time from 5.7 points (dimension concerning overall satisfaction) to 19 points (dimension concerning the meal). Seasonal variability is highlighted by the X11 program on certain dimensions, on the other hand it differs according to the dimensions type: higher scores observed for all months of June for dimension concerning admission, and all months of February for dimension concerning the received care. **Conclusions:** The patient satisfaction can be measured in a permanent way, ensuring the stability of the sample and allows to take into account the changes over time which can modify the patient appreciation's. In this case, the

index of satisfaction can be used like a warning indicator in the improvement programs of the quality of care.

# 1550/QUALITY OF CARE IS POORLY EVALUATED BY MEASURING PATIENT'S SATISFACTION

Laurent Boyer, Public Health, University Hospital of Marseille, Marseille; F. Barlesi, Pneumology; S. Antoniotti, University Hospital of Marseille, Marseilles; P.A. Thomas, Thoracic Surgery, University Hospital of Marseille; K. Barrau & P. Auquier, Public Health, University Hospital of Marseille, Marseilles, France

**Aims:** During the last decade, patient satisfaction has been increasingly considered as an important component in assessing quality of care. Considering the predominant place currently given to the patients satisfaction evaluation, a short-cut has been insidiously proposed to assimilate quality of care and patients satisfaction. The purpose of this pilot study was, firstly to develop an pragmatic tool to evaluate the quality of care in a thoracic surgery and secondly to look for a relation with the patient's satisfaction (evaluated by the French validated Questionnaire of Satisfaction of Hospitalised patients, QSH) and the quality of care. **Methods:** Patients over 18 years undergoing standard thoracic surgery for primary non-small cell lung cancer were eligible to participate in the study. Firstly we developed an instrument to evaluate the quality of care for lung cancer according to the recognised guidelines. Secondly patient satisfaction was measured using the QSH and quality of care was assessed retrospectively from the patients' files. Then we compared the figures of the patients' satisfaction with the data of the quality of care. **Results:** For quality of care, our instrument is divided in four parts: preoperative period, surgical procedure, pathological report and postoperative period. For satisfaction, all dimensions scores are standardized from 0 (poor) to 100 (excellent). A total of 18 inpatients participated to this study. Patients reported higher satisfaction scores for health care providers (staffs' index = 82.0) and lower for dimensions related to structural and environmental factors (structure index = 70.8). No simple relation between satisfaction and quality of care is highlighted in this pilot study. The least satisfied patients are not those who have the worst quality of care. Exact test and non parametric tests did not show any statistical significant difference. **Conclusions:** This first step allows us to check the feasibility of the study. Despite the sample-limited size, we are able to notice that the link between satisfaction and quality of care is far from being obvious. These results have to be confirmed.

# 1165/EXPLORING THE RELATION BETWEEN HRQOL AND SATISFACTION WITH PAIN MEDICATION (SPM) IN AMBULATORY PATIENTS: NEW EVIDENCE OF VALIDITY IN SPM QUESTIONNAIRE

Eva Baró & Alfonso Casado, Outcomes Research, 3D Health Research, Barcelona, Spain; Carles García-Cases, Luis Clerch, Medical, Lácer S.A., Barcelona, Spain

**Aims:** Little is known about the relationship between QoL and patient satisfaction. We explore if there is a relationship between QoL and SPM questionnaire score. **Methods:** A cross-sectional study was carried out in ambulatory patients treated for chronic or acute pain. Spanish normalized scores for the SF-12 (physical PCS and mental component summaries MCS) were obtained. SPM was assessed using the SPM questionnaire, whose overall and dimension (speed-duration of effect (SP), adverse events (AE), functional benefit (FB), overall satisfaction (OS) scores were used to classify patients as satisfied (SAT) and dissatisfied (DIS) with pain medication (the median was used as the cut-off point). Non-parametric tests were used to determine whether QoL differed between the two groups, overall and according to gender. A univariate general linear model was performed to detect first-level interaction between satisfaction and gender. **Results:** 330 ambulatory patients were included (58.5% women, mean age 51.9, 52.7% having osteoarthritis and 43% musculo-skeletal injuries). SAT patients (using the SPM overall score) had better QoL scores (PCS: 35.3 vs. 31,  $p < 0.000$ ; MCS: 50.1 vs. 46.1,  $p < 0.01$ ). When SPM dimension scores were used, PCS were higher in the SAT group whichever SPM dimension was used to classify (SP: 36.6 vs. 31.1; AE: 34.7 vs. 31.4; FB: 35.5 vs. 31.4; OS: 34.9 vs. 31.2,  $p < 0.01$  for all), but MCS were only higher in the SAT group when patients were classified according to scores on the SPM SP (50 vs. 46.8,  $p < 0.05$ ) and AE (50 vs. 46,  $p < 0.01$ ) dimensions. PCS were higher in both SAT men (37 vs. 30.8,  $p < 0.001$ ) and SAT women (34 vs. 31.2,  $p < 0.05$ ) compared to DIS ones. Only SAT women had a higher MCS than DIS patients (49 vs. 43.1,  $p < 0.01$ ). The interaction between satisfaction and gender was almost statistically significant ( $p = 0.069$ ). **Conclusions:** Patients with higher levels of SPM reported better QoL. Physical QoL seems to be more associated with SPM scores than mental QoL, which is consistent with the content of the SPM questionnaire. The association between mental QoL and SPM may be different in men and women.

# 1360/CAN WE WEIGHT SATISFACTION SCORES BY IMPORTANCE RATINGS? THE ROLE OF IMPORTANCE RATINGS IN QUALITY OF LIFE MEASUREMENT

Chia-huei Wu, Grace Yao, Psychology, National Taiwan University, Taipei, Taiwan, ROC

**Aims:** Weighting satisfaction scores by importance rating is a common scoring method in quality of life (QOL) measurement. At first glance, it appears straightforward on using importance weighting, since different life aspects may have different importance to an individual's QOL. However, Trauer and Mackinnon (2001) recently proposed that weighting satisfaction scores by importance ratings is undesirable and unnecessary, since (1) the weighted scores are difficult to interpret, (2) the weighted scores have undesirable psychometric properties, and (3) extreme dissatisfaction/satisfaction ratings were associated with higher importance ratings, suggesting that satisfaction ratings have incorporated the judgments of importance. However, they did not use real data to examine whether the weighted score is superior to the unweighted scores. In our study, different weighting approaches developed by Cummins (1997), Raphael (1996), Ferrans and Powers (1985) and Frisch (1992) were applied. Weighted scores computed by multiplying satisfaction scores with importance ratings were compared with unweighted scores in predicting a global life satisfaction measure. According to Trauer and Mackinnon, it was expected that the weighted scores would not have higher correlations with the global measure than the unweighted scores. **Methods:** One hundred and thirty undergraduate students at National Taiwan University participated in the study voluntarily. They completed a QOL questionnaire developed by the authors, which is consisted of satisfaction and importance ratings on 15 different items. Besides, they also completed the Satisfaction with Life Scale (SWLS), a global life satisfaction measure developed by Diener et al. (1985). **Results:** The correlation results

revealed that the weighted scores computed from different approaches did not have higher correlations with SWLS than the unweighted scores. **Conclusions:** The results suggested that the weighted scores were not superior to the unweighted scores.

# 1020/AN OVERVIEW OF SCALE TRANSLATION AND CULTURAL ADAPTATION OF CANCER SPECIFIC HRQOL QUESTIONNAIRES, WITH ASIAN PERSPECTIVES ON THE PROBLEMS AND THEIR SOLUTIONS IN TWO CULTURAL SETTINGS IN JAPAN AND TAIWAN

Gabor Toth, Biology and Function in the Head and Neck, Yokohama City University Graduate School of Medicine, Yokohama, Kanagawa, Japan; Wei-Chu Chie, Public Health and Graduate Institute of Preventive Med., College of Public Health, National Taiwan University, Taipei, Taiwan

The primary objective of this workshop is to encourage interactions and the exchange of information related to scale translation and cultural adaptation. A second major goal of this workshop is to compose applicable problem-solving strategies and an up-to-date compendium, a concise but comprehensive summary on the experience of the presenters in two Asian cultural settings: Japan and Taiwan. It is necessary to give an overview and provide experience-based recommendations for further research on scale translation and cultural adaptation of HRQoL tools in Asian cultural-settings, as it is a different socio-cultural region from the European and North-American countries, where the original developments of the questionnaires were done. The structure of the workshop will support interaction among participants by having both lecture type of presentation and intensive discussion sessions: a) brain storming, b) listing problem-solving strategies and c) open-questions. We would like to define and organize priorities and issues related to the subject and analyze the specific socio-cultural difficulties as well as their solutions during the adaptation process both in Japanese and Taiwanese cultural-settings. The presenters envision this workshop to be an unbiased statement of their knowledge and experience on the subject.

# 1054/PERCEIVED RELEVANCE OF GENERIC AND DISEASE-SPECIFIC PATIENT-REPORTED OUTCOME MEASURES IN PARKINSON'S DISEASE

Jan Reimer, Clinical Neuroscience, University Hospital, Lund, Sweden; Peter Hagell, Nursing, Lund University, Lund, Sweden

**Aims:** To assess how relevant patients with Parkinson's disease (PD) perceive the content of generic and disease-specific patient-reported outcome measures (PROs). **METHODS:** The generic health status questionnaires SF-36 and NHP, and the PD-specific PDQ-39 were mailed to 302 PD patients together with questions on how relevant they perceived the content of each PRO on a 1–10 rating scale (1 = not at all relevant; 10 = extremely relevant). Ratings were compared using Kruskal-Wallis and Mann-Whitney U tests. **Results:** The response rate was 73%. Overall relevance ratings (median; q1, q3) were: 7 (6, 8) for the NHP; 7 (5, 8) for the SF-36; and 7 (6, 8) for the PDQ-39 (n.s.). There were no gender differences. Patients with shorter PD duration (defined by the median, 8 yrs) found all PROs more relevant than those with longer duration ( $P < 0.05$ ), but there was no difference across PROs within the two groups. Patients who perceived their PD as mild found the NHP ( $P = 0.02$ ) and SF-36 ( $P = 0.003$ ) more relevant than those who perceived their PD as severe. No such differences were found for the PDQ-39. There were no differences in perceived relevance of the NHP or the SF-36 between younger and older patients, as defined by the median age (71 y.o.), whereas the PDQ-39 was rated as less relevant among older than younger respondents ( $P = 0.016$ ). Younger patients rated the PDQ-36 as more relevant than both the NHP and the SF-36 ( $P = 0.03$ ). **Conclusions:** We did not find support for the common assumption that disease-specific PROs are more relevant than generic questionnaires to specific patient groups in the case of the PDQ-39 vs the NHP and SF-36 in PD, except for among younger patients. Data indicate a bias by disease duration among all three PROs and an age bias for the PD-specific questionnaire. There is a need for new and more relevant PROs for this patient group.

# 1204/ASSESSING IMPACT OF SECONDARY CARDIOVASCULAR EVENTS ON HEALTH STATUS

Henk F. van Stel, Julius Center for Health Sciences, UMC Utrecht, Utrecht, The Netherlands; Jan J. Busschbach, Medical Psychology, Erasmus Medical Center, Rotterdam, The Netherlands; Miryam G. Hunink, Epidemiology & Biostatistics, Erasmus Medical Center, Rotterdam, The Netherlands; Erik Buskens, Julius Center for Health Sciences, UMC Utrecht, Utrecht, The Netherlands

*Aims:* Presently, reliable estimates on the impact of secondary cardiovascular events on health status in patients treated for cardiovascular disease are unavailable. However, precise estimates are obligatory to reduce uncertainty about the impact of secondary events, particularly for health economic modeling. *Methods:* We gathered data on health related quality of life (EQ5D, range 1 to -0.6) and secondary cardiovascular events during follow-up from several completed clinical trials comparing surgical interventions for patients with cardiovascular disease (Octopus, DIST, ARTS). A random coefficients model on the

utility scores, correcting for time and event, was fitted using S-plus. *Results:* This analysis included 1650 patients, with follow-up ranging from 12 to 36 months. Significant effects were found for myocardial infarction (impact score -0.03,  $p = 0.005$ ), cerebral infarction (impact score -0.05,  $p = 0.02$ ) and extracranial bleeding (impact score -0.05,  $p = 0.01$ ), but not for amputation. Intercept (0.65) and time (+0.05) were highly significant. Possible heterogeneity was ignored as the heterogeneity-tests F-max and ICC were negative. *Conclusions:* Subsequent cardiovascular events have significant impact in terms of utility. Impact of secondary events is in the same range as improvement due to surgery. Adding additional trial data and similar analyses performed on SF-36 domains will further increase the precision and validity of the results. The estimates obtained regarding the impact of secondary cardiovascular events will be useful in reducing the uncertainty in long-term economic modeling. Supported by Netherlands Heart Foundation grant 2002B45.