



International Society for Quality of Life Research ~ 2010 Conference Abstracts

London, England, October 27 – 30, 2010 ~ Schedule-at-a-Glance

The abstracts are grouped by symposia, followed by all of the oral presentations, and conclude with all of the poster presentations.

Wednesday, October 27, 2010

9:00 am – 4:00 pm **Workshops**
 4:30 – 7:00 pm **Mentor/Mentee Program and Welcome Reception**
 7:00 pm – 8:30 pm **Plenary Session: Getting G Theory to Work for You**

Thursday, October 28, 2010

8:00 am – 6:45 pm **Poster Session 1** on display (p. 46-78)
 7:45 – 9:30 am **Welcome Remarks and Plenary Session: Psychometric Methods**
 9:45 – 11:15 am **Oral session: Mixed Methods** (p. 14-15)
Oral session: Responsiveness I (p. 15-16)
Oral session: Pediatrics (p. 16-17)
Oral session: Oncology I (p. 17-18)
 11:15 – 11:30 am **Break**
 11:30 am – 1:00 pm **Oral session: Analysis Issues** (p. 18-20)
Oral session: Economic Evaluation I (p. 20-21)
Oral session: Mental Health (p. 21-23)
Oral session: Qualitative Methods (p. 23-24)
 1:00 – 2:00 pm **Lunch on Your Own/Committee/SIG Meetings**
 2:00 – 3:30 pm **Invited Symposium: Rating Scale Validity**
Symposium 1430: Development and Comparisons of Alternative Preference-Based Measures of Health (p. 2-3)
Symposium 1812: Recent Advances in the Genetic Underpinnings of QoL from the GENEQOL Consortium (p. 3-4)
Symposium 1173: Methodological Advances in Interpreting Change (p. 4-5)
 3:30 – 3:45 pm **Break**
 3:45 – 5:15 pm **Oral Session: Scale Selection** (p. 24-25)
Oral Session: Geriatrics & End of Life (p. 25-26)
Oral Session: Fatigue (p. 26-28)
Oral Session: Validity (p. 28-29)
 5:15 – 6:45 pm **Meet the Author Poster Session 1**
 6:45 pm **Special Meetings**

Friday, October 29, 2010

8:00 am – 6:45 pm **Poster Session 2** on display (p.79-111)
 7:45 – 9:30 am **President's Address and Plenary Session: The Routine Use of PROs in Health Service Decision Making**
 9:45 – 11:15 am **Oral session: Instrument Development** (p. 29-30)
Oral session: Assessment Mode Technology (p. 30-32)
Oral session: Pain (p. 32-33)
Oral session: Theory (p. 33-34)
 11:15 – 11:30 am **Break**
 11:30 am – 1:00 pm **Oral session: Psychometric Methods** (p. 35-36)
Oral session: Translation and Cross Cultural Issues (p. 36-37)
Oral session: Oncology II (p. 37-39)
Oral session: Obesity (p. 39-40)
 1:00 – 2:00 pm **Lunch on Your Own/Committee/SIG Meetings**
 2:00 – 3:30 pm **Symposium 1538: The Challenges of Symptom Assessment in Clinical Research** (p. 5-7)
Invited Symposium: Current Methods for Measuring and Valuing Health States
Symposium 1163: Translating PROs into Decision Making in Oncology (p. 7-8)
Symposium 1458: Using the WHOQOL – a Contemporary View (p. 8-9)
 3:30 – 3:45 pm **Break**
 3:45 – 5:15 pm **Oral Session: Responsiveness II** (p. 40-41)
Oral Session: Economic Evaluation II (p. 41-43)
Oral Session: Clinical Decision Making (p. 43-44)
Oral Session: Breast Cancer – Oncology III (p. 44-45)
 5:15 – 6:45 pm **Meet the Author Poster Session 2**
 6:45 pm **Special Meetings**

Saturday, October 30, 2010

8:00 am – 2:30 pm **Poster Session 3** on display (p. 112-144)
 7:45 – 9:15 am **Symposium 1370: Development and Health in Childhood** (p. 9-11)
Symposium 1408: Existing/Novel Methodologies for Testing the Effectiveness of Using PROs in Clinical Practice (p. 11-12)
Invited Symposium: Information Systems for Collection and Use of PROs in Clinical Practice
Symposium 1685: Adapting PROMs for Use with Diverse Populations (p. 12-13)
 9:15 – 9:30 am **Break**
 9:30 – 9:45 am **President's Award Talk**
 9:45 – 11:15 am **Plenary Session: Dissemination and Validation of PRO Data into Clinical Care**
 11:15 – 11:30 am **Break**
 11:30 am – 1:00 pm **Plenary Session: Incorporating PRO in Health Policy Decisions**
 1:00 – 2:30 pm **Meet the Author Poster Session 3 and Reception**
 2:30 – 3:30 pm **Members Meeting**
 3:30 – 5:15 pm **Break**
 3:45 – 5:15 pm **Plenary Session: Modern Test Theory and the Future of Health Assessment**
 7:00 pm **Banquet**

SYMPOSIA

Symposium 1430

Development and Comparisons of Alternative Preference-Based Measures of Health

Steven B. Clauser, *Outcomes Research Branch, National Cancer Institute, Bethesda, Maryland*, John Brazier, *School of Health and Related Research, Sheffield, Sheffield, South Yorkshire, UK*, David Feeny, *Center for Health Research, Kaiser Permanente Northwest, Portland, Oregon*, Dennis A. Revicki, *Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD*, Paul Kind, *Centre for Health Economics, University of York, Heslington, York, UK*

This symposium will examine alternative strategies for deriving preference-based measures of health from existing instruments, compare different approaches, and comment upon the appropriateness of different uses of the measures.

Individual Abstract Number: 1721**PROceeding with care**

Paul Kind, *Centre for Health Economics, University of York*

The use of utility-weighted index measures for reporting patient outcomes is contra-indicated in all but economic analysis. FDA guidance regarding the use of PRO measures runs counter to the requirements demanded by health economics orthodoxy. HrQoL measures for use in clinical decision-making should arise directly from the patient if they are to meet PRO standards. A proposed extension of the classification of PRO measures would include pPROs (processed PROs) which effectively rescale directly recorded patient responses. Any such rescaled HrQoL will depart from fundamental PRO design standards. Utility-weighted outcome metrics such as QALYs create non-standard PRO measurements that have no legitimacy in operational decision-making.

Individual Abstract Number: 1702**Health Preference Assessment in the PROMIS Project: Estimation and Variation in Preference Scores by Demographic and Disease Groups**

Dennis A. Revicki, *Center for Health Outcomes Research, United BioSource Corporation*

Aim: Preference-based health index scores provide a single summary score assessing overall health-related quality of life and are useful as an outcome measure in clinical studies, for estimating quality-adjusted life years for economic evaluations, and for monitoring the health of populations. We predicted EuroQoL (EQ-5D) index scores from Patient-Reported Outcomes Measurement Information System (PROMIS) global items and selected domain item banks. **Methods:** This was a secondary analysis of health outcome data collected in an internet survey as part of the PROMIS Wave 1 field testing. For this study, we included the 10 global items and the physical function, fatigue, pain impact, anxiety, and depression item banks. Linear regression analyses were used to predict EQ-5D index scores based on the global items and selected domain banks. Estimated EQ-5D scores were examined by demographics (gender, age, race) and by chronic disease group. **Results:** The regression models using eight of the PROMIS global items explained 65% of the variance in the EQ-5D. When the PROMIS domain scores were included in a regression model, 57% of the variance was explained in EQ-5D scores. Mean estimated EQ-5D scores varied by age groups ($p < 0.01$) and by chronic disease groups compared with those with no reported chronic diseases ($p < 0.01$). **Conclusions:** EQ-5D preference scores can be

predicted from either the PROMIS global items or selected domain banks. Application of the derived regression model allows the estimation of health preference scores from the PROMIS health measures for use in economic studies.

Individual Abstract Number: 1433**Developing preference-based measures from existing quality of life measures: why, how and should we?**

John Brazier, *School of Health and Related Research, Sheffield, Sheffield, South Yorkshire, UK*

AIMS: QALYs are increasingly being calculated using health state utility values provided by generic preference-based measures of health (e.g. EQ-5D). However, generic measures are not used in all studies and generic measures may not cover all dimensions of relevance to some medical conditions. **METHODS:** Recent years has seen the rapid development of methods for deriving preference-based measures from existing generic and condition specific measures, rather than developing new measures de novo. This presentation will review the rationale, the methods and the problems with this approach. **RESULTS:** Specific topics to be covered include: methods for deriving health state classifications to generate states for valuation, methods of valuation and modelling, validation and comparisons with generic measures, and concerns about the use of condition specific preference-based measures, including the hindrances to cross programme comparability from side effects, comorbidities and focusing effects. It will draw on experience from developing preference-based measures from the SF-36, SF-12, King Health Questionnaire, AQoL, OABq and EORTC QLQ-C30. **CONCLUSIONS:** Any advantages in improved relevance and sensitivity of the preference-based condition specific measures must be weighed against these concerns and they will vary between conditions.

Individual Abstract Number: 1434**Floors, Ceilings, and Foundations: Comparisons Among Generic Preference-Based Measures**

David Feeny, *Center for Health Research, Kaiser Permanente Northwest, Portland, OR*

Aims. There are two major components to generic preference-based measures: the health-status classifications system and the corresponding multi-attribute scoring system. The aim is to compare these two basic components of each of five widely used measures: EQ-5D, Health Utilities Index Mark 2 (HUI2) and Mark 3 (HUI3), the Quality of Well-Being Scale (QWB), and the Short-Form 36 (SF-6D). Floor and ceiling effects, characteristics of the health-status classification system, can attenuate the usefulness of measures in estimating the burden of illness or the effectiveness of interventions to treat or prevent health problems. With respect to scoring functions, ignoring quantitatively important preference interactions among attributes can attenuate the validity of scores. **Methods.** Results from clinical studies and population health surveys are used to examine each measure for evidence of floor and ceiling effects. The concept of preference interactions will be illustrated and evidence for each of the five scoring functions will be reviewed. **Results.** There is substantial evidence that scores from these measures are not interchangeable. There is evidence of substantial floor effects (coronary artery disease; elective hip arthroplasty, diabetes, low back pain) associated with SF-6D and substantial ceiling effects associated with EQ-5D (diabetes, population health surveys). In population health surveys, HUI2 and HUI3 have modest ceiling effects. With respect to scoring functions, there is substantial evidence (HUI1, HUI2, HUI3, ALSUI, ASUI, RSUI) of quantitatively important and statistically significant

preference complementarity, calling into question the validity of the linear additive functional form that ignores preference interactions. Conclusions. There are major differences among the health-status classification and scoring systems of the five measures. Investigators need to choose a measure with care to align their choice of measure with the context of their clinical or population health application. Users of results from utility studies need to interpret scores carefully.

Symposium 1812

Recent Advances in the Genetic Underpinnings of QoL from the GENEQOL Consortium

Jeff Sloan, Health Sciences Research, Mayo Clinic, Rochester, MN

The purpose of this session is to provide updates of three different confirmatory studies that indicate the genetic pathways that were theorized by the GENEQOL consortium roughly one year ago have been successfully completed with positive results. This session will present each of the three studies turn indicating: 1) the importance of the inflammatory pathways for cytokines as a contributing factor to overall QOL and fatigue; 2) the importance of the COMT opium expression pathways for pain 3) the TYMSDPYD cell structural pathway for fatigue and overall QOL The implications of these findings for genetic research, the relationship of these findings to other biomarker laboratory-based variables, and the future plans for the consortium will be provided.

Individual Abstract Number: 1210

Genes Selected For Their Relevance To Pain Are Also Associated With Fatigue And Dyspnea: Evidence Of The European Pharmacogenetic Opioid Study

Ailko H. Zwinderman, Medical Epidemiology and Biostatistics, Mirjam A. Sprangers, Medical Psychology, Frank Baas, Neurogenetics, Cornelis J. Van Noorden, Cell Biology and Histology, Academic Medical Center, University of Amsterdam, Amsterdam, Netherlands, Lukas Radbruch, Palliative Medicine, University Clinic, Aachen, Germany, Andrew Davies, Palliative Medicine, Royal Marsden NHS Foundation Trust, Sutton, United Kingdom, Dick F. Swaab, -, Netherlands Institute for Neuroscience, Amsterdam, Netherlands, Jeff Sloan, Health Sciences Research, Mayo Clinic, Rochester, MN, Stein Kaasa, Intensive Care Medicine, Frank Skorpen, Laboratory Medicine, Pal Klepstad, Intensive Care Medicine, Norwegian University of Science and Technology, Trondheim, Norway

AIMS: There is emerging evidence for a genetic basis of quality of life (QL). However, research into the direct associations between QL outcomes and genes is sparse. The objective is to determine the association between a selected set of QL domains with a selected set of candidate genes. METHODS: A group of 2294 patients with advanced cancer, heterogenous to cancer site, using an opioid for pain were recruited from 17 medical centers in 11 European countries. Overall QL, physical, role, and social functioning, fatigue and dyspnea were assessed with the EORTC QLQ-C30. Sociodemographic and clinical variables were used as covariates. DNA was extracted from blood. A total of 359 polymorphisms (SNPs; differences in one base-pair order between one portion of the population and another), belonging to 149 genes, were selected for their relevance to pain and opioid pharmacology. Univariate regression analyses were conducted between QL scale scores and SNPs, using Bonferroni corrections, and controlling for covariates. Canonical correlation analysis of the QL scores and the SNPs was performed with an elastic net penalty to account for the multicollinearity among the SNPs. RESULTS: On average, patients reported poor QL, but the variation was large, e.g., Fatigue: Mean = 63.8; sd = 25.0; Dyspnea: Mean = 32.9, sd = 33.9. Analyses of the

association between the QL scores and the SNPs revealed significant associations for Fatigue and Dyspnea ($p = 0.00014$). SNPs in the COMT and OPRM1 genes were related to fatigue (effect size 0.20) and SNPs in the COMT and HTR3B genes were associated with dyspnea (effect size 0.29). CONCLUSIONS: Genes selected for their relevance to pain were also found to be associated with fatigue and dyspnea, suggesting a common underlying biological substrate. Whereas these findings need to be replicated, such meaningful results may help identifying future patients who are susceptible to fatigue and dyspnea, to better target preventive strategies and/or specific support.

Individual Abstract Number: 1777

Expansion of the Wilson & Cleary Theoretical Model to Incorporate Genetic Influences on Quality of Life

Jeff Sloan, Health Sciences Research, Mayo Clinic, Rochester, MN, Mirjam Sprangers, Psychology, Amsterdam Medical Center, Amsterdam, Netherlands

AIMS: We expand the widely used theoretical model of Wilson and Cleary that links biological and patient-reported QOL to incorporate genetic influences. Wilson and Cleary acknowledged that the most fundamental biological determinants of health status are molecular and genetic factors. However, they had chosen not to incorporate these explicitly in their model because at the time these were not commonly measured and applied in routine clinical practice. METHODS: We present the original and revised Wilson and Cleary model. We describe multiple examples involving pain, fatigue and overall QOL in terms of how the theoretical framework for each of these patient-reported outcomes can be expanded to include genetic influences. We identify the physiological pathways for each of the three endpoints and recent data from the GENEQOL consortium that indicates confirmatory findings of specific genetic components for these three endpoints in studies involving cancer patients. RESULTS: Datasets involving colorectal and lung cancer patients demonstrate that genetic single-nucleotide polymorphisms involving the inflammatory pathway(SNPs) have been identified for fatigue including DPYD, TYMS, and cytokines. These are consistent with the biological pathways and variables previously identified by the GENEQOL consortium as being credible mechanistic models to explain a potential relationship between genetic influences and patient-reported outcomes. CONCLUSIONS: The expanded Wilson & Cleary theoretical framework can be used in combination with wstablished biological pathways to facilitat ethe exploration of genetic influences of patient-reported health-related quality of life.

Individual Abstract Number: 1585

A Genetic Link to QOL: The Relationship Between Cytokine Gene Single Nucleotide Polymorphisms and Symptom Burden and Quality of Life in Lung Cancer Survivors

Sarah M. Rausch, Health Outcomes and Behavior, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL, Matthew M. Clark, Christi Patten, Psychiatry and Psychology, Jeff Sloan, Biostatistics, Ping Yang, Epidemiology, Mayo Clinic, Rochester, MN

AIMS: Aims: Previous research has demonstrated that many lung cancer survivors will report difficulties with symptom control and will experience a poor quality of life (QOL). Although recent studies have suggested a relationship between single nucleotide polymorphisms (SNPs) in several cytokine genes with cancer susceptibility and prognosis, associations with symptom burden and QOL have not been examined. Therefore, the primary aim of this study is to identify SNPs related to symptom burden and QOL outcomes in lung cancer survivors. METHODS: Methods: All participants were enrolled in the Mayo Clinic Lung Cancer Cohort

upon diagnosis of their lung cancer. 1149 Caucasian lung cancer survivors, (440 surviving < 3 years; 354 surviving 3-5 years; and 355 surviving > 5 years) completed questionnaires and had genetic samples available. Outcomes included symptom burden (pain, fatigue, appetite, cough, dyspnea, hemoptysis) as measured by the Lung Cancer Symptom Scale (LCSS) and health related quality of life as measured by the SF-8. RESULTS: Results: Twenty-one single nucleotide polymorphisms in cytokine genes were associated with symptom burden and QOL outcomes. Our results suggested both specificity and consistency of cytokine gene SNPs in predicting outcomes. CONCLUSIONS: Conclusion: These results provide support for genetic predisposition to QOL and symptom burden and may aid in identification of lung cancer survivors at high risk for symptom management and QOL difficulties.

Symposium 1173

Methodological Advances in Interpreting Change: A Head-To-Head Comparison Of Response Shift Assessment in a National Sample of Multiple Sclerosis Patients

Carolyn E. Schwartz, *Medicine and Orthopaedic Surgery, DeltaQuest Fdn and Tufts U School of Medicine, Concord, MA*, Belinda L. King-Kallimanis, *Medical Psychology, University of Amsterdam, Amsterdam, The Netherlands*, Sara Ahmed, *School of Physical and Occupational Therapy, McGill University, Montreal, QC, CANADA*, Yuelin Li, *Behavioral Science, Memorial Sloan Kettering Cancer Center, New York, NY*, Carolyn E. Schwartz, *Medicine and Orthopaedic Surgery, DeltaQuest Fdn and Tufts U School of Medicine, Concord, MA*

The growth in the prominence and precision of patient-reported outcome (PRO) measures has facilitated increased recognition of the impact of adaptation on such measures. A growing body of evidence suggests that 'response shifts' take place over time when individuals experience health state changes. These response shifts comprise changing their internal standards, values, or meaning of the target construct one is asking them to self-report. Different methods have been proposed to detect response shift, including design approaches, individualized approaches, and statistical approaches, each having advantages and disadvantages. Although the understanding and application of these methods has actively evolved over the past decade, all of these research efforts have been conducted in different diseases, using different data sets, measures, and designs. Consequently, cross-measure validation has not been possible, that is do different methods identify the same patients undergoing the same type and direction of response shifts? This symposium will report the findings of an ISOQOL Special Interest Group collaboration that utilized one dataset of 3,008 people with multiple sclerosis and compared 4 recently developed methods for evaluating response shift: at the group level: (1) differential item functioning analysis based on Item Response Theory; and (2) structural equation modeling; at the individual level, (3) latent trajectory analysis; and (4) classification and regression tree modeling. All teams utilized the same characterization of three patient groupings for hypothesis testing: actively-relapsing (n=1582), progressing-without-relapsing (n=639), and stable (n=787). Median follow-up in the sample was 4 years. Each analytic team's findings will be presented with an emphasis on the similarities and differences in findings and how well the methods utilized all available data. Future directions for response shift research will then be discussed drawing on work done in people with HIV, comparing findings of the then-test and Appraisal-Profile.

Individual Abstract Number: 1177

Differential Item Functioning Over Time as a Preliminary Response Shift Detection Method

Carolyn E. Schwartz, *Medicine and Orthopaedic Surgery, DeltaQuest Fdn and Tufts U School of Medicine, Concord, MA*, Rita Bode, *Center for Rehabilitation Outcome Research, Feinberg School of Medicine*

AIMS: Differential Item Functioning (DIF) analyses were conducted to evaluate whether PRO item characteristics changed due to health state changes related to relapses or disease progression using MS Registry data. DIF analysis examines for differential functioning of items after controlling for overall group differences. Known Groups DIF investigated Recalibration DIF (i.e., Are disease trajectory groupings changing their internal standards of disability over time?) and Change DIF investigated Reconceptualization DIF (i.e., Are group differences consistent at baseline and follow-up?) METHODS: DIF was evaluated for Known Groups and for Change. Performance Scales data from 1816 MS Registry respondents who had 2 assessments at least 18 months apart was analyzed using LORDIF software; Rsquare change significant at the .01 level was used as the criterion for identifying items exhibiting DIF. Respondents were classified as Relapsing, Progressive, and Stable based on their survey responses. For Known Groups, item responses for Progressive and Relapsing groups were compared to responses for the Stable group, separately by assessment; For Change, item responses were compared over time for respondents within each classification. T-tests were conducted on the sum scores to examine overall group differences: independent t-tests for the Known Groups and dependent t-tests for the Change group comparisons. RESULTS: For the Known Group comparisons, independent t-test results show significant differences in sum scores at $p < .001$ for both comparisons at both assessments. For the Change comparisons, dependent t-test results suggested that sum scores were different only for the Progressive group ($p < .05$). No DIF was detected for Known Group or Change using the R-square change criterion. CONCLUSIONS: DIF analysis did not detect response shifts in this sample. We conclude that DIF-over-time is not a useful method for examining response shift in longitudinal data.

Individual Abstract Number: 1178

Using structural equation modeling to detect response shift in performance and QOL scores of multiple sclerosis patients

Belinda L. King-Kallimanis, *Medical Psychology, University of Amsterdam, Amsterdam, The Netherlands*, Frans J. Oort, *Education, Faculty of Social and Behavioural Science, University of Amsterdam*, Sandra Nolte, *Association of Dermatological Prevention*, Carolyn E. Schwartz, *Medicine and Orthopaedic Surgery, DeltaQuest Fdn and Tufts U School of Medicine*, Mirjam A. Sprangers, *Medical Psychology, University of Amsterdam*

AIMS: To illustrate two different ways in which structural equation modeling (SEM) can be used for response shift (RS) detection: with measurement occasions either random (Study 1) or fixed (Study 2), and health state operationalized either as a fixed group membership (Study 1) or as time varying covariates (Study 2). METHODS: In Study 1, we explored seven items of the Performance Scale measuring physical and mental aspects of perceived disability (latent variables PHYSDIS, MENTDIS) of 771 stable, 629 progressive, and 1552 relapsing patients. Time lags between the first three measurements varied and were accounted for by introducing time-since-diagnosis as an exogenous variable. In Study 2, we considered the SF-12 scales measuring physical and mental components of QOL (latent variables PHYSQOL, MENTQOL). We selected three fixed measurements of 1767 patients with equal six-month time lags. Health state was accounted for by exogenous variables RELAPSE (yes/no) and SYMPTOMS (worse/same/better) in single-group SEM.

RESULTS: In Study 1, progressive and relapsing patients reported greater disability than stable patients but little longitudinal change. RS was found with stable and relapsing patients: At the first measurement they reported greater sensory disability than would be expected based on their latent (“true”) scores on PHYSDIS and MENTDIS. In Study 2, RELAPSE and SYMPTOMS were associated with PHYSQOL and MENTQOL but no longitudinal change was found. RS: Patients seemed less inclined to report well on the role-emotional scale at the second measurement. To interpret this as RS is controversial as it occurred at the middle measurement occasion only. **CONCLUSIONS:** While small RS were found, they had little impact on the evaluation of true change in both the Performance Scale and the SF-12. A possible reason for the lack of RS is the absence of a catalyst such as an intervention between measurements. The two studies serve to show that SEM can be used with either random or fixed measurement occasions.

Individual Abstract Number: 1179
Latent Trajectory Analysis did not Detect Response Shift in General Health among MS Patients

Sara Ahmed, School of Physical and Occupational Therapy, McGill University, Montreal, QC, CANADA, Nancy Mayo, Susan Scott, Ayse Kuspinar, Stanley Hum, Medicine, School of Physical and Occupational Therap, McGill University, Carolyn E. Schwartz, Medicine and Orthopaedic Surgery, DeltaQuest Fdn and Tufts U School of Medicine

Aims: While most analytical approaches to date assess response shift (RS) at a group level, the Mayo et al latent trajectory analysis (LTA) method evaluates RS at the individual level. We aim to estimate the proportion of RS in individuals with MS as detected by LTA with subject-centered residuals. **Methods:** Recently diagnosed participants in the NARCOMS Registry were included if they responded to the general health (GH) question of the SF-12 in at least 3 surveys (median; 6 surveys, range 3-12). Linear growth modeling was used to identify predictors of self-reported GH. To assess reconceptualization and reprioritization RS, centered residuals from each time point were used to determine group-based trajectories. Dual trajectories of GH and a measure of severity (PDSS) were used to examine convergence in change patterns over time. **Results:** 10,332 surveys from 1,566 individuals were included in this study. The predictive GH model explained 55% of the variance. Trajectory analyses of the centered residuals for the GH model indicated that over 99% of subjects did not experience a RS (i.e., a flat trajectories over time), with 0.3% who lowered their rating of health although their time-dependent predictors indicated stable or better health indicators over time. Among 13% of subjects with flat trajectories of PDSS (i.e., no symptoms of MS), 87% were in GH trajectory groups lying between very good and excellent, and the remaining 14% in groups lying between good and very good, with 5% decreasing most strongly decreasing GH group (i.e., from very good to good). Among the 1.2% in the rapidly deteriorating PDSS group, 81% decreased from very good to good. **Conclusions:** Preliminary analyses suggest that a lower percentage of individuals experienced RS than previous research on smaller samples. These results may indicate the true absence of RS, or may be limited by using a categorical outcome on a single-item measure of GH, and by methodological caveats of large Registries, such as incomplete clinical information, and variable timing of follow-up surveys. Future analyses use growth curve analyses to assess RS at the individual level.

Individual Abstract Number: 1180
Using Classification and Regression Tree to Examine Evidence of Quality Of Life Response Shift in Patients with Multiple Sclerosis
Yuelin Li, Behavioral Science, Memorial Sloan Kettering Cancer Center, New York, NY, Carolyn E. Schwartz, Medicine and Orthopaedic Surgery, DeltaQuest Fdn and Tufts U School of Medicine

Aims: To examine evidence of QOL Response Shift (RS) in Patients with Multiple Sclerosis using Classification and Regression Tree (CART) technique. This analysis allows an examination of different pathways to similar QOL scores as well as pathway complexity by disease-trajectory group. **Methods Subjects/Design:** 3,008 MS patients from the NARCOMS Registry assessed an average of 6 times (range 3-12) at a median interval of 6 months. **Outcomes:** SF-12v2 Physical & Mental Component Scores (PCS, MCS). Covariates included Patient-Determined Disease Steps (PDDS), Performance Scales (PS) in 11 domains (e.g., pain, fatigue, mobility, etc.), & symptomatic therapies; 3 disease trajectory groups were identified: 1) Relapsing (n=1582); 2) Stable (n=787); and 3) Progressive Without Relapse (n=639). CART trees were fitted separately by trajectory group (6 trees). **Results** Plots of individual data suggested a remarkable stability in PS domain scores over time. Nonetheless, the CART detected interactions supporting 2 RS hypotheses. RS1: distinct paths to similar scores. The 3 trajectory groups reached similar PCS & MCS scores through different PS paths. For example, the highest PCS scores (~55 in all groups) were derived from different paths. The Progressive and Relapsing patients' paths to high PCS were defined by minimal gait and pain disability only, whereas the Stable patients' high PCS scores were also defined by minimal overall disability. In contrast, very low scores were derived from distinct paths: Progressive and Relapsing patients' low scores were determined by moderate pain, fatigue, mobility, and PDDS disability; whereas Stable patients' low scores were determined by pain and PDDS. RS2: tree-complexity. The groups' path complexity (i.e., interactions) for MCS were different, with Stable patients showing the most complex interactions, and Relapsing patients showing the least complex. Cognition was most important among Stable patients, and fatigue in Relapsing and Progressive patients. **Conclusions** The CART methodology elucidated a different disability configuration (RS2) in the 3 trajectory groups. CART may be used to understand recalibration (cut-points for interactions by group), reprioritization (order of domains in tree pathway) and reconceptualization (reduction in number of domains in a pruned tree).

Symposium 1538

The challenges of symptom assessment in clinical research: Illustrations in gastrointestinal conditions

Tara Symonds, Primary Care Business Unit, Pfizer Ltd, Sandwich, Kent, UK, Antoine Regnault, Statistics & Psychometrics, Mapi Values, Lyon, France, Robyn T. Carson, Health Economics & Outcomes Research, Forest Research Institute, Jersey City, NJ, Isabelle Mear, Mapi Institute, Lyon, France, Olivier Chassany, Université Paris 7 Denis-Diderot, Assistance Publique Hopitaux de Paris, Paris, France

Symptoms are the first, and probably the purest, reflection of patients' experience of their condition. As symptoms are the primary reason for consulting a physician, symptoms also intersect the clinical perspective and patient experience. Clinicians commonly deal with symptom reports by patients since symptoms are used for treatment and diagnostic decisions. Therefore including symptom assessment in clinical research can be used to capture key patient outcomes that may allow clinicians to assess the efficacy and value of a treatment

and aid clinical decision-making. However, symptoms have specific features compared to other patient outcomes, and their assessment therefore deserves particular attention. This symposium will show how specific features of symptom measurement can be addressed, using examples from the gastrointestinal disease area. Firstly, symptom measures require different measurement models than other commonly measured outcomes. The development of a formative measurement model for a symptom scale using real data from a clinical trial of chronic constipation will be presented. Secondly, symptom assessments are particularly challenging and essential in some populations: the assessment of symptoms in children will be illustrated with an example of qualitative research in children with Irritable Bowel Syndrome with Constipation (IBS-C), conducted to support the development of a pediatric IBS-C symptom measure. Thirdly, when designed to be used in international settings, symptom measures need to overcome specific cross-cultural challenges. The implications for the international development and the linguistic validation of symptom measures will be presented using a critical appraisal of a wide range of linguistic versions of a questionnaire assessing symptoms of upper gastrointestinal disorders. Finally, the symposium will be concluded with a discussion on specific uses and challenges of the symptom assessment in clinical research. This discussion will also address the European Medicine Agency perspective on this topic.

Individual Abstract Number: 1603

Similarities and differences in the expression of symptoms across countries: the translations of the PAGI-SYM 20

Isabelle Mear, Mapi Institute, Lyon, France, Katrin Conway, Mapi Research Trust, Antoine Regnault, Psychometrics & Statistics, Mapi Values, Catherine Acquadro, Mapi Research Trust

Objectives: To determine linguistic and/or cultural differences in the expression of symptoms in the translations of the PAGI-SYM 20, a 20-item, US developed PRO measure investigating symptom severity in patients with upper gastrointestinal disorders. **Methods:** 1. Identification of existing translations of the PAGI-SYM 20; 2. Review of translation documentation and coding of the differences observed in the expression of symptoms across languages. **Results:** 26 translations were identified corresponding to 6 linguistic families: Afro-Asiatic, Altaic, Dravidian, Indo-European, Uralic and Niger Congo. Observed differences were mostly linguistic. Where a literal translation was impossible, paraphrases, synonyms and different syntax were used. Items using 2 similar expressions in the original used a single term in the translation. In Kannada, Tamil, Xhosa, Zulu and Sesotho 'stomach or belly' was translated by one word. The word raising the most discussion was 'discomfort'. Paraphrases in the translations referred to 'unpleasant disturbing sensation' (Latvian), 'not feeling relaxed' (Xhosa); 'not feeling well' (Zulu). Synonyms included 'irritation' (Kannada) and 'uneasiness' (Malayalam). There was however no difference in the translation of other symptoms such as 'vomiting', where literal equivalents were found in all languages. **Conclusion:** Results show that differences in the expression of symptoms can be observed across all languages. Most differences were linguistic where Dravidian and Niger Congo languages revealed more differences with respect to the original than the Indo-European ones. However the case of "discomfort" raises the question of a potential cultural component in the expression of more subjective and less observable symptomatic experiences. It would be interesting to review other symptom questionnaires and their translations to see if the predominance of a linguistic impact on the cultural impact in symptom assessment can be generalized, and if a consistent difference pattern exists between the expression of signs (objective) and symptoms (subjective).

Individual Abstract Number: 1597

Development of symptom measures reflecting the relative impact of symptoms on Health-Related Quality of Life: Application to chronic constipation

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Aims: The objective of this study was to investigate symptom measurement. Symptom impact is commonly derived from self-administered symptom questionnaires by simple summation, but this approach does not account for the varying importance of symptoms to patients. We explored an approach allowing symptom indices to be developed: such indices would involve a weighting system based on the relative impact of symptoms on patients' health related quality of life (HRQOL). This approach, which uses formative measurement in the framework of structural equation modelling (SEM), was applied to a questionnaire assessing chronic constipation symptoms (PAC-SYM). **Methods:** SEM was applied on baseline data of 988 patients randomly selected from 1977 patients of 3 identical double-blind, randomised, placebo-controlled clinical trials of prucalopride, a selective 5-HT₄ agonist, to placebo in patients with chronic constipation. Patients completed the PAC-SYM questionnaire, a 12-item instrument assessing constipation symptoms, as well as a constipation-specific (PAC-QOL) and a generic (SF-36) HRQOL questionnaire. Models linking the PAC-SYM items to either generic or constipation-specific HRQOL were considered. **Results:** SEM models showed acceptable fit according to commonly used goodness-of-fit indices for both constipation-specific and generic HRQOL (e.g. Root Mean Residual of 0.05 and 0.06). More symptoms impacted HRQOL measured by SF-36 than by PAC-QOL. Discomfort in the abdomen and false alarm had a noticeable impact in both models. Pain in the abdomen had the greatest impact on SF-36 while its impact was negligible on PAC-QOL. **Conclusion:** Sorting symptoms according to their impact on HRQOL with formative SEM was shown to be theoretically defensible, practically doable and led to clinically sensible results. The HRQOL measure used as an anchor for the weighting system was shown to impact the resulting index and should therefore be selected cautiously. Our approach is promising to create symptom measures that would reflect the varying importance of symptoms to patients.

Individual Abstract Number: 1600

The Symptoms of Irritable Bowel Syndrome with Constipation (IBS-C): Results of Qualitative Interviews with Children and Their Parents

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Aims: The Rome criteria for children/adolescents define Irritable Bowel Syndrome with Constipation (IBS-C) as abdominal pain or discomfort associated with constipation symptoms. Historically, few, if any pediatric IBS-C trials have used symptom measures that have been developed with patient input. The aim of this study was to conduct qualitative interviews with children with IBS-C and their parents/caregivers to develop a pediatric PRO measure of IBS-C symptoms. **Methods:** Semi-structured interviews were conducted with children diagnosed with IBS-C aged: 6-8 (n=10), 9-11 (n=10) and 12-17 (n=10) years. One parent per child aged 6-11, and 5 parents of the 12-17 year olds were also interviewed separately. Play-

doh® and drawing activities were used to help children talk about their abdominal and bowel symptoms. Thematic analysis of transcripts was used to group quotes by concept and to evaluate conceptual saturation. Age appropriate items were developed to measure each concept and were reviewed by expert clinicians. Results: IBS-C symptoms identified as being bothersome to children included: abdominal symptoms - abdominal pain ('stomach hurts') and bloating ('tummy like a balloon'), and bowel symptoms - infrequent bowel movements ('don't go often'), difficulty defecating ('it won't come out'), straining on defecation ('have to push hard'), rectal pain during defecation ('butt hurts'), hard stools, large stools, and a feeling of incomplete evacuation ('some that won't come out'). Saturation was achieved for the above concepts. Conclusions: Results suggest bowel, rectal and abdominal symptoms are all important and bothersome to pediatric IBS-C patients and should be included in treatment assessments. These qualitative interview results were used to develop age-appropriate questions to evaluate this multi-symptom disorder, using methods consistent with regulatory guidelines. The instrument is currently undergoing testing to assess patient understanding and relevance.

Individual Abstract Number: 1619

Making sense of symptom data from clinical trials - the regulatory challenge

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This discussion on specific uses and challenges of the symptom assessment in clinical research will conclude the symposium. In particular, this discussion will address the European Medicine Agency perspective on this topic.

Symposium 1163

TRANSLATING PATIENT-REPORTED OUTCOMES INTO DECISION MAKING IN ONCOLOGY

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During the last decade PROs have been considered of increased importance in cancer treatment. However, in everyday clinical practice physicians rarely use QoL and symptom data in their decision-making. Therefore, translation of the results of PRO research into practice may improve its routine use and inform the clinical decision making process. Comprehensive symptom assessment in routine cancer care is a first step toward PRO implementation in clinical practice and improving quality of cancer treatment. Better symptom control can produce significant improvement in patient's QoL. Effective fatigue management is possible if it is assessed with instruments that can adequately evaluate its prevalence and severity. Information about the discrepancies in estimation of symptom severity between a patient and a physician may provide the basis for better understanding the role of symptom assessment in effective patient-physician communication and adequate symptom management. Incorporation of PRO in decision making in oncology gives solid grounds for the unified approach to cancer treatment and for the improvement of quality of cancer care. Thus, the symposium aims to provide the basis for implementation of

PROs in routine clinical decision making in oncology. In this symposium, we will: Present the state-of-the art of fatigue measurement and management in cancer patients. The focus will be given to the long-term cancer survivors. Discuss the results of the study on discrepancies in estimation of symptom severity between a cancer patient and a physician. The data presented will provide the basis for better understanding the role of symptom assessment in effective patient-physician communication and adequate symptom management. Propose treatment algorithm with incorporation of PRO as an important factor in cancer treatment. The examples of practical applications of this algorithm will be presented. The ultimate goal of the symposium is to make the links between patient-reported outcomes research and clinical practice in oncology, and in doing so to improve quality of cancer care.

Individual Abstract Number: 1201

Factors Influencing Quality of Life in Hodgkin's Disease

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The impact of fatigue on the quality of life of oncology patients is substantial and under-recognized. Fatigue in these patients may begin with a simple decrease in physical activities, but can progress to include a wide range of negative effects that often culminate in patients feeling out of control, lonely, and isolated. According to the general paradigm of cancer survivors and understanding, in general, surviving cancer patients experience some limitations after the end of treatment but ultimately attain a reasonably good level of functioning. An examination of subpopulations and further analyses of data suggest, however, different recovery patterns which may not be in accordance with the above mentioned principle. Patients may (1) improve in their functioning, reach a plateau at approximately year 2 or 3, and then remain at relatively high levels of functioning; (2) improve initially, but deteriorate again after year 2 or 3, never reaching the normal stage; (3) improve, returning to normal; or (4) have a very mixed pattern of high levels of fatigue that is to date very difficult to interpret. Disturbingly, around 60% of the survivors in our population of patients with Hodgkin's disease, who were treated in recent trials of the German Hodgkin Study Group and the European Organization for Research and Treatment of Cancer Lymphoma Group, have medium to high levels of fatigue after 5 cancer-free years and accordingly reduced levels of functioning in several quality of life domains. Similar findings come from recent late effects studies of the surviving patients who were treated for Hodgkin disease in childhood. The nature of this fatigue syndrome, its causes and the course over time remain unclear to date. The patient subgroups at risk have to be identified and possible consequences for treatment have to be developed.

Individual Abstract Number: 1204

Enhancing Patient-Physician Communication By Assessing Cancer-Related Symptoms: Discrepancies In Estimation Of Symptom Severity Between A Patient And A Physician

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Background. Communication between physicians and patients regarding symptoms and their burden continues to be hampered by attitudinal barriers and knowledge deficit among physicians as well as by poor or nonexistent symptom assessment. To provide the basis for better understanding the role of symptom assessment in effective patient-physician communication and adequate symptom management we aimed to study discrepancies in estimation of

symptom severity between a patient and a physician. Methods. 500 advanced cancer patients (male/female ratio - 285/215, mean age 54.2) being treated in institutions across Russia were enrolled in the study. Multiple cancer-related symptoms were assessed with M.D. Anderson Symptom Inventory. Physicians were asked to assess their patients' pain, fatigue, and distress severity as well as symptom interference with general activity on 0-10 numeric rating scale. Symptom severity was categorized as mild, moderate, and severe. The percentage of agreement on patients' and physicians' ratings within one symptom severity grade was defined. Results. Agreement in pain severity estimation between patients and physicians was 66.8 %. The overlap for fatigue and distress was lower (54% and 45%, respectively). Concord of physician and patient ratings of severe symptoms was generally worse than for ratings of mild symptoms. For moderate-to-severe pain ratings the percent of agreement was quite low (28%). Logistic regression model revealed that pain level 6-7 or higher declined probability of agreement on pain ratings between physicians and patients to 0.5 and less. Sixty four percent of clinicians' ratings of symptom interference with general activity were equal or higher than patients' ratings for the each item examined. Conclusion. The findings of this study support the concerns of inappropriate physicians' attitudes and knowledge regarding symptoms in advanced cancer patients. Physicians need to be aware of multiple symptom assessment to enhance communication with patients and to provide adequate symptom treatment.

Individual Abstract Number: 1527

PRO in Decision Making Paradigm in Clinical Oncology: Application to Clinical Practice

Andrei A. Novik, Hematology Dept., National Medical Surgical Center, Moscow, Russia, Tatyana I. Ionova, Quality of Life Dept., Multinational Center for Quality of Life Research, Gary Gorodokin, Quality of Life Dept., New Jersey Center for Quality of Life and Health Out

During the last several decades PRO have been considered of increased importance in cancer treatment. However, in everyday clinical practice physicians rarely use QoL and symptom data in their decision-making. The present work is aimed at developing a new paradigm of decision making with PRO as an important point in cancer treatment. This decision making paradigm consists of three major milestones: 1st - choice of the treatment strategy, 2d - identification of the treatment approach and 3d -determination of treatment outcomes. The paradigm has been tested in the decision making of treatment of more than 800 cancer patients within the network of cancer centers of the National Cancer Research and Treatment Center. The paradigm is based on the principle of balance of cancer treatment strategies. Treatment strategies are determined by the treatment goals. 1.The possible goals of treatment are as follows: - To cure a patient and to maintain his/her QoL (when a cure is possible) - To improve survival and QoL (when a cure is not possible, but we have a chance to improve the patient's life expectancy) - To improve a patient's QoL (when we have no chance to improve the patient's life expectancy) 2.Treatment approach is chosen depending on treatment goal(s). 3. PRO are important endpoints at any stage of the disease and is to be measured before, during treatment, and at follow-up using standardized PRO instruments. 4. Palliative care of cancer patients is to be started in the early stages with its proportional focus increasing as the disease progresses. 5. Management of a cancer patient should be provided in accordance with the treatment algorithm which starts and finishes with the evaluation of Integral QoL Index. The examples of practical applications of this algorithm will be presented. In conclusion, incorporation of PRO in decision making in oncology gives solid grounds for the unified approach to cancer treatment and for the

improvement of quality of cancer care. The proposed treatment algorithm can be used by physicians in their routine practice.

Symposium 1458

Using the WHOQOL - a contemporary view

Suzanne M. Skevington, Psychology, and WHO Centre for the Study of Quality, University of Bath, Bath, Somerset, England, Graeme Hawthorne, Graeme Hawthorne, Psychiatry, The University of Melbourne, Parkville, Victoria, Australia

This symposium considers new departures in using the WHOQOL to improve measurement, and inform care and policies. Uniquely, the WHOQOL offers a generic PROM containing genuinely international concepts expressed in the vernacular of users in the local culture. The papers include new international findings on ageing, and on spiritual quality of life, two long-awaited short-forms and a comparison between old and new measures, new applications for needy populations in the form of specific modules, and contributions from a variety of different cultures. This work makes the WHOQOL more accessible to users than before, and demonstrates some of the many recent advances.

Individual Abstract Number: 1039

The WHOQOL-Pain: Derivation of an instrument to assess Quality of Life in people with chronic pain

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AIMS: Chronic pain (CP) is known to have a significant impact on quality of life (QoL) and numerous generic instruments have been used to assess pain-related QoL in both research and clinical contexts. The WHOQOL is one such generic instrument which allows for the development of modules to assess the specific impact of different characteristics or conditions on QoL. This paper outlines the development of the WHOQOL-Pain. METHODS: This mixed methods longitudinal study involved three distinct stages: item generation (focus groups (n=6; 32 patients; n=3; 17 health professionals; n=2; 10 carers); web survey (n=177)), pilot testing (cognitive interviewing (n=9); cross-sectional survey (n=216)), and field testing (longitudinal survey; (n=133)) in adult patients with CP. RESULTS: From focus groups and a web survey, 108 items were generated representing 10 facets of QoL. After extensive field testing, this was reduced to 16 items representing 4 facets (pain relief, anger and frustration, vulnerability/fear/worry, and uncertainty). Preliminary psychometric properties support the instrument's internal consistency reliability ($\pm=.88$; range .66-.81), sensitivity to change, test-retest reliability, and aspects of validity. CONCLUSIONS: Addressing the health concerns of patients with long term conditions is seen as a priority in health care and this instrument can be used to assess QoL in patients with CP and to guide pain management priorities. This study has implications for future research and clinical practice by allowing for the comprehensive assessment of QoL across multiple domains. Through assessing both generic and pain-specific QoL, it is also possible to compare the QoL of different groups and to track QoL over time. Future research will validate an abbreviated version of the WHOQOL-Pain, will test the instrument in other pain populations, and will be translated into other languages to provide further support for its use.

Individual Abstract Number: 1090**Comparing the Importance of Different Aspects of Quality of Life to Older Adults Across Diverse Cultures**

Anita E. Molzahn, Nursing, University of Alberta, Edmonton, Alberta, Canada, Mary Kalfoss, Nursing, Diakanova University College, Oslo, Norway, Kara Schick Makaroff, Nursing, University of Victoria, Victoria, British Columbia, Canada, Suzanne M. Skevington, Psychology, University of Bath, Bath, UK

AIMS: The purpose of the study was to describe the relative importance of 38 areas of quality of life (QOL) to older adults in 22 countries. The research question was: What are the differences in importance ratings among older adults by gender, age group, level of national development, health status, and culture? **METHODS:** A secondary analysis was conducted of WHOQOL-OLD pilot study data, collected simultaneously in 22 centres (in Australia, France, Switzerland, England, Scotland, USA, Israel, Spain, Japan, China, Hong Kong, Turkey, Lithuania, Czech Republic, Hungary, Canada, Norway, Sweden, Denmark, Germany, Brazil, and Uruguay). Of 7401 older adults (mean 73.1 years), 57.8% were women and 70.1% were healthy. The survey measures were completed by: mail (n=2965); self-administration (not mailed) (n=2546); interviewer assisted administration (n=1381); and other culturally appropriate strategies (n=169). Data were analysed using independent t-tests, multiple regression analysis and MANCOVA. **RESULTS:** There were significant differences in the importance given to various aspects of QOL between: men and women, younger old and older old populations, and those who consider themselves healthy or not. There were significant differences in the importance given to various aspects of QOL for people living in medium and high development countries. Culture explained 15.9% of the variance in the importance ratings of QOL. However, the interaction showed that cultural differences were reduced once health status, gender and age were taken into account. **CONCLUSIONS:** Understanding self-reported importance of diverse aspects of QOL may assist policy makers to identify priorities for the development of programs for the ageing population and health professionals to focus on aspects of QOL of importance to older adults. In light of limited resources, it may be useful to make decisions about services for the ageing population on the basis of importance to the older adults themselves. Physical aspects of QOL might be considered further in future modifications of the WHOQOL-OLD.

Individual Abstract Number: 1285**Creating a short-form of the WHOQOL-SRPB: assessing quality of life in spiritual, religious and personal beliefs**

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AIMS: Research on spiritual quality of life (QoL) in health is in its early stages, yet demands of clinical practice means spiritual QoL is often ignored. The aims were to reassess the items of the long form WHOQOL-SRPB (2006) and gather new data to test the psychometric properties of a streamlined short-form version: WHOQOL-SRPB BREF. **METHODS:** There were three stages of research. First was to re-examine the international psychometric properties of WHOQOL-SRPB items using data contributed by 18 centres world-wide (N=5087) including UK (n=285). Analyses were reviewed and the 'best' item was selected for inclusion into the short-form version. These were integrated with WHOQOL-BREF items. Secondly, the new measure was piloted with a focus group (n=8) who provided feedback on the measure. The final stage involved examining the psychometric properties of the short-form with WHOQOL-SRPB importance items as part of a study of life events and QoL in a UK community sample. **RESULTS:** International data showed acceptable inter-item correlations ($r > 0.40$) and good

correlations for each item to their predicted facet (.41-.94). Twelve items were selected for the short-form questionnaire; one corresponding to each facet. They were integrated with WHOQOL-BREF items. The focus group led to adjustment of some items. The questionnaire was administered to 134 participants (77 female, mean age 40.4); 41 had a disease or impairment. For the total scale $\alpha = 0.84$. SRPB domain correlated with psychological (0.50), social (0.30) and environmental domains (0.34). Love, kindness, peace and inner strength were the most important facets, similar to previous UK findings. Overall spiritual QoL was no different between ill and well participants. The SRPB domain also correlated with positive mood. **CONCLUSIONS:** Findings show that SRPB correlates with aspects of QoL and is deemed important. Developing a streamlined measure allows more successful use and less burdensome assessment of spiritual QoL within health settings. The short-form needs to be investigated in other cultures.

Individual Abstract Number: 1473**Developing the WHOQOL-OLDSF (Short form)**

Graeme Hawthorne, Psychiatry, The University of Melbourne, Alain LePlege, Département d' Histoire et de Philosophie des Science, University of Paris

The aging of many societies worldwide will impose strains on social and health care systems. To provide an evidence-base to assist with decision-making regarding social and health care policies, there is a strong case for assessing the quality of life of older adults. One instrument which has been recently developed to assist with this task is the WHOQOL-OLD. However, at 24 items this is a long instrument for inclusion in questionnaire batteries which may be administered to older adults who may find completion tiring or who may have impaired cognitive function. This paper presents a short version of the WHOQOL-OLD, the WHOQOL-OLDSF. **Methods** To develop the WHOQOL-OLDSF we followed five sequential steps. First we reviewed the conceptual basis of the WHOQOL-OLD and the literature on its psychometric properties; second we sampled from the international WHOQOL-OLD database to ensure that our analyses were based on a representative sample of older adults; third we used item response theory (IRT) analysis to examine the internal structure of the WHOQOL-OLD and derive a more suitable descriptive system for use with older adults, fourth we examined the relationship between the WHOQOL-OLD and the new WHOQOL-OLDSF, and fifth we carried out validation tests in non-representative samples of the WHOQOL-OLD database. **Results** This paper reports the results of the study, including the shorter descriptive system of the WHOQOL-OLDSF and its psychometric properties. **Conclusions** Our results suggest that the WHOQOL-OLDSF, at half the length of the original WHOQOL-OLD, may be a suitable instrument for use with older adults where short measures are preferred.

Symposium 1370**Development and Health in Childhood: Setting the Stage for PRO Assessment Across the Life Course**

Christopher B. Forrest, Katherine B. Bevans, Pediatrics, Children's Hospital of Philadelphia, Philadelphia, PA, Stephen M. Haley, Health and Disability Research Institute, Boston University School of Public Health, Boston, MA, Ulrike Ravens-Sieberer, Center for Obstetrics and Pediatrics, University Medical Center Hamburg-Eppendorf, Hamburg, Germany, Donald L. Patrick, Seattle Quality of Life Group, University of Washington, Seattle, WA

Purpose of Symposium: Most treatments, medications, and devices in healthcare are used in both children and adults. Although objective

assessments of the effects of these interventions use similar measurement instruments across the life span, this is not the case for PRO assessment. The field has produced numerous child-only and adult-only PRO instruments, which has occurred largely because of developmental challenges that characterize childhood. The NIH's Patient Reported Outcome Measurement Information System (PROMIS) has expanded its focus to include a bigger emphasis on child PRO assessment. PROMIS is forging a life course approach to conceptualizing and measuring health so that the same tools (e.g., item banks) can be used across all age groups. PROMIS investigators in this symposium will explore how development affects children's HRQL and PRO assessment methods in order to motivate the theoretical and methodological basis for a life course model for PROs. Format: Part 1--The cognitive tasks involved in self report will be grounded in a theoretical model of child development; implications for PRO assessment at each stage of development will be addressed; Part 2--Longitudinal changes in HRQL that result from child development will be presented using data from the European KIDSCREEN project; Part 3--Alternative methods for linking PRO data across developmental stages and between childhood and adulthood will be evaluated as solutions for forging single instruments across the lifespan; and, Part 4--This final presentation will discuss how to turn challenges in developing PRO measures that span the life course into opportunities. Conclusions: It is now clear that children as young as 8 years-old can provide self-reports with sufficient precision for clinical, pharmaceutical, outcomes, and translational research. The theoretical models and empirical methods that underpin PRO development have advanced sufficiently to permit creation of single instruments that measure the same outcome across the life span.

Individual Abstract Number: 1665
Development of Children's Cognitive Capabilities: Implications for Pediatric Self-Report Measures

Katherine B. Bevans, Pediatrics, Children's Hospital of Philadelphia

A core assumption of PRO measurement is that individuals themselves are the most reliable and accurate observers of their health perceptions and experiences. Limitations in general cognitive competencies, self-awareness, and understanding of health and illness concepts pose barriers to self reporting among children. Aim: To examine theoretical and empirical knowledge of children's self-reporting capabilities in order to provide practical guidance on the use of specific PRO assessment strategies for children of varying developmental levels. Methods: We have elaborated a developmentally-focused framework of self-reporting capabilities that is grounded in theory and empirical evidence of children's rapidly-evolving processing potentials (e.g., processing speed/control, mental representation/manipulation of information), self regulation, and understanding of health concepts and terminology. Results: A review of children's cognitive capabilities and their effects on PRO reporting highlight the need to employ different assessment strategies for children of different age ranges (5-7, 8-11, 12-17 years). Findings will be presented for a broad array of cognitive capabilities. For example, processing speed which is considerably slower among children under 8 and develops rapidly in early adolescence, impacts the degree to which children can efficiently encode questions, retrieve relevant information from memory, integrate information into a summative judgment, interpret and choose response options, and communicate the final answer. Conclusion: Valid and clinically-relevant measures of child PROs must be developed with sensitivity to children's cognitive capacities (e.g., ask questions in language and formats that children can understand). Modern measurement theory may be applied to evaluate the equivalence of various assessment strategies and to equate

multiple versions of PRO assessment tools to ensure continuity of PRO measurement across diverse stages of cognitive development.

Individual Abstract Number: 1679
Empirical Approaches for Linking Child and Adult PROs

Stephen M. Haley, Health and Disability Research Institute, Boston University School of Public Health, David L. Tulskey, Kessler Foundation Research Center

Aims: An anticipated feature of contemporary patient reported outcome (PROs) instruments for clinical populations has been the ability to link items of instruments that have comparable content domains by calibrating scores to a common metric. An essential element for life-span studies is to have an overall measure that links child and adult quality of life measures so that scores from the pediatric studies can be related to scores in adulthood for comparability in studies that include both children and adults and in long-term follow-up studies. The purpose of this presentation is to discuss empirical approaches for linking pediatric and adult instruments in the context of two ongoing studies. Methods: Item Response Theory (IRT) linking studies include both sampling and linking strategies. Sampling procedures consist of common subjects or common items. Linking procedures include either putting all items on a single scale, (common calibration) or using calibration coefficients from common items to link the two instruments. In the first study conducted jointly at three North American Shriners Hospitals for Children Orthopedic Hospitals and through the Model Systems Spinal Cord Injury System in the USA, common items in mobility and self-care domains were collected in a non-equivalent group design from over 800 adults and 385 children with traumatic spinal cord injuries. Calibration coefficients from common items were used to link adult and child versions of the instrument. A second study was conducted using a prospective, common subjects (n=800) method to link PROMIS pediatric and adult domains in children and young adults with disabilities (cerebral palsy, traumatic brain injury, spinal cord injury). Results: We will compare and contrast the assumptions, type of analyses, and results of using non-equivalent group designs and prospective common subject designs for linking pediatric and adult quality of life domains. Conclusions: These linking procedures are fundamental to creating a 'network' of assessments that can be compared with one another in life-span research activities in clinical, pharmaceutical, translational, and long-term follow-up studies.

Individual Abstract Number: 1684
Age-related changes in self-reported quality of life of children and adolescents: a multilevel analysis across 13 European countries

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Aims: To assess possible gender and age differences in different aspects of health-related quality of life (HRQL) in children and adolescents, and to ascertain to what extent these results correspond to theoretical and empirical findings from developmental psychology. Methods: 22,830 youths aged 8-18 years from 13 European countries answered the Item-Response-Theory based "KIDSCREEN 52" questionnaire, which consists of 10 scales covering physical, psychological and social dimensions of HRQL. Using ANOVA, multilevel analysis, and effect sizes, the influence of age and gender on aspects of HRQL is reported. Results: Adolescents (12-18 years) answered the KIDSCREEN-52 Items in a slightly more internally consistent manner than children (8-11 years): Cronbach alpha ranged

from .78-.90 for the adolescents and from .70-.87 for the children. However, no sizeable differential item functioning (DIF) was found in ordinal logistic regression analysis. Below the age of 12, no systematic gender differences in HRQL were observed. After 12 years, HRQL decreased in the majority of HRQL aspects. A strong statistical interaction was observed: On the physical and psychological dimensions, a stronger decrease was found for females than for males. The “d” effect size measure for the decrease between 8 and 18 years was up to 1.2 in females and up to 0.7 in males. Multilevel analysis revealed significant cross-national variation in the gender differences of age-related decreases on some HRQL dimensions. These multilevel effects accounted for up to 1.4% of the total variation on the particular HRQL dimensions, e.g. Physical Well-being, Self-Perception, School Functioning/Wellbeing. Conclusions: Lack of age-related DIF suggests that the same instruments can be used in the 8-17 year-old age range. HRQL significantly decreases with age, a trend that is especially prevalent among girls.

Individual Abstract Number: 1687

A Life Course Approach to Patient Reported Outcomes (PRO) Instrument Development: Turning Challenges into Opportunities

Donald L. Patrick, Seattle Quality of Life Group, University of Washington

The life course perspective, encompassing, the sum total of a person’s actual experience in historical and socioeconomic context, is particularly relevant to development of PRO instruments. This perspective implies age-differentiated psychosociocultural phenomena that are informed by human development. PRO instruments developed from the life course perspective recognize the importance of time, context, process, and meaning within developmental change. Influences can be seen in the conceptual foundation including amassing evidence of content validity and in methodological differences in instrument formatting, mode of administration, and cross-cultural adaptation. This presentation summarizes experiences of this developer in creating PRO instruments for adolescents and adults of various ages who can speak for themselves and non-PRO instruments that rely on the observations of family or clinicians with infants, pre-schoolers, young children, and adults who cannot speak for themselves. In most cases, human needs theory was applied through a developmental lens leading to different item generation and cognitive interviewing approaches. Reading ability and language considerations have been of primary concern. Meaning and method considerations within practical constraints drove most choices. Experience is drawn from development of different generic instruments such as the Youth Quality of Life Instrument (ages 11-18) and Perceived Quality of Life Scale (particularly older adults) and creation of specific instruments for outcomes in cystic fibrosis from infancy to later life.

Symposium 1408

Overview of Existing and Novel Methodologies for Testing the Effectiveness of Using Patient Reported Outcomes in Clinical Practice

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Introduction. The demonstration of community effectiveness using evidence from experimental designs is regarded as providing the most rigorous and least biased information on the effectiveness of healthcare interventions. However, the challenges of conducting research in complex practice-based settings and the multiple and diverse potential sources of contamination may attenuate and sometimes even threaten the ability of a RCT to detect the effects of using PRO in routine clinical care. The purpose of the symposium is to discuss research designs and evaluation techniques for assessing the effectiveness of using PROs in routine clinical practice. The symposium will include presentations on: 1) review of RCTs conducted to evaluate the use of PROs in routine clinical care, illustrating successes and obstacles; 2) alternative study designs and statistical considerations; 3) discussion of applying the health technology assessment framework for diagnostic technologies to the evaluation of using HRQL measures in routine clinical care of chronically ill patients. Presentations 1. What has been done in the past years? Assessing the impact of routinely measuring patient-reported outcomes in clinical practice: critical appraisal of 34 randomized clinical trials. Medical Statistics Department of Public Health University of Aberdeen 3. Applying the Health Technology Assessment Framework for Diagnostic Technologies to Evaluating the Use of HRQL Measures in Routine Clinical Care. Maria José Santana, PhD Research Associate Lung Transplant Program University of Alberta Discussion

Individual Abstract Number: 1417

Assessing the impact of routinely measuring patient-reported outcomes in clinical practice: critical appraisal of 34 randomized clinical trials

Jose M. Valderas, Division of Public Health and Primary Health Care, NIHR School of Primary Care Research, University of Mireia Espallargues, Anna Kotzeva, Jordi Alonso, Health Services Research Unit, Institut Municipal d’Investigació Mèdica

Aim. The purpose of this paper is to critically appraise the best evidence regarding the impact of providing patient reported outcomes (PRO) information to health care professionals in daily clinical practice. **Methods.** We updated a previous systematic review of randomized clinical trials (Medline, Cochrane Library; reference lists of previous systematic reviews; and requests to authors and experts in the field), including hand searches of references citing relevant references on the topic up to May 2010. **Results.** The updated search provided with 6 additional studies for a total of 40 articles and 34 original studies proved eligible. Most trials (20) were conducted in primary care settings performed in the USA (21) and assessed adult patients (31). Information provided to professionals included generic health status (14), and mental health (17). Most studies suffered from methodological limitations, including analysis that did not correspond with the unit of allocation. Nineteen of 29 studies (66%) measuring process of care observed at least one significant result favouring the intervention, as did ten of 23 (43%) that measured outcomes of care. In most trials, the impact of PRO was limited. **Conclusions.** The evidence base for impact on patient outcomes and in settings other than primary care is expanding. There is evidence of improvement on the process of care. Methodological concerns still limit the strength of inference regarding the impact of providing PRO information to clinicians.

Individual Abstract Number: 1420**Alternative designs and statistical considerations**

Peter Fayers, *Medical Statistics, Department of Public Health, University of Aberdeen*

Although many of us believe there are major benefits to be gained by using patient-reported outcomes (PROs) in routine clinical practice, demonstrating tangible benefits has frequently proved elusive. Although randomised clinical trials (RCTs) have become accepted as the standard for comparing alternative forms of clinical interventions, when evaluating the effectiveness of using PROs in clinical practice there are a number of challenges both in terms of study design and the subsequent analysis. However, many RCTs in this setting continue to use simple two-group patient randomisations and comparisons. In this presentation the advantages and disadvantages of this approach will be illustrated. Alternative designs such as cross-over studies and cluster-randomised trials will be illustrated, together with other analytical approaches such as multilevel modelling. The role of non-randomised studies will also be addressed.

Individual Abstract Number: 1421**Applying the Health Technology Assessment Framework for Diagnostic Technologies to Evaluate the Inclusion of Patient Reported Outcomes (PROs) in Routine Clinical Care of Chronically ill Patients**

Maria J. Santana, *Division of Pulmunology, Lung Transplant Program, University of Alberta, David Feeny, Center for Health Research, Kaiser Permanente Northwest*

Aim: To apply the health technology assessment framework for diagnostic technologies developed by Guyatt et al. to the inclusion of PROs in routine clinical care. **Methods:** The evaluation consists of six steps: 1) Technologic capability refers: PROs should be easy to administer, score and interpret. 2) Range of possible uses: the choice of measure depends on the purpose of the measurement, type of measure, performance characteristics and other factors relevant to clinical practice. 3) Diagnostic accuracy: PROs should be valid, reliable and reproducible. 4) Impact on healthcare providers: Healthcare providers are able to interpret the results and use the PRO in the routine care of their patients. 5) Therapeutic impact: the provision of additional information should alter decisions made by healthcare providers. 6) Patient outcome. The use of technology should benefit patients. **Results:** 1) These measures assess a full range of health among diverse patient groups at a single point in time and overtime. PROs should exhibit minimal floor and ceiling effects and should be valid, reliable and responsive to change. 2) For this study the characteristics of the measure and its acceptability to patients and clinicians are relevant. Which of the measures add information to the routine clinical care of the patients? Help with patients' management? Help to improve patient health status? 3) PROs should be valid, reliable and reproducible. The measure should be able to discriminate (identify patients with no, mild, moderate, or severe disease), and evaluate (assess within-person change over time). 4) Healthcare providers find that using PROs improve communication, prompting their patients to reveal information otherwise not shared. 5) As a result of improved patient-clinician communication, changes in management occur and health care provider and patient satisfaction increases. 6) The use of the PROs in routine clinical care improve patient-clinician communication, affects patient management and patient outcomes. **Conclusion:** The inclusion of PROs in routine clinical care can be evaluated using the health technology assessment framework.

Symposium 1685**Adapting PROMs for use with diverse populations: Experiences with American Sign Language**

Steven Barnett, *Steven Barnett, Family Medicine, Erika Sutter, Poorna Kushalnagar, Community and Preventive Medicine, University of Rochester, Rochester, NY*

Objectives: 1) Introduce conference participants to deaf sign language users as a population frequently excluded from research and measures related to HRQOL and PROMs. 2) Describe a process for translating and adapting measures for use with deaf sign language users. 3) Give examples of how the translation/adaption process can identify ways to improve health-related measurement (including HRQOL & PROM) with other populations. **Background:** Deaf people who communicate in sign language are frequently excluded from health-related research and surveillance. Sign languages have no written form, and for complex reasons many deaf people have limited reading skills. Sign languages are not global (for example, American Sign Language and British Sign Language are quite different), nor are they visual representations of a local spoken language. Health research is rarely conducted in a sign language, and few health researchers are fluent in a sign language or deaf themselves. Most sign language users are deaf since birth or early childhood. In the USA, the number of sign language users is not measured by any survey or census; broad estimates range from 100,000 to 2 million users. **Content:** 1st presentation: Will first review the existing literature on health and healthcare experiences of deaf sign language users. Next, the presentation will review the process for adapting and translating patient reported outcomes measures and other health-related survey items for use in sign language. 2nd presentation: Will describe the development and evaluation of a computer-based, touchscreen survey instrument for use in sign language. Evaluation data include instrument beta-testing, key informant interviews, in-depth individual cognitive testing, and pilot testing with keystroke and time-stamp data. 3rd presentation: Will describe the translation and adaptation of health survey items for use with deaf adult sign language users in the USA. The presentation will focus on lessons learned regarding translation/adaptation, including what was learned about the original English language survey items and how they could be improved.

Individual Abstract Number: 1751**Sign Language health surveys: Designing & evaluating a computer-based interface**

Erika Sutter, *Community and Preventive Medicine, University of Rochester, Rochester, NY*

Aims: Many adults deaf since birth or early childhood communicate primarily in a sign language such as American Sign Language (ASL). ASL is different than English and has no written form. For complex reasons, many deaf adults have low reading levels. The best way to accurately collect survey data is in the participant's primary language. A survey in ASL requires use of a video to present survey items. We report our experiences adapting health-related surveys for use in ASL on a kiosk-computer with touchscreen interface. **Methods:** Deaf and hearing researchers, clinicians and community members collaborate to adapt the Consumer Assessment of Healthcare Providers & Systems (CAHPS) and the CDC Behavioral Risk Factor Surveillance System (BRFSS) for use with deaf ASL-users. We developed and evaluated the computer-based survey using individual and group interviews, and individual usability testing. We also conducted exit interviews and analyzed keystroke data. **Findings:** Exit interviews and keystroke data indicate we appropriately responded to feedback elicited during survey development. The presentation will describe

user feedback and team decisions regarding survey design and features. We will present survey use data including: a) race and gender concordance of participants with their chosen survey sign model, b) sociodemographic differences in survey completion time, c) comparison of response choice and order of response options, d) analyses of most and least used survey features. Conclusions: It is now possible to develop and administer a standardized and reproducible health survey in sign language. In addition to providing access to deaf consumers, a computer-based survey with participant-controlled options could allow any participant the opportunity to choose the most accessible survey presentation (written, spoken or signed language).

Individual Abstract Number: 1752

Sign Language health measures: Translation & adaptation

Poorna Kushalnagar, Community and Preventive Medicine, University of Rochester, Rochester, NY

Aims: Many adults deaf since birth or early childhood communicate primarily in a sign language, such as American Sign Language (ASL). ASL is different than English and has no written form. Some US deaf adults use signs with English-like syntax. Many adults deaf since birth/childhood experience fund of information gaps because of limited access to ambient information (e.g.: radio messages, television without captions, overheard conversations). Adapting a survey to be accessible for diverse sign language users requires attention to language, syntax, literacy and fund of information. Understanding data from deaf survey participants requires measuring deaf-related domains. **Methods:** Deaf and hearing researchers, clinicians and community members collaborate to adapt and translate health survey items for use with deaf adult sign language users. The adaptation and translation process includes unpacking (explaining concepts), decentering, translation, back-translation, and in-depth individual cognitive interviews. We used this process to develop two survey scripts, one in ASL and a second in English-based signing. We added deaf-related survey items based on feedback collected from key-informants during individual and group interviews. **Findings:** The presentation will describe the adaptation process, including bilingual team decisions regarding: a) survey items on education level and telephone communication, b) language differences in time-frame specificity, c) uncoupling compound questions, d) translating concepts behind some English terms such as "heart attack," "menopause" and "prescribed." The presentation will list some deaf-related domains and explain their importance for interpreting some health data. **Conclusions:** Researcher-community collaboration can successfully adapt commonly used health-related measures to be accessible for deaf sign language users, providing access to a new population to work with to measure patient-reported outcomes. The translation process provides a new perspective on the source survey items and can help us clarify the intent and meaning some English language items.

Individual Abstract Number: 1748

Deaf consumers' healthcare experiences: The need for accessible PROM

Steven Barnett, Family Medicine, University of Rochester, Rochester, NY

Aims: In the USA, adults deaf since birth or early childhood report poorer health than the general population and are less likely to have seen a physician in the past year. They also report frequent emergency department visits and negative experiences in healthcare, including perceptions of bias. Most users of American Sign Language (ASL) are deaf since birth/early childhood. ASL is different than

English, and English is a second language for many deaf ASL-users. For complex reasons, many deaf adults have low English literacy. Accessible PROMs are needed to identify and address health and healthcare disparities with ASL-users. **Methods:** Deaf and hearing researchers, clinicians and community members collaborate to adapt English language health measures for use with adults deaf since birth/childhood. We worked with a variety of surveys, changing English reading level, language (English to ASL), modality (from paper or telephone to computer-administered) and recruitment methods. We used community-based participatory research, including key informant interviews, translation/back translation, focus groups, in-depth individual cognitive interviews, and pilot testing with keystroke data. **Results:** Data from community focus groups and an adapted English language survey with deaf college students confirmed the need for accessible health-related measures. We developed a collaborative process for adapting, translating and evaluating health related measures. Evaluation of the adaptation process includes data collected during exit interviews, survey keystroke data, and recruitment success. Preliminary analyses of pilot data of a sign language health survey indicate previously unidentified health priorities, including those related to patient-reported illness, healthcare communication and access barriers. **Conclusions:** Community-researcher partnerships proved instrumental in adapting health surveys for use with deaf ASL-users. Deaf sign language users likely comprise populations with unmeasured health priorities. Researchers and health systems should work with local deaf populations to use accessible measures of patient reported outcomes.

ORAL SESSIONS

MIXED METHODS

1713/What do people with dementia and their proxies say about HRQL? A quantitative test of qualitative findings

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AIMS: We previously identified 5 domains of HRQL from people with dementia and their proxies (daily activities & looking after yourself, health & well-being, cognitive functioning, social relationships, self concept). These domains formed the basis of the DEMQOL and DEMQOL-Proxy instruments. The self concept domain was difficult to operationalise in questionnaire items due to high missing data. We now report the results of testing this conceptual framework using exploratory factor analyses with large samples. **METHODS:** Using new data from large samples (DEMQOL n=644; DEMQOL-Proxy n=683), we used principal axis factoring with varimax rotation and sensitivity analyses to determine the number of factors to extract, first for the whole sample and then for randomly selected split halves. **RESULTS:** Five-factor models were the most robust for both measures, accounting for 45.5% variance in DEMQOL (cognition, negative emotion, positive emotion, social relationships, loneliness) and 49.3% in DEMQOL-Proxy (cognition, negative emotion, daily activities, positive emotion, appearance). For both DEMQOL and DEMQOL-Proxy, cognition (factor 1 for both models) remained strong. In both models, well-being was separated into positive and negative aspects of emotion (DEMQOL factors 2 & 3; DEMQOL-Proxy factors 2 & 4). For DEMQOL, social relationships (factor 4) was also strong, though distinct from loneliness (factor 5). For DEMQOL-Proxy, daily activities was evident (factor 3), but appearance emerged as a separate factor (factor 5). **CONCLUSIONS:** Although cognition and positive/negative emotion were common to both models, some factors appeared to be unique to either the person with dementia (social relationships, loneliness) or their proxy (daily activities, appearance). This supports our previous qualitative findings showing important differences between the views of people with dementia and proxy reports of HRQL and highlights the complementary role of DEMQOL and DEMQOL-Proxy in evaluating dementia-specific HRQL.

1730/Validity in fatigue measurement: complementing quality and quantity

Stefan J. Cano, Jeremy C. Hobart, Clinical Neurology Research Group, Peninsula Medical School, Plymouth, Devon, UK

AIMS: Rating scales are increasingly used in clinical trials and practice as outcome measures. In this role they need to deliver scientifically sound and clinically meaningful measurements. However, establishing the extent to which a scale measures the things it purports to measure - its validity - is difficult. In this study we use the evaluation of a widely used fatigue rating scale as a vehicle to highlight the key issues in understanding the clinical validity of rating scales, the strengths and weakness of current approaches, and

potential routes for forward for research. **METHODS:** There were two independent phases to our evaluation of the 40-item Fatigue Impact Scale (FIS). First, using a modified Delphi technique, a qualitative evaluation in which the content and face validity of the FIS was examined through expert opinion (n=30). Second, using traditional psychometric and Rasch analysis methods, a quantitative evaluation (n=333 people with multiple sclerosis) in which the construct validity of the FIS was examined in data analyses. **RESULTS:** The qualitative phase did not support either the content or face validity of the FIS. Expert opinion agreed with the scale placement of only 23 items (58%), and classified all 40 items as non-specific to fatigue. The quantitative phase implied, largely, that the FIS was internally consistent and that it gave meaningful estimates of differences in fatigue among persons. **CONCLUSIONS:** Psychometric evaluations of scale validity can be very misleading when carried out in isolation to qualitative evaluation. Here, from a psychometric standpoint, the FIS was found to be internally consistent, but this is probably due to its items measuring some higher order generic, non-specific aspects of general functioning, as opposed to fatigue. Our findings lead to general recommendations for scale evaluation and scale development. The evaluation of existing scales should include both qualitative and statistical evaluations of validity. New scale development should be based on strong conceptual underpinnings, and clear definitions of the variables for measurement.

1640/The benefits of mixed methods in scale development II: Selecting optimal mode of administration

Claudia Gorecki, Clinical Trials Research Unit, University of Leeds, Leeds, West Yorkshire, UK, Jane Nixon, Clinical Trials Research Unit, University of Leeds, Leeds, West Yorkshire, United Kingdom, Donna L. Lamping, Health Services Research and Policy, London School of Hygiene & Tropical Medicine, London, United Kingdom, Julia M. Brown, Clinical Trials Research Unit, University of Leeds, Leeds, West Yorkshire, United Kingdom, Stefan Cano, Clinical Neurology Research Group, Peninsula College of Medicine and Dentistry, Plymouth, United Kingdom

AIMS: Selecting the optimum mode of administration for PRO instruments is a key aspect of the development process. This is usually tested through large scale quantitative field testing or qualitative pre-testing. We report the use of a novel mixed methods approach to determine the best mode of administration of the PU-QOL, a new PRO instrument for people with pressure ulcers. **METHODS:** We investigated mode of administration in two stages: 1) cognitive interviews (n=35) to determine the appropriateness of a self-completion version (i.e. ease of/reasons for difficulty with self-completion); 2) Rasch analysis of PU-QOL data (n=75) from patients randomised to self-completion or interview-administered groups to examine differential item functioning (DIF). **RESULTS:** Qualitative findings indicated problems with PU-QOL self-completion, with just under half of the sample requiring some assistance. Reasons for needing assistance included: i) too weak/ill to sit up and/or hold a pen; ii) visually impaired (i.e. did not have access to their glasses); iii) fatigued and could not complete the questionnaire on their own towards end; and iv) existing conditions prevented self-completion (e.g. spinal cord injury). The DIF analysis, however, indicated that mode of administration did not influence the way patients responded to PU-QOL pain scale items, thus providing initial evidence of the equivalence of self-completion and interview-administered versions for the PU-QOL pain scale and preliminary evidence for the appropriateness of PU-QOL to be developed for both modes of administration. **CONCLUSIONS:** Use of a mixed methods approach provides useful evidence in selecting the best mode of administration for a newly developed PRO instrument. Findings also provide further

support for the use of Rasch/DIF analyses in the early stages of scale development.

RESPONSIVENESS I

1572/Responsiveness and Minimal Important Differences in EORTC QLQ-C30, EQ-5D and 15D in patients with multiple myeloma - A prospective study

Ann Kristin Kvam, Haematology, Oslo University Hospital, Oslo, Norway, Peter Fayers, Applied Health Sciences, University of Aberdeen, Aberdeen, Scotland, Finn Wisløff, Medicine, University of Oslo, Oslo, Norway

AIMS: To estimate the Minimal Important Difference (MID) and responsiveness in one disease-specific (EORTC QLQ-C30) and two utility (EQ-5D, 15D) instruments in patients with multiple myeloma (MM). The MID is the smallest change in a quality of life score considered important to patients. **METHODS:** Between 2006 and 2008, 239 patients with MM completed the EORTC QLQ-C30, EQ-5D and 15D at inclusion (T1) and after three months (T2). At T2, a structured interview was performed. Responsiveness was calculated by dividing mean score changes by standard deviation (SD) of the change. We used Cohen's criteria for interpreting changes: >0.2 is a small change, >0.5 a moderate change, and >0.8 a large change. Wilcoxon tests for pair differences were used to calculate the significance of differences between pre- and post-test. MIDs were determined using anchor- and distribution-based methods. We calculated 1) mean score changes for patients who in the interview stated they had improved, deteriorated or were unchanged and 2) effect sizes using SDs of baseline scores. **RESULTS:** Higher score were reported in patients improving after 3 months and lower score in patients deteriorating. According to Cohen, the changes were of small to medium size. In patients rating themselves as unchanged, mean score changes clustered around zero. MIDs for the EORTC QLQ-C30 scores (scale range 0-100) ranged from 6.2 (physical function) to 14.7 (pain) for patients improved and from 8.6 (fatigue) to 17.3 (pain) in patients deteriorating (absolute values). MIDs for EQ-5D (scale range -0.62-1) and 15D (scale range 0-1) ranged from 0.08 to 0.11 (EQ-5D) and 0.03 to 0.05 (15D) in patients improved and from -0.05 to -0.10 (EQ-5D) and -0.02 to -0.03 (15D) in patients deteriorated. **CONCLUSIONS:** These results demonstrate that all three questionnaires are sensitive to changes reported by patients. Our results suggest that an absolute change of 6-17 points (EORTC QLQ-C30), 0.05-0.11 points (EQ-5D) and 0.02-0.05 points (15D) represent meaningful changes in patients with MM.

1483/Minimally important differences for six PROMIS-Cancer scales

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AIMS: The Patient-Reported Outcome Measurement Information System (PROMIS) Network developed cancer-specific short-form scales for which there are no guidelines on what constitutes minimally important differences (MIDs). We combined anchor- and distribution-based methods to estimate MIDs for PROMIS-Cancer scales. **METHODS:** Advanced cancer patients completed 6 PROMIS-Cancer scales and 23 anchor measures at an initial ($n=101$) and follow-up ($n=88$) assessment. One standard error of measurement constituted a distribution-based estimate. We defined 3 *a priori* criteria for anchor-based estimates: (1) correlation between an anchor (e.g., Brief Pain Inventory) and PROMIS-Cancer scale ≥ 0.3 ; (2)

sample size ≥ 10 in the clinically distinct group (e.g., ECOG 0, 1, 2, or 3) or change score group (e.g., better, worse) used to calculate a cross-sectional or longitudinal MID; (3) corresponding effect size within a plausible range of 0.2-0.8; that is, anchor-based estimates with effect sizes <0.2 are unlikely to be "important" and estimates with effect sizes >0.8 are unlikely to be "minimal." Our focus was on item response theory (IRT)-based MIDs estimated on a T-score scale. Raw score MIDs were estimated for comparison purposes. **RESULTS:** An average of 45 cross-sectional and 17 longitudinal MID estimates were calculated for each scale. Many cross-sectional (64%) and longitudinal (73%) anchor-based estimates were excluded because they did not meet *a priori* criteria. The following are recommended T-Score MID ranges: 17-item Fatigue (2.5-4.5), 7-item Fatigue (2.5-5.0), 10-item Pain Interference (3.0-6.0), 10-item Physical Functioning (3.5-6.0), 9-item Emotional Distress-Anxiety (2.5-4.5), and 10-item Emotional Distress-Depression (2.5-4.0). Effect sizes corresponding to these MIDs averaged between 0.34 and 0.62. **CONCLUSIONS:** This study is the first to address MIDs for PROMIS measures and it highlights the importance of applying *a priori* criteria to anchor-based estimates. Studies to confirm these MIDs in other patient populations and to determine whether these MIDs vary by patients' level of functioning are ongoing.

1294/Minimal important difference for individual subjects and groups of subjects - why the two cases should be distinguished

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AIMS: Usually in quality of life (QOL) research no distinction is made between individual subject level and group level when considering the minimal important difference (MID) of a scale. In this contribution we want to demonstrate why such a distinction is nonetheless useful. **METHODS:** Based on the usual definition of the MID as a threshold for relevant change in the individual subject, we consider the proportion of subjects in a group experiencing relevant improvement or deterioration. The difference between these two proportions is then compared with the mean change in QOL score. This forms the basis of a group level MID to be distinguished from the individual level MID. For demonstration purposes QOL data assessed with the EORTC QLQ-C30 in palliative cancer patients and a simulated data set are used. **RESULTS:** Already fairly small changes in mean QOL score were accompanied by a considerable imbalance in the proportion of relevant improvements vs. relevant deteriorations. Thus a mean change of 0.5 times the individual level MID resulted approximately in a 20% difference between improvements and deteriorations (e.g., 40% vs. 20%), i.e. a fairly large difference. This suggests the use of group level MIDs that are lower than individual level MIDs. **CONCLUSIONS:** A distinction between individual subject level and group level appears important when dealing with the concept of the MID. Our findings imply that suitable group level MIDs should usually be smaller than MIDs for individual subjects.

1487/Using Multiple Anchor and Distribution-based Estimates to Determine the Minimal Important Difference (MID) for the Urticaria Activity Score (UAS)

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James Zazzali, *Health Economics & Outcomes Research, Genentech Inc, S San Francisco, CA*

AIMS: Chronic idiopathic urticaria (CIU) is a skin disorder characterized by recurrent hives and/or angioedema for ≥ 6 wks. The urticaria patient daily diary (UPDD), based on the UAS, was designed to be comprehensive. Measurement properties have been established; we now estimated its MID. **METHODS:** CIU pts enrolled in a Ph2 multicenter, randomized, double-blind 4-wk study completed the UAS portion (hive #, largest hive size, intensity of pruritus) of the UPDD twice daily, and sleep, activity limitations, symptom management items once daily. After assessing correlations between "change in UAS scores and Patient Global (PaG) and Physician Global Ratings (PhG) anchors from baseline to wk 4, we computed anchor- and distribution-based (ie, effect sizes, standard error of measurement, and Guyatt_'s statistic) MID estimates without regard for treatment assignment. **RESULTS:** 86 pts (66% F, mean age 40.9 ± 15.1 yrs) provided data. Spearman correlations between UAS7 and item scores and the 2 anchors were ≥ 0.40 . We integrated data from anchor- and distribution-based results to estimate MIDs by considering measurement precision, amount of "change observed when anchors don'_t change, and amount of " change observed when anchors change by 1 meaningful unit. For UAS7 and PaG, when anchors don'_t change, mean "change was -6.5 for Mild rating, -10.0 for Moderate, and -0.3 for Severe. When PaG improved by 1 unit, mean change" was -24.7 for Mild baseline rating, -13.5 for Moderate, and -2.0 for Severe. When PaG worsened by 1 category, mean change" was -10.8 for Mild baseline rating and 2.7 for Moderate. Intercepts from regression models were also considered. MIDs ranged from 10 - 11 points for the UAS7, 4.5 - 5.0 points for pruritus and largest hive score, and 5.5 - 6.0 points for hive # score. **CONCLUSIONS:** These MID estimates are useful for interpreting baseline scores and changes over time. In addition, they are valuable in defining a clinical responder and interpreting cumulative distribution functions of response.

PEDIATRICS

1237/Assessing The Impact Of Musculoskeletal Impairment On Children's Quality Of Life In Malawi: Identifying The Concepts For Evaluation

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AIMS: Although 80% of children with disabilities - including children with musculoskeletal impairments (MSIs) - live in developing countries, instruments to evaluate the impact of rehabilitation interventions on QOL in these settings are rare. Moreover, the components of QOL as defined in high-income settings may not be the most relevant and culturally appropriate concepts to evaluate in low-income settings. This study aimed to identify the concept(s) that should be evaluated when assessing the impact of rehabilitation on QOL in children with MSIs in Malawi, Africa. **METHODS:** We conducted a qualitative study in 4 districts in Malawi using a data-led approach to data analysis. A total of 169 participants took part in 57 in-depth interviews, focus group discussions and observations. Participants included children with MSIs (aged 2- 10 years), their elder siblings, parents/guardians,

teachers, community leaders, health workers, and adults who experienced MSIs as children. **RESULTS:** The themes that consistently emerged as being most important in the lives of children with MSIs in Malawi were Participation and Dignity. Children with MSIs strived to be included in three main daily participatory activities (playing with friends, household chores, going to school) but were excluded from each for a variety of reasons including being unable to walk long distances. Indignity was experienced on a regular basis, mainly from being mocked by friends and peers. Apart from being an important outcome in itself, Indignity was a major barrier to the participation of children with MSIs, as they would withdraw or abstain from participation to avoid indignity. **CONCLUSIONS:** Concepts relevant to QOL in children with MSIs, such as participation in play, household chores, and school, are essential to assess in developing evaluative instruments to measure the effectiveness of rehabilitation interventions targeting both the child and the community.

1511/Predictors of Health Related Quality of Life of adolescents with Type 1 Diabetes

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AIMS: The purpose of the study was to assess the Health Related Quality of Life(HRQOL) of youths with Type 1 Diabetes Mellitus(T1DM) and its predicted factors. **METHODS:** It was a cross-sectional study conducted in a referral center for the treatment of adolescents with T1DM, in Brazil. A total of 245 adolescents were invited to participate during their visits to outpatient clinics. They responded to the Diabetes Quality of Life for Youths(DQOLY), Brazilian version, composed of 50 items distributed in domains Satisfaction, Impact and Worries. Rosenberg's Self-esteem(SE) scale, social and clinical data form were applied. Univariate statistics and General Linear Model were used for analyzes. **RESULTS:** Scores of DQOLY were 37.49 ± 9.89 for Satisfaction domain, 49.04 ± 11.37 for Impact, 23.73 ± 7.96 for Worries and 110.26 ± 24.43 for Total. Factors associated with HRQOL in domain Satisfaction were age,sex,frequency of physical exercises, duration of T1DM, carbohydrate counting, SE and glycated hemoglobin. Predictive factors of HRQL in Satisfaction domain were SE and glycated hemoglobin. The associated factors of Impact domain were frequency of blood glucose monitoring, presence of other diseases, carbohydrate counting, race, SE and glycated hemoglobin. Predictive factors of Impact were race, SE, scheme of insulin and glycated hemoglobin. The factors involved in Worries domain were age, sex, frequency of blood glucose monitoring, frequency of hyperglycemia in the last month, SE, glycated hemoglobin, carbohydrate counting and Body Mass Index. The only predictive factor of Worries domain was SE. Factors associated with DQOLY Total were sex, frequency of blood glucose monitoring, frequency of hyperglycemia in the last month, glycated hemoglobin, carbohydrate counting, SE and treatment duration. The predictive factors of DQOLY Total were glycated hemoglobin and SE. **CONCLUSIONS:** In general, HRQOL was evaluated positively by the sample. Recognition of the variables that influence the HRQOL enables the development of strategies that promote adequate metabolic control and well-being.

1786/On relationships of fatigue, quality of life and family impact among children with live-limiting illnesses

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AIMS: Little is known about how fatigue and quality of life (QOL) affect family functioning among children with life-limiting illnesses (LLI). We aim to examine the relationships of fatigue, QOL and family impact in this population. We specifically test whether QOL can mediate the relationship of fatigue with family impact.

METHODS: We conducted telephone surveys between 11/2007 and 04/2008 and collected 266 parents whose children had LLI and enrolled in Florida's Children's Medical Services. We measured total fatigue (comprised of general, sleep, and cognitive fatigue) using the PedsQL Multidimensional Fatigue Scale and measured physical and psychosocial functioning (comprised of emotional, social and school functioning) of QOL using the PedsQL Core. We measured family impact using the Impact on Family Scale. We analyzed the designated relationship using 3 linear regressions, testing whether there is an association of fatigue with family impact (Model 1), whether there is an association of QOL with family impact (Model 2) and whether the association of fatigue with family impact is changed after accounting for QOL (Model 3). We also used multiple mediation method (Preacher, 2008) to jointly test the mediating effects of physical and psychosocial functioning on the fatigue-family impact relations. **RESULTS:** Greater general and sleep fatigue as well as poor physical and emotional functioning (Models 1 and 2) were associated with greater family impact ($P < 0.05$). The magnitude on relationships of fatigue and family impact was decreased and not significant after accounting for QOL. Multiple mediation method suggests the direct effect of fatigue on family impact is weak ($\beta = 0.08$; $P > 0.05$). Physical and psychosocial functioning play a role to mediate the fatigue-family impact relationship ($\beta = 0.13$ and 0.14 , respectively; $P < 0.05$). **CONCLUSIONS:** Although fatigue is associated with family functioning among children with LLI, the impact is through the mechanism of impaired QOL.

1704/Testing the Item Response Theory properties of the KIDSCREEN-10 HRQOL Index in school-children from 15 European countries

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AIMS: The KIDSCREEN-10 index is an internationally developed and usable short HRQOL instrument for 8 to 18 year olds. The measure was originally developed from the longer KIDSCREEN-52 and -27 quality of life instruments. Previous examinations showed the KIDSCREEN-10 to exhibit good psychometric properties in terms of Rasch item fit, reliability and validity. However, in these previous analyses the KIDSCREEN-10 was applied in connection with the longer KIDSCREEN-52 instrument. The aim of this paper thus was to examine whether the psychometric properties of the KIDSCREEN-10 will still be retained if its items are applied alone and not within the (item-) context of the longer KIDSCREEN-52 instrument. **METHODS:** Within the cross-sectional Health Behaviour in School-aged Children 2005/2006 Survey, 78,000 pupils aged 11, 13, 15 from 15 European countries answered the KIDSCREEN and additional measures. Cronbach's alpha, Rasch partial credit model -itemfit and -measurement properties and ANOVAs were examined. **RESULTS:** Cronbach's alpha was 0.81. Rasch infit mean square residuals were 0.7–1.3 and similar to the results from previous studies. Examination of item step parameter also revealed similar ordering along the latent trait as had been observed in former studies. Mean scores varied 0.8 standard deviation across countries. Pupils with low socio-economic

status ($ES = 0.5$) or frequent health complaints ($r = 0.5$) reported decreased mental health. A statistical interaction between age and gender was observed: For the 11 year olds mean values of 51.1 (boys) and 50.3 (girls) were observed. For the 13 year olds the mean values were 48.8 (boys) versus 46.1 (girls). This difference further increased to 46.7 (boys) versus 43.5 (girls) for the 15 year olds. ES for the age-related decrease was 0.8 in girls and 0.5 in boys.

CONCLUSIONS: The KIDSCREEN-10 displayed good psychometric properties and proved to be working as a stand alone measure. Measured differences between countries, age, gender, SES, and health complaints comply with theoretical considerations

ONCOLOGY I

1533/Adapting existing HRQOL measures for use in routine oncology clinical practice

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AIMS: Despite the large number of HRQOL instruments validated for cancer patients, routine HRQOL assessment in oncology clinical practice is rare. In previous research clinicians and patients requested measurement to be more disease and treatment specific. The aim of this study was to adapt existing HRQOL measures for three oncology clinics (gynaecological, breast, colorectal) treating patients with chemotherapy. We present qualitative adaptation methods and preliminary psychometric outcome data. **METHODS:** 141 (72 gynaecological, 52 breast, 17 colorectal) audio recorded oncology consultations were analysed for content to identify the most common topics of discussion for different disease groups. Cancer-specific questionnaires were developed by comparing consultation topic lists to existing HRQOL measures and interviewing 25 clinicians and 30 patients. Adapted questionnaires included cancer-specific items plus 72 cancer-general items. 339 (129 breast, 96 gynaecological, 114 colorectal) patients completed pilot questionnaires in clinic. Rasch analysis was used to evaluate item fit of cancer-specific and cancer-general items and explore differential item functioning between cancer groups for functional subscales. **RESULTS:** Whilst all three cancer groups shared many symptoms and side effects in common, the level of difficulty reported for key functions varied, particularly for colorectal patients. Rasch analysis of differential item functioning showed that colorectal cancer patients reported significantly poorer physical function but better emotional function than gynaecological and breast cancer patients. **CONCLUSIONS:** When adapting HRQOL assessments for oncology clinical practice it is clearly important to select items that address cancer-specific clinical needs. When evaluating functions that are common across cancer groups (particularly physical and emotional function) it is important that item inclusion is tailored to capture differences in experienced functional difficulty of different cancer groups.

1404/Conceptual Model of Quality of Life in Sarcoidosis

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AIMS: Previous studies in sarcoidosis showed that depressive symptoms and fatigue were associated with patients' Quality of Life (QOL). Knowledge concerning correlates for the development of these symptoms and the relationship with QOL is lacking. Therefore, a conceptual model of QOL was developed and tested. **METHODS:** Outpatients of the Sarcoidosis Management Centre of the University Hospital Maastricht, the Netherlands, participated in this study. All

patients were diagnosed with sarcoidosis according to the WASOG guidelines. At inclusion, 443 patients completed questionnaires about fatigue, depressive symptoms, social support, trait anxiety, symptoms suspected of Small Fiber Neuropathy (SFN), and dyspnea. Sex, age, and time since diagnosis were taken from the medical records at inclusion. At 18 months follow-up, 317 (317/443=72%) patients completed the WHOQOL-Bref to assess QOL. The pathways were estimated by means of path analysis. Correlations between age, sex, and time since diagnosis were allowed. We tested hypotheses in which these variables predicted depressive symptoms, social support, trait anxiety, dyspnea, SFN, fatigue, and QOL. Depressive symptoms, social support, trait anxiety, dyspnea, SFN were hypothesized to predict fatigue. All inclusion variables were expected predictors of QOL. **RESULTS:** QOL was associated with depressive symptoms, fatigue, dyspnea, age, and sex. Depressive symptoms, dyspnea, trait anxiety, and SFN were positively related to fatigue. Fit indexes were good: Chi-Square badness-of-fit =26.81, df =25, p =.37. Adjusted Goodness of fit index =.96, Tucker Lewis Index =.99, and Root Mean Square Error of Approximation =.02 (CI .00-.05). The model explained 35% of the variance in QOL. **CONCLUSIONS:** Depressive symptoms and fatigue were the most important predictors of QOL. SFN and depressive symptoms were important predictors of fatigue. This model appears to be a valid for explaining variation in QOL. To improve QOL in sarcoidosis patients, it is recommended to focus especially on fatigue, SFN, and depressive symptoms in the management of sarcoidosis.

1711/Measuring the Symptom Burden of Lung Cancer: The Validity and Utility of the Lung Cancer Module of the M. D. Anderson Symptom Inventory (MDASI-LC)

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AIMS: The M. D. Anderson Symptom Inventory (MDASI) instrument measures common symptoms of cancer and its treatment. We report the psychometric characteristics of the MDASI developed specifically for patients with lung cancer (MDASI-LC) in three cohorts of lung cancer patients. **METHODS:** The 13 core symptom items of the MDASI as well as the lung cancer-specific items of coughing, constipation, and, for patients undergoing radiotherapy, sore throat were administered to cohorts of 259 patients with lung cancer undergoing cancer therapy. Cognitive debriefing of core and module items was performed. Internal consistency and test-retest reliabilities were calculated. Known-group validity of the MDASI-LC module was evaluated using the Eastern Cooperative Oncology Group performance status. Convergent validity was assessed using the Beck Depression Inventory-II and the 12-item Short-Form Health Survey. Finally, we demonstrated the sensitivity of the MDASI-LC to expected disease and treatment changes. **RESULTS:** Cognitive debriefing indicated that the original MDASI items and the additional items for lung cancer patients were clear, concise, relevant to lung cancer and easy to understand. During interview, no additional symptom items were suggested by more than 10% of the sample. The internal consistency and test-retest reliability of the module was adequate (Cronbach coefficient alpha 0.83 or higher for the all module items and subscales). The sensitivity of the module to changes in patient performance status (disease progression) as well as to continuing cancer treatment (effects of treatment) were also established. MDASI core items and as well as the lung-specific items

were more severe for patients with poorer performance status. **CONCLUSIONS:** This study demonstrates evidence for the reliability, validity and sensitivity of the MDASI Lung module that will enhance epidemiological and clinical studies of symptom status in lung cancer patients.

1762/Towards a Modeling of Health-Related Quality of Life in People with Advanced Cancer

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AIMS: Achieving measurable improvements and enhancing the Quality of Life of people living with cancer have been identified as key goals. But models of HRQL have only been seldom analyzed in this patient population. A comprehensive model of HRQL that is now well recognized is the one developed by Wilson and Cleary (JAMA 1995). Basing ourselves on the Wilson and Cleary Model, we hypothesized causal paths between symptom status variables, functional health, general health perceptions, and overall quality of life. **METHODS:** 120 persons with advanced non-small cell lung cancer, upper gastrointestinal, colorectal, hepatobiliary, pancreatic, breast, prostate, and head and neck cancers from the McGill University Health Center (MUHC) and the Jewish General Hospital (JGH) were evaluated using the Edmonton Symptom Assessment Scale (ESAS), the Short Form 36-item Health Survey (SF-36), and the McGill Quality of Life Questionnaire (MQOL). Path analysis was used to test the hypothesized theoretical model. **RESULTS:** The 13 parameters path analysis resulted in statistically significant direct paths between each Symptom variable and Physical Function, as well as between Physical Function and GHP, verifying for linearity and normality. Additionally, Vitality predicted GHP directly, while Appetite and Pain had only an indirect effect. Each path explained about 42% of the variance in endogenous variables. The model provided strong goodness-of-fit indices, with a near-zero model chi-square value. The model demonstrated high values on the Normed-Fit Index, the Non-Normed Fit Index, and on the Comparative Fit Index (in excess of 0.98). The limited sample size made it difficult to obtain as strong goodness-of-fit indices when including Overall Quality of Life. **CONCLUSIONS:** Only part of the model was explored and the constructs of interest are not directly measurable and would be better represented by latent variables. However, preliminary conclusions can be made that it appears that we cannot treat QOL directly, we need to optimize the components and the path.

ANALYSIS ISSUES

1189/Time to deterioration of quality of life score as a modality of longitudinal analysis in patients with breast cancer

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AIMS: To explore different definitions of the time to deterioration (TTD) of quality of life (QoL) score according to different cut-offs of the minimal clinically important difference (MCID), as modality of longitudinal QoL assessment in breast cancer patients.

METHODS: Based on a prospective multicentric cohort, 518 patients with breast cancer underwent axillary lymph node dissection (ALND), sentinel lymph node biopsy (SLNB) or SLNB+ALND. QoL was evaluated using the EORTC QLQ-C30 and QLQ-BR-23, before surgery, after surgery and 6 and 12 months later. Global health score (GHS), arm symptom score (ASS) and breast symptom score (BSS) were specifically analysed. Patients were considered as deteriorated for a given score if their change score from baseline was 5 points or higher at any time-point after baseline. Analyses were repeated using 10 points as MCID, taking the score after surgery as baseline score (to take into account response shift occurrence). The TTD were estimated from inclusion date using the Kaplan-Meier method and were compared using the Log-Rank test. Cox regression analyses were done to determine prognostic factors of TTD of QoL score. Results will be compared to those obtained with mixed model analysis of variance for repeated measures. **RESULTS:** Two hundred and thirty-five patients underwent ALND, 222 SLNB and 61 SLNB+ALND. The same number of events was observed when the MCID was 5 or 10 points ($n=199$) for the ASS. Patients underwent SLNB have a significantly longer TTD, HR=0.64 (95% CI: 0.48-0.86) than those underwent ALND. Medians of TTD were 7.2 months (3.76-12.96) versus 2.4 months (2.0-6.1), respectively. However, no significant difference was observed for GHS ($n=193$), medians of TTD were 6.63 and 6.73 for ALND and SLNB, respectively and for BSS ($n=134$): medians were 12.2 months in both ALND and SLNB groups. **CONCLUSIONS:** Exploration of different definition of TTD of QoL could allow the development of an optimal definition of time to event endpoints. This modality of analysis proposes meaningful longitudinal QoL results to clinicians.

1195/Tracking a Symptom Cluster over Time in Transplant Patients: Detecting Patterns of Response to Treatment Using Latent Class Growth Analysis

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AIMS: Symptom clusters are commonly reported by transplant patients. Interventions designed to reduce symptoms and enhance quality of life may efficiently improve outcomes in clinical care, if targeted to those subgroups of patients most likely to benefit. The objective of this study is to identify subgroups of patients based on their patterns of response to treatment using latent class growth analysis (LCGA). **METHODS:** Longitudinal data from 122 solid organ transplant patients (48% women, 62% married, age range 21 to 75 years) enrolled in a randomized controlled trial were used in this secondary analysis. Patients were randomized to either Mindfulness-based Stress Reduction (MBSR, $n=63$) or Health Education ($n=59$). Anxiety, depression and sleep symptoms (STAI, CES-D and PSQI scales, respectively) were recorded at baseline, 2-, 6- and 12-month follow-ups. A composite symptom cluster score was formed for each patient at each time point, using ranks. LCGA was used to identify subgroups of patients with similar composite symptom trajectories. **RESULTS:** Based on accepted benchmarks, 52% of the sample had at least one elevated symptom score at baseline, and STAI, CESD and PSQI scores were strongly correlated (correlations greater than .57). Based on patterns of change over time, LCGA identified two improved subgroups in the MBSR arm (lower baseline symptoms, $n=30$ and higher baseline symptoms, $n=33$). Within the Health

Education arm, LCGA identified an almost stable subgroup ($n=42$), and a stable subgroup ($n=17$) of patients. **CONCLUSIONS:** LCGA is a patient-centered approach that has the potential to complement conventional clinical trial analyses. LCGA can facilitate identification of variables that may be useful to guide future patients to the most appropriate treatments. Funding was provided from NIH grants P20 NR008992; R01 NR008585; and M01 RR00400.

1369/Effect of Time Windows in Analysis of Health-Related Quality of Life (HRQOL) Outcomes

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AIMS: Our aim was to assess whether HRQOL scores on the EORTC QLQ-C30 scores depend on the timing of questionnaire completion, relative to chemotherapy delivery, and whether including such information in the analysis could influence conclusions regarding treatment effect. **METHODS:** In a retrospective analysis of an EORTC 3-arm RCT of 480 advanced NSCLC patients comparing gemcitabine+cisplatin, paclitaxel+gemcitabine, and standard arm paclitaxel+cisplatin, a 'time window' variable was created to indicate when the QLQ-C30 was completed relative to each of the scheduled 6 chemotherapy administration dates: -1 (up to 10 days before), 0 (on cycle date), and 1 (up to 10 days after). HRQOL scores were analyzed in a linear mixed model including treatment, cycle number, treatment-by-cycle interaction, and the time window variable. **RESULTS:** The number of patients who completed the QLQ-C30 'before', 'on', and 'after' ranged 72-284, 69-116, and 13-32 respectively over the 6 cycles. No statistically significant differences in scores were noted for before-on comparisons, however 6 subscales showed significant differences ($p<0.05$) for on-after comparisons. We then formed 2 groups in whom questionnaires were completed before/on versus after. We observed the following statistically significant differences in HRQOL mean values between before/on vs after responses: decreased social functioning (4) and cognitive functioning (5), and increased fatigue (-4), nausea/vomiting (-6), appetite loss (-5), and constipation (-5). The mean score differences of about 4 or 5 points are below the 10 points conventionally accepted as clinically meaningful. Treatment effectiveness comparisons between arms were not significantly changed by the inclusion of the time window variable. **CONCLUSIONS:** These results suggest that after-treatment scores may be affected by treatment. The effect of time windows should be tested during the analysis of HRQOL scores. Accounting for this information did not alter the decision regarding treatment

comparisons in this case, but this might possibly vary in other situations.

1714/Longitudinal data with follow-up truncated by death:

Matching statistical analysis to research, clinical and policy aims
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AIMS: Diverse analysis approaches have been proposed to distinguish data missing due to death from nonresponse and to summarize trajectories of longitudinal data truncated by death. We demonstrate how these analysis approaches and their interpretations arise from factorizations of the distribution of longitudinal data and survival information. **METHODS:** Models are illustrated using hypothetical data examples (cognitive functioning in older adults, health related quality of life under hospice care) and up to 10 annual assessments of longitudinal cognitive functioning data for 3814 participants in an observational study. Focusing on the interpretation of the estimands and potential clinical and HRQOL research questions we explore 6 commonly used models: unconditional (mixed effects, random effects, latent variable regression), fully conditional (pattern mixture, principal stratification, terminal decline), partly conditional (generalized estimating equations (GEE) with working correlation), and joint models (GEE binary outcome, specialized multiple response methods). **RESULTS:** Unconditional models such as random effects models may implicitly impute data beyond the time of death. Fully conditional models stratify longitudinal response trajectories by time of death. Partly conditional models reflect the average response in survivors at a given timepoint, rather than individual trajectories. Joint models of survival and longitudinal response describe the evolving health status of the entire cohort. **CONCLUSIONS:** Researchers using longitudinal data should consider which method of accommodating deaths is consistent with research aims and use analysis methods accordingly. While subtly different wording is used to describe the analyses, the results can vary dramatically, impacting clinical and public interpretation of an analysis of longitudinal HRQOL data from clinical research.

ECONOMIC EVALUATION I

1727/Item Identification for the EXACT-U: A Preference-Based Measure to Report Utilities for COPD Exacerbations

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AIMS: A preference-based utility measure is needed that distinguishes among severity levels in COPD exacerbations, and is responsive to acute but important daily change. The EXACT is a 14-item condition-specific daily diary to measure the frequency, severity, and duration of COPD exacerbations. We aimed to identify items from the EXACT to develop the EXACT-U, a utility measure for use in UK cost-effectiveness studies. **METHODS:** We analysed previously collected EXACT-14 data on 410 COPD patients (stable & acute) to identify items for the utility instrument using factor analysis and Rasch analyses. Factor analyses conducted on two random halves. First half: items loaded using oblique and oblimin

rotations, and specified by the scree plot and Eigen values greater than 0.70; Second half: confirmed structure. We used Rasch analyses to identify items with greatest spread of severity, compared to EXACT-14, using overall model fit, individual item fit, person logit coverage, and response option reduction. Items evaluated using Chi-squared, p values, Person Separation Index (PSI), and item and scale means and SDs. Remaining items and levels grouped to form health states. Cognitive debriefings with 14 COPD patients ensured appropriate wording and structure. **RESULTS:** Five items with 3 to 5 levels comprised the EXACT-U, with fit as follows: model location=0, SD=0.51; Chi-Square(df)=30; p=0.18; item fit residual=0.28, SD=1.44; person fit residual=-0.19, SD=1.35; PSI=0.76; Cronbach's alpha=0.76. Severity of items ranged from -4.0 to 3.20 person logits in EXACT-14, while EXACT-U ranged from -2.4 to 3.20, where higher values reflect greater severity. The initial EXACT-14 factor structure remained after item identification. Minor adjustments were made to items following health state debriefing with 14 COPD patients with recent history of an exacerbation. **CONCLUSIONS:** Items representing the EXACT-U maintain a full spread of severity and dimensionality of the original EXACT-14. The 5-item EXACT-U is ready for utility valuations for preference-based algorithm development.

1356/Modelling the cost-utility of screening programmes for diabetic retinopathy in India: estimating utility values

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AIMS: India is in the midst of a diabetes epidemic. People with diabetes are at risk of developing diabetic retinopathy (DR) which can lead to irreversible blindness if untreated. Screening for DR among diabetics offers an important preventative measure against blindness but it is currently unknown how screening should be structured in India to be most cost-effective. As a first stage to address this question this study aimed to estimate utility values (UVs) associated with different stages of DR in India. **METHODS:** Study participants were diabetics aged >40 years from urban Chennai scheduled for a four-year follow up of a DR epidemiology study and the first two patients per week with sight threatening DR attending the laser clinic at Sankara Nethralaya hospital, Chennai from June 2009-Dec 2010. DR grade was determined using indirect ophthalmoscopy. Utility values were elicited during interviews using the time-trade off method. Data were also collected on vision functioning using the validated Indian visual functioning questionnaire. **RESULTS:** 241 diabetic participants were enrolled in the study and 238 participants completed the time-trade off. The mean UV associated with DR was 0.73(95%CI 0.69-0.77). Mean UVs decreased with increasing severity of DR (No DR: 0.87 (0.78-0.97), non-proliferative DR: 0.79 (0.72-0.86), sight threatening DR: 0.70 (0.64-0.77), blind from DR: 0.55 (0.46-0.64)). A moderate correlation was observed between UVs and vision functioning subscales ($r=0.50-0.54$, $p<0.001$). **CONCLUSIONS:** This study derived estimates of UVs which can be used in economic evaluations of alternative DR screening strategies in India. The UVs associated with DR were lower than those estimated previously in Canada, USA and Taiwan. This concurs with a previous study in India which found UVs associated with glaucoma were lower than other settings and may reflect socio-cultural differences. The relatively low UV associated with blindness from DR highlights the importance of screening to prevent visual loss from the disease in this setting.

1275/Estimating a Multi-Attribute Utility Function for the Health Utilities Index Mark 3 System Based on the Preferences of Singaporeans

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AIMS: The Health Utilities Index Mark 3 (HUI3) is a preference-based health-status measure that is widely used in clinical and population health studies. Currently, HUI3 index scores are based on preference scores obtained from the Canadian population which may or may not be representative of the health preferences of Asians. The objective of the present study was to estimate a multiplicative multi-attribute utility function for HUI3 based on the preferences of Singaporeans. **METHODS:** Community-dwelling Chinese, Malay and Indian adults were recruited nationwide in Singapore using a quota sampling design. Each subject was interviewed face-to-face to measure his or her preferences for a total of 25 HUI3 health states using the visual analog scale and the standard gamble (for 4 of the selected health states). The Canadian HUI3 research protocol was replicated for data collection and analysis. **RESULTS:** Data was collected from 570 subjects (Mean age: 48.3 years; male: 48.2%; Chinese: 232; Malay: 179; Indians: 159). Using the person-mean approach, parameters of a multiplicative utility function were estimated. The highest multi-attribute utility score (except for perfect health) and lowest possible utility score predicted by this function were 0.903 and -0.353, respectively. **CONCLUSIONS:** It is feasible to estimate a utility function for the HUI3 system based on the preferences of an urban Asian population. The utility function derived from the present study makes the HUI3 a more useful tool for measuring health outcomes in Asia. Further research is needed to assess differences in utility scores predicted by this and the Canadian HUI3 scoring function and the impact of these differences on cost-utility analyses.

1582/Beyond economic evaluation : an appropriate scoring system for EQ-5D based on real values for health

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AIMS: FDA guidance on patient-reported outcomes is crucially at odds with NICE requirements for economic evaluation used in HTA. The former requires a direct association with the patient whilst the latter is based on the social preferences of 3rd parties. Such preference have limited applicability in non-economic applications since they incorporate a value for the state dead which is irrelevant in most therapeutic settings and are based on hypothetical preferences obtained from individuals who may have no experience of the specific health states they are asked to evaluate. This paper reports on the construction of a scoring system for EQ-5D health states based on self-rated values generated by individuals with current experience of those states. **METHODS:** Self-rated health status recorded using EQ-5D defines 1 of 243 possible health states together with a 0-100 VAS rating of the value of that state as perceived by the respondent. Data from several different UK sources were pooled yielding a total of 23,679 useable observations. 139 unique EQ-5D health states were

identified in this dataset and the mean VAS rating was computed for each of these states. 0/1 dummy variables were defined for each of the EQ-5D dimensions and an OLS regression analysis was performed with the mean self-rated VAS rating as the dependent variable. **RESULTS:** Value losses in VAS ratings were greatest for extreme problems on the usual activity and anxiety/depression dimensions. The model proved to fit the mean VAS ratings data very well ($r^2=0.985$) when forced through the origin. Decrements within dimension were monotonic and internally consistent. Residuals were 5 points or lower. Estimated values for all EQ-5D health states were computed and transformed using a value for dead computed in previous studies. These 0-1 scale values were compared with the standard UK TTO utility weights. **CONCLUSIONS:** EQ-5D values based on "real" health status are significantly higher than those based on social preferences. Utility scoring of EQ-5D leads to massive errors in non-economic PRO applications.

MENTAL HEALTH

1379/Impact of Transdiagnostic Symptoms in the Measurement of Depression using the PHQ-9

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AIMS: Major depression disorder (MDD) is a prevalent and disabling complication of traumatic brain injury (TBI). Depression is more closely associated with persistence and recurrence of disability than initial injury severity or persisting cognitive impairment. A major impediment to screening for depression in TBI is concern regarding validity of trans-diagnostic symptoms. The Patient Health Questionnaire-9 (PHQ-9) is a widely used depression measure but no study has assessed whether the energy, sleep and concentration items of the PHQ-9 are valid for persons with TBI. We applied item response theory (IRT) and differential item functioning (DIF) methods to address this question. **METHODS:** We compared responses to PHQ-9 items in a large representative sample of people with TBI (N>500) versus the primary care sample used in the original PHQ-9 validation study (N= 3,000). Responses were modeled using an IRT model (graded response). DIF was evaluated using the software, LORDIF, which applies a hybrid of ordinal logistic regression and IRT. Standard criteria for meaningful DIF were applied. As a sensitivity analysis for these criteria, we followed up by setting an extremely stringent statistical criterion in order to identify items with even extremely low amounts of DIF. We then corrected for this over-identified set of DIF items and evaluated the impact on mean scores and at cut-off scores for levels of depression. **RESULTS:** Only negligible levels of DIF were identified. Direction of DIF varied across items. When item scores were corrected for even low levels of DIF, the net impact on mean scores was minuscule (<0.1 point on 0-27 scale). Differences at cut-off scores were also negligible. **CONCLUSIONS:** The inclusion of trans-diagnostic symptoms on the PHQ-9 does not invalidate it for use in populations with TBI.

1427/Longitudinal Course of Depression Symptoms in Multiple Sclerosis

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AIMS: Despite high lifetime prevalence of depression in multiple sclerosis (MS), its longitudinal course is poorly understood. The purpose of the study was to examine the longitudinal course of depressive symptoms in MS over 28 months, and to examine how specific baseline variables predict the level of depression 2 years and 4 months later. **METHODS:** Community-dwelling individuals with MS (n=458, 97% response rate) responded to a self-report mailed survey. Depression was assessed 7 times 4 months apart using the Patient Health Questionnaire 9 (PHQ9). Those who completed PHQ9 at least 4 times were included. Latent variable growth modeling was used to examine the trajectory of depression and to identify variables associated with the level of depressive symptoms. Demographic variables, general health (SF-8), disease duration, mobility, pain, fatigue, sleep, baseline stress and the use of antidepressants at time 3 (8 month follow-up) were evaluated as predictors of depression at the last time point (28 month follow-up). **RESULTS:** The mean level of depression was mild and ranged from 5.4 to 8.0 across the 7 time points. The proportion of participants with moderately severe or severe depression ranged from 8% to 12%. At the end of 28 months 50% of the sample had the same level of depression as at baseline, 32% were less depressed and 18% were more depressed. In each change group 43 to 49% reported taking antidepressants. The mean group trajectory was flat over time (no significant increase or decrease in the level of depressive symptoms). Greater fatigue, perceived stress, sleep problems, vision loss, more side effects from medications, and use of antidepressants were statistically significant predictors of higher levels of depressive symptoms at the end of the study. **CONCLUSIONS:** Results indicated that depressive symptoms fluctuated over time for individuals, but group values did not change significantly. Users of antidepressants were more likely to report greater symptoms. Future studies should examine long-term effectiveness of antidepressants in reducing depressive symptoms in MS.

1643/Screening for Major Depression Episode with the SF-12v1 in 6 European countries

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AIMS: To evaluate the SF-12 as a screening tool for 12 month Major Depression Episode (MDE) and to obtain optimal cut-off points of the Mental Component Summary of the SF-12 for MDE in 6 European countries. **METHODS:** Data come from the European Study of Epidemiology of Mental Disorders (ESEMeD), cross-sectional household interview survey of a representative sample of non-institutionalized adult general population of Belgium, France, Germany, Italy, the Netherlands and Spain (n=21,425). The SF-12 v1 was administered to all respondents and the Physical and Mental Component Summaries were obtained with US regression weights. The presence of mental disorders was assessed with the CIDI 3.0, a structured interview that allows obtaining diagnosis of main mood and anxiety disorders according to DSM-IV criteria. Receiver

Operating Curve analysis was used to evaluate sensitivity (Se), specificity (Sp), Area under the ROC curve (AUC) and other related measures across the full range of the MCS-12 to predict 12 month MDE for each country. Optimal cut-off points were determined by finding the MCS-12 values that allowed for the best balance between sensitivity and specificity. **RESULTS:** The mean value for the MCS-12 was 53.7 (SD=8.1) in the pooled sample (almost 4 points better than in the US general population), ranging from 52.6 (SD=8.9) in France to 54.7 (SD=7.9) in Belgium. For the pooled sample, the optimal cut-off point was MCS-12 \leq 47 (6.7 points below the mean), with an AUC=0.77, Se=67% (SE=2.1) and Sp=86.2% (SE=0.4). In most countries, such optimal cut-off point was more than 6 points below the mean of the country, with an AUC > 0.72 (range: 0.73, France to 0.80, Germany); Sensitivity range 61.8% - 75.1%; Specificity range: 82.0% - 88.1%. Further results using IRT methods will be presented. **CONCLUSIONS:** The SF-12 demonstrated acceptable results as a screening tool for 12 month MDE in six European countries. Optimal cut-off point differed from the value of MCS-12=42 published for the US population, but the results obtained on diagnostic accuracy were similar.

1355/Long-Term Health Related Quality of Life and Psychological Well-Being Outcomes in Rectal Cancer Patients Treated with Preoperative Chemoradiotherapy

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AIMS: Aim of the study was to evaluate long-term health related quality of life (HRQOL) and psychological well-being outcomes reported by rectal cancer patients treated with preoperative chemoradiotherapy (CRT) followed by surgery. **METHODS:** 77 patients with locally advanced mid-low rectal cancer were enrolled in the study. HRQOL was measured by the EORTC QLQ-C30 and its colorectal cancer module (QLQ-CR38). Psychological aspects, faecal incontinence and bowel functional outcomes were measured respectively with the Psychological Well-Being Index (PGWBI), the Faecal Incontinence Score (FIS) questionnaire and ad hoc questions. All self-reported scales were completed before CRT (T0), and 24 months after surgery (T1). Key socio-demographic and clinical data were also collected. Comparisons were made by paired Wilcoxon test for continuous domains and by McNemar test for paired proportions of bowel functional problems. A p-value <0.01 was considered statistically significant. **RESULTS:** Body image had a significant worse decline from T0 to T1 (p=0.0036); Male sexual problems, as measured with the QLQ-CR38, deteriorated significantly from baseline to T1 (p<.0001). PGWBI showed a significant improvement over time with regard to anxiety and well-being (p<.0015). Using FIS questionnaire, worse defecation scores were found at T1 compared to T0 (p<.0028). Fractionated defecation and use of pads showed a significant increase (respectively p<.0055 and p<.0001). **CONCLUSIONS:** 2 years after surgery, patients with rectal cancer treated with preoperative CRT show an impairment in many

physically-related aspects (Body image, Male sexual problems, FIS and defecation symptoms) but at the same time an improvement in psychological outcomes (Anxiety and Psychological well being).

QUALITATIVE METHODS

1375/Voice Outcomes in Head and Neck Cancer - What Matters to Patients?

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AIMS: Acute & chronic voice changes are well-recognised sequelae of (chemo)radiotherapy in head & neck cancer. Approaches to assessing treatment impact include objective computerised voice assessment, perceptual voice rating by expert listeners and validated patient-reported measures of voice quality. This qualitative study aimed to assess the content & face validity and acceptability to patients of 3 PROMs, the VOiSS, VPQ & VHI. **METHODS:** The qualitative study was embedded within a prospective cohort study of voice outcomes following (chemo)radiotherapy. Two focus groups of head & neck cancer patients were convened. One group comprised a purposive sample of patients from the cohort study, who had completed the VOiSS during that study. The second group were patients between 6 & 18 months post-treatment who were VOiSS naive. Participants were asked to describe the voice-related impact of their cancer & treatment. They were then asked to review the VOiSS, VPQ & VHI, indicating how relevant & acceptable each item was to head & neck cancer patients. Finally, they were asked to indicate which instrument they preferred. Discussions were tape-recorded, transcribed and thematically analysed. **RESULTS:** Seven patients participated in group 1 and four in group 2. All had experienced adverse impact of therapy on their voice, particularly immediately post-treatment. Persistent problems included not being able to speak as loudly as previously, alterations in voice quality over the course of the day, and problems related to dry mouth. The majority of items in all three of the PROMs were considered relevant & acceptable, though most participants indicated that their current response would be 'never' or 'no impact'. The VPQ was preferred to the other instruments, for its brevity and because it allowed respondents to report on improvements in voice quality. **CONCLUSIONS:** All three voice-related PROMs were acceptable to head & neck cancer patients and felt to have good face & content validity in this population. Subjective measures can form a useful addition to assessment of treatment effects.

1666/Understanding Perspectives of Adults with Sickle Cell Disease in Developing a Disease Specific Quality of Life Measurement System

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AIMS: A thorough, systematic approach to defining the life impact of sickle cell disease (SCD) and its treatments on adults has not been undertaken, but is required in order to develop a valid, disease-

specific health related quality of life (HRQOL) measure. The Adult Sickle Cell Quality of Life Measurement (ASCQ-Me) project was initiated to fill this void. The study goal was to determine the content that should be included in ASCQ-Me, to maximize its usefulness in assessing research and clinical outcomes. **METHODS:** Focus groups and interviews were conducted with 135 adults with SCD and 15 SCD healthcare providers across the U.S., representing a diversity of regions and urban and rural areas. The spectrum of disease severity and phenotypes was included. Participants described how SCD affected their life or the lives of the people they care for by using the critical incident technique - i.e., recounting specific events. Each event was recorded separately and anonymously. Project team members sorted the events into categories and met to resolve discrepancies. Interviews continued to saturation. **RESULTS:** Over 1,197 critical incidents were collected and fell into the following taxonomy: (1) Emotions; (2) Attitudes and Beliefs; (3) Family and Social Relationships; (4) Morbidities/Co-Morbidities; (5) Sexuality/Reproduction; (6) Medical Care; (7) Health Insurance; (8) Employment/Education; (9) Altruism; (10) Stress/Control/Predictability; (11) Activity Limitations. Sub-categories further described the ways a person's life is affected by SCD and its treatment. **CONCLUSIONS:** This taxonomy is a comprehensive model of issues that affect adults with SCD. In addition to HRQOL outcomes, it contributes unique information about the importance of non-HRQOL issues to this population of adults with SCD, including quality of and access to care. Subsequent phases of ASCQ-Me included the design of questions to address the HRQOL portion of the taxonomy and the evaluation of the comprehensibility and meaningfulness of the questions to people with SCD.

1368/Evidence-based management of uncertainty in rheumatic conditions: Comparing views of health care professionals and patients

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AIMS: Uncertainty and its impact in chronic conditions is a complex, multidimensional and poorly understood concept. However, despite the existence of psychological theories (e.g. Uncertainty in Illness Theory), the direct links between uncertainty and its impact are not clear. Therefore, there is a need for careful qualitative examinations to understand, more explicitly, uncertainty from a patient and from a clinical management perspective. The aim of this study was to compare the views of rheumatology health-care professionals (HCPs) and two groups of rheumatic patients, with the view to inform upon future evidence-based measurement and management. **METHODS:** Two sets of semi-structured interviews were conducted (i) with rheumatology HCPs (N=8) and (ii) with Systemic Lupus Erythematosus (SLE) (N=17) and Rheumatoid Arthritis (RA) (N=15) patients. Interviews were audio-taped and transcribed verbatim. Detailed line-by-line coding of themes was carried out, and these were categorised inductively and compared using a constant comparison method. **RESULTS:** Themes generated from the HCPs included uncertainty of diagnosis, prognosis, treatment and impact (including: occupational, functional, giving birth etc). Findings from patient interviews confirmed the views of the HCPs and added other key areas, such as symptom limitations and impact of role functioning. Several sources of uncertainty were indicated by the HCPs, including illness trajectory and severity, age and gender all of which were reflected in the patient interviews. Patient interviews further reflect the variability of uncertainty with

time as suggested by the HCPs. **CONCLUSIONS:** Both HCPs and patients agreed on the key aspects of uncertainty in terms of content, source, timing and the potential to impact on patients' quality of life. Future directions for evidence management of this important concept include: targeting specific patient management strategies including patient support, education and empirically testing their efficacy using appropriate, robust rating scales.

1612/Exploring needs-based quality of life (QoL) from the perspective of the individual with Post Polio Syndrome (PPS): A thematic analysis

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AIMS: The empirically supported needs-based model of Quality of Life (QoL) proposes that life gains its quality from the ability of individuals to satisfy their needs (Hunt & McKenna, 1992). Several studies have shown that Post Polio Syndrome (PPS) impacts QoL, however no PPS specific research has been conducted into needs-based QoL. Therefore, this study qualitatively investigates QoL in PPS based on the needs-based model. **METHODS:** 45 interviews, both face to face and via telephone, were conducted on a stratified sample of patients from a hospital PPS clinic and other volunteers who requested involvement in the research via the British Polio Fellowship. Volunteers were classed as eligible if they fulfilled standard diagnostic criteria for having PPS. The semi-structured interview format allowed interviewees to raise issues that they considered important to their QoL and these were probed in-depth by interviewers. Prompts were also used as a guide to allow examination of how the direct impacts of the condition actually affect the needs of participants. The interviews were recorded, transcribed, and analysed thematically. Each transcript was coded systematically and independently by 2 researchers from the same discipline and then by another researcher of a differing background. Statements were identified relating to needs that are affected by PPS and then themes were agreed which these items related to. **RESULTS:** Thematic analysis revealed a number of predominant themes: 1) a profound impact on identity with poor self esteem, 2) a marked effect on relationships with others, 3) limitations in day to day life, such as hobby restriction, 4) fear for the future, in relation to uncertainties surrounding disease progression and loss of independence and 5) coping strategies exhibited which could affect QoL, such as activity avoidance and daytime sleep. **CONCLUSIONS:** It is clear that PPS has a significant effect on needs-based QoL. Future research should recognise these themes in developing a measure to assess needs-based QoL in PPS.

SCALE SELECTION

1207/Reaching the right decision: Proposal of a scale selection strategy in stroke research

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AIMS: Evaluating the impact of new treatments requires the use of reliable, valid, and responsive outcome scales. Given the wide range of instruments currently available, it is not always straightforward for healthcare professionals to pick the most appropriate tool. In this

study, we describe one potential approach with the view to making initial recommendations for other related studies. **METHODS:** In designing a new study of the impact of a robotic device on stroke rehabilitation, we developed a scale selection strategy, based on three key qualitative stages. First, three guideline documents (Medical Outcome Trust, Food and Drug Administration, and International Classification of Health) were reviewed to identify relevant key scale assessment criteria. Second, a comprehensive literature search strategy and review were developed in conjunction with health care professionals, psychometricians and librarians. Third, following the completion of the searches and overall review, an iterative and interactive phase of scale appraisal including scientific and clinical input was conducted to select the final measures. **RESULTS:** Forty-five measures were identified, and appraised. From a clinical content perspective, none of the measures were sufficient on their own to capture all the important outcome domains in this study. However, three measures were identified that best met our review criteria: Stroke Rehabilitation Assessment of Movement, Chedoke Arm Hand Inventory and ABILHAND. Following the final stage of scale appraisal further upper limb scales were included (ie Fugl Meyer assessment and ARAT) based on clinical content and study design issues. **CONCLUSIONS:** In this study, we brought together clinical and psychometric criteria to select scales to evaluate upper limb recovery post stroke. This was found to be a useful method to select the best available scales from the large number of potential outcome measures available. Importantly, the strategy revealed there is currently no single reliable and valid tool that captures the complete range of arm function in stroke patients.

1205/Selecting patient reported outcomes in glaucoma studies: which instrument?

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AIMS: Investigators usually consider psychometric properties when selecting patient reported outcome (PRO) instruments. However, content validity should be the primary concern to ascertain what dimension of health is being measured and whether this is appropriate to address the research question. We conducted a systematic review to identify vision-specific PRO instruments that have been used in observational or randomised controlled trial studies involving patients with glaucoma. We evaluated the content validity of the instruments. **METHODS:** We searched for all studies reporting use of vision-specific PRO instruments in patients with glaucoma in electronic databases: MEDLINE, EMBASE and SCOPUS from 1950 to January 2009. In addition, we scanned reference lists to identify studies describing the development and/or validation process. The content quality of the instruments was graded using a modified quality assessment tool. **RESULTS:** We identified 34 vision-specific PRO instruments, of which 17 were glaucoma-specific. Based on the World Health Organisation (WHO) International Classification of Functioning, Disability and Health (ICF), we categorised vision-specific instruments into vision status, disability and satisfaction measures; and glaucoma-specific instruments into glaucoma status, medication related to health status, medication side-effects and medication satisfaction measures. The vision-specific instruments with the most positive rating were the Impact of Vision Impairment (IVI) and National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25), while the most positively rated glaucoma-specific instrument was the Treatment Satisfaction Survey-Intraocular Pressure (TSS-IOP). **CONCLUSIONS:** This review informs the first stage of choosing an appropriate content validated vision-specific

PRO instrument. Only then does the performance of the content relevant instrument need to be considered to determine if any of the existing instruments are sufficiently valid and reliable to measure PRO.

1228/The need for a new Hepatitis C Virus-Specific Health-Related Quality of Life measure

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AIMS: This study investigated whether the measures of health-related quality of life (HRQL) commonly used in hepatitis c virus (HCV) research effectively encompass the disease-specific experience of HCV. **METHODS:** A review of qualitative and quantitative literature was performed to identify important HCV HRQL dimensions. To identify appropriate studies, Medline and Embase were interrogated. Studies concerned with HCV HRQL were assessed for relevance and quality against FDA and EMEA guidelines. The review facilitated construction of a conceptual framework of HRQL that encompassed dimensions relevant to persons infected with HCV, treated and untreated. This framework was then contrasted against the content of a range of HRQL measures commonly used in HCV research, including the generic SF36, Hepatitis Quality of Life Questionnaire (HQLQ), Chronic Liver Disease Questionnaire (CLDQ), Liver Disease Symptom Index (LDSI 2.0), and Hepatitis B Quality of Life instrument (HBQOL).

RESULTS: A disconnect was apparent between the content of HRQL measures commonly used in HCV research and the dimensions encompassing the HRQL HCV experience. Among the HCV HRQL dimensions needing attention were liver disease severity, psychiatric complications, cognitive functioning, sexual dysfunction, stigma, treatment impact and management and adherence, drug addiction and treatment, HCV/HIV co-infection, resilience, emotional volatility, and fatigue variability. **CONCLUSIONS:** No single existing HRQL instrument fully addressed the disease-specific experience of HCV. Development of an HCV HRQL instrument that is sensitive to the relevant dimensions identified in this study would be highly beneficial. Such an instrument would result in greater precision in terms of monitoring patient outcomes during treatment, clinical practice more broadly and clinical research trials. Treatment research arising from the use of this instrument would provide clinicians, patients and their families with the knowledge necessary to choose appropriate disease management strategies.

1018/Inter-rater Reliability of the COSMIN (Consensus-based Standards for the selection of health status Measurement Instruments) Checklist

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AIMS: The COSMIN checklist is a tool for evaluating the methodological quality of studies on measurement properties of health-related patient-reported outcomes. The aim of this study is to determine the inter-rater reliability of each item (n=114) of the COSMIN checklist. **METHODS:** 75 articles evaluating measurement properties were randomly selected from the bibliographic database compiled by the Patient-Reported Outcome Measurement Group, Oxford, UK. Raters were asked to assess the methodological quality of three articles, using the COSMIN checklist. ICC (one-way ANOVA) and percentage agreement were calculated for each item. **RESULTS:** 88 raters participated. Of the 75 selected articles, 26 articles were rated by 4 to 6 participants, and 49 by two or three participants. Overall, the ICCs were low (89% was below 0.70), while the percentage agreement was appropriate (80% of the items was above 80% agreement). Reasons for low agreement were need for subjective judgement, accustomed to different standards, and to different terminology and definitions. **CONCLUSIONS:** The COSMIN items showed a large variation in agreement among raters. When using the checklist in a systematic review, we recommend getting some training and experience, completing it by two independent raters, and reaching consensus on one final rating.

GERIATRICS & END OF LIFE

1120/Enjoying Old Age: Perceptions of Older Adults Regarding Quality of Life

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AIMS: The increase of older adults in the population has emphasized the need for consideration of what it takes to live this phase of life with a sense of quality and satisfaction. This research aims at analysing the perceptions of which contributors older adults recognized as being a determinant of their QoL. **METHODS:** Information was gathered by a research tool composed of two parts: (a) a demographic questionnaire and (b) a qualitative semi-structured interview in which subjects replied to open-ended questions about their perception of QoL in one specific period in their lives: today. Interview transcripts were subjected to content analysis. The research sample comprised 33 elderly people between the ages of 74-100, from eight different nationalities and distinct cultural and professional backgrounds. **RESULTS:** Results yielded a set of seven descriptive categories that capture the distinct ways older adults acknowledged QoL: Accomplishment, Personal Fulfilment, and Future Projects; Occupation, Profession, Autonomy and Leisure; Health status, Physical and Intellectual Functioning; Valorisation of Time and Age and Sense of Limit; Family, Social and Interpersonal Status; Stability, Quality and Financial Situation; and Personal Attitudes. **CONCLUSIONS:** The results of this study are discussed in the context of existing research on successful aging of older adults, focusing in particular upon the perceived tensions between the determination to experience QoL and the challenges of old age. Current QoL was significantly associated with an increased likelihood of reporting specific themes in its definition. Interventions with older adults may benefit from clearly understanding QoL as an important component for promoting successful aging and reducing health disparities. Communication approaches in clinical practice, policies and program development should focus on shared perceptions of aging well and adapt to the shifting demographic

composition of reality. Recommendations for future research on older adults' QoL and clinical practice are also presented.

1101/Improving quality of care in geriatrics, Sweden

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AIMS: Quality of care was measured continuously at two geriatric wards in Linköping, Sweden. Identified problems concerned low scorings from patients and relatives regarding access to information; their ability to participate in decisions; and how they were treated by staff. Results from telephone interviews with patients and relatives were used for decisions about actions for improvement. **METHODS:** Actions taken concerned written information to the patient/relative and easy to access; 15-minutes daily briefing within the teams; continuously measures with Functional Independence Measure and a rehabilitation plan for all patients. Small work groups were responsible for planning, communicating and implementing the decided actions. Measures from different perspectives were carried out before and after quality improvement strategies were performed. Data from patients and relatives were collected during 9 months before interventions, and 9 months after interventions. Data from staff were collected at staff meetings 4 months before and 4 months after interventions. Telephone interviews were performed with patients, 3–4 weeks after discharge, using the PaPeR questionnaire (Wressle et al, 2006) consisting of 19 Likert-type items and 5 answer alternatives (1 = Totally disagree to 5 = Totally agree). Telephone interviews were performed with relatives to patients, 3–4 weeks after discharge, using a questionnaire with 26 Likert-type items with the same answer alternatives (Wressle et al, 2008). A staff questionnaire was used, 20 Likert-type items. Staff answered in written. **RESULTS:** The results showed positive effects of the quality improvement actions, higher scorings indicates better quality. Patients' perspective: 17 of 19 items had higher scorings after implementation. Relatives' perspective: 14 of 26 items had higher scorings after implementation. Staffs' perspective: 18 of 20 items had higher scorings after implementation. **CONCLUSIONS:** Actions for improvement need strong support among the staff and management support. Goals must be clear, actions simple and not too many. Keep the goals alive!

1435/Quality of Life of Elders with Dementia and Their Caregivers: Use of Multiple Measures for Community-Based Translational Research

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AIMS: To identify modifiable correlates of quality of life (QOL) in community-residing individuals with dementia and their carers. **METHODS:** Elders age 70+ with dementia (n=219) and their carers in a Baltimore community enrolled in a randomized controlled trial examining the efficacy of a dementia care coordination program. Interviews and clinical exams took place in residents' homes. Participant data included demographics, patients' health, function (ADLs), dementia-related unmet needs, depressive and neuropsychiatric symptoms, and two measures of QOL (QOL-AD, ADRQL). Caregiver data included caregiver health, care burden, symptoms of depression, and QOL (SF-12). Univariate analyses were run to describe the sample; bivariate and multiple regression analyses were run to identify baseline correlates of QOL. **RESULTS:** Most dementia patients (75%) lived with their caregivers. Most caregivers were a spouse (40%) or adult child (49%). Patient-rated QOL-AD scores were lower for those with more symptoms of depression (p<.001), unmet needs for dementia evaluation (p<.001), non-whites (p<.01), and taking more medications (p<.05). Caregiver-rated QOL-

AD scores were lower for patients with more symptoms of depression (p<.01), more distressing neuropsychiatric symptoms (p<.05), and more impairments in basic (<.05) and instrumental (p<.05) ADLs. ADRQL scores were lower for patients with more severe neuropsychiatric symptoms (p<.001), and more impairments in basic (p<.05) and instrumental (p<.001) ADLs. Caregivers with lower SF-12 Physical scores had lower self-rated health (p<.001), more symptoms of depression (p<.001), and older (p<.01). Caregivers with lower SF-12 Mental scores had greater care burden (p<.001), more symptoms of depression (p<.001), and females (p<.05). **CONCLUSIONS:** Dementia patients' QOL may be improved by dementia care that includes evaluation, treating depression and neuropsychiatric symptoms, and reducing total number of medications. Caregivers' QOL may be improved by treating depression and reducing caregiver burden.

1242/Health, attitudes to ageing and quality of life across cultures

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AIMS: There has been little attention in the research literature on the relationships between attitudes to ageing and QOL. Hence, in this study, we examined the relationships between older peoples' self-rated health, attitudes to ageing as markers of growth and development, and QOL. We were particularly interested in whether attitudes would mediate the effect of health. **METHODS:** We analyzed cross-sectional data collected in the 2003 WHOQOL-OLD field study from 20 international centres. Sample sizes varied between centres from 116 in Edinburgh to 455 in Umea. The measures used in the larger study were selected to assess the reliability and validity of two new instruments, the Attitudes to Ageing Questionnaire (AAQ) and the WHOQOL-OLD. Measures were completed using a variety of culturally appropriate methods, including mail-outs, self-administration, and interviews. For the purposes of this study, the WHOQOL-BREF and self-reported health were used. Almost all variables had fewer than 3% missing values, and there complete data were available for 4593 older adults. Using path analysis, controlling for age, gender and country of origin, we assessed the impacts of health on attitudes to physical changes, psychosocial loss and growth and the impact of these on QOL. Statistical testing of each of the multiple mediators were conducted using bootstrap resampling. **RESULTS:** All estimates were statistically significant (p<.01). Health had a moderate direct effect on QOL, and its effects are also mediated through attitudes towards physical change and psychosocial loss. Health appears to be a catalyst to attitudinal markers of growth and development which in turn impact QOL across cultures. **CONCLUSIONS:** This cross-cultural study illuminates links among health, physical and psychosocial development in older age, and QOL warranting further study across cultures among frailer populations over time. Using developmental frameworks in future research could help us better understand how older people psychologically adapt to health-related transitions and add quality to their remaining life years.

FATIGUE

1339/Malaise/weakness/fatigue a relevant symptom cluster for persons living with HIV: maybe, maybe not

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AIMS: Symptom management is increasingly recognized as a critical element of quality patient care. Symptom assessment that includes the recognition of symptom clusters should be foundational.

Evaluating symptoms in clusters versus a one-dimensional perspective is potentially more helpful to clinicians guiding clinical practice. However, interpreting the significance of a symptom cluster within a symptom checklist isn't always obvious. The purpose of this analysis was to further understand the dimensionality of a symptom checklist developed for persons living with HIV by examining it from a bifactor perspective. The symptom checklist was hypothesized to have six symptom clusters: malaise/weakness/fatigue, confusion/distress, fever/chills, gastrointestinal discomfort, shortness of breath, and nausea/vomiting. **METHODS:** The sample included 917 living with HIV with an average age of 39.35 (S. D.=8.13) and 83% were Caucasian from the AIDS Time-Oriented Health Outcomes Study. Mplus was used to estimate a series of confirmatory factor analysis models. The first hypothesized model tested was a second order factor model which consisted of one higher order general factor and six lower order factors. The second was a bifactor model that suggests there is a general factor that explains the item intercorrelations but in addition there are also factors that attempt to capture the item covariation that is independent of the covariation due to the general factor. **RESULTS:** The second order factor model fit the data adequately ($\chi^2(225)=493.42$, $p<.0001$, CFI=.99, RMSEA=.036). The residual variance for the malaise/weakness/fatigue cluster was very close to zero, suggesting that it didn't add any additional explanation beyond the second order factor. The bifactor model did not fit the data until the malaise/weakness/fatigue factor was removed. **CONCLUSIONS:** The potential for the bifactor model over a second-order factor model to detect problematic clusters and the implications of removing the malaise/weakness/fatigue cluster for clinical care will be discussed.

1681/Exploring fatigue from the perspective of the individual with Post Polio Syndrome (PPS): A thematic analysis

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AIMS: Fatigue is frequently experienced in Post Polio Syndrome (PPS) and many patients have identified it as their most debilitating symptom. This study explores the experience of fatigue from the perspective of the person with PPS, and reports the precipitants and features of PPS fatigue. **METHODS:** 45 semi-structured interviews were conducted with a stratified sample of volunteers with PPS attending a hospital clinic or recruited through the British Polio Fellowship. Interviews were carried out face to face or over the telephone and analysed using thematic analysis, which is a widely used method for identifying and reporting emerging themes in complex data. Each interview was systematically and iteratively coded by 2 psychology graduates to seek patterns, identify statements that relate to fatigue, and to agree themes which these items relate to. Both the transcripts and codes were checked by a third researcher from a different professional group. No new themes emerged during the final interviews, suggesting saturation was achieved. **RESULTS:** A number of distinct aspects of fatigue were reported: 1) physical fatigue is generally characterised by increasing muscle weakness in polio-affected and non-polio affected limbs upon physical exertion, 2) mental fatigue involves cognitive dysfunction regarding concentration, memory and motivation and/or a feeling of a clouded mind, 3) systemic fatigue is described as a tiredness throughout the whole body and mind which is different from ordinary tiredness, 4) extreme fatigue is characterised by a random and sudden onset of intense fatigue for unknown reason, 5) feelings of accelerated ageing disproportionate to normal ageing. Factors that influenced fatigue include pain, mental/physical exertion, rest, sleep, pain, appetite and temperature. **CONCLUSIONS:** The study reported different aspects of fatigue in PPS and gave insight to what may relieve or aggravate

fatigue. These findings will contribute to ongoing work on developing a self report measure for fatigue in people who have PPS.

1575/Symptom burden in chronic myeloid leukemia survivors treated with Imatinib

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AIMS: While Imatinib (IM) has greatly improved quality of life (QoL) outcomes compared to previous interferon based treatments, no evidence exists about the long-term burden of treatment from the patient's perspective. **METHODS:** CML survivors in complete cytogenetic response (CcgR) and in treatment with IM for at least three years were approached and invited by their treating physicians in the Hospital. All consenting patients were then handed over a QoL Survey Packet with the request to completing it at home and send it back with a pre-paid reply envelope. Patient-reported symptoms were measured with a previously developed CML-symptom checklist investigating key symptoms for this population. Item response were designed as a 4 point Likert scale ranging from "not at all" to "very much" with standardized scores ranging between 0 and 100 (i.e. higher scores indicating higher symptom intensity). Descriptive statistics and multivariate regression analyses were performed. **RESULTS:** Twenty-six research centers participated in the study and 480 patients were enrolled between March to December 2009. Patients compliance in returning valid QoL Survey Packet was 94%. Mean age was 57 years and median time since IM treatment start was 5 years. Current analysis is based on preliminary data on the first 249 patients. Fatigue, muscle cramps and edema had the highest mean scores being 41 (SD=27), 39.6 (SD=27) and 34 (SD=29) respectively. Severe fatigue was reported in 31% of the overall sample (48% and 25% of female and male patients respectively). A trend towards a worse symptom profile for female patients was identified and the relationship remained significant after adjusting for other key clinical and laboratory variables. An higher overall symptom burden was independently associated with female gender ($p<.01$) and with an earlier achievement of a CcgR ($p=.02$). **CONCLUSIONS:** Fatigue is the most relevant symptom in CML survivors and preliminary data suggest a worse symptom profile in female patients.

1117/A Randomized Clinical Trial of Cognitive Behavioral Therapy and Physical Exercise to Reduce Climacteric Symptoms and Improve Health-Related Quality of Life in Breast Cancer Patients Experiencing Treatment-Induced Menopause: Short-Term Results

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AIMS: Premature menopause is a major concern for younger women undergoing adjuvant therapy for breast cancer. Use of HRT in this population is contraindicated. The objective of this study is to assess the effectiveness of cognitive behavioral therapy (CBT) and physical

exercise (PE) on climacteric symptoms and health-related quality of life (HRQoL) in breast cancer patients experiencing treatment-induced menopause. **METHODS:** In this multicenter trial, breast cancer patients who have experienced chemotherapy-induced menopause are being randomized to: (1) CBT; (2) PE; (3) combined CBT/PE; or (4) a waiting list control group. Questionnaires are completed at baseline (T0), 12 weeks (T1) and 6 months (T2) follow-up. Outcomes include menopausal symptoms (FACTES; HFRS), sexuality (SAQ), body- and self-image (QLQ-BR23), urinary symptoms (BFLUTS), psychological distress (HADS) and HRQoL (SF36). Analyses include both intention-to-treat (ITT) and per-protocol (PP) strategies. **RESULTS:** To date, 352 patients have completed the baseline and first follow-up questionnaires. Significant short-term group differences favoring the interventions have been observed for menopausal symptoms (FACTES: ITT $p=0.015$; PP $p=0.014$) (HFRS: ITT and PP $p<0.001$), urinary symptoms (ITT and PP $p<0.001$), psychological distress (PP only $p=0.004$), self-reported physical functioning (ITT $p=0.004$; PP $p=0.001$), fatigue (ITT $p=0.033$; PP $p=0.015$), social functioning (PP only $p=0.036$) and general health perceptions (PP only $p=0.009$). **CONCLUSIONS:** In the short-term, both CBT and PE reduce climacteric symptoms and have additional HRQoL benefits. If proven effective over the longer follow-up period, implementation of this intervention program, perhaps with modifications to increase compliance, will be a welcome addition to the regular medical care of breast cancer patients experiencing treatment-induced menopause.

VALIDITY

1302/Dignity and the content validity of the Patient Dignity Inventory

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AIMS: Dignity is a topic which often arises in discussions about care for dying patients and preserving dignity can be considered as an important goal of palliative care. This study aims to analyse the construct of dignity and to assess the content validity of the Patient Dignity Inventory in people with an advance directive in the Netherlands. **METHODS:** Data were collected within the framework of a cohort study which consisted of people with different types of standard advance directives: euthanasia directive, refusal of treatment statement and the durable power of attorney provided by the Right to Die-NL or the wish to live statement provided by the Dutch Patient Association. Data for this study were collected in the second data-collection cycle and the response rate was about 90%. The cohort was randomly split into two: one half of the cohort ($n=2537$) received a written questionnaire including the Patient Dignity Inventory. The other half of the cohort ($n=2404$) received an open-ended question on factors would influence their dignity. Content labels were assigned to themes found in the open-end responses. Consequently, we judged the relevance and comprehensiveness of the items of the Patient Dignity Inventory. **RESULTS:** Dignity was defined by the topics which were considered important by the people with an advance directive in the Netherlands. The majority of the items of the Patient Dignity Inventory were thought to influence dignity at the end of life but the items were not completely comprehensiveness. The responses to the open-ended question indicated that communication and care-related aspects were also important for dignity. **CONCLUSIONS:** This study demonstrated that the items of the Patient Dignity

Inventory were relevant for people with an advance directive in the Netherlands. The comprehensiveness can be improved by including items on communication and characteristics of care.

1595/Construct validity of the ThyPRO assessed by multiple groups confirmatory factor analysis in patients with thyroid diseases

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AIMS: In order to assess overall model fit, causal indicators and to test a conceptual model simultaneously in several diagnostic groups, construct validity of the thyroid-specific ThyPRO was evaluated by multiple groups confirmatory factor analyses (CFA). **METHODS:** ThyPRO measures quality of life in 13 scales with 84 items. Study population: 907 patients with five different thyroid diagnoses. Scale structure was analyzed by CFA for ordinal data, using Mplus 5.21. Appropriate fit: comparative fit index (CFI) >0.95 and root mean square error of approximation (RMSEA) <0.08 . Models were fitted in the joint sample and in multiple groups according to thyroid diagnosis. Prior to the CFA, a theoretical model was specified, including a priori expectations regarding local dependence and low factor loadings. **RESULTS:** In the joint sample, 11 items were excluded, two scales were split in two, one method factor was identified (positive wording) and 12 local dependencies were found, yielding an overall fit of CFI=0.958 and RMSEA=0.051. The same factor structure was found in multiple groups analyses, but only 4 local dependencies were found; CFI=0.98, RMSEA=0.061. Sixty one out of 105 factor correlations were below .60, 23 were .60-.70, 11 were .70-.80 and 9 were .80-.90. Of the correlations above .70, 6 involved impact scales (e.g., impact of thyroid disease on daily life) in initial analyses. When modelling theoretically expected causal pathways between scales measuring symptoms, function and well-being and impact scales, all six factor correlations were reduced to below 0.50, indicating that the high factor correlations among these scales were due to causal effects of symptoms, function and well-being. **CONCLUSIONS:** Construct validity was found after scale modification of the ThyPRO questionnaire. Improved fit was obtained when separating patients according to diagnosis in a multiple groups CFA. We found evidence for causal effects of symptoms, function and well-being on impact scales, leading to high interscale correlations among the latter.

1426/Use of Structural Equation Modeling to Test the Construct Validity of the Iranian SF-12 Health Survey Version 2 (SF-12v2)

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AIMS: To investigate factorial structure and reliability of the SF-12v2 in a healthy Iranian sample, following translation and the establishment of content and face validity. **METHODS:** The translation process was included two forward and two blind backward translations based on the standard guidelines. In this cross-sectional study, the translated version of the instrument was

administered in a convenience sample of healthy people ($n = 289$) aged 17 to 74 years old. A test re-test was conducted one month later. Content Validity Index for Scale (S-CVI) was determined by an expert panel, and then final instrument pre-tested by 10 voluntary healthy subjects for face validity. Factorial structure of the instrument was estimated by Structural Equation Modeling (SEM) with four models comparison to the original SF-12. Internal consistency and stability were assessed by Cronbach's alpha and Intra-class correlation coefficients (ICC). **RESULTS:** The S-CVI (85.6%) and face validity of the instrument were verified. SEM results confirmed the existing two-factor structure, a physical component summary (PCS) and a mental component summary (MCS). All models of the Iranian SF-12v2 exceeded goodness of fit indices. Also, SEM results showed that the model 1 (two-factor and 12 items) and model 2 (two-factor and 8 scales) had similar items/scales loadings with the original SF-12. However the model 3 (two-factor with 12 items and cross-loading) and model 4 (two-factor with 8 scales and cross-loading) demonstrated that the General Health was loaded to the mental component rather than the physical component, construct validity of the instrument was confirmed. Furthermore, Cronbach's alpha values (> 70) and ICC (> 60) met the study's criteria. **CONCLUSIONS:** The Iranian SF-12v2 was shown to be a psychometrically sound instrument, implying that it is suitable for inclusion in large-scale surveys and for cross-cultural Quality of Life comparisons. SF-12v2™ © 2000 is a trademark of QualityMetric Incorporated - All rights reserved.

1213/Content validity of utility assessments in Type 2 Diabetes and Alzheimer's Disease

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AIMS: Generic utility instruments inform health technology assessment decision-making about resource allocation across competing interventions. Reference methods are used to combat inconsistencies between instruments due to the various approaches to economic evaluation, but the applicability of utility instruments to patients has not been assessed. The study explored the content of utility instruments relevant to type 2 (T2) diabetes and Alzheimer's Disease (AD) research to inform the trade-off between content coverage and consistency. **METHODS:** Literature review identified qualitative and quantitative studies about patients' experiences with T2 diabetes, AD and associated treatments. Generic and disease-specific instruments were mapped to conceptual models developed for each disease. **RESULTS:** Published descriptions of concepts important to patients with T2 diabetes or AD are available when deciding the most comprehensive utility assessment approach. While the 15-dimensional health related quality of life measure (15D) seemed most comprehensive for both diseases, the Health Utilities Index 3 (HUI 3) and the EUROQOL-5 (EQ-5D) seemed to have the least coverage for T2 diabetes and AD, respectively. Furthermore, some utility instruments contained items that could not be mapped onto either of the conceptual models. **CONCLUSIONS:** Important patient concepts vary from one disease to the next but generic utility measures often do not capture relevant concepts, contributing to lack of consistency in observable utility effects and incremental utility scores. Content validity appears to be omitted from utility method development considerations. Thus, we recommend that patients' perspectives, obtained via qualitative methods, are considered in ongoing methods development of health state descriptors for generic utility instruments. As a more immediate contribution to improve decision making, the chosen utility measure's content map with important patient-reported concepts should be provided as standard to improve the transparency of the trade-offs between patient relevance and consistency.

INSTRUMENT DEVELOPMENT

1183/Development of the individualised Eye-Dependent Quality of Life Questionnaire: EyeDQoL

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AIMS: To develop the EyeDQoL for UK and Germany, designed using existing related measures and interviews with patients with cataract, glaucoma, macular disease (MD), diabetic retinopathy (DR). **METHODS:** EyeDQoL has 2 overview items (present QoL, eye-specific QoL) and 23 domain-specific items, each with an impact and an importance scale, preliminary questions determine applicability for some domains. An open-ended question asks about any other effects on QoL. Data were collected from intervention studies of a) intraocular anti-VEGF injections for DR or MD, $n=50$, b) cataract surgery in patients with MD, $n=103$. Principal components analysis identified factor structure, Cronbach's alpha assessed internal consistency. Sensitivity to change following treatment and test-retest reliability (intraclass correlation) in stable patients were examined. Rasch analyses examined targeting, unidimensionality and differential item functioning (DIF) for unweighted impact ratings. Construct validity was examined by testing correlations between overview items and average weighted impact score (AWI, average product of impact and importance of each applicable domain) and expected relationships of EyeDQoL scores with visual acuity (VA). Content validity was explored using the open-ended question. **RESULTS:** A one-factor solution with 21 items had high internal consistency ($\alpha=0.96$) and test-retest reliability (0.9 for AWI score); sensitivity to change was more modest, perhaps due to short follow-ups. The scale was well targeted for the samples; 18/21 items displayed ordered thresholds, 3 showed some DIF across studies. As expected, worse VA was associated with worse EyeDQoL scores and AWI correlated with eye-specific QoL but not present QoL. Open-ended question responses mainly emphasised existing items: no additions were needed. **CONCLUSIONS:** The EyeDQoL is a valid and reliable measure of the impact of eye conditions and their treatment on individual's QoL; to assess sensitivity further, longer follow-ups are needed. Collapsing response options or dropping 3 items may further improve the scale.

1611/The EUROHIS-QOL 8: Comparative measurement properties to its parent WHOQOL-BREF measure

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AIMS: Our aim was to test the psychometric properties of the EUROHIS-QOL 8, a shortened version of the WHOQOL-BREF including 8 items. **METHODS:** The sample consisted of 2359 subjects identified from primary care settings with 1193 having confirmed diagnosis of depression. Data came from six countries (Australia, Brazil, Israel, Russia, Spain, and the USA) involved in a large international study, Longitudinal Investigation of Depression Outcomes (LIDO). The EUROHIS-QOL 8-item index structure follows that of the WHOQOL-BREF assessment. Internal consistency was measured using Cronbach's alpha. Convergent validity was assessed using correlations with different measures for

mental (SCL-90), physical health (self-evaluation) and QOL (WHOQOL-BREF and SF-36). Discriminant validity was assessed between diagnosed depressed and non-depressed patients. Differential item functioning (DIF) and unidimensionality was analyzed using Rasch analysis. Factor structure was assessed with structural equation modelling analyses (SEM). **RESULTS:** Internal consistency was acceptable (\pm ranged between 0.72 and 0.81 across countries) and the index discriminates well between depression ($t=6.31$ to 20.33 , $p < 0.00001$) across all countries. Correlations between EURO-HIS-QOL 8-item index and different measures: SCL-90 ($r^2 = -0.42$), physical health ($r^2 = -0.42$), WHOQOL-BREF domains ($r^2 = 0.61$ to 0.77) and SF-36 ($r^2 = 0.58$) were all significant ($p < 0.0001$). Applying Rasch analysis (unidimensionality), the index showed very good item fit statistics. In terms of residuals, 2 items (daily living activities and enough money to meet your needs) showed slightly problematic scores (residuals > 4). DIF was observed in general QOL, general health, relationships and home items for age, and no item shown DIF for gender. A common one-factor structure with a good fit was identified in most countries (CFI=0.85, RMSEA=0.11). **CONCLUSIONS:** The EURO-HIS-QOL 8-item index showed good cross-cultural performance and a satisfactory discriminant validity and would be a useful measure to include in studies to assess treatment effectiveness.

1718/Developing an oral HRQL measure for 5-year-olds
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AIMS: To develop and assess the psychometric properties of a new oral health related quality of life (OHRQL) measure applicable for 5-year-old children and their families in UK. **METHODS:** A cross-sectional study comprising: 1) a preliminary stage with qualitative focus group discussions with parents of 5-year-olds, and 2) a main quantitative stage whereby the new OHRQL measure, and other subjective oral health questions, were interviewer-administered to 5-year-old children at school and self-completed by their parents at home. In addition, data were matched to clinical status data (dental caries, pulp involvement, dental sepsis) from the National Dental Inspection Programme (NDIP). Schools were stratified into affluent, medium or deprived according to the Scottish Index of Multiple Deprivation score for their area. Overall, 6 affluent, 12 medium and 17 deprived schools were selected in Glasgow. Completed questionnaires were received for 326 parent-child dyads and 296 of them were matched with the respective NDIP records. **RESULTS:** Despite their young age, in general children understood the questions (82.4% had no question repeated / reworded). For the internal consistency of the new measure, the mean inter-item correlation was 0.29, item-total correlations ranged between 0.30 and 0.60, and the standardized item Cronbach's alpha was 0.75. Children's OHRQL scores were significantly related to self-reports of toothache, presence of oral cavities and oral health satisfaction ($p < 0.04$ in all cases); groups reporting worse perceptions had also higher OHRQL scores, indicating worse quality of life. In addition, children with clinically assessed dental caries, pulp involvement and dental sepsis had significantly worse OHRQL than children without these conditions ($p = 0.021$, 0.010 and 0.006 respectively). **CONCLUSIONS:** This new OHRQL measure for young children showed successful reliability and construct validity. It was able to discriminate between

different clinical oral health groups and could potentially be a valuable outcome in oral health promotion programmes and service initiatives for this age group.

1246/Developing and utilizing the EORTC QLQ-SWB33: a spiritual wellbeing measure for palliative care patients with cancer

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AIMS: Supportive and end-of-life care strategies for people with advanced cancer call for spiritual care to address their spiritual needs. The EORTC Quality of Life Group (QLG) is developing a spiritual wellbeing measure for palliative care patients with cancer. It has measurement and intervention characteristics, so serves both to measure the effects of interventions which seek to address spiritual needs and also, by raising issues related to spiritual wellbeing, to begin discussions of those issues. This may help patients make decisions about their futures. This paper considers the measure's development to date and its possible uses. **METHODS:** Following EORTC QLG guidelines for developing questionnaire modules, the measure has just completed Phase III of its development: pre-testing. Phase I gathered palliative care patients and professionals' views on possibly relevant issues, Phase II operationalised issues into items, and Phase III tested those items with patients. **RESULTS:** Collaborators in 10 European countries and Japan took part in Phases I-III of measure development. 84 issues in Phase I have been developed into a provisional 33-item measure ready for field-testing. Phase III collected data from 113 patients in 7 countries. Due to careful attention to translation and simultaneous development in multiple languages, items are consistent between languages. Phase III data show that patients find the items comprehensible. It is also noteworthy that during Phase III patient participants in several countries used the measure as a starting point for discussing the issues it addresses. **CONCLUSIONS:** The EORTC QLG's rigorous development process ensures that the EORTC QLQ-SWB33 identifies key issues for spiritual wellbeing and that items are comprehensible and consistent across languages. The measure also functions as a discussion tool, enabling patients to begin talking about issues related to spiritual wellbeing. This is both a supportive intervention of itself, and may also help patients with making decisions about their future care and treatment.

ASSESSMENT MODE TECHNOLOGY

1136/Just like the film: development of a computer-animation questionnaire to improve the measurement of functional limitations of patients with hip or knee osteoarthritis

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AIMS: Functional limitations of patients with hip or knee osteoarthritis (OA) can be measured by self-report questionnaires or performance-based tests. Both methods have advantages and disadvantages. Questionnaires are influenced by factors like pain, fatigue and the patients' interpretation of the questions. Performance-based tests require personal contact and are time-consuming and a burden for patients. We aimed to develop a new instrument; the computer-animation questionnaire. By showing animations we try to minimize the patients' reference frame. **METHODS:** The computer-animation questionnaire was developed in cooperation with a specialized company, based on movement analyses of a person, performing 7 different daily activities. Different videos of the same activity were made with two to five levels of difficulty. For each activity, patients were asked to choose the video that best indicates their way of performing the activity. We compared this new way of measuring with validated paper questionnaires (WOMAC and validated questionnaires on walking, stair climbing and rising/sitting down) and validated performance tests (walking, timed-up-and-go, timed-stair-test) and correlated the outcomes of 33 patients with hip or knee OA on each form of measurement. **RESULTS:** The computer-animation questionnaire showed a higher correlation with the performance tests than the WOMAC questionnaire (0.75 vs 0.49). From cognitive debriefing we learned that patients are enthusiastic about this new measurement instrument. Almost all patients prefer it over paper questionnaires and performance-based tests. **CONCLUSIONS:** The computer-animation questionnaire might be a good alternative instrument to measure functional limitations of patients with hip or knee osteoarthritis. This method can easily be used in other patient populations as well and can be administered by internet.

1423/Do cancer patients feel comfortable with QoL electronic data collection?

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AIMS: We aimed to verify whether cancer patients feel comfortable with the data collection of QoL using an electronic tool. This objective is part of a more general purpose of evaluating an automated method for routinely collecting data for cancer patients' QoL. **METHODS:** 200 oncology patients participated in this study, half of them firstly answering in paper and, subsequently, on the computer; the remaining patients followed the opposite procedure. Patients answered to the electronic version of QLQ-C30 questionnaire through specific software called ONQOL. After this experiment, they were asked to give their opinion about with which way they felt more comfortable, about their willingness to regularly answer QoL questions and whether they had any help to complete the questionnaires. **RESULTS:** 58.5% of the patients were female, the majority of them (79.5%) married. Their mean age was 57 years old (y.o.), from a minimum of 26 y.o. to a maximum of 96 y.o. Besides this, 83.0% had, at most, the ninth degree of education. There were

no statistical significant differences between the paper and the computer answers, 43.0% of the patients felt more comfortable with the electronic version, 52.5% had no preference. Regarding their preference about answering to electronic QoL questionnaires, 58.0% preferred to respond using electronic version and 36.5% had no preference. In what concerns the help they had when filling the questionnaire, 74.5% didn't required any help. Even for patients with age over 65 years old, 38.7% felt more comfortable with the electronic version and 40.3% of them required help. Besides these findings, we observed a higher acceptability among patients using the computer when comparing with the use of paper. **CONCLUSIONS:** The computer version of the QLQ-C30 showed similar results compared to the paper version and it proved to be better accepted and tolerated by the patients included in the study. This method has proven to be valid in oncology setting and useful for monitoring the patients' QoL in daily practice, in real time, as a useful means to support clinical decision making.

1006/Perceived Barriers to Implementing the Patient-Reported Outcomes-Common Toxicity Criteria Adverse Event (PRO-CTCAE) System in Cancer Clinical Trials

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AIMS: Patient-reported outcomes (PROs) have not been used in clinical cancer research to screen for adverse events (AE) although PROs would likely improve research and clinical work. In response, the National Cancer Institute initiated development of a PRO version of the Common Terminology Criteria for Adverse Events (CTCAE) system. To facilitate the success of the PRO-CTCAE initiative, it was recognized that potential barriers to its widespread implementation in multi-site clinical trials needed to be identified and addressed. **METHODS:** Barriers to implementing the PRO-CTAE were assessed by an anonymous survey distributed to affiliates of cooperative cancer groups, such as research staff, patient advocates, and federal employees. The survey included Likert-response items of barriers at the patient and clinic levels and open-ended questions inviting general comments. **RESULTS:** A total of 727 questionnaires were collected. Although 88% of respondents thought that patients would be willing to self-report AEs, 88% also thought that severe illness would be a barrier. At the clinic level, most participants agreed that a lack of computers (70%) and limited time (58%), personnel (57%), and clinic space (50%) would be problematic. Paper-based AE reporting was thought feasible by 82%, and among

electronic reporting options, portable devices (58%) were preferred over desktop computers (39%). Other barriers identified by qualitative responses included patient unfamiliarity with and at-home access to electronic PRO devices, and questionable accuracy and adherence of patients to AE reporting. **CONCLUSIONS:** Acceptance of the PRO-CTCAE will likely be based upon demonstration of the validity of the PRO data as well as the feasibility of its use for patients and staff. Funding for clinic resources might resolve some of the barriers, but other efforts at the system level must be conducted. The PRO-CTCAE system should be developed to be easy to use, include user training and real-time assistance, and have benefits for its users.

1622/A Randomized Trial of Weekly Symptom Telemonitoring in Advanced Lung Cancer

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AIMS: This randomized trial assessed the efficacy of a symptom monitoring and reporting system ("SyMon-L") in reducing symptom burden in patients with advanced lung cancer. **METHODS:** Patients were randomized to a monitoring-and-reporting arm (MR) or monitoring-alone arm (MA) and completed a weekly symptom survey for 12 weeks using an interactive voice response system. MR patients' scores meeting a pre-defined "alert" threshold triggered clinician notification for symptom care. MA patients completed weekly surveys without clinician notification. The primary endpoint was symptom burden; secondary endpoints were health-related quality of life (HQOL; FACT-G), treatment satisfaction, self-efficacy, perceived symptom management barriers, and patient/provider satisfaction with SyMon-L. **RESULTS:** Results on the full sample (n=254) will be available for presentation. Interim analyses of 150 patients found no significant differences between arms on demographic or clinical variables, refusals or drop-outs and no difference in symptom burden (Symptom Distress Scale, $p=.88$). There were no differences between arms at baseline (BL), Week 12 or over time in HQOL, self-efficacy or barriers except for a BL difference in a self-efficacy subscale ($p<.01$). Collapsing arms, physical and functional well-being and overall HQOL ($p<.05$) worsened over 12 weeks. The MA arm reported greater overall treatment satisfaction than the MR arm at Week 12 ($p<.05$). BL self-efficacy and perceived barriers were negatively correlated ($r=-.30$ to $-.44$). Neither barriers nor self-efficacy was associated with age or gender but both were correlated with education, race and income (all $p<.05$). Self-efficacy was related to smoking status ($p<.01$) and ECOG Performance Status ($p<.05$); barriers were related to insurance ($p<.05$). **CONCLUSIONS:** Interim results indicate negative findings for this symptom monitoring and reporting trial in lung cancer. Analyses of the full sample will focus on exploring efficacy on a per-symptom basis and identifying patients/clinical settings that may benefit most to guide future next steps.

PAIN

1578/Can Severity and Impact be Combined? An example using pain intensity and interference, in palliative care and chronic pain patients

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AIMS: Many HRQoL instruments contain items evaluating symptom severity and impact. Can severity and impact be combined, or are they separate dimensions? We explore the issues, using the ongoing controversy about dimensionality of pain: can intensity and interference be lumped together, as on many existing HRQoL instruments, or should they be retained as distinct dimensions.

METHODS: The European Palliative Care Research Collaborative (EPCRC) is developing a computer-based pain assessment instrument (<http://www.eprc.org>), targeting patients in palliative care. The 23 candidate pain items were evaluated on 562 patients, 394 in palliative care and 168 with chronic pain. A range of analyses were used to explore dimensionality, including bifactor analyses, IRT and multitrait analysis. **RESULTS:** Intensity and interference were highly correlated and the various statistical / psychometric analyses supported the view that a composite score forms a useful summary of the pain experience. Further, there is the potential to use interference items to gain greater precision outside the range mainly covered by pain intensity items. However, there was evidence of differential item functioning, in particular with respect to intensity versus interference items when considering palliative against chronic pain patients. Overall, the data supported arguments for both combining and keeping separate these dimensions. **CONCLUSIONS:** For group-based studies, e.g. clinical trials, our data supports the widely-used approach of summarising pain by a single combined measure of severity, although it should be recognised that differential item functioning may affect results in heterogeneous samples. However, most clinicians recognize the value of retaining separate dimensions and our results also strongly support that view. The overall conclusion is that, for any PRO, decisions about dimensionality must always take into account the intended use of the instrument, for example whether it is aimed at individual patient management or for clinical trials.

1625/Do People Interpret and Respond to Questions About Their Pain in a Comparable Manner?

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AIMS: Computerized adaptive testing requires invariant IRT-calibrated parameters that are equivalently applicable to all individuals in the target population. We examined this condition by evaluating the implications of sample heterogeneity with respect to (a) the invariance of discrimination and difficulty parameters of items measuring pain and (b) the IRT-predicted pain scores. **METHODS:** We used a pain item bank consisting of 36 items rated on Likert-type scales (Kopec et al., 2006). The data were obtained via pen and paper questionnaire from patients at a rheumatology clinic (N = 331) or on a waitlist for knee-replacement surgery (N = 340), and a community sample of adults in British Columbia (N = 995). A 2-parameter IRT mixture model was used to examine sample heterogeneity by allowing the items' difficulty and discrimination parameters to vary across two or three latent classes. Variables explaining latent class membership were identified using multinomial logistic regression based. **RESULTS:** The data were not consistent with a one-class

unidimensional IRT model. Relative to the one- and two-class models, improved model fit was obtained when three classes were specified. The predicted latent class proportions were 0.3, 0.3 and 0.4. Latent class membership was partially explained by statistically significant differences in several health-related variables (e.g., perceived health status, having been hospitalized during the past year, taking a medication, having osteoarthritis, having another chronic condition). A lack of invariance was observed for several of the items' parameters, resulting in considerable differences in the standardized IRT scores of the one-class model (ignoring sample heterogeneity) and the three-class model (adjusted for sample heterogeneity); an absolute difference of about 0.5 or greater was obtained for 10% of the sample. **CONCLUSIONS:** People may not interpret and respond to all items for the measurement of pain in a consistent fashion. Such inconsistencies could threaten the validity of comparing pain scores in heterogeneous samples.

1410/Interactions between cancer type, pain and personality type on self reported Quality of Life (QL) responses

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AIMS: Self reported health related QL may be modified by interaction of various factors. We investigated the relationship between cancer type, pain, personality and QL. **METHODS:** Group 1: 108 patients with prostate breast lung or colorectal cancer completed 2 questionnaires: BFI-44 (personality), EORTC QLQ-C30 (QL). Group 2: 19 patients with cancer pain completed the Brief Pain Inventory (BPI) and EORTC QLQ C-30 and a semistructured interview to identify themes related to pain. Group 3: 60 patients with cancer pain completed BPI, BFI-44, QLQ-C30 and semistructured interview (n=28) to explore attitudes to pain and analgesia. **RESULTS:** In Group 1, Personality types were similar, but in several scales, QL was different, between tumour sites. Neuroticism correlated negatively with emotional function ($p<0.001$) and other functions and symptoms ($p=0.001$ to 0.042); openness positively correlated with global health ($p=0.032$). Global QL was influenced by tumour site ($p<0.001$) and personality ($p=0.029$ to 0.036). Physical functioning varied with tumour site ($p<0.001$), emotional functioning with personality ($p<0.001$). In Group 2 there was an inverse relationship between pain and QL. Pain affected almost all aspects of QL including physical functioning, mobility, mood, sleep, ability to work and close relationships. Most patients felt their analgesia was effective. In Group 3, extroversion correlated with a better ability to function and a better QoL (Spearman's $R_2=0.058$). Neuroticism correlated with more severe pain ($R_2=0.051$). Other domains of personality had no bearing on pain or QL. Themes commonly reported by extroverted patients were perseverance and acceptance, and by neurotics defeat and helplessness. Extroverts used active coping strategies and a re-framing technique, neurotics were more inclined to use passive coping strategies. **CONCLUSIONS:** Personality type influences perceptions of pain and QL, by affecting choices of coping strategies. It may partly explain poor pain control, and should be incorporated into patient-centred treatment interventions.

1241/Willingness-to-Pay for a Quality-Adjusted Life-Year Due to Pain Associated with Herpes Zoster: Patient and Community Perspectives

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AIMS: We evaluated the willingness to pay per quality-adjusted life year (or WTP/QALY) using survey data from herpes zoster health outcomes. We aim to describe how much community members (CM) are willing to pay to save a QALY based on temporary health state scenarios; evaluate how WTP/QALY varies by disease experience and demographics; and evaluate how duration and intensity of pain influences WTP/QALY. **METHODS:** CM from a nationally representative survey research panel (n=478) completed an internet-based survey using time-tradeoff (TTO) and WTP questions to value scenarios that describe zoster cases of varying pain intensity (on a scale of 0 to 10) and duration (30 days to 1 year). Patients with shingles (n=354) or post-herpetic neuralgia (n=120) (i.e., symptoms >90 days or PHN) completed telephone interviews with similar questions. After discounted by 3% per year, WTP/QALY values were calculated for each scenario. WTP/QALY means were calculated after trimming the top and bottom 2.5% of responses. Multivariate analyses using generalized linear mixed models were conducted. **RESULTS:** Overall, WTP/QALY ranged from a trimmed mean of \$26000 to \$45000 and a median of \$7000 to \$11000, depending on the zoster scenario. WTP/QALY varied significantly with respondent characteristics, and among respondents with similar characteristics. In multivariate analyses, the mean WTP/QALY was higher among respondents who were younger, male, or had higher educational or income levels. After controlling for demographics, shingles patients gave responses with the highest WTP/QALY. PHN patients gave the lowest and CM the intermediate values. When pain intensity and duration are analyzed, lower duration was associated with higher WTP/QALY. This effect was due to increases in time willing to trade as duration increases, without proportional increases in the money willing to be paid. **CONCLUSIONS:** WTP/QALY values varied significantly with age, sex, socioeconomic status, experience with shingles, and duration of the health state evaluated.

THEORY

1691/THE PRO CONCEPT TAXONOMY: A STRUCTURE FOR IMPROVING COMMUNICATION ABOUT HEALTH OUTCOMES

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AIMS: In 2009, we introduced the PRO Concept Taxonomy for classifying health status and quality-of-life concepts and their inter-relationships and for improving communication in the drug approval process. In this context, concepts consist of statements of feeling or function that are qualified by a frequency or evaluative component and a temporal element. Within the taxonomy, we identified four levels: family, and compound, singular, and low-level singular concepts. This paper evaluates concepts and naming conventions used in existing instruments as a first step in populating the taxonomy. **METHODS:** Item content of health-related quality-of-life (HRQoL) instruments that have been developed for various diagnoses, including Arthritis, COPD, Fibromyalgia, and Head and Neck Cancer, will be compared to identify similarities and differences in concept terminology within the HRQoL literature. Item

content and concepts will also be matched with the WHO's ICF, drawing on published comparisons, to motivate a discussion of how to populate the taxonomy for use in the drug approval process. **RESULTS:** Comparisons of item content across instruments indicate linguistic and conceptual diversity when describing the same, or near same, concepts. For example, in a head and neck cancer instrument, the "Physical" concept assesses voice-specific feelings and functions. In a fibromyalgia instrument, a similarly named concept refers to impairments in mobility and communication. Matching with the ICF brings some standardization to terms used to describe concepts. **CONCLUSIONS:** This analysis illustrates the lack of a standardized vocabulary in the field of HRQoL. The PRO Concept Taxonomy, along with the PRO Instrument Hierarchy, are two structures proposed for eliminating confusion caused by diverse terminology. Methods, such as IRT, qualitative analysis, and taxometrics, might be useful for populating the taxonomy, thereby improving communication between researchers, the health care industry, and regulators and policy makers more generally.

1451/Psychosocial Biases in Quality of Life (QOL) Assessments

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AIMS: This presentation summarizes biases that affect patient and observer QOL ratings. Patient ratings are frequently promulgated as the gold standard for QOL measurements; however, patients, as well as physicians and other clinicians, are influenced by cognitive, social, and emotional variables that can create systematic errors in assessments. **METHODS:** This is a purposive review of recent publications that report QOL based on patient and/or provider ratings. Drawing from the social science literature, potential biases affecting study findings are identified. Illustrative examples of how biases can affect outcomes and conclusions are presented. **RESULTS:** Biases can result from unintended factors (e.g., related to cognition and information processing, and social and psychological influences); and intentional effects. Cognitive biases relate to memory (e.g., consistency bias, hindsight bias, rosy retrospection, availability heuristic), decision making (e.g., framing, negativity bias, neglect of probability, reactance), and perceived probability (e.g., clustering illusion, optimism bias, primacy effect, recency effect, disregard of regression toward the mean, survivorship bias, and the Texas sharpshooter fallacy). Social factors include the actor-observer bias and halo effect, while personality influences include dispositional optimism, resiliency, ye/naysaying, and state anxiety. Intentional effects include social desirability and purposeful distortion. Most of these biases may affect both patients and observers. Approaches to assess the extent of bias, include multi-method research with qualitative and quantitative assessments, and triangulation designs that incorporate QOL indicators from different sources (e.g., self-report, medication use, behaviors). **CONCLUSIONS:** No QOL assessment is free of bias and error, and such biases need to be acknowledged and measured. In the final analysis, the important question is not which assessment is the gold standard, but rather what is the predictive validity of a QOL score. Such analyses are key to health care policy decision making and clinical care.

1235/Conceptual issues in QoL research

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AIMS: Quality of Life (QoL) has become a major cornerstone of many research endeavors throughout many disciplines and is one of the most popular patient-reported outcomes in health research. Much

research has focused on content, scoring methods and technical properties of instruments, but has failed to properly define and conceptualize QoL. Our aim is to present different ways in which QoL is defined and conceptualized and to identify the causes for the lack of consensus on the definition of QoL. **METHODS:** Out of the prolific amount of articles dealing with the concept, an overview of definitions and conceptualizations that emerged from the literature was developed. Furthermore, the causes of the definition problems in QoL literature were outlined. **RESULTS:** The lack of consensus on the definition of QoL has created a situation where QoL has been used as an umbrella term for many patient-reported outcomes. The indiscriminate use of the term QoL has reinstated various instruments measuring health status as health-related QoL instruments. It seems as if not a sound theory, but the operational definition has assigned meaning to the concept, defining QoL as it were by the items that have been selected on whatever grounds. Thus the lack of consensus lies in the multidisciplinary use of the term QoL and the diversity within disciplines, the cultural setting, the operational definitions, and the interchangeable use of different QoL and health terms. **CONCLUSIONS:** To insure advances in this field we argue that it is imperative to recognize the ambiguity of the concept and to reevaluate the different conceptual frameworks underlying QoL.

1106/Measurement Properties: A new framework to contribute to the debate between the field of clinimetrics and psychometrics

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AIMS: We performed a literature search to revisit the roots of a debate between clinimetrics and psychometrics and suggested a simplified measurement model that respects the origin of both schools. **METHODS:** We searched Medline, CINAHL and EMBASE. Literature was identified using a combination of MeSH terms: psychometrics and health status; and key terms clinimetric and clinimetrics. Articles were selected based on relevance to the topic of the debate on the clinimetric and psychometric methods of measure development and evaluation. The selected articles were reviewed by two authors and a framework was developed based on consensus reached between the two reviewers. **RESULTS:** We selected 10 key articles for relevance to the debate. Four additional articles were obtained from searching the relevant article bibliographies. We found that the differences in the approach of each field are mainly apparent in the development stages of the measures irrespective of what is being measured. Specifically, methods that are more clinimetric include target criterion indices in the item development stage and more clinical consensus of structure in the structure and precision of the measure. In contrast, the psychometric side would include more untargeted indices, the use of factor analysis in the development of the outcome measure structure and internal reliability would be considered of great importance. In our framework, we propose that the developmental stage of the outcome measure would involve an informed zone of overlap or blending between the two measurement strategies. **CONCLUSIONS:** We proposed a new framework for assessing measurement properties of outcome measures that is inclusive of both the field of clinimetrics and psychometrics. Reaching a consensus on how outcome measures should be developed and how their properties should be assessed helps provide consistency in measuring outcomes relevant to population health. Consistency in measurement is vital in developing evidence used in formulation of recommendations in health care policy.

PSYCHOMETRIC METHODS

1733/Beyond traditional psychometric methods: Can Rasch help the DASH?

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AIMS: There are currently two main psychometric paradigms to examine scale reliability and validity; traditional (based on classical test theory) and modern (Rasch measurement and Item Response Theory). However, direct comparisons of traditional and modern methods in the medical literature are sparse. The aim of this study was to compare traditional and Rasch measurement methods in an evaluation of a widely used PRO instrument: the Disabilities of Arm Shoulder and Hand (DASH). **METHODS:** DASH data from 300 people with Multiple Sclerosis (pwMS) underwent two independent phases of psychometric analyses: 1) a traditional psychometric analysis including tests of: data quality; scale-to-sample targeting; scaling assumptions; internal consistency reliability; and construct validity; 2) a Rasch analysis, which included examinations of: person separation index (PSI); item fit indicators; ordering of response option thresholds; spread of item locations, and residual correlations. Rasch analyses were performed using RUMM2020 software. **RESULTS:** Overall, the traditional psychometric analysis supported the DASH as a reliable and valid measure of upper limb function in pwMS. However, the Rasch findings told a different story. Despite high reliability (person separation index 0.97), several findings questioned the validity of the DASH, including disordered item response option thresholds for 9/30 items, misfit in 13/30 items, limited item location spread, and six pairs of items with high residual correlations (>0.60) indicating local dependency. **CONCLUSIONS:** Rasch analysis uncovered a number of inherent problems with grouping DASH items into a symptom/disability score, which were not detected by traditional methods. In this instance, the added value of Rasch analysis is clearly highlighted by the key limitations it uncovered relating to the validity of the DASH; response categories and item misfit. Importantly, our findings support Rasch measurement methods as a powerful approach to take our understanding of rating scales further than traditional approaches.

1645/Application of Rasch Analysis to a Novel Dermatology-Specific Quality of Life Measure for Adolescents with Skin Disease

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AIMS: The aim of this study was to reduce and refine a novel QoL measure for adolescents with skin disease in order to produce a robust tool that is relevant to the population intended. **METHODS:** The Teenagers Quality of Life (T-QoL) profile was administered to 153 adolescent patients attending the dermatology out-patient clinics at the University Hospital of Wales. In its current form T-QoL has 30 items with a 5 response format. The scores of individual items are added to yield a total index score; higher score reflecting greater QoL impairment. Rasch analysis was conducted using RUMM 2030 software to assess the overall fit of the model, the item responses, individual item fit and differential item functioning (DIF). **RESULTS:** Rasch analysis of the whole scale did not support the validity of the T-QoL, as a unidimensional measure of QoL impairment. A factor analysis confirmed the presence of three domains within the scale. Each of the domains was then subjected to Rasch analysis individually. Three items in domain 1 (feelings about skin disease) did not fit the model and were therefore removed before

further analyses were carried out. When considered separately (and with the removal of the 3 items) all domains showed adequate fit to the model, good person separation, good internal consistency and no significant differential item bias for gender or age. It was however, necessary to reduce the response format to a 3-point response scale. Due to the multidimensionality found with the original T-QoL it was not deemed appropriate to combine the three subscales to form a total score. **CONCLUSIONS:** The results of the Rasch analysis support the use of domain 1 of the T-QoL at the individual level (Cronbach alpha = 0.91) in order to measure adolescents' QoL. The further two domains, 2 & 3 (Cronbach alpha = 0.78 and 0.81 respectively) could be used alongside domain 1 to provide additional information. Further use of Rasch analysis on the T-QoL in larger and broader samples is recommended to confirm these findings.

1103/Towards a generalized HRQoL measurement model

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AIMS: There is emerging consensus that patient-reported outcomes such as health-related quality of life (HRQoL) are warranted for comprehensive outcome measurement in health. However, lack of systematic and thorough implementation of modern measurement theory has led to the situation whereby contemporary HRQoL measures are only moderately informative. More sophisticated measurement models would be needed for an adequate (i.e., valid and precise) measurement of the HRQoL condition of patients. The objective of this presentation is directed to unifying two different measurement models to arrive at one generalized and effective HRQoL measurement model. **METHODS:** Recently, research has started to apply probabilistic discrete choice (DC) models for quantifying stated preferences (utilities) for hypothetical health states. Modern DC models came from econometrics and are developed to establish the relative merit of subjective phenomena. Another important measurement model is the Rasch model. The response task in Rasch modeling when applied to health states is not a choice between two or more health states as is the case in DC but comprises a series of monadic judgments about health states (yes/no, agree/disagree, worse/better). However, in principle the basic operation of the Rasch response task can also be performed for assessing overall health states by adapting the DC task in such a way that the specific measurement conditions of the Rasch model are satisfied. **RESULTS:** Values for different hypothetical health states used in economic evaluations are conventionally derived from a representative community sample. Many researchers assert that the patient's judgment should be elicited, not that of a sample of unaffected and inexperienced members of the general population. Incorporating the basic data collection procedure of the Rasch model makes it possible to approach patients to provide input. This may enhance the validity of the responses. **CONCLUSIONS:** Incorporating the basic elements of the Rasch model into the DC framework may provide a new and advanced measurement model with fundamental measurement characteristics.

1406/Developing a health state classification system for dementia using Rasch analysis

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AIMS: Economic evaluation using cost-utility analysis is used increasingly to inform resource allocation between competing health care interventions. This requires some means of valuing health states before and after interventions and typically generic measures such as the EQ-5D are used. These have been found not to work well in studies of people with dementia, meaning a lack of relevant data to undertake cost-utility analysis. This study develops health state classification systems amenable to valuation from the DEMQOL system, a measure of health-related quality of life in dementia consisting of self-report DEMQOL and carer-report DEMQOL-Proxy. **METHODS:** Factor and other classical psychometric analyses were used to investigate the reliability, validity and factor structure of both measures. Rasch analysis was used to investigate item performance across factors in terms of item level ordering, functioning across subgroups, model fit and severity range coverage. This enabled the selection of one item from each factor for the classification system. A sample of patients with a diagnosis of mild or moderate dementia (n=644) and a sample of carers (n=683) were used. **RESULTS:** The reliability and validity of both measures was acceptable. Factor analysis found a 5-factor solution (explaining 45.5% of the variance) for DEMQOL (cognition, positive emotion, negative emotion, social relationships and loneliness) and a 5-factor solution (explaining 49.3%) for DEMQOL-Proxy (cognition, positive emotion, negative emotion, daily activities and appearance). Following item reduction and selection using Rasch a 5-dimension classification for DEMQOL and a 4-dimension classification for DEMQOL-Proxy were developed. Each item contained 4 health state levels. **CONCLUSIONS:** Combining Rasch and classical psychometric analysis is a useful method of selecting items for dementia health state classifications from both the patient and carer perspective. The next stage is to obtain preference weights so that the measure can be used in the economic evaluation of treatments and care arrangements for dementia

TRANSLATION

1571/International co-validation of a new international quality of life instrument specific to physical appearance: BeautyQoL
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AIMS: The BeautyQoL instrument is a multi-dimensional, self administered questionnaire, specific in physical appearance, which has been in development for over three years in 16 languages. **METHODS:** Semi directive interviews were conducted by clinical psychologists simultaneously in 10 countries in 309 subjects. Then, the acceptability study in 16 cultures was conducted on 874 subjects in France, UK, Germany, Spain, Sweden, Italy, Russia, USA, Brazil, Japan, India (Hindi and English) China and South Africa (Zulu, Sotho and English). In the third phase, a total of 3231 subjects were

recruited to complete the BeautyQoL questionnaire, a skin clinical checklist, the generic SF-36 QoL questionnaire and a socio-demographic questionnaire. A re-test has been carried out at 8 days on a subgroup of 652 subjects. The database was randomly divided into two subgroups and analyzed using a Rasch analysis. Psychometric properties, construct validity, reproducibility, internal and external consistency were tested. **RESULTS:** From the item generation phase, 62 questions were selected. General acceptability was very good in the 16 cultures, with a very low rate of no answers. The validation phase reduced the questionnaire in 44 questions structured in five dimensions explaining 76.7% of the total variance : Social Life, Self confidence, Psychological life, Vitality and Seduction. Internal consistency was high (Cronbach alpha between 0.932 and 0.978). Reproducibility was satisfactory in all dimensions, except for Self confidence . External validity testing revealed that BeautyQoL scores correlated significantly with all SF-36 scores except for Physical Function. **CONCLUSIONS:** These results demonstrate the validity and reliability of the BeautyQoL questionnaire as the first international instrument specific to physical appearance. It is expected that BeautyQoL will be an instrument that will measure QoL affected by cosmetic products, techniques and agents that alter physical appearance.

1158/A Pilot Study on Validation of Traditional Chinese FACT-C on Patients with Colorectal Neoplasm

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AIMS: The functional Assessment of Cancer Therapy-Colorectal (FACT-C) was translated into traditional Chinese but has not been validated on any Chinese populations. The study aim is to establish the construct validity, reliability and sensitivity of the traditional Chinese (HK) version of the FACT-C (Version 4). **METHODS:** A convenient sample of 487 patients with colorectal neoplasm was recruited from a regional Hospital in Hong Kong. 383 samples self-completed the Traditional Chinese (HK) version of the FACT-C, Traditional Chinese version of the EORTC QLQ-C30 and QLQ-CR38, the Chinese (HK) SF-12v2 Health Survey and a structured questionnaire on clinical and socio-demographic data. The data were analyzed for item-scale correlation on discriminant validity, internal consistency by Cronbach's alpha, factor structure by confirmatory factor analysis (CFA), concurrent construct validity, and sensitivity. The FACT-C was administered by interviewers to 104 patients at recruitment and then 2 weeks later to assess the test-retest reliability. **RESULTS:** The FACT-C subscales had 87.5-100% scaling success indicating item discriminant validity. All subscales had good internal consistency (Cronbach's alpha: 0.777-0.919), and test-retest reliability (ICC: 0.714-0.786). Physical and social well-being subscales demonstrated sensitivity in detecting significant differences between patients with colorectal polyps and cancer (p<0.01; p<0.01). All subscales correlated significantly with criterion measures of subscales in SF-12v2. The basic five-factor CFA showed inadequate goodness-of-fit (RMSEA=0.09, GFI=0.75, AGFI=0.714). **CONCLUSIONS:** This pilot test was the first to show the validity and reliability of the FACT-C on Chinese patients with colorectal neoplasm including those with polyps. The results support the applicability of the instrument to evaluate the quality of life of patients with colorectal neoplasm and the impact of medical interventions. Further research is required to ascertain whether an alternative scaling structure of the FACT-C should be applied to Chinese patients.

1560/IRT-based Assessment of Differential Item Functioning in HRQL studies

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AIMS: We sought to provide sample-free estimates of uniform DIF on a newly developed HRQL questionnaire, PROQOL-HIV. We considered patients characteristics supposed to modulate HRQL, such as gender, country of residence but also ethnicity, given the high prevalence of HIV in migrant populations. **METHODS:** We used an iterative ordinal logistic regression framework where nested models are compared in order to test for significance of person covariates, while persons parameters are estimated using the Graded Response Model. DIF was tested on two constructs extracted from factor analysis: physical health and symptoms (PHS, 14 items accounting for 17% of the total variance) and emotional distress (ED, 10 items, 9%), on a subset of N=505 patients (71% males, median age 43 yrs.) from 5 countries (Australia, USA, France, Brazil, Thailand). Missing responses (<1%) were imputed using median scale score. **RESULTS:** Items belonging to the ED dimension were more frequently flagged as exhibiting bias compared to PHS items, especially when referring to ethnicity. Country-related biases were equally distributed on the two scales. In both cases, however, no DIF effects were found for gender. We reached similar conclusions when comparing the results to those obtained when using sum or rest scores as conditioning ability levels. Correlations between scores computed with or without flagged items were above 0.5. Restricting analysis on Western countries, however, yielded smaller hits. This suggests that, for these two dimensions of PROQOL-HIV, DIF effects should have a small to moderate influence on HRQL scores reporting, although more studies are needed to estimate DIF effect size and provide cut-off values specific to the questionnaire. **CONCLUSIONS:** The relevance of DIF effects need to be carefully studied through expert reviewing, and their higher frequency on bio-psychological constructs raise interesting questions for questionnaire development. Moreover, DIF can bring additional information about HRQL when testing also ethnic origin and not only country of residence in international clinical trials.

1669/Copyright of translations of PRO measures: rules and applications

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AIMS: To take stock of the situation about the copyright of the translations of PRO measures used in lung diseases, as part of the TCA-SIG activities. **METHODS:** 1. Review of the international rules relative to the protection of translations (Google search). 2. Development of a survey for developers of PRO measures used in lung diseases. This survey is intended to identify which copyright solutions developers adopted for the original questionnaires and their translations and why. The PROQOLID database was searched focusing on "respiratory tract diseases". 30 questionnaires and their translations were found. **RESULTS:** 3 documents were retrieved: the Berne Convention (1886), the UNESCO Resolution on the protection of translators and translations (1976); and the Translator's charter (1963). According to the Berne Convention authors have the exclusive right of making and authorizing the translation of their works. Translations are protected as original works without prejudice to the copyright in the original work. The UNESCO Resolution says that Member States should grant translators the same protection as authors in the light of the Berne

Convention and individual country laws but without prejudice to the rights of the authors of the original works. Article 15 of the Translator's charter indicates that the translator is the copyright holder of his translation giving rise to the misinterpretation that he has the same rights as the author of the original work. The survey is currently on-going and results will be presented. **CONCLUSIONS:** The analysis of the documents shows that the rights of both the authors of the original work and the translators are protected, but can potentially be conflicting. Nothing applies specifically to PRO measures. In the context of international clinical trials the quality of data collected with PRO measures depends on the quality of the translations and also on their legal status granted by the developers. Results of the survey will show which solutions are adopted in the real world, what the implications of these might be and what recommendations can be made on the basis of our findings.

ONCOLOGY II

1474/Influencing Ovarian Cancer Clinical Care through HRQOL Measurement

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AIMS: Health-related quality of life and patient reported outcome measurement has meaningfully contributed to advanced ovarian cancer clinical trial interpretation. Further examination of these outcomes can inform clinical care direction. The purpose of this study is to assess which HRQOL line items on the Functional Assessment of Cancer Therapy-Ovarian (FACT-O) are associated with low HRQOL in women who were receiving chemotherapy for ovarian cancer. **METHODS:** Patients with stage III or IV ovarian cancer on Gynecologic Oncology Group Protocols 152 and 172 who underwent primary surgery followed by intravenous paclitaxel and cisplatin completed the FACT-O. The FACT scale includes the 4 domains of physical, functional, social, and emotional well being (PWB, FWB, SWB, EWB, respectively). Women who had overall FACT-O scores in the lowest quartile (Q1) were compared with women in the upper 3 quartiles (Q2-Q4). The proportions of women in each group that selected the 2 worst categories for each item were compared. The level of significance was set at $P < .005$. **RESULTS:** Before Cycle 4, 361 patients (86.4%) provided valid assessments. For PWB, a significantly greater proportion of women in Q1 versus Q2 through Q4 selected the 2 worst categories of several physical symptoms (nausea, pain, feeling ill, and being bothered by the side effects of treatment). For FWB, significant differences included being able to work, being content with the quality of their life, and sleeping well. For EWB, there were significant differences in feeling nervous and worrying about dying. There were virtually no differences between groups in SWB. Low interest in sex was reported by 56% to 88% of all patients (Q1-Q4). **CONCLUSIONS:** A large proportion of women with FACT-O scores in the lowest quartile reported problems that potentially were amenable to clinical interventions, such as symptom management and psychosocial support. Given the

challenges associated with treating advanced ovarian cancer, this information can be used to further inform and enhance outcomes in clinical care and future clinical trials development.

1498/Quality of life detriments through lymphoedema of the legs in gynaecological cancer survivors: a prospective assessment

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AIMS: Lower limb lymphoedema of the legs is a pathological swelling, thought to be caused by injury to the lymphatic vessels and/or removal of lymphnodes during surgery or radiotherapy for gynaecological cancer. Very little is known about its prevalence, risk factors or quality of life effects. Thus in 2007, we initiated a prospective longitudinal cohort study to establish prevalence of, risk factors for and quality of life effects of, lymphoedema of the legs.

METHODS: By May 2010, almost 500 patients have been recruited and followed for a median of 8 months. Quality of life was assessed using the Functional Assessment of Cancer Therapy (FACT-G). Lymphoedema was assessed using circumference methods, bioimpedance spectroscopy (BIS) and patient self-reported swelling and symptoms (e.g. heaviness, skin tension). We summarised the proportion of women identified with extracellular fluid by BIS and women who self-reported symptoms of lymphoedema. We assessed whether such self report was associated with lower quality of life.

RESULTS: Point prevalence of lymphoedema as detected by BIS and self-reported swelling can be seen in the table below. Self-reported swelling was associated ($p < 0.05$) with reduced QoL (FACT-G mean+SD=82.8+17.7), compared with those who had no self-reported swelling of the lower limbs (FACT-G=90.7+15.9).

CONCLUSIONS: Results from this cohort study will for the first time establish prospectively the prevalence of lower limb lymphoedema among women with gynaecological cancer and describe the quality of life detriments associated with such diagnosis. This study will provide essential data to develop targeted early interventions.

Point prevalence and cumulative burden of lymphoedema

	6 Months %	9 Months %	12 Months %	15 Months %	Cumulative Burden
Lymphoedema-BIS	10.0	15.0	16.5	17.4	19.6
Self-report	30.3	21.7	17.5	35.7	32.6

1652/Is health related quality of life a prognostic factor of overall survival in metastatic pancreatic denocarcinoma?

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AIMS: the aim of this study was to explore prognostic value of QoL in patients with metastatic pancreatic adenocarcinoma (MPA) included in the FFCD phase III trial comparing LV5FU2-P followed by gemcitabine versus the opposite sequence **METHODS:** QoL was evaluated using the EORTC QLQ-C30 before randomisation and then every 8 wks until death. Overall survival (OS; event death all causes) was estimated using Kaplan Meier method. Univariate Cox analyses were performed for each QoL score (continuous) and to select clinical and biological variables ($p < 0.20$) eligible for independent prognostic value. Multivariate Cox model were then construct for each QoL scores and internally validated with bootstrapping. Harrell C index were calculated. Sensibility analysis was also done by imputing missing QoL scores **RESULTS:** From 08/2003 to 05/2006, 202 were included in the trials, 179 patients (88.61%) completed the QoL questionnaire at baseline. Trials had failed to demonstrate any OS benefit according to treatment arm. Anterior treatment, WHO PS, sex, tumor localization, Phosphatase alkaline and haemoglobin serum level were retained for multivariate analyses. Major univariate significant QoL scores were ($p < 0.005$): Global Health HR =0.99 [0.98; 1.00], Physical Functioning HR =0.99 [0.98; 1.00], Fatigue HR = 1.01 [1.00; 1.01], and anorexia (1.01 [1.00; 1.01]). After multivariate analysis, only Physical functioning (HR =0.99 [0.98; 1.00], $p = 0.05$) and anorexia (HR = 1.01 [1.001 -1.01], $p = 0.015$) had an independent prognostic value. Whatever QoL score investigated, Phosphatase alkaline was significantly associated with OS. When we replaced missing QoL scores by the worst QoL level, all dimensions were independently prognostic of OS. **CONCLUSIONS:** In MPA patients, physical and anorexia dimensions of QoL were independent prognostic factors of OS. QoL could be used as selection and stratification criteria for clinical trials in this setting.

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significant QoL scores were ($p < 0.005$): Global Health HR = 0.99 [0.98; 1.00], Physical Functioning HR = 0.99 [0.98; 1.00], Fatigue HR = 1.01 [1.00; 1.01], and anorexia (1.01 [1.00; 1.01]). After multivariate analysis, only Physical functioning (HR = 0.99 [0.98; 1.00], $p = 0.05$) and anorexia (HR = 1.01 [1.001 -1.01], $p = 0.015$) had an independent prognostic value. Whatever QoL score investigated, Phosphatase alkaline was significantly associated with OS. When we replaced missing QoL scores by the worst QoL level, all dimensions were independently prognostic of OS. **CONCLUSIONS:** In MPA patients, physical and anorexia dimensions of QoL were independent prognostic factors of OS. QoL could be used as selection and stratification criteria for clinical trials in this setting.

OBESITY

1556/Predictors of HRQOL in children and adolescents

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AIMS: In order to better understand HRQOL in children and adolescents, identification of variables predictive of HRQOL is needed. The aim of the study was to describe HRQOL in a sample of Norwegian children/adolescents, aged 8-18 years. In addition, the aim was to describe predictors of HRQOL and to explore the relationship between HRQOL and health related variables; body image, bmi, pain and being bullied, and further age and gender.

METHODS: A cross-sectional study was carried out in the eastern part of Norway, and a cluster sample of 1066 children/adolescents (response rate 74%) completed self-reported questionnaires at school. The KIDSCREEN-10 items were administrated to measure HRQOL, and questions about age, gender, pain, BMI, body image and being bullied were completed. Mixed model linear analyses in SPSS were used to evaluate the associations between HRQOL and the independent variables. **RESULTS:** A statistically significant relationship was found for all predictor variables ($p < 0.05$). The bivariate tests of relationship between the independent variables and HRQOL were used to create models; all the significant variables were included as covariates in the mixed models analysis. The analysis showed that the variables body image, age, experiencing pain and being bullied are all powerful predictors of HRQOL, however BMI and gender were not significantly associated with HRQOL in the full model. **CONCLUSIONS:** For children and adolescents, psychosocial variables (like being bullied, experience pain, and body image) in addition to age, are more important predictors of HRQOL than BMI. Moreover, in the final model, controlling for relevant variables, there are no gender differences, meaning that when children and adolescents experience problems, such as pain, a negative body image, being bullied, there are no differences in HRQOL between boys and girls. To strengthen HRQOL in children and adolescents, health promotion programmes, which aim to strengthen psychosocial wellbeing for both genders, should be developed.

1190/Weight and Quality of Life of Youth in Mexico and the United States: A Comparative Study

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AIMS: To investigate the association between weight and quality of life (QOL) among youth in the United States (US) and Mexico (MX).

METHODS: The study included 137 African-American (AA), 167 Mexican-American (MA), and 146 White (W) youth in the US and 181 youth in MX, all 11 to 18 years of age. Approximately half were female, 40% obese, 30% overweight, and 30% healthy weight. The outcome was a 21-item measure of weight-specific QOL (YQOL-W) scored from 0 to 100 such that higher scores indicated better QOL. The main independent variable was the youth's race-ethnicity and nationality. Other variables were standardized BMI (zBMI), a generic measure of QOL (YQOL-R), the Children's Depression Inventory (CDI), and the Child Health Questionnaire-Physical Functioning scale (CHQ-CF). Other covariates included self-reported health (excellent to poor), youth's age, mother's education, and father's education. Linear regression was used to estimate the association between youth's race-ethnicity/nationality and YQOL-W scores. The full model controlled for age, zBMI, mothers' and fathers' education, YQOL-R, CDI, and CHQ-CF. All analyses were stratified by gender.

RESULTS: For females, the mean YQOL-W scores adjusted for age and zBMI were: AA-76.37 ($p < .05$), W-67.24, MA-66.94, MX-60.64 (ref). By contrast, the YQOL-W scores for females, adjusted for all model covariates were: AA-75.16 ($p < .05$), W-64.90, MA-67.28, and MX-62.75 for MX (ref). For males, the mean YQOL-W scores adjusted for age and zBMI were: AA-84.88 ($p < .05$), W-81.92 ($p < .05$), MA-84.44 ($p < .05$), and MX-66.45 (ref). By contrast, the YQOL-W scores for males, adjusted for all model covariates were: AA-82.72 ($p < .05$), W-80.12 ($p < .05$), MA-82.28 ($p < .05$), and MX-68.97 (ref). **CONCLUSIONS:** Among females, weight-specific QOL was higher in AA girls than all other groups and among males, it was lower among MX boys than all other groups. These results suggest that AA females may face less weight-related stigma than their counterparts and that MX males may face greater stigma than their counterparts in the US, contrary to previous studies.

1740/HRQL evolution in overweight adolescents improving their BMI

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AIMS: To assess Health-Related Quality of Life (HRQL) evolution in overweight adolescents becoming normal-weight over a 2 year-period.

METHODS: We used a sample of 153 overweight adolescents (as defined by the IOTF guidelines) improving their Body Mass Index (BMI) over a 2-year follow-up among the 3,114 high school students who completed the PRALIMAP study, a cluster randomized trial assessing the effectiveness of interventions in overweight prevention. DUKE health profile physical, mental and social scores, and height and weight were measured by trained nurses to compute BMI at the 10th (T0) and the 12th (T2) grade year. The differences between T2 and T0 (DHRQL and DBMI) measurements were used as the dependent and independent variables, respectively. We used adjusted linear regression models stratified for gender to assess the association between DHRQL and DBMI. **RESULTS:** At

T0, 71(46.4%) adolescents were girls, 74(49%) had a relative in a low occupational category and 45(29.4%) had a school backwardness. Girls had a lower physical activity level (33.9% vs 13%, $p < 0.001$). The mean physical, mental and social scores was significantly lower in girls as compared with boys at T0 (respectively 71.1±21.1 vs 84.1±14.6, $p < 0.001$; 53.1±23.2 vs 72.6±18.8, $p < 0.001$; and 62.6±19.5 vs 74.8±16.5, $p < 0.001$). The mean BMI was significantly higher in girls at T0 (25.3±0.9 vs 24.8±1.4 kg/m², $p = 0.03$). DHRQL and DBMI did not differ according to gender (-1.6±20.5 for physical score, 3.2±22.5 for mental score, -0.8±21.2 for social score and -1.6±1.5 kg/m² for BMI). An adjusted 1 kg/m² DBMI decrease was associated with both a 4.7 points DHRQL increase in the physical score ($p = 0.04$) and a 4.4 points DHRQL increase in the mental score ($p = 0.04$) in girls, whereas in boys, an adjusted 1 kg/m² DBMI decrease was associated with a 4.9 points DHRQL decrease for the physical score ($p = 0.003$).

CONCLUSIONS: Over a 2-year period, in girls becoming normal-weight, physical and mental score significantly improved, whereas in boys, physical score worsened. Overweight prevention interventions should focus on HRQL improvement, especially in boys.

1608/Between psychological characteristics and health-related quality of life (HRQOL) of adolescent females with a tendency for eating disorders

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AIMS: We identified the characteristics and health-related quality of life (HRQOL) of adolescent females with tendency for eating disorders in order to protect their future health. To describe the development and investigate the psychometric properties of a new instrument to measure HRQOL for individuals with an eating disorder. **METHODS:** A questionnaire survey on health status, psychological features, and eating habits was conducted on 126 female high school students and college students. **RESULTS:** The responses revealed that there were more college students than high school students with the experiments for eating disorders. There were more high school students than college students with a low body weight (BMI < 18.5 kg/m²) or abnormal menses, and psychological characteristics and eating habits of two student groups were similar. The average of body mass index (BMI) was 20.5 kg/m². But they answered that the ideal BMI was 18.6. They hoped to get thinner more. The student of 16% was told to get thinner by the family. Fifty percent of students have wanted to be thinner, and 40% respectively, have attempted to lose weight. They were significantly more likely to perceive their ideal body size as a little smaller body size than their current size. Twenty % of the student skipped breakfast, and 60% compensated for skipped breakfast by eating between-meal snacks for keep their QOL. The QOL was significantly and independently predicted by subjective bulimic episodes and compensatory behaviors, including food avoidance. A strong negative correlation was observed between self-negation and normal menses. **CONCLUSIONS:** It is necessary to provide dietary education since many of the female students had no eating plan. These findings suggest that subjective bulimic episodes may be independently associated with impairment in the QOL.

RESPONSIVENESS II

1772/Clinically Significant Effect Sizes for Survival and Response Endpoints using the ½ Standard Deviation Rule

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AIMS: Clinically significant effect sizes have been the focus of much research for assessing patient-reported outcomes. Methods such as the empirical rule effect size (ERES) or ½ standard deviation method are useful for efficient design and improved interpretation of clinical studies. While the concept of clinical significance is ubiquitous in PRO research, it is less standardized in clinical trials involving tumor response and survival endpoints. **METHODS:** We applied the ½ standard deviation rule to survival and response endpoints in order to define clinically significant effect sizes for these types of studies. We demonstrate the method with application to published studies from ASCO putting their results into context. We reviewed studies published by ASCO in two separate clinical trial effect size reviews. We present clinically significant effect sizes for mean and median survival testing. **RESULTS:** In general, the clinically significant effect size for survival studies is roughly equivalent to ½ the expected mean survival. A small effect size 1/5 SD is equivalent to 1/5th of the mean survival. The clinically significant effect size for survival studies is roughly equivalent to ½ the expected median survival. A small effect size 1/5 SD is equivalent to 1/5th of the median survival. Many survival studies have involved very small effect sizes, putting the clinical significance of the results in question. Similarly tumor response studies have often been designed with a small effect size. **CONCLUSIONS:** This method allows for more ready interpretation of the clinical significance of survival and response studies. It allows for direct cross study comparison even if the endpoints are different. It also facilitates study design as it builds clinical significance into the study directly.

1507/Relative responsiveness and statistical efficiency of QLQ-C30 v FACT-G

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AIMS: QLQ-C30 and FACT-G are the two most widely used cancer-specific health-related quality of life (HRQOL) measures. They both cover four core HRQOL domains: physical, functional/role, emotional, social. While the validity of both measures is well established, their relative responsiveness (RR) to clinically important effects and statistical power to detect such effects (relative efficiency, RE) have not been determined. Our aim was to estimate RR and RE of comparable scales from these two measures. **METHODS:** 162 patients with mixed cancer diagnoses at variable stages of disease and treatment participated in a randomised trial of Medical Qigong (breathing & movement exercises); n=79 intervention, n=83 control. Responsiveness was calculated as mean change in the intervention group divided by standard deviation of the control group, and RR as mean difference in responsiveness, with 95% confidence intervals (CI) calculated after Tuley (1991). RE was computed as $[(t(QLQ)/t(FACT))]^2$ based on paired t-test (pre to post, intervention group only), with bootstrapped CI. **RESULTS:** FACT was more responsive and efficient than QLQ for the overall HRQOL scores [RR=-0.68 (-1.02, -0.35), RE=0.12 (0.032, 0.26)] and the emotional domain [RR=-0.48 (-0.78, -0.17), RE=0.22 (0.065, 0.49)]. The QLQ social functioning scale was more responsive and efficient than the FACT social wellbeing scale: RR=0.27 (0.009, 0.54), RE=4.27 (1.18,

61.16). In the physical and functional/role domains, neither FACT nor QLQ was more responsive or efficient. **CONCLUSIONS:** Given the conventional interpretation of the squared t ratio, our results suggest FACT total score would require about two thirds of the sample required by QLQ global QOL scale to detect a given effect, and FACT emotional wellbeing scale would require about three quarters of the sample required by QLQ emotional functioning scale. In contrast, FACT emotional wellbeing scale would require about four and a quarter times the sample size required for QLQ emotional functioning scale. Wide CI on RE reflect considerable uncertainty in the actual size of these differentials.

1148/Agreement About Identifying Patients Who Change Over Time: Cautionary Results in Cataract and Heart Failure Patients

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AIMS: Utility scores from measures such as EQ-5D, Health Utilities Index Mark 2 (HUI2) and Mark 3 (HUI3), Quality of Well Being-Self Administered scale (QWB-SA), and Short-Form 6D (SF-6D) are not interchangeable. Less is known about agreement among these measures in terms of clinically important change. **METHODS:** 221 cataract patients were assessed at baseline (pre-surgery) and one month (post-surgery) using the NEI VFQ-25 and EQ-5D, HUI2, HUI3, QWB, and SF-6D. Similarly, 86 patients with congestive heart failure were assessed at baseline and six months using the Minnesota Living with Heart Failure Questionnaire (MLHF) and the same five utility measures. Changes of 5.0 or more in the NEI VFQ-25 and MLHF, and 0.03 or more for each of the five utility measures were classified as clinically important. Pair-wise comparisons of agreement in identifying subjects who improved, were stable, or deteriorated were evaluated using the kappa statistic. **RESULTS:** In the cataract cohort, NEI VFQ-25, HUI3, and HUI2 detected clinically important improvement at the group level; in the heart failure cohort MLHF and QWB detected clinically important improvement. In the cataract cohort, the intra-class correlation coefficient (ICC) among change scores was 0.16; in the heart failure cohort the ICC was 0.07. In general, there was little agreement between pairs of measures in classifying subjects as improved, stable, or worse. A number of kappas were negligible. In the cataract cohort, the highest kappa observed was 0.25 between HUI3 vision and NEI VFQ=25; in the heart failure cohort the highest was 0.25 between self-rated health and MLHF. **CONCLUSIONS:** These results underscore both the lack of interchangeability of scores from different utility measures and the relatively low precision of measures of change. In choosing utility measures for studies investigators should consider the health status content relevant to the application and existing evidence on construct validity in that population. Users of evidence from studies should interpret results carefully.

1725/Effect sizes can be misleading: Is it time to change the way we measure change?

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AIMS: Rating scales are increasingly used as primary outcome

measures in clinical trials. Therefore, it is important that they detect meaningful changes when they occur. Not surprisingly the relative responsiveness of competing rating scales is a primary selection criterion. Previous comparisons of the ability to detect change of the Barthel Index (BI) and Functional Independence Measure motor scale (FIMm) have implied these two scales are equally responsive when examined using traditional effect size statistics. Clinically, this is counter-intuitive, as the FIMm has greater potential to detect change than the BI, and raises concerns about the validity of effect size statistics as indicators of rating scale responsiveness. To examine these concerns, in this study, we applied Rasch analysis to BI and FIMm data. **METHODS:** BI and FIMm data were examined from 976 people at a single neurorehabilitation unit. Rasch analysis was used to compare the responsiveness of the BI and FIMm at the group comparison level (effect sizes, relative efficiency, relative precision) and for each individual person in the sample by computing the significance of their change. **RESULTS:** Group-level analyses from both interval measurements and ordinal scores implied the BI and FIMm had equivalent responsiveness (BI and FIMm effect size ranges -0.82 to -1.12 and -0.77 to -1.05, respectively). However, individual person-level analyses indicated that the FIMm detected significant improvement in almost twice as many people as the BI (50%, $n=496$ versus 31%, $n = 298$), and recorded less people as unchanged on discharge (FIMm= 4% $n=38$; BI=12% $n=115$). This difference was found to be statistically significant (Chi-square, 273.81; $p<0.000$). **CONCLUSIONS:** Findings demonstrate that effect size calculations are limited and potentially misleading indicators of rating scale responsiveness at the group comparison-level. Rasch analysis at the individual person-level showed the FIMm superior responsiveness, supporting clinical expectation, and its added value as a method for examining and comparing rating scale responsiveness.

ECONOMIC EVALUATION II

1186/Relationships Between EQ-5D and FACT Scores in Patients with Esophageal or Gastric Cancer

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AIMS: The EQ-5D summary index is often used to adjust survival for quality of life. However, the EQ-5D may not equally reflect all aspects of quality of life as experienced by patients. The present study aimed to establish the relationships between EQ-5D and FACT (Functional Assessment of Cancer Therapy) scores, and to consider the implications for quality of life adjustment of survival. **METHODS:** Participants were patients with esophageal or gastric cancer in the COGNATE (Cancer of the Oesophagus or Gastric: New Assessment of the Technology of Endosonography) trial. They completed the EQ-5D, FACT General Physical, Social, Emotional, and Functional Well-Being scales, and FACT Additional Concerns Esophageal and Gastric scales at intervals throughout the trial. Psychometric analyses were conducted on the baseline ($N = 220$), Month 1 and Month 3 data. The FACT Well-Being scales were subjected to confirmatory factor analysis, and Additional Concerns to exploratory factor analysis. Structural equation modeling was used to test a model in which FACT Additional Concerns influenced FACT Physical, Social, Emotional, and Functional Well-Being, which in turn influenced EQ-5D. **RESULTS:** The factor analyses confirmed

the structure of the FACT Well-Being scales, and suggested that Additional Concerns is multidimensional. According to the final structural equation models, FACT Additional Concerns consistently predicted FACT Physical, Emotional, and Functional Well-Being, but not Social Well-Being. FACT Physical and Functional Well-Being predicted EQ-5D, but Social and Emotional Well-Being did not. The relationship between FACT Additional Concerns and EQ-5D was mediated by FACT Physical and Functional Well-Being. **CONCLUSIONS:** EQ-5D does not reflect the social or emotional aspects of quality of life experienced by these patients. Therefore, survival should be adjusted not only using EQ-5D but also, separately, using FACT. FACT General or Additional Concerns might be used, but, because the former is strongly influenced by the latter, it would be inappropriate to use them in combination.

1069/Assessing Health-related Quality of Life (HRQL) in Lung Transplant Recipients using the Health Utility Index Mark 3 (HUI3)

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AIMS: To compare HRQL among lung transplant recipients and identify determinants of health status in lung transplant recipients stratified by underlying diagnoses. **METHODS:** Consecutive lung transplant recipients attending the lung transplant outpatient clinic in a tertiary institution completed the 15-item HUI questionnaire on a touch-screen computer at every visit. Overall HUI3 scores are on a scale in which dead =0.00 and perfect health =1.00; disabilities categories include no (1.00), mild (0.89-0.99), moderate (0.70-0.88) and severe disability (<0.70). Descriptive statistics were used to compare health status by underlying diagnoses. Random-effect models were built to identify determinants of health status. **RESULTS:** 214 lung transplant recipients (61% male, mean age of 52 (19-75) years) were recruited into the study. With follow-up up to two years post transplantation, Chronic Obstructive Pulmonary Disease and Cystic Fibrosis patients displayed moderate disability (mean overall HUI3 scores of 0.70 and 0.74 respectively). Pulmonary Fibrosis (PF) and Pulmonary Arterial Hypertension patients displayed severe disability (mean HUI3 scores of 0.68 and 0.65 respectively). Ambulation, cognition, emotion and pain were the most affected attributes across diagnoses. Patients with PF had the highest burdens in emotion and cognition. The percentage of women in the severe category was higher than men (39% versus 28%). Within two years post-transplant, 65 patients (30.4%) developed Bronchiolitis Obliterans Syndrome (BOS) but only 16 (7.5%) died (10 women and 6 men). Random-effect models confirmed that time since transplant and development of BOS were major determinants of health status. **CONCLUSIONS:** The HUI3 allowed us to compare patients' HRQL and identify determinants of health among lung transplant recipients with different underlying diseases. HRQL differed among diagnostic groups; clinicians can use HRQL information to individualize patient care. BOS continue to be the main determinant of health status in lung transplant recipients.

1737/Health gain for a controversial operation on appropriately selected cases: VTs in childhood OME

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AIMS: Ventilation (tympanostomy) tubes (VTs) for otitis media with effusion (OME) is the commonest operation in children. Past over-intervention and largely null trial results with linguistic and cognitive test outcomes on young mild cases have recently fuelled scepticism, but symptom-driven demand remains. To capture total impact in OME, we developed a short-form parental questionnaire of symptom domains (OM8-30), with mapping formulae into HUI-3 utilities (Dakin et al.2010). **METHODS:** We used data from an RCT: TARGET, the UK multi-centre trial (N=376 randomised, aged >3.5 years). For stability, we chose 3-domain scoring (reported hearing, development & physical health). We first re-scaled the long forms into corresponding OM8-30 short-form scale values by linear regressions, with quadratic terms wherever this added >1% to R-squared. We next converted re scaled values to utility outcomes for three period averages 0-6, 7-24, and all 24 months follow-up and ran baseline-adjusted treatment GLMs. **RESULTS:** Long - short regressions explained 78-97% of re-scaling variance, according to degree of item reduction present. With such high aggregation over time and items, both baseline utility and surgical treatment determined utility reliably for each period (all six $p < 0.0005$, Rsq 0.43-0.52). Baseline-adjusted 2-year SD effect size re non-surgical controls was very large at 1.01 SD. Absolute baseline utility (ie need) predicted utility gain from treatment only marginally. Average (total) 2-year utility gain was 0.068 QALYs ($X2= 0.136$), but strongly front-loaded. **CONCLUSIONS:** The QALY gain on well-defined cases is competitive for purchase/reimbursement of VTs against UK cost-utility criteria. About half the OME-related baseline loss in utility is remedied in this severe sample, but between- and within-study evidence suggests less gain in younger, milder, or self-referred cases from less highly gate-kept health systems. Physical health has been neglected in OME, but contributes to this result, due to considerable weighting in utility and larger treatment effects.

1568/Using QALYs to assess changes in the impact of chronic conditions on population HRQL

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AIMS: The aim of this study was to use QALYs based on EQ-5D Index scores to quantify health-related quality of life (HRQL) losses associated with chronic conditions in the Catalan population between 1994 and 2006. **METHODS:** The Catalan Health Interview Survey (CHIS) is a periodic cross-sectional study of a representative sample of the non-institutionalised general population. The EQ-5D was administered to respondents aged 15 and over in the 1994 (n=12,567), 2002 (n=7,157), and 2006 (n=15,926) editions. EQ-5D

index scores based on time trade-off values from the Catalan general population were used to assess HRQL losses associated with 15 chronic conditions. A Tobit regression model was constructed to investigate the effect of chronic conditions on the EQ5D index over time, after adjusting for socio-demographic variables and comorbidity. Loss in QALYs due to morbidity associated with the disorders was calculated by multiplying the marginal effect of each condition by its prevalence and rescaled for 100 individuals/year. **RESULTS:** Prevalence of chronic conditions remained stable for most conditions, increasing in musculoskeletal diseases (12.7%), depression or anxiety (6.5%), hypercholesterolemia (4.8%), varicose veins (3.6%), and hypertension (3.3%). Beta coefficients in the Tobit model associated with most conditions remained stable over time. The largest QALY loss in each edition was associated with musculoskeletal diseases: QALYs lost per 100 individuals/year rose from 4.3 in 1994 to 5.8 in 2006. The largest absolute increase in QALY loss was seen with depression or anxiety, from 1.7 in 1994 to 3.4 in 2006. QALY loss associated with most of the chronic conditions studied increased over time. Overall QALY loss due to chronic conditions rose from 8.6 in 1994 to 12.9 in 2006. **CONCLUSIONS:** Using this approach, there was substantial and increasing health loss over time associated with most of 15 common chronic conditions in the Catalan general population. The approach can provide results which could be useful to health planners.

CLINICAL DECISION MAKING

1236/Velikova's Content Analysis System (VCAS): Inter-rater reliability and Feasibility regarding characterization of aspects related to HRQoL and medical decision making

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AIMS: The aim was to assess the feasibility and reliability of Velikova's Content Analysis System (VCAS) including the section characterising the medical decision making. **METHODS:** Sixty-nine routine physician consultations with gastro-intestinal (GI) cancer patients were audio-taped at two large University hospitals in Sweden as a historical control group before a randomized trial evaluating the effects on communication of two Patient-Reported Outcomes (PROs) (SEIQoL-DW and EORTC-QLQ-C30) in clinical practise. Two trained coders applied VCAS to the consultations of sufficient audio-quality ($n=61$) to capture different topics discussed or mentioned, e.g., symptoms, side effects, functional issues and health-related quality of life. Further, information about treatment, prognosis and results of medical investigations and medical decision makings were coded. This information was complemented by information from medical records. **RESULTS:** VCAS generally has good inter-rater reliability (IRR) regarding symptoms (0.649-1), functions (0.609-1), information on topics (0.201-0.870). Mean for all content categories were 0.798. Further, the medical decision section in VCAS was feasible in capturing these aspects of the consultations. IRR of the medical decisions section ranging from 0.748-1, mean 0.931. A few categories were not used due to differences in language and clinical tradition. The feasibility of VCAS was good and the coding time (excluding time for additional analysis of medical records) was 2 times the consultations actual length in minutes of the consultations. **CONCLUSIONS:** The results indicate good feasibility and reliability for VCAS including the section evaluating medical

decision making. VCAS seems to be a feasible tool for evaluating patient-physician communication regarding both content of communication and medical decision making. Further studies need to study the use of VCAS when evaluating the effects of PROs in clinical practise on patient-physician communication.

1176/The PANORAMA Pan-European Survey of Type 2 Diabetes - Patient vs Doctor Ratings of Patients' Treatment Satisfaction

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AIMS: PANORAMA, a pan-European cross-sectional survey (sponsored by AZ/BMS) of pts with type 2 diabetes (T2D) included reports of treatment satisfaction (TS) by patients (pts) and doctors (drs). **METHODS:** Pts aged ≥ 40 yr, diagnosed >1 yr, treatment unchanged for ≥ 3 months were selected randomly or consecutively from medical practices in 8 countries. All pts received diet/exercise advice, and most were also prescribed 1, 2 or 3+ oral hypoglycaemic agents (OHAs) and/or injectables (insulin regimens or GLP-1 receptor analogues), producing 13 treatment grps. Pts completed the 8-item Diabetes TS Questionnaire (DTSQ). Drs completed the DTSQ without knowing pt responses. DTSQ items 1 and 4-8 assessed TS (range 0 very dissatisfied to 36 very satisfied). Items 2-3 measured perceived frequency of hyper- and hypoglycaemia. (0=none of the time; 6=most of the time). Correlation coefficients were computed overall and by treatment grp. **RESULTS:** 5156 pts: (47.8% women, age [mean \pm SD] 65.9 \pm 10.3 yr, time since diagnosis 9.0 \pm 7.4 yr). TS was 29.9 \pm 6.1 for pts and 27.7 \pm 5.9 for drs ($r=0.37$; $p<0.001$ overall). Drs rated TS less than pts ($p<0.001$), and recognised pts were most satisfied with diet alone, then with 1 OHA but did not appreciate pts' reduced TS with insulin regimens when OHAs were included. Pts rated BID premixed insulin+OHAs as least satisfactory. Dr- and pt-perceived frequency of hyperglycaemia correlated significantly in 12/13 grps ($p<0.018$). Drs tended to underestimate frequency of hyperglycaemia perceived by pts, significantly for the 2 least intensively treated OHA grps ($p<0.029$). Dr- and pt-perceived frequency of hypoglycaemia scores correlated significantly in 11/13 grps but drs tended to underestimate hypoglycaemia in 10/13 grps, particularly in pts using bolus insulin+OHAs ($p<0.003$). **CONCLUSIONS:** Mean TS scores for the DTSQ in PANORAMA showed moderate correlations though significant differences between pt and dr scores. Pts reported more hypo- and hyperglycaemia than drs recognised, despite being more satisfied with treatment than perceived by drs.

1638/Development of a banding system for the Renal Quality of Life Profile (RQLP): An aid to clinical decision making

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AIMS: Health-related quality of life (HRQoL) assessment has

become increasingly important in clinical research, especially for such chronic conditions as end stage renal disease. However, whilst it is generally agreed that it is an important area of research, it still remains a difficult concept to translate into use in routine clinical practice. The aim of this study was to use an anchor-based technique to assign clinical significance to scores of the Renal Quality of Life Profile (RQLP) **METHODS:** Male and female patients with end stage renal disease aged 18 and over were recruited in this study from renal outpatient clinics of University Hospital Wales, Cardiff. The Renal Quality of Life Profile (RQLP) was used to collect HRQoL data. In order to examine the relationship between patients' assessment of their overall HRQoL and multidimensional RQLP scores, a global question (GQ) inserted into the RQLP was used. The mean, median and mode of the GQ scores for each RQLP score were used to devise several sets of bands of RQLP scores, and intraclass correlation coefficient (ICC) was calculated. **RESULTS:** High ICC values were obtained for the sets of bands proposed for both females and males. Since there was no difference in ICC values a series of combined female and male banding systems were generated. The set proposed for adoption is: RQLP scores 0–20 =no effect on patient's life (GQ=0, n=35); 21–51 =small effect on patient's life (GQ=1, n=66); scores 52–93 =moderate effect on patient's life (GQ=2, n=87); scores 94–134 =very large effect on patient's life (GQ=3, n=54); scores 135–172 =extremely large effect on patient's life (GQ=4, n=18). The ICC for the proposed banding was 0.80. **CONCLUSIONS:** Banding of the RQLP will aid the clinical interpretation of change in RQLP score. The use of a banding system as an aid to decision making will allow harmonization of treatment strategies, facilitate communication, help uncover patient's problems and monitor response to treatment.

1724/Health-related quality of life is an independent determinant of adherence to drugs in HIV-infected people

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AIMS: Aim: To evaluate the role of Physical Health Score (PHS) and Mental Health Score (MHS) as determinants of adherence to drugs in HIV+ people. **METHODS:** Methods: Prospective, cohort, monocenter study. A questionnaire on adherence, PHS and MHS, and self-reported symptoms was administered to any outpatient taking antiretroviral therapy. Self-reported adherence (SelfAdher) was assessed asking the patient: "How much do you think was your adherence to drugs during the last 4 weeks?" on a 0 to 100 visual analogue scale. Both PHS and MHS were assessed through a single-item visual analogue scale. **RESULTS:** Results: At 12/2009, 903 patients filled the questionnaire. 32% females, mean age 47 yrs (SD 8.5), IDU 20%, HCV+ 25%, median log HIV RNA 1.7 c/ml (IQR 1.7–1.7), 13 had HIV RNA >50 c/ml, median CD4 563/mm³ (IQR 405–745). 504 (57%) were taking protease inhibitors (PI) and 269 (29.7%) nonnucleoside analogue reverse transcriptase inhibitors (NNRTI). Mean SelfAdher was 80 (SD 18). Mean PHS: 72.2 (SD 17.8); mean MHS: 74.1 (SD 20.2). At multiple linear regression analysis, age (B 0.19; 95% CI 0.04; 0.33; p=0.01), IDU (B -3.89; 95% CI -6.96; -0.81; p=0.01), log HIV RNA (B -2.55; 95% CI -5.15; 0.05; p=0.05), CD4 (B for each 100 more 0.49; 95% CI 0.07; 0.90; p=0.02), PHS (B for each 10 points more 2.91; 95% CI 2.13; 3.70; p<0.001), and symptom score (B -0.21; 95% CI -0.35; -0.07; p=0.002) were correlated to SelfAdher to drugs. When considering only people taking IP or NNRTI (n=773), IDU (B -3.46; 95% CI -

6.75; -0.17; p=0.04), CD4 (B for each 100 more 0.72; 95% CI 0.27; 1.17; p=0.002), PHS (B for each 10 points more 2.66; 95% CI 1.80; 3.51; p<0.001), MHS (B for each 10 points more 0.90; 95% CI 0.17; 1.64; p=0.01), and taking NNRTI (B 5.00; 95% CI 2.30; 7.70; p=0.0003) were independently correlated to SelfAdher to drugs. **CONCLUSIONS:** Conclusions: Health-related quality of life is a strong determinant of adherence to drugs in HIV+ people. Further studies should address whether focusing care attention on patient-reported outcomes would improve efficacy of the treatment.

BREAST CANCER - ONCOLOGY III

1110/The Relationship between Distress and Quality of Life in Women Recently Diagnosed with Breast Cancer

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AIMS: Distress and quality of life are frequently assessed as indicators of the impact of cancer diagnosis and treatment, yet the association between these two constructs and related measurement instruments is relatively unexplored. The purpose of this study was to explore relationships between self-rated distress levels and quality of life (QOL) among women with breast cancer. **METHODS:** The National Comprehensive Cancer Network's (NCCN) Distress Thermometer, the Functional Assessment of Chronic Therapy Breast (FACT-B), the Functional Assessment of Chronic Illness Therapy Spirituality (FACIT-Sp) and a demographic questionnaire were completed by 111 women recently diagnosed with breast cancer. **RESULTS:** Bivariate correlations between distress scores and the total and all subscale QOL scores were statistically significant (p < 0.01). Substantial correlations (r > 0.52) existed between distress scores and FACT-B total, Additional Concerns, Functional Well-Being subscale, and FACIT-Sp scores. Correlations existed to a lesser degree between distress scores and Physical Well-Being, Emotional Well-Being, and Social Well-Being subscale scores. Hierarchical regression analysis indicated that Physical Well-Being, Social/family Well-Being, Emotional Well-Being, Functional Well-Being (step 1) and Additional Concerns subscale scores (step 2) predicted 33% of the distress score. **CONCLUSIONS:** Self-assessment of distress in newly diagnosed breast cancer patients significantly correlates with their self-assessed QOL. Higher scores on the Distress Thermometer may indicate the need for exploration of important quality of life issues which could be identified by using QOL measurements to supplement assessment of distress and clarify targeted domains for intervention.

1701/Longitudinal Joint Pain in Postmenopausal Women with Early Breast Cancer Taking Aromatase Inhibitors

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AIMS: To prevent cancer recurrence, each year over 100,000 women in the US begin a 5-year course of aromatase inhibitors (AIs) for early stage hormone-sensitive breast cancer. Oncologists are concerned that joint pain secondary to AI leads to nonadherence; information is lacking on baseline pain severity and predictors of worsening joint pain over time in this population. Joint pain prevalence estimates in women taking AIs vary widely (10–74%) due to poor measurement methods. We aimed to identify patient-reported risk factors for worsening joint pain over the 1st 12 weeks of AI therapy. **METHODS:** We collected data from postmenopausal female oncology outpatients with early stage breast cancer initiating AI. Paper surveys were completed prior to AI initiation, and every 2 weeks thereafter for 12 weeks. Pain was measured in 16 joint locations using a 0–10 numeric rating scale adapted from the Regional Pain Scale. Covariates include performance status (ECOG), physical function (PROMIS), comorbidities, menopausal symptoms (FACT-ES), time since last menstrual period, age, education, and major depressive disorder (PHQ-2). We used exploratory linear regression with clustered robust standard errors to assess individual associations of baseline factors with longitudinal joint pain. **RESULTS:** We report preliminary data from 24 women who have 12 weeks' followup in the Breast Cancer Adjuvant Therapy prospective longitudinal cohort. Mean age is 61 yrs (SD=10, Range=42–78). The majority were fully active (n=21) and not depressed (n=20) at baseline. Median worst pain in any joint prior to AI initiation was 3.5 (Min=0, Max=10, IQR=1–5). Women who had greater ECOG restriction ($\beta=11.9$, 95%CI=4.2–19.6), more severe menopausal symptoms ($\beta=0.84$ [0.15–1.52]), worse physical function ($\beta=0.97$ [0.01–1.92]), or existing osteoporosis, fibromyalgia, or arthritis ($\beta=20.4$ [6.3–34.5]) at baseline had greater risk for increasing joint pain. **CONCLUSIONS:** These findings will be used to develop and validate the Patient-Reported Arthralgia Inventory. This program of research is designed to improve PROM in breast oncology populations, and guide efforts to improve AI adherence.

1757/Measuring and managing patient expectation for breast reconstruction: A new preoperative patient assessment tool

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AIMS: The overriding goal of post-mastectomy breast reconstruction is to restore body image and satisfy patient expectations. Measuring individual patient expectations may allow surgeons to identify patients who have unrealistic expectations, and implement targeted education programs. There is currently a lack of expectation scales for this population. The aim of this study was to develop a new patient rating scale to measure individual patient expectations for breast reconstruction. **METHODS:** Interviews were conducted with 44 women undergoing breast reconstruction. The interviews were recorded, transcribed, and analyzed thematically. Conceptual domains were used to organize statements into a preliminary version of the questionnaire. This version was then pilot tested, through cognitive interviews, with 23 women undergoing breast reconstruction. This was then administered to 146 women prior to breast reconstruction. Rasch analysis was used to guide the formation scales. **RESULTS:** Patient interviews revealed that expectations for breast reconstruction fall into 4 main domains: Breast Appearance and Outcome, Physical Well-being, Psychosocial Well-being, and Process of Care. These domains formed the organizational structure for the questionnaire, under which 9 preliminary scales were

grouped. Pilot testing resulted in minor wording changes, clarified ambiguities, and recognized missing content. Scale formation resulted in minor changes, and preliminary confirmation of psychometric properties including item fit (all), item location span (2.0–5.5), and Person Separation Index (0.73–0.87). **CONCLUSIONS:** Patient expectations for the results of breast reconstruction are complex, and encompass not only breast appearance, but physical well-being, psychological well-being, and process of care. This study is essential in the quest to improve patient satisfaction with the results of breast reconstruction. The use of the new measure in clinical research and practice will help to facilitate dialogue, shared medical decision-making, and improved patient education.

1295/Impact of response shift (RS) in longitudinal post-operative quality of life (QoL) analysis among breast cancer (BC) patients: A randomized multicenter cohort study

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AIMS: RS could bias QoL analyses when comparing treatments. One objective was to characterize the Change in internal standard, change in value, reconceptualization components of RS and to study its impact on longitudinal QoL in patients with primary BC. **METHODS:** A prospective multicentric cohort included women hospitalized or consulting for a primitive BC or a suspicion. QLQ-C30, BR23 and EuroQOL EQ-5D was assessed at the 1st (before treatment) and at the end of the 1st hospitalization and then at 3 and 6 months. We used then-test, ideal scale and successive comparison approaches to characterise the 3 components of RS. Change in internal standard at the end of the 1st hospitalization was identified calculating mean difference (MD) between pre-test and then-test (retrospective measure) baseline QoL assessment and using matched pair signed rank tests. **RESULTS:** From February 2006 to February 2008, 381 women were included in 4 centres. Mean age was 56 years, 36% had a suspicion of BC while only 10% were not confirmed, 28% had mastectomy and 43% sentinel node biopsy. At the end of the 1st hospitalization, retrospective assessment of QoL at baseline (Then-test) highlighted that women had initially underestimated QoL level ($p < 0.0001$) for Emotional (MD = + 5.3 points) and cognitive (MD = + 2.9 points) functions resulting respectively in a true QoL change of + 3.3 points ($p = 0.0008$) and - 3.3 points ($p = 0.0002$) instead of observed change of + 8.6 and -0.4 points. In the same way fatigue (MD = - 1.3), dyspnea (MD = - 2.2), insomnia (MD = -5.1), appetite (MD = -3.4) and diarrhoea (MD = -3.1) symptoms as well as Sexual enjoyment (MD = -2.9) and perspective futures of BR23 (MD = + 7.9) were initially significantly better at inclusion after retrospective evaluation ($p < 0.01$). **CONCLUSIONS:** Occurrence of RS after 1st hospitalization for 7/15 dimensions of QLQ-C30 and 2/8 of BR-23 suggests to take into account RS to interpret longitudinal QoL change in BC. Other components of RS are under investigation.

POSTER SESSION 1

GENERAL

1/1594/Poor health-related quality of life of mothers after severe preeclampsia: results from a prospective cohort study
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AIMS: Preeclampsia is a common, serious complication of pregnancy that affects health of both mother and child. The aim of this study is to describe health-related quality of life (HRQoL) 6 and 12 weeks after delivery in women with a pregnancy complicated by preeclampsia, and to evaluate determinants of HRQoL. **METHODS:** In 4 Dutch hospitals, 255 women with a delivery date between February 2007 and June 2009 and preeclampsia were invited to participate in a prospective cohort study evaluating consequences of preeclampsia. HRQoL of the mother was measured 6 and 12 weeks postpartum, using the RAND 36-item Short-Form. Scores among patients were compared with HRQoL in a gender/age adjusted Dutch reference population. Preeclampsia was defined as mild or severe according to the criteria of the International Society for the Study of Hypertension in Pregnancy. Multivariate regression analyses were applied to evaluate the effects of severity and other factors on HRQoL. **RESULTS:** Participation rate was 68.2%; 128 participants (73.6%) completed both HRQoL questionnaires, of which 95 had severe preeclampsia; mean age was 31.1 years (SD 4.5). All HRQoL scale scores, except General health, improved from 6 to 12 weeks postpartum ($p < 0.05$). Physical component score of patients was low compared to the reference population: 6 weeks Cohen's effect size (ES) 1.04, 12 weeks 0.33; $p < 0.01$. Mental component score was relatively low 6 weeks postpartum (ES 0.42, $p < 0.01$). Severity of preeclampsia was significantly associated with HRQoL scores in all domains 6 weeks postpartum and with scores in the mental domains 12 weeks postpartum ($p < 0.05$); intensive care admission of mother and infant, and perinatal death were associated with low scores in the mental domains 6 and 12 weeks postpartum ($p < 0.05$). **CONCLUSIONS:** Obstetricians should be aware of the impact of severe preeclampsia on HRQoL, and the need for postpartum care for these women. Special attention should be given to women who have experienced perinatal death, and women whose offspring had been admitted to intensive care.

2/1387/Choice of Recall Period for PRO Measures: One Size Does Not Fit All

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AIMS: Understand the choice of recall period for PRO measures based on intended use, characteristics of the disease, treatment, and attributes of studies in which the measure will be used. **METHODS:** The FDA PRO Guidance suggests a preference for patients to describe their current or recent health state with as short a recall period as possible. Current practice and considerations were reviewed within a variety of disease areas (overactive bladder, menopausal hot flashes, niacin-induced flushing, osteoarthritis pain, irritable bowel symptoms, benign prostatic hyperplasia, and alopecia) where the choice of recall may depend on the rate of disease progression,

frequency, fluctuation and burden of symptoms. Additionally, SEALD reviews were examined for feedback on recall periods. **RESULTS:** Across disease areas, rationales were identified for using different recall periods, including event-driven (immediate), daily, up to weekly, and longer than weekly recall periods. This review demonstrates that: 1) length of recall varies depending on what the PRO measure captures, its intended use, and attributes of the disease and study; 2) within the same disease area, recall can vary depending on the concept or phenomenon of interest (e.g. variability, frequency, or overall impact); 3) recalls must consider patient burden and ability of patients to easily and accurately recall the information requested; 4) recall must be consistent with the duration of the trial and the scheduled clinic visits. **CONCLUSIONS:** The selection of the recall period is an important decision in the development of a PRO measure. Shorter recall periods are being encouraged at the US regulatory level for PROs supporting label claims. Shorter recall periods may underestimate symptom burden when symptoms have diurnal or day-to-day fluctuation and may place undue burden on patients. On the other hand, recall intervals that are too long may either over- or under-estimate the health state. Therefore, a "one size fits all" approach is not effective, and a variety of factors should be considered to optimize data quality and completeness.

3/1347/A Targeted Review of Measures of Social Isolation and Perceived Social Support

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AIMS: The aim was to review the scientific and grey literature on instruments used for the effective assessment of social isolation for clients of aged care and disability services. **METHODS:** A literature search was undertaken on the MEDLINE and PsycINFO databases using terms associated with the assessment of social isolation, loneliness and perceived social support. Major psychometric texts were also examined and 155 instruments were identified. As the focus was to identify generic instruments useful for the assessment of social isolation in routine care, disease specific instruments and lengthy assessments were excluded. The remaining 69 instruments were subject to an impact and clinical appropriateness assessment. Ten instruments were short listed and following an examination of the range and quality of the psychometric evidence 4 instruments were selected for comprehensive review. These were: the De Jong Gierveld Loneliness Scale (DJGLS), the Lubben Social Network Scale (LSNS), the Medical Outcomes Study Social Support Survey (MOS-SSS) and the Multidimensional Scale of Perceived Social Support (MSPSS). A comprehensive review of the instrument's applicability, availability, administration requirements, psychometric properties (reliability, validity and responsiveness) and the availability of normative and clinical reference data was undertaken. **RESULTS:** The instruments chosen all scored well on a comparative and standardised assessment system indicating good psychometric properties and applicability/feasibility. In sum, if the focus of the intervention is to reduce feelings of loneliness amongst clients then the DJGLS may be preferred but if an assessment of perceived social support is required then the LSNS might be used. **CONCLUSIONS:** Although sometimes used in epidemiological surveys it is noted that validated instruments were rarely used to assess the outcomes of social isolation interventions. Given that there are a number of valid and reliable instruments available, researchers should be encouraged to investigate such standardised measures in outcomes evaluation.

4/1085/Psychosocial Consequences of Genetic Testing in Li-Fraumeni Syndrome

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AIMS: Aim: Li Fraumeni Syndrome (LFS) is a hereditary cancer syndrome, characterized by a high risk of developing cancer at various sites and ages. To date, limited clinical benefits of genetic testing for LFS have been demonstrated, and there are concerns about the potential adverse psychosocial impact of genetic testing for LFS. In this study we evaluated the uptake of genetic testing and the psychosocial impact of (not) undergoing a genetic test for LFS. **METHODS:** Method: In total, eighteen families with a p53 germline mutation in the Netherlands were identified. Eligible family members were invited to complete a self-report questionnaire assessing motives for (not) undergoing genetic testing, LFS-related distress and worries, and health-related quality of life. **RESULTS:** Results: Uptake of presymptomatic testing was 55% (65/119). Of the total group, 23% reported clinically relevant levels of LFS-related distress. Carriers were not significantly more distressed than non-carriers or than those with a 50% risk who did not undergo genetic testing. Those with a lack of social support were more prone to report clinically relevant levels of distress (OR 1.3; 95% CI 1.0-1.5). **CONCLUSIONS:** Conclusions: Although preventive and treatment options for LFS are limited, more than half of the family members from known LFS families choose to undergo pre-symptomatic testing. An unfavorable genetic test result, in general, does not cause adverse psychological effects. Nonetheless, it is important to note that a substantial proportion of individuals, irrespective of their carrier status, exhibit clinically relevant levels of distress which warrant psychological support.

5/1008/High-risk Pregnancies and Quality of Life

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AIMS: The treatment of women with complications during pregnancy resulting in a high-risk pregnancy is a challenge for obstetricians. The aim of this study was to explore the influence of hypertensive disorders, gestational diabetes and preterm birth as risk factors for health-related quality of life (HRQL) and depressive symptoms during late pregnancy and postpartum. **METHODS:** A prospective, longitudinal study was performed with three assessments. Ninety women were recruited in the study including 29 controls. HRQL was measured using the WHO-QOL-BREF questionnaire. Depressive symptoms were assessed with the Edinburgh Postnatal Depression Scale (EPDS). Statistical analyses were performed using ANOVA and the chi-square test to explore HRQL and depressive symptoms between three pregnancy risk groups and controls. **RESULTS:** Women of the preterm group had statistically significant higher depression scores and lower HRQL score on the physical domain during pregnancy than those without complications. Women with hypertensive disorders showed the second most depressive symptoms. Physical and global HRQL improved and depressive symptoms decreased significantly from late pregnancy and early postpartum period to late postpartum. **CONCLUSIONS:** Pregnant specific health problems, especially the risk for preterm delivery is associated with more depressive symptoms and decreased HRQL. Guidance and communication for these women is important. The counselling

should be multi professional including psychological support to prevent postnatal difficulties for mother and child.

6/1686/Quality of life, Sense of Coherence, Religious and Spiritual aspects in a sample of Iranian family caregivers of patients with breast cancer at the time of diagnosis and six months later

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AIMS: To describe quality of life (QoL) aspects, sense of coherence and religious coping strategies in family caregivers of patients with breast cancer in an Iranian sample, and identify predictive factors of change in total quality of life. **METHODS:** In this prospective study data were collected in 150 family caregivers. Five standardized instruments were used at the time of diagnosis and six months later; The Caregiver Quality of Life Index-Cancer, Sense of Coherence scale, Spirituality Perspective Scale, Brief Religious Negative and Positive Coping Scales and Health Index. **RESULTS:** The results showed significant increase in overall rated QoL ($p=0.008$) and well-being ($p=0.034$) in family caregivers after six months. However, rating of their sense of coherence ($p=0.025$), spirituality ($p=0.01$) and, negative religious coping ($p=0.000$) decreased. Multiple regression analysis revealed that overall quality of life at the time of diagnosis, sense of coherence and negative religious coping after six months predicted change of overall score of CQOLC ($R^2=0.56$; $p=0.000$). **CONCLUSIONS:** Overall the family caregivers of Iranian women with breast cancer improve in quality of life aspects from the time of diagnosis to 6 months later. On the other hand coping skills decreased especially in those family caregivers that clinically deteriorated in overall QoL compared to those who increased their QoL or were stable.

7/1558/Exploring the contribution of spirituality, religious and personal belief (SRPB) to quality of life (QOL) in Hong Kong Chinese

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AIMS: Many existing studies on spiritual QOL reflect the traditional Judeo-Christian perspective. This under-represents the traditional Chinese religious or the non-religious perspective. The purpose of this study was to explore the contribution of SRPB to QOL in Hong Kong Chinese. **METHODS:** The WHOQOL-SRPB questionnaires were administered to adults ($N=445$) from diverse religious background (Christian 32.3%, Buddhist 23.1%, Taoist 5.2%, folk and ancestral worship 1.5%), mean age 51.6 years, female 54.2%. Those practicing Buddhism, Taoism, ancestral or folk worship were categorized as Chinese religion group, while Catholics and Protestants were classified as Western religions. **RESULTS:** The SRPB domain score correlated moderately with overall QOL ($r=.52$, $p<.01$). The SRPB facets displayed strong correlations ($>.74$) within the domain. A difference in General QOL was noted in healthy and unhealthy subgroups but this was not found between gender or age groups (young vs old). ANOVA showed that the SRPB domain scores distinguished the Western and Chinese Religion groups ($F=41.81$) Faith ($F=49.39$), $p<.0001$ remained the facet that most differentiated the QOL of Chinese and Western religion groups. Moreover, within the SRPB module, their corresponding standardized beta coefficients showed that Hope ($\beta=.309$), Peace ($\beta=.238$), Wholeness ($\beta=.237$) and Faith ($\beta=.132$) were the most

significant predictors of the General QOL. Adjusted R^2 was .414 in the finalized model. When importance questions for the SRPB facets were examined, the Chinese religious group reported means from 2.89 (SD = 1.1) to 3.64 (SD = 1.0), with lowest scores in *Faith*. In contrast, the Western group scored 3.57 (SD = .9) to 4.22 (SD = .7) with highest scores in *Faith*. **CONCLUSIONS:** SRPB is a distinctive component that provides an holistic measure of QoL for Chinese, having both traditional and Western spiritual beliefs. Faith best discriminated the traditional religious culture from Christianity in both importance and QOL.

8/1361/Development and validation of an observational instrument for the measurement of canine HRQL in veterinary medicine, using dog owner as respondent

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AIMS: To develop a valid observational instrument for measurement of canine HRQL, and to validate the instrument development methodology for this purpose. **METHODS:** Canine HRQL was defined. Relevant domains were identified through semi-structured interviews with 17 owners of dogs suffering chronic degenerative joint disease (DJD). Questionnaire exercises involving 165 dog owners generated items to describe healthy dogs and dogs with chronic pain and item selection was validated by an expert group of experienced dog owners and veterinary practitioners. An instrument incorporating validated items was designed and pre-tested. Field testing was conducted using owners of 108 dogs suffering DJD, 48 dogs with lymphoma, and 48 healthy dogs. Data were used to provide evidence for construct validity and to select items for short form generic and disease-specific instruments.

RESULTS: Disturbances in 32 areas of behaviour were identified in dogs with DJD. 93 dog owners generated an initial item pool and 72 owners subsequently selected from that pool descriptive terms and phrases to describe attitude and demeanour of dogs in good health and when suffering chronic pain. Following expert validation of item relevance and adequacy, 109 items were incorporated into an instrument for completion by dog owners in the home. Field-test data for dogs suffering DJD revealed a sensible factor structure accounting for 65% of variance. Scores computed for each of the identified factors (domains of HRQL) showed 88% discrimination between dogs in pain and pain free dogs as identified by clinicians. Candidate items for generic and disease-specific short form instruments have been identified by comparing item response distributions for clinical and control groups. **CONCLUSIONS:** This novel application of psychometric methods will have clinical impact in veterinary medicine; the methodology can be applied to instrument development for other animal populations and to the development of observational instruments for non-verbal human populations.

9/1765/Cross-Cultural Adaptation and Validation of the Daily Spiritual Experience Scale for the Brazilian culture

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AIMS: Spirituality is a subject of growing interest in health care and is considered as an important dimension of quality of life. However, few instruments for its measurement are available in Brazil. The aims of this study were to translate into Brazilian-Portuguese, to cross-culturally adapt and to evaluate the psychometric properties of the

Daily Spiritual Experience Scale (DSES). **METHODS:** DSES is a unidimensional 16-items instrument designed to provide a self-report measure of spiritual experiences in daily life. After formal consent of the author (Lynn G. Underwood), the instrument was translated to Portuguese, translated back into English and culturally adapted to Brazilian environment following the internationally recommended methods. The adapted version was administered by interview to 179 patients from two hospitals in Sao Paulo city. Reliability was assessed by internal consistency (Cronbach's alpha 3 0.70) and temporal stability (ICC 3 0.70). For the test-retest, patients were interviewed twice within a period of 14 days. Convergent validity was examined by correlation with the Duke Religious Index – DUREL (Spearman correlation coefficient). **RESULTS:** After cultural adaptation, Brazilian-Portuguese version of DSES kept the equivalence basically the original structure, with slight modification in four items. Of the 179 patients, 90 (50.3%) were from the public hospital and 89 (49.7%) from the private. The mean age was 53 years (sd=18.2), 53.1% were women, 67.6% catholic, 56.4% with spouse or partner and 39.6% with higher education level. Cronbach's alpha coefficient was 0.91 and ICC was 0.94 (CI 95% 0.88-0.97). The correlation between DSES and DUREL total score was moderate and significant ($r=0.51$; $p=0.000$). **CONCLUSIONS:** The results of this study suggest that the Brazilian-Portuguese version of the DSES can be used as a reliable and valid measure of experiences of spirituality in daily life. Other studies are needed to test its psychometric properties in different contexts and samples.

10/1089/Spirituality, Depression, Symptoms of Distress and Other QOL

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AIMS: To study Spiritual Well being (Sp WB) and its influence on symptoms of distress, depression and other dimensions of Quality of life in advanced cancer patients undergoing palliative care. **METHODS:** The study was cross sectional in nature where 50 patients with advanced cancer from a hospice were assessed with Visual analogue scale for pain (VAP), M.D. Anderson symptom inventory (MDASI), Hospital Anxiety Depression Scale (HADS), Functional assessment of cancer therapy – Palliative Care (FACT-pal) and Functional assessment of chronic illness therapy-spiritual well-being (FACIT-sp). Spirituality was correlated with different variables of other scales. **RESULTS:** Depression and anxiety were negatively correlated with Spiritual well-being (Sp WB). (Sp WB) was significantly correlated with fatigue ($r=-0.423$, $p=0.002$), symptom distress ($r=-0.717$, $p<0.001$), memory disturbance ($r=-0.520$, $p<0.001$), loss of appetite ($r=-0.399$, $p=0.004$), drowsiness ($r=-0.400$, $p=0.004$), dry mouth ($r=-0.381$, $p=0.006$) and sadness ($r=-0.720$, $p<0.001$). Sp WB was positively correlated with all the other aspects of QOL measures. Predictors like palliative care well-being ($t=2.840$, $p=0.008$), distress ($t=-2.582$, $p=0.015$), sad ($t=-2.765$, $p=0.010$), mood ($t=2.440$, $p=0.021$) and enjoyment in life ($t=-3.586$, $p=0.001$) were significantly correlated with Sp WB after regression analysis. **CONCLUSIONS:** This study suggests that Spiritual well being is an important component of quality of life of advanced cancer patients, and is closely related to physical and psychological symptoms of distress. It should be addressed appropriately and adequately in palliative care settings.

CLINICAL PRACTICE & RESEARCH

11/1349/Influence of vision and quality of life on the medication adherence in elderly with diabetic retinopathy

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AIMS: The study aimed to analyze the influence of vision-related quality of life (VRQoL) on medication adherence and the moderator effect of visual acuity (VA) in relationship between VRQoL-adherence in elderly with diabetic retinopathy. **METHODS:** A cross-sectional study was composed of a hundred elderly patients with diabetic retinopathy taking oral antidiabetic/insulin and antihypertensive drugs. Medication adherence was assessed by the proportion of adherence and its association with the care taken in drug administration. The National Eye Institute Visual Function Questionnaire was used to evaluate VRQoL. The joint relation and bivariate analysis (VRQoL x VA) were applied to test the moderator effect of VA in relationship between VRQoL-adherence. **RESULTS:** The majority (58%) was classified as Adherent. Those with worse VRQoL and severe low vision or blindness showed 3.34 and 2.95 higher probability of nonadherence, respectively. The analysis of moderator effect, however, showed that VA does not moderate the relationship between VRQoL and nonadherence, confirming the effect of both on adherence occurs independently. **CONCLUSIONS:** VRQoL is an important determinant of compliance, namely, the perception about the impact of vision on quality of life directly interferes with medication adherence. The perception of worsening VRQoL can not be attributed only to VA, but by other intrinsic and extrinsic factors, not measured in this study.

12/1344/The relationship between medication adherence and quality of life among the elderly with diabetic retinopathy

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AIMS: The aim of this study was to investigate the factors related to medication adherence and its relation to health-related quality of life (HRQoL) in elderly people with diabetic retinopathy. **METHODS:** One hundred elderly out-patients (between 60 and 80 years) diagnosed with diabetic retinopathy in the use of oral antidiabetics/insulin and antihypertensives, were interviewed. Adherence to the prescribed medication was evaluated by the proportion of adherence and its association with the care taken in the administration of the medications and by the Brazilian version of the Morisky Medication Adherence Scale. The National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) was used to evaluate HRQoL. **RESULTS:** The majority of the elderly (58%) reported the use of 80% or more of the prescribed dose and the necessary care in utilizing the medications. These individuals were classified as Adherents. The proportion of adherence was positively correlated to monthly income only for the use of oral antidiabetic/insulin. The analysis of multivariate linear regression demonstrated that the item Interrupt the use of the medication due to feeling worse, from the Morisky Scale, explained 12.8% and 13.5% of the variability of proportion of adherence to antihypertensives and oral antidiabetics/insulin, respectively. The HRQoL (NEI VFQ-25) and the scores on the Morisky Scale influenced medication adherence: individuals with lower scores on the NEI VFQ-25 and higher scores on the Morisky Scale presented a greater chance to be nonadherent. **CONCLUSIONS:** Medication adherence in elderly with diabetic retinopathy was affected by monthly income,

interruption of the medication due to feeling worse and measure of vision-related quality of life. New investigations are suggested with the simultaneous application of generic instruments referring to quality of life, in addition to research on the influence of other factors possibly related to adherence, such as social support, depression and interpersonal relationships.

13/1247/Development of the Eye Treatment Satisfaction Questionnaire: EyeTSQ

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AIMS: To develop UK English and German versions of the EyeTSQ, design based on the DTSQ for diabetes, the MacTSQ for macular disease (MD) and the RetTSQ for diabetic retinopathy (DR) and interviews with patients with cataract, glaucoma, MD, DR. **METHODS:** The EyeTSQ included 14 items about aspects of treatment and an open-ended question about any other sources of satisfaction/dissatisfaction. Data were collected from intervention studies of a) intraocular anti-VEGF injections for DR or MD, n=50, b) cataract surgery in patients with MD, n=103. Principal components analysis identified factor structure, Cronbach's alpha assessed internal consistency. Rasch analyses examined targeting, unidimensionality and differential item functioning (DIF). Construct validity was examined by testing expected relationships of EyeTSQ scores with visual acuity (VA). Content validity was explored using the open-ended question. **RESULTS:** Scores for cataract surgery were extremely positively skewed, those for anti-VEGF injections more normally distributed; Rasch analyses relied on anti-VEGF data. A one-factor solution (all loadings >0.45) had high internal consistency (alpha=0.89), a possible pain/side effects subscale was not sufficiently supported. The full scale was well-targeted; item response options also covered a more negative range than participants' evaluations of treatments studied. Several items displayed disordered thresholds, no DIF was shown across the sex differences found. Women were more apprehensive and less satisfied with risks and side effects. Three items were dropped from the scale to reduce redundancy and improve unidimensionality. As expected, worse VA correlated with worse EyeTSQ scores in the anti-VEGF study (r=0.4). Open-ended question responses (all from UK) indicated no need for new EyeTSQ items but a need for a service satisfaction measure such as the MacSSQ for MD patients. **CONCLUSIONS:** Satisfaction with cataract surgery had a strong ceiling effect in this study. The EyeTSQ is a valid and reliable single-scale measure of satisfaction with anti-VEGF injections for patients with MD or DR.

14/1316/Assessment of Unidimensionality for the Visual Function Questionnaire-Utility Index (VFQ-UI) Items in Patients with Central Vision Loss

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AIMS: The VFQ-UI is a preference-based index based on 6 items from the 25-item National Eye Institute Visual Function Questionnaire (NEI-VFQ-25). This analysis evaluates the

unidimensionality of the VFQ-UI items in patients with vision loss due to macular edema following retinal vein occlusion (RVO) or with noninfectious uveitis. **METHODS:** Secondary analysis of baseline data from 3 clinical trials evaluating the efficacy of dexamethasone intravitreal implant versus sham injection. The analysis includes patients with noninfectious uveitis from a 26-week, multicenter, randomized, double-masked, sham-controlled, parallel group study and patients with RVO from two 6-month, multicenter, masked, randomized, sham-controlled trials. Unidimensionality of the VFQ-UI was evaluated using confirmatory factor analysis (CFA) and item response theory (IRT) analysis (graded response model). Model fit and IRT parameters were compared to the original VFQ-UI development sample. **RESULTS:** For uveitis, there were 229 patients with mean age 44.3 years; 60% were female; and the majority (61%) were Caucasian. For RVO, there were 1,171 patients with mean age 65 years; 54% were male; 78% were Caucasian. The CFA demonstrated a good model fit for the 6 VFQ-UI items in the uveitis (CFI = 0.94, SRMR = 0.038) and RVO samples (CFI = 0.96; SRMR = 0.035). The graded response model fit the data: for uveitis, slopes range from 1.75 to 3.01, and the item responses covered from -1.28 to 2.39 of the construct. In RVO, slopes range from 1.40 to 2.55, and the item responses covered from -1.37 to 4.35 of the construct. The CFAs and IRT analyses are comparable to those from the original VFQ-UI development sample. **CONCLUSIONS:** The CFA and IRT analyses confirmed the unidimensionality of the items within the VFQ-UI and were consistent with the results from the original development sample of patients with central and peripheral vision loss. This study supports the generalizability of the original development sample.

15/1565/Development of pre-validation methodology in the design of a theory-informed instrument: the Aberdeen Glaucoma Questionnaire

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AIMS: To develop a systematic method of item generation and reduction for use in the design of a theory-informed, glaucoma-specific instrument, the Aberdeen Glaucoma Questionnaire (AGQ). A *bottom up* approach using qualitative methods to determine item content ensures that items reflect the intended populations' perspective. However, it fails to use accumulated knowledge from existing instruments, pre-validation item reduction methods are often poorly reported, and instruments may lack a theoretical basis. The International Classification of Functioning, Disability and Health (ICF) includes theoretical constructs representing health outcomes from an individual and societal perspective and was used in this study. **METHODS:** We created an item bank by deconstructing 26 instruments used in glaucoma populations. All items were entered into an Excel spreadsheet and grouped by content. Two phases of de-duplication involved: condensing identically worded items into a single item; merging items with similar content but different timescale or attribution of action. Three phases of item reduction involved discarding items: covered by generic instruments to be administered with AGQ (ie SF-36); irrelevant to glaucoma, or did not measure health outcomes; adjudged poor quality or inferior to other items. Wording of remaining items was adapted to maximise consistency. We assessed the prototype AGQ for coverage of ICF constructs: Impairment, Activity Limitation, Participation Restriction. **RESULTS:** The item bank included 727 items. The two de-duplication phases resulted in reduction of 91 and 225 items respectively. The item reduction phases discarded: 48 items covered

by SF-36; 70 items with irrelevant content and 222 items considered poor or inferior. The prototype AGQ contains 71 items with good ICF coverage. **CONCLUSIONS:** We used systematic methods of item reduction on an existing body of knowledge to develop a prototype theory-informed glaucoma-specific PRO instrument. This methodology is applicable to the development of other new PRO instruments.

16/1439/Development of the Patient-Reported Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)

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AIMS: The standard lexicon for reporting adverse events in National Cancer Institute (NCI) sponsored clinical trials is the Common Terminology Criteria for Adverse Events (CTCAE), which consists of 790 individual items. Currently, all adverse events are reported by clinicians. However, multiple studies have found that clinicians tend to underreport symptom severity and onset compared with patient self-reports. In 2008, the NCI contracted a multi-institution consortium to develop patient versions of CTCAE items and an electronic platform for capturing symptoms from patients and reporting data to healthcare providers and researchers. **METHODS:** A committee including clinical investigators, methodologists, patients, and representatives of NCI and FDA systematically identified CTCAE items with a subjective component amenable to patient reporting. Systematic review and analyses of publications and existing symptom survey datasets and questionnaires were conducted to determine optimal formats for questions, response options, and terms for new *PRO-CTCAE* items. **RESULTS:** 81 symptoms were identified in the CTCAE to be amenable to patient reporting. The format and content of these items were found to be inappropriate for patient reporting in their current form, due to mixing of symptom attributes within items and technical jargon. The committee determined that measured attributes for each symptom should include frequency, severity, and activity interference. Questions and response options were standardized, along with plain language terms for each symptom. A web-based platform was developed for administering the new *PRO-CTCAE* items. **CONCLUSIONS:** In response to a charge from the NCI, the *PRO-CTCAE*, a patient version of the CTCAE system, has been developed. The prototype is undergoing testing to assess validity, usability, and logistical feasibility in a variety of cancer care settings. The *PRO-CTCAE* system has the potential to

enhance adverse event reporting by integrating patient experiences and can foster consistency of data collection methods across studies.

17/1683/Development of a Quality of Life Measure for Evaluating Mucopolysaccharidoses: Preliminary Results From Focal Groups
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AIMS: To create and validate questionnaires to assess QOL of patients with MPS. Mucopolysaccharidoses (MPS) are very rare lysosomal storage disorders. There are only few studies in the literature on quality of life (QOL) for these disorders to better evaluate the efficacy of enzyme replacement therapy, a high-cost therapy presently available for MPS I, II and VI. **METHODS:** The methodology used is that proposed by the WHOQOL group (World Health Organization Quality of Life) (WHOQOL, 1998), which includes the following steps: literature review of the construct QOL in MPS; meeting with specialists; focal groups: 1) health professionals; 2) adult patients; 3) adolescent patients; 4) child patients; 5) relatives and caretakers); pilot study; **RESULTS:** Specialist panel included 15 health professionals, who developed a draft instrument of 41 items covering the main facets of the WHOQOL instrument plus others, such as: happiness, relationship with family and health professionals, protection from relatives and health professionals, autonomy, stigmatization, hope, death, social security, human rights. Focal groups met for 1-3 hours. They were very productive and confirmed the majority of the facets proposed by the specialist's panel. In the social relationships questions, all group concluded that it's an important issue. Patients suggested that to include a definition of treatment to introduce questions on treatment which should be generic. Psychological domain was the most discussed by the groups. Relatives/caretakers and child groups suggested that the questions about appearance and rejection were not important to be in the questionnaire about QOL. Happiness and religiosity were considered important for all groups in this context. Patients generally had a good comprehension of the topics proposed. **CONCLUSIONS:** Using focal groups, we obtained a view of relevant questions to be evaluated in QOL in Mucopolysaccharidoses, also they were very productive pointing to the facets which should be kept, excluded or even added to compose this specific instrument.

18/1217/Assessing the Clinical Significance of Real-time QOL Data in Cancer Patients Treated with Radiation Therapy(RT)
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AIMS: To determine if real time patient-reported QOL can be collected & effectively used by the RT clinical team. **METHODS:** A 2 group, longitudinal design study of 132 head & neck, GI, & lung cancer patients receiving curative RT ± chemotherapy is ongoing to

assess the impact of QOL data on RT practice & patient QOL. Data are collected in 2 groups: a control group (completed) & intervention group (ongoing), 66 patients per group with a 2 month break period between. Patients complete a web based 12 item Linear Analogue Self Assessment (LASA) electronically in exam room before the first RT treatment, during weeks 1, 3, 5 & RT end. In the control group, clinicians had no access to the QOL data for weekly treatment visits. In the intervention group, prior to the weekly visit, clinicians have electronic access with data displayed showing changes in the LASA domains. Disease management pathways, linked to the LASA domains, are displayed electronically to assist in care. At RT end, patients complete the Interpersonal Patient-Provider Relationship (IPPR) Scale & Was it Worth It (WIWI) questionnaire. Clinicians complete the Global Satisfaction Score questionnaire at weeks 1, 3, 5 & RT end & will be interviewed at study end to obtain feedback on use of the QOL data. **RESULTS:** In the control group, 94.6%, 90.5%, 82.4%, 87.8%, and 82.4% had LASA data at baseline, weeks 1, 3, 5 and last week, respectively; 83.8% had IPPR and 82.4% had WIWI data. Decreased LASA scores of overall QOL ($p < 0.001$), mental well being ($p=0.007$), physical well being ($p=0.005$), & social activity level ($p=0.003$) occurred with an increase in pain ($p=0.016$) & fatigue ($p=0.023$) during RT. 82% of patients felt the study worthwhile. 95% would participate again. 94% of clinicians were satisfied/highly satisfied with the communication with their patients. **CONCLUSIONS:** This study is the first reported use of real time QOL data during RT. Collection of PRO/QOL data during RT is feasible. Implementation & lessons learned from the control phase of this real time QOL assessment will be discussed.

19/1393/Using Group-Based Trajectory Modeling to Examine Heterogeneity of Cancer-Related Symptoms
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AIMS: Current knowledge of the longitudinal course of symptoms in patients with cancer is based on single-group studies, regardless of the inter-individual variability that has been revealed by cross-sectional studies. We applied Group-Based Trajectory Modeling (GBTM) to determine whether distinct symptom trajectories can be identified. **METHODS:** Eighty-five patients with head and neck cancer being treated with chemoradiotherapy were recruited. The M. D. Anderson Symptom Inventory-Head and Neck Module (MDASI-HN) was used to assess patient symptoms weekly from starting treatment to 10 weeks after. With an average score of top 5 symptoms (the 5 most severe symptoms at end of treatment) as the dependent variable, GBTM was used to identify patient subgroups with distinct symptom trajectories. The model with the optimal number of groups was determined as that with lowest Bayesian Information Criteria and that with at least 10% of the sample in each group. Using the same model, we also described how these trajectories differed in terms of demographic, disease stage, cancer site, and performance status. **RESULTS:** The top 5 symptoms were problem with tasting food, difficulty swallowing or chewing, problem with mucus, fatigue, and dry mouth. Two trajectories were identified: 33% of patients experienced low symptom burden during the entire period, whereas 67% started with low symptom burden but suffered increasingly severe symptoms during treatment. Patients with ≥ 1 ECOG score at baseline were more likely to experience the increasing symptom trajectory. **CONCLUSIONS:** The two trajectories characterized the heterogeneity in the timing and magnitude of symptoms during chemoradiotherapy of patients with head and neck cancer. Two thirds of patients experienced increasing

symptoms during treatment, which was predicted by poorer baseline performance status. This heterogeneity should be considered in symptom management for cancer patients. Further research is needed to determine additional factors, such as genetic variations, for identifying patients at risk for high symptom burden.

20/1264/Nursing perceptions in Implementation of Health Related Quality of Life Assessment Oncology daily practice

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AIMS: Health Related Quality of Life (HRQoL) assessment by routine and its application represents a crucial step in nursing experience. This paper aims to discuss the routine HRQoL assessment and its use in Oncology Nursing clinical practice. **METHODS:** The nursing perceptions and concerns were registered by direct observation, interviews and questionnaires monitored every week until one month after implementation and since then monthly until three months of experience. Nursing implementation perceptions were evaluated through the manifested accordance of proposed statements in a scale ranging from 1 to 3 (1 - very; 2 - little; 3 - none). Nursing concerns were considered in open questions. **RESULTS:** All nurses involved in routine HRQoL assessment implementation expressed the highest agreement for all aspects considered: HRQoL assessment relevance in Oncology Nursing clinical practice; HRQoL assessment and its useful viability; HRQoL as a health education tool; HRQoL as promoter of patient-centered healthcare. The main concerns expressed related to confidentiality and the limited space available, the Quality of Life Informatics Platform (QoLIP) use; head and neck cancer patients limited autonomy and EORTC QLQ-C30 and EORTC H&N 35 questionnaires results interpretation. One month later, all these concerns had disappeared. **CONCLUSIONS:** In this study we conclude that the development and application success of HRQL assessment in oncology daily practice deeply depends on caregivers involvement. The communication between researchers and health professionals team minimize the implementation risks and may contribute to eliminate all the concerns that inevitably might appear in the HRQoL Assessment Implementation.

21/1644/The FACT-G is Valid for Monitoring HRQoL in Non-Hodgkin Lymphoma Patients

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AIMS: The Functional Assessment of Cancer Therapy-General (FACT-G) was initially validated in a sample of mixed cancer patients, of which only 8% were hematologic cancers. Furthermore, the FACT-G is intended to assess HRQoL for patients on active treatment. Our objectives were to 1) assess the validity of the FACT-G in a large sample of non-Hodgkin lymphoma (NHL) patients; and 2) determine the validity of administering the FACT-G over time in patients on active treatment/progression, in remission and on observation. **METHODS:** Using a longitudinal study of

prospectively enrolled, newly diagnosed NHL patients, the FACT-G was assessed at baseline (n=611), 12 months (n=434), 24 months (n=422) and 36 months (n=231) after diagnosis. Initial FACT-G validation analyses conducted by Cella et al. (2003) were replicated using the baseline and 12 month data. In addition, we evaluated corrected item-total correlation (ITC) and percent missing for each item at all assessments to identify items that may be less useful in certain patient subsets. **RESULTS:** The FACT-G subscales and total score demonstrated good internal consistency reliability (alphas 0.73-0.90). The FACT-G total score was convergent with measures of mood disturbance, anxiety, performance status (PS) and global QoL. Results for known-groups (PS, disease severity) validity and sensitivity to change in PS and global QoL were comparable to those in Cella et al. (2003). The item "I am bothered by side effects of treatment" had a low ITC (<0.40) and high percent missing (>10%) among patients on observation. Two other items, "I have nausea" and "I am losing hope in the fight against my illness," had low ITCs among patients in remission. One item, "I am satisfied with how I am coping with my illness," had low ITCs among all three groups. Most of these ITC results are not remarkably different from item-level data for other cancer samples. **CONCLUSIONS:** The FACT-G is a valid measure for monitoring HRQoL over time in NHL patients. However, sensitivity analyses based on subscale scoring that excludes potentially problematic items may be warranted.

22/1323/Culturally Relevant Cancer Risk Counseling for Underserved Latinas

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AIMS: The primary purpose of this project was to evaluate the effects of a culturally relevant GCRA intervention and QOL for Latinas. **METHODS:** Four focus groups were conducted consisting of Latinas that have undergone GCRA. Participants completed a demographic questionnaire that included items assessing perceived cancer risk and satisfaction with GCRA. The focus groups entailed a facilitated discussion of the key study variables and other culturally relevant issues that may impact the GCRA intervention and QOL. **RESULTS:** Perceived sense of lack of information and uncertainty about what to expect appeared to play a key role in distress. Most women initially had negative expectations (expecting the worse or bad outcome), but ultimately felt hopeful that they could learn more about the GCRA process and what it meant for them. Information was cited as the primary contributor to positive psychosocial outcomes specifically increased locus of control and self-efficacy. The major cultural themes identified were destino, religious and spiritual coping, how cultural attitudes and belief influence lack of information, community awareness, and public health issues. **CONCLUSIONS:** The pre-GCRA window may be most distressing for this population indicating that this may be the most appropriate time for psychological intervention.

23/1109/The Relationship between Weight Loss and Quality of Life in Persons Treated for Head and Neck Cancer

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AIMS: This study explores the relationship between weight loss, quality of life (QOL) and symptom burden in patients treated for

head and neck cancers. **METHODS:** Participants completed the Functional Assessment of Cancer Therapy Head and Neck (FACT-HN) and the Memorial Symptom Assessment Scale (MSAS) pre-treatment, mid-treatment and post-treatment. Weights were recorded prior to treatment and at the post-treatment follow-up visit and percentage weight loss was tabulated. Relationships between weight loss, QOL and symptom burden were evaluated using the nonparametric Spearman Rho. A simple linear regression model was developed to examine the influence weight loss has on QOL in a predictive manner. **RESULTS:** Average weight loss per patient was 12.4 pounds with a modal value of 19. Weight loss was found to be significantly correlated with decreases in physical well-being, functional well-being, the Head and Neck specific subscale and composite QOL scores. No significant correlations were found between weight loss and symptom burden as measured by the MSAS. Linear regression suggested that a 10% decrease in baseline weight resulted in a 19% decrease in the FACT-HN score.

CONCLUSIONS: The strong association between weight loss and quality of life supports the importance of efforts to prevent weight loss via patient education, aggressive monitoring and immediate intervention to stop or reverse weight loss during treatment. New approaches to the weight-loss and wasting experienced by patients should be developed and tested.

24/1505/Developing a disease specific PRO reporting system for patients receiving radiotherapy

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AIMS: We describe a new computer application designed to acquire symptom and function PRO's from patients undergoing radiotherapy and generate reports in time for clinician visits. **METHODS:** For the computerized assessment instrument we used a graphic user interface we previously developed for elderly patients receiving chemotherapy. Designed to run as a series of web pages, subjects use a touch screen monitor to input their responses. The graphic user interface uses vivid contrast colors, large font type, and large response buttons to maximize ease-of-use. Initial items were adapted from the Memorial Symptom Assessment Scale. However, feedback from a focus group of radiation oncologists suggested that a general questionnaire would not be as useful as one that included items for radiotherapy and specific cancers. Therefore, through 1 on 1 interviews with clinicians we identified what they perceived to be the most important site specific cancer symptoms from lists compiled by abstracting symptoms included in site specific cancer HRQOL instruments created by the EORTC, FACT, and others. **RESULTS:** The final version of the computerized symptom assessment summary includes 4 sections: General (self rated Karnofsky performance status, ADLs, overall QOL, etc.), Common cancer symptoms (pain, nausea, fatigue, depression, etc.), Skin changes, and 12 different site specific cancer question groups (brain, prostate, breast, head & neck, palliative, etc.). Branching question architecture minimizes response time for patients with fewer symptoms. The application prints a 2 page report summarizing current symptoms and up to 3 previous time points. The report is organized anatomically and provides other visual cues to make it easier to rapidly decipher (e.g. severe symptoms have darker shading). **CONCLUSIONS:** Radiotherapy is an understudied HRQOL area compared to chemotherapy. The next step is testing this application's usefulness and impact on patient symptoms and clinician behavior in a randomized clinical trial.

25/1531/Effects of mood disturbance, fatigue, insomnia, and pain on quality of life of patients receiving cancer therapy

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AIMS: Most patients with cancer suffer from a multitude of intense physical and psychological symptoms. The current paper describes the prevalence of mood disturbance, fatigue, insomnia, and pain (MFIP), alone and in combination in cancer patients, as well as the inter-correlations among these four symptoms, and whether MFIP predicted the impairment of quality of life (QoL) during cancer therapy. **METHODS:** This cross-sectional study used secondary data from a convenience sample of 214 patients, 18 years of age and older, with solid tumor receiving chemotherapy or radiotherapy. Measuring instruments included the respective items from the SDS (C), and the FACT-G (C). The influence of the MFIP on patients' QoL was determined by hierarchical multiple regression. **RESULTS:** 87% of the patients reported mood disturbance, 66% reported fatigue, 68% reported insomnia, and 38% reported pain. 29% and 30% of patients reported co-occurrence of any three symptoms of MFIP and all of the four symptoms, respectively. The inter-correlations among MFIP were mild to moderate ($r = 0.29$ to 0.43 , $p < 0.01$). The mean FACT-G (C) physical, social, emotional and functional subscale scores were 20.5 ± 5.8 , 19.2 ± 4.1 , 17.4 ± 4.4 and 13.5 ± 6.5 , respectively. The mean FACT-G (C) total score was 76.0 ± 17.2 . Correlations between the FACT-G (C) subscale/total scores and the MFIP scores showed moderate negative correlations of the physical ($r = -0.39$ to -0.55 , $p < 0.001$), emotional ($r = -0.24$ to -0.53 , $p < 0.01$), and functional ($r = -0.43$ to -0.52 , $p < 0.001$) subscales and total ($r = -0.44$ to -0.57 , $p < 0.01$) scores with the four symptoms. Significant differences were found in all FACT-G(C) subscale/total scores among with different number of combinations of MFIP ($p < 0.01$). About 8.5 to 42.5% of variance in QoL is explained by the MFIP after adjustment for confounders. **CONCLUSIONS:** Our results suggest that MFIP are highly prevalent in patients who were undergone cancer therapy. These four symptoms may negatively influence patients' QoL during cancer therapy.

26/1542/Applicability And Characteristics of the New Instrument for Comprehensive Symptom Profile Assessment in Patients with Malignant Lymphomas

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AIMS: Symptom assessment before and during treatment of lymphoma patients might ensure adequate symptom control. Comprehensive assessment of symptoms due to the disease and its treatment is worthwhile. We aimed to develop a new symptom assessment tool: Comprehensive Symptom Profile in Lymphoma Patients (CSP-Lym) and test its applicability in this patient population. **METHODS:** CSP-Lym is being developed to assess the severity of 45 symptoms specific for lymphoma patients. It consists of numerical rating scales, scored from (no symptom) to 10 (most expressed symptom). Thirteen clusters of symptoms have been

identified, which were clinically relevant and increased the practicability of the tool. Applicability of CSP-Lym with preliminary analysis of psychometric properties was tested in a pilot study. Forty seven patients with different types of malignant lymphomas (Stage II-IV) were included in the study: Non-Hodgkins lymphoma 13; Hodgkins lymphoma 33. Mean age was 34 years old; male/female distribution 15/22. **RESULTS:** The utility of CSP-Lym was demonstrated: all the items were easy for the patients to read and understand; the data produced by the tool were clear for interpretation by physicians and were used by them in clinical decision making. Reliability of CSP-Lym was satisfactory (Chronbachs alpha coefficient varied from 0.60 to 0.98). The construct validity of CSP-Lym was proved by factor analysis and known-group comparison. Statistically significant differences ($p < 0.05$) in symptom severity were found in the groups with different patient status. Sensitivity to changes was demonstrated by comparison of symptom severity before and after treatment. **CONCLUSIONS:** Thus, CSP-Lym is an appropriate and practical tool to assess the symptom severity in lymphoma patients. The utility of the questionnaire was shown; preliminary psychometric properties appeared to be satisfactory. Further studies are needed before the wide-spread use of CSP-Lym in clinical practice and clinical trials.

27/1087/Development and Validation of the System of Quality of Life Instruments for Cancer Patients (QLICP) in China
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AIMS: To develop a Chinese QOL instruments system called QLICP (Quality of Life Instruments for Cancer patients), considering that the Chinese cultures are not fully captured in most existed QOL instruments such as FACTs and EORTC QLQs. The QLICP are expected to include more than 20 cancer-specific instruments such as lung cancer (QLICP-LU), breast cancer (QLICP-BR) and head and neck cancer (QLICP-HN). **METHODS:** Based on WHO's definition of QOL and programmed decision procedures including nominal group, focus group discussion, in-depth interview, pilot test and field test, the QLICP was developed by the modular approach, with general module (QLICP-GM) being used to all types of cancers and developed first and then specific modules developed only for specific cancers. Psychometric properties of the scale were evaluated by the field tests of longitudinal design with some indicators of Cronbach alpha, Pearson r, SRM (standardized response mean) and statistical methods of correlational analysis, t-tests, factor analysis and structural equation modeling. **RESULTS:** The 32 items QLICP-GM and 12 specific modules with the numbers of items ranging from 8 to 20 have been developed. All QLICP instruments have a very clear hierarchical structure (items-> facets-> domains-> overall). Correlational and factor analysis or structural equation model indicated good construct validity for all 12 available instruments. Good criterion-related validity coefficients were confirmed given relevant FACTs and/or EORTC QLQs as the criterions (for example, QLICP-LU vs FACT-L). Test-retest reliability coefficients for most domains of most instruments were higher than 0.80, and the internal consistency alpha were higher than 0.70. Most domains and overall scores of most instruments had a statistically significant change after treatments with moderate or higher effect size, SRM. **CONCLUSIONS:** The all scales of the system of QLICP have good validity, reliability and responsiveness and can be used as QOL instruments for cancer patients in China.

28/1563/An interpretation strategy for outcomes from the Expanded Prostate Index Composite (EPIC)

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AIMS: Clinical interpretability of Quality of Life scores has been identified as one of the barriers to the use of this type of measure. Our objective was to facilitate the interpretability of results using a classification of symptoms' severity according to EPIC. **METHODS:** This is a prospective study of 612 patients with localized prostate cancer. The EPIC was administered before and after treatment up to three years of follow-up. The EPIC includes 50 items grouped into five scales (urinary incontinence, urinary irritative/obstructive symptoms, bowel, sexual and hormonal) with scores ranging from 0 to 100. Furthermore, a classification based on the distressful levels of symptoms was constructed: "No relevant problem"; "small to moderate problem" for patients reporting at least one distressful symptom; and "severe problem" for patients with one or more very distressful symptoms. To show the occurrence of treatment adverse effects, bar charts were constructed for outcomes at three years, according to their symptoms' severity at baseline. Differences on mean scores by severity groups were tested using analysis of variance. **RESULTS:** Considering patients with no relevant problem at baseline, around 60%, 45% and 35% of patients presented sexual, hormonal and urinary side effects (small to severe problems). Improvement was observed in around 30% of patients with urinary symptoms at baseline. Bowel side effects were less frequent (23%). All EPIC scales showed statistically significant mean differences among severity groups (i.e. urinary incontinence mean scores were 100, 74.9 and 43.8 for "no relevant", "small to moderate" and "severe" problems groups; $p < 0.001$). **CONCLUSIONS:** This interpretation approach provides outcomes at an individual level and it could facilitate communicating the results in a meaningful way for patients. The high magnitude of

mean differences obtained among severity groups supports the validity of the proposed classification.

29/1624/Gender and age differences on quality of life and psychopathological symptoms of HIV-infected patients

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AIMS: The aim of this study was to determine gender and age differences and interaction effects in quality of life (QoL) domains and psychopathological symptoms in a sample of Portuguese HIV-positive patients, and to examine to which degree psychopathological symptoms are associated with quality of life in addition to sociodemographic variables, and which domains are most affected. **METHODS:** The WHOQOL-HIV-Bref was administered to a sample of 1065 HIV-positive patients, attending the main services/departments of infectious diseases of Portugal. Patients also completed the Portuguese version of Brief Symptom Inventory (BSI). **RESULTS:** Controlling for clinical status, there was a significant effect of gender on QoL ($p < .001$), and psychopathology ($p < .01$). Women reported lower scores on Psychological and Spirituality QoL and higher scores in psychopathology. Age by gender interactions emerged on all QoL domains but Independence, and on Somatization and Anxiety. Patients under 34 years reported significantly higher QoL on Physical and Independence domains. The interaction effect between gender and age was significant on QoL ($p < .05$) and Depression ($p < .05$). Overall, women under 34 reported higher QoL and lower psychopathology. Women over 45 years showed poorer scores on QoL and higher psychopathological symptoms. Psychopathological symptoms contributed significantly to the variance of QoL domains. **CONCLUSIONS:** Understanding gender and age differences (and their interaction) may provide potentially useful information for tailoring interventions to improve QoL and mental health among people infected with HIV/AIDS, especially among women.

30/1629/Assessing the factor structure and factorial invariance across gender and HIV status of the European Portuguese Version of WHOQOL-HIV-Bref

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AIMS: The aim of this study was to investigate the factor structure of the European Portuguese version of the abbreviated version of the World Health Organization's Quality of Life Instrument in HIV Infection (WHOQOL-HIV-Bref). Also, we intended to test the factorial invariance across gender and HIV status. **METHODS:** Exploratory confirmatory analysis (EFA) and confirmatory factors analysis (CFA) were conducted on self-report WHOQOL-HIV-Bref data from 1196 HIV-positive patients, attending the main services/departments of infectious diseases of Portugal. **RESULTS:** The EFA yielded a five-domain structure for the WHOQOL-HIV-Bref, suggesting some modifications in the original six-domain model (in Psychological and Spirituality domains). A CFA was conducted to compare the performance of our EFA model with the original WHO model and a modified six-domain model. The results of CFA revealed that the EFA model and the modified model had similar performances on the fit indices, and fitted better than the original WHO model. Overall, the modified model showed the best fit. Gender and disease stage models were satisfactory. In general, all models fitted best for men and asymptomatic patients. **CONCLUSIONS:** The CFA results revealed

that there is alternative model for the WHOQOL-HIV-Bref. Although the original model is still acceptable, more studies on the factor structure of this instrument are warranted.

31/1269/Psychometric evaluation of a new measure of QOL for Chinese people living with HIV/AIDS

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AIMS: HIV infection causes great impact to the QoL of infected people. As there is a lack of measure developed from the perspective of Chinese people living with HIV/AIDS (CHA), a study is undertaken to develop and validate a QoL measure for CHA in Hong Kong (HK). This paper describes the concurrent and known-groups validities. **METHODS:** A cross sectional survey was used and 240 CHA of two major HIV clinics completed the new measure CHAQoL, WHOQOL-BREF (HK), and HIV Stigma Subscale (HSS). Clinical data: HIV diagnosed date, antiretroviral therapy start date and side effects, latest disease stage, CD4 count, and viral load, were collected from subjects and their records. Descriptive statistics, Pearson correlation, independent sample T-test were used for data analysis. **RESULTS:** From Feb to April 2009, 289 CHA were invited, 239 (83%) consented and participated in this study. Subjects' mean age was 43 ± 11 (range 20–75) years, and 215 (90%) were males. About 73% ($n=174$) of them were receiving antiretroviral therapy, 46% ($n=109$) with heterosexual contact, 22% ($n=52$) diagnosed HIV ≤ 1 year, and 22% ($n=52$) with latest CD4 count ≤ 200 cells/uL. All CHAQoL subscales had small to moderate correlations ($r=0.26$ to 0.79 , $p < 0.01$) with WHOQOL-BREF domains but only three subscales significantly correlated with HSS ($r=0.22$ to 0.50 , $p < 0.05$). CHAQoL could distinguish subjects of HIV diagnosis ≤ 1 year from those > 1 year in 2 subscales: living with HIV (mean difference=7, $p=0.02$), stigma and discrimination (mean difference=12.4, $p < 0.01$); of CD4 count ≤ 200 cells/uL from those above in 4 subscales: life satisfaction, emotion wellbeing, living with HIV, and intimate relationship (mean differences=13.2, 11.0, 8.5, 12.9 respectively, all $p < 0.01$). **CONCLUSIONS:** These results suggest that CHAQoL, WHOQOL-BREF, and HSS measured related but different constructs. CHAQoL has good psychometric properties and can distinguish CHA with recent diagnosis and low CD4 count. Much work is still needed in strengthening the psychometric qualities by demonstrating its ability to detect outcome changes over time.

32/1124/Quality of Life, Pessimism and Life Satisfaction in HIV Positive People (A study from India)

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AIMS: This study aims to assess the quality of life and life satisfaction of HIV positive persons along with the extent of hopelessness(pessimism)manifested in them. The correlates of these dimensions with selected demographic and socio-economic variables have also been brought out. **METHODS:** The participants were HIV positive adults ($N=309$, male-100, female-209), registered with Network for Positive People a NGO in Tamilnadu, India. The Hopelessness Scale (Beck & Wiseman, 1974), Satisfaction with Life Scale (Diener, 1985) and Quality of Life Scale (WHOQOL-HIVBREF-31, 2002) were administered. **RESULTS:** The mean age of the respondents was 33.3 years, a quarter of them were illiterate and the rest of them had varying levels of school education. Most of them were agricultural labourers on daily wages with an average monthly

family income of Rs.3427(\$75).60% of the women had contacted the infection from their husbands and had it for a mean duration of 3.7 years. Based on group mean for each dimension, results indicate that the majority of respondents scored *_low_* on quality of life (59.9%) and were classified as being *_low_* (55%) on pessimism and life satisfaction (48%). The quality of life score showed a highly significant positive correlation with the life satisfaction score ($r=0.46, p<0.01$) and a highly significant negative correlation with the hopelessness score ($r=-0.57, p<0.001$) and all its sub-dimensions. No statistically significant gender based differences were observed on the total quality of life score. However female respondents showed a significant difference from male respondents on the overall pessimism score ($p<0.05$) and the life satisfaction score ($p<0.01$). Regression analysis shows that two sub-dimensions of pessimism namely feelings about the future and future expectations along with the life satisfaction score account for 36.9% in predicting quality of life. **CONCLUSIONS:** The findings are in consonance with the Western literature which indicates that there is substantial morbidity associated with HIV (Hays et al. 2000) and indicate areas of intervention which merit attention.

33/1150/Doing research into social participation in people with aphasia: yes, we can!

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AIMS: Background and aims: People with aphasia are often excluded from research because of their communication impairments, especially when an investigation into the communication impairment is not the primary goal. In our research concerning social participation of people with aphasia, we wanted to include people with mild, moderate as well as severe aphasia. We aimed to suggest strategies and techniques for research in people with aphasia based upon experiences in conducting research in this group of people. **METHODS:** We conducted a qualitative study in 13 people with aphasia (mild to severe) and a quantitative cross-sectional study in 150 people with aphasia (mild to severe) concerning their social participation. In these studies different strategies were developed to facilitate inclusion of people with aphasia, even with severe communication problems. Several strategies have been evaluated. The psychometric properties of the CIQ adjusted for people with aphasia were investigated and were positive (see submission for poster presentation) **RESULTS:** It is possible to conduct research in this group. Several strategies can help to make this mission possible: the use of pre-structured diaries, the use of in depth interviews with attention to the non-verbal utterances, the use of existing measurements (like the Barthel Index, COOP-WONCA, the Community Integration Questionnaire, Life Satisfaction Questionnaire), adjusted for people with aphasia by: using pictograms, placing one question per page, bolding the key concepts in the question, using large font, visualizing the answering possibilities in word and in picture, reducing the question length, and excluding negatives in the question. **CONCLUSIONS:** Research into social participation in people with aphasia is possible when using strategies adjusted to the communicative impairment.

34/1151/The psychometric properties of the Community Integration Questionnaire adjusted for people with aphasia
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AIMS: People with aphasia are often excluded from research. We adjusted the Community Integration Questionnaire for people with aphasia to make inclusion into research possible. The aim of this study was to describe the feasibility of the Community Integration Questionnaire adjusted for use in people with aphasia and to report its psychometric properties in people with aphasia (internal consistency, factor analysis, test-retest reliability, convergent validity). **METHODS:** A cross-sectional, interview-based psychometric study was conducted. Test-retest reliability was evaluated in twenty people (minimal to severe aphasia) by two different interviewers within a two week period. In total 490 stroke survivors with (minimal to severe) aphasia were approached of which 165 (34%) participants returned the answering letter. 150 participants agreed to take part and were interviewed using a structured interview format. The main outcome measures were the Community Integration Questionnaire, Frenchay Aphasia Screening Test, Barthel Index, COOP-WONCA Charts and the Life Satisfaction Questionnaire. **RESULTS:** A total of 150 stroke survivors with aphasia completed the Community Integration Questionnaire adjusted for people with aphasia. The CIQ adjusted for people with aphasia was a feasible instrument. Results showed good internal consistency for the CIQ total (standardized Cronbach's alpha = 0.75), excellent test-retest reliability (ICC=0.96), moderate correlations with the Barthel Index, the COOP-WONCA and the Life Satisfaction Questionnaire with regard to construct validity. Significant relations were found with regard to age and aphasia severity. **CONCLUSIONS:** The CIQ adjusted for people with aphasia seems to be an adequate instrument to assess participation in people with aphasia.

35/1425/The importance of guidelines for ClinROs: the ADAS-Cog, a case study

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AIMS: Since its development in the 80's, variations of the Alzheimer's Disease Assessment Scale-Cognitive subscale (ADAS-Cog), a Clinician-Reported Outcome (ClinRO) measure, have been used to monitor disease progression and treatment efficacy in Alzheimer's disease. The objective of this study was to identify all versions used as a basis for translation in MAPI Institute's projects and to take stock of existing translations. **METHODS:** The review was based on all ADAS-Cog translation projects performed by MAPI Institute. **RESULTS:** Sixteen projects were identified representing a total of 70 languages and 219 translations. Translations were based on 11 source versions which differed in terms of content (number of items, order of items and instructions), and format. The number of items ranged from 11 to 15. Four studies used 13 items, but only in two cases the same items were used although in a different order. Four studies used 12 items: only two studies used the same items (with a different list of words for the Word Recognition Task), but again in a different order. Format and instructions differed in all cases. In most projects the source version provided by the sponsor was a single document mixing instructions with the rater and response forms. Only in 3 cases the original consisted in a separate

instruction manual and response forms. With regard to available translations, more than one translation was identified in 56 of the 70 available languages, and in one language (Swedish) as many as 7 translations, all different in terms of content and format. **CONCLUSIONS:** The abundance of different versions of the same questionnaire both in its original US English form as in translations makes comparisons between studies or pooling of data difficult for both researchers and users. In its recent guidance for the use of PRO measures in clinical trials, the FDA requests scientific rigor in the development and use of PRO measures. In the light of our findings, it might make sense to ask for the development of a similar document for ClinROs.

36/1143/Using Novel Information Technology to Assess Baseline Health and Functional Status of Patients with Multiple Sclerosis in a Clinical Population: proof of concept and clinical findings
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AIMS: To describe baseline demographics and patient- and clinician-reported health and functional status measures (HSMS) collected during routine processes of care of patients with multiple sclerosis (MS) at Cleveland Clinic Mellen Center for MS by using The Knowledge Program (TKP), an innovative information technology (IT) program. **METHODS:** Data extracted from TKP database were limited to MS or related conditions at the first visit after TKP rollout, January 1, 2008–June 23, 2009. Demographic data were obtained plus HSMS: EuroQoL, Personal Health Questionnaire-9 (PHQ-9), MS Performance Scales (MSPS), Timed 25-Foot Walk (T25-FW) and 9-Hole Peg Test (9-HPT). Analyses used non-parametric methods (SAS, 9.2). **RESULTS:** 4,185 unique patients were identified. Mean(SD) age was 47.3 (11.6) years, 74.2% female, 64.5% married, 84.1% white, 10.3% African-American; 79.0% had a primary diagnosis of MS. Mean(SD) EuroQoL score=0.71(0.21), PHQ-9=6.77(6.09), MSPS=12.10(7.83), T25-FW=7.81(8.43), 9-HPT=25.11(12.94). The 9-HPT which had the greatest number of univariate associations with demographic variables and regression analysis demonstrated Females, Caucasians, married, and younger patients reported shorter times, indicating better hand function. **CONCLUSIONS:** While this cross-sectional data provides a profile of our clinic population, routine longitudinal data collection using this method is proving useful in monitoring individual patients as part of clinical care.

37/1411/Using the Liverpool Quality of Life battery to develop a health state classification system for Epilepsy

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AIMS: Cost-utility analysis requires health state values before and after each intervention. Generic measures of health related quality of life (HRQOL) are usually used to produce these values, but there are concerns about their relevance and sensitivity in epilepsy. The Liverpool QOL battery is a validated questionnaire for measuring QOL in epilepsy, but has too many dimensions and items to

incorporate values. This study develops a health state classification system for epilepsy, and is the first system amenable to valuation to be produced from a battery. **METHODS:** Factor, Rasch and other psychometric analyses were undertaken to assess the validity and responsiveness of all items, investigate the factor structure of the battery and inform dimension and item selection for inclusion in the classification. Analysis was carried out on a trial dataset of patients with epilepsy (n=1611). Rasch and factor analysis were performed on one half of the sample and validated on the remaining half. Dimensions and items were selected that performed well across all analyses. Rasch item selection criteria included item-level ordering, item fit, severity range coverage and non-differential functioning across subgroups. **RESULTS:** The battery demonstrated reliability and validity, but responsiveness across time periods for many of the items was low. A 5 factor model (explaining 53% of the variance) performed best and following the Rasch analysis 2 factors were split into 2 separate dimensions and a further dimension added. Combining all analyses a 6 dimension classification system was developed: worry about seizures, depression, memory, cognition, stigmatisation and mastery, each with 4 response levels. **CONCLUSIONS:** It is feasible to develop a health state classification system from a battery of instruments using a combination of classical psychometric, factor and Rasch analysis. This is the first condition-specific health state classification developed for epilepsy and the next stage will produce preference weights to enable the measure to be used in cost-utility analysis.

38/1564/Development of a conceptual model of quality of life in care home residents with multiple sclerosis

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AIMS: Some people with multiple sclerosis (MS) will eventually require care provided by care homes. However, there is limited research on care home residents with MS, who are often younger and more disabled than the average resident. The experiences of MS residents were investigated, and a conceptual and measurement model of quality of life (QoL) was developed to guide construction of a measure of QoL for this population. **METHODS:** Individual in-depth interviews were conducted with 21 people with MS living in a range of care homes. A literature review of QoL in care homes and focus groups with care staff and family members were also conducted. The interviews and focus groups were transcribed verbatim and analysed using an approach informed by grounded theory, using constant comparative approach to formulate open, axial and selective codes that resulted in core domains. **RESULTS:** Four core model domains were identified with several subcategories: 1) What the care home means to the residents (Acceptance of care home, Moving to care home, Missing their own home), 2) Self (Self concept, Control, MS, Life Satisfaction), 3) Environment (Physical environment, Engagement in Activities, Privacy, Feeling safe, Personal care) and 4) Relationships with others (Relationships with important others, Interactions with care staff, Relationships with other residents). The domain, what the care home means to the residents, was central to the understanding of QoL. MS residents differed in their attitudes to the care homes, with some expressing more acceptance of their situation than others. **CONCLUSIONS:** QoL is a broad, multidimensional construct for care home residents with MS. A perspective focusing on interactions of factors that are both intrinsic (e.g. attitudes to care home) and extrinsic (e.g. environment) to the individual are necessary to facilitate good QoL in the care home, and services and policy decisions need to reflect these views of MS residents. A

measurement tool based on this conceptual model, for use in audit and treatment evaluations, is now in development.

39/1709/Quality of Life in persons with Physical Disabilities caused by neurodegenerative disorders: Using the WHOQOL-DIS

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AIMS: Neurodegenerative (ND) disorders have a major impact on Quality of Life. ND might cause physical disability and place a substantial burden on patients, their families and carers, as well as on society. This study examined Quality of Life in persons with Multiple Sclerosis (MS) and Parkinson's disease (PD) using a battery of subjective assessments including the WHOQOL-BREF and the WHOQOL-DIS (Disability module). Preliminary psychometric properties of the WHOQOL were investigated and its suitability was assessed. **METHODS:** Participants (n=149) were recruited and interviewed at two specific units for MS and PD in Barcelona (Spain) to obtain sociodemographic information, health perceptions, depressive symptoms (HADS-D), fatigue (FAS), generic QoL (WHOQOL-BREF and WHOQOL-DIS), and specific QoL (MSIS-29 and PDQ-39). **RESULTS:** WHOQOL-BREF/DIS reliability was good. Internal consistency measured by Cronbach's alpha range from .81 (Disability) to 0.67 (Social Relations). Associations were confirmed between WHOQOL-BREF/DIS domains with HADS-D, FAS, MSIS-29 and PDQ-39. Discriminant validity tests, in the form of known group differences, showed that WHOQOL-BREF/DIS scores significantly discriminated between healthy and unhealthy, participants reporting low-moderate versus severe-profound effect of the disability in their life, and depressed and non-depressed (using a cut-off of 8 on the HADS-D). **CONCLUSIONS:** This study is the first to report on use of the WHOQOL-BREF/DIS in persons with neurological disorders causing physical disabilities. These results indicate that WHOQOL-BREF/DIS is a useful tool in assessing Quality of Life in these groups.

40/1353/Cognition and quality of life in multiple sclerosis patients: BRB-N and MusiQoL

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AIMS: Nearly half of all patients diagnosed with multiple sclerosis (MS) will develop cognitive dysfunction. Studies shown from no/weak impact to a strong impact of cognitive impairment on quality of life (QoL). The aim of this study was to assess the impact of cognitive dysfunction on the self-reported QoL in MS patients while taking into account the key confounding factors. **METHODS:** Design: cross-sectional study. Inclusion criteria: MS patients of any disease subtype. Data collection: sociodemographic (age, gender, marital status, education level, occupational activity) and clinical data (MS subtype, disease duration); MS disability (Expanded Disability Status Scale, EDSS); depression (Beck Depression Inventory); fatigue (Modified Fatigue Impact Scale); QoL (SF36 and MusiQoL);

and neuropsychological performance (Brief Repeatable Battery of Neuropsychological Tests, BRB-N). Statistical analysis: multiple linear regressions (forward-stepwise selection). **RESULTS:** One hundred and twenty-four patients were enrolled. Performance on BRB-N subtests varied widely (6% to 70% abnormal). The BRB-N classified 37% of the patients as being affected by cognitive impairment. A multivariate analysis showed no links between the MusiQoL index and cognitive subtests, whereas marital status, age, EDSS, and depression were found to be independent predictive factors. **CONCLUSIONS:** The present study demonstrated the weak and scarce association between cognitive impairment and QoL, when confounding factors were accounted for. These results need to be confirmed with larger samples, using more accurate tests of cognitive function.

41/1272/Changes and differences in the health-related quality of life among patients undergoing rehabilitation

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AIMS: Many of the various health-related quality of life (HRQL) scales currently being used in rehabilitation involve self-assessment by the subjects themselves. However, in many cases the individuals undergoing rehabilitation have difficulty assessing themselves due to conditions such as impaired consciousness, aphasia, and cognitive impairment. We therefore evaluated HRQL using a utility measure, which enables proxy-assessment, and investigated the effectiveness of rehabilitation as well as differences between diseases. **METHODS:** A multicenter longitudinal study was conducted on patients with cerebrovascular disease or fracture of the proximal femur. The Japanese version of the Health Utilities Index Mark 3 (HUI3), which enables calculation of both the global (for all domains) and single (for each domain, specifically vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain) utility scores, was used as the HRQL scale. The scale was completed at the start of rehabilitation and at either discharge by proxy by the therapists providing care. **RESULTS:** Subjects were 120 patients comprising 72 patients with cerebrovascular disease and 48 with fracture of the proximal femur. The mean ages were 74.3 overall, 69.7 for patients with cerebrovascular disease, and 81.2 years for patients with fracture of the proximal femur. Utility scores significantly increased following rehabilitation from 0.00 to 0.16, 0.02 to 0.19, and -0.03 to 0.12, respectively. Comparison of utility scores for cerebrovascular disease and fracture of the proximal femur showed no differences between diseases for the global score, but single scores for speech and dexterity were lower for cerebrovascular disease and those for ambulation and pain were significantly lower for fracture of the proximal femur. **CONCLUSIONS:** The present findings indicate that rehabilitation enhances HRQL, and differences in single scores were observed between cerebrovascular disease and fracture of the proximal femur, and this finding may be useful as reference for rehabilitation in the future.

42/1070/The Construct Validity of the Health Utilities Index Mark 3 (HUI3) in Assessing Health Status in Lung Transplantation

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AIMS: To assess the cross-sectional construct validity of the HUI3 in lung transplant patients. **METHODS:** 213 patients (103 pre- and 110 post-transplant) with mean age 53 years old (SD 13) were recruited during a randomized controlled clinical trial at the out-patient clinic of a tertiary institution. At baseline, patients self-completed HUI3, EuroQol EQ-5D, Hospital Anxiety and Depression Scale (HADS) and socio-demographic questionnaires. Six-minute walk test (6MWT) scores and forced expiratory volume in 1 second data were collected from patient's medical records. A priori hypotheses were formulated by members of the transplant team about the expected degree of association between the measures. Correlation coefficients of <0.1 were considered as negligible, 0.1 – <0.3 as small, 0.3 – <0.5 as medium, and >0.5 as large. Convergent and divergent validity and known-groups comparisons were made. Pearson correlations and Spearman's Rho test, and Kappa statistics were conducted. **RESULTS:** Correlation between HUI3 overall score and EQ-5D index was large ($p < 0.05$). HUI3 emotion correlated moderately with HADS anxiety ($r = 0.40$; $p < 0.01$) and HADS depression ($r = -0.43$; $p < 0.01$). Correlation between HUI3 ambulation and 6MWT was large ($r = 0.59$; $p < 0.01$). As predicted, marital status and HUI3 ambulation did not correlate ($r = 0.00$; $p > 0.01$). Differences between pre- and post-transplant patients (known groups) in overall HUI3, ambulation and pain scores were statistically significant and clinically important. In 48% of the cases, predicted and observed associations were in agreement; were off by one category in 42% of the cases; and by two categories in 10% of the cases. The chance-corrected agreement measured by unweighted Kappa statistics was 0.25 ($p < 0.001$). **CONCLUSIONS:** This is the first study to provide evidence of cross-sectional construct validity of HUI3 in lung transplantation. The HUI3 was able to capture the burden of lung disease before transplantation. Post-transplant patients enjoyed higher health-related quality of life than pre-transplant patients.

43/1084/Quality of Life in Patients with Microtia Plastic Operation

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AIMS: The purpose of this study was to investigate the quality of life (QOL) in patients with microtia plastic operation. **METHODS:** Thirty-two patients with microtia plastic operation participated in this study. Our new original self-administered QOL questionnaire including 34 questions divided into 15 categories and microtia specific 20 questions were used. **RESULTS:** Cronbach's alpha coefficients of our questionnaire were high enough to accept for clinical use: 0.95 in environmental problems, 0.90 in mental function, etc. before operation, and 0.93 in environmental problems, 0.91 in mental function, etc. after operation, respectively. Our QOL questionnaire contained 10 main factors and cumulative contribution was 0.82. Compared with before operation, one half patients indicated the improved total QOLs but one fourth ones showed the deteriorated total QOLs after operation. There was significant improvement in total QOL after operation compared with before one as a whole ($P < 0.05$). Compared with before operation, significant improvements of QOLs were demonstrated in the strata of well-

being ($P < 0.01$), social participation and passion for life ($P < 0.05$) after operation as a whole. In addition, there were significant improvements of QOL after operation compared with before one in males ($P < 0.05$), but beyond our expectation, there was no significant improvement in females. There were significant positive correlations between total QOL and environmental problems ($r = 0.75$ $P < 0.01$), total QOL and psychological problems ($r = 0.70$ $P < 0.01$) etc. **CONCLUSIONS:** These findings indicate that our QOL questionnaire has high enough reliability and potency of validity to evaluate the QOL on microtia plastic operation. Microtia plastic operation showed the significant total QOL improvement after operation as a whole, but we must also pay more attentions to merits and demerits on microtia plastic operation as the comprehensive medicine and care including the differences between males and females, especially for females' specific demerits.

44/1712/Associations of Patient vs. Clinician Adverse Event Reports with Functional Status

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AIMS: Current drug-labeling practices for adverse events are based on the theory that patients' subjective experiences can be accurately captured by clinicians' documentation alone. However, mounting evidence shows that clinicians systematically downgrade the severity of patients' symptoms, patients' self-reports frequently capture side effects that clinicians overlook, and that clinicians' failure to note these symptoms can result in the occurrence of preventable adverse events. The prospective collection of adverse symptom event data directly from patients is an alternative approach that could add valuable information to current practice. **METHODS:** Patient-reported symptoms were collected from patients with breast, lung, genitourinary, or gynecological malignant conditions at Memorial Sloan-Kettering Cancer Center. Clinician-reported symptoms were recorded by physicians and nurses treating those patients at the same visits as a part of standard institutional documentation. Patients and clinicians reported symptoms (i.e., appetite loss, constipation, diarrhea, dyspnea, fatigue, nausea, vomiting) according to the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE). Overall health status was measured using the EuroQol EQ-5D. **RESULTS:** Kendall tau rank-correlation coefficients were calculated to quantify concordance of reports from 467 patients across a total of 4034 clinic visits with overall health status. These coefficients were compared with the concordance of corresponding symptom reports made by physicians and nurses. Patients' reports were observed as being more highly concordant with overall health status than clinicians' reports. **CONCLUSIONS:** Patient-reported information is a better indicator of daily overall health status when compared to clinician reports. These results underline the clinical and scientific value of patient-reported adverse symptom events and are further evidence that scientists, regulators, and clinicians should have access to this information when evaluating drugs for their inclusion in clinical trials.

45/1332/Quality of Life Measurement in Chronic Urticaria: A Systematic Review

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AIMS: There is strong evidence indicating that chronic urticaria

(CU) has a detrimental impact on quality of life (QOL) but despite 13 years of research the suitability of the measures used to determine this relationship had yet to be undertaken. The aim of this study was to systematically review the psychometric properties of these instruments. **METHODS:** This review searched the literature from January 1997 to April 2010 using electronic databases. A criterion was developed to identify papers containing instruments used in all study designs. If the main assessor was uncertain of what papers to include this was discussed to a consensus with a second. Data was extracted on instrument type, study design, instrument development, description, feasibility, psychometric properties and cultural validation. **RESULTS:** A total of 7 instruments from 38 papers met the criteria. They consisted of 3 generic (WHOQOL-BREF, NHP, SF-12 and 36), 3 dermatology-specific (Skindex-29, FLQA-d, DLQI) and 1 disease-specific instrument (CU-Q2oL). Instrument items and subscales varied substantially. Generic measures lacked specificity, were insensitive to clinical and socio-demographic factors and psychometric data was limited. The absence of a disease-specific instrument preceding 2005 appeared to result in the substantial use of the one-dimensional DLQI which was included to avoid narrowing the review. Regardless CU validated instruments demonstrated good reliability, validity and responsiveness but cultural adaptation were rarely presented. **CONCLUSIONS:** QOL measures have considerably contributed to our understanding of CU. Measures allow CU to be compared to other illnesses for funding where conventional measures do not consider psychosocial functioning. The importance of this may sell to clinicians that QOL measurement may further guide decision making by providing a more comprehensive picture of patient functioning leading to more targeted cost effective interventions. The CU-Q2oL was recommended for adjunct use with the SF-36 or Skindex-29 for general population and skin disease comparisons respectively.

46/1461/Measurement Properties of the Urticaria Activity Score (UAS)

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AIMS: Chronic Idiopathic Urticaria (CIU) is a skin disorder characterized by recurrent hives and/or angioedema for ≥ 6 wks. The urticaria patient daily diary (UPDD) was developed based on the UAS, the gold standard for assessing CIU activity. Content validity has already been established. We now assessed its measurement properties. **METHODS:** CIU subjects enrolled in a Ph2 multicenter, randomized, double-blind 4-wk study completed the UAS portion (hive #, largest hive size, intensity of pruritus) of the UPDD twice daily, sleep, activity limitations, symptom management items once daily, and other measures. UAS7 was calculated as the sum of daily UAS scores for hive # and intensity of pruritus over 7 days. Response characteristics (floor and ceiling effects); test-retest reliability (between days -14 and -7; days -7 and 0); internal consistency reliability (using daily UAS scores); responsiveness (using standardized effect size, standardized response mean, and responsiveness statistic); known-groups validity [based on Physician Global Rating (PhG) and Physician In-Clinic UAS (PhUAS) at baseline]; and, construct validity (with DLQI, MOS Sleep Scale, Patient Global Rating, PhG, and PhUAS) were assessed. **RESULTS:** 86 pts (66.3% F, mean age 41 ± 15 yrs) provided data. At baseline, approx 13% were at the ceiling; 19% at wk 4 were at the floor on hive #, largest hive, pruritus and UAS7 score. Test-retest reliabilities of UAS7 ranged from 0.62 to 0.77. Cronbach's alpha coefficients for daily UAS ranged from 0.84

(pruritus) - 0.93 (largest hive). All responsiveness coefficients were ≥ 1.0 , indicating good responsiveness. Known-groups validity results were inconsistent. Spearman correlations between UAS changes and changes in collateral measures from baseline to wk 4 provided strong support of construct validity. **CONCLUSIONS:** Acceptable evidence of validity was found for UAS7 and individual UAS items, indicating items can be analyzed individually or as a summary UAS7 score. More research is needed to further document its measurement properties, particularly test-retest reliability and known-groups validity.

47/1562/Relevance of symptoms in end-of-life care

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AIMS: Advanced cancer patients are polysymptomatic. One of the most important objectives in palliative care is the relief of symptoms and managing complications, which are essential in improving their quality of life. POS-S was developed by Irene Higginson to be used in daily assessment of patients under palliative care. It evaluates the presence and how much they affect the patient of 10 symptoms: pain, shortness of breath, weakness or lack of energy, nausea, vomiting, poor appetite, constipation, mouth problems, drowsiness, immobility. The purpose of this study was to create and to validate the Portuguese version of the POS-S. **METHODS:** To create and validate the POS-S, the first step was the production of the linguistic equivalent version into Portuguese. Next, we asked a palliative care doctor to perform a clinical review and a small group of patients was asked to give their opinion about the understandability, completeness and lack of ambiguity of the questionnaire. Having obtained a new version into Portuguese with correction made after the previous steps, we asked patients to fill the questionnaire, in a week apart, in order to test the reliability of POS-S. Finally, we initiated data collection in order to perform further validations, mainly with the EQ-5D, the EORTC QLQ-C30 and the ESAS. Patients were recruited from palliative care units that voluntarily accepted to participate in the study. **RESULTS:** The validation study included 46 patients from 7 different palliative care units. 61.3% were female and the mean age was 67 years old. The test-retest reliability part of the study showed scores from 0.55 to 0.82. On the other hand, EQ-5D revealed a very low score for their quality of life (0.28). Correlating POS-S scores with EORTC and ESAS scores, we found high scores ranging from 0.52 to 0.92. **CONCLUSIONS:** POS-S can be considered a valid, reliable and feasible instrument for symptom assessment in palliative care. The face validity recognized by both patients' and experts' panels, as well as the results obtained by comparisons of POS-S scores and other symptoms and quality of life instruments were very good.

48/1062/Do PROs Predict what Bothers Patients the Most? "Absolute-ly"

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AIMS: Efforts to use patient-reported outcome (PRO) measures in clinical practice for individual patient management would be supported by evidence that PRO scores are useful indicators of

patients' most bothersome issues. This analysis evaluated whether PRO scores predict the issues patients report as bothering them the most. **METHODS:** 131 cancer patients receiving outpatient palliative chemotherapy (mean age 57 years, 27% male) completed the EORTC-QLQ-C30 at up to 3 consecutive visits. At each visit, patients reported up to 2 function issues that bothered them the most (using categories related to QLQ-C30 function domains) and up to 2 symptoms that bothered them the most (using categories related to QLQ-C30 symptom domains). Two methods were used to investigate whether QLQ-C30 scores predict patients' most bothersome issues: (1) the two worst function/symptom scores in absolute terms and (2) the two function/symptom scores that worsened the most from the previous timepoint. **RESULTS:** Absolute scores predicted patients' most bothersome issues better than change scores. For patients reporting 1 bothersome issue, absolute scores predicted accurately 92% of the time for function and 91% of the time for symptoms, whereas change scores predicted accurately only 39% and 28% of the time, respectively. For patients reporting 2 bothersome issues, absolute scores predicted at least one correctly 98% of the time for both function and symptoms, predicted both correctly 42% of the time for function, and predicted both correctly 66% of the time for symptoms. In contrast, for patients reporting 2 bothersome issues, change scores predicted at least one correctly 63% of the time for function and 61% of the time for symptoms. Change scores predicted both issues correctly only 23% of the time for both function and symptoms. **CONCLUSIONS:** These data suggest that PRO scores are useful indicators of the quality-of-life issues bothering patients the most. Absolute scores are better indicators than change scores. These findings support the usefulness of PROs in clinical practice for identifying patients' problems.

49/1722/Development of the US National Frequent Heartburn Index (HBI) and Associated Composite Score

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AIMS: Development and validation of a brief instrument for the measurement of overall psychosocial impact of frequent heartburn (HB; heartburn experienced 2+ times weekly) in the general US population, yielding a single, composite score. **METHODS:** Item reduction of an existing Frequent HB Survey, followed by psychometric analyses and construct validity of the derived brief item set. The existing HB survey is a 50-item, 13-domain, patient-reported outcomes (PRO) survey assessing the impact of frequent HB on psychosocial quality of life. Content areas and items were derived from literature, patients, and clinicians. The survey was fielded on a US national sample by Harris Interactive. **RESULTS:** Confirmatory factor and reliability analyses led to a reduced set of 9 items (HBI-Full), following removal of all non-work-related dichotomous items from the original HB Survey. All retained items had moderate to strong factor loadings on the underlying factor (range: 0.66 - 0.85) and an acceptable overall model fit (CFI = 0.93, SRMR = 0.04). The coefficient alpha for internal consistency reliability was 0.92. A separate HBI (HBI-Brief) was created that excludes the two employment-related items, relevant for those who are not currently employed. The HBI-Brief had a coefficient alpha of 0.90. The HBI-Full and HBI-Brief showed acceptable construct and discriminant validity: moderate correlations were found between each index and conceptually related variables. **CONCLUSIONS:** Both HBI versions have good psychometric properties and can successfully capture a full range of psychosocial effects of frequent heartburn. The HBI single composite score (0 - 100) reflects the overall psychosocial experience of frequent heartburn sufferers in America. Normed,

national scores for the HBI are available against which an individual can compare their own HBI score. The HBI can help patients and their clinicians determine where they are in the range of national scores of psychosocial effects of frequent heartburn, potentially aiding in treatment and lifestyle decisions.

METHODS & METHODOLOGY

50/1639/Response shift which occurred to healthcare provider influenced satisfaction of the service users

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AIMS: "Then-test" was frequently used to measure the scale recalibration construct of response shift. Although a lot of researchers reported the occurrence of response shift in PRO, little is known about what the difference score between pre-test and then-test means. The aim of this study was to evaluate whether the response shift which occurred to healthcare provider related to satisfaction of the service users and to explore the meaning of the score which measured response shift. **METHODS:** We conducted secondary analysis of the interventional study which evaluated the effects of communication skill training for the healthcare providers for preventive long-term care service. Pre-test, post-test and then-test data were collected from 75 providers using self-rated communication skill scale. In addition, 220 service users completed the modified American Board of Internal Medicine, Patient Satisfaction Questionnaire (ABIM-PSQ) and the SF-36. By the difference score between pre-test and then-test, they were divided into shift group and non-shift group. User's satisfaction and HQOL of both groups were compared. **RESULTS:** The shift group included 45 (60.0%) providers who realized after the training that, before the training, they were worse than they thought they were. The response shift scores (then-test - pre-test) were -3.3 for the shift group and 4.5 for the non-shift group. There was not significant change between the scores of pre-test and post-test in the shift group (pre: 34.6±3.5, post: 34.8±4.9), while there was significant change in non-shift group (pre: 32.0±7.0, post: 37.6±6.4, $p < 0.05$). The score of user's satisfaction of the shift group was significantly higher than the non-shift group (36.9±6.3 vs 35.2±5.9, $p < 0.05$). The scores of SF-36 were not significantly different in both groups. **CONCLUSIONS:** The difference score between pre-test and then test might represent some sort of change in consciousness. Our results suggested that the providers who had change in consciousness might offer a more satisfying service through their advanced communication skill.

51/1243/Response Shift in Quality of Life Measurement among Patients with Hypertension in a Community in China

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AIMS: The aim of the study was to determine whether patients with hypertension experience a response shift after participating in community disease management program. **METHODS:** Research design: case series. Setting: A community health center in Hangzhou, China. Study population: 240 consecutive consulting or followed up patients with diagnosed hypertension were recruited. Intervention/Instrument: The SF-36 and EQ-5D questionnaires were self-administrated at baseline (Time 1). After the 4-week disease management intervention, the study cohort completed two questionnaires: one on how they felt currently (Time 2), and one on

how they perceived themselves to have been 4 weeks ago (Then-test). Differences between Time 1, Time 2 and Then-test score were examined using paired t tests and nonparametric tests. Partial correlations and hierarchical regressions were used to detect the predictors of response shift. **RESULTS:** Data from 211 patients (87.9%) were eligible for analysis. Mean age of the participants was 66.0 years (SD 10.8), and 46.9% were male. About half of the patients have response shift in each domains of QOL. The direction of response shift varies. At the group level, response shift was observed in the SF-36 PF, RP, BP, SF, PCS scores and EQ-5D index. Then-test scores were higher than Time 1 scores in those domains. The unadjusted change of HRQoL was larger than the response shift adjusted change of HRQoL ($p < 0.05$). Patients with positive recalibration in VAS had higher baseline mental health, and gain a significant improvement from time 1 to time 2 in mental health. After controlling for the Time 1 score, age and education explained a small but significant amount of variance in response shift in most of the domains of QOL ($p < 0.05$). **CONCLUSIONS:** This study showed that patients with hypertension experienced a response shift after participating in community disease management program, which resulted in an over or underestimation of change in HRQoL. (Grant 2007BA107A06 from the Ministry of Science and Technology of China)

52/1220/Understanding Appraisal Processes Underlying the Thentest: A Mixed Methods Investigation

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AIMS: The retrospective pretest (thentest) is commonly used to assess recalibration response shift (RS), but qualitative methods have not been used to understand the cognitive processes reflected in thentest discrepancy scores. We investigated appraisal processes over time in a longitudinal study of people with HIV/AIDS, and evaluated the association of these processes with thentest discrepancy scores at 6- and 12-mo. post-baseline. **METHODS:** 467 people with HIV/AIDS were interviewed at baseline and 6- and 12-mo. post-baseline using the QOL Appraisal Profile, the MOS-36, and General Health thentest and recall items at 6- and 12-mo. Open-ended appraisal questions were coded by 2-3 raters, and factor analyses reduced the data. RS groupings were based on the magnitude of thentest discrepancy scores: large-RS group and no-RS group. Uni- and multi-variate linear models investigated associations between frame of reference, experience sampling, standards of comparison, and salience overall and by RS grouping. Cohen's cut-off for a small effect size (ES) ($r = 0.10$) was used to avoid Type I error. **RESULTS:** Reliability of Appraisal Profile codes was high ($\kappa = 0.59-0.66$). The most prevalent QOL themes were health, contentment, independence, and family/friends. They were largely independent of other appraisal variables, although reporting more goals was associated with more complex and positive themes ($p < .01$). Thentest ES were larger than standard change scores, even controlling for recall bias. Large-RS patients mentioned more themes and "recalibration", as compared to no-RS patients (13% vs. 0%). Multivariate models revealed that changes in frame of reference, experience sampling, and salience explained 9% more variance over the standard (unadjusted for RS) model. **CONCLUSIONS:** The Appraisal Profile is useful for gaining a richer understanding of the thought processes underlying QOL item response. Our data support a convergence between the thentest and appraisal methods, and the use of the thentest as a discrepancy score for appraisal research.

53/1314/A Philosophical Explanation of Response Shift

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AIMS: Patient-Reported Outcome Measures (PROMs) are meant to assess patients' collective perspective on many facets of health care. But findings from studies that use these measures raise questions about their ability to meet these expectations and thus the validity of these measures. Response shift is sometimes blamed for some of these discrepancies and here I provide a new analysis of this phenomena. **METHODS:** In this paper I propose that the different and changing interpretations that are at the heart of response shift are natural. To explain this phenomenon I turn to examine the ethical as opposed to psychological components of patients' understandings of quality of life. One way to think about these ethical components is in terms of Charles Taylor's distinction between weak and strong evaluations. Weak evaluations deem that something is good just insofar as it is desired; strong evaluations determine that something is good insofar as the desire itself is worthy. For the latter type of evaluation our choices are deemed worthy in terms of the quality of life they express relative to the life we want to lead. I argue that patient responses in quality of life measures are often taken to be weak evaluations. Nevertheless, studies that listen to respondents as they fill out PROMs suggest that their answers are better understood as strong evaluations. **RESULTS:** This analysis has consequences for how we should use and understand PROMs. For instance, we should not understand them as a series of questions and answers that have only one correct meaning. PROMs ought to be used as tools for enhancing communication about perceived health status or quality of life. This suggestion has some similarities and some differences with Carolyn Schwartz and Bruce Rapkin's work on appraisal. I end my discussion with an exploration of some of these synergies and departures. **CONCLUSIONS:** This paper suggests that in light of response shift, if we want PROMs to be theoretically sound we should alter how we conceptualize and use them.

54/1382/BiblioPRO: online library of PRO instruments in Spanish

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AIMS: BiblioPRO (<http://bibliopro.imim.es>) is an online library of Patient Reported Outcomes (PRO) instruments in Spanish. Its aim is

to facilitate information and access to PRO questionnaires and user manuals as well as promoting their appropriate use in research, clinical practice, and socio-sanitary management. **METHODS:** Instruments are identified by systematic literature reviews. The BiblioPRO Scientific Committee members extract information on a series of instrument characteristics: constructs measured, target population (by gender, age-group, and culture), disease-specific category based on the ICD-10, measurement model (psychometric, econometric, clinimetric, other), dimensions, and number of items. A user-friendly search engine allows users to identify suitable instruments according to this scientific taxonomy and key words. Additional downloadable documentation provides detailed descriptions, relevant bibliographic references, and scoring rules for their correct use. Because most Spanish instruments are derivative works, BiblioPRO requests formal authorisations to reproduce and distribute the instruments to both authors of the original and the derivative works. **RESULTS:** Currently, information is available on 524 PRO instruments in Spanish. Of these, 273 are Health Related Quality of Life measures, 48 Symptoms Scales, 18 Satisfaction with Care, 12 ADLs Scales and 158 other. Most are disease-specific instruments and 62 Spanish generic instruments are included. Among the latter, the most frequent are Mental and Behavioural Health (156), followed by Neoplasms (34). Most instruments are designed for adult populations, with 36 instruments for children and adolescents. **CONCLUSIONS:** BiblioPRO may produce a clear knowledge transfer by facilitating access to potential users of PRO instruments in Spanish speaking countries, including Latin America. Its impact could be enhanced through the inclusion of recommendations on the robustness and adequacy of each instrument, provided through future standardised evidence-based evaluations. CIBERESP-MINISTERIO DE CIENCIA E INNOVACIÓN-ISCIII-FEDER, FUNDACIÓ IMIM.

55/1123/Do SF-36 item scores mean the same for different subgroups of a population? comparing different methods of detecting differential item functioning

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AIMS: An important, but frequently overlooked, aspect of validating health outcome measures is to establish if items work in the same way across subgroups of a population. That is, if respondents have the same underlying level of an attribute, does the item give the same score in different subgroups or does it exhibit differential item functioning (DIF)? This study compared 3 different methods of testing for DIF. **METHODS:** Three methods for detecting DIF were applied to the SF-36 (Ware et al., 1999) physical subscale with respect to gender. The sample comprised 767 people with osteoarthritis who participated in the Somerset and Avon Survey of Health (Eachus et al., 1996). DIF was explored using ordinal regression methods as proposed by Swaminathan and Rogers (SR; 1990) and Zumbo (1999) and an item response theory method (IRT; Thissen, 2001). **RESULTS:** The SR and IRT methods resulted in the same item related to 'lifting' having the highest level of DIF (SR $X^2(1)=27.6$ $p<.0005$; IRT $X^2(2)=26.0$ $p<.0005$). The item 'climbing several flights of stairs' was also significant using SR ($X^2(1)=10.1$ $p=.001$) and for IRT was the item identified as having the second highest level of DIF but failed to reach significance ($X^2(2)=4.0$ $p=.13$). Zumbo's method also identified these two items as having the greatest levels of DIF but statistical significance was not reached. For both items men were more likely to report that they had fewer problems than women when they had the same actual level of limitation. **CONCLUSIONS:** These results show that scores on the SF-36 physical subscale are not equivalent for men and women. They

emphasise the importance of DIF detection as a standard part of validity testing for measures of healthcare outcome and quality of life. To date this has been limited by the need for complex statistical methods and specialist software. However, our results suggest that the relatively simple SR method produced similar results to the more complex IRT method and SR can be implemented through a standard statistical package.

56/1214/Is it necessary to adapt the UK English original of the Diabetes Treatment Satisfaction Questionnaire (DTSQs) before use in other countries?

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AIMS: 1. To review existing English versions of the Diabetes Treatment Satisfaction Questionnaire (DTSQs) developed using a standard adjusted linguistic validation methodology; 2. To identify differences between the original and other English versions, and explain where possible. **METHODS:** 1. Collection of the existing English versions; 2. Analysis of the differences; and coding of the differences as cultural, lexical, and grammatical. **RESULTS:** Ten English versions were identified: in Australia (AU), Canada (CA), Hong Kong (HK), India (IN), Malaysia (MY), New Zealand (NZ), Philippines (PH), Singapore (SG), South Africa (ZA), and United States of America (US). Three versions are identical to the original: HK, SG and US. Items 1, 6, 7, 8 and their response choices are identical across all 10 versions. In decreasing order of frequency changes were observed as follows: PH (8) (the only country here colonized by the US rather than by Britain), IN (5), MY (4), NZ (3), AU, CA, ZA (2). All changes were either requested or validated by the patients during cognitive debriefing. Changes were mostly grammatical or lexical. The most problematic item across all versions was Item 5 (flexibility) (for 6 countries: AU, CA, IN, MY, NZ, PH), then items 2 and 3 (perceived frequency of hyper- and hypoglycaemia) and 4 (convenience). For items 4 and 5, AU and CA shared the same grammatical change (replacement of "have been finding" by "have found"), as well as IN and NZ (deletion of the infinitive "to be"). In PH, the adjective "adjustable" was added in Item 5 to clarify the meaning of "flexible". In MY, item 5 was completely reworded as the patients understood it backwards (i.e. their flexibility in adapting themselves to the treatment), perhaps because their treatment regimens are not at all flexible. **CONCLUSIONS:** Observed differences relate to history, evolution of language and treatment differences across countries, and confirm the importance of careful review and, where necessary, development of specific English versions of PRO measures for different English-speaking countries.

57/1122/Predictors for satisfaction with activity participation and cultural specific items for Taiwanese with mental illness using longitudinal dataset

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AIMS: This study is to examine the predictors for six items of the

WHOQOL-BREF-TW. The first four items were chosen based on their relevance to activity participation according to WHO ICF. The last two items were selected because they are culturally specific for Taiwanese. **METHODS:** 104 persons with depression were recruited from a psychiatric outpatient unit of a university affiliated hospital. The research was approved by the hospital IRB board. Subjects were tested on the baseline and 70 subjects (mean age=47.2, SD=12.5) were followed up with the duration of 26.11 months (SD=7.4). They were tested on the QOL, sense of competence (SoC), sense of mastery (SoM), social support (SS) and severity of depression (SoD). The data were analyzed by mixed effect model to identify the predictors for six models from baseline and follow up. Multiple regressions were used to analyze the variance explained by the first significant predictor. **RESULTS:** In ADL model, SoC, SoM, SoD, and use of antidepressants were significant predictors with SoC explained 48.8% of variance. In work model, SoC, SoD, and employment status were significant predictors with SoC explained 56.7% of variance. In leisure model, SoC, SoM, and educational level were significant predictors with SoC explained 43.6% of variance. In sleep model, SoD was the only significant predictor explaining 37.8% of variance. In face saving model, SoD, SoM, use of antidepressants and hypnotics were significant predictors with SoD explained 30.4% of variance. In eating model, SS and employment status were significant predictors with SS explained 22.4% of variance. **CONCLUSIONS:** SoC was one of the most important variables for ADL, work, and leisure models. SoM was predictive for ADL and leisure models. SoD was predictive for sleep and face saving models. SS was predictive for eating model. To facilitate the activity participation for clients with mental illness, professionals need to target at clients' skills, habituation, volition, severity of symptom and social support.

58/1809/Correlates of Quality of Life: A Cross-cultural Comparison between the United Kingdom and the United States. The Whitehall II Study and the Western New York Health Study
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AIMS: Subjective health represents a measure of quality of life and a strong predictor of mortality and morbidity outcomes. We performed a cross-cultural comparison of a number of socio-demographic, lifestyle, and co-morbidity factors that could affect subjective health, in two large populations from the UK and US. **METHODS:** Participants were 6,472 white subjects from the Whitehall II Study (mean age: 55.8 years) and 3,684 white subjects from the Western New York Health Study (mean age: 58.7 years). Subjective health was assessed using the physical and mental health

component summaries of the Short Form-36 questionnaire. We used analysis of covariance to compare gender-specific mean scores for the two populations across several potential correlates. **RESULTS:** In fully-adjusted models, there were significant, consistent associations in both samples. Increasing age was associated with poorer physical health but with higher mental health scores ($P<0.001$). Being unmarried was associated with poorer mental health only ($P<0.05$). Lower SES was associated with lower physical and mental health scores in the US sample only ($P<0.05$). Overall, lifestyle variables were more associated with the physical than the mental health component. Specifically, excess body weight, smoking, low physical activity, and short sleep duration were all associated with lower physical health scores ($P<0.05$). Depressive symptoms were strongly associated with poorer mental health in both samples and genders ($P<0.001$). CVD was consistently associated with poorer physical health ($P<0.05$), whereas no consistent associations were found between co-morbidities and mental health. **CONCLUSIONS:** Consistent findings from this cross-cultural comparison between two populations from the UK and US corroborate the multifaceted nature of subjective health. Lifestyle and co-morbidity factors mainly affected the physical health component and had a little impact on mental health. This is a novel finding which warrants further consideration.

59/1663/Cross-cultural Comparisons: Lessons from Friedreich's Ataxia

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AIMS: Friedreich's Ataxia (FA) is an incurable, progressive neurological disorder, its rarity necessitates multi-national studies and the scales used must be interpretable in a common frame of reference. Rasch methods provide powerful means for testing scale properties across samples. The patient-reported FA Impact Scale (FAIS) contains five physical and three psycho-emotional subscales. This study examined scale performance across two international centres, focusing on Differential Item Functioning (DIF), and implications for assessing change in patients. **METHODS:** UK ($n=307$) and Australian ($n=195$) person measurements were Rasch analysed for: targeting, scale performance, and person measurement across three time points over 24 months. **RESULTS:** Targeting for all subscales was adequate, performance was generally good. Item thresholds were ordered with little significant misfit (13/126 items fit residual > 2.5), little item bias (4% of residual correlations > 0.3). Person separation indices (PSI) were 0.71 - 0.93. Person fit residuals were adequate (range -3.63 - +3.60). Eight items (6.3%) showed DIF by country, but with no significant effect on person location estimates. Analysis of change over time (Australian cohort) indicated statistically non-significant trend to worsening in all five physical functioning subscales, but with profound variability. Individual profiles ranged from progressive worsening to progressive improvement. **CONCLUSIONS:** Our findings indicate stability across countries, generally good scale performance but possible local dependence in one subscale. Some PSI values were lower than might be predicted given good targeting and number of items. Whilst some items exhibited DIF, no significant impact on person measurement was evident, enabling meaningful patient comparisons. Analysis of the longitudinal data should be interpreted cautiously due to sample size. With no significant deterioration over two years detected, longer

clinical trials or larger samples may be needed. Patient profiles over time were surprisingly labile given current understanding of FA and require investigation.

60/1796/Quality of life after a heart attack: East vs West
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Objective. The quality of life after a heart attack in the East has been understudied compared to the West. This study aimed to adapt MacNew questionnaire to an Eastern sample of Indonesians and to test this newly adapted to a sample of heart attack survivors in Indonesia. The main objective of this study is to compare heart disease Health-Related Quality of Life (HRQoL) following a heart attack in a sample of Indonesians with the sample of British-Whites and minority ethnic groups of British South-Asians. **Design.** This study was cross sectional and data were collected shortly before MI patients were discharged from hospital. Ethical research committee approvals were granted from Cambridgeshire IV Research Ethics Committee Cambridgeshire in the United Kingdom and from the local hospital ethics committee in Indonesia. **Methods.** A sample of 242 individuals from six hospitals in and around London and two hospitals in Jakarta were recruited. Emotional-, physical- and social-related QoL was measured using MacNew questionnaire. The Indonesian version of MacNew was tested to the 113 participants who were also participating in the main study. **Results.** Not only the newly adapted questionnaire, but the original version of MacNew was also tested in the UK sample. Forced-three factor solutions were adopted for both samples. They showed moderate reliability ranging from .61 to .75 for all three aspects of HRQoL. The results showed that Indonesians showed lower average scores on all aspects compared to the British-Whites and British South-Asians. British-White sample showed the highest emotional- and social-related quality of life, and British South-Asians reported better physical-related compared to the others. **Conclusion.** The results demonstrate that people in the East and minority ethnic groups have worse HRQoL compared with those in the West. The findings suggest that there is an urgent need for smoking cessation campaigns in the East, while the West could benefit from tailored-cardiac rehabilitation programme emphasising exercise in the older groups to improve HRQoL.

61/1418/Recommendations about Translations in the final FDA Guidance on PRO Measures: What has changed and what has remained

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AIMS: Almost four years of discussion were necessary to develop the final FDA guidance on the use of PRO measures in clinical trials. Our objective is to compare how the recommendations about translation and cultural adaptation have evolved from the 2006 draft to the 2009 final guidance. **METHODS:** Both guidances were retrieved on the FDA website and analyzed. **RESULTS:** Structure and content were modified. Recommendations on translation and cultural adaptation were moved to another section within the Evaluating PRO Instruments Part: from "IV.D. Modification of an existing instrument" to "III.G. PRO Instruments intended for specific populations". As for the content, the text in the body of the final guidance is more concise (95 words) compared to the draft (162 words). The novelty lies in the stipulation that the FDA will review the process used to translate/culturally adapt the instruments. As a

consequence, an appendix (section VIII) was added in which the FDA explains which topics should be addressed in the PRO documents provided to the FDA for review: description of process used, patient testing, rationale for decisions made, copies of versions and evidence about validity. They are however key points which did not change: the insistence on the need for providing evidence that content validity and other measurement properties are adequately similar between all versions. **CONCLUSIONS:** The recommendations are more concise and precise, especially the expectations of the FDA. The FDA however does not indicate a preference for a specific translation methodology. Interestingly patient testing is clearly indicated as a key point of the process. The need for documenting all decisions is crucial and raises the question of developing standardized system of reporting to structure the evidence to be provided to the FDA. The last point of the Appendix is debatable as we anticipate that it might add a burden in term of costs to provide evidence about the psychometrics of all versions.

62/1540/Measurement Invariance of the SAMHSA Mental Health and Alcohol Abuse Stigma Assessment

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AIMS: To assess measurement invariance of the SAMSHA Mental Health and Alcohol Abuse Stigma Assessment (SA), which is necessary to make valid comparisons across three measurement occasions and between two treatment groups, Referral and Integrated care. **METHODS:** Data come from the Primary Care Research in Substance Abuse and Mental Health for Elderly database, a longitudinal multisite, randomized, comparative trial examining two modes of care. A sample of 1,207 adults over the age of 65 who completed all three SAs and screened positive for depression, anxiety, and/or at-risk drinking was used. Structural equation modeling was used to assess measurement invariance in the SA, and assess the potential of the subject of stigma (alcohol/mental health), gender, age, depression/anxiety, alcohol abuse, and mental and physical HRQoL to cause measurement bias. **RESULTS:** A measurement model was established with two common factors, Perceived Stigma and Comfort Level. Six biases were found. The first bias related to Item 4 that assessed if it would be difficult for patients to start treatment if others knew. The item was more important to Perceived Stigma in the Referral than the Integrated Care group. Four biases were found regarding Item 3 that assessed if the respondents felt people would think differently of them if they received treatment. These biases indicated that sex, mental HRQoL and the subject of stigma had undue influence. Finally, Item 6 that assessed respondents comfort in talking to a mental health provider, indicated that people with higher mental HRQoL felt more comfortable even when Comfort Level was held constant. **CONCLUSIONS:** We found a satisfactory fitting measurement model for the SA. We expected that treatment may cause respondents to re-evaluate their conceptualization of stigma. However, the psychometric properties of the SA items remained invariant over the study, thus group differences and changes in stigma can be compared.

63/1543/Validation Research Results of the Japanese version of the WHOQOL

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AIMS: In order to validate the Japanese version of the WHOQOL-BREF, we conducted a field survey with healthy Japanese

participants, selected using stratified sampling methods to be proportionally equivalent in age and sex distributions at each of three sites in Tokyo, Osaka, and Nagasaki in April 1998. **METHODS:** We surveyed 1,410 participants, which consisted of 679 males and 731 females, with an average age of 48.1 ± 15.6 . The average QOL score was 3.29 out of 5 (male 3.24; female 3.34). The WHOQOL-BREF consists of four domains: Psychological Health, Physical Health, Social Relationships, and Environment. **RESULTS:** In the Psychological Health domain, average QOL was higher in Tokyo than in Nagasaki. For the total QOL score, as well as in the Social Relationships and Environment domains, females had higher scores than males. Those over 60 years old had higher QOL scores than those in their 30s. General Health Questionnaire (GHQ-12) scores derived at the same time were highly correlated with the WHOQOL-BREF, with lower QOL scores associated with lower health status. **CONCLUSIONS:** While the previously unpublished data in this study are starting to age, we validated here that the Japanese version of the WHOQOL-BREF has high sensitivity and reliability.

66/1549/Use and value of back translation review in the translation of PROMs

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AIMS: Back translation is considered a vital step in the generally accepted methodology for the translation of PROMs (Wild et al. 2005, 2009). However, critics question its use, suggesting that it can cast doubts on the abilities of the translators who translated the original version into the source language, and that the back translation could create misleading impressions of the translation (e.g. McKenna et al. 2005). There is agreement that more research is needed. Before embarking on more detailed research it would be helpful to consider how back translation is currently being used as a step in the methodology for the translation of PROMs. **METHODS:** A review was undertaken of 50 back translation reports from 4 past projects at Oxford Outcomes. Examples of how back translation contributed to the translation process were gathered. **RESULTS:** - Project managers use back translation review as an opportunity to question what is in the translation, but do not force changes to be made to the forward translation. Review of the back translations can identify important misunderstandings/errors in the forward translation. The back translations can show forward translators that their translation may be open to misinterpretation, thereby allowing them to limit instances of ambiguities. 14% of items within the sample were changed as a result of back translation review. The structure of the translated language can cause reviewers to question items that are not incorrect. Reviewers question more items in languages that are from cultures that differ widely from their own (e.g. Indic languages). **CONCLUSIONS:** Back translation is an essential component of the generally accepted methodology for the translation and linguistic validation of PROMs. This review provides evidence to suggest that review of back translations by project managers highlighted some important aspects of translations which would have been overlooked in the absence of back translation, as shown in both the reduction of ambiguity and correction of errors.

66/1357/Self-Rated Health: Alternative Translations OF RESPONSE CATEGORIES APPLIED IN THE SAME GROUP OF STUDENTS

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AIMS: The objective of the study was to compare two versions of

Polish translation of a standard question on self-rated health (SRH) with four response categories (excellent, good, fair, and poor). The first translation, faithful to the English original, had been discussed in detail with English native speaker. The other one, which retained the order of responses, featured definitions and wording typical for similar national studies, which can be considered a cultural adaptation. **METHODS:** The translations were compared in two parallel studies in 2010. In the first study, 146 students, aged 20-22 years, had been asked to assign numerical values from the range 0-10 to (random) health-related words from either translation. In the other study, both translations had been included in distant passages of a 32-page survey questionnaire. Data on 824 students, aged 17 on average, were analysed. **RESULTS:** Usually, the assumption is to analyse responses to the SRH item using dichotomous division, and to determine the percentage of people with lowered health assessment. The results of the first study showed that in two translations the third response was assigned on average 5.21 and 4.35 points, and the fourth response 2.94 and 2.02 points, respectively. Only 75.2% of students surveyed in the second study chose the answer which was on the same position in the ordinal system ($\kappa=0.581$; $p<0.001$). 34.0% and 23.8% of respondents were categorized as having lowered SRH (combined two negative responses) in both translations, respectively - ($p<0.001$ for McNemar's test). **CONCLUSIONS:** The results of those studies should be taken into consideration in international projects. The comparability of response categories in different languages largely affects the comparability of results. Especially, phrases which can have either more or less positive meaning, depending on the context, should be avoided in the original questionnaire which will be the source text for translation.

POPULATION & POLICY

66/1282/Urban health-related quality of life: do municipal services matter?

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AIMS: To investigate the relationship between health-related quality of life among the general population and urban services provided by a metropolitan municipality. **METHODS:** This was a population-based study. A random sample of healthy individuals aged 18 years and over living in Tehran, Iran were entered into the study. To select a representative sample of the general population a stratified multi-stage area sampling was applied. Every household within 22 different districts in Tehran had the same probability to be sampled. Quality of life was assessed using the SF-36. In addition, a 42-item urban services questionnaire was used to measure citizens' satisfaction with services are provided by Tehran municipality including items on public transportation, public nighttime lights, pedestrian, etc. **RESULTS:** In all 9863 citizens were took part in the study. The mean age of participants was 37.6 (SD = 15.1) years and 50% of both gender. The mean score for physical component summary was 51.0 (SD = 9.6) and for mental component summary it was 45.4 (SD = 10.2). In general people were moderately satisfied with urban services (municipal services). They were most satisfied with public transportation. To assess the relationship between health-related quality of life and urban services, logistic regression analyses were performed to find out the type of services that contribute to physical and mental component summary scores. The results showed that physical component summary was associated with services such as public transportation whereas mental component summary score was associated with traffic in passageways. **CONCLUSIONS:** The findings from this study provided useful information on health-

related quality of life and urban services. It seems that to improve health-related quality of life among people in Tehran those services indicated in this study should receive priority.

67/1280/Urban health-related quality of life: does the place of living matter?

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AIMS: To assess the relationship between health-related quality of life and the place of living among an Iranian general population. **METHODS:** This was a population-based study. A random sample of healthy individuals aged 18 years and over living in Tehran, Iran were entered into the study. To select a representative sample of the general population a stratified multi-stage area sampling was applied. Every household within 22 different districts in Tehran had the same probability to be sampled. Quality of life was assessed using the SF-36. **RESULTS:** In all 9863 citizens took part in the study. The mean age of participants was 37.6 (SD = 15.1) and 50% of both gender. The results showed that the study sample scored higher on physical functioning (mean = 83.4, SD = 23.5). They scored lower on general health and vitality (mean score 62.5, SD = 19.9; and 62.6, SD = 18.4 respectively). The score for mental health also was low (mean = 66.3, SD = 17.8). Overall people living in better-off districts indicated better scores for health-related quality of life subscales while people living in deprived areas indicated the worse conditions. **CONCLUSIONS:** The findings from this study showed that health-related quality of life to some extent was associated with the place of living. The findings might be explained in the context of social determinants of health framework.

68/1570/Impact of influenza A (H1N1/2009) infection on quality of life and health services

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AIMS: To describe the impact of influenza A (H1N1/2009) on health-related quality of life (HRQL) in hospitalized and out-patients in Spain from June 2009 to March 2010; and to evaluate the effect of the infection on direct and indirect costs. **METHODS:** Hospitalized and outpatient with influenza H1N1 infection were selected from those participating on a national case-control study. Recruitment evaluation asked for: a) that moment; and b) one week before the symptoms. A follow-up evaluation was done several weeks after recovering. The interviews included the EQ-5D, use of health services, and days out of work (of patients and caregivers). EQ-5D mean score differences among the 3 evaluations were tested using analysis of variance. Direct costs of health services, pre and post admission, was calculated in order to compare between in and out-patients. Days out of work of patients and caregivers were used to assess indirect costs of the H1N1 infection. **RESULTS:** At the moment there are around 400 hospitalized patients recruited with their respective ambulatory control. The telephonic follow-up

evaluation has been conducted for half of the current sample. Interim analyses presented here were conducted with the first 74 hospitalized patients for whom full electronic clean data was available. Almost 40% of hospitalized patients were below 16 years old. Before admission, 60% used health services because of the infection symptoms and had a EQ-5D index of 0.88 (SD=0.19). They were hospitalized around 8 days in average, during which they presented a mean of 0.46 (SD=0.48). After discharge, 50% of patients were on sick leave for more than 15 days; and when required, caregiver spent a mean of 9 days out of work. Half of the sample, still needed medical care after discharge; but when finally recovered their EQ-5D index was 0.88 (SD=0.21). **CONCLUSIONS:** Patients infected with Influenza A showed a significant deterioration on their HRQL during hospitalization, but regain their initial health status after recovering. These results should be confirmed re-conducting analysis with the whole sample

69/1360/The impact of quality of life and other patient characteristics on health care use in patients with congenital heart disease

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AIMS: To control a congenital heart defect (CHD) and to reduce its impact on patients' quality of life (QoL), life long care is needed. To deliver tailored care, we need to identify patient characteristics that are related to current health care use. **METHODS:** 1,800 CHD patients were randomly selected from the Dutch National Registry for adults with CHD. Patients completed a web-based or paper version of the questionnaire. Outpatient health care use was assessed by the number of contacts with 19 health care providers. Inpatient health care use was measured by the number of hospitalizations, emergency room visits and operations. A one-year time frame was employed. We adopted a model where health care use is the result of (1) socio-demographic and clinical variables (i.e. disease severity and functional status), the interaction of (2) disease-specific (i.e. illness-perception, pain and fatigue) and psychological variables (i.e. type-d personality, anxiety, depression, and optimism), and (3) QoL. This model will be tested by Structural Equation Modelling. Preliminary analyses consisted of three hierarchical multiple regression analyses, where the three predictor sets were entered sequentially. **RESULTS:** A total of 1,109 patients completed the questionnaire (response rate = 66%). Preliminary analyses show a significant ($p < .05$) increase in explained variance for both out- and inpatient health care use after the addition of each set of predictors (12%, 17%, 19% and 7%, 13%, 16% respectively). Lower out- and inpatient health care use was independently related to better illness perception and higher disease-specific QoL. **CONCLUSIONS:** Preliminary results show the additional value of each of the three sets of variables in predicting health care use. If confirmed in the final analysis, these results may enable the delivery of tailored care. For example, interventions targeted at modifying illness perceptions and increasing disease-specific QoL may improve patients' overall QoL and may lower unnecessary health care consumption.

70/1290/Similarities and differences in the meaning of "Quality of Life". An Information Integration study with similar but culturally distinct groups

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AIMS: Previous research with the WHOQOL-BREF has shown that important cross-national differences exist in the Quality of Life concept, and therefore the exact comparability of Quality of Life levels in international comparisons needs to be questioned. The current study determines the relative importance of particular satisfaction levels in different life domains to similar groups (to exclude confounders) with distinct cultural backgrounds: Belgian, Israeli-Jewish and Israeli-Palestinian students. The unconscious heuristics that people apply when combining domain satisfaction levels into an appraisal of Quality of Life are compared across groups. **METHODS:** In parallel, three web-based experiments are being run with 3 groups of psychology students in Belgium and Israel. The specific methodological strength of this study is that the same 3 experiments with a 4x4x4 factorial designs are completed by quite similar groups (students) that however differ in cultural backgrounds. Participants are required to rate Quality of Life in unknown persons that are described in vignettes providing information on satisfaction in 1 to 3 life domains. A Functional Measurement approach determines how people integrate information on different life domains into "Quality of Life". **RESULTS:** Previous, similar studies with solely Belgian students have learned that a weighted average best describes how information on life domains is integrated into overall Quality of Life. However, our previous findings indicate that culturally distinct groups may use different strategies to do so. The integration heuristics of the included participant groups are compared. **CONCLUSIONS:** The results of this study learn that particular life domains have a different significance in constituting Quality of Life in different cultural groups. It is concluded that particular life domains are more robust to cultural differences and therefore should particularly be used in cross-cultural research, whereas other life domains should not.

71/1274/Quality of Life Deterioration by Pandemic Panic Influenza Viral Infection

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AIMS: The purpose of this study was to investigate the quality of life (QOL) deterioration by pandemic panic influenza viral infection. **METHODS:** Ninety-three university students whose university was closed for a week due to pandemic panic influenza viral infection one week before participated in this study. Our new original self-administered QOL questionnaire including 37 questions divided into 15 categories was used. **RESULTS:** Cronbach's alpha coefficients of our questionnaire were high enough to accept for clinical use: 0.90 in mental function, 0.84 in environmental problems, 0.77 in student life, etc., before pandemic panic influenza viral infection, and 0.90 in mental function, 0.88 in environmental problems, 0.77 in dietary problems, etc., after one, respectively. Our QOL questionnaire contained 11 main factors and cumulative contribution was 0.74 before pandemic panic influenza viral infection. And our QOL questionnaire also contained 11 main factors

and cumulative contribution was 0.72 after one, too. There was significant deterioration in total QOL after pandemic panic influenza viral infection compared with before one ($P < 0.01$). Compared with before pandemic panic influenza viral infection, significant deteriorations of QOLs were demonstrated in the strata of well-being ($P < 0.01$), social participation ($P < 0.01$), environmental problems ($P < 0.01$), etc. after one. Compared with students live with their families, the QOLs of students who live alone showed the tendencies of more deteriorations after pandemic panic influenza viral infection. In addition, there were significant positive correlations between total QOL and environmental problems ($r = 0.69$, $P < 0.01$), between total QOL and well-being ($r = 0.68$, $P < 0.01$) etc. **CONCLUSIONS:** These findings indicate that our QOL questionnaire has high enough reliability and potency of validity to investigate the QOL deteriorations by pandemic panic influenza viral infection. Beforehand the pandemic panic influenza viral infection in future, we must take sufficient measures to meet the panic from the view point of QOL.

72/1509/The New Zealand version of the WHOQOL-BREF: Confirming the factor structure and making multi-group comparisons

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AIMS: The New Zealand WHOQOL Group has recently collected WHOQOL-BREF data from the general population using a random sample from the national electoral roll. **METHODS:** As is standard practice when validating the generic WHOQOL instrument in a new country, a confirmatory factor analysis was conducted. **RESULTS:** The four-domain structure of physical, psychological, social and environmental quality of life was confirmed. In addition to presenting these results, some technical aspects of using confirmatory factor analysis with WHOQOL questionnaires will be considered, such as method of estimation used. **CONCLUSIONS:** Multi-group confirmatory factor analyses are a useful tool for comparing the factor structure across groups, as will be demonstrated using a moderately sized ($n = 713$) sample of university students.

73/1781/Longitudinal response in the agricultural community - Lessons from the Regional Rural Injury Study-III (RRIS-III)

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AIMS: To identify factors related to non-response among agricultural households (HH), to facilitate adjustment in analysis of HUI23 data. **METHODS:** The U.S. Department of Agriculture National Agricultural Statistics Service randomly sampled 32,000 agricultural operations from their Master ListFrame, in equal numbers from five Midwest states. Computer-assisted telephone interviews screened operations for eligibility. Many were not farming/ranching, others had no children (under 20 years), and interviews could take an hour, so 1,460 participated. A single respondent was used for each HH, with the female head of HH preferred. Baseline (BL) interviews for the period from 7/1-12/31/06, included demographics, HUI23, work history, lost work time, child health care and behavioral profile. Two follow-up interviews for the first and second six months of 2007 updated demographics, HUI23 and collected injury reports. **RESULTS:** Females were 66.4% of

respondents, mean age 43.9 (7.8), with 4.3 (1.2) people per HH. Response to the two follow-up surveys was 80.7% and 71.6%, respectively. Slightly increased response to the first follow-up was associated with age of the BL respondent (RR=1.03, 95% CI=1.01, 1.04). Factors associated with decreased response to the first follow-up were: having someone in the HH miss farm work or be unable to do home chores/childcare, due to a child's illness, injury or health condition (O.R.=0.675, 95% CI=0.466, 0.976 and O.R.=0.558, 95% CI=0.360, 0.867, respectively), and having a child - hospitalized (O.R.=0.552, 95% CI=0.333, 0.914), visit an emergency department (O.R.=0.672, 95% CI=0.486, 0.929), and receive other health care (O.R.=0.761, 95% CI=0.589, 0.985). No significant factors were identified for the second follow-up. **CONCLUSIONS:** Most factors identified increased the length of the BL interview, so a decrease in follow-up response is no surprise. However, data from the missing HH are far from missing at random and failure to appropriately adjust for these factors could falsely represent the health status of the agricultural community.

74/1257/The Development and Validation of a Sub-health Questionnaire (SHQ)

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AIMS: The WHO health concept of physical, social and psychological well-being is an ideal state that is difficult to attain. Many people have symptoms or problems that do not meet disease criteria. Sub-health state (SHS) is defined as an intermediate state between health and disease, but no standard diagnostic method is available. The aim of the study is to develop and validate a Sub-health Questionnaire (SHQ) to identify people with SHS to facilitate the study on the epidemiology and clinical significance of SHS.

METHODS: Theoretical framework for classifying different health states (Health, SHS & Disease) was established for SHQ. Items were generated using a conceptual model based on the literature review of WHO health concept, SHS criteria of Chinese medicine and medical unexplained symptoms (MUS) and disease criteria. The clarity and relevance of SHQ were reviewed by experts and lay persons by cognitive debriefing, and unclear and misinterpreted items were revised. Psychometric testing was carried out by a cross-sectional survey followed by a repeat test in 353 Chinese adults. All enrolled subjects also completed the SF-12v2 and a questionnaire on sociodemographic data & chronic morbidity. **RESULTS:** The SHQ demonstrated high internal consistency (Cronbach's alpha=0.803). All items had high Content validity index (CVI) on clarity and relevance. Confirmatory factor analysis showed that the structure fitness was good (Cumulative=55.076%). Test-retest reliabilities of diagnostic consistency for health states were high with Kappa > 0.5. There were significant differences in SF-12v2 summary scores (PCS & MCS) between different health states supporting construct validity. Item means of SHQ were generally have significant correlation ($r > 0.3$) with SF-12v2 scores as hypothesized. All but a few items satisfied all scaling assumptions, suggesting conceptual equivalence. **CONCLUSIONS:** We conclude SHQ meets established psychometric criteria for reliability and validity and its diagnostic application for SHS is confirmed.

75/1789/CVT-GOHISALO Questionnaire to measure Quality of Work Life, "Validation"

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AIMS: To develop and validate a questionnaire to measure the Quality of Work Life (QWL) in a sample of workers, doctors and nurses, of a health institution in Mexico. **METHODS:** The questionnaire was developed in three phases, at first we worked on the development of the items on the basis of a theoretical framework, which is also used for the validation of content and construct. This content validation was completed by consulting with experts. The second phase was carried out by applying it to a sample of 322 doctors and nurses, of the Ministry of Health in Guadalajara. They were randomly selected from the three levels of health care attention of the institution. Simultaneously it was applied the Goldberg's General Health Questionnaire (GHQ 28) used as external criteria for validation of criteria and in the last stage it was analyzed the data to complete the studies of reliability and validity of the instrument, seeking the validity of construct. **RESULTS:** To validate the approach, items were rated according to the correlation between the answers of the experts, leaving the 74 items in seven dimensions. The construct validation factor analysis was performed using the method of principal axes to seven dimensions, obtaining a significant validity for the questionnaire of 0.68 and for the validation criteria, in which the Goldberg's General Health Questionnaire was used as an external criteria, the risk of mental illness with the least QWL was agreed. The reliability of the instrument was of 0.967 same as measured with Cronbach's Alpha Coefficient. **CONCLUSIONS:** Based on the content validation process, construct and criterion, which was submitted the questionnaire CVT-GOHISALO, proved to meet the psychometric properties for measuring the QWL in this population. For its psychometric properties, this questionnaire is potentially useful for measurements in places where workers differ in their specific social and economic status, in addition to their own working conditions and will give us the opportunity to use it and validate it in other workers.

76/1576/Health related quality of life in patients with chronic obstructive pulmonary disease-a comparison with general population norms

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AIMS: A substantial burden associated with chronic obstructive pulmonary disease (COPD) has been reported. Thus, increasing attention is being given to how COPD patients experience their health related quality of life (HRQOL). However, few studies have compared HRQOL in COPD with general population norms. The aim of this study was to evaluate HRQOL in patients with COPD compared with general population norms. **METHODS:** A cross sectional, comparative design was applied. The samples consisted of 100 COPD patients (response rate 74%) waiting for a pulmonary rehabilitation program and 3,594 individuals from the Norwegian general population. The patients filled in a questionnaire consisting of 1) Demographic data and 2) SF-36 Health Survey. Chi-square and Analysis of Variance were used as statistic analysis. **RESULTS:** COPD patients were older, less educated, frequently lived alone, and there were more males compared to the healthy general population ($p < 0.003$). For the COPD patients, the SF-36 scores were as follows; physical function=52.44(SD=25.19), role physical=30.11(SD=39.62), bodily pain=63.15(SD=29.27),

general health=46.34(SD=22.98), vitality=49.85(SD=21.73), social function=74.37(SD=27.69), role emotional=47.99(SD=44.50), and mental health=73.78(SD=17.88). For the unadjusted healthy general population, the SF-36 scores were as follows; physical function=88.42(SD=17.13), role physical=82.28(SD=33.32), bodily pain=78.52(SD=23.69), general health=80.31(SD=18.02), vitality=67.09(SD=19.09), social function=90.11(SD=17.97), role emotional=88.35(SD=27.56) and mental health=83.92(SD=13.89). Compared with the age matched healthy general population, COPD patients reported significantly lower scores on all SF-36 components compared with the healthy general population norms ($p < 0.001$). Large differences were found in physical function, physical role, general health, vitality, social function, and emotional role (Effect size ≥ 0.9). **CONCLUSIONS:** COPD patients reported significantly lower HRQOL than the age matched general population norms.

77/1245/Factorial invariance of the SF-36 among disease groups
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AIMS: To compare health-related quality of life (QOL) across groups, researchers have to assure that items of a QOL measure represent the same constructs across groups. This study investigated factorial invariance of the SF-36 between a healthy population and populations with diseases 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 13,374 participants aged 18–98 who completed the SF-36. The analysis was limited to 7 diseases where at least 200 individuals had that specific single condition; these were diabetes, heart disease, hypertension, liver disease, peptic ulcer, pulmonary disease and sinusitis. In this study, confirmatory factor analyses (CFA) on the original model with eight first-order factors and two second-order factors were conducted. Two-group analyses with unconstrained/constrained parameters were conducted to confirm the comparability of CFA factor structures between groups. **RESULTS:** In general, the χ^2 discrepancy tests showed that three disease groups (heart disease, pulmonary disease and sinusitis) and their matched (with age and gender) healthy groups shared the same factor loadings. Four disease groups (diabetes, hypertension, liver disease and peptic ulcer) and their matched healthy groups did not share the same factor loadings. Moreover, six pairs of different disease groups shared the same factor loadings, including diabetes and heart disease, diabetes and hypertension, diabetes and peptic ulcer, heart disease and peptic ulcer, heart disease and pulmonary disease, and liver disease and peptic ulcer. **CONCLUSIONS:** In other words, after controlling age and gender, same perceptions on the SF-36 questionnaire were found between heart disease, pulmonary disease and sinusitis and their matched healthy groups and six pairs of different disease groups.

78/1593/Haemophilic Patients Health Related Quality of Life: Relationships Between Generic and Disease Dimensions
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AIMS: To describe relationships between generic and specific disease health-related quality of life (HRQoL) dimensions in French patients with haemophilia. **METHODS:** We performed in 2008 a cross-sectional study on French adult population with moderate or severe, A or B haemophilia of 28 centres ($n = 1413$). HRQOL was measured with one generic questionnaire (SF-36), one specific questionnaire for rheumatoid arthritis patients (AIMS2-SF) and one specific questionnaire for patients with haemophilia (HAEMO-QOL). Associations between generic and specific dimensions were measured with multitrait multimethod. **RESULTS:** 635 men (2 women were excluded) (mean age: 37.0 ± 14.5); haemophilia A: 79.6%; severe haemophilia: 61.9%. returned the questionnaires. All HRQOL generic dimensions were positively correlated with both HRQOL specific disease dimensions. The AIMS2-SF Physical and Symptom dimensions were highly correlated with respectively SF-36 Physical functioning and Bodily pain dimensions ($r \geq 0.7$). Only HAEMO-QOL Social and physical activities dimensions were highly correlated with SF-36 Physical functioning, General health and Physical Component Summary (PCS) dimensions ($r \geq 0.7$). The seven other dimensions of HAEMO-QOL were moderately or weakly correlated with SF-36 dimensions especially Observance ($r < 0.2$). **CONCLUSIONS:** These results will be discussed in terms of difference and convergence in explored dimension, complementarities of information brought by disease specific questions, redundancy between instruments and utility of combining generic and disease specific instruments.

79/1244/Life enjoyment and cause-specific mortality among men and women: The Japan Collaborative Cohort Study
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AIMS: The association between optimism and health outcome has been attracting increasing research interest. To date, no clear associations between mortality and psychological variables related to quality of life (QOL) have been established. We aimed to examine the effects of perceived life enjoyment on cause-specific mortality among the residents of a Japanese community. **METHODS:** The Japan Collaborative Cohort Study, a multi-institutional collaborative research effort, began in 1988–1990 and involved 110,792 individuals (46,465 men and 64,327 women) living in 45 communities throughout Japan. After the exclusion of subjects with medical histories of cancer or cardiovascular diseases or with missing data on items related to life enjoyment, 33,403 men and 47,063 women (mean age \pm SD of 56 ± 12 years) were included in the analysis. The median follow-up period was 16 years. Data on perceived life enjoyment and other variables were obtained via self-administered questionnaires. Life enjoyment was categorized as *low*, *medium*, *relatively high*, or *high*. Using Cox proportional-hazard models, hazard ratios (HRs) and 95% confidence intervals (CIs) were calculated after adjusting for age and other potential confounding factors. **RESULTS:** Japanese men and women expressing less enjoyment in life showed increased total mortality risk. The multivariate HRs for total and cause-specific mortality for men and women with the highest versus the lowest levels of life enjoyment were: 0.74 (95% CI, 0.65–0.85) and 0.73 (95% CI, 0.63–0.83) for total mortality; 0.73 (95% CI, 0.56–0.94) and 0.64 (95% CI, 0.51–

0.80) for mortality related to cardiovascular diseases; and 1.0 (95% CI, 0.81–1.3) and 1.1 (95% CI, 0.84–1.5) for mortality related to cancer. **CONCLUSIONS:** Life enjoyment is independently associated with total mortality and mortality related to cardiovascular diseases among Japanese men and women. Improving QOL and having high level of life enjoyment may contribute to decrease mortality risk.

80/1129/Psychological Correlates and Quality of Life of HIV Infected Persons (A study from India)

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AIMS: The aim of this study was to evaluate Depression, Anxiety, Stress, and quality of life (QOL) of HIV positive persons and examine its correlates with selected socioeconomic and HIV/AIDS related factors. **METHODS:** The participants were adults (N= 309, male-100, female-209), registered with Network for Positive People an NGO in Tamilnadu, India. Symptoms of depression, anxiety and stress were evaluated with the DASS-21 by Lovibond and Lovibond (1995). The WHOQOL-HIVBREF-31 (2002) was used as a measure of their quality of life. **RESULTS:** The respondents had a mean age of 33.3 years, more than half of them had basic school education and were agricultural labourers. The average monthly family income was \$75 and the average period of infection was 3.7 years. Majority (60%) of the women had contacted the infection from their husbands and were in phase II of HIV/AIDS (63%). Based on group mean, results indicate that the majority of respondents scored low on quality of life, anxiety, depression and stress. Highly significant gender differences were seen on the depression and stress scores but not on anxiety or QOL. Bi-variate analysis of data shows that all dimensions of QOL show significant ($p < .01$) negative correlations with the depression, anxiety and stress scores. The duration of the infection correlated negatively with the anxiety score ($p < .01$) but not with other dimensions. The income of the respondents showed significant negative correlations with depression and stress scores and positive correlations with the total quality of life scores and its sub-dimensions such as physical and psychological health, level of independence, environmental resources and beliefs related to spirituality. Highly significant negative correlations were obtained ($p < .001$) between depression, anxiety, stress and the QOL scores. **CONCLUSIONS:** These findings agree with the Western literature on depression and anxiety in HIV positive people (Basu et al. 2005) and indicate areas of intervention while working with this population through the use of appropriate psychotherapeutic procedures.

81/1632/Quality of Life & Socio-demographic Characteristics

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AIMS: This project is carried out with the purpose to describe the possible association among some socio-demographic characteristics, being gender, parents education, monthly family income, as well as a number of public medical, common and recreational services that exist in the communities of residence of the sample, with the Quality of Life. **METHODS:** 418 high school's students (248 female and 169 male) from four municipalities of the state of Jalisco in Mexico

were evaluated. The instruments applied were the WHOQOL-100 and a survey of socio-demographic variables. Also included was a question regarding which elements diminished the quality of life of the subjects. **RESULTS:** The results originating from the analysis of correlation, demonstrated that the socio-demographic variable that correlated the most with the facets and life quality controls were the monthly family income that correlated with the general life quality score ($r = .157$), with the facets of the psychological control, positive affections ($r = .18$), thoughts ($r = .14$), interpersonal relations ($r = .14$) and social support ($r = .17$). Furthermore there was a correlation with the facets that corresponded environment domain which are: Residential environment ($r = .15$), Finances ($r = .31$), Informative Media ($r = .22$) and leisure ($r = .25$). The second Socio-demographic variable that had correlation was the father's education. It associated to the facets of thought ($r = .16$), Social backup ($r = .13$), Residential environment ($r = .14$), Finances ($r = .22$), Informative Media ($r = .20$) and Leisure ($r = .17$). Also 42% of the sample that was questioned about which elements affected their quality of life referred their physical environment, 25% mentioned social problems (addictions, unemployment, injustice and marginalization), 15% referred the social systems (public security, impartation of justice and poverty) and an 11% declared a deficiency in public services. **CONCLUSIONS:** Quality of Life is associated with monthly family income. The father's education is related to psychological, social and environment domain.

82/1646/Health-Related Quality of Life and Sociodemographic characteristics in High School students

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AIMS: To investigate the relationship between Health Related Quality of Life (HRQL) and sociodemographic characteristics in adolescents. **METHODS:** The inclusion data was 5226 adolescents 14 to 18 years old, at the entry in 10th grade, from PRALIMAP study, a cluster randomized trial performed in 24 high schools to assess the effectiveness of three overweight and obesity prevention strategies. HRQL was measured with the Duke Health Profile-Adolescent. Sociodemographic characteristics included gender, age, residence background, type of high school, perception of family economic status, family size, socio-economic status and occupation of relative in charge. Bivariate and multivariate analyses were performed with HRQL as the dependent variable. **RESULTS:** Girls represented 55% of the sample ($n = 2872$). The mean age was 15.7 ± 0.6 years. Half of the students (51%) lived in urban setting, 68.5% attended general school and 6.4% found family economic status low. On average 3.4 ± 1.3 persons lived in a household, 5.4% of parents did not work. Most of the students' relatives (56%) were employees, workers, farmers or craftsmen. It was seen that gender, age and socio-economic level had a significant effect ($p < .0001$) on mental, physical and social scores. But residence background, type of school, perception of family economic status, family size, socio-economic status and occupation of relative in charge did not. Girls were significantly ($p < 0.0001$) more likely to report poor HRQL scores compared to boys on mental (57.3 vs 73.3), physical (70.1 vs 82.2) and social (66.2 vs 71.9) dimensions. Age was negatively correlated with all explored scores ($p < 0.0001$). The three scores increased significantly with family economic status ($p < 0.0001$) in adolescents. Mental health scores were lower in vocational school than general school ($p < .05$), only in girls. **CONCLUSIONS:** Being girl, older and from lower socio-economical level predicted poor HRQL scores. Economic status is the most powerful indicator of social HRQL inequalities.

83/1729/Differential Item Functioning in the Center for Epidemiological Studies: Depression between English and Spanish versions in a Latino Cohort

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AIMS: To determine whether items in the Center for Epidemiological Studies: Depression (CES-D) perform similarly in the English and Spanish versions of the CES-D for differential item functioning in Latino subjects. **METHODS:** Data were collected in the Los Angeles Latino Eye Study. Participants could select the language of their choice, English or Spanish, to complete an interviewer-administered questionnaire. Mplus was used to assess unidimensionality of the data. Multilog was employed to estimate a two-parameter graded response model using marginal maximum likelihood estimation. Item Response Theory Likelihood Ratio Differential item Functioning (IRTLRDIF), an IRT based method which uses the likelihood ratio, was used to evaluate DIF. The difference in the mean score for English and Spanish respondents was estimated in a two group fully constrained model in Multilog. The changes in mean group difference between a fully constrained model and a model which frees up one item at a time were also estimated to evaluate the magnitude of the DIF. **RESULTS:** Running IRTLRDIF revealed that at least one item parameter was not equal for 7 of the 11 items. Based on the 0.02 effect size cutoff (0.2/11 items) for change in mean score differences, Items 2 (« My sleep was restless »), 4 (« I felt depressed ») and 5 (« I felt everything I did was an effort ») perform differently in the threshold parameters for the English and Spanish language groups. At the same level of depression, Spanish respondents are less likely to endorse these items than English respondents. **CONCLUSIONS:** Three of the 11 items of the CES-D showed potential noteworthy differential item functioning in this analysis of Latinos responding in English versus Latinos responding in Spanish. English-speaking and Spanish-speaking Latinos with the same level of depression respond differently to these items. This study has important implications in the study of depression among diverse populations.

84/1208/Paranoid ideation: predictor of Quality of Life?

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AIMS: At clinical levels persecutory delusions are known to be associated with reduced QoL. The aim of this study was to investigate the relationship between paranoid ideation and quality of life (QoL) in a non-clinical sample after controlling for negative affect. **METHODS:** We assessed QoL, paranoid ideation and negative affect in a sample of 171 student participants (mean age 25 (SD 6.6): 86% female). We used the World Health Organisation Quality of Life Scale (WHOQOL-100) to assess the following domains of QoL: physical health, psychological health, level of independence, social relationships, the environment, and spirituality religion and personal beliefs. Paranoid ideation (ideas of reference (e.g. “people are gossiping about me”) and ideas of persecution (e.g. “someone intends me harm”) scales) was assessed with the Green et al Paranoid thoughts scale (GPTS), and negative affect with The Depression Anxiety Stress Scales (DASS-21). **RESULTS:** Scores on the ideas of reference and ideas of persecution scales were negatively correlated with QoL. Overall, depression scores were the best predictor of QoL. However, after controlling for negative affect, scores on the ideas of reference scale were significant negative predictors of scores on all domains except spirituality, religion and

personal beliefs. Ideas of reference were a marginally significant ($p < 0.07$) predictor of the environment domain. **CONCLUSIONS:** Our findings suggest that paranoid ideation has a negative impact on QoL ratings even after controlling for negative affect. Consequently, this may have implications for interventions to improve QoL and enhancing clinical outcomes in persons experiencing paranoid ideation and negative affect. Furthermore, such assessments could inform policies and program development to attenuate the impact of paranoid ideation and depression on QoL.

85/1437/The Use of mixed method to study the psychometric qualities of the unsupported social interactions inventory

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AIMS: The aim of this study is to examine the construct validity, sensitivity, item spread and differential item functioning (DIF) of the Unsupportive Social Interactions Inventory (USII) using Rasch measurement model and confirmatory factor analysis (CFA). **METHODS:** 485 patients with mental illness were recruited from an inpatient unit of a hospital in northern Taiwan. Their mean age was 41.1 (SD=13.3). They were diagnosed as schizophrenia (51.8%) and depression (48.2%). The Winsteps, AMOS and SPSS were used for data analysis. The study was approved by the university IRB board. **RESULTS:** Two items were deleted due to poor item total correlation. The rating structure of the 4 subscales was adequate. All items fit with the Rasch measurement model to form 4 subscales which were distancing, minimizing, blaming and bumbling. The result of the principal components analysis of the residuals of each subscale confirmed the unitary dimension of each subscale (eigenvalue<3). The results of the CFA demonstrated that the requirement of model fit (GFI>.90, AGFI>.90, NFI>.90, CFI>.90) were met for all subscales. There were 6% to 17% of the subjects who were beyond the range of 10% confidence interval to be accurately targeted at. However, since these were the subjects who may not need further intervention, we would not worry about them. The separation reliability ranged from .93 to .99. There were 6 and 4 DIF items for diagnostic and gender groups. **CONCLUSIONS:** The study showed that the USII was comprised of 4 subscales when applied to a group of subjects with mental illness in Taiwan. The sensitivity and spread of the items were adequate to measure the level of the unsupported social interactions. The internal consistency of the 4 subscales was good. There were DIF items for diagnostic and gender groups needing further development. Since unsupportive social interaction will likely to impact on the level of adjustment of the clients. It is important for professionals to measure it and provide intervention toward lessen the level of unsupportive social interaction.

86/1449/The KIDSCREEN to Assess Quality of Life of Adolescents with Autism Spectrum Disorders

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AIMS: The purpose of this study was to determine the validity of the KIDSCREEN-27 in a sample of adolescents with Autism Spectrum Disorders (ASDs) from the United States. **METHODS:** Thirty-nine adolescents with ASDs and their parents completed the KIDSCREEN along with the 23-item Pediatric Quality of Life

Inventory (PedsQL), the Screen for Child Anxiety Related Emotional Disorders (SCARED), the Rosenberg Self-Esteem Scale (RSES) and the Short Mood and Feelings Questionnaire (SMFQ). Parents completed the forms acting as a projective-proxy, answering the questions as they believed their child would answer. **RESULTS:** Correlations between adolescents' reports on the KIDSCREEN and on the PedsQL were significant for all sub-scales except one: $r = .59$ for Physical Functioning ($p < .01$), $.78$ for General Mood and Feeling ($p < .01$), $.48$ for Friends and Social Functioning ($p > .01$) and $.28$ for School and Learning. Parent and adolescent KIDSCREEN reports showed significant correlations in three out of five subscales: $r = .41$ for Physical Functioning ($p < .01$), $.45$ for General Mood and Feelings, ($p < .01$) $.11$ for Family and Free Time, $.36$ for Friends and Social Functioning ($p < .05$) and $.23$ for School and Learning. The adolescent self-report data for the KIDSCREEN's General Mood and Feelings scale was also significantly correlated with all other measures used: $r = .64$ for the RSES, ($p < .01$), $-.57$ for the SCARED, ($p < .01$) and $-.72$, for the SMFQ ($p < .01$). **CONCLUSIONS:** The results of this study indicate that the KIDSCREEN can provide valuable information about the QoL of adolescents with ASDs. The KIDSCREEN shows good correlation between adolescent and parent report on most of its subscales and correlates well with other reports of QoL. Although the correlations are high, the KIDSCREEN accounts for a significant degree of unique variance compared to the PedsQL. This is not surprising given the range of questions on the KIDSCREEN, which are not limited to problems but also include positive areas of functioning.

87/1358/The Schizophrenia Caregiver Quality of Life questionnaire (S-CGQoL): development and validation of an instrument to measure quality of life of caregivers of individuals with schizophrenia

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AIMS: This study aims to validate a self-administered, multidimensional QoL instrument based on the point of view of caregivers of individuals with schizophrenia. **METHODS:** Data were collected through the departments of six psychiatric hospitals in France ($n = 246$). The item reduction and validation processes were based on both item response theory and classical test theory. **RESULTS:** The S-CGQoL contains 25 items describing seven dimensions (Psychological and Physical Well-Being; Psychological Burden and Daily Life; Relationships with Spouse; Relationships with Psychiatric Team; Relationships with Family; Relationships with Friends; and Material Burden). The seven-factor structure accounted for 74.4% of the total variance. Internal consistency was satisfactory; Cronbach's alpha coefficients ranged from 0.79 to 0.92 in the whole sample. The scalability was satisfactory, with INFIT statistics falling within an acceptable range. In addition, the results confirmed the absence of DIF and supported the invariance of the item calibrations. **CONCLUSIONS:** The S-CGQoL is a self-administered QoL instrument that presents satisfactory psychometric properties and can be completed in 5 min, thereby fulfilling the goal of brevity sought in research and clinical practice.

88/1108/Health-Related Quality of Life among Greek adults: Obesity-related predictors

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AIMS: Obesity is adversely associated with Health-Related Quality of Life (HRQoL), which has been defined as an individual's perceived physical and mental health over time. However, the association between obesity and HRQoL in Greek population has not been previously examined. The aim of the present study was to identify obesity-related predictors of HRQoL in a sample of Greek adults. **METHODS:** Participants were 327 healthy adults (30–50 years). Body mass index (BMI), body fat (BF) and waist to hip ratio (WHR) were calculated from the measurements of: Weight and height, biceps, triceps, suprailiac and abdominal skinfolds, waist and hip circumferences. HRQoL was assessed with the Greek version of SF-36, which consists of the physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role and mental health subscales each measuring a separate health factor (physical and/or psychological health). Leisure time and sport physical activity (PA) was estimated by the Baecke PA questionnaire. A series of hierarchical regression analyses were conducted to examine the obesity-related predictors of HRQoL. **RESULTS:** The three obesity indexes negatively predicted the physical health factor ($F(7,319)=13.54$, $p=.00$), whereas they did not predict any of the psychological health scales. Specifically, BMI was a predictor of physical health ($\beta=-.25$, $t=-2.54$, $p=.01$), physical functioning ($\beta=-.38$, $t=-4.82$, $p=.00$) and physical-role ($\beta=-.23$, $t=-2.13$, $p=.03$). Also, BF was a predictor of physical health ($\beta=-.19$, $t=-1.97$, $p=.05$) and physical functioning ($\beta=-.16$, $t=-2.10$, $p=.04$), whereas WHR was a predictor of physical functioning ($\beta=-.25$, $t=-3.18$, $p=.00$). **CONCLUSIONS:** These results confirmed the negative association between obesity and physical health in a Greek adult population underlying the need for public efforts aimed at combating the current epidemic of obesity. Considering that the sample size was relatively small, further research needs to focus on the causes of such obesity and HRQoL associations in a more representative sample.

89/1147/Bodyweight, Gender, and Health-Related Quality of Life: Results from a National Longitudinal Survey of Canadian Adults

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AIMS: The aim is to describe the trajectories of health-related quality of life (HRQL) for males and females associated with each of five categories of body mass index (BMI): underweight, acceptable weight, overweight, obese class I, and obese classes II and III. **METHODS:** Data come from the longitudinal Canadian National Population Health Survey. An inception cohort of non-institutionalized respondents was created in 1994/95. Analyses are based on data for 3864 males and 4745 females who were 40+ in 1998/99 and followed through 2006/07. HRQL was measured with the Health Utilities Index Mark 3 (HUI3). Multi-level growth modeling was used to account for the effects of age and BMI category on trajectories of HUI3 scores. **RESULTS:** In general, HRQL declined with age. For males, there was a substantial HRQL

decrement for being underweight. The HRQL and its trajectories for all other BMI groups were very similar. The results for females are much more complicated. Being underweight was associated with modestly higher HRQL at younger ages but a substantial decrement at older ages. Otherwise the acceptable weight category enjoyed the highest HRQL trajectory, followed by the overweight, obese class I, and obese classes II and III. **CONCLUSIONS:** Given that being overweight and obese are risk factors for a number of chronic conditions that are associated with decrements in HRQL the results for males are surprising. Perhaps the 10-year follow up period was insufficient for these problems to become manifest. The HRQL results for females may reflect the importance of body image and the health effects of excess weight.

90/1599/Personal factors associated with Health Related Quality of Life in patients attending patient education courses while waiting for Bariatric Surgery

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AIMS: In Norway, patients who are on the waiting list for bariatric surgery have to attend a comprehensive patient education course at a Patient Education Resource Center. Previous research has shown that obesity is related to the individuals self-report of physical and mental health. The aim of this study was to explore factors related to HRQoL that might be targeted in future health promotion interventions among participants in patient educational courses. **METHODS:** Data were collected in a cross-sectional correlation design by self-reported questionnaires. Setting: Day 1 or 2 in health promotion educational courses in Norway. Subjects: Out of the 185 patients who attended the courses, 142 (76.8%) volunteered to participate and 128 had valid responses on all items. Mean age was 42.4 years (SD=10.4) and 90 of the participants (70.3%) were women. Measures: HRQoL was measured with the Short Form-12v2. Other standardized instruments measured Self-Esteem Scale (RSES 4 item version), Sense of Coherence (SOC-13), Self efficacy (GSE), Coping style (BACQ), social support, and regular physical activity. **RESULTS:** Descriptive, correlational and multivariate linear regression. **RESULTS:** The obese scored lower on all the HRQoL sub-domains compared with norms. Lower age, having a paid job, being physical active was related to the participants physical health. Multivariate analyses showed that personal factors explained 3.6% of the variance in physical health and 41.6% in the mental health. **CONCLUSIONS:** Personal factors as self-esteem, sense of coherence and a high approached coping style are strongly related to obese peoples mental health.

91/1267/Changes in body mass index and change in obesity-related quality of life in working adults

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AIMS: Obesity is associated with lower health-related quality of life. This study examined whether changes in body mass index (BMI) were associated with changes in Obesity and Weight-Loss Quality Of Life (OWLQOL). Also estimated were the relative roles of dietary behavior change and physical activity behavior change in the

observed changes in OWLQOL. The paper may inform intervention program development in the area of obesity prevention and thereby reduce health disparities **METHODS:** The analyses are part of a large worksite-randomized trial of a multilevel intervention on diet and physical activity behaviors aimed at reducing or maintaining body weight. The theoretical framework for the intervention was a modification of the ecological model. The OWLQOL was developed using the principles of Maslow's needs hierarchy. Data were analyzed for individual-level associations using linear mixed models, accounting for both random worksite effects and fixed effects. **RESULTS:** Gender was an effect modifier of the body mass index - OWLQOL relationship, so analyses were conducted for males and females separately. Adjusting for intervention arm, age, race, income, education, and smoking, a 1.9 unit difference in BMI change (the interquartile range) was associated with a 3 unit OWLQOL decrease (95% CI: -5.1, -1.5) in males and a 4 unit decrease (95% CI: -5.4, -2.8) in females. Similarly, a 23 unit difference in physical activity change (from Godin score) was associated with a 2 unit increase (95% CI: 0.1, 3.8) in OWLQOL score in women only. This association with physical activity change was attenuated by adjustment for confounding factors. **CONCLUSIONS:** Our results suggest that decreases in BMI may improve obesity-related quality of life. The potential to improve obesity-related quality of life could be included as an additional motivating factor in future weight maintenance or physical activity interventions, which may in turn improve the overall well-being of both women and men.

92/1350/Quality of life, weight perception and weight control behavior by gender in Mexican adolescent students

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AIMS: To analyze quality of life (QOL) of adolescent students from University of Guadalajara, Mexico, according to body weight self-perception and weight control behaviors, by gender. **METHODS:** Were included 2401 adolescents (17-19 years) new students of a Mexico's University which were admitted between 2007 and 2009, 61.9% women, 19.4% worked and 99.2% single. An online self-administered questionnaire was used which included the perceptual module of YQOL-R Instrument, and seven items about body weight, adapted from YRBS 2007. Statistics: one-way ANOVA, Post Hoc test Tamhane's T2 and Scheffé were used with STATA 10. Ethics: informed consent, voluntary, private and confidential. **RESULTS:** 57.7 % considered that they had a right body weight. 52% women and 31.7% men were trying to lose weight. Significantly highest QOL scores were for those who felt to be near to right weight, those who were trying to stay in the same weight and those who exercised (p<.05). The lowest QOL scores were reported for those who perceived very overweight (p<.05), those who were trying to lose weight (p<.05), eating less (p<.001), stop eating (p<.001), unsupervised dieting (p<.001), vomiting or taking laxatives (p<.001). Women QOL scores were different (p<.05) among stay in the same weight with those who want to gain weight or those who want to lose weight, while for men only were different with gain weight. **CONCLUSIONS:** This study remarked the domains of QOL associated to perceived body weight, QOL was different depending of body weight self-perception and control behaviors considering gender. This information could be useful in educational process, for prevention programs and to evaluate interventions.

93/1401/The Relationship of Body Mass Index and Health-Related Quality of Life Among Factory Workers: a Pilot-Study
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AIMS: Obesity rates have reached epidemic proportions in many developing nations, including Brazil. The link between obesity and life-threatening illnesses is well established. Likewise, obesity has been considered one of the most important risk factors for workers, negatively influencing their productivity. However, less is known about the relationship of body weight to health-related quality of life (HRQOL), especially for workers. The purpose of this pilot-study was to demonstrate the relationship between Body Mass Index (BMI) and HRQOL in a sample of workers. **METHODS:** For such a purpose, a cross-sectional study was designed and two groups were randomly selected: the first one composed by obese workers ($n=35$) and the second one composed by non-obese workers ($n=33$) from a petrochemical industry in Campinas, Brazil. Body Mass Index (BMI in kg/m^2) was categorized as non-obese (<30) and obese (≥ 30). For the assessment of HRQOL, all of the workers filled out the World Health Organization Quality of Life Questionnaire Abbreviated Version (WHOQOL-Brief), composed of four domains (physical, psychological, social relations and the environment). **RESULTS:** The statistical analysis by the Mann-Whitney test shows that the obese workers group possesses worse quality of life indexes, mainly in the physical ($p<0,033$) and psychological ($p<0,04$) domains when compared to the non-obese group, not being found the same difference in the social ($p<0,20$) and environmental domains ($p<0,47$). **CONCLUSIONS:** Results suggest that the BMI can negatively affect HRQOL. In other words, obesity not only increases the risk of morbidity and mortality, but also affects the perceived quality of life negatively. In conclusion, excess weight was related to worse physical and psychological HRQOL. As the interest for Quality of Life programs at workplace grows among companies, special attention should be given to obesity. More research is needed to elucidate which workplace programs would be effective in reducing obesity and improving the quality of life of workers.

94/1292/Parenting practices as predictors of mental health of adolescents with different body mass index

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AIMS: To investigate the relationship between parenting practices and mental health of underweight, overweight and normal weight adolescents. **METHODS:** The examination was conducted in 2008 as a part of prospective cohort study of 605 children (305 girls and 300 boys). They had been observed in neonatal period, later at age of 3 years old and now at age of 13 years old. Adolescents received by mail questionnaires with Short Form of the Alabama Parenting Questionnaire (APQ-9) and General Health Questionnaire (GHQ-12). School nurses were asked to measure weight and height of pupils. Hierarchical linear regression models were assessed for mother and father parenting practices, both for all adolescents and for adolescents in groups stratified by Body Mass Index (BMI). **RESULTS:** Stepwise linear regression revealed that in total sample, positive parenting of mother explains 5% of variance of adolescents mental health (father's positive parenting explains 4%), consistent discipline of mother or father - 1%, supervision of mother - 0,4%, of father - 2,5%. In group of overweight adolescents positive parenting of mother explains 13% (in normal weight group 3%) of adolescents mental health variance, positive parenting of father - 15%

(in normal weight group - 2%). Supervision of father explains 7% of overweight adolescents mental health (in normal weight group - 1,5%). For overweight girls the most important predictors of mental health are positive parenting of both parents and mother's consistent discipline, for overweight boys - positive parenting of both parents and father's good supervision. **CONCLUSIONS:** Positive parenting (complimenting and praising) is a very important predictor of mental health in overweight adolescents.

95/1322/Weight-related self perceptions in people with type 2 diabetes who are obese

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AIMS: Weight-related self-perceptions may be low in people with type 2 diabetes (T2D) and obesity. We explored factors associated with low weight-related self-perceptions in people with T2D and obesity. **METHODS:** A cross-sectional web survey was administered to people with T2D who were obese (BMI 30-40 kg/m^2). Survey questions included demographics, co-morbidities, measures of life satisfaction, social support, physical/emotional function, concerns related to self-perception, and Impact of Weight on Self Perceptions (IWSP) scale. Data were split randomly in two halves (model building and model validation) and stratified by three levels of IWSP status [low (>1 SD below mean), moderate (<1 SD below mean to <1 SD above mean), and high (>1 SD above mean)]. Classification and regression tree (CART) analysis was used to predict low IWSP. Factors that were significant (chi-square $p<0.05$) in both halves were maintained. **RESULTS:** Analysis included 349 participants (mean age=59 years, 44% male, mean BMI=35 kg/m^2). The first CART dichotomization was based on life satisfaction: of 40 people who were dissatisfied with life, 53% had low IWSP scores versus 10% of those satisfied with life ($p<0.001$), validation set: 62% vs. 8%, $p<0.001$. Those with low life satisfaction were further split based on self-perception concerns: of 34 who had concern with dissatisfaction with appearance, self-consciousness in social settings or overall perception of yourself, 62% had low IWSP scores compared to 0% who answered avoidance of social situations or none of these ($p=0.007$), validation set: 71% vs. 17%, $p=0.02$. Those with high life satisfaction were split based on self-reported rating of anxiety/depression: of 36 individuals who were moderately or extremely anxious/depressed, 19% had low IWSP, compared to 6% who were not anxious/depressed ($p=0.04$), validation set: 21% vs. 3%, $p=0.002$. **CONCLUSIONS:** Although some concepts may overlap, results suggest that for certain patients with T2D and obesity, clinicians may need to address a cluster of psychosocial issues to improve outcomes related to obesity and diabetes.

96/1541/Omega-3 consumption and quality of life : real or marketing effect ?

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AIMS: To assess relationship between omega-3 consumption and quality of life in middle-aged French adults. **METHODS:** Data were collected from participants aged of 45-60 at enrolment in the SU.VI.MAX study, initially designed in 1994 as a primary prevention

trial to test the effect of a daily supplementation with antioxidant vitamins and minerals at nutritional doses in reducing the incidence of cancer and ischemic cardiovascular disease in the general French population. Data were assessed in the first 2 years of SU.VI.MAX. Dietary data collections were based on repeated 24-h dietary records. Value omega-3 intake was calculated through a food composition table when at least 3 dietary records were available. Quality of life was assessed using the SF-36 questionnaire. Cross-sectional analysis used substitutive models to reflect effect of substituting 1 g of omega-6 for 1g of omega-3 and 1g of saturated fatty acids for 1g of omega-3 on quality of life. **RESULTS:** 4876 subjects were included. 53 % were male. Mean age was 51.8 ± 4.6 . Mean daily omega-3 intake was $1.4 \text{ g} \pm 0.5$. SF-36 Mean physical component summary (PCS) was 52.1 ± 6.5 and mean mental component summary (MCS) was 47.8 ± 9.7 . In multivariate analysis, there were a negative significant association between PCS and omega-3 intake, when substituting 1g of omega-6 for 1g of omega-3 ($\beta = -0.78, p = 0.002$) and 1g of saturated fatty acids for 1g of omega-3 on quality of life ($\beta = -0.69, p = 0.004$) and a positive significant association between MCS and omega-3 intake, when substituting 1g of omega-6 for 1g of omega-3 ($\beta = 1.07, p = 0.005$) and 1g of saturated fatty acids for 1g of omega-3 on quality of life ($\beta = 1.11, p = 0.002$). **CONCLUSIONS:** The results demonstrate a real link between omega-3 consumption and quality of life. Due to the statistical opposite ways of the association, no recommendation should be done in terms of public health.

97/1284/To survey young stem cell transplanted (SCT) patients HRQOL as an intergrated part of the comprehensive care program, can this affect the planning of follow-up care?

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AIMS: How can we detect problems with very longterm HRQOL following allogeneic stem cell transplantation in childhood? Can this information have an effect on the planning of continuous follow-up care in adult life? **METHODS:** This intervention are based on a single center study (Löf et al. 2009) exploring HRQoL in adults post paediatric SCT (<5-28 years since SCT). Previous results indicated an urgent need to integrate and survey psychological and health aspects when the patient are in the transition to become an adult. The present approach is to use relevant supportive measures to capture psychosocial problems in time to plan follow-up care. Following measurements are suggested; SWEDQUAL, HAD, SOC 13. **RESULTS:** Our previous results indicate that, by using HRQoL measurements, detecting their individual resources, anxiety and depression as well as thoroughly evaluate cognitive faculties; this can be used for planning long term follow-up support. Cognitive and psychological problems were common and indicated a need to support these young ex patients when entering adult life. One approach is to aid them to develop and cope with difficulties in order to improve school aptitude and academic skills, which will strengthen their position in establishing themselves in the labor market. Self-rated health correlate with HRQoL and not the severity of physician-rated late effects, this indicates the importance of PROM of health aspects. **CONCLUSIONS:** Change in HRQoL over time is an important aspect to be aware of in this group with long term survivors after pediatric SCT, as medical and psychosocial late effects can occur later in life. However perhaps more importantly, when patients enter adulthood the medical follow-up should be integrated with a survey and evaluation to continuously plan follow-up support. This in order to be able to give relevant neuropsychological- and

psychosocial support including advice in sexuality and infertility to aid patients to a better life situation and QoL in adult life.

98/1653/Conceptualizing Quality of Life in Children with Cancer and Childhood Cancer Survivors

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AIMS: There is a growing interest in assessing QOL in children with cancer, especially now that most children survive their disease. Our team identified and appraised all pediatric cancer-specific QOL questionnaires [1]. After appraising the content of these instruments, it was apparent that there is a lack of clarity about what constitutes QOL of childhood cancer patients. This study seeks to address this issue. We aimed to identify the most important components of QOL from qualitative and quantitative studies of QOL in children with cancer. **METHODS:** MEDLINE, CINAHL, EMBASE, PsychINFO, Cancerlit, and Sociological Abstracts were searched from the inception of each database to June 2009 for studies of QOL in children with cancer. The following were examined in detail: (1) content (items and scales) from all cancer-specific and generic QOL questionnaires; and (2) themes about QOL described in qualitative studies. A concept sorting exercise was used to organize the questionnaire content and qualitative themes into a conceptual model of QOL for children with cancer and childhood cancer survivors. **RESULTS:** A total of 5133 English language articles were screened, and 115 studies used 10 generic and 11 cancer-specific QOL questionnaires. These questionnaires along with themes from 6 qualitative studies provided close to 1000 QOL items. Our concept sort identified the following 4 domains of QOL: physical, psychological and social wellbeing and cancer/treatment. Each domain included multiple sub-domains. Interestingly, few differences were found when items from cancer-specific measures were compared with items from the generic measures suggesting that a common pool of items potentially could be developed. **CONCLUSIONS:** Our study helps to clarify and organize the range of content thought to be important to understanding QOL of children with cancer into a conceptual model. 1. Klassen AF, Strohm SJ, Maurice-Stam H, Grootenhuis M. Quality of life questionnaires for children and childhood cancer survivors: a comparison of available measures. Supportive Care in Cancer 2009 Oct 16.

99/1771/Solving the Conceptual Discontinuity Problem for Instruments used in Childhood Cancer Research: A systematic review & content analysis using the ICF-CY & WHO definitions

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AIMS: The impact of cancer on children can be assessed through health status and quality of life (QoL). The comparison of data collected through these instruments has been difficult due to lack of conceptual continuity or understanding of overlaps and gaps between them. This study delineates the conceptual discontinuity problem by using standardized methods of linking instruments to the ICF-CY as well as World Health Organization (WHO) definitions of health and QoL. **METHODS:** MEDLINE, CINAHL, EMBASE, PsychINFO, Cancerlit and Sociological Abstracts were searched from the inception of each database to 2009 for health status and QoL

instruments. The six most common cancer-specific and generic instruments employed in primary research of child cancer were analyzed by two content assessors on an item by item basis. The assessors applied ICF linking and WHO definitions of health and QoL using a standardized iterative technique developed at the ICF Research Branch. **RESULTS:** Most instruments emphasize a majority health status perspective according to WHO definitions of health. QoL perspectives composed greater than 15% of the items in 2/6 instruments. The generic instruments stress activities and participation health domains over body functions or environment factors according to the ICF while cancer-specific instruments vary in their emphasis. Initial phase of coding agreement between assessors was in the substantial range 0.6–0.8 using Cohen's kappa. **CONCLUSIONS:** A systematic content analysis of the 6 most employed health status and QOL instruments in childhood cancer was employed. Two criteria were described: the perspectives of the instruments (ie: health vs QOL) and the health content (according to ICF-CY components). No one instrument demonstrated an ideal balance of content characteristics or perspectives according to these criteria and thus each one must be considered carefully relative to one's particular research or clinical evaluative purpose.

100/1455/Measuring Transition Readiness in Childhood Cancer Survivors: Development of a Patient Reported Outcome (PRO) Instrument

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AIMS: Childhood cancer survivors are at increased risk of long-term morbidity that is mainly related to their prior cancer therapy, and require regular follow-up care focused on their specific risks. However survivors often fail to recognize the benefit of follow-up once they reach adulthood and frequently drop out of the cancer care system. The aim of this study is to use modern psychometric methods (i.e., Rasch analysis) to develop a PRO instrument for use in clinical practice to identify survivors at high risk of failing to transition or drop out of adult survivor care. **METHODS:** Developing a PRO instrument is a multi-phased project. This presentation covers Phase I: conceptual model formation and item generation. Methods include literature review, qualitative interviews and expert input. Thirty interviews were conducted with survivors aged 15–26. They varied by age at diagnosis, gender, type of cancer and stage of transition (pre, successful or failed to transition). Analysis involved line-by-line coding and constant comparison to examine relationships within and across codes and to develop a conceptual framework. Scales representing the model's major concepts were developed by thematically grouping potential questionnaire items extracted from the coded material. **RESULTS:** Barriers and facilitators to transition were categorized into the following 4 key domains for which scales and items were developed: healthcare factors (i.e., supportive healthcare providers), psychological issues (i.e., fear of cancer recurrence), informational and educational factors (i.e., provision of written materials), and familial and social support (i.e., parental concern). A preliminary version of a multi-dimensional questionnaire will be field-tested with a large sample of cancer survivors. **CONCLUSIONS:** Once completed, this PRO instrument

will provide healthcare professionals with a new tool that can be used to identify and address an individual cancer survivor's barriers to successful transition to adult care before discharge from the pediatric setting.

101/1569/Development and validation of a questionnaire measuring quality of life (QOL) in the parents of children treated for acute leukaemia (AL)

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AIMS: Parents of children who survived after AL were very involved in their child's care. During treatment time their usual activities may have been modified, leading to physical and psychological affliction and impacting on their QOL. But even once treatment completed, the disease and its treatment could have durably shifted the parents' life. There is no instrument to specifically assess the impact of AL in caregivers' QOL. The study objective was to validate a specific QOL questionnaire for caregivers with a child treated for an AL. **METHODS:** A 75-item questionnaire generated from content analysis of interviews with caregivers was self-completed by 294 parents of children aged 2 - 17 years recruited from 7 cancer centers in France. In addition to sociodemographic data, clinical and children's QOL (VSPA questionnaire) data were collected. The item selection resulted from an approach combining statistical methods (relying on both classical test theory and item response theory) and item content review. **RESULTS:** A 30-item questionnaire describing 9 dimensions (emotional (Em), day by day issues (DDI), burden (B), psychological (Ps), physical (Ph), parent/health professional relationship (PHR), caregiver own time (COT), support (S), self appreciation as caregiver (SAC), private life (PF)) was isolated from principal component analysis explaining 78% of the total variance. Missing data and floor effects were low. Some ceiling effects were found for B (37%) and SAC (27%). Cronbach's alpha ranged from 0.7 to 0.9 showing strong internal consistency reliability (QOL Index: Cronbach's Alpha 0.92). Unidimensionality of the scales was confirmed by Rasch analyses. **CONCLUSIONS:** These results suggest that the caregivers's questionnaire may provide a reliable and valid measure of parents' quality of life related to their children's AL. Further exploration of external validity of this questionnaire is needed.

102/1587/French Cohort of Childhood Leukaemia Survivors: Impact of Haematopoietic Stem Cell Transplantation (HSCT) on Health Status and QOL

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AIMS: The French LEA program was initiated in 2003 to study health status and QoL of long-term survivors of childhood acute leukaemia (AL). Using data from this cohort, the aim was to compare late side effects and patient's quality of life (QoL), based on whether

they had undergone HSCT or not. **METHODS:** Were included: all children diagnosed and treated for AL since January 1980 (incident and prevalent cases), being under 18 at diagnosis, completion of chemotherapy or HSCT at least 1 year before inclusion. Informations collected: sociodemographic and socioeconomic data; clinical and therapeutic data relating to the AL; data on physical late effects (weight-height growth, puberty-fertility, thyroid, cardiac and pulmonary function, visual function, secondary tumors, viral contaminations, bone tissue metabolism, metabolism of iron, metabolic syndrome, other late effects); psycho-behavioural and cognitive data; data on QoL of the subjects and their family (VSP-A or SF36 based on age); environmental data; data on the patient relations with the health-care system. After the date of diagnosis of AL, data collection was made every 2 years until the patient is 20-year-old and has a 10 years follow-up duration. Thereafter, assessments were planned every 5 years. Cox model analyses were used to compare risk of each type of late effect in the two groups of treatment. QoL scores were compared to a French general population of reference and for each QoL dimension, multivariate logistic regression were performed to construct models of association with the treatment group. **RESULTS:** Final results on the total sample will be available in September 2010. Currently, 941 children survivors have been included: 253 underwent HSCT (male 52.8% and AML 8.1%) and 688 did not (male 62.5% and AML 31.2%). Statistical analysis is ongoing. **CONCLUSIONS:** The important size of our sample allows to expect interesting results to discuss. In addition to the risk of physical adverse effects, clinical consequences of the treatment on the QoL are interesting to evaluate.

103/1359/Long-term survivors of childhood cancer report quality of life and health status in parity with a comparison group

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AIMS: In the growing population of long-term survivors of childhood cancer treatment related health problems have been widely acknowledged. Little is known about how young adult survivors perceive their current lives and about what influence health status has on their quality of life. The objective was to describe quality of life in relation to self-reported health status and socio-demographic characteristics among long-term survivors of childhood cancer as compared to that among a sample from the general population.

METHODS: Telephone interviews were performed with a cohort of 246 long-term survivors and 296 randomly selected from the general population using the Schedule for the Evaluation of Individual Quality of Life- Direct Weighting (SEIQoL-DW). The participants nominated the areas they considered to be most important in life and rated the current status of each area on a seven-point category scale. An overall individual index score was calculated as a measure of quality of life. Self-reported health status was assessed using the Short Form Health Survey (SF-36). **RESULTS:** Long-term survivors rated their overall quality of life and self-reported health status almost in parity with the comparison group. In both groups, family life, relations to other people, work and career, interests and leisure activities were the areas most frequently reported to influence quality of life. The survivors only differed from the comparison group on one of eight SF-36 scales reflecting problems with daily activities owing to physical health. **CONCLUSIONS:** Health status was not shown to have a major impact on overall quality of life, indicating that health and quality of life should be evaluated distinctively as different

constructs. This should be taken in consideration in clinical care of children with childhood cancer and long-term survivors.

104/1804/Innovative media for quality of life of Thai children with terminal cancer

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AIMS: This study is a multi-disciplinary R&D project of which objectives are to study quality of life, needs, and factors influencing end-of-life learning for children with terminal cancer; to explore learning models, develop prototype media, and evaluate quality/satisfaction by experts and all concerned parties. An essential goal of such learning is to enhance quality of life in holistic manners which encompass physical, mental, and spiritual needs of patients as well as emotional support for parents. **METHODS:** The researcher collected and compiled data from qualitative research by using various study techniques including documentary review, observation/participatory observation, in-depth interview, focus group interview, informal opinion survey among users/experts that participated in a working group. Sample groups comprised parents who lost their children from cancer, parents of children with terminal cancer who are still alive, pediatricians/medical professionals, and competent persons in relevant fields. Statistics used is Mean, Weighted average, and Interval Scaling. **RESULTS:** In study findings, design of end-of-life learning for children with terminal cancer must take into account numerous influencing factors. This study presents an innovative instructional system model and an end-of-life teaching model. Edutainment, Multi-sensory communication and Buddhism were found to be accepted core educational treatments in Thai children with terminal cancer and meet expectation of parents, experts, and concerned parties at very good level. Furthermore, experts, parents and concerned parties expressed satisfaction with all project media prototypes at very good level. They accepted that it is an innovative form of learning that needs a sustainable development and expansion plan. **CONCLUSIONS:** Educational technology is playing new vital role that will create and provide end-of-life learning, a new context of education at a critical time of mankind, for holistic quality of life in the final days of lives in all Thai society, no matter where those dying people are so remotely

POSTER SESSION 2

CLINICAL PRACTICE & RESEARCH

105/1330/The Value of Quality of Life Information to Hormone Refractory Prostate Cancer Patients Facing Treatment Decisions

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AIMS: In symptomatic patients with hormone-refractory prostate cancer (HRPC), chemotherapy has been shown to modestly increase survival and pain control but can be associated with substantial toxicity. Decision-making therefore requires translating the risks and benefits of treatment for patients. This pilot study explored the feasibility and the apparent value of using clinical trial health-related quality of life (HRQL) data in decision support for patients in this context. **METHODS:** Presentation boards containing 5 information types (treatment description, risks, survival, symptom improvement, and HRQL outcomes) were developed for 2 treatment options: best supportive care and docetaxel (based on clinical trial results and clinician input). Participants were recruited from 2 medical oncology practices. A 1-hour structured interview with a research associate was conducted after the initial medical consultation. A 10-pt Likert scale anchored with 'definitely want chemotherapy' and 'definitely do not want chemotherapy' was used to evaluate treatment preference prior to and after information provision. Patients rated the usefulness and the understandability of each type of information using a 10 point scale, and debriefed the interviewer on their perspectives. **RESULTS:** Sixteen patients participated in this pilot study. The mean strength of treatment preference (SOTP) at baseline was 7.3, indicating strong average preference for chemotherapy. Following information presentation, the mean preference of the group increased further to 8.03 ($p=n.s.$). Individual changes in SOTP ranged from -3 to +5. Six patients (37.5%) demonstrated a shift in SOTP > 2 points (10 pt scale). Patient ratings for the clarity and usefulness of all types of information were high, (mean 9.2 to 9.4). **CONCLUSIONS:** Treatment decision-support information was rated highly by HRPC patients, and shifted strength of treatment preferences of some. Limitations inherent in using existing clinical trial HRQL data to inform patient decision-making will be discussed.

106/1299/Comparative-effectiveness of surgical approaches for robotic prostatectomy

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AIMS: Robotic prostatectomy has supplanted the retropubic approach in the U.S., with nearly 80,000 performed in 2009. The vast majority are performed intraperitoneally (IP), which is a departure from the historical extraperitoneal (EP) approach. The advantages of the IP approach are easier access and fewer anatomical constraints. Potential disadvantages include bowel-related side effects and their implications for recovery. We compared oncologic and QOL outcomes among patients undergoing IP or EP robotic prostatectomy for prostate cancer. **METHODS:** 169 patients undergoing IP ($n=53$) or EP ($n=116$) robotic prostatectomy were included. Cancer control was evaluated using margin status. Recovery after surgery was measured using CARE, a validated questionnaire assessing convalescence in 4 domains (activity, GI, cognition, pain). Functional

health was measured using EPIC, a validated questionnaire for prostate health in 5 domains (incontinence, irritative urinary, sexual, bowel, hormonal). All questionnaires were self-administered and analyses were performed using the chi square test. **RESULTS:** Patients undergoing EP had similar positive margin rates compared to those undergoing IP (14.7% vs. 13.2%, $p=0.08$). At 12 months, there were no differences in functional outcomes by approach, as measured by EPIC. Convalescence after surgery favored the EP approach in both the GI and activity domains. While patients undergoing IP had lower GI scores at 2 weeks (91.9 vs. 84.0, $p=0.03$), these differences abated by later assessments. In contrast, differences in activity were similar between EP and IP at 2 weeks (55.5 vs. 49.4, $p=0.1$), but then diverged at 4 (80.6 vs. 71.6, $p<0.01$) and 6 (87.5 vs. 80.7, $p=0.03$) weeks. **CONCLUSIONS:** Cancer control and functional (i.e., sexual and urinary health) outcomes after robotic prostatectomy are similar when using either the EP or IP approach. However, convalescence after surgery is superior for the EP approach with respect to GI and activity recovery. These data support efforts to broaden the adoption of the EP approach for robotic prostatectomy.

107/1649/Participation in Cervical Cancer Screening and Quality of Life, a Longitudinal Study

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AIMS: As all screening, cytological screening for cervical cancer has unfavourable effects as well. We assessed the health-related quality of life (HRQoL) in screen invitees in the Netherlands during the process of invitation, smear taking and receipt of the test results, and compared it with a reference group from the female general population. **METHODS:** In a prospective, longitudinal design we addressed 2,300 women invited for cervical screening. Attached to their screen invitation they were sent an initial questionnaire on screen specific anxiety (PCQ), generic HRQoL (SF-12, EQ-5D) and anxiety (STAI-6). Sixty percent of screen participants responded at baseline, participation was known at the individual level in 905 women. These women were sent a subsequent questionnaire after they had a Pap smear taken. The third questionnaire, which was completed by 93% of the original cohort, was attached to the smear results. Data on test results at the individual level was obtained from the screening organisation conditional on permission of the women involved. **RESULTS:** At baseline, screen participants reported less screen-specific anxiety ($p < 0.001$) than the reference group ($n=567$), with differences indicating clinical significance. SF-12, EQ-5D, and STAI scores were similar in both groups. Screen specific anxiety increased slightly over time in screen participants. 140 women (19%) were quite or very much bothered by feelings of shame, pain, inconvenience and/or nervousness during the process of smear taking, and 101 women (12%) reported to have experienced symptoms such as lower abdominal pain, vaginal bleeding, discharge, and/or urinary bother for at least 2 days following the smear taking. **CONCLUSIONS:** Although unpleasant effects of smear taking were reported by considerable numbers of women, no indications of relevant negative HRQoL consequences of the invitation, the smear taking and the receipt of the test results were found. The lower level of screen-specific anxiety in screen participants may indicate a reassurance effect, but needs to be addressed in more depth.

108/1633/Genetic Risk Factors and Quality of Life in Colorectal Cancer Patients - is there a Correlation?

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AIMS: In a combined effort of two major research projects, that is POPGEN (populationsgenetisches Forschungsprojekt des Nationalen Genomforschungsnetzes) population based genetic research project of the National Genom Research Network) and the quality of life databank at the reference center on QoL in oncology the correlation between risk factors and differences in QoL is studied. Mutations in the k-ras and TP53 genes, as well as microsatellite instability (MIN), are frequent genetic alterations in colorectal carcinomas and are known to represent 3 different mechanisms in the carcinogenic process. POPGEN aims at identifying others than these established risk factors. One of the multiple research questions in this 10-years-research project concerns QoL: are these known factors as well as others not yet identified have a distinct influence on the postoperative survival time or the postoperative quality of life. About 1200 patients of whom there are data in both databanks entered the analysis, that is currently starting. First result of this study will be presented as a poster. **METHODS:** Out of the about 10.000 blood samples already collected from the northern Germany population 3.000 patients with colorectal cancer were identified. Out of the RZLQ databank 1.400 patients who have been operated for CR-cancer were identified as well. We found a match for a total N of 1.200. Depending on the individual risk factors HRQL of those subgroups will be compared using standard statistical methods. **RESULTS:** We're not that far yet! **CONCLUSIONS:** The expected results can lead to further steps of our way to an individualized therapy of patients with colorectal cancer focussing as well on their specific risk factors as well on their specific HRQL.

109/1268/Early and late quality of life recovery after surgery for endometrial cancer: results from a randomised trial (LACE)

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AIMS: To assess in a clinically relevant fashion the quality of life (QoL) benefit incurred by treatment with Total Laparoscopic Hysterectomy (TLH) compared to Total Abdominal Hysterectomy (TAH) for stage I endometrial cancer within a randomised controlled trial (LACE). **METHODS:** The first 361 LACE participants (TAH n= 141, TLH n=191) were enrolled in the QoL substudy. QoL was measured at baseline, 1 and 4 weeks (early), and 3 and 6 months (late) after surgery using the Functional Assessment of Cancer Therapy-General (FACT-G) questionnaire. Intention-to-treat analysis was performed using generalized estimating equations on differences from baseline for the early and late QoL recovery. This allows answering clinically relevant patients questions such as: "how quickly will I recover?" **RESULTS:** In the first four weeks after surgery, patients undergoing TLH reported significantly greater improvement of QoL from baseline compared to TAH (e.g. 14% better for functional wellbeing ($p < 0.001$)). Recovery in QoL up to 6 months post-surgery continued to favour TLH (functional wellbeing 6% ($p=0.01$); body image 5.4% ($p < 0.001$)). Overall, 52% of patients with TLH experienced clinically important ($>5%$) improvements in their QoL from baseline to 4 weeks following surgery compared with

30% of patients treated with TAH ($p < 0.001$). By 6 months post-surgery QoL improved for 68% of patients with TLH compared to 55% with TAH ($p = 0.01$). **CONCLUSIONS:** Clinicians can use this data to inform their patients about average QoL recovery after surgery for Stage I endometrial cancer during early and later recovery periods. Results indicate a clinically and statistically significant advantage for patients treated with TLH compared to TAH.

110/1554/Integrating health-related quality of life (HRQL) and clinical data to inform decision making: a systematic review of reporting in randomised controlled trials (RCTs) in gastrointestinal cancer (GI)

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AIMS: Many RCTs include measurement of HRQL but evidence suggests data may not influence decision-making. A possible explanation is that assimilation of HRQL information may be hindered by a lack of integrated clinical and HRQL reporting, decreasing awareness of HRQL treatment effects. We examined the reporting of HRQL and clinical outcomes in GI cancer RCTs. **METHODS:** MEDLINE, EMBASE and Cochrane databases were searched (Jan 2000-July 2009) for GI cancer RCTs in chemotherapy, radiotherapy or surgery with HRQL. Titles and abstracts were screened using pre-determined criteria. Further screening assessed risk of bias using the Cochrane Collaboration tool. Independent data extraction recorded whether trials reported HRQL with clinical data or separately, and assessed the time difference between publications. When outcomes were reported simultaneously, abstracts were examined for integration of HRQL. **RESULTS:** Of 1330 abstracts screened, 66 papers were retrieved and assessed for risk of bias, and 48 (reporting 45 trials) retained. Some 13 (29%) RCTs reported HRQL results separately to clinical outcomes, of which 7 (54%) did not report any HRQL data in the clinical paper and 6 (46%) made no suggestion that HRQL results would follow. Two RCTs published HRQL results before clinical data. Median time between publishing main trial and HRQL results was 22 months (IQR 9-30). 32 publications integrated clinical and HRQL data in one paper, but 9 (28%) showed no HRQL results in the abstract. This was more likely to occur if HRQL results did not reach significance ($p=0.03$). Simultaneous or separate reporting of clinical and HRQL outcomes was not associated with a positive trial outcome, or whether HRQL supported clinical data. **CONCLUSIONS:** This study shows poor integration of clinical and HRQL data in GI cancer RCTs. Standards for reporting HRQL with clinical outcomes are needed to facilitate clinical interpretation of trial data and to inform participatory decision-making.

111/1810/Quality of Life in members of prostate cancer support groups

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AIMS: Prostate Cancer is one of the most common forms of cancer in Germany. For patients with localized cancer, several treatment options are available. The HAROW Study was designed for a comprehensive analysis of health care in prostate cancer patients in Germany. This study focuses on members of prostate cancer support groups. **METHODS:** Health related quality of life (QoL) was

assessed cross sectionally using standardized questionnaires such as the EORTC QLQ-C30 and the German Prostate Specific Module (PSM). Altogether, QOL data from 504 patients (members of cancer support groups) were included in the analysis. All medical data were self-reported by the patients. Statistical analyses were performed parametrically using independent sample t-tests and analyses of variance (ANOVA). **RESULTS:** Looking at different treatment regimens we found significant differences in both general and specific quality of life. Especially patients with hormonal and radiotherapy report poor QoL. Patients with a cured tumor report significant better QoL than patients under treatment or who are not cured. Compared to German reference values we found similar scores for general QoL (EORTC QLQ-C30 functional and symptom scales), but also higher levels of symptoms (Prostate Specific Module). **CONCLUSIONS:** Overall QoL in this very special sample (members of cancer support groups) was better than expected. Even though we found differences between different treatments, the most important factor in this analyses determining the patients' QoL seems to be whether the tumor is cured or not.

112/1219/Psychometric Evaluation of a 6-Item Short Form of the Female Sexual Function Index (FSFI) in a Sample of Cancer Survivors

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AIMS: Female sexual dysfunction (FSD) is an important QOL outcome that can be adversely affected by many medical conditions and treatments, including cancer. Assessment of FSD is often avoided due to time constraints and lack of measures or training. An abridged FSFI-6 short form (SF) of the full FSFI-19 was recently shown to be valid in female outpatients at reproductive medicine clinics; however, its usefulness in cancer survivors is not established. This study evaluates the psychometrics of this FSFI-6 SF in a cohort of cancer survivors using both classical and IRT methods. **METHODS:** Female survivors of Gynecological cancers (n=153) and malignancies requiring Bone Marrow Transplant (n=69) age 18-50 completed the full FSFI-19, from which we extracted the FSFI-6 responses. Graded response models (GRMs) were fitted to assess the discrimination, difficulty, and standard errors of the SF items. The area under ROC curves (AUC) estimated the accuracy of the FSFI-6 in classifying FSD based on the clinical cutoff of the full FSFI-19. **RESULTS:** Internal consistency was high ($\alpha=.97$ & $.86$ for FSFI-19 and FSFI-6, respectively). The GRMs, however, suggested that replacing 4 of the 6 FSFI-6 items yields a more precise SF, which was confirmed by follow-up analysis ($\alpha=.91$). AUC analysis indicated that the revised FSFI-6 more accurately classified women with FSD than did the original SF. **CONCLUSIONS:** For cancer survivors living with threat of FSD, a different 6-item set performed better. The revised items' contents measured sexual functioning more reliably in this cohort, particularly in the domains of Lubrication and Satisfaction, perhaps reflecting differences in the nature of FSD between cancer survivors and outpatients in reproductive medicine clinics.

113/1457/Five year Expanded Prostate cancer Index Composite (EPIC) based quality of life outcomes after prostatectomy for localized prostate cancer

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AIMS: The Expanded Prostate cancer Index Composite (EPIC)

documents prostate cancer treatment specific quality of life outcomes covering urinary, sexual, bowel and hormonal domains. Our objective was to document the EPIC results for men followed for five years after radical prostatectomy. **METHODS:** EPIC and demographic information were prospectively obtained from 382 patients who received questionnaires preoperatively and 1, 4, 12, 24, 36, 48 and 60 months post-operatively. Paired t-tests compared scores at individual time points. Percentage return to baseline was calculated at all post-operative time points and multivariate analyses evaluated post-operative trends. **RESULTS:** Mean age was 63.4 years. Mean urinary function and incontinence worsen after prostatectomy with recovery stable 12 months after surgery. Mean urinary bother returned to baseline by 4 months post-prostatectomy. 55.8% and 77.5% of patients returned to their urinary function and bother baselines respectively one year after surgery. Mean sexual function and bother both declined after surgery with new stable baselines achieved by 24 and 36 months post-prostatectomy respectively. 24.2% return to their sexual function baseline by 24 months. No post-operative improvement was noted in mean sexual bother until the 12th month post-prostatectomy. 36.8% returned to their sexual bother baseline by 36 months. Minimal change was noted in the bowel and hormonal domains. **CONCLUSIONS:** Mean urinary function and incontinence did not recover to pre-operative baseline after prostatectomy, but did not add distress as mean urinary bother returned to pre-prostatectomy levels. Mean sexual function declined post-prostatectomy with continued recovery through the 24th month. Sexual bother recovered later, but once it reached a new baseline the distress does not lessen with time, likely indicating an inability to adjust to their functional loss.

114/1750/Health Related Quality of Life of Women with Cervical Cancer

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AIMS: This cross-sectional study aimed to evaluate the health related quality of life (HRQoL) of women with cervical cancer and to identify predictors of quality of life among sociodemographic, clinical and sexual life factors. **METHODS:** The study was conducted at the Outpatient Clinic of Oncology, Radiotherapy section, of the Brazilian Institute of Cancer Control. A total of 149 women with cervical cancer, aged at least 18 years were interviewed, after signing the Informed Consent Form. The Brazilian Portuguese version of the Functional Assessment of Cancer Therapy-Cervix Cancer (FACT-Cx) was used to assess HRQoL. Descriptive statistics were used for the patients' characteristics and FACT-Cx scores and multiple linear regression analysis to identify predictors of HRQoL. **RESULTS:** The mean age of the women was 53.1 years ($sd=11.5$), 55.7% lived with spouse or partner, 60.4% had only primary level of education and 33.6% were employed; 57.7% had locally advanced disease and 54.4% had undergone surgery and radiotherapy, with or without concomitant chemotherapy in the last two years; hypertension (43.6%) and diabetes mellitus (21.3%) were the most prevalent comorbidities; 58.4% evaluated their health as very good; 59.1% reported having no sexual activity in the last four weeks and 38.9% said they did not assign any importance to this activity. In general, the FACT-Cx scores indicated positive evaluation. Items with worse evaluation were: interest in sex, fear of having sex, feeling less sexually attractive and feeling the vagina too narrow or short. In multiple regression analysis, 8 out of 18 chosen variables were predictors of HRQoL: self-perceived health, leisure, smoking, sexual activity, importance of sexual activity, time after radiotherapy, marital status and presence of comorbidities. **CONCLUSIONS:** The predictive factors of HRQoL identified in this study should be the focus of more attention in the health care of

women with cervical cancer and represent starting points for future studies. Special attention should be given to the sexual dysfunctions of these women.

115/1561/Health Related Quality of Life of Nursing Professionals and Medications Errors in Intensive Care Units

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AIMS: This cross-sectional study aimed to analyze the association between health related quality of life (HRQoL) of nursing professionals and medication errors in Intensive Care Units (ICU), after controlling for sociodemographic and work-related factors. **METHODS:** We studied 94 nursing professionals - 39 (41.5%) nurses and 55 (58.5%) nursing technicians - in three ICUs of a private general hospital. A specific instrument was used to collect sociodemographic, work-related and medication errors data. HRQoL was assessed by the Brazilian Portuguese version of the SF-36 Health Survey. The professionals were compared in two groups, according to the self report of having or not involved in medication error during the four weeks before the survey. Variables with $p < 0.20$ associated in univariate analysis were entered in logistic regression models. **RESULTS:** Most professionals were female (79.8%), with average age of 33 years ($sd=6.45$), married or with partner (52.1%). About 40% were family caregivers of children, elderly or other dependents. Participants had an average of 5 years working in ICU ($sd=4.95$) and were allocated mainly in adult ICUs (76.6%). Among the 18 professionals (19,1%) who reported having involved in medication error, 6 were nurses and 12 were nursing technicians. All of the SF-36 scores were significantly lower among those involved in errors, with significant differences between the groups in six of the eight domains: Physical functioning ($p=0.02$), General Health ($p=0.02$), Vitality ($p=0.01$), Social Aspects ($p=0.01$), Emotional Aspects ($p=0.01$) and Mental Health ($p=0.01$). Emotional Aspects domain ($OR=0.97$; $IC\ 95\%=0.95-0.99$; $p=0.001$) and the work shifts of the afternoon ($OR=0.10$; $IC\ 95\%=0.01-0.63$; $p=0.015$) showed significant association with medication errors as protective factors. **CONCLUSIONS:** These results could be used for the adoption of institutional policies specifically targeted to the nursing professionals' health and well-being, thus contributing to a safer care to patients.

116/1278/New QOL Questionnaire Development for Chief Nursing Officers

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AIMS: The purpose of this study is to develop a new QOL questionnaire for chief nursing officers because they are the key persons in the management of the hospital ward. **METHODS:** We first held a focus group interview with 91 questions, and then, question deleting questions similar, set the 21 domains with 63 items. We developed the new QOL seven domains to those relating to the chief nursing officer position's characteristics, and conducted a preliminary test by using with six domains and 20 items new questionnaire for the overall QOL of chief nursing officers. According to testing the 38 cases data of Cronbach's alpha coefficients ranged from 0.57 to 0.95, and seven domains were extracted. We rewrote the questions to a 6-domain 27-item questionnaire, and finally used this questionnaire for our study of 1495 chief nursing officers employed at hospitals 487 of respond, response rate 32.6%, valid responses 94%. **RESULTS:** Cronbach's

alpha coefficients of domains were Organization Management 0.84, Personnel Training 0.87, Relation Building 0.78, Trust & Evaluation 0.90, Sense of Achievement 0.85, and Mission & Faith 0.90 respectively, Our QOL questionnaire contained 6 main factors and cumulative contribution was 72.6%. After factor analysis, we readjusted the domain names, and named the first factor 'Group management', the second 'Relation Building', the third 'Mission & Faith', the fourth 'Trust & Evaluation', the fifth 'Support System', and the sixth 'Organization Consistency'. **CONCLUSIONS:** These finding indicate that our QOL questionnaire has high enough reliability and potency of validity for practical use. For factor validity, 6 factors were extracted and the domains readjusted. But we must continue the improvements on new QOL questionnaire development continuously especially on validity.

117/1486/The role of information on discharged patients

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AIMS: Issues related with the discharge from the hospital planning have been lately approached in the sense of identifying the factors that influence it and what determines it efficient, allowing the outcomes of care, the patients' recover and their reintegration into the community. In this context, the present research is a cross-sectional study aiming at translating and validating both patients and carers versions of the PREPARED Questionnaire into Portuguese, through the identification of its metrical properties. **METHODS:** Patients' sample was composed by 129 individuals staying in a surgical department more than three days, and discharged from the hospital. The carers version was composed by 118 main carers. To guarantee an anonymous and confidential data collection, the questionnaires were given to patients during the discharge process within a closed envelope. **RESULTS:** From the process indicators we evidence that communication is essential for the discharge planning. Based on patients' opinions the information received was the needed on in what concerns the medication (57.6%), the secondary effects (40.8%) and the written instruction about drugs (37.2%). In what concerns the carers and the information about medications patients carried with them, 39.1% referred that they were the needed and 35.4% told not having received any kind of information in the discharge. **CONCLUSIONS:** The Portuguese version of the PREPARED patient and carers questionnaire was reached by this study, offering a valid structure to obtain information in communitarian context, based on the patients and carers opinion related to the perception regarding the quality of the activities that constitute the discharge planning process.

118/1791/Results According to Gender in the Evaluation of the Quality of Work Life in Health Care Providers

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AIMS: To identify gender differences in the evaluation of the Quality of Work Life (QWL) in health professionals. **METHODS:** The study was descriptive and was conducted with doctors and nurses of both genders in an institution in the health sector in Guadalajara, Mexico. The sample was probabilistic, with a size of 351 subjects and assessed the satisfaction of respondents with CVT.-GOHISALO validated instrument. The design of the instrument

allowed us to measure the satisfaction of the QWL in seven dimensions for each gender in order to make comparisons. **RESULTS:** 322 subjects were interviewed, 150 doctors and 172 nurses, of whom 32% (102) were male and 68% (220) female. Males predominated in the doctors with a 65.3% (98), while in the nursing industry 97.7% (168) were women. The differences in the perception of workers according to their gender were present and so we have that the percentage of people who reported being satisfied with each of the dimensions of the QWL was higher in four of the seven dimensions for men, while women only had higher satisfaction than men in the dimensions: job satisfaction 82% to 75%, personal development achieved 84% against 75% and free time management 86% to 75%. However, it is worth noting that the percentage of people dissatisfied with their QWL in general, ranging from 10 to 25% for men, while women showed dissatisfaction with 13–20%. **CONCLUSIONS:** Dissatisfaction in the QWL is higher for female than male. Both men and women in the dimension that had higher levels of dissatisfaction was "Satisfaction with the job". Being the most affected dimension for both sexes of job satisfaction, it is a serious problem for expressing dissatisfaction with work performed, enables us to identify the lack of commitment that the person shows to the mission of the institution and his own aims, highlighting the negative aspects of work and dissatisfaction with the reward he obtains on doing his duties.

119/1500/The quality of life from the perspective of students in health sciences

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AIMS: The objective of the study was to explore the conceptual dimensions of the quality of life of future professionals in psychology from a Public University of the State of Jalisco, Mexico, seen from a cultural conceptualization of the Quality of Life. **METHODS:** The design of the study was exploratory transversal with a descriptive and correlation analysis. In between September and October of 2008, the project had two successive recollections of information: one with the free listings technique and another with the drawing of piles. In both recollections 20 informants were interviewed by gender, being a total of 40. It had a selection oriented to find a certain variation of characteristics of the informants. A factorial analysis was done of the principal Components that grouped individuals based on their responses. The criteria of bondage of adjustment that was used to obtain consensus in the models implies that the first factor reaches a reason three times more than the second factor, signifying that there is a higher agreement in the informants responses. The different analysis was processed with the ANTHROPAC v. 4.1 package. **RESULTS:** The conceptual organization of the different dimensions of well being had a cultural consensus. It reached a level of reason =10.44 in the case of men and 7.26 in the case of women. The norm is that this factor had to score more than three times the variance of the second factor, which is what happened in this case (it was 11.79 times major in the case of men and 7.26 in the case of women). The percentage accumulated of the variance for the ratio factor 1 was major in 70% and the average of the individual cultural competence was major than 0.6 in the case of men. The values found also validate the consensus. **CONCLUSIONS:** In general the male students of psychology mentioned a major variety of terms than the women. For the men, the two major dimensions are: Optimum health and a Bad Quality of life. For Women: Worthy life and Accomplishment.

120/1232/Health Related Quality of Life of Kidney Living Donors: Development of a Course Donation Questionnaire
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AIMS: To build a questionnaire to investigate the life and course donation of kidney donors. The final goal is to propose monitoring indicators of the living donors HRQL. **METHODS:** Three focus groups were performed to identify the themes and main items to be explored: one with 3 donors, 2 recipients and 2 close relatives and one with a multidisciplinary group of 10 professionals of the medical field and of the research field in epidemiology, sociology and psychology and of patients associations federation. The third focus group allowed to give priority order to the identified items. Each of the focus groups was analysed with a thematic qualitative approach. After the final formulations of questions have been decided, questionnaires were tested near 11 donors within 2 hospital centers. **RESULTS:** A self-administered questionnaire is to be used at three times before, three and twelve months after donation. The 1st chapter is constituted of validated scales (SF36, HAD, Euroqol and Self-esteem) and explores the donor health and HRQL; it is repeated at each measurement time. The 2nd chapter includes questions about donation and its course over the three measurements: decision-making, donation motivations, received information, donation course, kidney representation, renal disease, kidney donation, hospitalization, return to everyday life, follow-up, relations with family proxies and recipient. The 3rd chapter varies according to the measurement time: general information before donation, care course of the recipient three months after surgery and global appreciation of the donation one year later. The 4th chapter investigates the changes change in life and the economic impact of donation and is planned at the third measurement point. **CONCLUSIONS:** The performance of focus group allows to confront the points of view of patients and professionals of the kidney donation and is a necessary stage to obtain a relevant, acceptable and understandable questionnaire. This method turns out relevant to analyze the meaning given to events from each witness point of view.

121/1130/Quality of Life in Patients with Total Hip and Knee Arthroplasty

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AIMS: The purpose of this study was to evaluate the quality of life (QOL) in patients with total hip and knee arthroplasty. **METHODS:** Seventy three patients with total hip and knee arthroplasty participated in this study. Our new original self administered QOL questionnaire including 37 questions divided into 12 categories and the Life Satisfaction Index (LSI) were used. **RESULTS:** Pearson's correlation coefficients between our questionnaire and LSI was

$r=0.70$ ($P<0.001$). Cronbach's alpha coefficients of our QOL questionnaire were high enough to accept for clinical use: 0.90 in dietary problems, 0.88 in environmental problems, etc. before surgery and 0.90 in environmental problems, 0.87 in dietary problems, etc. after surgery, respectively. Our QOL questionnaire contained 10 main factors and cumulative contribution was 0.77. Compared with before arthroplasty, beyond our expectation, one fifth patients indicated the improved total QOLs but three fifths patients showed the deteriorated total QOLs after arthroplasty. The remarkable QOL impairments were demonstrated in the strata of well-being ($P<0.01$) and psychological problems ($P<0.001$) etc. after arthroplasty. All patients whose total QOLs were deteriorated before surgery showed improvement of total QOLs after one. But many patients whose total QOLs were excellent before surgery demonstrated impairment of total QOLs after one. There were significant positive correlations between total QOL and well-being ($r=0.78$, $P<0.001$), psychological problems ($r=0.83$, $P<0.001$), etc., respectively. **CONCLUSIONS:** These findings indicate that our QOL questionnaire has high enough reliability and potency of validity to use for patients undergoing total hip and knee arthroplasty. Although it is easy to understand the merits of arthroplasty from the standpoint of medical specialists, we should also pay many kinds of attentions to the postoperative care and counseling especially in well-being and psychological problems from the viewpoint of patients, too.

122/1315/The Role of a Workplace Physiotherapy Pain Management Program in Musculoskeletal Pain and Compensation Days

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AIMS: Pain and discomfort are one of the workers' largest complaints, negatively influencing their quality of life. Also, musculoskeletal disorders account for a large number of workers' compensation days. The objective of this work is to investigate the efficacy of a physiotherapy pain management program at the workplace in the intensity of pain and compensation days. **METHODS:** An uncontrolled pretest-post-test study design tested the acute effects of physiotherapy in the pain of 92 factory and administrative petrochemical workers ($n=92$) from Campinas - Brazil, who attended the program. For such a purpose, the workers answered a questionnaire about the existence of pain symptoms, a numeric rating scale (NRS) from 0 to 10 for the intensity of pain and a pain drawing for the designation of its local. The questionnaire was answered before and right after the treatment. Each employee had one appointment, which after he would go back to work or, if pain persisted, sent to a hospital or to rest at home. **RESULTS:** The most affected area was the spine (85% of subjects), followed by the lower limbs (8%) and upper limbs (7%). The statistical analysis by the paired t-student test shows that there is a decrease in pain intensity ($p<0,000$) of 5,11 points in the NRS, from 6,64 to 1,53. The Mann-Whitney test showed a significant decrease in compensation days ($p<0,000$) since 95% of attended workers returned to work after physiotherapy. **CONCLUSIONS:** The intervention program is associated with significant improvements in the intensity of pain. A reduction in compensation days can also be noticed since all the employees were sent home or to the hospital before the program was installed. We call attention to the low cost of the intervention, since the manipulative therapy was the most used technique. Substantive health and organizational benefits may result from this pain management program. It is recommended that the companies use a pain management program carried out in the facilities of the very

company for the reduction of pain complaints and compensation days.

123/1105/A Test-retest Reliability Study of the Whiplash Disability Questionnaire (WDQ) in Patients with Recent Whiplash-Associated Disorders (WAD)

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AIMS: The purpose of this project was to determine the short-term test-retest reliability of the WDQ in a sample of individuals with recent WAD. **METHODS:** We conducted a test-retest reliability study. Ontario residents 18 years of age or older were recruited within 21 days of their motor vehicle collision. The WDQ consists of 13 items measuring pain and disability from WAD with the total score ranging from 0 (no disability) to 130 (maximal disability). At baseline, data on demographics, whiplash disability, and neck pain intensity was collected. Three days after the initial interview, the WDQ was re-administered by phone. Change in neck pain over the three days was assessed using a single recovery question: "How do you feel your neck pain has changed since the injury?". We computed the Intra-class Correlation Coefficient (ICC) [Model (2,1)] and 95% confidence intervals (CI) for the total score of the WDQ as well as for the individual items (each out of 10). The total score ICC was also calculated for participants who reported slight to no change in neck pain at the three day follow-up. **RESULTS:** Our study sample included 66 participants. The mean age was 41.6 years (s.d.= 12.7) and 71.2% participants were female. 28.8% had WAD I and 71.2% had WAD II. Time since injury ranged 0-19 days. At baseline, the mean WDQ score of our sample was 49.3/130 (s.d.=28.8) and the mean neck pain intensity was 5.7/10 (s.d.=2.0). The ICC for the total score of the WDQ was 0.89 (95% CI 0.85-0.92). Of the 54 participants who were asked the change in neck pain question at follow-up, 32 reported that their neck pain changed slightly or not at all. The ICC for those who reported no change in neck pain since their injury ($n=15$) was 0.82 (95% CI 0.69-0.93). **CONCLUSIONS:** The results of this study suggest that the WDQ has adequate test-retest reliability in individuals with recent WAD who report that their neck pain was stable. The validity and responsiveness of the WDQ still needs to be determined in individuals with recent WAD.

124/1403/Differences in the Health Related Quality of life of Asmatic patients according to the illness classification

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AIMS: The aim of the study was to evaluate the differences in the Health Related Quality of Life (HRQoL) of Asmatic patients according to the illness classification using the Saint George Respiratory Questionnaire (SGRQ), an specific instrument for patients with respiratory diseases. **METHODS:** A cross-sectional, descriptive and observational study with 103 outpatients with Asthma (65 women and 38 men) with mean age of 58.48 years (SD 18.30 years) recluted from the Pneumology Service of the University Hospital of Salamanca, Spain between january and july 2009. It were excluded the patients with cognitive and communication problems.

Sociodemographics (age, gender, study level, occupation, monthly income and history of cigarettes habits) and spirometrics (criteria by the American Thoracic Society) data were collected. The HRQoL was evaluated by the SGRQ. Descriptive analysis, one-way analysis of variance and the t-student test were applied for the statistic analysis. **RESULTS:** The distribution of the classification in the sample was: 30.1% Intermittent (I), 35% Mild Persistent (MP), 25.2% Moderate Persistent (MOP) and 9.7% Severe Persistent (SP) (by the Global Initiative Asthma criteria). The mean of the domains were: Symptoms 39.93 scores (SD 21.83 scores), Activity 43.50 scores (SD 28.10 scores), Impact 24.61 scores (SD 17.81 scores) and the Total 32.84 scores (SD 19.07 scores). There were significant differences (ANOVA) between the classification groups at the forced expiratory volume in 1s (FEV1), the Vital Capacity (VC) and all domains and the Total of the SGRQ. The comparative analysis between groups (t-student tests) there were no signification in the FEV1 and the VC between I and MP. Also in the same analysis there was no signification between the three contrasts between the MP, MOP and MS in all domains and in the total of the SGRQ. **CONCLUSIONS:** The HRQoL is related to the asthma classification in the studied sample finding higher differences between the Intermittent Asma and the others classifications.

125/1074/Using the SF-36 Sub-Scales as a Composite Outcome to Evaluate a Complex Intervention

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AIMS: This traditional approach of having a single primary outcome may well serve the evaluation of pharmaceutical therapies but many health care interventions involve multiple components with tailoring to patients' needs and the 'one-outcome-for-all' model may not yield valid information on effectiveness. A previous randomized trial evaluated the effectiveness of a 6-week nursing case-management intervention after hospital discharge following acute stroke (n=96) in comparison to usual care (n=94). The primary outcome for the trial was the Physical Component Summary of the SF-36 and no average difference between groups was found on this or any other measured outcome. The intervention comprised over 50 different components with an average of 6 different interventions (range 2 to 15) per person; depending on need, the number of contacts at home or over the telephone ranged from 3 to 30. The purpose of this reanalysis to reassess the effectiveness of this complex intervention using a composite outcome involving 7 of the 8 SF-36 subscales; Physical Function subscale was not included as the nursing intervention did not specifically target this outcome. **METHODS:** A re-analysis of stratified, balanced, randomized clinical trial was conducted. Binary response variables were created for each of the 7 targeted SF-36 scales using the ½ standard deviation criterion for response. Logistic regression for multiple binary clustered data through generalized estimating equations (GEE) was used. **RESULTS:** The composite odds ratio (OR) was 1.31 with a 95% confidence interval from 1.04 to 1.67. **CONCLUSIONS:** The results indicated a benefit from the nursing intervention, a result that was more concordant with the nurses' clinical reports. This analysis demonstrates a methodology to deal with the evaluation of complex interventions.

126/1366/Implementation of measurement instruments in physical therapist practice: development of a tailored strategy

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AIMS: a) to investigate the facilitators and barriers in using patient reported outcome measures frequently recommended in Dutch physical therapy clinical guidelines; b) to select and develop strategies for implementation strategies; c) to evaluate of the feasibility of the strategies **METHODS:** A systematic implementation model (Grol et al, 2005) was used, starting with a problem analysis of aspects of physical therapist practice. A literature search, structured interviews, an online-survey and sounding board meetings were used to identify barriers and facilitators. Based on these factors, various strategies were selected and developed through the use of a planning model for process of change. The strategies were tested in four pilots. **RESULTS:** Barriers and facilitators were revealed in various domains: physical therapists' competence and attitude (when to use which instrument for what patient), organization, patients (different expectations) and measurement instruments (feasibility). The strategies developed were: 1) development of two core-sets of instruments (for elderly and primary health care); 2) self-analysis list (to become aware of barriers and facilitators and individual learning goals); 3) education module directed at the knowledge and self efficacy of the physiotherapist and organisation; 4) recommendations for the policy of the Royal Dutch Society of Physical Therapy. The strategies developed were applicable. Self-analysis, education, and attention to the practice organization made the physical therapists aware of their actual behavior, increased their knowledge, and improved their attitudes toward and their use of measurement instruments. For the preservation of change, more time is needed to integrate the use of measurement instruments in their daily routines. **CONCLUSIONS:** The use of a planning model made it possible to tailor multifaceted strategies toward various domains and phases of behavioral change. At the moment the strategies are implemented and evaluated in education programs of the Royal Dutch Society for Physical Therapy.

127/1013/Factors Associated with Quality of Life in Patients with Heart Failure

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AIMS: Factors contributed to hospital admission (or re-admission) among patients with heart failure (HF) include: demographic characteristics, the absence of social support, single marital status, lower income, comorbidities, and troublesome symptoms of HF. Moreover, symptoms experienced with HF have been found to be associated with diminished quality of life (QOL). Even though investigators have described those factors among individuals with HF, findings of those key attributes remain inconsistent. This study aimed to examine the effect of demographics, clinical characteristics, and social support on QOL. **METHODS:** The sample (n=98), for this cross-sectional cohort study, was recruited from the HF/Transplant Program at Virginia Commonwealth University Health System. Subjects were asked to complete four mailed survey questionnaires including: 1) Demographic Questionnaire; 2) Charlson Co-morbidity Index; 3) Medical Outcomes Study Social Support Survey; and, 4) Living with HF Questionnaire. Data were analyzed by using multiple regression. **RESULTS:** The sample (mean age = 56.33 years, SD = 13.65) included 56.1% males and 43.9% females and consisted of 48% Caucasians and 52% non-Caucasians. Approximately, 55% were married and 60% had an annual income < \$30,000. The majority of the sample (72.5%) had at least a high

school education. Half of the sample were somewhat functionally impaired (NYHA Class II) and had an ejection fraction < 30%. Ninety-three percent of the sample had been diagnosed with HF < 10 years (mean = 5.05, SD = 3.34). Seventy percent of the sample had 0 to 4 comorbidities, and 17.7 % reported that they only had HF and no other diagnoses. In addition, the sample reported mean score of social support at 71.72 (SD = 17.30). The results demonstrated that better QOL was predicted by being younger ($R^2 = .223$; $p = 0.020$), lower NYHA functional class ($R^2 = .284$; $p = 0.003$), and less comorbidity ($R^2 = .238$; $p = 0.013$) ($R^2 = .250$; $F = 7.346$, $p = 0.000$). **CONCLUSIONS:** The results revealed that better QOL was predicted by being younger, lower NYHA functional class, and less comorbidity.

128/1390/Cultural adaptation and validation of Ostomy Adjustment Inventory-23 (OAI-23) for Brazilians

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AIMS: To adapt and validate the Ostomy Adjustment Inventory-23 (OAI-23) for Brazilians. **METHODS:** After accomplishment of ethical issues, OAI-23 cultural adaptation and validation was based on modified Beaton et al (2007) methodology. OAI-23 is a specific tool to assess adjustment in stoma patients and was developed by Simmons, Maekawa and Smith (2007). For adaptation process, the OAI-23 was translated from English to Portuguese by two independent translators. The Portuguese translations were evaluated by a Panel consisting of 4 researchers: 2 stoma-therapy nurses, 1 proctologist and 1 specialist in Quality of Life research. After administering the questionnaire to 13 stoma patients, the new version was back-translated by two different independent translators. The adapted version was completed by a convenience sample of 191 adult stoma patients (57.1% women; mean age of 58.9 (SD=14.6) years old; 74.1% with colostomy) from 4 Brazilian cities to analyze the following psychometric properties: internal consistency (Cronbach's alpha superior and/or equal 0.70); stability (ICC superior and/or equal 0.70); convergent validity, using scores on Brazilian adapted version of Janis & Field Self Esteem Scale (Ulhoa 1980) as the correlate (Spearman coefficient); and discriminant validity related to demographic and clinical variables (Kruskall-Wallis test). **RESULTS:** Full agreement among experts was obtained after a focus group process; and almost all stoma patients understood the Portuguese version, suggesting few changes to improve it, confirming its content validity. Cronbach's alpha were 0.85; 0.65; 0.67; 0.61 and 0.58 respectively for overall score and OAI-23 factors (acceptance, anxious preoccupation, social engagement, anger); ICC=0.90 ($p < 0.001$); $r = 0.51$ to 0.22 ($p < 0.001$ for almost); overall OAI-23 discriminated groups according to age ($p = 0.024$) and acceptance ($p < 0.004$), anxious preoccupation ($p < 0.008$) and social engagement ($p < 0.043$) factors for religious activities. **CONCLUSIONS:** OAI-23 can be considered reliable and valid to assess adjustment in Brazilian stoma patients.

129/1398/Cultural adaptation of City of Hope Quality of Life Ostomy Questionnaire (COH-QOL-OQ) for Brazilians

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AIMS: To cross-cultural adapt the City of Hope Quality of Life Ostomy Questionnaire (COH-QOL-OQ) for Brazilians. **METHODS:** After accomplishment of ethical issues, the COH-QOL-OQ cultural

adaptation and validation was based on modified Beaton et al (2007) methodology. COH-QOL-OQ is a specific tool to assess quality of life in stoma patients and was developed by Grant et al (2004). For adaptation process, the COH-QOL-OQ was translated from English to Portuguese by two independent translators. The Portuguese translations were evaluated by a Panel consisting of 3 stoma-therapy nurses, who analyzed the semantic, idiomatic, cultural and conceptual equivalences among them and the original instrument. After analysis performed by the authors, the version was administered to a focus group consisting of 7 stoma patients. The new version was back-translated by two different independent translators and the back translations were sent for the main author of the original instrument, Dr Marcia Grant, for her evaluation. **RESULTS:** Translation difficulty was rated as moderate for few words or expressions, mainly the word how, but also for others like severe and great deal, which were modified to obtain adequate Brazilian semantic and language equivalence. Consensus among experts was also difficulty for some of the qualitative descriptions of Likert scale. Few stoma patients in the focus group had moderate difficulty to understand some items suggesting few changes to improve it. For the final adapted version, all items remained with the same meanings as the original instrument as confirmed by Dr Marcia Grant evaluation. **CONCLUSIONS:** COH-QOL-OQ adapted version kept semantic, idiomatic, conceptual and cultural equivalence to the original instrument, also confirming its content validity. Furthermore, a study of 215 stoma adult patients, recruited from Stoma Care Centers in Rio Grande do Sul (Brazil) is planned to perform the evaluation of the psychometric properties of COH-QOL-OQ adapted version.

130/1476/Work, Job Satisfaction and Quality of Life

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AIMS: The present assignment intends to verify the relation and effect of dynamic person-work environment on Quality of Work Life (QWL), Job Satisfaction, and Quality of Life (QOL), clarifying: _What is the relationship between Quality of Work Life, Job Satisfaction and Quality of Life?. The conceptual model is based on Danna & Griffin's studies (1999), Six Areas of Worklife of Leiter & Maslach (1999) and Spillover approach of Sirgy, Reilly, Wu and Efraty (2008). The study goals are determine the effect of the dynamic person-work in QWL, Job Satisfaction and from this last in QOL and the influence of work domain in other areas of life. These intend to verify: a) Which are the effects of individual-organization dynamic in QWL, of QWL in Job Satisfaction, and finally, of Job Satisfaction in QOL? b) What is the influence of work domain in other areas of life? The proposed hypothesis were: 1. The dynamic person-organization has a predictive effect on QWL; 2. QWL is predictive of Job Satisfaction; 3. Job Satisfaction predicts QOL; 4. Evaluation of work domain is a predictor of the perception of physical, psychological, social and environmental domains of QOL. **METHODS:** This is a transversal study, intending to verify predictive relations between variables. Regarding the goals with N=128, the measure used for the assessment was the General Population Questionnaire of the Investigation Unit in Health and Occupational Health Psychology. The SPSS 18 Program was used for statistical analysis of multiple regression and correlations, in order to test the model. **RESULTS:** The person-work dynamic predicts the QWL ($R^2 = .880$; $p = .000$), this Job Satisfaction ($R^2 = .403$; $p = .000$) and this last, the QOL ($R^2 = .151$ $p = .000$). Job satisfaction influences the perception in general QOL and its domains: general QOL ($r = .388$, $p < 0.01$), physical ($r = .383$, $p < 0.01$), psychological ($r = .427$, $p < 0.01$),

social ($r=.341$, $p<0.01$), environment ($r=.444$, $p<0.01$). **CONCLUSIONS:** The conceptual model and its predictive validity was confirmed, verifying that the elements of the relation work and QOL converge in an inter-dependent relation.

131/1567/The local environment and quality of life: focusing on individuals with disabilities

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AIMS: Perceived problems with community and housing have been found to accompany declines in quality of life (QOL). Less is known regarding specific effects for social groups who may be encountering multiple sources of stress. Members of such groups may be more resilient, perhaps due to enhanced use of coping resources, or more vulnerable as different stressors compound one another. Comparing individuals who report themselves as disabled with those who do not, differences in the relationship between local environment and QOL are investigated. The transition into disability and adaptation to it is also modelled, comparing QOL between those who report no environmental problems with those who report 5 or more. **METHODS:** Data from the British Household Panel Survey (BHPS) is analysed using quantitative techniques. The BHPS provides 17 waves of data from a nationally representative sample. Fixed effects regression models that include a range of control variables are used to investigate the associations between environmental problems and QOL. QOL is measured via a 36 item scale which consists of self-reported problems such as stress and anxiety and a 7 point scale focusing on self-evaluations of life satisfaction. **RESULTS:** An increase in environmental problems is associated with declines in QOL, with significantly larger declines for individuals who report themselves as disabled. This suggests that different sources of chronic stress combine to intensify declines in QOL. The presence of environmental problems also suggests an enhanced decline in QOL at the time of disability onset and 2–3 years after onset. **CONCLUSIONS:** These findings further confirm the impact of environmental factors upon QOL. Improving environmental conditions should therefore be a key policy area in enhancing the QOL amongst the general population, and in particular amongst those with disabilities. This social group are seen to be particularly vulnerable to environmental stressors, and the experience of them appears to worsen the declines in QOL at the time of onset and lessen the possibility of adaptation.

132/1667/Factors contributing to Good Quality of Life for people who live in Care Homes: A Thematic Synthesis

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AIMS: Long term care involving a move to a residential home affects people of all ages, resulting in significant lifestyle changes that can have a tremendous effect on quality of life (QoL). A tension exists between care homes as places that take care of severely disabled people and as places where people live. A qualitative review was conducted on residents' views of life in a care home, to provide an evidence base on what contributes to good QoL in a care home. **METHODS:** Electronic databases including Pubmed, PsycINFO, Web of Science and CINHAL were searched for qualitative studies that evaluated people's opinions of QoL/ what is important when living in a care home. Two authors independently extracted and assessed study quality. Studies were analysed using

thematic synthesis that aims to identify and collate the main themes across the studies. **RESULTS:** Twenty-four studies were identified, of which five met all methodological quality criteria. The core themes found were: connectedness with others, living in an environment akin to what a home should be like, and the care home promoting practices conducive to the enactment of caring for a person. However, the most prevalent theme found was the ability to adapt to the changes necessitated by a move to the care home, that is, one's mental attitude towards living in a care home. **CONCLUSIONS:** For people living in a care home the most important mediator between factors that contribute to living well is a shift in participants' internal attitudes towards their new environment. This shift involved re-evaluating internal expectations and values and also what resources one uses to cope. This review may act as a reference for care home staff to understand that good QoL for residents can be achieved, by adopting an individualized approach to care in helping residents to adapt to their environment. Most studies presented views of older people, thus further research is needed with younger people in a care home to ascertain whether they struggle in this domain or that they can make the necessary changes for adaptation.

133/1381/Utilizing the theory of planned behavior to understand how exercise affects lower limb disabilities' quality of life

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AIMS: The purpose of the study is to use the theory of planned behavior to inspect that how lower limb disabilities' regular exercise intuition predict exercise behavior, as well as observe whether the exercise behavior can improve the quality of life. **METHODS:** The subjects are lower limb disabilities in Taiwan. After receiving the informed consent, subjects were asked to complete Regular Exercise Questionnaire, Seven-Day Exercise Behavior Recall Questionnaire and WHOQOL-BREF. The collected data was analyzed by Chi-square test of homogeneity of proportions test, Pearson product-moment correlation and multiple regression analysis. **RESULTS:** The results indicated that: (1) There was no significant proportion difference in regular exercise habits among various background factors. (2) Regular exercise intuition was significantly predicted by regular exercise attitude, perceived behavioral control, subjective norms had little effect; Regular exercise behavior was significantly predicted by regular exercise intuition and perceived behavioral control. (3) The regular exercise can significantly predict the quality of life in physical health domain, social relationships domain, and environment domain, where as the psychological domain is excluded. **CONCLUSIONS:** Accordingly, the study shows that in order to encourage regular exercise intuition and exercise behavior, the most effective method is to increase the perceived behavioral control of each individual. By doing so, the lower limb disabilities' achieve better quality of life.

134/1689/Fatigue in Spinal Cord Injury (SCI), Muscular Dystrophy (MD), Post-Polio Syndrome (PPS) and Multiple Sclerosis (MS): Age Group Comparisons to U.S. Norms

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AIMS: Though individuals with disabilities are living longer, secondary conditions developed as they age contribute to dysfunction over and above effects of the disability itself. Fatigue is among the most common secondary conditions. This study compared age-group levels of fatigue in SCI, MD, PPS, and MS in a large community sample to those of the U.S. general population. **METHODS:** The Patient Reported Outcomes Measurement Information System

(PROMIS) Fatigue Short Form was administered to a community sample of 478 persons with SCI, 337 with MD, 441 with PPS, and 580 with MS. PROMIS Scores are reported on a T-score metric (mean=50, SD=10) anchored to mean levels of fatigue in the U.S. general population. Age-specific norms are available for the age ranges: 18-34, 35-44, 45-54, 55-64, 65-74, and 75 and above. Mean fatigue scores were calculated in these score ranges for each disability group and compared to PROMIS norms. **RESULTS:** At every age range and for each disability group, fatigue scores were higher than those of the general U.S. population. The highest scores were reported by persons with PPS, followed by MD and MS, and then SCI. Differences relative to the general U.S. population were greatest in older age groups. For example, for those with PPS, in the age groups 55-64, 65-74, and 75, mean fatigue scores were 0.9, 1.1, and 1.2 standard deviations units higher, respectively, than those of the U.S. population. In the same age ranges, for those with MS, scores were 0.8, 0.9, and 1.0 SD units higher, respectively. **CONCLUSIONS:** Availability of scores anchored to the U.S. population and age-specific norms makes it possible to draw substantive conclusions regarding “accelerated aging” with a disability. The results suggest that not only is greater fatigue experienced by persons with SCI, MD, PPS, and MS, but that the disparities between their fatigue levels and those of the general U.S. population are more pronounced as persons age with a disability.

135/1395/Development of an Excessive Sleepiness Diary

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AIMS: To develop a diary designed to assess sleepiness and its impact among patients experiencing Excessive Sleepiness (ES). ES is a symptom associated with sleep disorders (e.g. narcolepsy, obstructive sleep apnea), non-sleep disorders (e.g., multiple sclerosis, cancer, depression), and certain occupations (e.g. physicians, military personnel, and other night shift workers). **METHODS:** Diary versions were drafted based on interviews with sleep clinicians and researchers, and through literature review. Semi-structured cognitive debriefing interviews, including concept elicitation, were conducted at 5 US sites with patients confirmed to have ES (Epworth Sleepiness Scale ≥ 10) recruited through a sleep clinic. Patients completed the draft diary and were then engaged in a standardized retrospective debriefing interview. After 10 interviews, the diary was modified based on patient feedback for use in the subsequent interviews. **RESULTS:** Patients with ES due to a sleep disorder ($n=21$) or a non-sleep disorder ($n=10$), or occupation-associated ES ($n=21$) were included. 32 were male; the mean age was 48 years. Description of a typical night's sleep varied. Patients with sleep disorders often described waking up as a result of their treatment while non-sleep disorder patients described waking throughout the night or waking too early in the morning. Many described near-miss car accidents and mistakes at work due to tiredness, and forgetfulness or lack of concentration. The recall period (today) and items were well understood. Patients across groups reported items related to ES, concentration, forgetfulness, and accidents/mistakes as relevant to their sleepiness experiences. Patients differentiated between tired versus sleepy and dozing off (accidental) versus napping (intentional). **CONCLUSIONS:** Results suggest that experiences with sleepiness were similar across etiologies. Also, items were relevant, comprehensive and easy for patients to interpret. Patients indicated ability to reliably report their sleepiness experiences over

today. The sleepiness diary demonstrated content validity across patient populations experiencing ES.

136/1273/A randomized controlled cross-over clinical trial using oral appliances in the management of obstructive sleep apnoea

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AIMS: Obstructive sleep apnoea (OSA) is a common disorder characterized by episodes of sleep disturbances which ultimately impacts considerably on life quality. Oral appliances (OAs) have been increasingly advocated in the treatment of OSA as they offer a safe and reversible treatment option that has good acceptance among patients. However, the efficacy of different types of oral appliances is unclear to enhance outcomes in clinical care. **METHODS:** This randomized controlled cross over clinical trial compared two different types of OAs: Monobloc Vs Twinbloc in the management of OSA. Forty-three subjects with confirmed mild-moderate OSA were block randomized into two different treatment arms. Health-related quality of life was assessed using the Sleep Apnea Quality of Life Inventory (SAQLI) and the Epworth Sleepiness Scale (ESS). Polysomnograph readings were recorded by a trained and a calibrated examiner at sleep centre. **RESULTS:** There were significant reduction in SAQLI scores following treatment ($P<0.001$). However there was no significant difference in SAQLI changes with respect to OA used ($P>0.05$). Likewise there were significant changes in ESS scores following treatment ($P<0.001$) but no significant difference between OA type ($P>0.05$). **CONCLUSIONS:** In conclusion, oral appliances were effective in improving the quality of life of patients with mild-moderate sleep apnoea. There was no significant difference in treatment efficacy with respect of quality of life between monobloc and twinbloc appliances. These findings illustrate the use of quality of life measures to assess outcomes in clinical care.

137/1710/Developing New Outcome Measures for Fatigue and Quality of Life in People with Spinal Damage

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AIMS: Quality of life (QoL) and fatigue are becoming increasingly popular measures in research as indicators of treatment outcome, including post-surgery¹. Despite this there are only two validated spinal-specific QoL measures available and no spinal-specific fatigue scales². We explored the views of people with monophasic spinal problems on their experiences of fatigue and needs based QoL, (a) to identify spinal specific themes related to QoL and fatigue; and (b) to gather items for new spinal-specific quantitative measures of fatigue and QoL. **METHODS:** Semi-structured interviews were carried out via phone and face to face with participants from spinal clinics at the Walton Centre for Neurology and Neurosurgery, Liverpool. Transcribed interviews were independently subjected to thematic analysis by medical and psychological researchers and those results triangulated to agree themes and items. **RESULTS:** Interviews were conducted with a view to reaching saturation of themes. Analysis of 10 interviews shows saturation of themes for the fatigue arm of the study. However saturation of themes for the QoL arm of the study has not yet been reached, currently 16 themes have been identified in the QoL arm of the study. A number of themes were identified for fatigue relating to monophasic spinal events:- including causative, exacerbating and relieving factors, and defining features of fatigue. **CONCLUSIONS:** Many themes identified in the interviews span across both fatigue and

QoL with patients finding that issues with fatigue in turn have an effect upon their quality of life. New areas of potential for future fatigue and QoL measures were identified that are specific to spinal patients. These include areas such as fatigue related to driving and travel, and a cyclic relationship between back pain, sleep patterns, fatigue and quality of life.

138/1400/Work in Progress: Developing and validating self report measures for fatigue and need-based quality of life in Post Polio Syndrome (PPS)

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AIMS: Fatigue is a common symptom in both well and ill people, but appears to be more complex and severe in people with Post Polio Syndrome (PPS). Furthermore, empirical research suggests that fatigue in PPS impacts Quality of Life (QoL). However, research is currently hindered by the lack of measures for post-polio fatigue and QoL in PPS. Therefore, this study aims to develop and validate specific PPS self report measures for fatigue and needs-based QoL. Secondary aims are to assess the relationships between fatigue, mood, disability, handicap, pain, perceived impact of the condition, and QoL in people with PPS and to compare fatigue and QoL in healthy individuals. **METHODS:** Semi-structured interviews were conducted with participants who met standard diagnostic criteria for having PPS. Themes and potential questionnaire items were derived from the interview transcripts and assessed by an expert panel of clinicians and a group of PPS patients. After any changes are made, the final questionnaire will then be tested in large sample of participants with PPS recruited nationally in the UK, and also healthy age and sex controls. The novel fatigue and needs-based QoL questionnaires and other generic measures comprising the Fatigue Severity Scale, a Visual Analogue Scale on fatigue, QoL and pain, the Hospital Anxiety & Depression scale, WHOQoL-BREF, a Barthel Index, an Epworth Sleepiness Scale, the London Handicap Scale and the Perceived Impact of Problem Profile will be trialled in a large sample of PPS participants. A test-retest phase will occur after about 2 weeks, and measurement properties of the questionnaire will be improved and assessed by a number of statistical techniques including Rasch analysis. **RESULTS:** 45 interviews were conducted on a sample of participants, stratified by sex and disease duration. Saturation of themes was reached at 40. **CONCLUSIONS:** This study will generate a validated self report measure for fatigue and needs-based QoL in PPS, which can assist with further research.

139/1657/Does a Rasch-modified FSS deliver better measurements?

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AIMS: Fatigue is a disabling consequence of multiple sclerosis (MS), affecting approximately 90% of patients. Identifying effective treatments requires rating scales, capable of generating clinically valid scores. The 9-item Fatigue Severity Scale (FSS) is frequently used to measure fatigue, but a recent Rasch analysis suggested reducing items would deliver better measurement. Our study, examined if this was sufficient to deliver clinically valid measurement. **METHODS:** FSS data from a longitudinal study of people with MS (n=1019) was examined using Rasch analysis.

Clinical validity was established using known groups validity (based on additional questions). Participants were divided into “fatigue” (n=780) and “non-fatigue” (n=239). Relative measurement precision (RMP), relative measurement efficiency (RME) and standardised response mean (SRM) was compared between the original and Rasch modified versions. **RESULTS:** Rasch analysis identified significant weaknesses including poor targeting, disordered thresholds and substantial misfit in two items. Only 7 items fitted the Rasch model. Total FSS scores ranged from 0 to 100, standard deviations were wide (approximately 20%), mean scores were lower in participants without fatigue on both versions. The FSS-7 was 11% more efficient in separating clinical groups (RMP). The FSS-7 identified a significant difference in change scores across time and it was 66% more efficient in detecting change (RME). Although the SRM in the FSS-7 was slightly larger, both versions had small SRM, suggesting that both had limited responsiveness. **CONCLUSIONS:** Our results indicate that the FSS-7 is slightly superior. However, problems interpreted as fatigue by participants were not defined as fatigue by either FSS and vice versa. Caution needs to be exercised when evaluating outcome measures using Rasch analysis. Simply reducing items to fit the Rasch model does not guarantee precise or sensitive measurement. If measures are to be useful and interpretable in clinical research settings they should be conceptually grounded as well as vigorously evaluated with modern psychometrics.

METHODS & METHODOLOGY

140/1559/Patient-reported outcomes in Chronic Myeloid Leukemia: what do we know? A systematic review from 1980 to 2010

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AIMS: The treatment of chronic myeloid leukemia (CML) has changed dramatically, mainly due to targeted therapies (TT) that greatly improved clinical outcomes. No evidence exists regarding the amount and the quality of patient-reported outcomes (PROs) research in this area. **METHODS:** A systematic review was performed of all studies having PROs as an endpoint. A literature search was undertaken on a number of databases by two independent reviewers. The following databases (1980–2010) were used: PubMed, Cumulative index of Nursing and Allied Health Literature (CINHAL), SCOPUS, PsycINFO and PsycARTICLES. All studies, regardless of the treatment and the design were considered. All studies were evaluated on their methodological quality according to a previously developed protocol. This included a number of methodological and statistical quality criteria such as questionnaire used, timing of assessment, PRO missing data documentation, and discussion of outcomes in terms of clinical significance. **RESULTS:** Fifteen articles were identified, describing some 2000 patients. Six studies dealt with interferon (IFN) based-treatments, seven with bone marrow transplantation (BMT) and only two with the newer TT. No study was published before 1995. Ten studies included less than 100 patients thus limiting the interpretation of PROs. The EORTC QLQ-C30 was the most frequently used measure and no CML PRO tools were used. Patients receiving IFN reported major quality of life (QoL) impairments, especially

cognitive and emotional impairments. Significant QoL impairments were also evident with BMT treatment, even in the long run (mainly in terms of physical functioning). The most robust evidence stemmed from a RCT demonstrating that TT (i.e. imatinib) greatly improved QoL over IFN-based treatments. **CONCLUSIONS:** TT has greatly improved clinical outcomes (7 years, overall survival is now 86%) thus making PROs even more critical when evaluating overall treatment effectiveness in the near future. A CML PRO tool is needed to address new challenges in this area.

141/1526/Factors affecting overall quality of life in untreated patients with hematological malignancies

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AIMS: To investigate possible factors associated with perception of quality of life (QoL) in untreated patients with hematological malignancies, as no such evidence currently exists. **METHODS:** A convenience sample of 133 patients diagnosed with chronic lymphocytic leukemia (CLL) (N=67) or myelodysplastic syndromes (MDS) (N=66) were administered the EORTC QLQ-C30 at baseline (i.e. before receiving any kind of treatment) as part of a larger ongoing project. A number of key socio-demographic (age, gender), clinical (comorbidity, performance status, time since diagnosis and type of disease) and laboratory variables (white blood cell-WBC-counts, hemoglobin levels-Hb) were also collected. Overall QoL was taken as the dependent variable. Two models were initially fitted to investigate the contribution of sociodemographic in combination with clinical data, and patient-reported QLQ-C30 data, respectively. A third model including significant variables resulting from the previous models was then constructed. Variance inflation factor (VIF) was computed to investigate harmful multicollinearity among all variables. **RESULTS:** Mean age of patients was 68 years, mean Hb was 11.2 g/dL (min: 6.2; max: 15.8) and mean WBC count was $34 \times 10^9/L$ (min: 0.8; max: 161). The large majority of patients (73%) were diagnosed within 1 year and 49% had 1 or more comorbidities. VIF values showed no major collinearity in all models investigated. Only gender was a significant predictor of QoL ($p < .05$) in the first model, whereas fatigue ($p < .01$), insomnia ($p < .01$) and constipation ($p = .02$) were identified as independent predictors of QoL in the second model. The final model confirmed the following parameters to be independently associated with QoL: fatigue ($\beta = .41$), insomnia ($\beta = .20$), and constipation ($\beta = .16$), overall explaining 46% of the variance of QoL (adjusted

$R^2 = .46$). **CONCLUSIONS:** Fatigue is the major factor influencing perception of QoL in both patients with CLL and MDS, already before treatment starts.

142/1407/Patient-Reported Outcome Instruments Used to Assess Pain and Functioning in Studies of Treatment for Bone Metastases

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AIMS: When treating metastatic bone disease, relief of bone pain is often a key outcome. Because pain cannot be quantified with objective clinical measures, patient-reported outcome (PRO) measures are required to assess patients' subjective experience. The current review examined measures used to assess pain, as well as the impact of pain on functional status and health-related quality of life (HRQL), in trials of bisphosphonates for the treatment of bone metastases. **METHODS:** A literature search focused on articles published from January 1999 to April 2009. **RESULTS:** A total of 49 articles were located that used PROs to assess pain-related outcomes of bisphosphonate treatment for bone metastases. The Brief Pain Inventory was the most commonly used multi-item instrument. However, the most common approach for assessing pain was a single-item scale such as a visual analog scale, numerical rating scale, or verbal rating scale. Of the 49 studies, 19 included a PRO assessing functional status or HRQL. The European Organization for Research and Treatment of Cancer QLQ-C30 and the Functional Assessment of Cancer Therapy - General (FACT-G) were the most commonly used measures of HRQL and functional status, while five other measures were each used in only one study. **CONCLUSIONS:** Although pain is an important outcome of trials examining treatment for bone metastases, results of this review suggest that there is little consistency in PRO measurement across published studies. Furthermore, presentation of measures often lacked clear description, information on measurement properties, instrument citations, clarity on method of administration, and consistent instrument naming. Recommendations are provided for thorough instrument validation conducted within the target population, assessment of content validity of frequently used instruments, use of PRO instruments recently developed for patients with bone metastases, clear description of instruments, and implementation of measures consistent with recommendations from instrument developers.

143/1078/The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for patients with Endometrial Cancer: EORTC QLQ-EN24

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AIMS: To evaluate the psychometric properties of the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire Endometrial Module (EORTC QLQ-EN24), designed to assess disease and treatment specific aspects of

the quality of life (QoL) of patients with endometrial cancer. **METHODS:** The EORTC QLQ-EN24 was developed in a multi-cultural, multidisciplinary setting to supplement the EORTC QLQ-C30 core questionnaire. The QLQ-C30 and the endometrial cancer module were administered to 268 endometrial cancer patients treated with total hysterectomy and bilateral salpingo-oophorectomy, with or without radiotherapy and/or chemotherapy. **RESULTS:** Multi-trait scaling analyses confirmed the hypothesized scale structure of the QLQ-EN24. Internal consistency reliability was good with Cronbach's alpha coefficients ranging from 0.74 to 0.86 (Lymphoedema 0.80, Urological symptoms 0.75, Gastrointestinal symptoms 0.74, Body Image problems 0.86, Sexual/Vaginal problems 0.86). Convergent and discriminant validity did not show any scaling errors for the subscales. The QLQ-EN24 module discriminated well between clinically distinct patients problems of different clinical conditions. All items exhibited a high completion rate with less than 2% missing values except for the sexuality items (19%). The majority of patients completed the EORTC QLQ-C30 and the QLQ-EN24 in less than 15 minutes. **CONCLUSIONS:** The validation study supports the reliability, the content, and construct validity of the EORTC QLQ-EN24. This newly developed EN24 module is a useful instrument for the assessment of the QoL in patients treated for endometrial cancer in clinical trials and in clinical practice.

144/1233/Implementation of Quality of Life Evaluation in Oncology daily practice: Validation of EORTC-QLQ C30 and EORTC- H&N 35 Portuguese PC-software version

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AIMS: The introduction of Pc-software instruments in healthcare has promoted the reduction of bureaucratic procedures, an immediate access to information and therefore allowing the effective information and knowledge management obtained with Patient Reported Outcome Measures (PROM). The present study aims to analyze the results of the EORTC-QLQ C30 and EORTC- H&N 35 Portuguese PC-software version validation, in order to implement Quality of Life (QoL) evaluation in the Portuguese Oncology Institute, Porto (IPO-Porto). **METHODS:** Two hundred and sixteen questionnaires were completed by fifty four head and neck cancer patients from IPO-Porto, otorhinolaryngology service after their informed consent. To validate the EORTC-QLQ C30 and EORTC-H&N 35 Portuguese PC-software version, patients completed the questionnaires QLQ-C30 and QLQ-H&N35 on paper (n=54 and 54, respectively) and on a computer using Quality of Life Informatics Platform (QoLIP) designed for this study (n=54 and 54, respectively). The Wilcoxon test and percentiles calculus were used to evaluate whether the data were different in two samples. **RESULTS:** Answers obtained by computer self-administration method were found to be similar to the original paper/pen approach. The results of percentiles calculus (minimum, 50th percentile, 75th percentile and maximum) were for minimum in QLQ C30 e QLQ H&N 35 questionnaires were 62, 5% and 57, 45% respectively, for maximum were 100% and 97, 67% respectively. Most of the patients (63%) reported to prefer the PC-software version. **CONCLUSIONS:** The QoLIP revealed to be a powerful and effective tool for QoL assessment, which may be the

first step for routine implementation in IPO-Porto. The routine QoL PC-software assessment is essential to get clinical meaningful data that can support clinical decisions, identify potentially unmet needs and support a stepped care model optimizing cancer patients and their relatives QoL and refining healthcare systems.

145/1456/Can a prophylactic percutaneous endoscopic gastrostomy for enteral nutrition prevent malnutrition and improve health related quality of life in head and neck cancer patients? A randomized study

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AIMS: Malnutrition and poor health related quality of life (HRQOL) is common in head and neck cancer patients. This randomized study aimed to examine if a prophylactic percutaneous endoscopic gastrostomy (PEG) for enteral nutrition could prevent malnutrition and improve HRQOL. **METHODS:** Newly diagnosed patients with advanced head and neck cancer were randomized to either prophylactic PEG (study-group) or nutritional care according to clinical praxis (control-group). Patient's weight, BMI, HRQOL (using EORTC QLQ-C30 and QLQ-HN35) and need for hospital care were noted longitudinally at seven occasions during two years. **RESULTS:** 134 patients were included in the study and no significant differences in patient characteristics, nutritional status or HRQOL were found at inclusion between the two groups. Therefore the two groups were considered comparable. After six months quality of life was significantly better for global quality of life as well as for physical functioning, role functioning, cognitive functioning, fatigue and feeling ill and at the same time-point the weight-loss was significantly less in the study- group. The number malnourished (>10% unintended weight loss the last six months) was consistently about ten percent lower in the study-group during the first study-year. The study-group started to use enteral feeding significantly earlier and for a significantly longer time-period compared to the control-group (p<0.0001). **CONCLUSIONS:** Prophylactic PEG was associated with significant earlier start and longer use of enteral nutrition, fewer malnourished patients over time and a reduction in weight loss and improved HRQOL at six months post treatment start.

146/1547/Development of a computer-adaptive version of the EORTC QLQ-C30 Fatigue Scale

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AIMS: Computer-adaptive testing (CAT) is an advanced method for measuring patient-reported outcomes. With help of an algorithm CAT selects the items most relevant for an individual patient from an item bank. Our study aim was the development of a CAT version of the EORTC QLQ-C30 Fatigue scale, its implementation in a software package and its use in daily clinical routine. **METHODS:** Our

project is part of a large project on CAT development conducted by the EORTC Quality of Life Group. To set up an initial English fatigue item list an extensive literature research was performed. These items were refined through multi-stage expert reviews, translated to German, Danish, Spanish, French and Dutch, and filled in by a pilot patient sample to collect feedback. In a next step a large patient sample is recruited for all language versions to gain data for development of the item bank and the CAT algorithm. **RESULTS:** Literature research resulted in 588 fatigue items, from which 44 were selected after comprehensive expert reviews. Based on feedback from 52 oncological patients wording and translation of several items were revised. Data collection for item response theory analysis has started in November 2009 (1050 patients recruited in eight countries; aim n=1500). Preliminary results of the CAT-analysis will be presented. **CONCLUSIONS:** By generating individually tailored item sets, CAT reduces patient burden and assessment duration, and increases measurement precision. In addition, electronic data capture increases data quality and reduces the amount of human resources required for data collection.

147/1194/Six-month postoperative quality of life predicts long-term survival after esophageal cancer surgery

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AIMS: Patients treated with curatively intended surgery for esophageal cancer have an approximately 30% chance of 5-year survival. Little is known about associations between postoperative health-related quality of life (HRQL) and long-term survival. The aim was to examine whether specific postoperative HRQL aspects predict survival. **METHODS:** A Swedish nationwide cohort of esophageal cancer patients treated surgically between 2001 and 2005 was followed up until death or end of August 2009. Nine HRQL aspects were selected for analyses through EORTC QLQ-C30 and QLQ-OES18 questionnaires answered six months postoperatively. The HRQL measures were categorized into two groups: "good function" versus "poor function" and "no or minor symptoms" versus "symptomatic". Associations between HRQL and survival were analyzed using Cox proportional hazard ratios (HR) and 95% confidence intervals (CIs), adjusted for potential confounding factors. **RESULTS:** All 401 esophageal cancer patients who survived at least six months postoperatively and responded to the questionnaires were included. For each of the nine selected outcomes, poor scores were associated with an increased hazard ratio of mortality: global HRQL (HR=1.55; 95% CI 1.19-2.02), physical function (HR=1.56; 95% CI 1.23-1.99), social function (HR=1.52; 95% CI 1.19-1.94), fatigue (HR=1.65; 95% CI 1.30-2.11), pain (HR=1.45; 95% CI 1.22-1.87), dyspnea (HR=1.54; 95% CI 1.19-2.01), appetite loss (HR=1.69; 95% CI 1.32-2.14), dysphagia (HR=1.69; 95% CI 1.13-2.51) and esophageal pain (HR=1.29; 95% CI 1.02-1.65). **CONCLUSIONS:** HRQL assessed six months after esophageal cancer surgery can be used as a clinically useful prognostic factor

148/1184/Development of computerized adaptive testing (CAT) for the EORTC QLQ-C30 physical functioning dimension

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AIMS: Computerized adaptive test (CAT) methods based on item response theory (IRT) enable adaptation of a patient reported outcome instrument to the individual patient while maintaining direct comparability of scores across patients. CATs are generally more flexible and have higher precision and/or reduced response burden compared to traditional questionnaires. Because of these advantages the EORTC Quality of Life Group is developing a CAT version of the widely used EORTC QLQ-C30. Here we present the development and psychometric validation of the CAT item pool for the first of the scales, the physical functioning (PF). **METHODS:** The development of the PF item pool included a literature search for existing PF items, formulation of new items, expert and patient evaluations, field-testing, and psychometric analyses including factor analysis, calibration/evaluation of the IRT model, and differential item functioning (DIF) analysis. **RESULTS:** We identified 975 PF items in the literature. Of these, 407 items were deemed to measure one of the PF aspects measured by the five PF items currently used in the QLQ-C30. These items were used as inspiration to develop 86 new items. Based on evaluations by the EORTC CAT-project group, external experts, and cancer patients the list was reduced to 51 items. Responses to these items and the QLQ-C30 were collected from 1,176 patients from Denmark, France, Germany, Italy, Taiwan, and UK. Factor analyses indicated that 34 items (including the five QLQ-C30 PF items) could be included in a unidimensional model with acceptable fit. Of these items, 31 had an acceptable fit to the IRT model and good content coverage. There were several findings of significant DIF among the 31 items, particularly across countries. However, the DIF findings seemed to have little impact on the PF estimation. **CONCLUSIONS:** We believe that we have established a useful and suitable item pool for CAT measurement of physical functioning. The new EORTC PF CAT will be further tested.

149/1680/The Use of Patient-Reported Outcome Measures (PROMs) For People with the Four Most Common Cancers in the UK: A Structured Review

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AIMS: Patient-reported outcome measures (PROMs) offer enormous potential to improve the quality and results of health services; however, there is a lack of general agreement on the most appropriate instruments for monitoring cancer outcomes. This report aimed to review the psychometric evidence of PROMs for the four most common cancers in the UK (breast, prostate, lung and colon) and generate recommendations to advise the Department of Health in relation to its PROMs programme (Darzi, 2008). **METHODS:** A systematic review was conducted which included a comprehensive search across several databases namely EMBASE, MEDLINE, PsycInfo, AMED and the Group's online bibliography. Studies were included if they reported psychometric evidence for the PROM in

English speaking populations. **RESULTS:** A total of 264 papers (breast: 95, prostate: 76, lung: 58, colorectal: 35) were identified. The SF-36 and EQ-5D generated the most promising evidence. More robust evidence was found for the EORTC QLQ-C30 and the Functional Assessment of Cancer Therapy General (FACT-G), along with their cancer site-specific modules. These formed the basis of the review recommendations; however, limitations were identified. **CONCLUSIONS:** The SF-36 has the benefit of allowing comparison across health conditions, whilst the EQ-5D has the additional advantage of generating a utility value. However, these measures do not fully capture important issues that are specific to cancer. The general cancer-specific instruments, such as the EORTC QLQ-C30 and FACT-G, can be applied across all cancers. However, issues that are specific to types of cancer and essential to the patients may not be captured by the dimensions covered in these PROMs. The cancer site-specific modules offer more relevant items and domains but may be burdensome to patients due to length. Furthermore, complexity in scoring methods impedes feasibility. Instruments that find support in standard reviews have largely been applied in the context of clinical research. Governments concerned with quality of services may need instruments of broader relevance to population health.

150/1291/Prognostic significance of patient heterogeneity in a dataset of 10,108 cancer patients

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AIMS: Patient-centered outcome research investigates heterogeneity in survival based on patients' socio-demographic, clinical and health related quality of life (HRQOL) factors. Various modeling techniques can result in different hazard ratios (HR), confidence intervals (CI) and their significance (p). Frailty models aim to capture hidden heterogeneity to improve accuracy in HR, CI and p. Our analysis compares a stratified Cox model with a frailty model. **METHODS:** A pooled dataset of 30 EORTC Randomized Controlled Trials in 11 cancer types included patient-reported baseline measures of HRQOL using the EORTC QLQ-C30. Age (≤ 60 vs. > 60), gender, distant metastasis (no vs. yes) and World Health Organization (WHO) performance status (0-1 vs. 2-3) were included as common factors. The prognostic significance ($p < .05$) of the clinical variables and 15 QLQ-C30 scales were investigated using 2 models: a Cox proportional hazard model with cancer site as a stratification factor and a frailty model where cancer site was defined as a random effect. **RESULTS:** In the stratified model, physical functioning (HR 0.94; 95% CI 0.92-0.96; $p < 0.001$), pain (1.04; 1.02-1.06; < 0.0001) and

appetite loss (1.05; 1.03-1.06; < 0.0001) added significant prognostic information alongside the parameters age (1.17; 1.06 -1.28; 0.0001), gender (0.74; 0.67-0.82; < 0.0001) and distant metastasis (1.70; 1.49-1.93; < 0.0001). In the frailty model, including both clinical and HRQOL data; physical functioning (0.94; 0.93-0.95; < 0.0001), pain (1.04; 1.03-1.05; < 0.0001) and appetite loss (1.05; 1.05-1.05; < 0.0001) provided significant prognostic information alongside the parameters age (1.15; 1.10-1.20; < 0.0001), gender (0.73; 0.70-0.76; 0.0005) and distant metastasis (1.72; 1.62-1.82; < 0.0001). **CONCLUSIONS:** Our results show that both models retain the same parameters as significant and report similar HR and p, but the frailty model reports smaller CI. A frailty model may benefit analysis of clinical trials with correlated data and provides a rationale for future protocol as it increases the robustness of our findings.

151/1535/Randomized trial of adjuvant chemotherapy with gemcitabine plus cisplatin versus docetaxel plus cisplatin in patients with completely resected non small cell lung cancer: quality of life, efficacy, and safety

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AIMS: Management of early stages of lung cancer is based on thoracic surgery and adjuvant chemotherapy. Standard regimens for adjuvant chemotherapy are based on cisplatin (CDDP). CDDP/vinorelbine improves survival and impaired quality of life (QoL). Other CDDP-based chemotherapies can be provided. We proposed to compare two recent CDDP-based regimens in terms of QoL, efficacy, and safety in patients with completely resected non small cell lung cancer (NSCLC). **METHODS:** Design: Randomized trial. Population: patients resected NSCLC pIB to pIII stages. Arms of adjuvant chemotherapy: 3 cycles with gemcitabine plus cisplatin (GC arm) versus docetaxel plus cisplatin (DC arm). Primary endpoint: EORTC QLQ C30 4 weeks after the end of chemotherapy. Secondary endpoints: EORTC LC13, SF 36, overall survival, hematological and non hematological toxicities. Time of evaluation: inclusion (T0), 4 weeks after chemotherapy (T1), 6 months (M6), and 12 months (M12). **RESULTS:** 132 patients were randomized (68 GC arm and 64 DC arm). Demographic and initial clinical characteristics were not different between the 2 arms. EORTC QLQ C30, EORTC LC13, and SF36 dimensions were not different between the 2 arms at each evaluation time, except for alopecia more frequently reported in GC arm. Neither overall survival (medians in months: GC= 48.7, DC= 48.3, $p=0.85$), nor Gr 3/4 hematological and non hematological toxicities differed between arms. **CONCLUSIONS:** Adjuvant GC and DC have comparable effect on QoL outcomes and do not differ in terms of 3-year overall survival. These results have to be confirmed by 5-year follow-up data.

152/1626/Self-reported quality of life independent of tumour location and tumour stage - no change in quality of life over time in melanoma patients

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AIMS: To assess whether recently diagnosed melanoma patients showed change in quality of life over time, and whether tumour location and tumour stage had an impact on self-reported quality of life. The study was based on two hypotheses: 1) quality of life scores of recently diagnosed melanoma patients improve over time based on the assumption of disease adaptation; 2) tumour location and tumour stage have a significant influence on patients' self-reported quality of life, with tumours located at face, head, neck, and advanced tumour stage (UICC II/III) showing worse quality of life. **METHODS:** A total of 446 recently diagnosed melanoma patients filled out the EORTC QLQ-C30 (pre-test) as part of the OVIS Study. Post-test questionnaires were administered two years after pre-test. In addition to mean comparisons, data were stratified by a) tumour location (face, head, neck; shoulder, hip; torso), and b) tumour stage (UICC I; UICC II/III). **RESULTS:** Across all scales of the EORTC QLQ-C30 neither statistically nor clinically significant differences were found between pre-test and post-test. Contrary to our hypotheses, no significant differences were found after data stratification (tumour location and tumour stage). Overall, results suggest that melanoma diagnosis had little influence on self-reported quality of life. **CONCLUSIONS:** We assessed data of recently diagnosed melanoma patients, with follow-up after two years. Given that no intervention took place during this time and respondents already had been diagnosed at pre-test, this might explain the lack of finding any significant differences in quality of life over time. However, the lack of finding any difference between subgroups, in particular when stratifying data by tumour stage, is surprising. This might be an indication that the core EORTC QLQ-C30 is not sensitive enough to detect differences in melanoma patients. This assumption is supported by the call for additional melanoma-specific items that are currently being developed by the EORTC Quality of Life Group.

153/1373/Development of computer-adaptive testing (CAT): Building new systems or transforming existing instruments? An analysis of the consequences of the EORTC CAT strategy
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AIMS: To compare the 'typical approach' for developing CAT used in e.g. PROMIS and the 'atypical approach' used by the EORTC Quality of Life Group (EORTC QLG). **METHODS:** The EORTC QLG CAT approach was designed to produce a CAT instrument

measuring the same 15 dimensions as the parent instrument, the EORTC QLQ-C30. The CAT version should be fully compatible with QLQ-C30. The basic idea was to add the advantages of CAT to those of a well-established, extensively used and tested standard instrument. **RESULTS:** Three years of work have produced ten item banks in various stages of testing and shown that the EORTC QLG CAT approach has several implications. Choice of dimensions: the EORTC CAT must include the 15 dimensions selected when the QLQ-C30 was developed. In contrast, other projects can freely choose which HRQL dimensions to include. Conceptualization of each dimension: the EORTC CAT measures each dimension in the same well-known way as the QLQ-C30. In contrast, other researchers may develop new conceptualizations. Construction of item banks: because the EORTC CAT needs to measure the same concepts as the QLQ-C30 scales, the creation of large item banks by assembling the previously used items is not ideal. Instead, new items are designed to match the existing items with regard to content, style, time period, and response categories. This may lead to smaller item banks. Cross-cultural aspects: Following the EORTC QLG's tradition new items are tested in several European countries (+Asia) and this may delay the process. Statistical analyses: In addition to all the 'usual' psychometric considerations, the QLQ-C30 items must be preserved as the core of the item banks. **CONCLUSIONS:** The EORTC QLG decision to maintain full compatibility with an existing instrument had several implications for the CAT development. The coming years will elucidate the advantages and disadvantages of developing a new CAT instrument vs. transforming existing instruments into CAT.

154/1363/Creating consistency in translations: Case study of three Slavic languages

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AIMS: Currently the EORTC Quality of Life Dep. administers over 700 questionnaires in ca. 60 languages for the EORTC QLG. In order to enhance consistency of translations, two IT tools were developed: Item Bank and translation memories (TMs). Yet, they have been in use recently and the vast majority of translations had been developed prior to their routine use. As a result, a lack of consistency is visible within languages, especially in highly repetitive items: introductory sentences, the Likert scale (not at all/a little/quite a bit/very much) and time frames. This project's aim was to investigate inconsistencies using IT tools in order to harmonise translations. **METHODS:** Three Slavic languages were chosen: Czech, Slovak and Polish. Available versions were summarised in a table and grouped accordingly. To determine the final version, three approaches were defined: (1) quantitative if translations were equally correct (i.e. choosing the most commonly occurring translation); (2) expert's opinion if translations were correct but the less used one was superior to the mostly used ones; (3) additional opinions and discussions if the most commonly occurring translation was not entirely correct. Being finalised in accordance with the EORTC QLG Translation Procedure, all versions were equally valid from the procedural point of view and thus could be replaced with the chosen option. **RESULTS:** Analysis of 37 questionnaires (12 in Czech, 9 in Slovak, 16 in Polish) showed 6, 7 and 6 different translations of instructions (in the respective languages); 2, 2 and 3 of answer scales; and 2, 3 and 2 of time frames. Approach (1) was used to harmonise 3 elements, (2) for 5 and (3) for 1. Then the TMs and Item Bank were updated to ensure a consistent use of the best option in future. The general quality of the analysed questionnaires has thus improved and will be

maintained. **CONCLUSIONS:** Specialised language based IT tools, i.e. the Item Bank and TMs, have proved useful to identify inconsistencies in older translations and will be helpful to maintain consistency of key elements in new translations.

155/1140/Development of the Japanese version of the HRQOL instrument for patients with bone metastases: EORTC QLQ-BM22

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AIMS: Bone metastasis is a frequent complication of cancer. Previous clinical trials on bone metastases have largely focused on skeletal-related events (SREs) as objective endpoints. However, it is also important to consider subjective health outcomes such as health-related quality of life (HRQOL) because complications of skeletal metastases can seriously impair patients' HRQOL. Therefore, the European Organisation for Research and Treatment of Cancer Quality of Life Group (EORTC QLG) developed the Bone Metastases-Specific Questionnaire (QLQ-BM22). In this study, we performed the two-stage semi-structured interviews for cancer patients to develop the official Japanese version of the EORTC QLQ-BM22. **METHODS:** In the first stage, we interviewed 15 patients with bone metastases who had answered the first preliminary version of the BM-22 to evaluate whether it was easy to read and understand, and ethically acceptable. The first preliminary version had been translated from original English to Japanese by forward- and backward translation procedures. In the second stage, we interviewed 22 patients who had answered the second preliminary version concurrently with the EORTC QLQ-C15 PAL to confirm the content validity, and especially cross-cultural functional equivalence of the BM-22. **RESULTS:** The results of this study indicated that the BM22 was easy to answer and no excessive burden was needed. However, 12 items of the first provisional version and 11 items of the second provisional version were linguistically revised based on patients' interviews. After examining these results, the EORTC QLG authorized the Japanese version of the BM22. **CONCLUSIONS:** We developed the official Japanese version of the EORTC QLQ-BM22. This questionnaire was simultaneously translated into 14 languages including French, German and Chinese. We expect that this instrument will be broadly used in multinational clinical trials, and will be helpful for clinicians and patients to make decisions regarding treatment selection or care for bone metastases.

156/1584/Longitudinal analysis of quality of life in oncology using generalisations of the mixed Rasch model

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AIMS: Quality of life is often included as an objective in oncology clinical trials. In oncology, the European Organisation for Research and Treatment of Cancer developed the QLQ-C30 questionnaire which includes 5 dimensions, 9 symptoms and a Global Health Status. Follow-up questionnaires are performed during and after treatment and the recommended analysis of results are usually descriptive and graphical in nature. The aim of this study is to propose more elaborate statistical analyses using models for longitudinal data for the analysis of the QLQ-C30. **METHODS:** First, we propose an analysis based on classical survival methods. The event is defined as a clinically significant deterioration of quality of life from the baseline measurement and without further improvement. Secondly, we focus on an Item Response Theory (IRT) method and we use a generalisation of the Rasch model which considers ordinal responses such as in the QLQ-C30: "Not at all", "A little", "Quite a bit" and "Very much". We also include in the model a time effect and a group effect in order to take into account both the longitudinal aspect and the treatment effect. Quality of life can be considered a latent variable and item responses as data to access it. Items parameters will include difficulties. The ordinal response generalisation allows us to focus on the partial credit model and on the rating scale model. These different approaches have been implemented within Stata 10.0 with the GLLAMM procedure. **RESULTS:** We apply these different methods on quality of life data analysis to the CO-HO-RT study (NCT00208273) which evaluates acute and late radiation-induced skin toxicities for 150 patients with breast cancer. QLQ-C30 evaluations were performed before the beginning of the treatment (baseline) and every 3 months during 36 months. **CONCLUSIONS:** Results of the longitudinal analysis will be presented in order to complete clinical trial results using huge amounts of quality of life data.

157/1654/Quality of life scores as possible stratification factors in clinical trials of mesothelioma: An analysis from the MRC MS01 trial

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AIMS: Stratification is often used in the design of clinical trials to produce balanced treatment groups and ensure accurate estimates of treatment effects. In oncology, factors such as disease stage, histology and performance status are regularly used to stratify randomisation, but may be difficult to obtain or inaccurate. We look at the prognostic value of certain quality of life (QoL) parameters and discuss whether they should be considered as stratification factors in clinical trials, especially when clinical factors commonly used are inaccurate or invasive. **METHODS:** This analysis uses data from the recently published MRC MS01 trial of chemotherapy in mesothelioma to investigate the effect of baseline QoL parameters, as assessed by the EORTC QLQ-C30 questionnaire, on survival, and compare the prognostic value of these variables with the stratification variables used in the trial. **RESULTS:** Using Cox models, baseline QoL scores for pain, constipation and limitation in performing strenuous activities were found to be highly prognostic (all p-values <0.001). Patients reporting any pain or constipation had a significantly worse median survival than those reporting no pain or constipation, and patients whose ability to perform strenuous activities were limited either "quite a bit" or "very much" had significantly worse prognosis than those with either "a little" or no limitation. The prognostic value of these variables was comparable to that of WHO performance status, and superior to histology, which

were both stratification factors in this study. All three factors remained highly significant in a model containing the other trial stratification variables. **CONCLUSIONS:** Patient reported QoL scores are simple to obtain and were highly prognostic in the MS01 trial. They should be collected and reported in clinical trials as for any other prognostic factor, and may be considered when discussing stratification variables for future clinical trials in order to ensure we obtain the best possible estimates of treatment effects.

158/1371/Feasibility of quality of life measurement among cancer patients treated with palliative pelvic radiation: A pilot-study
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AIMS: There is a lack of studies investigating symptoms and quality of life (QOL) among cancer patients treated with palliative pelvic radiation (PPR). As a result, clinicians are left with mainly retrospective studies, without QOL data on which to base treatment decisions. The purpose of this study was to determine whether it is feasible to prospectively measure QOL among patients treated with PPR. **METHODS:** Patients referred for fractionated palliative radiation of soft-tissue pelvic tumors were invited to enter the study. Radiation schedules were predetermined. QOL was assessed by the EORTC QLQ C-30 questionnaire and site specific modules (PR25, CR38 or BL24) prior to start of radiation and 6 and 12 weeks after its completion. A radiation therapist was available to participants in order to answer their questions and ensure that questionnaires were completed. **RESULTS:** Patients with prostate cancer (14), colorectal cancer (5) and bladder (3) cancer were included in the study. The median age was 75 years (range 62–90). Five women and 17 men were included. Twenty patients were still in the study at the 6-week follow-up and 18 patients at the 12-week follow-up. Twenty-one patients had valid responses within all the EORTC QLQ C-30 scales at baseline, 20/20 at the 6-week follow-up (except for diarrhea with 19 valid responses) and at the 12-week follow-up 17/18 patients still in the study had valid responses within all scales. This level of response was consistent in the site-specific questionnaires. Questions regarding sexuality were answered by 20 patients at baseline, 18 at the 6-week follow-up and 13 at the 12-week follow-up. **CONCLUSIONS:** This evaluation of QOL among PPR patients at 6 and 12 weeks after treatment yields response rates far better than previously described. The availability of a radiation therapist to assist patients during data collection appears to have contributed to increasing response rates. The study is feasible and should be implemented in a larger sample in order to reach clinically significant conclusions.

159/1623/Cross cultural study on the level of information received by cancer patients, through the EORTC information module.

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AIMS: Information about the disease and treatments is one of the key elements of the support that can be offered to cancer patients. Previous studies showed that the level of informational needs among cancer patients is similar in different cultures, and that there could be differences in the information disclosed in each cultural area. We present the results of an international / crosscultural study on the information received. **METHODS:** As part of an international validation study, the EORTC information questionnaire, EORTC QLQ-INFO25, was administered with other EORTC instruments during patients' treatment process. The QLQ-INFO25 evaluates the information patients report to have received on the different areas of the disease, treatment and care process. Crosscultural differences in information have been evaluated through stratification analyses. **RESULTS:** 451 patients have filled in the questionnaire: 202 from North Middle Europe (Austria, Germany, Sweden, U.K), 207 from South Europe (Italy, Croatia, Spain) and 42 from Taiwan. Significant differences among the three cultural areas have appeared in eight QLQ-INFO25 dimensions (Kruskal-Wallis): information about the disease, medical tests, and different places of care; written information, information on CD tape / video, wish to receive more information and considering the information helpful. Differences between pairs of these areas have also been evaluated (U Mann-Whitney): patients from North-Middle and South Europe received more information in some of these aspects than patients from Taiwan. Patients from North Europe received more information in some aspects and less in others compared to South Europe. These results are confirmed when repeating the analysis in subgroups of patients based on age, gender, level of studies and treatment aim. **CONCLUSIONS:** There are cross-cultural differences in the information received. Some of these differences, as diagnosis disclosure, are based on the characteristics of each culture, whereas other could offer some key to improvements in this field.

160/1327/Validation of Neuro-QOL Measures for People Diagnosed with Epilepsy

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Aims: The Neuro-QOL effort seeks to create and test new patient reported outcomes (PROs) for neurology clinical researchers using modern test theory (IRT) approaches. **Methods:** Neuro-QOL has developed and tested generic item banks and targeted scales for adults and children with major neurological disorders. Calibrated short forms were assembled and tested alongside external validity measures during a multi-site clinical validation study. This symposium presentation provides empirical results from this validation study with a sample of adults diagnosed with epilepsy. **Results:** 120 people diagnosed with epilepsy participated, of which half were male (50%), Caucasian (86%), with a mean age of 47.3 (SD=16.9). Baseline assessments included Neuro-QOL short forms and general and external validity measures. Pearson correlations ($p < .01$) between Neuro-QOL forms of emotional distress (Anxiety, Depression, Stigma) and the QOLIE-31 Emotional Wellbeing Subscale were in the moderate to strong range (r 's = -.66, -.71 & -.52, respectively), as were relations with the PROMIS Global Mental

Health subscale (r 's = $-.56$, $-.74$ & $-.52$, respectively). Associations with QOLIE-31 Seizure Worry were also in the moderate range (r 's between $-.42$ to $-.55$). Moderate correlations were observed between Neuro-QOL Social Role Performance and Satisfaction and the QOLIE-31 Social Function (r 's = $.58$ & $.52$, respectively). In measuring aspects of physical function, the Neuro-QOL Mobility and Upper Extremity forms demonstrated moderate associations with the PROMIS Global Physical Function Subscale (r 's = $.60$ & $.61$, respectively). Neuro-QOL measures of perceived cognitive function (executive function and general concerns) produced moderate to strong correlations with the QOLIE-31 Cognition subscale (r 's = $-.65$ & $-.75$, respectively) and moderate relations with the Liverpool Adverse Events scale (r 's = $.51$ & $.69$, respectively). Finally, the Neuro-QOL Fatigue/Weakness measure demonstrated moderate associations with the QOLIE-31 Fatigue subscale ($r = -.65$), Liverpool Adverse Events Scale ($r = .69$) and the Liverpool Seizure Severity Scale ($r = .50$). Conclusions: These results support the validation of NQ measures in this patient population. This symposium presentation will review these findings as well as present available sensitivity to change data, all within the context of clinical trials research with this group.

161/1308/Targeted Assessment for Individuals with Spinal Cord Injury: Extending the Neuro-QOL and PROMIS Measurement Systems

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AIMS: Early in Neuro-QOL's contract period, the investigative team selected a subset of neurological conditions from which to focus the next 5 years of research. Selection decisions were based on numerous sources, including a comprehensive literature review, a web-survey from 44 neurology experts and NINDS staff, and feedback from a day-long consensus meeting of external neurology experts. Ultimately, five adult and two pediatric conditions were selected, based on the prevalence of the disease/disorder/disability, the magnitude of the disease/disability's impact on individuals, the number of promising new treatment approaches on the horizon, and the number of HRQL domains affected. Although spinal cord injury (SCI) ranked highly as the 8th most important neurological condition in the web-survey and 6th most important in the consensus meeting, it was not retained in the Neuro-QOL contract, which retained the top 5 adult disorders. Because of the unique and important HRQL issues that arise in SCI, the NIH has also funded the development and validation of a new targeted SCI patient reported outcomes system, called SCI-QOL, that is based on the Neuro-QOL and PROMIS systems. **METHODS & RESULTS:** All Neuro-QOL items were reviewed and most were retained in subsequent item banks; however some were also flagged as being less relevant for an SCI population (primarily cognition items, which are only relevant in about 20-25% of the SCI population). During patient focus groups, individuals with SCI identified gaps in the Neuro-QOL domain framework and item bank content and raised new issues that are important (and unrepresented) for persons with SCI. These new areas (e.g., resilience, grief/loss, sexual functioning, independence and autonomy, as well as specific medical issues) were added to existing Neuro-QOL item sets as SCI-specific supplemental domains that would ensure adequate coverage of SCI-relevant issues. **CONCLUSIONS:** The SCI-QOL measurement extension has incorporated and enhanced relevant Neuro-QOL item banks and scales for testing in an SCI sample. This symposium session will highlight strategies used to identify and develop new SCI-specific

item content for more targeted, sensitive, and psychometrically sound HRQL outcomes for SCI clinical trials research.

162/1325/Validation of Neuro-QOL Measures for People Diagnosed with Multiple Sclerosis

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Aims: Neuro-QOL is an NINDS-funded project to construct a relevant and useful health-related quality of life (HRQL) measurement system for major neurological conditions. Following item bank development and calibration testing activity, short forms were created and tested in a national, multi-site clinical validation study. We describe the baseline characteristics of these short forms in a Multiple Sclerosis (MS) sample. **Methods:** MS subjects were recruited from adult Neuro-QOL testing centers across the US and Puerto Rico. Inclusion criteria: age >18, English speaking, confirmed diagnosis. MS subjects completed all Neuro-QOL and legacy HRQL measures as well as the Multiple Sclerosis Functional Composite (MSFC) and the Multiple Sclerosis Performance Scale (MSPS). **Results:** 162 participants were enrolled and completed select Neuro-QOL and external measures. The mean age was 49.5 (SD=10.8) and the majority were female (86%) and Caucasian (88%). Pearson correlations ($p < .01$) between Neuro-QOL Emotional Distress short forms (anxiety, depression, stigma) were moderately to strongly associated with FAMS Emotional Wellbeing (r 's = $-.59$, $-.77$, $-.71$, respectively) and PROMIS Global mental health (r 's = $-.67$, $-.75$, $-.58$, respectively). Neuro-QOL Mobility was moderately associated with a 25 ft walk test ($r = -.50$) and strongly related to the FAMS Mobility ($r = .86$) and MSPS Mobility ($r = .85$). Neuro-QOL Upper Extremity/ADLs was moderately associated with the 9 hole pegboard ($r = -.55$), IADL scale ($r = .69$) and strongly related to MSPS Hand Function ($r = .73$). Neuro-QOL Perceived Cognition (General Concerns, Executive Function) produced small relations with Symbol Digit Modalities (r 's = $-.37$ and $-.28$, respectively) and moderate - strong correlations with FAMS Thinking & Fatigue (r 's = $-.68$ & $-.79$, respectively) and MSPS Cognitive Symptoms (r 's = $.63$ & $.75$, respectively). Neuro-QOL Fatigue/Weakness was strongly associated with FAMS Thinking & Fatigue ($r = -.84$) and MSPS Fatigue ($r = .81$). **Conclusions:** Neuro-QOL measures demonstrated relations with external validity correlates in expected magnitudes and directions. This symposium will highlight these associations and offer next steps for use in future clinical research.

163/1306/Quantifying our Progress: Calibration and Validation Testing of the Neuro-QOL Tool

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AIMS: The first years of Neuro-QOL were primarily spent in qualitative development activity, including: 1) identifying the neurological conditions that would be the focus of this work; 2) conducting a comprehensive literature review of HRQL and neurological disorders; 3) surveying neurology experts to identify the most important areas to include in a HRQL questionnaire; and 4) engaging patients and their caregivers through focus groups and cognitive interviews. These efforts led to the creation of different item pools reflecting emotional, cognitive, social and physical health, as well as fatigue, personality/behavioral change and sleep. **METHODS & RESULTS:** Finalized, OMB-approved item pools

were field tested with large, diverse (e.g., stratified by gender, economic status, and race/ethnicity) samples of general (n=3000 adults: 2000 English-speaking; 1000 Spanish-speaking and 1500 children: 1000 English-speaking; 500 Spanish-speaking) and clinical (n=553 adults diagnosed with epilepsy, stroke, ALS, MS or Parkinson's disease and 59 children with epilepsy or muscular dystrophy) populations. Online panel administration enabled collection of extensive psychometric data used to calibrate items along a conceptual hierarchy within each domain. Following psychometric analysis of these data, calibrated short forms were constructed from the item banks. These short forms, along with targeted scales, were evaluated for reliability, responsiveness to change, and the usefulness of proxy data in a sample of English speaking patients and proxies. Enrollment included over 500 adults across 5 clinical conditions with 100 proxies matched to the Stroke sample, and 100 children (with 100 proxies) across 2 clinical conditions. Physician ratings, administration of concurrent measures and/or chart review were conducted at baseline and at a 180-day follow up. Preliminary results show good psychometric properties. **CONCLUSIONS:** Neuro-QOL is a new patient reported outcome assessment tool that is brief, sensitive, reliable and valid. This session will highlight the testing and analysis efforts that have resulted in this new tool.

164/1326/Clinical Validation of Neuro-QOL Measurement Tools in Parkinson's Disease

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Aims: Neuro-QOL (NQ) is an NINDS-sponsored effort to develop and validate an HRQL measurement system for neurology clinical research. **Methods:** Using modern measurement approaches, NQ has developed 11 generic (cross-disease) item banks and 4 targeted scales for adults. We present clinical validation data on the use of NQ with a Parkinson's disease (PD) sample. **Results:** 120 people diagnosed with PD participated: 61% male, 95% white; average age=65; Hoehn and Yahr Stages were 1 (16%), 2 (60%), 3 (18%), 4 (5%). Baseline assessments included NQ short forms and general and external validity measures. Pearson correlations ($p < .01$) were in the moderate range between NQ forms of emotional distress (anxiety, depression, stigma) and the Parkinson's disease Questionnaire-39 (PDQ-39) Emotional Wellbeing subscale (r 's = .70, .69 and .50, respectively) and the PROMIS Global Mental Health subscale (r 's = -.61, -.67, -.49, respectively). The PDQ-39 Stigma subscale was also moderately related to the NQ stigma scale ($r = .50$). PDQ-39 ADL and Mobility scores were moderately associated with NQ Upper Extremity/ADL and Mobility forms (r 's = -.75). The PDQ-39 Cognitive Impairment subscale was moderately related to NQ's Perceived Cognitive forms, General Concerns & Executive Function, (r 's = .56 and .52, respectively), while these were in the small range of association for Symbol Digit Modalities (r 's = -.22 & -.33, respectively). PDQ-39 Social Support subscales demonstrated small relations with NQ social role performance and satisfaction forms (r 's = -.35 & -.42). The PDQ-39 Index score demonstrated moderate to strong relations with NQ's symptom focused forms of fatigue/weakness ($r = .80$), emotional and behavioral dyscontrol ($r = .42$) and sleep difficulty ($r = .66$). **Conclusions:** These clinical validation results suggest NQ measures demonstrate satisfactory psychometric properties for use with PD populations. This symposium presentation will focus on these different relationships, the NQ measures' sensitivity to change over

several months, and next steps for future use of these tools in clinical research.

165/1693/Extending the Neuro-QOL to Huntington's Disease (HD): The development of the HD-HRQOL

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AIMS: Currently, there are no Huntington's disease (HD) specific, rigorous outcomes measures of health-related quality of life (HRQOL). To address this, the HD-HRQOL study was designed as an extension of the Neuro-QOL project to develop a valid HD-specific measure of HRQOL to accurately measure both clinical and research outcomes. **METHODS:** We conducted 5 at-risk/pre-symptomatic (n=16), 6 patient (n = 24), 3 caregiver (n=17), and 2 provider (n=25) focus groups to identify relevant HRQOL domains/themes in HD. Two independent investigators are currently conducting qualitative analysis of all focus group to identify major content areas and develop an initial list of HRQOL domains in HD. **RESULTS:** Preliminary findings from qualitative analyses will be discussed. Specifically, we will provide a summary of the content areas that are not already examined in the Neuro-QOL and appear unique to HD such as chorea, speech difficulties, swallowing difficulties, planning for the future and end of life issues. We will also compare and contrast findings from participants that are at risk for HD, participants that are experiencing HD symptoms, their caregivers and providers. **CONCLUSIONS:** Findings highlight the need for targeted measure of HRQOL in HD. Ultimately, the HD-HRQOL will hopefully be used alongside measures of physical functioning, emotional functioning, participation, and adverse events as a core outcome measure for clinical trials in HD.

166/1170/Progress on the PROMIS® Sexual Function Measure

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Aims To improve measurement of self-reported sexual function for use in diverse cancer populations as part of the National Institutes of Health's Patient Reported Outcomes Measurement Information System (PROMIS®). Our goal was a comprehensive and sensitive measure that was broadly applicable with respect to age, gender, sexual orientation, partner status, and literacy. **Methods** Guided by a conceptual model of sexual function and following the PROMIS® development process, our multidisciplinary domain committee identified 1136 extant items. We explored the impact of cancer on sex in 16 focus groups with 109 patients across cancer sites and the continuum of care. We revised extant items and wrote new items based on the focus group input. Sensitivity and clarity of candidate items were assessed in 39 cognitive interviews. We tested 81 items in 819 patients with cancer in web (79%) or phone (21%) surveys. Psychometric analyses for latent-variable subdomains included confirmatory factor analysis (CFA) to assess unidimensionality and item response theory (IRT) to calibrate items. We tested if common domains could be measured for men and women in multisample

CFAs. Items were omitted due to problems with comprehension or if IRT analyses showed local dependence or low item information. Results Preliminary results show 65 items in 5 collections of stand-alone items (Activities, Orgasm, Interfering Factors, Therapeutic Aids, Anal Discomfort) and 5 latent-variable subdomains (Interest in Sexual Activity, Lubrication (women), Vaginal Discomfort (women), Erectile Function (men), Satisfaction). Latent-variable subdomains were unidimensional and internally consistent; comparative fit indices $> .98$ and Cronbach's alphas $> .90$. Conclusions Preliminary analyses suggest that the PROMIS® measure provides a comprehensive, flexible tool to assess sexual function that is easily understood and applicable across cancer populations. The measure is designed to allow researchers to selectively use specific subdomains and/or items within subdomains. Testing in non-cancer populations is planned.

167/1768/The NIH Patient-Reported Outcomes Measurement Information System Cancer Fatigue Item Bank (PROMIS Ca-FIB): Validation with Cancer Population

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AIMS: Fatigue is a common complaint for people with chronic illness. We developed a 72-item fatigue item bank (PROMIS-FIB) to enable comparisons between general population (GP) and chronic illnesses. Of these 72 items, 56 items highly relevant to people with cancer (Ca) were selected by content experts to create the Ca-FIB. This paper reports validity of the Ca-FIB. **METHODS:** 513 patients (M age=56 yr; 72% women) completed the Ca-FIB and PROMIS global physical & mental health (GPH & GMH) items. They comprised 5 cancer care continuum groups: 22% on-treatment (tx) early stage disease (G1), 13% on-tx advanced stage disease (G2), 11% on-tx disease stage unknown (G3), 32% post-tx, ≤ 5 yrs post-diagnosis (G4), 21% post-tx, > 5 yrs post-diagnosis (G5). The Ca-FIB's unidimensionality was evaluated using confirmatory factor analysis (CFA). Differential item functioning (DIF) between Ca and GP was evaluated using logistic regression. Fatigue scores were estimated using PROMIS GP parameters (M T=50, SD=10) on unidimensional, non-DIF Ca-FIB items. Pearson correlations were used to evaluate relationships between the Ca-FIB, GPH & GMH. Analysis of variance (ANOVA) was used to evaluate whether the Ca-FIB differentiated samples by functional performance status ratings (ECOG PSR) and a single global fatigue item. **RESULTS:** CFA results supported the Ca-FIB's unidimensionality; 6 items showed DIF; 48 were retained for the final PROMIS Ca-FIB. On-treatment respondents (G1-G3) reported more fatigue than those post-treatment (G4-G5): T=54, 55, 58, 52 & 50 for G1-G5, respectively. Ca-FIB scores significantly differentiated groups on ECOG PSR ratings, $F=102$, $p<.001$, and responses to the single fatigue item, $F=161$, $p<.001$. The Ca-FIB moderately correlated with GPH ($r=0.69$) & GMH ($r=0.64$). **CONCLUSIONS:** The PROMIS Ca-FIB is a reliable tool for measuring cancer fatigue. Sharing item parameters with the PROMIS-FIB, the Ca-FIB allows for score comparisons with GP norms. Future studies are warranted to evaluate clinical sensitivity.

168/1328/Development of Targeted Patient Reported Outcome Item banks for Spinal Cord Injury: The SCI-CAT/SCI-QOL Measurement System

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AIMS: Traumatic spinal cord injury (SCI) is associated with a broad constellation of physiological changes and secondary medical complications that significantly impact patients' health-related QOL (HRQOL). Traditional outcomes measures in Spinal Cord Injury (SCI) research have focused on limited domains of functioning or researchers have used generic functional outcome measures. The scales lack the sensitivity needed to detect meaningful differences in SCI intervention research. **METHODS:** The objective of these multi-center studies was to develop a computerized adaptive test linked to Neuro-QOL and PROMIS that would assess patient reported outcomes across a variety of domains of functioning, including physical functioning/activity limitations, secondary complications significantly impact one's physical health (e.g., pain, toileting, skin breakdown/pressure ulcers, respiratory), emotional health, social participation, and sexual functioning. **RESULTS:** Two field studies were conducted with 819 adults that were stratified by traumatic paraplegia, severity of injury and time since injury. The item pools (across all domains) include 1054 items, of which 287 Neuro-QOL and 141 PROMIS items have been embedded. In addition to the more generic items (from PROMIS), the item banks also include targeted issues to individuals with SCI (hand function, wheelchair mobility, standing/walking, communication function, bowel, bladder, respiratory functioning, resilience following injury, grief/loss for a previous lifestyle, self esteem, stigma, positive psychological functioning, social participation roles/satisfaction, independence/autonomy, depression, anxiety, and trauma. Factor analytic techniques are being performed to ensure unidimensionality within each of the anticipated item banks listed above. Two parameter Item Response Theory (IRT) analyses are being conducted and item calibrations will be presented. **CONCLUSIONS:** These new item banks are being developed as computerized adaptive tests and will extend the Neuro-QOL measurement system for use in SCI clinical trials research. This symposium session will focus on presenting calibration results on item banks for the physical functioning and key physical medical issues.

169/1717/Development of a Vision-Targeted HRQOL Item Bank

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AIMS: To develop a vision-targeted health-related quality of life (HRQOL) item bank for the NIH Toolbox project. **METHODS:** A literature review of existing vision-targeted HRQOL surveys was conducted to identify relevant HRQOL domains. With expert input, items from existing measures were classified into domains (binned) and then winnowed to eliminate poorly worded items and eliminate redundancy. Items were then revised to impose consistency in wording and response options. Ten cognitive interviews were conducted with people recruited from the waiting rooms of the ophthalmology clinics at the Doheny Eye Institute, University of Southern California, to evaluate the wording of items. Following cognitive interviews, items were revised. **RESULTS:** A 53-item vision-targeted HRQOL survey encompassing 8 domains (Color Vision, Low Luminance, Distance Vision, General Vision, Near Vision, Ocular Symptoms, Psycho/Social, and Role Performance) was created that was then ready to be field tested. **CONCLUSIONS:** A multi-step process of expert input

review of the literature, and cognitive interviews was used to develop a vision-targeted item bank. The items were administered to a sample of 819 field test participants recently. Analyses of the data will provide information on psychometric properties and item calibration.

170/1788/Comparing health status profiles administered to common samples when their range, variability and available norms vary

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AIMS: Comparisons of health-related quality of life (HRQL) measured by different instruments can be complicated by varying scales of measurement, score variability, and norms. The goal of this study was to compare PROMIS and SF-36 profiles in a sample of patients (pts) with neuroendocrine tumor (NET) and to suggest procedures to facilitate fair comparisons. **METHODS:** Pts with NET participated in a survey that included the SF-36 and the PROMIS-29. T-scores for both HRQL instruments are normed to a US general population. T-scores were compared between 3 groups: without current NET; with current NET, but without carcinoid syndrome; and current NET with carcinoid syndrome. Profile scores of the instruments were anchored on their respective norms. Variability and effect sizes for group differences were examined. Error bars were used to account for the differences in score variability between the instruments. To minimize the potential effect of scale/norm differences, scores were standardized based on sample means & SDs. Groups were again compared using these transformed scores. **RESULTS:** A sample of 663 pts participated in the survey. Compared to pts with no current NET, pts with current NET had significantly worse HRQL scores and those with carcinoid syndrome reported the worst (all $p < .01$). Several of the SF-36 subscales displayed larger group differences than the PROMIS-29. However, the SF-36 profile scores also showed larger errors. When rescaled using sample distributions, the group differences in the profile scores became more comparable. **CONCLUSIONS:** The same general conclusion was tenable from the two profile scores. The relative effectiveness of the measures, however, appeared more comparable when the score variability was considered. Norm-based profile scoring can reflect the impact of a disease sample in reference to a norm. Comparing profile scores from different instruments without adjustments can be misleading due to differences in scaling and the comparative norms used. This can be handled by creating comparable z-transformed scores.

171/1429/Acceptance and Usability of Assessment Center
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AIMS: Assessment Center (AC), a free, online research management software tool funded by the Patient-Reported Outcomes Measurement Information System (PROMIS) initiative, was released in 2007 to provide researchers an application to track item development, administer PRO instruments including computerized adaptive tests (CATs), manage accrual and export data. Software improvements have been implemented regularly to enable new features and improve system reliability and ease-of-use. In 2010, an end-user survey was administered to identify strengths and

limitations of the software. **METHODS:** The 1700 AC users were invited to complete an online survey that included the modified Computer System Usability Questionnaire (CSUQ) and questions concerning specific features. **RESULTS:** Data from 180 participants indicated the top reasons for interest in AC were creating data collection websites that included PROMIS instruments (47.6%) and gaining access to print copies of PROMIS tools (27.2%). The majority considered the ability to capture patient-level data online and administer CATs as quite a bit or very important (85.7% and 77.9% respectively). Desired new system features were diverse with 15.9% wanting participants to be able to track their progress through an assessment, 12.6% wanting to capture PROs in multiple languages, and 12.6% wanting a data collection platform on a wireless handheld device (e.g., iPhone). Overall, 95.5% would recommend AC to others. CSUQ scores for system usefulness, information quality, and interface quality were moderate (means = 3.3, 3.2, and 3.3 respectively on a 1 to 5 scale) and not significantly different from each other ($p > .05$). **CONCLUSIONS:** AC use appears driven by interest in PROMIS measures yet their use is not a system requirement. Although users would recommend the platform to others, many system enhancements were identified. CUSQ scores were moderate and identified areas for improvement including clarifying error messages, facilitating rectifying errors, and improving the user interface. Results will be used to improve AC's user interface and prioritize new feature development.

172/1742/Agreement Between PROMIS Global Health Scale and SF-36 Scores Among Surgical Patients

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AIMS: PROMIS measures have undergone extensive validity testing in community populations, but have been much less studied in clinic patient populations. We examined the patterns of correlation between the PROMIS Global Health Short Form measure and various scale scores on the SF-36 among patients being seen in clinic prior to surgery. **METHODS:** A series of patients ($N = 24$) being seen for pre-surgical consultation were recruited from Henry Ford Hospital surgery outpatient clinic. They were invited to complete a set of PROMIS Computerized Adaptive Testing (CAT) measures and the Global Health short form using the Assessment Center, and were also asked to complete the SF-36 survey as part of the regular clinical care process. SF-36 dimensions were scored on a 0-100 scale. Responses to the PROMIS Global Health Short Form were used to score two components: Global Physical Health and Global Mental Health. Spearman correlation coefficients were calculated as the primary measure of agreement between the SF-36 and Global Health raw score measurements. All statistical testing was done at the 0.05 level. **RESULTS:** All SF-36 measurements were highly correlated with the PROMIS Global Physical Health component, except for Role Emotional and Mental Health. All SF-36 measurements were highly correlated with the PROMIS Global Mental Health component, except for Role Emotional. The SF-36 Vitality and Bodily Pain scale scores were particularly highly correlated with both PROMIS measures. **CONCLUSIONS:** In a population of clinic patients being seen prior to surgery, scores on the PROMIS Global Health Short Form were highly correlated with scores on all domain scales of the SF-36, providing evidence for the validity of the PROMIS measures in this setting. The consistently high correlations across domains suggested the absence of a clear measurement distinction between physical and mental health concepts.

POPULATION & POLICY

173/1664/Assessment of quality of life of family and their willingness to trade off pay and time for symptom free patients with skin disease

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AIMS: Aim was to assess impact of inflammatory skin conditions on family members' QoL & to investigate how much time & money relatives would be willing to spend on a hypothetical treatment to relieve patient of all disease symptoms. **METHODS:** Patients' family members who met inclusion criteria were recruited & were asked to complete the Family Dermatology Life Quality Index (FDLQI), a dermatology-specific QoL measure, a global self-assessed disease severity global question (GQ). Family members also completed 2 utility measures: WTP question that asked family members what percentage of their monthly income they would be willing to pay for a hypothetical treatment that would completely suppress patients' symptoms of skin disease & finally a TTO question that asked family members how much time per day in minutes or hours would they be willing to spend for a hypothetical treatment that would completely suppress patients' symptoms. **RESULTS:** Total of 52 family members (M=12, F=40) with a mean age of 44.5 years participated. 54% were parents & 33% had a monthly income of under £1000. Patients mainly suffered from acne (35%) psoriasis (27%) & eczema (25%). The mean FDLQI score = 6.5 (SD=5.2). Family members were willing to spend 13% of monthly income, the mean amount of time they would give to this treatment was approximately 3 hrs/day. There was moderate but significant correlation between family members' FDLQI scores, WTP ($r=31$ $p=0.027$) & TTO ($r=0.38$ $p=0.005$). The correlation between the 2 utility measures was high ($r=0.5$ $p<0.001$). A strong positive correlation ($r=0.604$ $p=0.01$) was found between perceived disease severity (GQ) & impact on family members' QoL. FDLQI showed high internal consistency (Cronbach's $\alpha=0.83$). **CONCLUSIONS:** This study has further validated FDLQI & demonstrated importance of families' QoL in treatment decision making. The more severe the disease, the greater the impact on relatives' QoL & the more time & money relatives are willing to spend on a treatment reflecting burden of skin disease on the family.

174/1114/Quality of Life and Burden in Caregivers of Elderly in Outpatient Treatment

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AIMS: The aim of this study was to evaluate the quality of life related to health (HRQOL) and the burden of 126 caregivers of elderly patients from two geriatric clinics of an university hospital, as well as to study the association between feeling of burden and demographic and clinical variables. **METHODS:** This is an exploratory, descriptive, cross-sectional and quantitative approach conducted with family caregivers of elderly being cared in the Outpatient Psychogeriatric and in the Outpatient Geriatrics from Hospital of Clinics of the State University of Campinas, Brazil. It was used an instrument to collect socio-demographic and clinical data, the Zarit Burden Interview for assessing the perceived burden, and SF-36 to assess Health Related Quality of Life. Descriptive, comparison, correlation and multivariate analysis were made. **RESULTS:** It was found significant difference between the rates burden on caregivers of the two clinics and all

sociodemographic and care were associated with worsening of at least one dimension of the SF-36. The most frequent diseases in the elderly were strongly related to worsening of HRQOL. **CONCLUSIONS:** The results concerning the involvement of family in care, the diseases and symptoms reported by the caregivers portray an important overload situation, which points to the urgent need to design support interventions that are effective for the management of care and reducing burden. Moreover, it could also reduce significantly caregivers' burden and stress, resulting in the prevention or postpone the entry of the elderly caregivers in nursing homes. So that public programs should provide guidance for caregivers to cope with such specific conditions of stress because, beyond all the physical wear of the caregivers, there is the emotional impact and related social gathering prior to the infirm elderly, lack of leisure time, feelings of guilt and fear of the disease to each other, plus the financial difficulties imposed against the abandonment of work activities.

175/1627/Age and Ethnic Variations in Caregiver Burden, Self-Efficacy, and Quality of Life among Working Caregivers

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AIMS: Research has shown that employees caring for older adults may experience physiological and psychosocial effects and require family supports that may vary across different age and ethnic groups. The purpose of this study was to explore age and ethnic differences among working caregivers in caregiving skills, caregiver burden, self-efficacy, and quality of life, health, and well-being. **METHODS:** METHODS: A total of 276 working White, African American, and Latino adults currently providing care for an older adult were personally interviewed. **RESULTS:** The typical working caregiver was a 47 year-old woman caring for her 77 year-old mother who had taken more than twenty hours off work for caregiving responsibilities during the past six months. Caregiver Self Efficacy was positively related to Caregiver Rewards ($r=.424$, $p<0.001$) and negatively related to Burden ($r=-.310$, $p<0.001$). African Americans rated their caregiving skills in communicating with their older loved ones more highly than other groups ($\beta=.332$, $p<0.001$) and were more likely than others to have taken more than 20 hours off work ($\beta=.201$, $p<0.05$). Both African Americans and Hispanics remained less confident of finding caregiving information and resources ($\beta=-.175$, $p<0.05$ and $\beta=-.183$, $p<0.05$ respectively). Those caregivers with greater self-efficacy and who experienced Caregiver rewards reported greater quality of life. There were significant differences in Caregiver Burden ($F=7.35$, $df=2$, $p=.001$) with African Americans feeling greater level of burden. There were no significant differences across age groups. **CONCLUSIONS:** The differing effects of elder caregiving among ethnic groups may require different caregiver supports. Programs that raise the levels of knowledge, skills and self-efficacy may reduce the caregiver burden, increase feelings of rewards, and greater quality of life.

176/1601/The secondary impact of skin disease on the Greater Patient

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The partner and close family of a person with skin disease, who closely share each other's lives, may experience a major impact on their own quality of life, even though it is their relative who has the condition. Our research across all skin diseases and also specifically in psoriasis and atopic dermatitis has demonstrated the impact of skin disease on the social life, work, sporting activities and personal relationships of family members. It is clear that skin disease not only

affects people “in the present”, but that having skin disease may influence major life changing decisions, affecting the lives of those close to the patient. In our qualitative studies, family members frequently stated that no health professional had ever enquired previously about how their quality of life had been affected by their relatives disease, and often described profound effects. In order to draw attention to this wider secondary impact of skin disease, we have suggested the concept of “The Greater Patient” (1). This describes the close and interrelated social unit of the partner and family who “surround” the patient's life. It is now possible to measure this secondary impact of skin disease, by using the Family Dermatology Life Quality Index (FDLQI)(2, 3), or one of the disease specific measures such as the Psoriasis Family Index or in childhood atopic dermatitis the Dermatitis Family Impact questionnaire. The FDLQI has demonstrated high internal consistency and test-retest reliabilities, good construct validity and appropriate responsiveness (2,3). Further validation studies are underway. There is now the potential to understand the problems experienced by patients' family members in more detail, and to assess how different therapies and strategies may be of benefit to the patient and to members of the Greater Patient. It is also possible to compare the secondary impact between different skin diseases. There is now the need to develop new types of intervention, for example educational opportunities, to try to alleviate this secondary impact of chronic skin disease. 1. Basra MKA, Finlay AY. *Br J Dermatol* 2007; 156: 929-937. 2. Basra MKA, Sue-Ho R, Finlay AY. *Br J Dermatol* 2007; 156: 528-538. Erratum: *Br J Dermatol* 2007; 156: 791. 3. Basra MKA, Edmunds O, Salek MS, Finlay AY. *J EADV* 2008; 22: 813-821.

177/1270/Health-related quality of life and depressive symptoms in mothers of children and adolescents with myelomeningocele
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AIMS: Taking care of a child/adolescent with myelomeningocele (MM) may create stress, anxiety and depression in the mother - the main caregiver. This may impair their health-related quality of life (HRQL). This study aimed at assessing the HRQL of mothers of children/adolescents with MM in comparison with mothers of healthy children/adolescents and the association between the intensity of depressive symptoms and HRQL. **METHODS:** The study group consisted of 50 mothers of children/adolescents with MM under 18 years of age in treatment at a Brazilian institution for children with disabilities (AACD-MG), matched with 100 mothers of healthy children/adolescents by patients' age and gender in the proportion of 2:1. Participants answered to the Medical Outcomes Study Short Form Health Survey (SF-36) by interview. Internal consistency reliability was assessed by Cronbach's alpha coefficient. The Beck Depression Inventory (BDI) was completed by self-application. Scores of the two groups were compared by Mann-Whitney test and effect size (ES) was calculated to measure the magnitude of statistical significant differences. Spearman's correlation coefficient was used to assess the association between the intensity of depression symptoms and HRQL. **RESULTS:** Study group's mean age was 34.9. Cronbach's coefficient ranged from 0.6 to 0.8. SF-36 scores in the study group were significantly lower in the physical component summary ($p=0.01$; $ES=0.3$) and in other 3 domains: role limitations due to physical problems ($p=0.01$; $ES=1.0$), global health ($p=0.00$; $ES=0.6$) and role limitations due to social problems ($p=0.03$; $ES=1.0$). BDI scores were negatively correlated with all SF-36 domains

and components ($-0.6 < r < -0.29$; $p < 0.05$). There was no difference in BDI scores between groups. **CONCLUSIONS:** Mothers of children/adolescents with MM had a physical and mental impairment in HRQL in comparison to mothers of healthy children/adolescents. The intensity of depressive symptoms is negatively related to HRQL.

178/1671/Psoriasis Family Index (PFI-15): Validation of a Disease Specific Quality of Life Tool for Family Members of Psoriasis Patients

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AIMS: Psoriasis is a chronic, incurable skin condition that not only affects the patient but their close group of family members, known as 'the Greater Patient'. The aim of this study was to examine validity of a novel psoriasis-specific HRQoL tool for family members of psoriasis patients, the Psoriasis Family Index (PFI-15). **METHODS:** 51 pairs of patients & their family members were recruited from outpatient & day care clinics at the Dermatology Department of UHW, Cardiff. Patients completed Dermatology Life Quality Index (DLQI), Impact of Psoriasis Questionnaire (IPSO) & Patient's Global Assessment of Disease Severity (PGADS). Family member's completed Family Dermatology Life Quality Index (FDLQI), PFI-15 & Family Member's Global Assessment of Disease Severity (FGADS). **RESULTS:** Patients' ($M=26$, $F=25$) & family members' ($M=17$, $F=34$) mean age was 47 years (median=49) & 50.6 years (median=51) respectively. Mean disease duration was 21 years. Most family members were partners/spouses (71%). Patients' mean DLQI score was 9.8/30, mean IPSO score was 10/22, & mean PGADS score was 4.9/10; there was no sig. difference between males & females. Family members' mean FDLQI score was 8.5/30, mean PFI score was 15/45; again no sig. difference was seen between male & female family members. The new psoriasis-specific instrument PFI showed a strong correlation with generic FDLQI score ($r=0.93$, $p < 0.0001$) & both moderately correlated with FGADS ($p < 0.001$). Stronger correlation was seen between 2 psoriasis-specific tools i.e. PFI & IPSO ($r=0.66$, $p < 0.0001$) as compared to that between psoriasis-specific PFI & generic DLQI ($r=0.52$, $p < 0.0001$). Internal consistency reliability (Cronbach's alpha) of PFI-15 was 0.95. **CONCLUSIONS:** The results of this study have reinforced our understanding of the magnitude of the secondary impact of psoriasis on the family members of patients. The findings indicate that the PFI-15 is a reliable and valid questionnaire for measuring family QoL in psoriasis that can help healthcare professionals better understand this impact.

179/1720/Family's quality life for children with Spinal Muscular Atrophy

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AIMS: Aim to evaluate the quality of family life for children with Spinal Muscular Atrophy, seeking to identify relevant areas from the perspective of parents **METHODS:** The participants were eight families registered by the Brazilian Association of Spinal amyotrophy. The period was from January to May 2009. The instruments of data collection were related quality of life related to health (HRQOL) in Brazil validated for use with relatives of patients with chronic diseases - PedsQL 2.0 module impact on the family. For quantitative data, descriptive analysis was performed to know the areas affected. **RESULTS:** The results showed that the area is preserved in family relationships, getting the best scoring average

(59.58). The concern was the area more affected at the individual level (20.83), and even worse results in relation to physical functioning (27.78). The emotional functioning (42.08), communication (39.68) and cognitive functioning, the results were variable, showing that the parents had different feelings and behaviors in the face of situations. Already the social functioning (32.81) and the difficulty in finding time for social activities (83.33%) were found different results. Within the area family relationships in the family had been preserved, and the average score of 59.58. The opposite was observed for the domain daily activities, which was most affected of all studied (score 4.17). These results provided an understanding of factors that influence quality of life of these families, as well as the identification of other relevant fields. **CONCLUSIONS:** It becomes essential to consider the important guidance for families and be more informed about the type of disability and consequences for the future development of the child and the resources needed to encourage it. Furthermore, attitudes must be taken by health administrators with regard to the comprehensive care of these children, realizing that the parents remain unable to work due to demand care about their own gravity and requirements of pathology.

180/1174/Extended vs. Sextant Prostate Biopsy: A Cost-Effectiveness Analysis Supporting Acceptance of Extended Biopsy Schemes as Standard of Care

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AIMS: Prostate cancer (PCa) poses a significant world health problem. The diagnosis of PCa relies on the histopathological evaluation of prostate needle biopsy specimens. Historically, a sextant prostate biopsy was employed, obtaining 3 biopsy cores from each side of the prostate. Over time, extended biopsy patterns (10–18 cores) have gained favor, but the cost-effectiveness of an extended compared to a sextant prostate biopsy approach has yet to be considered. **METHODS:** We constructed a Markov model that allows diagnosis-dependent health state transitions and repeat biopsy. The base-case is a 65-year-old man referred for prostate biopsy, followed until death. Subjects transitioned through clinically distinct health states as they progressed through the model. Biopsy-specific parameters and health state transition probabilities were adapted from the available literature. We applied a societal perspective and extracted cost parameters from SEER-Medicare datasets. **RESULTS:** The base-case incremental cost-effectiveness ratio (ICER) for the extended biopsy pattern is \$15947/life year gained (LYG). The extended biopsy pattern appears cost-effective and results in life-year gains at all likely PCa prevalences (Table) and remains cost-effective at a test sensitivity as low as 0.65 and an incremental biopsy cost up to \$6291. **CONCLUSIONS:** This novel analysis indicates that an extended prostate biopsy is likely cost-effective when compared to a sextant pattern and can result in significant gains in patient life-years. We believe an extended prostate biopsy scheme should be accepted as the standard-of-care for diagnosing PCa.

PCa Prevalence	0.1	0.3	0.5	0.7
LYG/1000 Patients	229	382	713	942
ICER	\$35956	\$15947	\$13148	\$13454

181/1741/Multinational Evaluation of Conditional Median Models of EQ-5D Health State Preferences

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AIMS: Shaw et al. developed an approach to predict median US population preferences for EQ-5D health states. Although the median modeling approach performed well when applied to the US EQ-5D valuation study data, its usefulness when applied to data collected in other countries has not been studied. The purpose of this investigation was to evaluate the fit of conditional median models of EQ-5D health state preferences in countries outside the US. **METHODS:** Data were taken from health state valuation studies conducted in the UK ($N=3,335$), Spain ($N=967$), the Netherlands ($N=298$), and the US ($N=3,970$). Eight model specifications were evaluated using the data collected in each country. Model parameters were estimated using least absolute deviations regression and without the transformation of values for health states judged worse than dead. The predictive accuracy of each model was evaluated using $k \times 2$ cross-validation. **RESULTS:** Pseudo- R^2 values ranged from a minimum of 0.076 for models fit to the US data to a maximum of 0.095 for certain models fit to the Spanish data. Models fit to the US and Dutch data differed trivially with regard to goodness of fit with tests of ancillary variables (e.g., constant, D1) being insignificant. For the UK and Spanish data, fit indices favored D1 model specifications that included terms to capture the effects of interactions among the EQ-5D dimensions (i.e., I_2 , I_2^2 , I_3 and I_3^2). While models fit to the UK and Spanish data yielded predicted preferences less than -1, no model fit to the US or Dutch data did so. Models fit to the UK and Spanish data yielded greater numbers of prediction errors than did those fit to the US and Dutch data. **CONCLUSIONS:** Medians are widely used in economic research, and a theoretical rationale exists for using median preferences in cost-utility analyses. A linear additive model appears to provide an adequate description of median health state preferences for the US and Dutch populations. It is likely that the observed differences between countries reflect differences in valuation study methodology.

182/1495/Efficiency of Statistical Analyses of the US Population Median-Based EQ-5D Index

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AIMS: Shaw et al. developed a mean-based EQ-5D index (MnI) for the US population. Recently, the investigators developed a median-based index (Mdl) that has a number of conceptual advantages over its predecessor. A study was conducted to evaluate the comparative efficiency of statistical analyses of Mdl and MnI scores. **METHODS:** Data were taken from the 2001–2002 Medical Expenditure Panel Survey (MEPS). Adult survey participants completed the EQ-5D and 12-item Short-Form Health Survey (SF-12); rated their physical and mental health; and reported on the presence of chronic conditions. Associations of MnI and Mdl scores with health status measures and chronic conditions were estimated using conditional mean (CM) and conditional mean rank (CMR) regression. Associations of changes in index scores with changes in health status measures were similarly estimated. Relative efficiency (RE) statistics were derived to evaluate the comparative efficiency of analyses of Mdl and MnI scores. All analyses accounted for the complex sampling design of MEPS. **RESULTS:** RE statistics

(CM/CMR) for associations of index scores with select health status measures and chronic conditions were as follows: SF-12 mental summary, .55*/1.39*; SF-12 physical summary, .44*/.72*; mental health rating, .60*/1.25*; physical health rating, .57*/1.10; anxiety, .70*/1.27*; depression, .64*/1.18*; diabetes, .57*/.97; and hypertension, .60*/.98. RE statistics (CM/CMR) for associations of index score changes with changes in SF-12 physical and mental summaries were 0.59*/0.76* and 0.58*/1.31*, respectively. (* $p < .05$, RE statistic different from 1) **CONCLUSIONS:** The CM estimator suffered efficiency losses of 40–50% when used to analyze Mdl scores. Conversely, the CMR estimator suffered few efficiency losses and exhibited improved efficiency when used to analyze associations of Mdl scores with neuropsychiatric measures. The inefficiency of the parametric procedure can be attributed to differences between the Mdl and Mnl score distributions. It is recommended that robust statistical procedures be used to analyze Mdl scores.

183/1043/Race Differences in Preference-based Health-related Quality of Life in the United States

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AIMS: Although the literature about health and race in the U.S. is quite extensive, there is a lack of studies that comprehensively examine the relationship between race and generic HRQoL both in terms of general scores and their health domain-specific scores. Given the widespread use of these measures, it becomes important to understand the extent of the race differences in these HRQoL scores. The goal of this work is to examine the differences in HRQoL, between blacks and whites, using the summary and domain specific scores of the SF-6D, EQ-5D, QWB-SA, HUI2, HUI3. **METHODS:** The data are from the National Health Measurement Study, a nationally representative survey of U.S. adults, conducted in 2005/2006. Our study included only blacks and whites. The final sample size was 3,578. Survey-weighted least square (WLS) regression models were used to analyze the relationship between race/gender categories and general domain scores, assumed to be continuous. For domain-specific analyses, weighted ordered probit models were used. **RESULTS:** HRQoL differences were more pronounced within older age groups. Higher lifetime and everyday discrimination were associated with higher disparities. We observed that results were consistent across instruments, although coefficient sizes varied. Some of the differences between black women and white men were associated with income and discrimination, and black men moved towards positive HRQoL after adjustments for SES and discrimination. **CONCLUSIONS:** Our results confirmed the importance of SES, especially of income in explaining HRQoL race disparities. We also identified that discrimination (lifetime and everyday) play a role in the differences observed between blacks and whites. Overall, there were consistencies in results across instruments. Our results underscore that the most important factors related to disparities in HRQoL are SES, especially income, and also discrimination. Effective efforts to address racial disparities in HRQoL must address SES disparities.

184/1310/Population Health Status of 5354 South Asians and African-Caribbeans in the United Kingdom: Implications for Health Policy

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AIMS: Population health status scores are routinely used to inform economic evaluation and evaluate the impact of disease and/or treatment on health. However it is unclear whether the health status in black and minority ethnic groups is comparable to these data. The aim of this study was to evaluate population health status in South Asian and African Caribbeans. **METHODS:** Evaluation of the health status of 5354 South Asian and African Caribbean subjects aged > 44 years residing in the Heart of Birmingham, United Kingdom, who were enrolled in the Ethnic-Echocardiographic Heart of England Study (E-ECHOES) study from 2006 to 2009. Health status was assessed by interviewer using the EuroQoL EQ-5D. **RESULTS:** The EQ-5D descriptive system was complete for all study participants. 3849 (71.89%) reported no problems in any dimension. Compared with normative data from the UK general population (Kind et al, 1998) substantially fewer African-Caribbeans and South Asians reported problems with mobility, usual activities, pain and anxiety when stratified by age. Those aged 60 and over did however report increased problems in self-care compared to a sample of the UK general population. **CONCLUSIONS:** This is the first large study assessing the health-related quality of life of South Asian and African-Caribbean subjects in the UK. Compared to data from the UK general population these minority ethnic groups appear to experience substantially better health status. Our findings may reflect differences in perception of quality of life, social cohesiveness or methodological limitations. Our results suggest than current valuations of health status used in economic evaluation may underestimate population values in ethnic minority groups, which may have important implications for international health policy.

185/1386/Psychometric comparison of EQ-5D and EQ-5D-5L in student population

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AIMS: The new five level version of the EQ-5D is now officially available. A pilot five-level version of EQ-5D questionnaire was successfully tested in patients with cancer. Other studies, using the official EQ-5D-5L, in moderately or severely disabled populations of patients with stroke, diabetes, injury or psychiatric conditions are under way. Nothing is known about how EQ-5D-5L performs in relatively young and healthy populations. Aim of the study was to compare a polish version of the three-level EQ-5D questionnaire (3L) with the five level version (5L) in a student population. **METHODS:** In March 2010, all students from the Faculty of Pharmacy, Medical University of Warsaw were surveyed with a set of HRQoL questionnaires (5L, EQ-VAS, SF-36, 3L). We examined percentage of reported problems, proportion and size of logical inconsistencies, ceiling effect, redistribution properties, convergent validity with SF-36 domains and discriminatory power using Shannon's indices. **RESULTS:** Four hundred eighty five students were approached and 443 responded to all questionnaires (5L, SF-36 and 3L). The domains with the highest and the lowest proportion of reported problems by 5L were Anxiety/Depression (57.1%) and Self-Care (0.2%), respectively. 3L and 5L responses were highly correlated in Pain/Discomfort (Pearson's Rho = 0.71), Usual Activities (0.64) and Anxiety/Depression domains (0.64). Mean rate of logical inconsistencies was 3.02%, with 93% of them being level 1 (according to Janssen et al., 2008). The ceiling effect was identified

in 47% of 3L questionnaires and 34% of 5L questionnaires. Absolute informativity was higher for 5L, with similar relative informativity for both instruments. **CONCLUSIONS:** Results obtained in students support introduction of new 5-level version of EQ-5D in young and healthy populations. EQ-5D-5L appears to be more favourable in terms of ceiling effect and absolute informativity.

186/1399/Health status preferences and population norms for the SF-6D

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AIMS: There has been an increasing interest in the study of the health state valuations across countries. Evidence suggests that health state valuations may differ from country to country. In recent years there has been increasing interest in surveys conducted to obtain value sets for the most used preference-based instruments, such as the EQ-5D, the HUI and the SF-6D. A Portuguese system weight for the SF-6D was recently published. However this system weight had some limitations that needed to be corrected. This study seeks to present the Portuguese system weight for the SF-6D without inconsistencies. It also aims at providing Portuguese norms for the SF-6D. **METHODS:** Inconsistencies were found in some levels of some dimensions of the SF-6D. These levels were aggregated and parsimonious models were estimated through generalized estimating equations. The data used to obtain the Portuguese norms came from a random sample of the Portuguese working age population ($n=2,459$). The SF-36v2 was applied to this sample and results from the best parsimonious model were used to obtain the Portuguese preference-based values. **RESULTS:** Aggregating levels of each dimension whenever inconsistencies occurred enabled to obtain a Portuguese system weight for the SF-6D. However there are still some problems of under prediction in some states assigned to poor health. The mean utility value obtained for the Portuguese working age population was 0.81 (associated to a standard deviation of 0.12). Portuguese norms for the SF-6D for the working age population were computed by gender, age, marital status and educational level. Lower levels of utilities were observed in women, the elderly, individuals with low educational level, widowed and individuals living in rural areas. **CONCLUSIONS:** This research demonstrates that it is possible to estimate preference weights for measuring health related quality of life. This model improves significantly the results previously presented. There is still evidence of under prediction in some states. The Portuguese norms play an important role in the interpretation of research results.

187/1783/Calibration of Quality-Adjusted Life Years (QALYs) for Oncology Clinical Trials (OCT)

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AIMS: Quality-adjusted life year (QALY) estimation is a well-known but little-used technique to compare survival adjusted for complications in OCT. Lack of calibration and interpretation guidance hinder implementation of QALY analyses. The aim of this work was to develop a way to calibrate QALY methods for ease of interpretation. **METHODS:** We conducted simulation studies to assess the impact of differences in survival, toxicity rates and utility value on QALY results. Survival comparisons used both log-rank and Wilcoxon testing. We examined power considerations for an NCCTG phase III lung cancer clinical trial for which a QALY analysis had been previously undertaken. **RESULTS:** Sample sizes of 100 events

evaluable for survival per treatment have low power to generate a statistically significant difference in QALYs unless the toxicity rate is 65% higher in one arm. For sample sizes of 200/arm and equal survival time, toxicity would have to be at least 50% more in one treatment arm for the result to be statistically significant, using a utility of 0.5 for days with toxicity. Sample sizes of 300(500)/arm provided 80% power if there is a 40%(33%) toxicity difference. If the overall survival hazard ratio between the two treatment arms is 1.25, then samples of at least 150 pts and 20% increased toxicity are necessary to have 80% power to detect QALY differences. In the lung cancer clinical trial under study, there was only 56% power to detect the observed QALY differences, clarifying the enigmatic conclusion of no statistically significant difference in QALY despite an observed 14.5% increase in toxicity between treatments. **CONCLUSIONS:** This calibration analysis allows researchers to interpret the clinical significance of QALY analyses and will facilitate QALY inclusion in OCTs through improved study design.

188/1283/Is Health Preference Derived from the SF-36v2 Equivalent to that Measured by the SF-6D Health Survey?

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AIMS: The SF-6D is a preference based measure of health (PBMH) derived from the SF-36 Health Survey. The aim of this study was to find out whether the health preference value extracted from SF-36v2 data was equivalent to that measured by the SF-6D PBMH. **METHODS:** A cross-sectional survey was carried out on 589(86% of 684 eligible) Chinese chronic hepatitis B (CHB) patients in Hong Kong. Each subject completed the SF-6D PBMH, the SF-36v2 Health Survey and a structured questionnaire on sociodemographics, and was classified by the clinician into one of four disease severity groups: uncomplicated with normal liver function (AHB), uncomplicated impaired liver function (ILF), complicated with cirrhosis (CC) or complicated with hepatocellular carcinoma (HCC). Health preference values were measured by applying the Hong Kong population specific SF-6D scoring algorithm to data obtained by the Chinese(HK)versions of the SF-6D PBMH and SF-36v2 Health Survey, respectively. The difference in preference values by the two measures were tested by paired t tests. The relative efficiency in differentiating between disease groups of the two measures were tested by the t statistics ratio. **RESULTS:** There was significant difference between the SF-6D health preference measured by the SF-6D PBMH and that extracted from SF-36v2 data, overall and by groups. The SF-36v2 derived health preference values explained around 50% of the total variance measured by the SF-6D PBMH. The relative efficiency of the SF-36v2 was much lower (0.2 - 0.3) compared with the SF-6D PBMH in detecting a difference in health preference between CHB disease groups. **CONCLUSIONS:** The SF-6D Health Survey should be used to collect data for the calculation of health preference because it is more accurate and sensitive.

189/1252/Confirmatory Factor Analysis of the Domains from Four Health-Related Quality of Life Preference Measures

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AIMS: Although sometimes treated as interchangeable, different preference-based health-related quality of life (HRQOL) measures do not produce the same scores. This study examines the extent to which domains or attributes of the different measures are associated with

one another. **METHODS:** A sample of 3,454 adults participating in the National Health Measurement Study completed the SF-36v2, EQ-5D, HUI-3 and QWB-SA in a random-digit dial telephone survey. Confirmatory factor analysis (CFA) and the robust maximum-likelihood estimator were used to evaluate 2-, 4- and 5-factor models, treating domains of each measure as continuous variables. We also performed analyses in which the EQ-5D and HUI-3 domains were treated as categorical variables. Goodness-of-fit indices included the Satorra-Bentler (S-B) chi-square, root mean square error (RMSEA), comparative fit index (CFI), normed fit index (NFI), and non-normed fit index (NNFI). **RESULTS:** We found that a 5-factor model (physical functioning, self-care, pain, mental health, and social functioning) fit the data slightly better than alternative models [S-B chi-square=2000.1 ($p<0.001$), RMSEA=0.04, CFI=0.89, NFI=0.87, NNFI=0.87 for continuous-variable analysis; S-B chi-square=810.8 ($p<0.001$), RMSEA=0.02, CFI=0.99, NFI=0.98, NNFI=0.99 for categorical-variable analysis]. In both continuous- and categorical-variable analyses, standardized factor loadings were ≥ 0.71 for most SF-36v2 and EQ-5D domains, HUI-3 pain and emotion, and QWB physical activity domains, indicating convergent validity among corresponding domains. Factor correlations were ≤ 0.62 between mental health and physical functioning, pain, and self-care, providing support for discriminant validity. **CONCLUSIONS:** At least one scale from the SF-36v2, EQ-5D, HUI-3, and QWB-SA similarly capture the construct of physical functioning. The SF-36v2, EQ-5D, and HUI-3 also provide similar information about pain and mental health. Finally, some HRQOL preference measures appear to better capture some domains of health than do others.

190/1659/Multinational Evaluation of Conditional Median Models of EQ-5D Health State Preferences

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AIMS: Shaw et al. developed an approach to predict median US population preferences for EQ-5D health states. Although the median modeling approach performed well when applied to the US EQ-5D valuation study data, its usefulness when applied to data collected in other countries has not been studied. The purpose of this investigation was to evaluate the fit of conditional median models of EQ-5D health state preferences in countries outside the US.

METHODS: Data were taken from health state valuation studies conducted in the UK (N=3,335), Spain (N=967), the Netherlands (N=298), and the US (N=3,970). Eight model specifications were evaluated using the data collected in each country. Model parameters were estimated using least absolute deviations regression and without the transformation of values for health states judged worse than dead. The predictive accuracy of each model was evaluated using $k \times 2$ cross-validation. **RESULTS:** Pseudo-R² values ranged from a minimum of 0.076 for models fit to the US data to a maximum of 0.095 for certain models fit to the Spanish data. Models fit to the US and Dutch data differed trivially with regard to goodness of fit with tests of ancillary variables (e.g., constant, D1) being insignificant. For the UK and Spanish data, fit indices favored D1 model specifications that included terms to capture the effects of interactions among the EQ-5D dimensions (i.e., I2, I22, I3 and I32). While models fit to the UK and Spanish data yielded predicted preferences less than -1, no model fit to the US or Dutch data did so. Models fit to the UK and Spanish data yielded greater numbers of prediction errors than did those fit to the US and Dutch data. **CONCLUSIONS:** Medians are widely used in economic research, and a theoretical rationale exists for using median preferences in cost-utility analyses. A linear additive model appears to provide an adequate description of median health state preferences for the US and Dutch populations. It is likely

that the observed differences between countries reflect differences in valuation study methodology.

191/1477/Cross-cultural adaptation of the KIDSCREEN-52 questionnaire to measure quality of life in a national sample of Chilean adolescents

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AIMS: To translate and to culturally adapt the KIDSCREEN-52, a health-related quality of life measure developed in 13 European countries, for the Chilean adolescent population. This research is part of the project _National study of quality of life in Chilean adolescents_ which is being carried out by the University of Chile which involves a sample of roughly 8,000 adolescents. **METHODS:** The translation and the cultural adaptation processes were carried out. Two independent, forward translations of the English version and the Spanish (from Spain) version were compared and merged into one forward translation. Back translation, back translation review, harmonization, cognitive debriefing, review of the cognitive debriefing results, proofreading and final report were the steps that followed. The translations were done by professional translators. 6 boys and 6 girls from the three age range (10-12, 13-15 and 15-18 years old) and different socio-economic status (low and high) participated in the cognitive debriefing. **RESULTS:** Most of the items were considered to have low translation difficulty and high semantic equivalence. Most of the participants in the cognitive debriefing had no major problems with the understanding of the questionnaire. Some of the low-income adolescents had difficulties with the comprehension of some items. To aid in the understanding of these words, some colloquial synonyms were added within parentheses. It was considered culturally relevant to change the word padres (parents) to mamá y/o papá (mom and/or dad) because of the high incidence of single parent families in Chile. **CONCLUSIONS:** The Chilean version of the KIDSCREEN-52 questionnaire obtained through the cross-cultural adaptation process is culturally appropriate and semantically equivalent to the English and Spanish (from Spain) versions. This version will be useful for studying the quality of life within a national sample of Chilean adolescents.

192/1631/Validation of the KIDSCREEN-52 Instrument for Chilean School Teenagers Population

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AIMS: To validate the Kidscreen-52 instrument in a national study of Chilean teenager school population, previously adapted from English version. **METHODS:** The national sample was 7910 school teenagers, between 10 to 18 years old, representing the North, Central and South regions of the country and the three school types: public, state subsidized and private education. The questionnaire was applied by training personal. The mean age was 14 years old with SD of 2.3 years. The gender distribution was 47% men and 53% women. Reliability was assessed by Cronbach alpha with CL of 95% will

confident limit. The Confirmatory Factorial Analysis (CFI), by the Lisrel software was 8.5. **RESULTS:** For the 52 items the Cronbach was .936. All dimensions, were over .70 with exception of dimension Sobre ti, that was .61. The CFI was .96 with $\chi^2(1229) = 20996.7$ and RMSEA = 0.045. RMSEA under .06 means a satisfactory adjusted model (Bentler y Bonett, 1980 and Bollen, 1986). **CONCLUSIONS:** The validation of this KIDSCREEN-52 chilean version provides and adequate instrument to study the quality of life for school chilean teenagers and for future comparison with other studies.

193/1300/CHQ-PF28 Profile in 13-year-old Polish Adolescents in Relation to Family Socioeconomic Status in the First Year of Their Life

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AIMS: To evaluate the impact of living conditions in early childhood on HRQL among 13-year-olds. **METHODS:** Prospective, three-wave study carried out on the sample of 605 children born in 1995. Standardized HRQL scores obtained from the Polish version of the CHQ-PF28 (Child Health Questionnaire Parent Form) questionnaire was considered as outcome measure. Information on socioeconomic status (SES) was derived from: 1) a questionnaire completed by parents in 1998: living conditions and fulfilment of families' material needs during the first year of children's life; 2) a questionnaire completed by parents in 2008: parents' education and a subjective evaluation of family affluence; 3) a questionnaire completed simultaneously by children: the family affluence scale (FAS) and a subjective evaluation of family and neighbourhood well-off. For all CHQ-PF28 scores, multivariate linear regression models were estimated. **RESULTS:** The mean summary score of psychosocial health increased from 71,9 to 76,1 ($p=0,029$) when comparing children who lived in bad and good conditions during the first year of life. When comparing families which were able and unable to satisfy their material needs 13 years earlier, poorer HRQL results in adolescents were noted in the latter group both in relation to the summary scale of physical (81,1 vs. 77,9; $p=0,009$) an psychosocial health (75,6 vs. 71,0; $p<0,001$). In 5/12 multivariate models, fulfilment of families' material needs during the first year of children's life proved to be a HRQL predictor independently of the current SES. However, those models were related only to psychosocial health dimensions. **CONCLUSIONS:** Family material status during the first year of children's life has a strong impact on children's psychosocial health in adolescence. This impact remains, even if current social status was taken into account. The study has confirmed the need for implementing programmes for preventing social inequities in health aimed at families with small children or expecting children.

194/1380/Is health related quality of life among school children associated with level of semantic memory?

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AIMS: Studies of the association between childrens school performance and health related quality of life (HRQL) are still relatively rare. The aims were to study (1) if there were differences in HRQL between girls and boys, and between children with different level of performance, and (2) if there was any interaction between gender and performance level on HRQL. **METHODS:** This cross-sectional pilot study included 99 children ($n=51$ girls, $n=48$ boys)

from grade 5 (ages 10-13 years) in a Swedish school. The children answered a word comprehension test and the KIDSCREEN-52 instrument covering 12 dimensions of HRQL. The word comprehension test was used to stratify between high and low performing children. Correlations were calculated and analyses of variance (ANOVA) were conducted in order to investigate differences in HRQL between girls and boys and between high and low performance, as well as interaction effects. **RESULTS:** High performing children were less exposed to bullying, were less afraid, and truanted less than low-performing children. The HRQL dimension that differed most between the sexes was self-perception ($F(1,90)=3.90$, $p=.05$). A tendency to interaction effect between gender and performance level was found ($F(1,93)=3.24$, $p=.07$), where high-performing girls rated their family relationships more negatively than high-performing boys, while for low performing children the opposite pattern was shown. **CONCLUSIONS:** The boys rated higher than girls on HRQL items concerning self-perception, i.e. boys experienced to a greater degree than girls that they were satisfied with themselves, their looks, and boys wanted to a less extent than girls to change their bodily appearance. Based on the interaction effect we conclude that among the high-performing children, girls struggle more to deal with requirements and expectations from home, than boys. It might be the case that girls suffer to a higher degree from performance-based self-esteem than boys, and therefore reported they were less understood and loved by their family.

195/1166/Valuing social and conduct disorders in children and adolescents; results from expert panels

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AIMS: Valuations of health states are used to compare the balance between costs and health outcome, which is helpful for decision makers in allocating resources to where they deliver the largest benefits. Valuations are available for a broad range of health states. However, regarding social and conduct disorders in child and youth care they are lacking. We aimed to obtain valuations of typical states of youths with social and conduct disorders. **METHODS:** Two panels were organized comprising experts from various professions involved in youth with social and conduct disorders. The following professions were represented (among others): psychiatrist, pedagogue, judge, family guardian, teacher, pediatrician and police officer. We constructed 18 descriptions of typical cases (vignettes), based on three main categories: Oppositional Defiant Disorder (ODD), Conduct Disorder (CD), and Disruptive Behavior Disorder (DBD) and two types of comorbidity: Attention Deficit Hyperactivity Disorder (ADHD) and substance abuse. Panel meetings followed a predefined protocol. First, experts had to value vignettes with an EQ-5D and a Visual Analogue Scale (VAS). Next, the applicability of the instruments for the valuation task, problems met and opportunities for improvement, as well as the valuations as given were discussed in a plenary, structured, discussion. **RESULTS:** The first panel (focusing on 12-18 year olds) comprised 10 experts, the second panel (4-12 year olds) 15. Experts were positive about the feasibility and necessity of valuing behavior/conduct disorders. DBD + substance abuse was valued as the most severe vignette, ODD without substance abuse was the least severe vignette. Overall, VAS-valued

vignettes seemed a little more severe compared to EQ-5D valued vignettes. This trend was consistent for all vignettes except CD. **CONCLUSIONS:** Valuing the vignettes was feasible with both methods and both discriminated between different diagnoses. The valuations as obtained may support decision making in care for youth with behavioral and emotional problems.

196/1770/Physical Activity, Sedentary Behavior and Quality of Life in Ethnically Diverse U.S. Youth

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AIMS: To examine the association between physical activity (PA), sedentary behavior and quality of life in adolescents of varying weight status. **METHODS:** 454 youths aged 11–18 were recruited of whom 53% were female, 53% 11–14 years old, 30% African American, 37% Mexican American and 33% White. Height and weight were measured. Age and gender specific body mass index (BMI) were calculated with 34% of youth of healthy weight range (<85th percentile), 20% overweight (85th - <95th percentile), and 46% obese (≥ 95th percentile). Participants completed health survey including generic (YQOL), weight-specific quality of life (YQOL-W) and self-report of PA and sedentary behaviors. American Academy of Pediatrics (AAP) recommendation for PA (e3 times/week, e 20 min/session) and screen time (d 2 hours/day) were used to classify health behaviors. **RESULTS:** 46% of youth reported moderate to vigorous PA 2–3 times/week for 20 minutes or more, and 57% reported d 2 hrs of computer/video game screen time/day. Significant associations were observed between weight status and meeting AAP PA (55%-healthy, 37%-overweight, and 43%-obese; $p=0.014$), and screen time recommendations (64%, 42%, and 60%; $p=0.003$). Having a parent who cares about exercise is associated with d 2 hrs screen time/day in youth (61% vs. 39%; $p=0.057$). Significant differences in YQOL (81.7 vs. 77.9; $p=0.004$) and YQOL-W total scores (81.5 vs. 73.2; $p<0.001$), self (72.5 vs. 62.0; $p<0.001$), social (84.3 vs. 78.1; $p=0.007$), and environment (82.4 vs. 70.3; $p<0.001$) domain scores were found between youths that met AAP PA recommendations vs. youths that did not. Differences between YQOL total scores (82 vs. 78.6; $p=0.017$) and YQOL-W environment domain scores (81.6 vs. 75.7; $p=0.013$) remained after adjusting for age, sex, ethnicity, and weight status. **CONCLUSIONS:** Higher generic and weight-specific environment QoL is associated with meeting recommendations for PA regardless of weight status. Informing parents and youth about increasing PA to improve QoL may be one strategy to improve overall health of U.S. youth.

197/1276/New Card System Quality of Life (QOL) Questionnaire for Infant

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AIMS: The purpose of this study was to develop the desirable original new card system QOL questionnaire for infant. **METHODS:** Eighty-three infants under 5 years (30 children 5 year, 30 children 4 year, 23 children 3 year) participated in this study. Our original new card system QOL questionnaire consists of 18 questions (18 picture

cards) divided into 5 categories. **RESULTS:** The Cronbach's alpha coefficients of our questionnaire was high enough to accept for clinical use for 5 year children: 0.73 in social circumstances, 0.71 in playing habits, 0.70 in parent-child interaction (5 year children) etc. furthermore 0.60 in social circumstances, 0.56 in everyday life (4 year children) etc. and 0.40 in eating habits, 0.40 in playing habits (3 year children) etc., respectively. There was significant positive correlation between first test and re-test in 5 year children ($r=0.99$, $p<0.01$). But there were no significant correlations between first test and re-test: $r=0.68$, $p>0.05$ in 4 year children, $r=-0.14$, $p>0.05$ in 3 year children. Our original new card system QOL questionnaire (18 picture cards) contained 6 main factors which matched the 5 categories (5 year children), and 8 main factors which matched the 5 categories (4 year children). Their cumulative contributions were 0.65 in 5 year children and 0.63 in 4 year children. Average QOL levels on children playing with fathers were more excellent in the 5 and 4 year children compared with the 3 year children ($p<0.05$, $p<0.05$). For the high QOL over 4 year children, connection with fathers are most important for children. **CONCLUSIONS:** These findings indicate that our original new card system QOL questionnaire has a sufficient reliability and potency of validity to use for 5 year children, and it has somewhat sufficient reliability and potency of validity to use for 4 year children. In future, we must pay more attention to age of children, testing time and number of question on children. And, it will be important to consider many kinds of problems on children, mothers and fathers taking care of various developmental stages of children, prospectively.

198/1697/Relation Between Functionality and HRQOL of Patients with Juvenile Idiopathic Arthritis According to Age Group

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AIMS: Functional disability and reduction in health-related quality of life in patients with juvenile idiopathic arthritis (JIA) are aspects that frequently extended into adulthood. The aim of the study has been to verify the age group with the highest level of functional impairment and its relation with the health-related quality of life (HRQOL) of patients with JIA by means of Brazilian versions of CHAQ and PedsQL 4.0. **METHODS:** Cross-sectional study of JIA patients that responded both to PedsQL 4.0, in order to assess the HRQOL, and CHAQ as measurements of functional incapacity. The reliability of the internal consistency of the instruments was verified by Cronbach's alpha coefficient. Comparisons among the CHAQ scores and their correlations with the physical domain and total score of PedsQL 4.0, according to age group, have been made with the Kruskal-Wallis test and Dunn's post-test as well as Spearman's rank correlation coefficient, respectively. **RESULTS:** In the study, 52 children with the age group of 2–7, 8–12 and 13–18 have taken part. The Cronbach's alpha coefficient of CHAQ and PedsQL 4.0 has been above 0.7. The 2–7 year-old patients have obtained CHAQ median and percentiles (25/75) of 1.5 (1.2/2.2) superior and significant ($p<0.05$) to the 8–12 year-olds group with 0.6 (0.4/1.0) and to the 13–18 year-olds group with 0.7(0.4/1.0). The correlations between CHAQ, physical domain and total score have been weak (variation of -0.09 to 0.27) and non-significant ($p>0.05$). **CONCLUSIONS:** The perception of functional disability occurred from the age of 8. That may be justified by the beginning of cognitive maturation of patients above this age group. This result indicates the need to promote actions in order to enhance the functional capacity within this

population. The absence of correlation between functional impairment and HRQOL may have occurred due to the small size of the sample. Studies with a larger number of patients will certainly detect this difference. Support: FAPEMIG and CNPQ

199/1699/Postnatal Quality of life and Mental Health in Normal and Caesarean Delivery

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AIMS: Postnatal quality of life (QoL) and mental health in women with vaginal delivery and caesarean section has increasingly been recognized in recent years. The debate on the best method of delivery to protect QoL losses and minimize postnatal depression is still a matter of controversy. This study aimed to investigate postnatal quality of life and mental health in women with normal delivery and caesarean section. **METHODS:** 109 women from a public and a private hospital, with normal delivery and caesarean section, were recruited in the study. Quality of life was measured using WHOQOL-BREF, mental health by GHQ-28, and depression with the semi-structured interview SCID-NP of DSM-III-R. Administration was conducted at two points in time (T0 on the 2nd day of delivery, and T1 after 8 weeks. All instruments have been validated in Greek populations. **RESULTS:** 59.6% of women of the study had normal delivery, while 40.4% caesarean section. 87.2% of the sample was identified as normal, while 12.8% was diagnosed with depression and mental disorders. Using t-tests and ANOVA, postnatal quality of life for the two groups of delivery was found to be improved from time 1 to time 2, with better quality of life and physical well being were reported by the normal delivery group. Using regression analysis, significant associations were found between QoL dimensions and method of delivery, type of hospital, mental health, education and type of work. **CONCLUSIONS:** The study provided evidence of certain benefits in favor of the normal vaginal delivery, suggesting that it may contribute to a better QoL and physical and mental health. Sociodemographic variables like education and type of work seem to have a significant contribution to postnatal QoL.

200/1746/Psychometric proprieties of the Youth Quality of Life Instrument-Research (YQOL-R): Brazilian version

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AIMS: The aim of this study is to study preliminary psychometric proprieties of the YQOL-R in a sample of Brazilian children and adolescents. **METHODS:** This is a cross-sectional community study conducted in the catchment area of the family medicine sanitary unit of HCPA (Hospital de Clinicas de Porto Alegre), Brazil. All 10-17 years old children and adolescents, from the six schools in the catchment area were invited to participate. Three scales were administered in classrooms: the YQOL-R, the Screen for Children and Related Emotional Disorders (SCARED) and a questionnaire about Bullying behavior in childhood. A principal component analysis with orthogonal varimax rotation was used for factors analysis. Comparison of YQOL-R scores between the four quartiles of the SCARED score and groups of frequency of bullying were compared using the Analysis of Variance (ANOVA). **RESULTS:** A total of 419 students, 209 (49.9%) female, with a mean age of 13.9 (SD=2.45), participated in the study. The mean of total score of YQOL-R was 81.52 (SD=20.8). Chronbach's alpha for the 41 items

was 0.931. Principal component analysis with varimax rotation for a four factor solution resulted in a first factor accounting for 15.5% of the variance, the second factor for 14.8%, the third 11.4% and the fourth 3.9% with a very similar factor structure with the original factors proposed by Patrick et al. Total quality of life scores of YQOL-R show significant differences between all SCARED quartiles of symptoms, SMD between 25th percentile and 75th percentile was 13.8 (CI95% 8.27 to 19.5; $p < 0.001$). Bullying groups also show significant differences between all groups of frequency. **CONCLUSIONS:** The YQOL-R seems to have acceptable preliminary parameters in a community Brazilian sample of children and adolescents. Since measures of validated measures of quality of life are needed in this population, studies evaluating its psychometric proprieties are equally relevant to the field.

201/1388/Quality of life of youth who were born premature or with a congenital heart defect: How do they measure up?

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AIMS: Today, infants born as young as 23-24 weeks gestation survive and more than 80% of the children born with a cardiac anomaly reach adolescence and adulthood, due to medical and surgical advances. They are at high risk for motor, cognitive, behavioral and other developmental impairments, which may have a negative impact on quality of life (QoL). The objectives of this review were to systematically assess and compare QoL in adolescents (12-18 years) and young adults (19-30 years) born PT and those with CHD. **METHODS:** Eligible articles published in journals were identified through Medline, Embase, PsycInfo, and CINAHL using MeSH-term and/or relevant text word search. Studies were selected based on defined inclusion and exclusion criteria. Methodological quality of the included studies was rated using a standardized checklist. Data on the study design, characteristics of the sample and control group, measurement of QoL, and findings were extracted into tables. **RESULTS:** The search strategy yielded a total of 1522 hits, 45 studies met the inclusion criteria and were included (PT: 20; CHD: 25). Methodological quality was moderate to high in 42 studies. Using the SF-36, both PT youth and youth with CHD reported worse QoL in the area of physical functioning compared to healthy peers (9 out of 11 studies). Determinants of poorer QoL included ELBW, BPD, IVH, and having a handicap (PT youth), low education, unemployment, unstable heart disease, poor functional status, cyanosis, depression, and low self-esteem (youth with CHD). **CONCLUSIONS:** Current studies indicate that adolescents and young adults born PT and those with CHD generally report worse QoL compared to healthy peers, especially in the physical functioning domain. To improve QoL, physical aspects must be considered by encouraging exercise and avoiding unnecessary restrictions and parental overprotection. Adolescents and young adults born PT and with CHD may be medically stable, nonetheless, their functional limitations and participation restrictions clearly indicate a need for intervention.

202/1415/Health-related quality of life(HRQOL) measurement in children and adolescents in Iberoamerican countries, 2000-2010

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AIMS: To analyse characteristics of instruments assessing HRQOL

in children, either developed or adapted in Argentine, Chile and Spain. **METHODS:** Databases (Medline, ISI Science Citation Index), hand searching, and previous reviews were searched to find measures of HRQoL, health status or well-being addressed to children and adolescents. Country-specific filters were applied to identify studies carried out in participating countries. Type of studies and instruments characteristics were analysed. Descriptive characteristics and psychometric properties (reliability, validity and sensitivity to change) were analysed following guideline recommendations of the Scientific Advisory Committee of the Medical Outcomes Trust. **RESULTS:** Preliminary results included 61 documents from Spain, 16 from Argentine and 8 from Chile. Twenty five instruments were developed or adapted in the study period. Most of them were developed in the USA, and few instruments were developed following an international universalistic approach including population from the analysed countries (n=4). Disease-specific instruments were adapted for a total of 11 different diseases. There was substantial variability in the number and characteristics of the dimensions included. Reliability was generally acceptable, and the majority of instruments provided data on internal consistency (n=21), and to a lesser extent test-retest reliability (n=14). Nearly all of them reported construct validity, but only 2 analysed sensitivity to change. **CONCLUSIONS:** There are scarcity of instruments available which are designed specifically to measure HRQoL of children and adolescents in the analysed countries. Some psychometric characteristics have been reasonably well tested, but others, most notably sensitivity to change, have not been tested in the majority of instruments. The extension of this study to the rest of Latin American countries would be helpful in identifying gaps in this area and promoting the use of HRQOL measurement in children and adolescents in Spanish-speaking cultures.

203/1428/Adaptation and Validation of the Pediatric Quality of Life Inventory PedsQL 4.0 - Generic Core Scales to the Portuguese culture

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AIMS: The aim of this paper is to validate the use of the PedsQL 4.0 Generic Core Scales for the ages of 5-7 and 8-12, in versions for children and parents. **METHODS:** The Portuguese version was obtained through a forward/backward translations, with a post analysis from a panel of patients. The reliability and validity was tested by applying the measure to a sample of healthy children, children with type I diabetes and spina bifida, and their parents, making a total of 320 people. **RESULTS:** After obtaining the semantic and content equivalence, the Portuguese version of PedsQL showed good levels of reproducibility ($r > 0.95$ in all versions) and acceptable levels of internal consistency with Cronbach's Alpha at 0.70 on most scales. The validity was confirmed by the capacity to differentiate between healthy children and children with health problems through the concordance values between the children's and parents' perception (r between 0.36 and 0.78, as well as the relations with the KINDL Questionnaire). **CONCLUSIONS:** PedsQL 4.0 proved to be equivalent in both cultures, and useful, reliable and valid for use in Portugal.

204/1482/Evaluation of the content of quality of life instruments applied to children and adolescents with cerebral palsy, according to the International Classification of Functioning, Disability and Health(ICF)

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AIMS: Cerebral palsy (CP) is a group of motor disorders resulting from a lesion in the developing brain that can cause functional limitations and impair well-being. The questionnaires to evaluate quality of life (QoL) and the International Classification of Functioning (ICF) are two different but related perspectives to understand functioning and the perception of health and well-being of children with CP. This study aimed to verify the content covered by the QoL instruments available to evaluate children and adolescents with CP, according to ICF. **METHODS:** 5 generic instruments and 5 specific ones were identified in the literature to evaluate the QoL of children and adolescents with CP. Two researchers performed an independent analysis of all the items of these questionnaires. Each item was related to ICF by means of internationally recognized rules. The Kappa statistic was used to describe the degree of concordance among the researchers. **RESULTS:** 488 items, 637 concepts were identified and 524 correlated with 175 different categories of ICF: 130 with the body function component, 314 with the activity/participation component, 50 with the environmental factors component and 51 with the personal factor component. **CONCLUSIONS:** The QoL tools available here to apply to children and adolescents with CP mainly cover the activity/participation component and the body functions component of ICF, but environmental factors and personal factors are not much studied. The body structures component was not covered by any of the correlated tools. This analysis can guide clinicians and researchers in choosing the most appropriate instruments for the content to be evaluated.

205/1532/Determinants of agreement between self-reported and parent-assessed quality of life for children in Germany

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AIMS: The aim of this study is to quantify the level of agreement between self-reporting and proxy-assessment of children's health-related quality of life using KINDL-R in a large population based study in Germany and to identify factors which are associated with agreement. **METHODS:** The German Health Interview and Examination Survey for Children and Adolescents included the KINDL-R questionnaire on health-related quality of life. 6388 children and adolescents filled in the questionnaire while their parents answered the proxy version. Means and standard deviation for the self- and proxy ratings, and also the Pearson and Intra-Class correlation coefficients for the absolute agreement were calculated. The relationship between other variables and parent-child agreement were determined by means of logistic regression. **RESULTS:** In the Physical, Self-esteem and School dimension and for the total score, the parents significantly overestimated the quality of life of their child. In contrast, the quality of life of the children in the dimensions Psychological well-being and Family were considerably underestimated by the parents. The proportion of parent-child ratings

in agreement (difference < 0.5 SDs) ranges from 34.9% for the Self-esteem scale to 51.9% in the Psychological scale. The most important factor explaining parents rating was the level of the child's self-assessment followed by the parent's assessment of the subjective health, or reported emotional abnormalities. **CONCLUSIONS:** Our study shows that parental reports cannot adequately replace self-assessment for 11–17 year olds. In view of the different underlying perspectives, the parental assessments should where possible only be regarded as providing supplementary information.

206/1555/Quality of Life of Children Born Preterm at School-Age

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AIMS: The aims were 1) to describe the quality of life (QoL) of a cohort of children born preterm aged 6–10 years; 2) to determine whether socio-demographic factors, neonatal features and neurocognitive status were impacting their QoL. **METHODS:** Inclusion criteria: all singleton infants born between 24–32 weeks of amenorrhea (WA) between January 1997 and December 2001, survivors in 2007 (6–10 years old of age) and having undergone a complete clinical pediatric follow-up. Data collection: maternal and perinatal data by chart review; regular clinical examination; cognitive evaluation by BREV test, when children were between 4 and 8 years old of age; children's schooling and QoL (VSP-A questionnaire parent version) reported by the parents in 2007. Children's QoL was compared to a French general population of reference. **RESULTS:** Eighty-two children participated: mean age was 7.9±1.4yr, mean birth weight was 1130.0±361.4g, 23 children were born before 28WA, 46 were female and 11 had major neurocognitive disorders. The remaining 120 non-respondents were not significantly different. Parents of children born preterm reported a significantly lower perception of QoL of their child when compared to the parents of general population, regarding the VSP-Ap Index and the dimensions: "Body image", "Vitality", "Psychological well-being" and "School performance". In multivariate analyses, 3 factors were found significantly associated with at least one dimension VSP-A in the preterm children: presence of major neurocognitive disorders, negatively correlated with "Vitality", "Relationships with friends", "Physical well-being" and "School performance"; maternal parity, positively correlated with "Psychological well-being"; socioeconomic status of family, positively correlated with "Relationships with friends". Maximal R² was 15%. **CONCLUSIONS:** In addition to neurocognitive disorders, other variables have a significant impact on preterm children's QoL at school-age, as socioeconomic status of family. Given the low proportion of QoL variability explained by the models, other factors (environmental...) are needed to be explored.

207/1609/T-QoL: a novel dermatology-specific measure for adolescents with skin diseases

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Aim: There is a lack of instruments for adolescents with skin disease. The aim of this study was to develop and validate a dermatology-specific quality of life instrument for adolescents with skin diseases. **Methods:** Semi-structured interviews were conducted with a cohort of 50 adolescents aged 12–19 years recruited from the dermatology outpatient clinic. Interviews were then transcribed verbatim using standardised technique which resulted in the first version of T-QoL. Content validity was carried out using a pilot study of 20 adolescents and led to a revised second version of T-QoL. This was followed by

psychometric evaluation conducted on 153 adolescents including the application of Rasch analysis. Results: 50 patients (M=17, F=33; mean age=16, range=12–18 yrs) were interviewed. A total of 33 aspects of adolescents' HRQoL were identified, which were grouped into 12 domains with psychosocial being the most common, leading to a 32-item first version of the T-QoL. 20 adolescents (M=8, F=12; mean age=16.5) completed the T-QoL and provided feedback on its clarity, focus, relevance, practicality and applicability. Changes were made to the first version taking into account patients' and 4 clinicians' feedback resulting in 30-item T-QoL which was then completed by 153 adolescents (M=70, F=83; mean age=16.5, range=13–19). Cronbach's alpha was 0.94. Rasch analysis of the whole scale did not support the validity of the T-QoL, as a unidimensional measure of QoL impairment. A factor analysis confirmed the presence of three domains within the scale. Each of the domains was then subjected to Rasch analysis individually. Three items in domain 1 did not fit the model and were therefore removed before further analyses were carried out. When considered separately all domains showed adequate fit to the model, good person separation, good internal consistency and no significant differential item bias for gender or age. It was however, necessary to reduce the response format to a 3-point response scale. **Conclusions:** The initial results of this study demonstrate that T-QoL could provide a simple, relevant and valid tool for assessing the impact of skin disease on adolescents QoL. The validity of the T-QoL will be further examined in a larger sample to confirm these findings.

208/1362/Health Related Quality of life in children and adolescents: Reliability and validity of the Norwegian version of KIDSCREEN-52 questionnaire, a cross sectional study

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AIMS: As part of a larger investigation in Norway about pain and HRQoL, the KIDSCREEN-52, a cross-cultural 10-scale questionnaire, was translated into Norwegian. The aim of this study was to examine some psychometric properties of the first Norwegian version of KIDSCREEN, particularly reliability and construct validity. **METHODS:** A cross-sectional study, and a cluster sample of 20 randomly selected schools was drawn, and the final study sample encompassed 1,123 children and adolescents, aged 8–18 years. The analyses were conducted using SPSS (16.0), Lisrel (8.7), and AMOS (7.0). Internal consistency reliability was assessed using Cronbach's alpha. Construct validity was examined by confirmatory factor analysis (CFA), and through comparison of the KIDSCREEN scales with similar scales of KINDL, another HRQoL instrument. **RESULTS:** The Cronbach's alpha value was above 0.80 for all KIDSCREEN scales, suggesting good internal consistency reliability for the instrument. CFA shows that most of the KIDSCREEN scales fit the data well. Fit statistics for the 10-factor model were satisfactory, although some scales displayed residual covariance. Several CFA models were fitted to the data, and the model specified according to the 10-dimensional KIDSCREEN-52 measurement model with correlated first-order factors fitted the data well (RMSEA = 0.04; CFI = 0.98). The KIDSCREEN scales correlated sufficiently highly with comparable KINDL scales. **CONCLUSIONS:** The results of the present study indicate that the Norwegian version of the KIDSCREEN-52 seems to work well in a Norwegian context, and is a valid and reliable generic HRQoL instrument.

POSTER SESSION 3

CLINICAL PRACTICE & RESEARCH

209/1239/Perceived communication between patients and healthcare providers as a determinant of health-related quality of life in breast cancer patients : longitudinal approach

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AIMS: Communication between patients and healthcare providers is recognized as an important aspect of the quality of life of cancer patients. Nevertheless, no study has examined whether perceived communication between healthcare providers (doctors, nurses, radiotherapy technicians) and breast cancer patients is a determining factor in explaining their health-related quality of life along the disease's trajectory. This study aimed to ascertain whether communication between breast cancer patients and healthcare providers influence the quality of life of these women at diagnosis, during radiotherapy and at follow-up. **METHODS:** The sample consisted of 120 French-speaking women with stage I or II breast cancer, aged 18 years and over (55 years \pm 9,5) who underwent a lumpectomy. They filled out questionnaires three times: Around diagnosis, during half-way of radiation therapy and between three and four months after radiation therapy. They completed, either at the hospital or at home, a questionnaire pertaining to demographic and medical data, the MOS SSS, the EORTC QLQ-C30/BR23, and the MCCS. **RESULTS:** GEE analyses indicate that women's perceptions of their own communication skills towards doctors had a greater impact on their health-related quality of life than those of healthcare providers. The women had better role and emotional functioning as well as fewer side effects and symptoms during radiotherapy and at follow-up when they perceived themselves as competent communicators at diagnosis and during radiotherapy towards surgeons and radio-oncologists. **CONCLUSIONS:** The results of the study underscore the importance for breast cancer patients to be proactive so that they can feel competent with regards to seeking information and with the socio-emotional aspect of the relation between them and the doctors in oncology in order to enhance their health-related quality of life.

210/1450/Evolution of the association between perceived communication and health-related quality of life among breast cancer patients in relation to clinical, intrapersonal and interpersonal factors

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AIMS: Many studies have assessed the health-related quality of life of breast cancer patients along the disease's trajectory according to their intrapersonal characteristics. Yet, few studies has attempted to examine the evolution of the association between the way breast cancer patients perceive communication with healthcare providers and their health-related quality of life throughout the disease's trajectory in relation to clinical, intrapersonal and interpersonal factors. The objective of this study was to identify the factors that influence the evolution of the association between perceived communication and health-related quality of life among breast cancer patients along the disease's trajectory. **METHODS:** The sample consisted of 120 French-speaking women with stage I or II breast cancer, aged 18 years and over (55 years \pm 9,5) who underwent a lumpectomy. They filled out questionnaires three times: Around

diagnosis, during half-way of radiation therapy and between three and four months after radiation therapy. They completed, either at the hospital or at home, a questionnaire pertaining to demographic and medical data, the MOS SSS, the EORTC QLQ-C30/BR23, and the MCCS. **RESULTS:** GEE analyses indicate that the women's age, their perceived social support, the stage of their cancer and the type of treatments received are factors that had an impact on the association between the way they perceived their communication towards healthcare providers and their health-related quality of life. **CONCLUSIONS:** By better understanding how perceived communication affects the health-related quality of life of these women along the disease's trajectory in relation to clinical, intrapersonal and interpersonal factors, it should enable healthcare providers to adjust their approach towards their patients by using better communication strategies in order to improve the health-related quality of life of women afflicted with breast cancer.

211/1553/Perceived quality of life in Portuguese women with breast cancer and their partners. Presentation of an explanatory mode
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AIMS: Living with breast cancer is an experience with losses and imposes great challenges to women and their partners. The disease and treatments introduce significant changes. The management of emotions and feelings, the ability to solve problems of daily life are put to the test, interfering with the perception of quality of life. Studies in this area focuses on identifying factors which will contribute to distress, and the problem of changes in body image and experience of sexuality occupied a prominent place. The purpose of this study was to understand how the various dimensions of pain and suffering and vulnerability to stress, strengthen the perception of quality of life of women with breast cancer and their partners. **METHODS:** The authors tested a predictive model that explains the perceived quality of life for Portuguese women with confirmed diagnosis of breast cancer, and their partners. The 208 participants also were being followed in Oncology Centres. **RESULTS:** 46.6% are vulnerable to stress, 25% with criterion for emotional distress majority with a poor perception of quality of life. The test of global model shows that the psychological and existential suffering are predictors of vulnerability to stress, which in turn, explains the development of emotional disorders and a poor perception of quality of life. **CONCLUSIONS:** For these women and their partners the physical suffering does not explain the development of frameworks for vulnerability-related stress. However, the way it is meant the disease appears as a determinant for the management of individual resources for the well-being and perceived quality of life. For these women, the presence of vulnerability to stress leads to the emergence of psychological distress, which does not happen with their partners who seem to get resources in order to support their wives. However and in contrast with the women, the vulnerability to stress in men, appears to lead to a negative evaluation of the environmental and social relations dimensions of quality of life

212/1648/Development of a new BREAST-Q module for Breast Cancer Patients: The Breast-Conserving Therapy (BCT) Module
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Jhanwar, Psychiatry and Behavioral Sciences, Monica Morrow, Surgery, Memorial Sloan-Kettering Cancer Center, New York, NY

AIMS: Advances in early detection and adjuvant therapies have resulted in a growing population of breast cancer survivors. Multiple randomized trials have demonstrated that for early stage breast cancer, breast-conserving therapy (BCT) and mastectomy offer equivalent survival. To facilitate the process of informed decision-making, reliable and valid outcome data regarding patient satisfaction and QOL following oncologic breast surgery must be considered. The aim of this study was to develop a new BREAST-Q [Pusic et al. *Plast Recon Surg* 2009] module to capture the unique outcomes of BCT patients. **METHODS:** We performed in-depth qualitative interviews with 20 patients who had undergone BCT. Interviews were audio-taped, transcribed, coded line-by-line, and analyzed thematically, in order to identify concepts and domains of importance to patients. Items to measure each domain relating to breast appearance were identified from patient statements taken verbatim from interview transcripts. The BCT item list was then examined by experts and pilot-tested with 10 patients using cognitive debriefing techniques. **RESULTS:** Issues of importance to BCT patients were categorized into the following 5 domains for which scales and items were developed: (1) satisfaction with breast appearance (2) psychosocial well-being (3) sexual well-being (4) physical sequelae and (5) process of care. This conceptual framework mirrors that of other BREAST-Q modules, and contains items specific to BCT patients that address changes in breast appearance from radiation and lumpectomy. A preliminary version of this module is ready for field-testing. **CONCLUSIONS:** Once completed, the BREAST-Q BCT module can be used to study the impact and effectiveness of BCT from the patient perspective. This instrument will complement existing scales and provide a means by which surgical outcomes for breast cancer patients may be compared. It will also inform the decision-making process, patient selection and the evaluation of new surgical techniques and technologies for BCT patients.

213/1376/Outcomes and Costs of Nanoparticle Albumin-Bound(nab-) Paclitaxel Compared to Docetaxel in Women with Pretreated Metastatic Breast Cancer

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AIMS: To assess the benefits and costs of nab-paclitaxel compared with the currently recommended therapy, docetaxel, in women with metastatic breast cancer who had failed first line chemotherapy, and explore implications for UK health technology assessment. **METHODS:** No studies have compared nab-paclitaxel to docetaxel in the licensed population. An indirect comparison (IDC) between nab-paclitaxel and docetaxel was undertaken. Efficacy and adverse events were included in the IDC and an economic model constructed. Pairs of trials (nab-paclitaxel vs solvent based (sb) paclitaxel & docetaxel vs sb-paclitaxel) were combined using the common comparator sb-paclitaxel. The IDC used risk or hazard ratios for efficacy. Adverse events were analysed using odds ratios (ORs). **RESULTS:** The IDC found no clinically or statistically significant difference in overall survival, with a hazard ratio of 1.03 between nab-paclitaxel and docetaxel (95% confidence interval, CI, 0.74-1.45). However, docetaxel was associated with a significantly higher rate of grade III or IV neutropenia (OR 22, CI 11-45), stomatitis, diarrhoea and peripheral oedema. The cost-effectiveness analysis found that nab-paclitaxel was associated with more quality adjusted life years (QALYs) than docetaxel (0.803 vs 0.799). Sensitivity analysis suggested that economic benefits were strongly

dependent on efficacy and less sensitive to safety differences and utility estimates. Nab-paclitaxel was accepted as an option for management of these patients by HTA bodies in the UK. **CONCLUSIONS:** The model found that nab-paclitaxel was associated with better outcomes and lower total costs than docetaxel. This rested on a more favourable AE profile, which improves health related quality of life and marginally reduced management costs. The QALY analysis was able to capture benefits resulting from a statistically significant improvement in toxicity. Although the size of the QALY difference was small, this appears to have been sufficient to be acceptable to UK decision makers.

214/1009/Study on the Quality of Life & Determinants for Patients Undergoing Lithotripsy for Urinary Stones

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AIMS: to evaluate the HRQoL for patients with urinary stones after lithotripsy & to compare the HRQoL according to type of lithotripsy performed and to identify the most significant factors that could have an impact on the patients' HRQoL. **METHODS:** A comparative cross sectional approach was used at the main University and main MOH hospitals in Riyadh, Saudi Arabia. All patients admitted to the urology service whom underwent lithotripsy for urinary stones during a period of 9 months were included in the study. An observation period of 3-15 months following the last treatment was applied. Socio-demographic, medical data, number and type of lithotripsies were collected. The Medical Outcome Study Short-Form 36-item survey (SF-36), was used to assess HRQoL. For comparison, the HRQoL was applied for an equal number of healthy population, multivariate analysis of variance was used. **RESULTS:** lithotripsy cases had significantly higher mean scores in physical functioning, role physical, vitality, role emotional and mental health subscales. Patients whom underwent percutaneous lithotripsy had significantly worse mean score, in all HRQoL dimension, except for bodily pain. Patient's age, location of the stone (being in the kidney) and recurrent stones (multiple lithotripsies) were affecting significantly the HRQoL of patients, in addition to obesity and diabetes Mellitus. **CONCLUSIONS:** Lithotripsy patients, after a reasonable period of recovery from surgical procedures, had a favorable HRQoL in comparison to normal population, yet invasive procedures had a negative impact on the patient QoL. Further longitudinal and prospective studies are warranted to help assess the impact of different factors and surgical interventions on the QOL and to overcome the drawbacks and bias that could arise from backward studies.

215/1221/Quality of Life after cholecystectomy: results of a prospective study

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AIMS: Removal of the gallbladder (cholecystectomy) is the standard treatment of symptomatic gallstone disease, aiming at a relief of symptoms. However, many patients report persistence of symptoms after cholecystectomy. Quality of Life (QoL), defined by the World Health Organisation (WHO) as the patient's subjective evaluation of his physical, psychological, social functioning and other aspects of life, has not been investigated after cholecystectomy. The aim of the study was to identify predictors of QoL at six weeks after cholecystectomy. **METHODS:** Consecutive patients ($n = 142$), with uncomplicated symptomatic gallstone disease, 18-65 years, indicated

for cholecystectomy, were included in this prospective follow-up study. Patients completed symptom checklists, psychological questionnaires, and the WHOQOL-BREF. Multivariate regression analysis was used to identify predictors of QoL. **RESULTS:** Patients (47.5 ± 11.3 years, 76.2% females) reported improvement in QoL in the first six weeks after cholecystectomy. In the period from six weeks till one year after cholecystectomy, no improvements in QoL were found. Personality predicted six weeks QoL within all domains of the WHOQOL-BREF ($-0.50 < \text{Beta} < -0.32$) and Overall QoL and general health ($\text{Beta} = -0.23$). Depressive symptoms had a negative impact on the WHOQOL-BREF domains Psychological health and Environment ($\text{Beta} = -0.34$) and ($\text{Beta} = -0.21$), respectively). Fatigue predicted QoL at six weeks within the domain Physical health and Overall QoL and general health ($\text{Beta} = -0.27$) and ($\text{Beta} = -0.23$), respectively). Clinical and demographic variables did not predict QoL at six weeks. **CONCLUSIONS:** Improvement of QoL only takes place in the first six weeks after cholecystectomy. Personality is the major predictor of QoL at six weeks. Other psychological variables also predict QoL at six weeks, whereas clinical and demographic variables do not. Preoperative screening for psychological risk factors will improve clinical decision making in cholecystectomy. Watchful waiting should be considered in patients with a high psychological risk profile.

216/1318/HRQOL and Side effects on Cessation of Medical Therapy for Benign Prostatic Hyperplasia (BPH)

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AIMS: The objective of this paper is to quantify the relative impact of BPH-related HRQOL and side effects on cessation of medical therapy. **METHODS:** The BPH Registry is a multicenter, cohort study of men with BPH. Analyses were limited to those who started BPH medical therapy ($n=761$). BPH HRQOL, (International Prostate Symptom Score (IPSS) and Mens Sexual Health Questionnaire (MSHQ)), side effects, and cessation of therapy were measured prospectively. Time-dependent Cox models adjusting for age and comorbidities quantified impact of HRQOL and side effects on cessation of therapy. **RESULTS:** Hazard ratios for cessation were relatively higher for treatment related side effects (Table). The impact of sexual and urinary HRQOL were moderate. **CONCLUSIONS:** Side effects arising from therapy are more likely to result in cessation of therapy compared to urinary or sexual QOL effects.

Reported Side Effect	Overall HR	Wald Chi-square
Dizziness/light-headed	11.00	21.4
Depression	15.59	13.3
Urinary Retention	6.52	11.8
Hematuria	7.73	7.9
Change in MSHQ-Satisfact (4 units)	1.45	7.3
Edema-peripheral	8.61	4.5
Syncope	8.28	4.4
Incontinence	ns	1.7
Change in IPSS (4 units)	ns	0.8
Impotence/Erectile Dys	ns	<0.01

217/1690/Application of Exploratory Factor Analysis to Support the Conceptual Framework of PRO Measures: Results from a Phase 2 Study of Irritable Bowel Syndrome with Constipation
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AIMS: A set of patient-reported outcome (PRO) measures assessing symptoms of constipation-predominant irritable bowel syndrome (IBS-C) was developed and administered in a large phase 2b study. Empirical PRO data were analyzed to better understand the relationships among these symptoms and to provide support for the underlying conceptual framework. **METHODS:** 420 adult IBS-C patients participated in a multicenter, randomized, double-blind, dose-range-finding, clinical study of linaclotide (75, 150, 300, or 600 μg linaclotide, or placebo) administered orally once daily for 12 weeks. Seven daily IBS-C PROs for abdominal symptoms and bowel function and 4 weekly global PROs were assessed using interactive voice response system (IVRS) technology. Principal component (PCA) and exploratory factor (EFA) analyses explored the correlational structure of the daily PRO symptoms. Consistent with standard EFA methodology, a factor loading 0.4 was considered salient. **RESULTS:** PCA of the 7 PRO measures yielded 2 emergent dimensions accounting for 75% of the total variance. A 2-factor EFA produced one factor consisting of abdominal symptoms (abdominal pain, abdominal discomfort, and bloating) and a second factor consisting of bowel function (spontaneous bowel movement [SBM] frequency, complete SBM frequency, stool consistency, and straining). These 2 factors were strongly intercorrelated ($r = 0.62$), and also correlated strongly with the 4 weekly global PROs (adequate relief, global relief, IBS-C severity, and constipation severity; $r = 0.60$ to 0.84). **CONCLUSIONS:** These quantitative analyses support the relationships depicted in the proposed conceptual framework, which was based on previous qualitative research. The symptoms elicited from patient interviews cluster into 2 factors -- abdominal symptoms and bowel function. This pattern of correlations between IBS-C abdominal symptoms and bowel function and global assessments should be considered when developing endpoint models for IBS-C clinical trials.

218/1604/Conceptual definition of PRO measures: a case study with the Quality of Life in Inflammatory Bowel Disease Questionnaire (IBDQ)

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AIMS: In its guidance on the development and use of PRO measures (2009), the FDA has stressed the need to establish a clear conceptual framework. Questionnaires developed prior to the guidance may not have formally documented this information. The objective of this study is to describe the pathway followed to develop a concept list for the Quality of Life in Inflammatory Bowel Disease Questionnaire (IBDQ) during its translation into several languages. **METHODS:** Interactive discussion with the developers of the IBDQ was undertaken to formalize a concept list which would: 1. explain and clarify the conceptual notions underlying each item in

simple language so they would be accurately reflected in each language version produced; and 2. provide acceptable approved translation alternatives. All IBDQ translation projects performed by Mapi Institute were then reviewed to identify where changes had occurred. **RESULTS:** 9 projects, involving translation of the IBDQ into 47 languages were undertaken from August 2001 to August 2008. For the first list we constructed a table of all 32 items of the IBDQ and two columns describing a) the corresponding "concepts" and b) all possible options for translation. The concept list was revised 7 times and widely expanded. In total, 39 definitions were added to the column "concepts" and 12 changes were made to existing definitions. For instance, the 1st response choice of item 1 (Bowel movements as or more frequent than they have ever been) was clarified as "the most frequent they have ever been". Some changes were prompted by unanticipated language idioms or cultural idiosyncrasies identified when new translations were required. More examples from the list will be shown as well as the evolution of the list for specific items. **CONCLUSIONS:** It is crucial to define the initial constructs and document the evolving changes in developing a conceptual framework for a PRO measure that will allow accurate cultural adaptations. The IBDQ example shows that the development of a concept list is a dynamic process fed by questions raised at each new translation.

219/1331/Relative Impact of Urinary Conditions on Quality of Life

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AIMS: To compare the impact of urinary conditions to comorbidities on QOL. **METHODS:** The BPH Registry of 6,823 BPH patients, assessed QOL using Short Form 12 physical and mental health component scores. Lower urinary tract symptoms (LUTS) using the International Prostate Symptom Score (IPSS), urinary incontinence (UI), overactive bladder (OAB) and urinary tract infection (UTI) were evaluated. Linear regression estimated associations between QOL and urinary conditions and comorbidities adjusted for demographic/lifestyle factors. **RESULTS:** The prevalence of urinary conditions was less than other comorbidities. Severe LUTS (IPSS>19) and UI were associated with lower PCS scores. These reductions were greater than those for CVD, cancer and diabetes. Urinary conditions were also associated with greater MCS reductions compared to other comorbidities. **CONCLUSIONS:** These findings demonstrate that the physical and mental effects of urinary conditions on QOL is comparable if not greater than other major chronic diseases.

URINARY CONDITIONS	Prevalence	SF-12 PCS Change	SF-12 MCS Change
Severe LUTS	14.4%	-3.9	-4.0
Incontinence	4.3%	-2.9	-2.4
UTI	2.7%	-1.5	-0.5
OAB	5.7%	-1.4	-1.6
COMORBIDITIES			
Depression	16.4%	-2.9	-6.1
Diabetes	17.6%	-2.3	-0.3
CVD	72.7%	-2.1	-0.5
Cancer	3.1%	-1.2	-0.4

220/1590/Abdominal symptoms in relation to perceived health in patients with familial adenomatous polyposis

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AIMS: The aim of the study was to investigate presence, frequency and troublesomeness of abdominal symptoms in relation to physical and mental health in adults with familial adenomatous polyposis (FAP) after prophylactic colorectal surgery. **METHODS:** All patients in the Swedish national polyposis registry who were aged 18-75 years, diagnosed with FAP and had undergone prophylactic surgery were invited to participate (N=281). Data was collected using two standardised questionnaires, the Abdominal Symptom Questionnaire (ASQ) and the Short Form Health Survey (SF-36). Demographic and clinical characteristics were obtained from the Swedish polyposis registry. **RESULTS:** Two hundred and nine patients (116 women) accepted to participate in the study (i.e. response rate 75 %). All 21 symptoms in the ASQ were reported (mean 6.5 symptoms), with diarrhea as the most commonly reported symptom (67%) followed by borborygmi (62%) and nighttime urge of defecation (60%). Only nineteen patients (9 %) reported having no symptoms at all. Symptoms were rated regarding troublesomeness on a scale ranging from 1-7; mean 3.2 (the higher the number the more troublesome symptom). Women reported a statistically significant higher amount of symptoms compared to men. The only variables statistically significant influencing self-reported physical and mental health, as measured with the SF-36, was number of symptoms and age that together with sex accounted for 29% and 33% of the variance of the PCS and MCS, respectively. **CONCLUSIONS:** As patients with FAP who have undergone prophylactic colorectal surgery suffer from a large range of abdominal symptoms, communicating symptoms is crucial. Health professionals bear responsibility of supporting patients in finding strategies to alleviate or cure symptoms, which should be based on patients' perception of perceived symptoms. Since number of abdominal symptoms have been found to have an impact on patients' physical and mental health, identifying those patients who suffer from a high number of symptoms is important when caring for patients with FAP.

221/1592/Development of Patient Reported Outcomes (PROs) in Ulcerative Colitis and Crohn's Disease

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AIMS: Ulcerative colitis (UC) and Crohn's disease (CD) impact >1 million people in the U.S. Measurement of disease activity relies heavily on objective measures of intestinal inflammation and limits patient input. This is a report of the process used to develop UC and CD PRO measures for regulatory submission and preliminary findings. **METHODS:** UC and CD PRO development involves: (1) patient focus groups; (2) item development and refinement; (3) patient testing and cognitive debriefing; (4) further item refinement; and (5) longitudinal testing. Clinical sites in Oakland, CA; Chapel Hill, NC; San Diego, CA; and Baltimore, MD were selected to maximize regional differences and ensure sociodemographic variability. Eligible subjects were males and females between 18 and 75 years of age, fluent in English, and presenting with a range of disease severity. Focus groups discussed broad, open-ended questions about symptoms, impact on daily activities, monitoring flares and remission, coping strategies, and patient-derived definitions of meaningful improvement. Participants then engaged in an item

importance exercise to rank identified symptoms. Participants also rated their present disease state and worst ever disease state on 100-point disease activity meter. **RESULTS:** Separate focus groups for UC and CD patients have been held at three clinical sites; the fourth site is scheduled. A total of 22 UC and 30 CD patients participated. Efforts to recruit minority patients were successful; 41% of UC and 37% of CD participants were drawn from communities of color. NVivo qualitative analysis of transcripts yielded symptom domains including stool frequency, stool consistency, pain, blood and mucus, nausea, and weight changes. Concept frequency and saturation across disease type and clinical site were assessed. The item importance exercise demonstrated key differences in the disease experience between UC and CD. **CONCLUSIONS:** Validated PROs for UC and CD will provide an important complement to objective measures of intestinal inflammation for clinical trials of new therapies.

222/1093/The Development of a Social Morbidity Score in Patients with Chronic Ulcerative Colitis as a Guide to Treatment

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AIMS: Present quality of life (QoL) instruments for inflammatory bowel disease (IBD) do not evaluate many social aspects of patients' lives that are potentially important in clinical decision making. We have developed a new Social Impact of Chronic Conditions - IBD questionnaire (SICC-IBD) to assess these areas. **METHODS:** A 34-item questionnaire was piloted to determine quality of life relating to education, personal relationships, employment, independence and finance. It was compared with the SF-36v2 and Inflammatory Bowel Disease (IBDQ) questionnaires in 150 patients with chronic ulcerative colitis on an endoscopic surveillance register who had never had surgery. **RESULTS:** Reliability and validity testing enabled the questionnaire to be shortened to only 8 items. There was a high level of reliability (Cronbach's $\alpha = 0.72$). The questionnaire correlated well with the social functioning domain of the SF-36 ($r=0.56$) and was able to distinguish clinical severity of disease. **CONCLUSIONS:** The SICC-IBD is a new tool for assessment of patients with ulcerative colitis, which has identified new aspects of social disability for further study and for use as an additional tool in therapy decisions.

223/1596/The development of the Ascites Impact Measure questionnaire to assess patient symptoms that trigger a paracentesis

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AIMS: Paracentesis is the treatment mainstay for providing temporary relief of patients with symptomatic malignant ascites (SMA) in ovarian cancer. Because no instrument exists to assess the symptoms of SMA that drive patients' decisions to undergo paracentesis for relief, a new patient reported outcomes questionnaire termed the Ascites Impact Measure (AIM) has been developed. **METHODS:** The development of the AIM questionnaire followed a carefully documented three-step process including 1) concept elicitation phase through literature review and gathering of clinical expert opinion, 2) concept confirmation phase through the conduct of patient interviews, and 3) cognitive debriefing phase that allowed for the content and face validation of a draft version of the AIM. The development of the AIM was carried out in US-English

and French using a simultaneous development process. **RESULTS:** The original items in the draft AIM were tested and understood by 10 patients, with no issues with the words "ascites" or "paracentesis". The questions were found clear and comprehensive. Patients selected 4 of the items as the most relevant elements that can affect their decision making-process to request a paracentesis (abdominal bloating, abdominal discomfort, abdominal pain and impact of symptoms on ability to move normally). In addition, patients confirmed that a 6-point Likert response scale was detailed enough and appropriately captured the severity of their symptoms. Completing the questionnaire every day is considered acceptable and is pertinent with regard to the rapid evolution of the ascites related symptoms between two successive paracentesis, with a preference for an evening completion. **CONCLUSIONS:** Patient interviews confirm the face and content validity of the 4-item AIM questionnaire to assess the symptoms of malignant ascites driving patients' decisions to undergo paracentesis for relief. Linguistic validation into other languages and psychometric validation of the AIM questionnaire was conducted separately in 2 phase II studies.

224/1616/Psychometric validation of the Ascites Impact Measure questionnaire to assess patient symptoms that trigger a paracentesis

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AIMS: Paracentesis is the treatment mainstay for providing temporary relief of patients with symptomatic malignant ascites (SMA) in ovarian cancer. No specific endpoints exist for SMA. The Ascites Impact Measure (AIM) questionnaire was developed to assess the symptoms of SMA that drive patients' decisions to undergo paracentesis for relief and the psychometric validation had been explored in clinical studies. **METHODS:** The AIM questionnaire consists of 4 items assessing the daily severity of abdominal discomfort, abdominal bloating, abdominal pain, and the patient's ability to move normally. The psychometric performance of the AIM and its total symptom score (TSS) was documented based on data from 2 pooled PII studies in patients with advanced ovarian cancer with recurrent SMA. **RESULTS:** 38 patients completed the AIM the day before the randomization paracentesis. No floor or ceiling effects were identified. The analyses showed good construct validity (items are related but not redundant), good internal reliability (Cronbach's $\alpha > 0.70$) and good test-retest reliability (measured 8 days apart, using weight to define stable patients). Concurrent validity was assessed using the FACT-O questionnaire. The individual symptom scores and TSS were responsive to change before and after paracentesis with statistically significant improvement and large standardized effect size (> 0.90 , except for pain). Abdominal Pain tended to behave differently from the other items. Exploratory analyses were conducted on the minimal important difference (MID) to support a potential endpoint: time to worsening of symptoms. Using a distributional approach, a MID of 3 points was identified. **CONCLUSIONS:** The analyses confirmed that the AIM is a valid, reliable, and responsive instrument. The results of psychometric analyses should be interpreted with regards to the limited sample size, the severity of the disease and the use of proxy assessments to define stable patients. Additional studies should be conducted to confirm the MID and its impact on time to worsening.

225/1187/Relationship between changes in opioid induced constipation symptoms and patient satisfaction in response to prucalopride

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AIMS: To assess opioid induced constipation (OIC) symptoms and patient satisfaction after 4 weeks treatment with prucalopride, a selective 5-HT₄ agonist, approved in EU for treatment of chronic constipation in females in whom laxatives do not provide adequate relief. **METHODS:** OIC symptoms were assessed in 234 subjects (146 females and 88 males) of 2 placebo controlled Phase II trials. Symptoms were measured by the PAC-SYM severity index, a 12-item self-report instrument with Abdominal- (AS:4), Rectal- (RS:3) and Stool- (SS:5) Symptom subscales. Patient satisfaction with bowel habit and treatment was evaluated by the 5-item satisfaction subscale of the PAC-QOL questionnaire. The relationship between changes in PAC-SYM items and patient satisfaction was evaluated using partial least squares path modeling (PLSPM). **RESULTS:** Treatment with prucalopride 2–4 mg once daily resulted in a relief of OIC symptoms. Moderate effect sizes (ES) were observed for all 3 symptom subscales (ES: 0.5–0.8), with the largest ES for stool related symptoms. ES for individual items varied from small (ES: 0.2–0.5) to moderate (ES: 0.5–0.8) with the largest ES for bowel movements that were too hard. Prucalopride treatment also resulted in a moderate ES for patient satisfaction with bowel habit and treatment, with the largest ES for satisfaction with bowel functioning. PLSPM showed that improvement in patient satisfaction was largely attributable to relief of abdominal and stool symptoms ($r^2=0.46$). Changes in RS could be discarded as determinants of improved patient satisfaction. A final model with only the SS (extended with the painful bowel movements item of the RS subscale) and AS subscales allowed to explain 47% of the variance in changes in patient satisfaction. **CONCLUSIONS:** Prucalopride is effective in relief of abdominal and stool related OIC symptoms. Partial least squares path modeling provides a useful analytical tool to assist with the interpretation of the relationship between changes in symptom severity and patient satisfaction.

226/1545/Depression and Anxiety in Patients with Autoimmune Hepatitis

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AIMS: Evidence about the mental status of patients with autoimmune hepatitis (AIH) is scarce. Our study aimed to assess the impact of AIH on the mental health status and the quality of life of those patients. **METHODS:** Consecutive patients with a diagnosis of AIH, treated in an outpatient clinic for liver diseases were asked to fill out a battery of validated self-assessment questionnaires, including the Patient Health Questionnaire (PHQ) and the SF-12. Clinical data were drawn from the medical records. T-tests were used to compare severity of mental impairment of AIH patients with other populations. Multiple regression analysis was applied to identify significant predictors on depression as the criterion. **RESULTS:** 103 AIH-patients participated, comprising 83% of all AIH-patients treated during the recruitment period of 15 months (age 50±18, 71% female). AIH-patients had significantly higher depression (PHQ-9: 6.1±5.8) and anxiety scores (GAD-7: 4.3±4.7) than the German

general population (3.6±4.1 and 2.9±3.3, respectively). 4.2% of participants reported severe anxiety symptoms (GAD-7ge15), 10.8% fulfilled the criteria for major depressive disorder in the PHQ-9. Years of known diagnoses, age and Azathioprin medication did not significantly predict depressive symptoms, whereas sex (beta=.20), Prednisolon medication (beta=.22), concerns regarding alcohol stigmatization (beta=.21) and regarding consequences of liver diseases (beta=.44) explained a significant amount of variance of depressive symptoms in AIH patients (adjusted Rsquared=.32). Overall, the mental health status of the patients was significantly reduced compared to the general population (MCS of SF-12: 46.0±12.0 vs. 49.9±10.1), not significantly differing from cancer-patients (47.7±10.7). 28.9% of participants believed to be stigmatized as alcohol addicted, 55.7% expected to live shorter than others. **CONCLUSIONS:** AIH significantly impacts the mental health of the patients, independent from their present medical condition. Dysfunctional health attributions may play a role to explain this finding and could be a target for psychotherapy.

227/1343/Clinical Validation of a Short Urinary Incontinence Measure and its Correlation with Measures of HRQOL

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AIMS: A new 5 item tool for assessing urinary incontinence, the Revised Urinary Incontinence Scale (RUIS), was developed from an examination of data drawn from a community sample (n=2915) using classical psychometric analyses. Although previous research has shown that the RUIS is useful for evaluation and epidemiological research further validation in clinical settings is required. **METHODS:** Patients were recruited from 11 Australian continence clinics (specialist and community). The study examines clinical and patient definitions of continence status, treatment outcomes and success, across four treatment types (Continence Advising, Physiotherapy, Surgery and Combined treatments). The study protocol contains the RUIS, other items from continence specific questionnaires, HRQOL instruments (eg. SF-36, AQoL) and patient satisfaction items (eg. Short Assessment of Patient Satisfaction scale). 200 patients have been recruited and this presentation will focus on initial reliability and validity including HRQOL data. **RESULTS:** Cross-sectional data from the community survey indicated the internal consistency reliability for the RUIS=0.91. Pre-treatment internal consistency reliability estimates in the clinical sample for the RUIS=0.72. Basic descriptive statistics indicate the mean pre-treatment score for females is 11 and this drops to 6 following treatment indicating that the RUIS is sensitive to change. The RUIS correlates well with the other urinary incontinence items and HRQOL instruments (SF-36 PCS=-0.29; AQoL=-0.32). These results are consistent with findings in the literature showing a negative association between incontinence and HRQOL. Patients who had improved RUIS scores following treatment also had higher patient satisfaction (SAPS). **CONCLUSIONS:** Indications are that the RUIS is performing well in clinical settings demonstrating adequate to good internal consistency reliability; correlations with other measures are in the expected directions; and there is evidence that it is sensitive to changes in continence status as a result of treatment.

228/1157/Validation of the International Classification of Functioning, Disability and Health (ICF) Core Sets on stroke-specific outcome measurement

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AIMS: Background and Purpose: The empirical use of International Classification of Functioning, Disability and Health (ICF) on Stroke-Specific Quality of Life (SSQOL) is unknown. This study aimed to identify the determinants most affecting the SSQOL in terms of ICF 3 Core Sets. **METHODS:** Methods: A total of 195 stroke patients were recruited. Five indicators were used to represent the 3 Core Sets of the ICF, including National Institutes of Health Stroke Scale (NIHSS), Barthel Index, ADL&IADL domain, Social participation domain, and the 9th item of self-rated recovery of Stroke Impact Scale (SIS) 3.0. Multiple regression was conducted to identify determinants of each of 12 domains of SSQOL. **RESULTS:** Results: In total, 84.6% of 12 domains plus total score of SSQOL has been significantly explained by 2 or 3 of the ICF 3 Core Sets. Nearly 61.5% of domains (i.e., 8 of 12 domains plus total score) of SSQOL had about 80%–25% of total variance explained. The 2 major significant determinants of SSQOL domains in terms of ICF 3 Core Sets were (1) Body structure/function impairment and (2) Activities limitation. Moreover, the significant determinants were mostly rated by patients' subjective perspectives. The self-rated recovery and self-rated ADL & IADL were the most significant determinants for most domains of SSQOL. **CONCLUSIONS:** Conclusions: This study successfully validated the empirical use of mapping the ICF 3 Core Sets onto the regression model of the stroke-specific HRQOL. The empirical use of the ICF framework is recommended to facilitate effective communication and decision making of rehabilitation services internationally.

229/1307/Impact on Functioning and Quality of Life of Hemiplegia after Stroke

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AIMS: The aim of the study was to assess functional impairment, psychological distress, social support and HRQL in a sample of patients with hemiplegia after stroke. **METHODS:** In a prospective study patients were evaluated during hospitalization, by the first and sixth month after stroke. The Barthel Index (BI) was recorded and a set of questionnaires was filled out by the patients consisting of the Duke-UNC Social Support Questionnaire, the Hospital Anxiety and Depression Scale (HADS) and the SF-36. **RESULTS:** Of the 160 patients admitted after stroke during the study period, 79 (49%) were included. The stroke was ischemic in 84% of the patients, 53% were male and 76% were older than 65 years. Only the results of the first month assessment will be presented here. At that point, 53 patients (67%) completed at least one of the questionnaires, 17 (22%) had died, 4 were too sick to respond, and 5 (6%) were missing. BI showed that 82% had moderate to severe impairment that persisted after recovery from hemiplegia. The SF-36 PCS mean score was 31.2 (range:14–51; SD 7.76), median 31 points. The SF-36 MCS mean score was 45.2 (range:18.6–65; SD 12.6) with nearly 25% of the

patients reporting scores 2SD below the population mean. Consistently, 21% of HADS scores were in the range of moderate to severe depression. According to Duke-UNC, 83% of patients had low social support. Patients with moderate to severe impairment in the BI had lower scores in the SF-36 PCS (ANOVA, $p < .01$), and more frequently reported moderate or severe depression (chi-square, $p < .01$). No association was observed between the degree of impairment and the level of social support. **CONCLUSIONS:** This study highlights the severe impact of hemiplegia after stroke on functioning and HRQL, associated with depression and lack of social support. The need for programs of rehabilitation including early treatment of mood disorders, adequate support to patients and families, and use of community resources is remarked. The analysis of data at 6th month follow up is pending and may provide information of the long term impact of the disease.

230/1341/Adaptive domestic activities improve quality of life (QOL) in chronic stroke patients

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AIMS: The aim of this study was to investigate the QOL of post-stroke female patients with chronic hemiparesis who perform housework. **METHODS:** Seven chronic stroke female patients with hemiparesis (mean age 65.4+/-6.7 years) participated in this study, and 7 healthy women (mean age 68.6+/-1.4 years) as a control group. All of them took part in some housework, especially cooking almost everyday. We examined relations between their physical functions and QOL by SF-36. **RESULTS:** Three patients have right hemiparesis and four left hemiparesis out of seven. Six patients use only their non-paralysis hands in their daily life, and two of them had to use their non-dominant hands. Four patients used a short leg brace, and six patients needed a one-point cane to walk. Six patients had limitation in the movement of their joints, 2 patients had a sensory disorder. In the grip power of both groups, there was a significant difference in their right hands; the post-stroke patients (the right side 12.8+/-6.1 kg, the left side 12.1+/-10.8 kg), and the control group (the right side 24.6+/-12.5 kg, the left side 20.9+/-4.5 kg). As for the result of the QOL, general health (GH) and role emotional (RE) scores in the post-stroke group were higher than those of the control group. It was only physical functioning (PF) score that has a significant difference between the two groups. **CONCLUSIONS:** Chronic extremity hemiparesis following a stroke is a serious impairment that can limit a person's independence in all aspects of their daily life. However, it may be possible for patients with physical disabilities to maintain high level of QOL when they spend positive life. It is also important to have a domestic role as a member of family, which may be able to improve their QOL.

231/1432/Reliability and validity of the Portuguese version of the Stroke Impact Scale 2.0

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AIMS: To test the reliability and validity of the Portuguese version of the Stroke Impact Scale 2.0 (SIS 2.0). **METHODS:** Two samples (N = 448 and N = 50) of stroke patients attending physical therapy were evaluated. The Portuguese versions of the SIS 2.0 and Chedoke-McMaster Stroke Assessment (CMSA), and a set of individual patient characteristics were the measures used.

RESULTS: Reliability was good with Cronbach's alpha coefficients ranging from 0.83 to 0.96, and intraclass correlation coefficients (ICC) between 0.70 and 0.95 for the SIS 2.0 domains. Construct validity was supported by six predefined hypotheses involving expected correlations between SIS 2.0 domains, CMSA dimensions and age. An additional predefined hypothesis was also confirmed with subjects without complications during hospitalization obtaining significantly higher scores in 7 of the 8 SIS 2.0 domains ($P < 0.05$). **CONCLUSIONS:** The Portuguese SIS 2.0 evidenced suitable psychometric characteristics, in terms of reliability and validity.

232/1459/Sexual experience in disability - comparative study in Spinal Cord Injury and Stroke

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AIMS: The purpose of this study is to evaluate the sexual experience between couples with disability, either with Spinal Cord Injury or Stroke. **METHODS:** The Marital Adjustment Check-List for the Disabled was applied to ten individuals, five with SCI and the other five with Stroke. The questionnaire analyzed several areas such as: sexual satisfaction, sexual behavior, emotional feelings and sexual problems. **RESULTS:** These results showed that sexual satisfaction on SCI subjects were more affected than on the stroke group. The results revealed that erection and lubrication were successful achieved by most of the participants of both groups, as well as the orgasm. Regarding sexuality related feelings the study discovered that both groups felt worse than during pre-injury period. The most common sexual problems professed by the both groups were the now painful positions, the libido decrease and the lack of sensation. **CONCLUSIONS:** With this inquiry one concludes the SCI seems to be pathology with more sexual implications than the stroke which must result in different interventions for the different pathology.

233/1506/Use of the LIFE-H in stroke rehabilitation: a structured review of its psychometric properties

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AIMS: To perform a structured review of the psychometric properties specific to the stroke population of the Assessment of Life Habits (LIFE-H). This tool measures quality of social participation, an important but under-evaluated aspect of stroke recovery. **METHODS:** A structured review of publications at MEDLINE, Embase, CINAHL and the Cochrane Library using the following terms: LIFE-H, life habits, psychometric properties, measurement properties, reliability, repeatability, validity, responsiveness, appropriateness, ceiling effects, and floor effects. **RESULTS:** Eleven studies were identified specific to stroke. Test-retest reliability was excellent (Intraclass correlation coefficients [ICCs] ranging from 0.80-0.95). Inter-rater reliability ranged from adequate to excellent ($r = 0.64-0.91$) as well as agreement between responses of clients with stroke and their proxies (ICC ranging from 0.73-0.82). Convergent validity was adequate to excellent ($r = 0.57-0.91$) between the LIFE-H and two measures of functional independence. Two studies, one using patients and one using caregivers, suggest the LIFE-H is able to detect change over time. **CONCLUSIONS:** The LIFE-H is a psychometrically sound measure of quality of social participation for use in post-stroke assessment. The LIFE-H, both because of its pragmatic and

psychometric properties, is an interesting tool to consider for use in stroke rehabilitation practice, and is especially valuable in that it is client-centred. Furthermore, the LIFE-H shows ability to detect change over time and, hence, should be considered as a valuable tool when clinicians wish to measure the impact of stroke interventions on the important constructs beyond basic activities of daily living.

234/1656/Development and Validation of a Model of Participation Post Stroke: A Mixed Methods Approach

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AIMS: The purpose of this sequential mixed methods study was to develop and validate a model of participation post stroke, as a construct of health related quality of life (HRQL). The first objective was to develop a model of participation; the second, to explore self perceived aspects of participation post stroke, as a validation of the developed model. **METHODS:** For the first objective, secondary analysis of a longitudinal observational study of 678 individuals at 1,3,6,12 months post stroke was conducted. Structural equation modeling was used to develop cross-sectional and longitudinal models of the participation construct of HRQL. Objective 2 incorporated photovoice, a participatory research method where participants can inform researchers of issues using self-selected photographic images. Eight stroke survivors living in the community who were part of a multi-centre trial about participation post stroke were given cameras and asked to take photographs of what participation meant to them. Photographs were discussed individually, and in the context of 2 focus groups. Interpretation of the photographic data focused on the meanings, intentions, and relationship of photos to the construct of participation as discussed by the participants. **RESULTS:** Mean age of the 678 participants was 67 years; 55% male. The structural equation model included latent variables of accomplishment, restricted roles, and health efficacy. Reasonable fit was demonstrated at 1 month (normed chi square = 3.32; RMSEA = 0.061, 90% CI = 0.050 - 0.073). The mean age of the 8 participants was 65 years; 63% male. Preliminary analysis of photovoice data suggested that participants supported the Participation Model in term of established categories. **CONCLUSIONS:** Results of this mixed method study suggest that a model of participation post stroke should consider accomplishments, restricted roles, and health efficacy. Information from this study may be used to provide an understanding of participation post stroke and as a theoretical basis of future outcome measures of participation post stroke.

235/1409/The Relationship Between Habitual Physical Activity and Exercise Capacity to Quality of Life in Stroke Patients in Primary Care

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AIMS: Stroke patients have lower fitness levels than age matched healthy counterparts. The degree to which this reduced fitness relates to their Quality of Life is poorly understood. This study examines the relationship of habitual physical activity and exercise capacity to Quality of Life indices in chronic stroke patients in primary care. **METHODS:** A cross-sectional study of 81 adults >1-year post ischaemic stroke, mean age 65(Sd 11.6),72% (n=58)male was conducted. Measures included the Stroke Specific Quality of Life (SSQoL), EuroQoL 5D, Physical activity (mets.min/week) by self-reported short form International Physical Activity Questionnaire

(IPAQ) and an objective measure of physical exercise capacity VO2 peak (mlO₂/kg/min) tested by the Astrand Rhythmic submaximal fitness test. Pearson's correlation coefficient tested the linear relationship between indices where data were interval. Spearman's correlation co-efficient was used for ordinal data. **RESULTS:** A significant relationship was observed between self reported QoL (EuroQoL) and both physical activity (IPAQ) and exercise capacity (VO2 peak): $r=0.356$, $p=0.001$ and $r=0.495$, $p<0.001$ respectively. Physical activity was associated with the SSQoL subscales of energy ($\rho=0.33$, $p=0.003$), family roles ($\rho=0.351$, $p=0.001$), mobility ($\rho=0.327$, $p=0.003$), selfcare ($\rho=0.434$, $p<0.001$), upper extremity function ($\rho=0.344$, $p=0.002$) and work ($\rho=0.457$, $p<0.001$). Physical exercise capacity also demonstrated a significant relationship with SSQoL subscales of energy ($\rho=0.363$, $p=0.001$), family roles ($\rho=0.435$, $p<0.001$), mobility ($\rho=0.497$, $p<0.001$), selfcare ($\rho=0.395$, $p<0.001$), upper extremity function ($\rho=0.356$, $p=0.002$), work ($\rho=0.361$, $p=0.001$) and mood ($\rho=0.315$, $p=0.006$). **CONCLUSIONS:** A clear relationship between both physical fitness and habitual physical activity and Quality of Life after stroke exists. Further study is required to examine the effects of aerobic fitness training and physical activity interventions on Quality of Life in the stroke population.

236/1778/Quality of life measurement in head neck cancer patients: systematic review

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AIMS: Head and neck cancer is the sixth-leading cause of cancer deaths in Taiwan in 2008. It is diagnosed at a relatively young age (i.e., 56.1 years for males, 63 years for females) and in the late stages of the disease (i.e., stage III or IV). A negative impact on these patients because of the disfigurement and dysfunctions associated with the cancer itself and its treatment has been identified. Therefore, a reliable and valid instrument to measure the quality of life of these cancer patients is extremely important. The purposes of this review were to describe and appraise the existing validated quality of life instruments used in head and neck cancer patients. **METHODS:** A literature search of 8 major electronic databases in English or in Chinese was conducted using the terms head and neck cancer, oral cancer and quality of life. Articles published in either English or Chinese from January 1990 to Dec. 2009 were searched. Subsequently, quality of life instruments were selected for head and neck cancer and measurement properties of selected instruments were evaluated. **RESULTS:** A total of 21 validated multidimensional quality of life instruments were identified from 21 articles. These instruments could be classified into four categories: generic, cancer-specific, cancer site-specific and cancer survivor-specific instruments. 15 instruments reported internal consistency (>0.7) whereas Half of the instruments report test-retest (>0.7). Many types of validity (content validity, concurrent validity, convergent validity, discriminate validity, factor analysis, and known-groups) have been conducted. Although all these instruments met the minimum requirements of reliability and validity, the original versions of these instruments were mainly in English. **CONCLUSIONS:** Although quality of life can be affected by culture. Following the validation process, instrument with different language versions has been established. The results of these measurements make international comparison possible.

237/1522/The Impact of Comorbidity to HRQOL in Nasopharyngeal Cancer Patients

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AIMS: This study was to investigate the impact of comorbid medical conditions in patients with nasopharyngeal cancer (NPC) on their long term health-related quality of life (HRQOL). **METHODS:** A convenience sample of NPC cancer patients were recruited from outpatient department of radiation oncology clinic from initial treatment to the long term follow-up. Health-related quality of life was measured by the Functional Assessment of Cancer Therapy-Head and Neck measuring 4 primary aspects of HRQOL and H&N-specific concerns. **RESULTS:** A total of 347 patients were recruited. These NPC patients received radical treatment from 2000 to 2005. The median age is 48 with range 14 to 79 and 43 (12.4%) patients were more than 65 years old. Seventy percents of all patients are male, 81.3% are married and 70.6% of patients received 6-12 years of education. Most (64.8%) patients were with stage III-IV disease and will receive chemotherapy and radiotherapy. Twenty nine patients received total laryngectomy. The results indicate that patients with comorbid medical conditions had uniformly poor HRQOL than those did not. Patients in earlier years after of their treatment, comorbidity has greater impacts. Patients with chronic chest problems had worse HRQOL in functional, social, and emotional well-being and H&N specific concern at 2nd years after radical treatment. Patient with diabetes had worse HRQOL at 2nd and 3rd years after radical treatment in overall HRQOL and functional well-being. Patient with order age or not seems to be no strong impact to HRQOL after radical treatment. There were no comorbid medical condition will impact to HRQOL after 5th years after radical treatment. **CONCLUSIONS:** Pre-existing medical conditions appear to have varying impacts on different dimensions of quality of life during the years pass by. Help reducing or better controlling these conditions may help patients improve their HRQOL. Knowing these conditions during their early visits may help clinicians to better plan their nasopharyngeal cancer related treatments

238/1524/The Impact of Total Laryngectomy and Comorbidity to HRQOL in Laryngeal Cancer and Hypopharyngeal Cancer Patients

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AIMS: This study aimed to examine the impact of the total laryngectomy and comorbid medical conditions on the quality of life of patients with laryngeal cancer during and after the course of radical treatment. **METHODS:** A convenience sample of laryngeal cancer and hypopharyngeal cancer patients were recruited from outpatient department of radiation oncology clinic from initial treatment to the long term follow-up. Health-related quality of life was measured by the Functional Assessment of Cancer Therapy-Head and Neck measuring 4 primary aspects of HRQOL and H&N-specific concerns. **RESULTS:** A total of 142 laryngeal or hypopharyngeal cancer patients received radical radiotherapy with or without total laryngectomy were recruited. The median age is 54 with range 33 to 88 and 26 (18.3%) patients were more than 65 years old. Ninety five percents of all patients are male, 93% are married and 82.5% of patients received 6-12 years of education. Most (86.6%) patients were with stage III-IV disease. Patients received chemotherapy and radiotherapy when patients had more than stage

III-IV disease. The results indicate that patients with comorbid medical conditions had uniformly poor HRQOL than those did not. Laryngectomy or not has negative impact to HRQOL in functional well-being and H&N concern at 2nd year and emotional well-being at 3rd year but no more effect to HRQOL after then. The patients with chronic cardiovascular or rheumatic problems are the most important factors that influence HRQOL outcome since 5th year after radical treatment however age and total laryngectomy or not. **CONCLUSIONS:** Larynx preservation had influence to the HRQOL in first 3 years but no long term effect. Pre-existing medical conditions appear to have varying impacts on different dimensions of quality of life during the years pass by but age has less impact. Help reducing or better controlling these conditions may help patients improve their HRQOL.

239/1588/Implementation of a quality of life assessment into the routine of a Dermatological University Clinic. First experiences in a pilot study

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AIMS: Modern patient-oriented medicine increasingly incorporates psychosocial aspects of disease processes in therapy evaluations. We conducted a pilot study on the implementation of a suitable device assessing the quality of life (QL) of patients with non-melanoma-skin-cancer in clinical routine. **METHODS:** Inclusion criteria were non-melanoma skin cancer, capability to fill out a German questionnaire, and informed consent. Patients had to fill out the German version of the Dermatology Life Quality Index (DLQI). This is a 10-item questionnaire including six content areas that is commonly expressed as a single score ranging from 0 (no burden) to 30 (highest burden). In addition, four study-specific items were administered. Clinical documentation included basic information about the nature and severity of the disease. In addition, the treating physicians also evaluated patients' QL using the DLQI. **RESULTS:** A consecutive series of 52 patients (34 males, 18 females) were included, median age was 70 (35 to 89). Missing values were low (< 1%) and most patients found the questions relevant. 31% of patients experienced moderate to strong restrictions in QL. This restriction involved symptoms, emotions, everyday activities, and leisure activities, whereas work and school were of minor importance. The variables age, gender, and diagnosis were of little importance for patients' quality of life (all $p > .10$). On average, the treating physicians evaluated patients' QL worse than did patients on 3 score points. QL-profiles were generated in order to graphically depict patients' restrictions in QL regarding the six content areas. **CONCLUSIONS:** Quality of life assessment was easily implemented into the daily routine of a Dermatological University Clinic. The topic and the questionnaire were well received by patients. This will serve as the basis for further studies that will address clinically relevant research questions regarding the quality of life of dermatological patients.

240/1193/Translation and linguistic validation of the FACT-M for use with melanoma patients across the globe

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AIMS: Translation of patient reported outcomes (PRO) measures is an essential component of research methodology in preparation for

multinational clinical trials. One such measure is the FACT-M questionnaire (FACT-M), which evaluates the health related quality of life (HRQOL) of melanoma patients. **METHODS:** This study was designed to linguistically validate the FACT-M for use in Austria, Belgium, China, Denmark, Finland, Germany, Israel, Italy, Netherlands, Norway, Poland, Russia, Spain, Sweden and Taiwan. The study sample consisted of 169 patients (81 males/88 females) diagnosed with melanoma. Patient mean age was 52 years, and at the time of administration, 77 patients were receiving some form of treatment. The sample consisted of patients speaking 14 languages including: Arabic, Chinese, Danish, Dutch, Finnish, French, German, Hebrew, Italian, Norwegian, Polish, Russian, Spanish and Swedish. The FACT-M translations were carried out based on the FACIT methodology. Patients diagnosed with melanoma completed their respective translated version of the questionnaire and then participated in a cognitive debriefing interview to determine if there were any problems with the translations or the content of the FACT-M. Quantitative analyses (descriptive statistics and reliability analyses) were performed on the combined sample. Participant comments were analyzed qualitatively. **RESULTS:** The FACT-M translations proved relevant to patients from a wide range of countries and were well understood. Very few items required adjustments as a result of pilot testing. In addition, the FACT-M translations exhibited good reliability when all languages were analyzed as a combined sample ($\alpha = 0.96$ for the total FACT-M scale, with individual subscale alphas ranging from 0.80 to 0.92). **CONCLUSIONS:** The FACT-M demonstrated content and linguistic validity for all 14 languages. We consider these translations acceptable for PRO assessment in international research and clinical trials.

241/1223/The Association of Pretreatment Quality of Life with Survival of Patients with Foregut Carcinoma

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AIMS: Background: Cancers of the esophagus and stomach, known as foregut carcinoma, have a range of prognoses. These malignancies also affect many aspects of a patient's quality of life. The purpose of this study was to determine if pretreatment quality of life was a predictor of posttreatment survival. **METHODS:** Methods: Patients who were referred for carcinoma involving either the esophagus or stomach were evaluated. Prior to treatment, patient routinely completed the SF-36, a generic quality of life instruments measuring 8 domains of quality of life (physical functioning, PF; role-physical, RP; role-emotional, RE; bodily pain, BP; vitality, VT; mental health, MH; social functioning, SF; general health, GH), with the best possible score being 100 and the worst possible score being 0, including the "health transition", measured from a best score of 1 to a worst score of 5. Patients then completed treatment appropriate for their cancer. Data collected included gender, age, stage, resection, adjuvant therapy, and survival. They were followed indefinitely or until death. **RESULTS:** Results: 76 patients were included. Cox's proportional hazard regression demonstrated no significant independent predictors of survival. Comparing patients who survived <1 year after treatment to those who survived >1 year after treatment, patients surviving <1 year had worse scores in the health transition item (4 vs. 3, $p=0.005$), and in 4 of the 8 domains: RE (33 vs. 100, $p=0.02$), BP (41 vs. 74, $p=0.05$), SF (37.5 vs. 87.5, $p=0.004$), and GH (52 vs. 72, $p=0.02$). **CONCLUSIONS:** Conclusion: This study demonstrates that patients with foregut carcinoma who survive <1 year after treatment had worse quality of life scores in 4 of 8 SF-36 domains. This implies that pretreatment quality of life scores may be useful in identifying foregut carcinoma patients with a particularly poor prognosis.

242/1224/The Importance of Method in the Variation of Pain Measurement in Surgical Patients

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AIMS: Measuring the intensity of pain has become an important component of patient care. The pain visual analogue scale (VAS) and the bodily pain component of the SF-36 (BP-SF-36) are most commonly used. We aimed to determine if there is a correlation between the VAS and BP-SF-36. **METHODS:** Patients were routinely administered the VAS (best score 0, worst score 10) and SF-36 (best score 100, worst score 0). A sample of preoperative and postoperative general surgery patients who complete both the VAS and BP-SF-36 were evaluated for gender, age, the VAS and BP-SF-36 score, primary surgical diagnosis, preoperative or postoperative status, type of operation, associated medical conditions, and medications. Patients were grouped into preoperative (Preop) and postoperative (postop) status, and those with chronic pain (CP) conditions and acute/no pain (AP) conditions. **RESULTS:** 269 patients were included. Overall results of regression analysis: BP-SF-36 = -6.7VAS + 69.7, $p < 0.0001$, $r = -0.61$, $r^2 = 0.37$ Preop (n=194): BP-SF-36 = -6.5 + 67.5, $p < 0.0001$, $r = -0.61$, $r^2 = 0.37$ Postop (n=75): BP-SF-36 = -6.2 + 74.1, $p < 0.0001$, $r = -0.51$, $r^2 = 0.26$ Preop vs. postop: BP-SF-36: 51 (22-84) vs. 72 (51-100), $p = 0.05$ Preop vs. postop: VAS 0 (0-4) vs. 0 (0-1), $p = 0.05$ CP Patients: BP-SF-36 = -4.6VAS + 45.5, $p = 0.0006$, $r = -0.54$, $r^2 = 0.29$ AP Patients: BP-SF-36 = -5.9VAS + 69.6, $p < 0.0001$, $r = -0.55$, $r^2 = 0.31$ CP vs. AP: BP-SF-36 22 (10-41) vs. 61 (36-84), $p < 0.0001$ CP vs. AP: VAS 4 (3-6) vs. 0 (0-3), $p = 0.0001$ **CONCLUSIONS:** Although there are statistically significant associations between the BP-SF-36 and VAS, the correlations are not as strong as expected. When groups were compared with each score, the BP-SF-36 appeared to have more precision. Therefore, this study demonstrates that different instruments may measure different aspects of pain and the precision with which pain is measured in surgical patients.

243/1160/Is the combined WHOQOL-Brèf and Pain and Discomfort Module a valuable outcome measure to use in assessing chronic pain

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AIMS: The aim of this work was to select suitable outcome measures for an RCT of pharmacist-led chronic pain (CP) management compared to usual GP care, following the MRC framework for complex interventions. **METHODS:** Patients (n=149) were randomly selected and approached from 2 general practices in Scotland; 28 agreed, and 22 (mean age 63.5 years) returned a questionnaire including: 1) WHOQOL-Brèf and Pain and Discomfort Module (PDM); 2) The SF-12; 3) the Chronic Pain Grade (CPG). Measures were correlated using Spearman rho. **RESULTS:** The WHOQOL-Brèf and PDM and the SF-12 correlated significantly on appropriate subscales. The WHOQOL-Brèf correlated significantly with the CPG on physical subscales and the PDM subscales. **CONCLUSIONS:** This is the first co-administration of the WHOQOL-Brèf with the PDM. The measures overlapped with the SF-12 and CPG indicating that the WHOQOL-Brèf and PDM do not add information.

Correlations of WHOQOL-Brèf and PDM with SF-12 and CPG

	Phys health	Psych health	Social rela	Envir- onment	Relief	Anger	Vulner- abilit	Uncer- tainty
Phys func	.616; p=.004	.081; p=.733	-.070; p=.771	.501; p=.024	.743; p=.001	.470; p=.037	.233; p=.322	.561; p=.010
Role phys	.771; p<.001	.504; p=.023	.218; p=.355	.669; p=.001	.519; p=.019	.800; p<.001	.419; p=.066	.685; p=.001
Bodily pain	.609; p=.004	.155; p=.514	-.222; p=.346	.511; p=.021	.730; p<.001	.555; p=.011	.402; p=.079	.608; p=.004
Gen health	.582; p=.007	.249; p=.290	.066; p=.781	.391; p=.088	.659; p=.002	.475; p=.034	.387; p=.092	.348; p=.133
Vitality	.606; p=.005	.582; p=.007	.222; p=.347	.213; p=.368	.091; p=.701	.094; p=.094	.151; p=.151	.223; p=.345
Social func	.435; p=.055	.300; p=.198	-.096; p=.687	.395; p=.084	.586; p=.007	.365; p=.113	.298; p=.201	.479; p=.032
Role emo	.773; p<.001	.608; p=.004	.205; p=.386	.696; p=.001	.293; p=.211	.381; p=.007	.603; p=.005	.676; p=.001
Ment health	.387; p=.092	.859; p<.001	.317; p=.173	.620; p=.004	.290; p=.215	.578; p=.008	.531; p=.016	.668; p=.001
CPG	-.676; p=.001	-.197; p=.404	.259; p=.270	-.545; p=.013	-.668; p=.001	-.591; p=.006	-.632; p=.003	-.756; p<.001

244/1153/Predictors of Function in Chronic Pain Patients

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AIMS: This study investigated predictors of function (physical, emotional, social) in chronic pain patients at baseline, before participating in a rehabilitative pain program. Function may be the most important treatment outcome in this population and is often more modifiable than pain. **METHODS:** Subjects were outpatients at SMDC Health System Pain Center. All chronic pain diagnoses were included, but patients under age 18 excluded. Study variables included demographics, clinical variables, Brief Pain Inventory (BPI), Functional Assessment (FX-13), Beck Depression Inventory (BDI), SF-36 Health Survey. Exploratory analysis utilized stepwise regression to assess associations with and predictors of baseline function variables among all patients assessed between 10/1/1999 and 06/1/2004. Variables tested included demographics, clinical variables and baseline test scores. Confirmatory analysis applied resultant regression models to new patients assessed between 06/1/2004 and 07/1/2007, with predicted values compared to actual values. **RESULTS:** In exploratory analysis, 478 patients had multiple pain diagnoses: back, 53%, fibromyalgia, 49%, neuropathic, 28%, headache, 26%, other pains, 45%. Patients: 63% female, ages 19-83 years (mean 44.7), 24% employed, 53% married, with 8.1 years (mean) of pain. The predictive model for summary interference with function score (BPI-SUM) included BDI, SF-36 PCS, employed, CPI, SF-36 MCS and married (R^2 change=0.425, 0.087, 0.032, 0.033, 0.023, and 0.007, respectively, with Total $R^2=0.607$). In the confirmatory analysis, 248 patients had all data necessary to compute predicted values and BPI-SUM predicted and actual values were found to be strongly correlated ($r = 0.724$, 2-tailed, $p < 0.001$). **CONCLUSIONS:** In the confirmatory analysis, there was a strong correlation between the predicted and actual values for interference with function. Although the predictive model contained 6 variables that explained over 60% of the variance, BDI score explained the majority of the variance. These data may help determine the treatment plan, stratify risk, and predict outcomes in chronic pain patients.

245/1436/Reliability and validity of Portuguese version of the Pain Impact Questionnaire

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AIMS: The objective of this study was to test the reliability and validity of the Portuguese version Pain Impact Questionnaire (PIQ-6). **METHODS:** The Portuguese version was obtained with forward/backward translations and consensus panels. The PIQ-6, the Medical Outcomes Study - 12 item Short Form (SF-12) questionnaires, a qualitative pain scale and a form for the characteristics of the patients were applied to 104 subjects with chronic pain. **RESULTS:** After obtaining the semantic and content equivalence, the Portuguese version of PIQ-6 showed good levels of reproducibility (ICC between 0,82 and 0,94) and acceptable levels of internal consistency with Cronbach's alpha of 0.92. The factor analysis confirmed the unidimensionality of the measure (initial eigenvalue=4,29, 71,6%). Construct validity was supported by the correlations obtained with a qualitative pain scale ($\rho=0,705$), SF-12 subscales ($r = -0,723$ and $-0,656$) and the age of the patients ($r=0,274$). **CONCLUSIONS:** The PIQ-6 proved to be equivalent in both cultures (American/Portuguese), and reliable and valid for use in Portugal.

246/1165/Quantifying the Patient-Reported Burden of Herpes Zoster and Post-Herpetic Neuralgia in the UK: Practical Considerations

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AIMS: The impact of Herpes Zoster (HZ) and Post-Herpetic Neuralgia (PHN) on patients' Health-Related Quality of Life is currently being assessed as part of a large-scale UK prospective study. Challenges encountered during the initial stages of this study are discussed. **METHODS:** A unique, non-interventional, multi-centre, UK-wide study is currently being conducted. Approximately 450 patients (270 HZ; 180 PHN) have been targeted for recruitment. Patients are to be recruited via referrals from primary and secondary/tertiary care centres (45 centres originally targeted). R&D Management Approval has been sought using the NHS Integrated Research Application System. **RESULTS:** Challenges encountered can be summarised as follows: 1) *Patient Recruitment:* Lead times for patient recruitment are estimated at 6-8 months, with each centre expected to recruit approximately 7 HZ and 5 PHN patients over this period. To ensure an adequate patient sample, more centres than originally planned have been enrolled. 2) *Establishing Centres for Participation:* In excess of 900 individual centres have been invited to participate. The already considerable work commitments, limited research experience of staff and lack of Good Clinical Practice training has made it difficult to recruit eligible centres. However, approximately 55 centres have been recruited by working closely with the National Institute for Health Research 3) *Obtaining R&D Management Approval:* Despite the non-interventional nature of the study, following overall R&D Management Approval, approval from the local R&D departments of participating centres is also required. Lead times associated with individual submissions can be in excess of 3-4 months, contributing to extended study timelines. To minimise delays in R&D submissions, multiple centres affiliated with the same R&D departments have been targeted for recruitment. **CONCLUSIONS:** These experiences highlight some of

the key difficulties in conducting large-scale prospective studies in the UK at present. Implications for future studies are discussed.

247/1100/Clinical outcome of a multidisciplinary pain management program, focusing on occupational performance

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AIMS: To evaluate the effect of a Multidisciplinary, biopsychosocial pain management program, in terms of clients' perceptions of and satisfaction with their occupational performance. **METHODS:** Design: Observational with repeated measures. Subjects: All participants (n=85) in a multimodal pain management program introduced during 2006, were included. The Canadian Occupational Performance Measure (COPM) was used as an outcome measure. Each participant was interviewed on three occasions; before the program, on conclusion of program and six months after the program ending. For statistical analysis, the Wilcoxon matched pair test, Friedman's ANOVA, Chi squared test and Spearman's rank correlation coefficient were used. **RESULTS:** The interviews resulted in 555 individually prioritised occupational problems related to pain. The overall occupational performance and satisfaction with performance scores improved between baseline and conclusion of the program as well as at the follow-up 6 months later, $p < 0.001$ for performance and $p < 0.0001$ for satisfaction with performance. The correlation between occupational performance and satisfaction with performance increased over time from $r_s = 0.59$ before intervention, to $r_s = 0.89$ at the 6 months follow-up. Discussion: Before intervention, the estimated overall mean score for satisfaction with performance was significantly lower than that for performance, which could be expected. Above all, satisfaction with performance improved over time, and at the six months follow-up, there was no longer a difference between satisfaction and performance scores. This is an interesting result since the overall aim of the pain management program is to help the participants adjust to a life with undesirable physical restrictions by increasing their physical capacity and optimising their activity level, improving satisfaction with life. **CONCLUSIONS:** The results from the COPM demonstrate, above all, that satisfaction with performance increased over time, which was an overall aim of the multidimodal program.

248/1442/Chronic Pain Management: Impact on Spiritual Functioning and Quality of Life

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AIMS: This study investigated the relationships between perceived chronic pain, quality of life, and functioning in a population who participated in a community-based pain management program. This abstract reports the impact of program participation on enrollees' spiritual functioning and quality of life. **METHODS:** Between 2000 and 2007, 511 people enrolled in the SMDC pain program in Duluth MN. Enrollees completed pre-and post-evaluations including the SF-36, 13-measure Functional Report, and demographics; records of their participation in the program, including the spiritual counseling and group sessions, were also accessed. The analysis evaluated these factors' relationships to changes in ability to function spiritually and to changes in reported quality of life. **RESULTS:** There were 416 people with full data who completed at least one week of the program (range 1-16, mean 5.8 weeks). This sample was 57% female; between 18-90 years of age (mean 45 years); 28% employed; 52% married; 47% had more than high school education; and 43% had a history of

substance use disorder. Participation in the program improved their ability to participate in spiritual activities ($p < 0.001$); related program factors included: more weeks in the program ($p < 0.001$); more spiritual counseling sessions ($p < 0.001$); and treatment for depression using non-SSRI's ($p = 0.02$). Participation in the program also improved enrollees' SF-36 scores, but only the physical subscale was changed by a spiritually-related factor. Participants who reported having a church home also had improved physical subscale scores ($p = 0.04$). **CONCLUSIONS:** Enrollees in a community-based pain management program report improved ability to participate in spiritual activities after completing the program, and the program's spiritual intervention is an important factor in that change. Enrollees who were part of a church community also reported improved (physical) quality of life.

249/1479/A world-wide-web study of patients with cardiac disease and continuing chest pain

Brian Tiplady, PRO Consulting, Edinburgh, UK

AIMS: Chest pain is a key symptom in cardiac disease, but may be due to other causes, such as gastrointestinal and musculoskeletal. Cardiac and noncardiac causes of chest pain may co-exist. We ran a web survey on patients with cardiac disease who still had chest pain to assess the impact on patients' lives, and to inform decisions on measures to assess burden of illness. Our hypothesis was that continuing chest pain, and in particular uncertainty about its cause, would be a potent source of concern and anxiety in these patients. **METHODS:** Users of a UK cardiac patient support website were invited to complete the survey if they were being treated for coronary heart disease and continued to experience chest pain. The survey collected data on: diagnosis and duration of illness, treatment, frequency and severity of chest pain, other symptoms, patients' views on causes of pain, worry, and interference with activities. **RESULTS:** 92 patients (55 male) took part: median age: 51-60; median chest pain frequency: 5-10 per month; intensity covered the full scale range. 35 patients were considered to have a probable GI source for the chest pain on the basis of reported symptom patterns. 91% of patients frequently worried about chest pain (the same proportion in the probable GI group). 64% (81% of those with suspected GI pain) worried they might not recognise a heart attack because it was like "normal" pain. Uncertainty about the cause of chest pain was a substantial concern for these patients. **CONCLUSIONS:** Chest pain was frequent, and could be severe. There was considerable concern, uncertainty and limitation reported by these patients. Identifying and treating sources of non-cardiac pain in cardiac patients may reduce this uncertainty and some of their resulting anxiety and limitation to activities. Surveys conducted on the world-wide-web are a useful source of information, complementing that obtained from clinicians and face-to-face patient interviews.

METHODS & METHODOLOGY

250/1481/A qualitative interview study of patients with cardiac disease and continuing chest pain

Brian Tiplady, PRO Consulting, Edinburgh, UK

AIMS: Chest pain is a key symptom in cardiac disease, but may be due to other causes, such as gastrointestinal and musculoskeletal. Cardiac and noncardiac causes of chest pain may co-exist. We interviewed patients with coronary artery disease who still had chest pain to understand the impact on patients' lives, and to inform decisions on measures to assess burden of illness. Our hypothesis was that continuing chest pain, and in particular uncertainty about its

cause, would be a potent source of concern and anxiety in these patients. **METHODS:** 13 patients (8 male, 5 female, aged 52 - 63 years) were interviewed in groups of 3 - 5. Descriptive analysis was carried out on the interview transcripts by identifying keywords from the interviews. Three domains were explored: experience of illness and pain; understanding and affective response to the illness and pain; and behaviour in response to illness and pain. Key themes were identified and organised within these domains. **RESULTS:** Most patients reported at least weekly pain. Severity was very variable. There was considerable uncertainty about the source of pain. Several patients reported having been investigated, being told that pain was not cardiac, but not being told what caused it. This led to frustration and anxiety. Chest pain and other symptoms caused substantial limitations in patients' lives, ranging from reduction or leaving work, to changing daily patterns of activity in light of possibly having angina, to reduction in exercise and other social activities. Most patients did not expect significant improvement in their condition. **CONCLUSIONS:** Uncertainty about source of pain was important, and contributed to anxiety and to limitations in patients' lives. There is scope for reducing this impact through effective identification and treatment of ongoing pain in cardiac patients.

251/1231/Assessing and demonstrating data saturation in qualitative patient-reported outcomes (PRO) research

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AIMS: Regulatory requirements for qualitative research contributing to the development of PRO instruments emphasise the importance of both reaching saturation and providing documentary evidence that it has been reached. This presentation aims to provide practical recommendations for assessing and documenting saturation in qualitative PRO research. **METHODS:** Existing PRO and broader qualitative methodological literature was reviewed for definitions of saturation and for practical approaches to assessing saturation. Approaches were assessed in light of regulatory requirements for PRO research and wider requirements for flexibility and creativity in qualitative research. **RESULTS:** Assessment of whether or when saturation has been reached is typically left to the subjective judgement of individual researchers or research teams. Recent regulatory guidance does not discuss saturation in the context of methods of purposive sampling or qualitative analysis. Consideration of wider qualitative literature suggests these are important issues for achieving saturation. Current recommendations in the PRO literature rely on saturation tables to assess saturation. These risk encouraging 'thin' qualitative studies that stop at mapping breadth of content rather than developing depth of understanding. We recommend building in procedures to document and assess saturation from an early stage using a combination of saturation tables and documented codebook development: the saturation tables to assess and document breadth of interview content, the documented codebook development to assess depth of analysis content. **CONCLUSIONS:** Attempts to introduce rigour to qualitative research must not be at the expense of the subjectivity and creativity necessary to develop a meaningful understanding. We hope this review and our recommendations will point the way towards a more meaningful approach to assessing and documenting saturation in PRO research in future years. We plan to evaluate these recommendations in forthcoming qualitative PRO studies and encourage others to do the same.

252/1203/Responsiveness and Minimally Important Difference of the 10-Item MOA Quality of Life Questionnaire (MQL-10): Results from a 12-Week Follow-up Survey on Complementary Health Practices

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AIMS: The 10-item MOA (Mokichi Okada Association) Quality of Life Questionnaire (MQL-10) has been developed for assessing quality of life (QOL) in large-scale health surveys, and it has established validity (ISOQOL, 2009). This study was conducted to demonstrate the responsiveness of the MQL-10 in a follow-up survey on complementary health practices and to determine the minimally important difference (MID) for this measure. **METHODS:** Japanese adults ($n = 62,056$) participated in a survey on health practices from February to November in 2007 (baseline). Of these, 10,615 participants were reexamined after 12 weeks (follow-up). The MQL-10 scores were analyzed together with the following factors: gender, age group, membership, disease, motive for participation, and complementary health practices including food and eating; art and culture; and bio-field therapy. Responsiveness and MID were examined by using a distribution-based approach. **RESULTS:** Mean baseline MQL-10 score was 26.4 ± 5.83 (SD) and the mean follow-up score was 27.6 ± 5.45 (SD) with the mean change being 1.20 ± 4.41 (SD). The effect size for change was 0.21 and the standardized response mean was 0.27. The MQL-10 scores in the baseline condition were associated with gender, age group, disease, motive for participation, and complementary health practices. Moreover, the changes of the MQL-10 during the 12 weeks were associated with age group, membership, disease, motive for participation, and complementary health practices. Since the increase in frequency of health practices was significantly related to improvements in QOL, it is suggested that health practices may have improved the QOL of the participants. **CONCLUSIONS:** The results of this study suggested that the MQL-10 is useful for assessing the effects of complementary health practices on QOL. The estimate of three points for the range of this measure (0–40) was higher than half of the standard deviation of scores, therefore it was considered reasonable for the MID.

253/1320/Choosing a Patient-Reported Outcome Measure

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AIMS: In 2009 the FDA published guidelines on the evaluation of PROMs. We examine their criteria in order to illustrate the complexity in choosing a PROM, and discuss how theoretical concerns can be of practical value. Theoretical concerns are often overlooked in the PROMs literature and this paper provides an important corrective to this state of affairs. Our paper has been accepted for publication in *Theoretical Medicine and Bioethics*. **METHODS:** We first discuss the FDA's recommendation regarding content validity and then turn to consider how we ought to choose a PROM given the totality of psychometric evidence. The FDA recommends that qualitative research should be used to improve content validity. Qualitative research is meant to improve the consensus over the wording and understanding of questions and answers. But as Carolyn Schwartz and Bruce Rapkin have argued better qualitative research cannot wholly overcome differences in understanding meaning. Moreover, we should not attempt to overcome all of these differences. Drawing on arguments in philosophy we support the point made by Schwartz and Rapkin. The

FDA provides guidance on how they will assess other measurement properties, but they do not provide guidance on how researchers should weigh up the sum of this evidence. We look at two different approaches to evaluating a PROM and argue that although helpful they are both imperfect. We suggest that their imperfections lie in attempts to codify our rational judgments into hierarchies, guidelines and measurement scales. Turning to arguments in philosophy we argue that these attempts involves a mistaken assumption regarding correct application of judgment. **RESULTS:** Our concerns about judgment and the nature of understanding are linked by the role that application plays in both. We end by further explaining this role and provide some suggests for further research. **CONCLUSIONS:** This paper provides an analytic assessment of a PROM's adequacy. We suggest that although hierarchies, guidelines and measurement scales can be helpful in choosing PROMs there is room for practical judgment based on experience.

254/1715/Key Evidences Required to Support Content Validity for Patient Reported Outcome (PRO) Instruments

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AIMS: The need to establish Content Validity for Patient Reported Outcome (PRO) instruments is emphasized by the recent FDA guidance document. Content validity is the relationship between an instrument's content and the construct it intends to measure. Content validity is determined by the concepts presented in each PRO item, and the relevance of those concepts to the patient experience. This paper presents eight key points of criteria for supporting evidences of content validity for PRO instruments. **METHODS:** Language is the primary means of patient recognition and expression of concepts, requiring the assessment of concept relevance to be done qualitatively. Qualitative data is collected via a process of Concept Elicitation, and further assessed for comprehension of concept during a cognitive interview process. The design of interviews and treatment of results must focus on specific criteria in order to support content validity of the PRO. **RESULTS:** The eight key criteria required to support PRO content validity are: (1) concepts are relevant to the patient experience with their condition; (2) qualitative data collection has been conducted to the point of saturation of concept; (3) concepts are presented in the language of the patients; (4) the appropriate aspect of the concept is being evaluated; (5) the presentation of the concept in a PRO can be properly comprehended by patients; (6) response options are meaningful and clear; (7) the recall period is appropriate to the patient experience of their condition; and (8) the concepts and language used in the PRO are adaptable for use in global trials. This paper presents examples of data collection, and documentation for each criterion. **CONCLUSIONS:** Evidences of content validity are can only be provided by qualitative data. The qualitative interview process may vary in specific methods but should adhere to consistent objectives, and should cover at least eight key evidences in order to provide adequate support for content validity of a PRO.

255/1758/Assessing Relevance of Concepts to Support Content Validity for Patient Reported Outcome (PRO) Instruments

Mona L. Martin, Health Research Associates, Mountlake Terrace, WA

AIMS: Establishing Content Validity for Patient Reported Outcome (PRO) instruments requires evidence that concepts presented in the PRO items are relevant to the patient experience. Concepts begin in patient awareness as words and phrases, therefore necessitating a qualitative approach to data collection and analysis. However,

qualitative analysis is not always straightforward, and decision making based on qualitative results is heavily influenced by the approach used to summarize and present the data. This paper addresses key considerations in the treatment of qualitative data used to assess concept relevance and support the content validity for PRO instruments. **METHODS:** Standard theoretical methods for qualitative analysis were combined and expanded to include criteria to support content relevance specific to PRO development. A multi-vectorized framework was developed for data presentation and assessment. Examples of each type of data were identified by source, analytic approach, presentation and interpretation of results. **RESULTS:** A coding framework should guide the structure of the data for analysis and interpretation. Data can be presented in quotation lists that support a single concept and show patient language. Concepts can be grouped by whether or not they were offered spontaneously or whether they resulted from detailed probes. Electronic coding systems allow qualitative data to be organized and presented by topical predominance or proportion. Additional interview exercises can add useful information such as ratings of difficulty or importance. The overall study objectives can add further context of for assessing relevance of the concept and its relationship (strong fit or weak fit) to the measurement strategy. **CONCLUSIONS:** Multi-vectorized analysis of concept relevance allows the instrument developer to use a number of independent modalities for qualitative analysis to build a broader more meaningful picture, resulting in improved interpretation of the balances and interplay of key concepts in the patient experience.

256/1041/The Wheel of Life: a Novel Method for Exploring Health-related Quality of Life (HRQoL)

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AIMS: The impact of a condition and its treatment on quality of life (QoL) is recognised as important in health research and clinical practice. Qualitative research methods are well-suited to exploring patients' experiences and questionnaires enable systematic evaluation of new interventions/treatments. HRQoL interview schedules are needed to establish the content validity of HRQoL questionnaires. Our aim was to devise a novel interview method to capture the impact of a condition and its treatment on all elements of life important for patients' QoL. **METHODS:** In semi-structured interviews, 19 people with diabetes (10 pre- and 9 post-islet transplantation; 4 UK and one Canadian centre) were given a drawing of a wheel. They were asked to think of the wheel as their life and the spokes as elements of their life important for their QoL. Interviewees labelled the first spoke, explaining (a) why that element was important, (b) how diabetes affected it (c) how the transplant had already affected it or how they expected the transplant to affect it. They marked points on the spoke (centre 0; outer edge 10) to rate how good/bad this aspect of life was before/after the transplant. Participants continued around the wheel, using as many spokes as they needed. **RESULTS:** Interviewees were actively involved in drawing their wheels, which they found engaging, thought-provoking and enjoyable. The Wheel of Life acted as a concrete focus and provided an impactful, evolving record of the interview. The elements of life elicited were pooled from all interviewees to generate questionnaire items. **CONCLUSIONS:** The Wheel of Life offers a novel approach to assessing the impact of a condition and its treatment on QoL. Whilst we used the wheel to evaluate the impact of an intervention on QoL in a research context, it may also have applications in clinical settings to facilitate problem-solving, goal-setting or behaviour change.

257/1628/The benefits of mixed methods in scale development I: The added value of Rasch analysis in pre-testing

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AIMS: Pre-testing is a key aspect of the development of patient-reported outcome (PRO) instruments. Conventional pre-testing procedures are based solely on qualitative methods. However, as new psychometric methods, such as Rasch analysis, are able to provide useful exploratory data in small samples ($n > 30$), there is good potential to use these for pre-testing. This study describes the synthesis of interview and Rasch data in pre-testing a new PRO instrument for patients with pressure ulcers, the PU-QOL. **METHODS:** We pre-test the PU-QOL with 35 patients with pressure ulcers using cognitive interviews. Interviews were analysed using a schema based on the Tourangeau cognitive process model to highlight any problematic items (e.g. item wording, relevance). In addition, data from the 35 pre-test PU-QOLs were subjected to Rasch analysis using RUMM2030 software. The quantitative Rasch analyses were compared with qualitative interview data in an interactive and iterative process to identify the potential strengths and weaknesses of PU-QOL items. For example, items flagged as potentially problematic in the Rasch analysis were cross referenced with interview data and vice versa, in order to guide decision-making about further item revisions. **RESULTS:** Interviews identified problems with layout, response options and comprehension. Rasch analysis complemented the qualitative results. For example, the PU-QOL pain scale showed no item misfit; supporting patients' views that items made contextual sense, but 6/11 items had reversed thresholds; reflecting problems regarding the appropriateness of response categories. **CONCLUSIONS:** Use of a mixed methods approach to identify problematic items in PRO pre-testing was effective in identifying and resolving problems with scale layout (item order in scale), response options and framing/wording of items. Rasch analysis provides a complementary tool to standard qualitative pre-testing for evaluating the strengths and weaknesses of PRO instruments during the early stage of questionnaire development.

258/1468/Using Choice-Format Conjoint Analysis to Assign Meaning to PRO Scores

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AIMS: Developers of patient-reported outcome (PRO) instruments use rigorous methods to determine the importance of items in reliably measuring unobservable constructs. However, common psychometric methods such as item response theory (IRT) do not assess if a particular score on an instrument is meaningful to patients. This presentation discusses the potential for use of choice-format conjoint analysis to evaluate the importance of items to patients themselves and to assign meaning to PRO scores. **METHODS:** IRT methods often utilize data describing patients' current health states, while conjoint analysis commonly utilizes data representing patients' preferences for hypothetical health states. Despite the differences in the type of patient-reported data collected, the two methods apply analytical models that have similar probability distributions. Further, item parameter estimates from both can be used to calculate domain

scores; IRT parameters weight items according to their relationship to the underlying construct, while conjoint analysis parameters weight items according to their implied importance to patients. Combined, these methods produce PRO scores that reliably measure the underlying construct while also providing interpretation of the scores and changes in scores based on patient health state preferences. **RESULTS:** The relationship between IRT and conjoint analysis is applied to patient responses to and preferences among items from the Impact of Weight on Quality of Life-Lite questionnaire. Scores calculated using IRT methods are interpreted using conjoint analysis weights, resulting in an assessment of patient-perceived meaning for various change scores. **CONCLUSIONS:** Preference weights obtained using choice-format conjoint analysis have the ability to assign meaning to PRO scores based on patient preferences for these scores. Based on the assigned patient-perceived meaning, criteria for meaningful change and PRO responder definitions can be established and aid in the interpretation of clinical study results.

259/1630/Clustering of Health-Related Quality of Life (HRQoL) items in metastatic prostate cancer patients

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AIMS: HRQoL is generally viewed as a multi-dimensional construct covering various aspects of a patient's life. Subsets of HRQoL items can form clusters. Previous studies have shown 3 main symptom clusters can be found in both metastatic and non-metastatic cancer patients: a physical function-related cluster, a psychological function-related cluster and a gastrointestinal function-related cluster. However, these clusters may differ by patient characteristics. The aim of this study was to explore the cluster structure of HRQoL items in metastatic prostate cancer patients. **METHODS:** Retrospective pooling of 3 EORTC randomized clinical trials yielded baseline HRQoL data, collected using the QLQ-C30 questionnaire, for 382 metastatic prostate cancer patients. The mean (M) age was 70, 69% of patients had a good (0-1) WHO performance status and 66% had received systemic and/or hormonal treatment. Ward's method was used to explore the cluster structure of the 15 HRQoL items. R-squared (R) was used to assess quality of the clustering, Cronbach's alpha (A) to evaluate internal reliability of clusters. **RESULTS:** In the pooled dataset, 3 main clusters were observed (R=0.534). The

first one (A=0.76) included physical and role functioning. The second one (A=0.83) included emotional, cognitive and social functioning, quality of life, fatigue, pain and insomnia. The third one (A=0.72) included nausea/vomiting, appetite loss and constipation. Fatigue (M=45) and pain (M=55) have a strong impact on patients whose physical and role functioning are poor (M=58 and M=59 respectively) not only because of the disease, but also because of age; this may explain why the second cluster included both physical (fatigue, pain) and psychological (emotional and cognitive functioning, insomnia) items. **CONCLUSIONS:** Knowing how HRQoL items inter-relate in different malignancies may help clinicians to provide more individualized symptom cares and policy-makers to support tailored psycho-social programs. Patient-reported outcomes offer a unique opportunity to incorporate patient needs in care planning.

260/1734/Filling in the gaps: content validity for older questionnaires

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AIMS: The FDA Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims emphasizes that the ability of a PRO questionnaire to support medical product labeling claims is dependent upon adequate demonstration of the questionnaire's content validity. However, previously developed questionnaires may not have documented content validity evidence. This research examines approaches to demonstrate content validity for pre-existing questionnaires. **METHODS:** Researchers examined three projects that each assessed the content validity of an existing questionnaire. All three questionnaires had been used without a priori demonstration of content validity. Content validity was considered to be demonstrated if all major themes in the qualitative studies were consistent with the content areas of the questionnaire. The limitations of each approach were examined. **RESULTS:** Each project used evidence gathered from a different source to support content validity: newly conducted patient interviews for questionnaire 1, a review of transcripts from focus groups conducted prior to questionnaire 2's development, and a review of the published literature for questionnaire 3. Although, most major themes were captured in the questionnaires, gaps were evident for each approach. The qualitative analysis of the patient interviews identified additional concepts that were not included in the content areas of questionnaire 1. The qualitative analysis of the previously conducted focus groups was hindered by the poor quality of the transcripts used to gather patient input for questionnaire 2. The existing literature did not provide sufficient direct-from-patient input needed to properly document the content validity for questionnaire 3. **CONCLUSIONS:** The challenges encountered in the assessment of content validity for older questionnaires can be overcome as long as researchers are able to conduct additional patient interviews/focus groups, as necessary, and developers are willing to consider modifications after a questionnaire is in use as changes may be required.

261/1396/A systematic review process can inform our understanding of PRO

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AIMS: To describe the use of a systematic review tool and process to evaluate PRO **METHODS:** We developed a tool and process to assess and summarize the quality of individual psychometric studies

for patient reported outcomes (PRO). A generic 12 item critical appraisal tool was developed; where each item is rated on a scale of zero to 2 with descriptors provided. The tool was used by different investigating teams to conduct 9 systematic reviews. **RESULTS:** A total of 4 reviews were published, 3 are under review and 2 are in progress. Reviews have been conducted to synthesize information on a single PRO or compare multiple PRO. Quality was rank ordered and data extraction identified knowledge gaps. There was consistent high reliability on the pre-consensus quality ratings. The inter-rater reliability of the scores from the total quality score was excellent (ICC = 0.91; 95% CI=0.86-0.94), with agreement on individual item ranging from fair to excellent ($k = 0.43$ to 0.92). Quality ratings indicated wide diversity ranging from 23% to 90%. Inadequate sample size and failure to state clear psychometric hypotheses were the most common design flaws. **CONCLUSIONS:** A generic structured tool can be useful in conducting a systematic review of PRO. Systematic reviews of PRO are important to understand how these measures can be applied in different contexts; and where gaps and flaws exist.

262/1181/Parent-reported Perceived Cognitive Function Item Bank for Children

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AIMS: Cognitive dysfunction is a concern for children with brain tumors and neurological conditions. Routine assessment of cognitive changes is critical for prompt referral to comprehensive testing or intervention services. There is need for a screening tool that can provide brief-yet-precise estimates of neurocognitive functioning. Observer-reported cognitive function may be a useful approach to screening given its association with brain structure changes. This study presents the development and psychometric properties of a new pediatric perceived cognitive function item bank (pedsPCF) designed to fill this need. **METHODS:** The initial pedsPCF consists of 45 items developed via literature review and interviews with children, parents, clinicians, and teachers. The calibration/normative sample included 1,409 parents (60% mothers) of children aged 7-17 (57% male, average age=12.8, 22.6% with a neurological condition). Data were randomly divided for exploratory factor analysis (n=747) and confirmatory factor analysis (n=750). Hierarchical logistic regression and Mantel chi-square statistics were used to evaluate differential item functioning (DIF) on parent gender, child gender, parent education. Samejima's graded response model was used to estimate item parameters. Firestar software was used to simulate computerized adaptive testing (CAT). **RESULTS:** Of 45 items tested, 1 item did not meet the unidimensionality requirement and 1 item had DIF on the same variables using both methods, resulting in 43 items retained in the final pedsPCF. The range of scores was well-covered by item threshold parameters, with reliabilities all > 0.7. In CAT simulation, mean number of items used was 5.9, with scores correlated 0.98 with those from the full-length bank. **CONCLUSIONS:** The pedsPCF possesses sound psychometric properties. US general population based norms are available to serve as a reference for clinical populations. CAT simulation results are promising. Our next step is to evaluate generalizability of the pedsPCF to other clinical populations.

263/1775/Developing initial item pools to measure quality of life for young adult survivors of childhood and adolescent cancer

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AIMS: Little attention has been paid to developing quality of life (QOL) tools for young adult survivors of childhood and adolescent cancer (YASCAC). This study aims to develop QOL item pools for YASCAC based on two extant instruments. **METHODS:** We identified YASCAC who are between 21 and 30 years old and being off therapy > 2 years without cancer using University of Florida's Tumor Registry. Data were collected (N=141) via telephone interviews between 05/01/2009 and 09/30/2009. QOL was measured using the Quality of Life in Adult Cancer Survivor (QLACS; 12 domains with 47 items) and the Quality of Life-Cancer Survivor (QOL-CS; 4 domains with 41 items). Based on our experience and literature, we grouped items into one of 12 designated domains (physical functioning, distress, worry about future event, life satisfaction, self-efficacy, social functioning, spiritual functioning, cognitive functioning, financial problem, sexual functioning, appearance concern, and family functioning). We conducted confirmatory factor analyses (CFA) to analyze unidimensionality and local independence. We deleted items if they are redundant in content, lower factor loading (<0.4), and local dependency (residual correlation > 0.2). We further conducted Rasch analyses to examine item fit using the index of mean square/information-weighted fit (MnSq/INFIT: between 0.7 and 1.3). **RESULTS:** CFA suggests the assumptions of unidimensionality and local independence were not held in all domains. Using the MnSq/INFIT index, Rasch analysis suggests one item from each domain fits the designated QOL domain poorly. Person/item separation indexes and person-item maps suggest items from two instruments measure lower level of QOL, whereas YASCAC reported higher level of QOL. **CONCLUSIONS:** Although we developed initial item pools to measure QOL based on two extant instruments, psychometric properties are not satisfied. Future studies need to revise existing or develop new items to improve quality of the item pools.

264/1345/Examining the Implications of Sample Heterogeneity with Respect to the Measurement Validity of Computerized Adaptive Tests

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AIMS: Computerized adaptive testing (CAT) requires invariant IRT-calibrated parameters that are equivalently applicable to all individuals in a target population. Using a CAT simulation approach, we examined the implications of sample heterogeneity with respect to CAT-predicted scores using up to 39 Likert-type items from a daily activities item bank (Kopec et al., 2006). **METHODS:** We previously conducted a graded-response-mixture analysis of these items and obtained support for a two-class model in an aggregated sample of rheumatology clinic patients (N = 331), knee-replacement surgery waitlist patients (N = 340), and people from the general population of British Columbia, Canada (N = 995). Latent class membership was partially explained by several health-related variables and age. In this simulation analysis, we used the same two-class model parameters and randomly-generated normally-distributed "true theta scores" to produce 100 datasets (of N=1,000 each). These data were used to fit a misspecified (naïve) one-class model to ascertain potential bias resulting from ignoring the heterogeneity in

the generated data. We compared the true theta scores with the expected-a-posteriori (EAP) scores predicted by the misspecified one-class models. Potential bias with respect to the conditional standard error of measurement (CSEM) was also examined. **RESULTS:** Substantial differences between the true scores and the predicted scores were observed when using all 39 items; up to 20% of the cases had predicted scores that were ± 0.5 standard deviations from their true scores. The CSEM was overestimated in one class and underestimated in the other. Similar findings were observed when varying numbers of items and stopping rules were used in a CAT simulation. **CONCLUSIONS:** These preliminary analyses suggest that substantial bias in the predicted scores may result when sources of sample heterogeneity and consequential lack of item parameter invariance are ignored. Interestingly, the bias was not substantially exacerbated through the use of CAT.

265/1453/Do printed symptom reports improve symptom control? A longitudinal controlled trial of PROs in patients receiving chemotherapy

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AIMS: This study examined whether providing patient reported symptom summaries improves patient symptoms and communication in outpatient oncology visits. **METHODS:** A sequential group controlled trial where first the control group (CG) then the intervention group (IG) patients used a tablet computer to record symptoms. The intervention was a printed summary of current symptom intensities and graphs showing up to 5 prior ratings given to IG patients and clinicians in time for each office visit. Patients were all receiving chemotherapy for either breast or prostate cancer. Symptoms were measured using the QLQ-C30 and 0-10 numeric rating scales (NRS) for each of 8 symptoms: pain, dyspnea, anorexia, insomnia, constipation, diarrhea, nausea and fatigue. The printed summaries reported the NRS scores whereas the QLQ-C30 scores were used in analyses. To assess communication, audiorecordings were made of a convenience subset sample of CG and IG patients at the 4th study visit. The audiotapes were coded to count the # of symptoms discussed, % of visit spent talking about symptoms, and the degree to which symptoms discussed matched patient reported symptoms. **RESULTS:** 118/123(96%) patients participated. 57 CG patients provided an average of 5.4 data collections, and 61 IG patients provided 6.0 data collections. The CG and IG did not differ significantly in gender, age, education, employment, race/ethnicity, or diagnosis. At baseline the IG had less fatigue, anorexia, dyspnea, and diarrhea. Univariate (t-test) comparisons show significantly better symptom scores for 6 of the 8 symptoms and global HRQOL for patients receiving the intervention, but a random effects regression controlling for potential confounders is pending. Audio analysis (n=19 in CG and 20 in IG) showed no differences between groups except that there was more symptom and non-symptom talk in the IG (visits averaged 6 minutes longer). **CONCLUSIONS:** This study tests an important potential use of PROs in cancer care. Proper conclusions await completion of the regression analysis.

266/1497/Development of a Computerized Outcome Assessment Tool for Head and Neck Cancer Patients

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AIMS: This study aimed to validate and evaluate the use of a computerized outcome assessment tool (COAT) for head and neck cancer (HNC) patients to facilitate patient-physician communication about health-related quality of life (HRQOL) during clinical encounters. **METHODS:** The traditional Chinese character version of the Functional Assessment of Cancer Therapy-Head and Neck (FACT-H&N) questionnaire along with other demographic and clinical questions were transcribed into a touch-screen computer administration program. The FACT-H&N questions were presented one at a time to maximize the readability. A total of 203 HNC patients were recruited to participate from a community-based medical center in northwestern Taiwan. Each patient completed the COAT survey in an exam room. A summary report was generated upon the completion of the survey and used for clinical discussions. **RESULTS:** Patients were mostly males (78%), had a mean age of 52.5 years (ranging from 23-81), and had a Karnofsky score of 70 or higher. The FACT-H&N scales were found to be reliable; the Cronbach's coefficient Alpha for the FACT-G subscales ranged from .72 (Emotional Well-Being) to .88 (Functional Well-Being) and the H&N subscale had a coefficient of .75. Patients were able to complete the COAT survey with ease. The structured summary reported with HRQOL and other relevant clinical information in different sections allowed the identification of areas needing clinical attention. **CONCLUSIONS:** It is feasible to apply touch-screen-based COAT-HNC in a routine HN oncology clinic. COAT is potentially a valuable tool for HRQOL data management when applied to patients with HNC and other chronic illnesses.

267/1552/Doctors' evaluation of HRQoL electronic data collection

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AIMS: Traditional tools used to assess HRQoL in clinical practice aren't usually easy to implement. This's overcome by electronic tools that allow the doctor to have a measure of HRQoL in real time. We aimed to test whether the report of HRQoL, electronically captured and processed by a Rasch model, brings some added value to the medical consultation. **METHODS:** 5 doctors (3 oncologists, 1 hematologist, 1 internal medicine) accepted to participate by looking at a sample of 77 reports issued after the patients had filled the electronic version of QLQ-C30 in specific software (OnQoL). A report was then generated using Rasch model. This report was given to the doctor before the consultation. The physician was trained in the report interpretation and asked to fill out a questionnaire about it: how easy was the report to interpret; what kind of influence it had on the duration of the consultation; on the communication with the patient; to the detection of problems that otherwise might not have been discussed in the consultation; and if the report has generally been helpful in consultation. At last, principal components factor analysis was used to understand how doctors evaluate the usefulness of the report. **RESULTS:** 97.4% of the reports were considered easy to interpret, in 90.9% of the cases they were helpful to improve communication, in 76.7% they allowed to highlight problems, and in 26.0% the report was responsible for an increase of the consultation time. In general, doctors felt that the reports were useful (97.4%). A factor analysis showed a 2-factors model. These axes can be named as 'consultation burden' and 'report utility' and explain 67.6% of the total sample variance. **CONCLUSIONS:** The reports produced by the Rash model were very well accepted by doctors and their

evaluations were valid in terms of construct validity. With the report, doctor can see information about patient's HRQoL and their evolution over time; confirm some symptoms experienced by patients and even have access to problems that otherwise the patients would not inform. Rasch analysis allows highlighting the problematic items.

268/1613/Development and Use of Touch-Screen Computer-Assisted Self Interviewing in Portuguese Patients with Chronic Immune Diseases: An Inicial Evaluation of NA Electronic Version of SF-36v2

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AIMS: Aim: The major purpose of this study is to evaluate alternative automated methods of collect data on health related quality of life (HR-QoL). In order to achieve this, we formatted the founding objectives: (1) evaluated the feasibility of electronic version in patients with chronic dysfunction of immune system using Short Form 36version2 (SF-36v2), (2) to evaluate the construct validity of SF-36v2 using the electronic data capture, and (3) to compare electronic version questionnaires with paper questionnaires in terms of patients' acceptance, data quality, and reliability. **METHODS:** Methods: Out-patients with chronic immune diseases (HIV infection, lupus, scleroderma, rheumatoid arthritis, Behçet and Sjögren), were randomly selected to completed electronic and paper SF-36v2 (n=50) before consultation in Clinical Immunology Unit, in Hospital Santo António-Centro Hospitalar do Porto (CI-HGSA). **RESULTS:** Results: There were very high correlations in SF-36v2 responses ($p < .001$) between the paper and electronic forms. Internal reliability coefficients (Cronbach's α) showed good internal consistency for all reported responses in either, computer and paper. There were no missing data in electronic version or paper. About 84% of patients prefer to use the computer version in future. **CONCLUSIONS:** The electronic HR-QoL assessment is technically possible and it can provide reliable and valid clinically significant information which can either be used in consultation for routine care.

269/1216/An Audio Urdu LupusQoL in clinic

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AIMS: Systemic Lupus Erythematosus (SLE) is a disease that is more severe in patients of Asian and Afro-Caribbean origin. To optimise management, disease activity, damage and HRQoL should be assessed. In UK, many older South Asian women are unable to speak or read English and have difficulty reading their native language. An audio HRQoL version for self-administration has advantages as allows privacy in answering sensitive questions. The aims of this study are to translate the LupusQoL into Urdu, to produce a CD of this version and to examine the user-friendliness in

outpatient clinics. **METHODS:** The LupusQoL was translated into Urdu by 2 native speakers fluent in English. The 2 translators harmonised the version which was back-translated to English by 2 other translators. A meeting was held to reconcile any discrepancies. An audio version (AV1) was created and administered to 3 patient/partners whose opinions were used to refine it. A revised version (AV2) was administered to 4 SLE patients whose comments were noted, AV3 created and recorded onto a CD. This CD was tested in outpatient clinics in 3 centres. A semi-structured interview was used to gauge the patient's and clinician's acceptability of this method of administration. **RESULTS:** 15 Urdu-speakers were recruited. The native languages spoken (n) and Urdu literacy [n] were: Urdu (9)[4], Punjabi (3)[1] and Gujarati (3)[1]. All 15 patients thought an audio version would improve communication between them and the clinician, improving their management. One centre encountered problems in arranging for the patients to listen to the CD. 6 patients (Urdu illiterate) preferred to have a translator administering the LupusQoL. Some non-native Urdu speakers would have preferred a CD in their native language. Many patients suggested that colloquial Urdu, slower speech, better quality recording and a quieter environment would help them understand the CD better. **CONCLUSIONS:** The patients were positive about the idea of an audio version of an HRQoL measure. However, the optimal method of administration and recording responses is still unclear from this pilot study.

270/1365/Uncertainty in Systemic Lupus Erythematosus (SLE): Development of a Conceptual Model

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AIMS: For many years, the role of uncertainty in chronic illness has been the subject of much interest across a range of clinical disciplines. As such, there is growing evidence that patient uncertainty can directly influence illness outcomes including quality of life (QoL). The aim of this study was to develop a conceptual model for uncertainty in Systemic Lupus Erythematosus (SLE). **METHODS:** A three-phase qualitative investigation was conducted including: (i) a review of the literature across chronic conditions; (ii) consultation with rheumatology health care professionals (HCPs) (n=8) to further explore their understanding of uncertainty issues in SLE; and (iii) in-depth, semi-structured qualitative interviews with SLE patients (n=17). Interviews were audio-taped and transcribed verbatim. A detailed line-by-line coding of uncertainty themes was carried out, which was combined with information from the literature review and HCPs' opinion to develop the conceptual model. **RESULTS:** (i) The literature review revealed a paucity of comprehensive qualitative conceptualisation of uncertainty. However, findings raised important key issues as to the role of uncertainty in areas of patient QoL (e.g. role limitations). (ii) HCPs suggested that SLE patients experience various types of uncertainty, some of which are specific to their condition (e.g. the variability of organ involvement). (iii) Patient interviews revealed multiple dimensions including uncertainty of diagnosis, prognosis, symptomatology, treatment and illness-impact (e.g. occupational, functional, giving birth, & future planning). These findings were used to construct a conceptual model, which spans the spectrum of clinical, functional and QoL outcomes in SLE. **CONCLUSIONS:** This study provides the first step in capturing the important areas of uncertainty in SLE. This work will

form the basis for the development of a patient rating scale that will further allow us to quantify the role of uncertainty in patient QoL and potentially help improve patient management.

271/1484/The Influence of Decision Making Behavior on Outcomes Reflecting Quality of Life

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AIMS: The influence of decision making processes and outcomes on subsequent quality of life is a relatively unexplored area of investigation. The aim of this paper is to synthesize three separate studies of cancer patients' decision making into a preliminary theoretical model to guide future hypothesis testing and ultimately to design prescriptive decision support interventions. **METHODS:** Study I focused on the decisions of women with recurrent breast cancer. Study II identified decision points throughout the terminal phase of cancer care. Building on the concept analysis of the two qualitative studies, Study III is a measurement study designed to provide psychometric data on the decision making concepts as well as psychological well being and quality of life. Taken together, the qualitative studies identified key concepts to construct a model which is being empirically tested with a battery of measures linked to each concept. **RESULTS:** Study I interviewed 48 women with recurrent disease facing treatment decisions that are complex, uncertain, and distressing. These results inform our understanding of hindsight bias, regret, decision satisfaction, and even resilience and optimism in the face of this life-threatening disease. Study II interviewed 37 terminal cancer patients and family members regarding decisions such as transfer to hospice, termination of treatment, or the continuation of aggressive therapy. The two qualitative studies revealed that both positive and negative post-decision outcomes appear to directly influence quality of life indicators (e.g., depression). Study III is testing the model by administering a survey of selected decision making and quality of life measures to 250 breast cancer patients to provide empirical evidence of the relationship among the relevant concepts of decision behavior and quality of life. **CONCLUSIONS:** Testing this empirically-derived model may further our understanding of the mechanism(s) whereby decision making behavior is linked to post-decision satisfaction, psychological well being and a desirable quality of life.

272/1673/Understanding the Burden of Treatment in Patients with Multiple Chronic Conditions: Evidence from Exploratory Interviews

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AIMS: Burden of treatment (BoT) refers to the negative and sometimes undesirable impact of medical treatment on a patient's daily routine through the incremental investment of time, money, and effort into healthcare. Some attempts have been made to measure BoT within specific disease contexts; however, its scope in primary care and in patients with multiple chronic conditions is less understood. We are conducting exploratory interviews to, (1) identify issues and inform questions about BoT, and (2) outline a preliminary conceptual framework that will serve as foundation for developing a

patient-reported measure of BoT in primary care. **METHODS:** Qualitative, semi-structured interviews were conducted with 6 patients (38% response rate) from a hospital medication therapy management program. Two trained interviewers conducted the interviews which were audio-taped, transcribed, and coded independently. Codes were harmonized via discussion and consensus. Data were analyzed using grounded theory methods. **RESULTS:** Three men and 3 women were interviewed (age range: 52-82 years). Number of health conditions ranged from 3 to 7 and all patients were taking several medications daily. Themes emerging from the interviews included (1) dependence on healthcare providers, (2) reduced capacity to work, (3) limitations in social activity (e.g., time with family and friends), and (4) financial concerns related to care costs. Patients received extensive support from healthcare providers, but also reported that treatment involves substantial self-learning. While maintaining a complex care regimen is a daily challenge, patients show resilience through personal coping and adaptation. **CONCLUSIONS:** These interviews inform us of the most critical questions to ask to reveal BoT and provide a preliminary understanding of what BoT means to the primary care patient. We continue to build a conceptual framework and will work to develop a sensitive, yet simple self-report measure for use in practice settings to identify patients at risk for treatment non-adherence.

273/1492/Assessing the added value of performing interaction analysis on focus group data generated to identify important and relevant HRQoL domains

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AIMS: Group interaction is a unique characteristic of focus groups and its purported advantages include synergy, collective insight and lessened inhibition. The aim of this study is to assess the added value of interaction analysis on focus group data to identify domains of HRQoL important and relevant to Systemic Lupus Erythematosus patients. **METHODS:** English-speaking SLE patients were recruited for the focus group discussions to identify domains of HRQoL. The discussions were recorded and transcribed verbatim. The transcripts were coded independently by two analysts using codes from a codebook designed a priori. The codebook was designed to capture group interaction data, based on an existing analytical template and a list of questions previously proposed for this purpose. **RESULTS:** Six focus group transcripts involving 27 female SLE patients were analyzed. Participants identified their disease experiences as being similar or dissimilar to another. Despite having similar experiences, they had differing opinions on the resultant impact on HRQoL. Participants suggested reasons for these different opinions, such as age, disease duration and marital status differences. They identified with various social roles, such as being a married woman or an employed worker. The impact of SLE was subsequently described from these perspectives. Conversational flow was moulded equally by the moderator and participants, as slightly more than half of all topic changes were participant-initiated. This suggests that themes elicited include patient perspectives that are not restricted to responses from moderator probes, which are guided by pre-existing knowledge of HRQoL in SLE. **CONCLUSIONS:** Interaction data provided a deeper understanding of how and why the impact of SLE on HRQoL varies between patients and can be used to guide future HRQoL studies. By understanding the conversational context of the

discussion, interaction analysis can add confidence to content analysis by demonstrating that patients' perspectives have been incorporated.

POPULATION & POLICY

274/1521/Height and quality of life in ethnic Chinese: An observational study

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AIMS: Final height has been suspected to associate with quality of life and mental health, from both a developmental and social point of view. The association is also a clinical concern in the use of synthetic growth hormone for short but otherwise healthy children. This study aims to assess the associations in ethnic Chinese in Singapore. **METHODS:** This is a cross-sectional study of 4,300 polyclinic outpatients aged at least 21. Height was measured by clinic nurses using an ultrasonic height sensor. Participants were interviewed for socio-economic, behavioral, health and quality of life information. Clinical data was collected from the participants' treating physicians. The SF-6D utility index and its Mental Health domain were the main outcomes. Linear regression and ordinal logistic regression analyses were performed on the utility index and the Mental Health score respectively. **RESULTS:** SF-6D utility index ($P < 0.05$) and Mental Health domain ($P < 0.01$) were associated with height in cm, even after adjustment for age and gender. Further adjustment for health, socio-economic and behavioral co-variables made little difference. Analyses based on height categories showed similar but less statistically significant gradients. **CONCLUSIONS:** Adult height has a positive association with mental health as measured by the SF-6D domain among the ethnic Chinese people in Singapore. Socio-economic status and physical health status do not explain this association. Adult height has practically no association with health utility.

275/1066/Gender Inequalities in Quality of Life in Iran

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AIMS: Although women on average live longer than men, they always report less quality of life. Estimates of healthy life expectancy in a research in the US showed that in almost all countries women have fewer healthy years of life than men. Nowadays, as individuals live longer than before, their Health-Related Quality of life (HRQoL) becomes more important. This paper tends to show gender inequalities in health and HRQoL of Iranian elderly and argue on its likely explanations. **METHODS:** This study was a cross-sectional survey. A sample of 400 community resident who were 65 years old and more were selected and interviewed from all districts of Tehran using the stratified sampling method. The questionnaire of Iranian version of SF-36 was applied as the data collection instrument. Data

Analysed using logistic regression analysis. **RESULTS:** The most of the participants were men (56.5%) in the age group of 65-69 years old (38.3%). The physical and mental health aspects of HRQoL, irrespective of gender, were 55.01 and 63.86 out of 100 respectively which demonstrated worse physical health compared with mental health for both sex. However, women reported significantly poorer HRQoL compared with men in both physical and mental health ($p = 0.001$). More interestingly, women also had worse scores in all 8 subscales of HRQoL. **CONCLUSIONS:** Women need to pay a serious and substantial attention by health associated authorities and policy makers in Iran. Also, as HRQoL is highly associated with different factors such as socioeconomic status, living standards and emotional support, improving women health and their HRQoL demands a population-based, multi-sectoral, multi-disciplinary, and culturally relevant approach to create a suitable environment for providing better living conditions for women.

276/1196/Differences in the Quality of Life of patients with Chronic Obstructive Pulmonary Disease between Brazil and Spain

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AIMS: The aim of this study was to evaluate the differences in the quality of life (QoL) of patients with Chronic Obstructive Pulmonary Disease (COPD) between Brazil and Spain. **METHODS:** A cross-sectional and comparative study with 80 outpatients with COPD of the Pneumology Service of public hospitals of Salamanca (Spain) and Fortaleza (Brazil). It were excluded the ones with cognitive and communication problems. The sample was selected by pairs depending on the severity of the COPD (by the Global Initiative for Chronic Lung Disease criteria). Sociodemographics and spirometrics (by the American Thoracic Society criteria) data were collected. The QoL was evaluated by the Saint George Respiratory Questionnaire (SGRQ) and the World Health Quality of Life-Bref (WHOQOL-BREF). Descriptive analysis, the t-student test and the chi-square test (Statistics SPSS Software) were applied. **RESULTS:** The severity distribution of the sample was: 7.5% mild, 30% moderate, 47.5% severe and 15% very severe. The mean age of Brazilian patients was 66.6 years (SD 8.0years) and the Spanish one was 69.1 years (SD 8.9years). There are significant differences in gender, civil state, monthly income, place of residence, being smoker and ex-smoker between the samples. The mean of the forced expiratory volume in 1s (FEV1) of Brazilian patients was 43.11/min (SD 16.51/min) and the Spanish sample was 50.5 l/min (SD 15.6/min), also with significant differences. There are also significant differences in all domains and the total of the SGRQ and in all of WHOQoL-Bref domains except in the Environment. The higher values of the SGRQ (worse QoL) were found in Brazilian patients while the lower values of the WHOQoL-Bref (worst QoL) were found in Spanish patients. **CONCLUSIONS:** There are differences in the QoL between Spanish and Brazilian patients with COPD which can be related with the differences in the FEV1. The instruments (generic and specific) don't evaluate de QoL at the same way at this sample which can be justified by the differences in the sociodemographics characteristics.

277/1225/Quality of Life and Frailty in older Brazilians: results from the SABE study - a 6 year follow up survey in São Paulo, Brasil

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AIMS: Frailty is highly prevalent in old age and, rises the risks for falls, disability and mortality, and is considered an important issue in Public Health. However, the association with self reported quality of life has not been clearly evaluated as yet. In this paper we investigate the association of frailty with self reported Quality of Life, controlling for relevant variables as sex, age, morbidity and basic activities in daily life. **METHODS:** Data comes from two rounds of a longitudinal survey: ESTUDO SABE - São Paulo. The 2000 sample included population aged 60 and plus, living in São Paulo, Brasil (n= 2143, from a multi stage clustered sampling). In this paper we selected individuals in the baseline with no frailty, no self reported diseases, with no difficulties in the basic activities of daily living (BADL), and who survived and agreed to be re interviewed in 2006. (n = 358) In this second round the SF12 questionnaire was used to assess Quality of Life, Frailty was defined using the criteria designed by Fried, and people were classified according to the categories of the binomial variables: self reported disease, difficulty in ABVD, sex and age (up to 74 and 75 and plus). Descriptive statistics included tests for associations using the Rao-Scott procedure with correction for sample-design. Multi variable analysis was done by adjusting logistic regressions with robust estimation. **RESULTS:** Univariate analysis indicated association of frailty with the terciles of the SF12 score distribution in the physical component (P = 0,006) but not in the mental (P = 0,05). In the logistic regression presence of frailty resulted significant with an Odds Ratio of 4,7. Having difficulty in BADL is also significant: Odds Ratio = 8,2. **CONCLUSIONS:** Quality of life is affected by frailty and difficulties in the BADL. Clinical care centers and Public Health Services may enhance their outcomes by gathering this simple information on their patients' conditions.

278/1227/Follow up about QOL of all islander who live in a remote island (Ohshima island) of Japan

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AIMS: We investigated Quality of Life (QOL) of all islander in 2005, and reported that QOL was low for elderly people, women, thin people, and agriculturist. Since then, we performed various interventions through clinic duties and medical care activities. Similarly, we reinvestigated QOL in 2010. **METHODS:** For the QOL investigation, we used MOS Short-Form 36-Item Health Survey (SF-36), for which we obtained permission from iHope International. In addition, we explained the contents of the questionnaire to an islander representative who was informed that the islander could choose to participate and that they would not be put at a disadvantage even if they did not answer it. After obtaining the islander's consent, we distributed questionnaires to all islander above 20 years of age in a manner similar to that in 2005, and collected them a week later. In 2005, we distributed 726 questionnaires and received 360 effective answers (166 men, 194 women); in 2010, we distributed 737 questionnaires and received 368 effective answers (156 men, 212 women). The average age was 55.4±15.6 and 59.9±16.7 years in 2005 and 2010, respectively. The eight scales of SF-36 as per gender and generation, body mass index, and occupation were compared for

2005 with those for 2010. **RESULTS:** The eight scales (PF, RP, BP, GH, VT, SF, RE, and MH) in 2005 were 78.7, 76.7, 63.4, 53.3, 55.1, 81.2, 77.6, and 63.8, respectively, while those in 2010 were 81.0, 79.7, 66.1, 56.4, 62.4, 82.9, 81.6, and 68.2, respectively. GH, VT, RE, and MH had increased significantly. Largely, these results exhibited the same tendencies of the last time, additionally 2010 results had higher tendencies compared to the 2005 results. The scores of thin people and agriculturalists also improved. **CONCLUSIONS:** Despite the increase in the average age of islander who answered the questionnaires, the general QOL scores improved. We suggested that islander's QOL could be potentially raised by intervention through clinic duties and medical care activities.

279/1230/Perceiving quality of life and emerging life worries of Chinese child caregivers in Hong Kong: A mixed method study

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AIMS: This study aims to describe the health-related quality of life of both in-service and pre-service teachers who engaged in the Hong Kong Early Childhood Education (HKECE) programme. The research questions are: (a) What is the health-related quality of life of ECE teachers in Hong Kong? (b) Are there differences between ECE teachers in Hong Kong and those in other South-East Asian Chinese communities? (c) What demographic factors are related to the quality of life of ECE teachers? **METHODS:** The sample comprised 1,026 ECE teachers, including 834 in-service and 192 pre-service teachers of early childhood education. Participants completed the self-administered Chinese version of the Health-Related Quality of Life (HRQOL) (SF-36) questionnaire. The HRQOL has been validated for use with the Chinese communities in Hong Kong, China, Singapore and Taiwan. Mean values of the HRQOL main scale and subscales for this sample were compared against previous similar samples in other Asian countries. Subgroups (according to age, housing-related socio-economic status, and experience of illness/diseases) were compared on the HRQOL main scale and subscales using the methods of MANOVA and ANOVA. **RESULTS:** The results suggest that the HKECE teachers were found to have not only a poor self-rated, health-related quality of life, but also a low quality of life compared to four other Chinese samples in South East Asian communities that were reported in the literature. Analysis showed that in-service teachers had a significantly poorer quality of life than pre-service teachers, and mature teachers tended to have a worse quality of life than their younger colleagues. Significant differences were also found in socio-economic status and experience of illness/disease. **CONCLUSIONS:** Hong Kong healthcare and education policy makers should be aware of the fact that some ECE teachers are in a serious state of ill health, especially those in-service teachers who have families, low socio-economic status and a previous record of illness or disease.

280/1780/Measuring Health-Related Quality of Life (SF-36) among Chinese Caregivers in Preschool Settings in Hong Kong

Christine Mei Sheung Chan, *Magdalena Mo Ching MOK, Psychological Studies, The Hong Kong Institute of Education, Hong Kong, Hong Kong*

AIMS: This study aims to describe the health-related quality of life of both in-service and pre-service teachers who engaged in the teacher education of the Hong Kong Early Childhood Education (HKECE) programme. The research questions are: (a) What is the health-related quality of life of ECE teachers in Hong Kong? (b) Are

there differences between ECE teachers in Hong Kong and those in other South-East Asian Chinese communities? (c) What demographic factors are related to quality of life of ECE teachers? **METHODS:** The sample comprised 1,026 ECE teachers, including 834 in-service and 192 pre-service teachers of early childhood education. Participants completed the self-administered Chinese version of the Health-Related Quality of Life (HRQOL) (SF-36) questionnaire. The HRQOL has been validated for use with the Chinese communities in Hong Kong, China, Singapore and Taiwan. Mean values of the HRQOL main scale and subscales for this sample were compared against previous similar samples in other Asian countries. Subgroups (according to age, housing-related socio-economic status, and experience of illness/diseases) were compared on the HRQOL main scale and subscales using the methods of MANOVA and ANOVA. **RESULTS:** The results suggest that the HKECE teachers were found to have not only poor self-rated health-related quality of life, but also low quality of life compared to four other Chinese samples in South East Asian communities that were reported in the literature. Analysis showed that in-service teachers had significantly poorer quality of life than pre-service teachers, and old teachers tended to have worse quality of life than their young colleagues. Significant differences were also found in socio-economic status and experience of illness/disease. **CONCLUSIONS:** Hong Kong healthcare and education policy makers should aware of the phenomenon that some ECE teachers are in a serious state of ill health, especially those in-service teachers who have families, having low socio-economic status and previous record of illness or disease.

281/1250/Utilising SEIQoL-DW to evaluate and enhance Indigenous programs in the Northern Territory

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AIMS: Can measuring individualised quality of life be a meaningful way of assessing the success and value of various Indigenous services in the Northern Territory of Australia, addressing the social determinants of health? The research will evaluate the SEIQoL-DW tool and its potential broad application to Indigenous programs for adult literacy, housing, palliative care, gangs and incarcerated youth. **METHODS:** The SEIQoL-DW tool will be used pre and post intervention to assess the broad application. The research will be supported by qualitative research methods: participant observation, interviews and focus groups. **RESULTS:** Indigenous programs have a history of causing frustration and despair for policy makers and funders as the desired outcomes are not always met, which brings one to question the cultural appropriateness of the programs. By evaluating individualised quality of life, anecdotal evidence has thus far determined that there are broader and more complex effects for Indigenous programs than one may envisage. For instance, the Indigenous adult literacy program, while not always succeeding in teaching the Indigenous participants to read and write, has had a positive effect on the level of self esteem, hope for the future and improved mental health of its participants: their quality of life has improved. **CONCLUSIONS:** The SEIQoL-DW can be used as a multidimensional tool for case management, quality improvement, data collection for funding purposes, and evaluating interventions. Its easy to use and visual quality also supports culturally appropriate cross-communication. The different view of assessing the success of Indigenous programs via SEIQoL-DW, offers a kaleidoscope of success variants than a limited, uni-dimensional outcome focus. The integration of the SEIQoL-DW tool in Indigenous program evaluations potentially depicts a complex explanation of what really brings quality of life to Indigenous

Australians, so that programs that address the social determinants of health may be purposely planned and managed.

282/1726/Health related Quality of Life and dietary patterns in middle age French population

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AIMS: To estimate the relations between dietary patterns at adulthood in reference to nutritional recommendations and health related quality of life (HRQoL) evolution over a 13 year period. The hypothesis was that dietary patterns in adulthood influence HRQoL evolution and the purpose was to identify dietary patterns influencing evolution of the HRQoL. The secondary aim was to identify the food model the most beneficial in terms of quality of life. **METHODS:** The subjects were volunteers among those who have been followed more than 13 years in SU.VI.MAX 2 cohort. Volunteers were 45-60 year of age at inclusion in 1994. Dietary patterns were expressed by two diet indexes, the National Nutrition health Guidelines Score program, (PNNS-GS) (on a -1 to 15 points scale in reference to the French Nutrition Health Program), and Mediterranean Diet Score (MDS) (on a 0-9 scale in reference to adherence Greek diet). The HRQoL was measured by the SF-36 in 1996 and 2008. The primary endpoint is physical component summary (PCS) and mental component summary (MCS) in 2008 adjusted for respectively PCS and MCS measured in 1996 (PCS and MCS evolution over time). **RESULTS:** 2770 subjects answered to SF-36 in 1996 and 2008. They had at least 3 dietary records, a body mass index, PCS and MCS calculated at inclusion. PNNS-GS and MDS were 7.8 points and 3.7 points. PCS and MCS were respectively 52.2 and 50.3 points at inclusion and 48.0 and 51.3 points at final measurement. There were no significant relationships between MDS and PCS or MCS. However, PCS and MCS at inclusion and at end of the follow up were related to PNNS-GS. HRQoL was MCS evolution was not significantly related to PNNS-GS and PCS evolution was nearly significant. **CONCLUSIONS:** A better HRQoL was related at inclusion and at end of the follow up to better dietary patterns but dietary patterns doesn't influence HRQoL evolution. PNNS-GS includes physical activity, what MDS doesn't take into account. The different results observed with PNNS-GS and MDS could result from physical activity.

283/1493/Nationwide survey of awareness and understanding of quality of life in Japan: A comparison of surveys in 2004 and 2010

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AIMS: For health and medical care specialists, quality of life (QOL) has become a well-known term. However, few attempts have been made to date to examine the degree of awareness about QOL among the general public. We examine the degree of awareness and understanding about QOL among the general public. **METHODS:**

In October 2004 and January 2010, we conducted nationwide interview surveys in Japan regarding degree of awareness of QOL, understanding of the concept of QOL, and degree of QOL of respondents. For each survey we used random, stratified, two-stage sampling of 2,000 people aged 20 and older from the Basic Resident Registers of local governments nationwide. **RESULTS:** The number of participants was 1,385 in 2004 (response rate 69.3%) and 1,345 in 2010 (response rate 67.1%). Degree of awareness of QOL was 20.1% and 19.4% in 2004 and 2010, respectively. Degree of awareness did not differ between men and women, but declined among those aged 60 and above. The three most highly selected items regarding the participants' understanding of the concept of QOL were, "daily life", "financial security" and "motivation in life" in descending order. This order did not change between the surveys. The pattern by among items describing participants understanding of the concept of QOL in the two surveys was similar. In the 2010 survey, those with the highest degree of QOL were residents of urban areas, women, and participants who understood the concept of QOL to include, "a role in society", "motivation in life" and "individuality". **CONCLUSIONS:** In Japan, the degree of awareness of the term "quality of life" is low. There is a need for dissemination of the concept of QOL among the general population considering the health and health care of the population. Public understanding of the concept of QOL has remained similar between the 2004 and the 2010 surveys except that the items of "daily life" and "financial security" increased while "individuality" decreased. Future studies should investigate possible causes of these changes.

284/1419/The WHOQOL-BREF questionnaire: Psychometric properties of the Turkish National Data Pool 2000-2010
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AIMS: WHOQOL-Bref has become one of the most popular generic HRQoL instruments in Turkey. WHOQOL Turkish centre gives methodological support to the researchers on WHOQOL. This study aimed to present the psychometric properties of the Turkish National WHOQOL-Bref data pool by Turkish WHOQOL centre. **METHODS:** National WHOQOL data pool consists of 17 037 subjects 14-96 years old. 8856 subjects' data were belonged to representative population based studies, 2818 came from health personnel data and 5360 subjects were ill persons. Normative data for the data pool were analyzed by age, gender, level of education, income, employment status and health insurance. Reliability and validity analyses were conducted on the overall data. **RESULTS:** 39.6% of the respondents were male and 60.4% were female. Mean age of the overall sample was 42.8 (sd 16.7); median age was 41.0 and skewness 0.38 (SE 0.020). 45.7% of the respondents had primary education (less than 9 years). 51.8 % was employed, 37.7% unemployed and 10.5% were retired and 91.9 % had health insurance. Internal consistency of the overall data was good (physical: 0.79; psychological: 0.77; social: 0.60 and environmental: 0.76). Scale success for each of the domains was good as well. Criterion, discriminant validities were very good and Confirmatory analysis results revealed good indices (CFI=0.94 and RMSEA= 0.076). **CONCLUSIONS:** Our data provide normative scores for the general Turkish population for four dimensions of the WHOQOL-BREF that can be useful to researchers using this measure of health-related quality-of-life assessment and to clinical practitioners.

285/1080/Health Related Quality of Life Measured by SF-36v2: A Population-Based Study In Portuguese Patients with Disorders of the Immune System

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AIMS: Health related quality of life (HRQL) in patients with chronic diseases is a research topic that has attracted increasing interests around the world. The 36-item Short Form version 2 (SF-36v2) is a commonly used instrument for measuring HRQL, and it has been validated to the Portuguese population. This paper reports on the feasibility of using the Portuguese version of SF-36v2 to evaluate HRQL in the population of patients with disorders of the immune system, in the outpatient Clinical Immunology ambulatory, in the Hospital Santo António, Centro Hospitalar do Porto, on a daily clinical practice. **METHODS:** A total of 106 subjects were selected (by convenience sampling), corresponding to all of patients' that attended to the outpatient to this department, during a period of four months. Demographic and clinical information was collected, and SF-36v2 was used to measure HRQL. **RESULTS:** Reliability and validity analysis showed satisfactory results, which were basically in accordance to the theoretical construction of SF-36v2. **CONCLUSIONS:** The Portuguese version of SF-36v2 is a valid and reliable tool for assessing HRQL in patients with disorders of the immune system.

286/1107/The association between Health-Related Quality of Life and anxiety in a Greek adult population

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AIMS: Anxiety is inversely associated with Health-Related Quality of Life (HRQoL), which has been defined as an individual's perceived physical and mental health over time. Given that the association between anxiety and HRQoL in the Greek general population has not been previously examined, the aim of the present study was to examine the hypothesis that trait anxiety is a significant predictor of HRQoL in a Greek adult population. **METHODS:** Participants were 327 healthy adults (30-50 years). Age, gender and other socio-demographic variables were recorded. HRQoL was assessed with the Greek version of SF-36, which consists of the physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role and mental health subscales each measuring a separate health factor (physical and/or psychological health). Anxiety was estimated with the State-Trait Anxiety Inventory (STAI), which consists of the state and trait anxiety factors. However, only the trait anxiety factor was assessed. A series of hierarchical regression analyses were conducted to examine the study's hypothesis. **RESULTS:** Analyses showed, that adjusted for the socio-demographic variables, trait anxiety highly predicted the psychological health factor (beta=-.60, t=-12.97, p=.00) and all its subscales: Vitality (beta=-.48, t=-9.57, p=.00), social functioning (beta=-.35, t=-6.64, p=.00), emotional-role (beta=-.41, t=-7.71, p=.00) and mental health (beta=-.61, t=-12.95, p=.00). However, trait anxiety was a predictor only of the physical health factor subscales: Physical functioning (beta=-.19, t=-3.60, p=.00), physical-role (beta=-.24, t=-4.35, p=.00), bodily pain (beta=-.23, t=-

4.17, $p=0.00$) and general health ($\beta=-.39$, $t=-7.43$, $p=0.00$). **CONCLUSIONS:** The results support the negative association between anxiety and HRQoL, a finding that should be taken into account in improving the quality of life of Greek adults. One limitation of this study was that the sample size was relatively small and the results could not be generalized to the entire Greek population.

287/1496/Frailty and Health Related Quality of Life in A Community-Based Elders in Taiwan

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AIMS: Health-related quality of life (HRQoL) in frail elders has not been well explored yet. The aim of this study was to examine the effect of frail status on HRQoL in community-dwelling elders in Taichung City, Taiwan. **METHODS:** A total of 849 elders were recruited in a community-based cross-sectional survey in Jan, 2009 in Taichung, Taiwan. All elders completed comprehensive geriatric assessment, five frail components defined by Fried et al., Short Form 36 (SF-36) and a structured questionnaire. Sixty-eight elders with impaired cognitive function determined by Mini-Mental State Examination score <14 and incomplete SF-36 questionnaire were excluded. Chi-square test, one-way analysis of variance (ANOVA) and multivariate linear regression model were applied to examine the association between frailty and HRQoL. **RESULTS:** The overall prevalence of frailty was 10.6% in elders. After multivariate adjustment, non-frail elders had significant higher scores than frail elders in all scales and two summary scales, ranging from 10 to 23 points for scales and 4 to 8 points for summary scales. There was a similar but attenuated effect for differences between pre-frail and frail elders except for role-limitation scale. We further examined the relationship between number of frail component and two summary scores. We found a significant quadratic nonlinearity decrease in PCS after multivariate adjustment. The decrease rate in mean PCS score increased as number of frail component increased. We observed a U-shape relationship between MCS score and number of frail component. As number of frail component increased, the mean MCS score decreased at first and reached its lowest at frail components of 3. And then the mean scores of MCS increased as number of frail component increased. **CONCLUSIONS:** Comparing with non-frail elders, frail and pre-frail elders exhibit significantly lower HRQoL. The implication of the current study findings is that HRQoL is one of domains that interventions should target at when caring for frail elders.

288/1086/Estimating HR-QOL and Longevity Using the "Illness-death" Model

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AIMS: Health-related quality of life is a non-fatal health outcome measure. It measures only the quality of life for persons who are still alive. Sometimes, it may be necessary to measure health-related quality of life and longevity. In a clinical study for example, the focus may be on a small number of individuals who are being followed after starting specific treatments and the interest could include measuring the average number of years each patient survived and the

portion of average life with optimum HR-QOL. The main purpose of this paper is to discuss the application of the "illness-death" model when a follow-up study focuses both on fatal and non-fatal health outcomes. We will also explain the "illness-death" model and how the life table technique is combined with the concepts of matrix algebra and discrete measure of time in the process of estimating HR-QOL and longevity simultaneously. **METHODS:** In the study both HR-QOL and expected years of remaining life are estimated using the "illness-death" model. The "illness-death" model is a multi-state model and uses the increment-decrement life table technique. The method also involves the application of matrices for expressing probabilities of surviving with various levels of health states and the formatting of the input data and the creation of a parameter file. **RESULTS:** Results that will be presented will include illustrative examples of raw and formatted data files, a parameter file and estimates of average years of remaining life and expected years with various levels of HR-QOL for a hypothetical cohort. **CONCLUSIONS:** The method can be used for estimating HR-QOL and longevity, measuring population health and summarizing clinical and medical studies that focus on the outcomes of treatments and medications. The results from such analyses will be useful for population surveillance, health policy and resource allocation, quality of care evaluation and clinical practice.

289/1813/Outcome Measure for the Long-term Care

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AIMS: Primary goal of interventions in the cure sector is to achieve health gains and in the cost-utility analysis "health-related quality of life (HRQL)" is the core outcome. In the Netherlands the long-term care sector comprises care for people with long-term impairments (e.g. disabled care, nursing, etc). Interventions focus to a considerable degree on managing or reducing the effect of impairment on people's daily lives and therefore on maintaining or improving well-being. Due to differences between cure and long-term care, it can be questioned if existing instruments aimed at measuring HRQL can be used to measure the effect of interventions in the long term care sector. We aimed to explore which domains are important in the well-being of people with long-term physical, cognitive, psychological and/or sensory impairments. **METHODS:** A literature search and expert interviews, which were carried out simultaneously. **RESULTS:** Our main finding is that frequently applied HRQL instruments are not suitable to determine the effects of interventions in the long-term care sector. Our exploration identified the following well being domains: psychological or emotional well-being; social and civic well-being; meaning in life & spiritual well-being; physical well-being; autonomy, control and being in charge of one's own life; financial well-being & administrative burden. **CONCLUSIONS:** New instruments that focus on well being are necessary to compare the effectiveness of intervention in long term care. This new instrument should include the identified well-being domains.

290/1736/Quality of Life and Urinary Incontinence in Elderly with Criteria of Frailty in an Ambulatory Care

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AIMS: This study aimed to evaluate the quality of life of 65 frail and pre-frail elderly with urinary incontinence (UI) being cared at the Geriatric Clinic of an University Hospital of Campinas, São Paulo, Brazil. **METHODS:** It was used an instrument to collect socio-demographic and clinical data and the International Consultation on Incontinence Questionnaire-Short Form (SF-ICIQ) to assess the presence of UI and quality of life of subjects. The five criteria of frailty proposed by Fried and colleagues were used to select the sample. **RESULTS:** The age of 65 elderly participants varied between 60 and 93 years. Most were frail (70.70%), aged e 80 years (46.15%), female (81.53%), with schooling up to 4 years (93.84%) and 34.42% are illiterate. The frailty ($p < 0.001$) and level of education ($p = 0.012$) were the variables that affect the QOL. 65.22% of the frailty subjects rated their QOL related to UI as very serious. The interference of UI on QOL as very serious was significantly higher in the illiterate elderly (71.43%) and no elderly with higher education to 4 years showed the same interference. The QOL related to situations of urinary loss (UL) had no statistically significant differences between the variables. However, when performing physical activities, p -value ($p = 0,078$) was close to the significance for this study. Most consider the situations of UL as variables that interferes with QOL in a very serious way, especially when coughing or sneezing and before reaching the bathroom. **CONCLUSIONS:** All the subjects had at least one criterion for frailty, and therefore significantly lower QOL. Whereas there are large illiteracy rates among the elderly in Brazil, these findings portray the reality experienced by most of the elderly population living with no social support. The PU to perform physical activity may be associated with criteria of frailty related to physical activity, which in turn is linked to muscle strength and gait speed. The variation of age suggests that frailty may be present among older youth, with no association between age and frailty.

291/1755/Association between SF-12 and basic and instrumental activities of daily living in older adults

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AIMS: To determine the association between quality of life related to health (HRQOL) and sociodemographic data, Basic Activities of Daily Living (BADL), Instrumental Activities of Daily Living (IADL) in elderly people in São Paulo, Brazil. **METHODS:** This study is part of the Health, Welfare and Ageing Study (SABE), which started in 2000 with the objective to identify the profile of elderly in Latin America and the Caribbean. From 2006 the Study SABE became longitudinal in Brazil. Up this year 1115 interviews were conducted with elderly residents in the urban area of São Paulo using a standardized questionnaire. It was verified the association between the "The 12-Item Short-Form Health Survey (SF-12) and demographic data (gender, age, marital status), ABVD (eating, dressing, bathing, mobility, locomotion) and IADL (use the phone, shopping, using transportation, managing money, taking medication). **RESULTS:** The variable age between 65–74 years had a mean physical component greater than 75 years and over ($p < 0.0001$). Regarding gender, women showed a mean physical and mental components smaller than those of men ($p < 0.0003$). The difficulties and needs to perform BADL ($p < 0.0001$) and IADL ($p < 0.05$) were statistically significant for the physical and mental components, except the need to help eating related to mental component. **CONCLUSIONS:** The elderly aged 75 and over and women had worse HRQOL, as well as the elderly who had difficulties and they

needed help to perform BADL and IADL. Whereas this is a population study and the instrument used is of HRQOL, it is concluded that the functionality of the elderly is a key parameter in evaluating your health, because it was a variable that showed significant association between the activities of daily life and quality of life in their physical and mental sphere. Therefore, it becomes necessary intervention strategies to prevent aggravation of health problems of older people, preserving their independence for the performance of BADL and IADL.

292/1444/Life Quality Evaluation of Elderly Men Living In South of Minas

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AIMS: 1) identify the biosocial, familiar, economic and health features of elderly men, living in the south of Minas; 2) evaluate their QL and 3) relate the biosocial, familiar, economic and health features with the QL. **METHODS:** it is a quantitative, descriptive and transversal study. The sample was composed of 300 male people, aging 60 years or more, living in the cities of Itajubá, Maria da Fé and Brazópolis, MG; Brazil. It was an intentional, non probabilistic kind. The interview was a direct structured one, applied on the period between March and December of 2009. Three instruments were applied: 1) Biosocial, familiar, economic and health features: developed by Silva and Kimura, (2003); 2) WHOQOL-bref; 3) WHOQOL-old. **RESULTS:** : 97,66% of participants lived in urban area; the average age was 71,08 years; 92,66% had a religious practice. The average monthly income was R\$ 1.664,89. In a scale of 0 to 100 points, the evaluation of general QL, through WHOQOL-bref, presented $M = 74,20$ and $DP = 8,65$. The psychological dominium was the one that most qualified the QL with $M = 76,2$ and $DP = 9,86$; the "environmental" dominium got the lower score in relation to the others ($M = 70,45$ e $DP = 9,77$). Regarding the total QL evaluation by through WHOQOL-old (in a scale of 0 to 100 points), it got $M = 75,6$ e $DP = 8,12$. When relating the biosocial variables with the WHOQOL-old, it was found a positive and significant correlation with the married status ($r = 0,6$ e $p = 0,011$); number of children ($r = 0,5$ e $p = 0,029$); better health condition ($r = 0,5$ e $p = 0,033$). When the biosocial variables were related to the dominions of WHOQOL-old, there was a positive and significant correlation to the religion ($r = 0,5$ e $p = 0,032$); with the factor "death and die"; have children ($r = 0,4$ e $p = 0,007$), with the aspect "social participation"; do not present chronicle disease with the dominions "autonomy" and "sensory working" ($r = 0,6$ e $p = 0,001$ e $r = 0,5$ e $p = 0,034$, respectively). **CONCLUSIONS:** elderly people qualified their lives as very good, both from general and the specific point of view.

293/1513/The Association of Probable Depression and Frailty in Elderly Taiwanese

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AIMS: The aim of study was to examine the association of probable depression and frailty in elders, and to identify the risk factors of probable depression in Taiwan. **METHODS:** A community-based cross-sectional survey was conducted in Jan, 2009 in Taichung, Taiwan. Seven hundred and eighty elders without impaired cognitive function and complete questionnaire were enrolled in this study. The

Geriatric Depression Scale (the GDS-15) was used to measure self-rated depressive symptoms, and a score of higher than 5 was defined as probable depression. All subjects were measured five components of frailty defined by Fried et al. Chi-square test, student's t test and multivariate logistic regression were applied to analyze the relationship between associated factors and probable depression. **RESULTS:** Ninety-seven study elders (11.5%) were defined as probable depression. Higher proportion of probable depression was found in frail elders than pre-frail and non-frail elders (30.12% vs. 10.98% and 6.83%). In multivariate logistic regression, significant factors associated with probable depression were frail status (odds ratio [OR]: 3.15, 95% confidence interval [CI]: 1.18–8.44), female gender (OR: 2.18, 95% CI: 1.075–4.44), 7–12 years of education (OR: 0.38, 95% CI: 0.15–0.95), fall history (OR: 2.09, 95% CI: 1.07–4.10), hyperuricemia (OR: 3.86, 95% CI: 1.52–9.77), sleep impairment (OR: 2.09, 95% CI: 1.15–3.79), someone listening what you talk (OR: 0.32, 95% CI: 0.12–0.88), having not enough money (OR: 4.20, 95% CI: 1.52–11.62), and clinical albuminuria (OR: 0.13, 95% CI: 0.02–0.88). **CONCLUSIONS:** Probable depression was associated with multiple dimensions of frail status, demographic characteristic, chronic illness, psychosocial support, and sense of mastery. Prevention or education programs on depression should target at elders who owned characteristics that were associated with higher risk of probable depression.

294/1515/Successful Aging Defined by Health-Related Quality of Life and Its Determinants in Elderly Taiwanese

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AIMS: This analysis was undertaken to evaluate successful aging via better physical and mental function in Taiwan elders without impaired cognitive function and to explore its determinants. **METHODS:** A community-based cross-sectional survey was conducted in Jan, 2009 in Taichung, Taiwan. Seven hundred and eighty-one elders without impaired cognitive functioning and incomplete questionnaire were enrolled. Elders whose physical and mental component scores of Short-Form 36 were both at top tertile were defined as successful aging. All elders completed comprehensive geriatric assessment, measurements of five components of frailty defined by Fried et al. and a structured questionnaire. Chi-square test, student's t test and multivariate logistic regression were applied to analyze the relationship between related factors and successful aging. **RESULTS:** The prevalence of successful aging was 11.0% in elders. Elders who were successful aging tended to be older, and with better cognitive function and physical fitness. Higher proportion of successful aging was found in non-frail, pre-frail than in frail elders (16.9%, 9.1% vs. 1.2%). In multivariate logistic regression, Factors associated with lower likelihood of successful aging were pre-frail status (odds ratio [OR]: 0.55, 95% confidence interval [CI]: 0.30–0.99), arthritis (OR: 0.30, 95% CI: 0.10–0.91), pain problem (OR: 0.41, 95% CI: 0.22–0.75), sleep impairment (OR: 0.32, 95% CI: 0.16–0.61), hearing impairment (OR: 0.42, 95% CI: 0.20–0.87), and having not enough money (OR: 0.19, 95% CI: 0.04–0.93). **CONCLUSIONS:** Successful aging was associated with multiple dimensions of frail status, chronic illness, hearing capacity, and sense of mastery, but not associated with demographic status (e.g. education, married status) and health related

practices (e.g. smoking, exercise). Whether these associations were causal needs to be explored in the future studies in order to make efforts to identify the possible biologic mechanisms in successful aging.

295/1279/Quality of Life Model: Predictors of Quality of Life among Older Adults

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AIMS: The aim of this study was to explore how depressive symptoms, physical function, health satisfaction, age and environment predict Quality of Life (QoL) among older adults in a conceptual model based on Wilson and Cleary's Model (WCM). **METHODS:** A stratified sample by age, gender and living area was drawn from the Norwegian population of older adults (n=401, mean age of 75.1 year, range 60–91, 54.1% female, 43.9% male, 59.4% married or partnered). A postal survey was conducted using the WHOQoL-Old, the WHOQoL-Bref Environment domain, the Geriatric Depression Scale, the Short Form SF-12 and socio-demographic and health questions. The study is part of a larger international study (WHOQoL-Old study). **RESULTS:** A path analysis (structural equation modelling) showed that the overall model provided empirical evidence for linkages in the WCM. Results showed that QoL is likely to be manifested by direct effects of environmental conditions, health satisfaction and age. In addition, environmental conditions and age had indirect effects on QoL, in particular via depressive symptoms. Environment had both a significant direct and an indirect effect on QoL. An indirect effect of environment on QoL was shown by depressive symptoms, physical function and health satisfaction as mediators. There was only minor evidence for age predicting QoL. **CONCLUSIONS:** This model may help health care workers to collect and assess information, to suggest suitable interventions and to guide decision making.

296/1297/Impact of treatment and metabolic control on Quality Of Life of Adolescents with Type 1 Diabetes Mellitus

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AIMS: This study aimed to identify relations between HRQOL, metabolic control, demographic and clinical variables of adolescents with Type 1 Diabetes Mellitus (T1DM). **METHODS:** Data were collected in a reference center for the treatment of T1DM, in Brazil. Participated in this study, 245 adolescents, who responded to the Brazilian version of Diabetes Quality of Life for Youths (DQOLY). It consists of 50 items, distributed in domains Satisfaction, Impact and Worries. Data were obtained through interviews and consultations in medical records. **RESULTS:** The sample consisted mostly of girls (n=145), the mean age was 14.86±2.53 years old. Means of application of insulin and blood glucose tests/day were 3.25±0.82 and 3.01±1.14, respectively. Only 38 adolescents performed carbohydrate counting. Metabolic control, assessed by glycated hemoglobin, was 10.39±2.49% at the time of data collection. Scores of DQOLY were: 110.26 for Total, and 37.49, 49.04, 23.73 for Satisfaction, Impact and Worries, respectively. Older teenagers had worst scores for Satisfaction (r=0.177) and Worries (r=0.127). Girls had worst scores

on domains Satisfaction, Worries and Total($p < 0.005$). The less frequent was the blood glucose monitoring, the worst scores for Impact($r = -0.136$), Worries($r = -0.191$) and Total($r = -0.158$). Adolescents who did not perform carbohydrate counting showed worse scores in all domains($p < 0.005$). Higher levels of glycated hemoglobin determine worse HRQOL in all domains($r = 0.268$ in Satisfaction, $r = 0.270$ in Impact, $r = 0.260$ in Worries and $r = 0.324$ in Total). **CONCLUSIONS:** Overall, HRQL was positively evaluated in this study. Special attention should be given to older adolescents and girls who had worst DQOLY scores. Frequent blood glucose checking and carbohydrate counting positively influenced HRQoL. Metabolic control and HRQoL had a strong relationship. This study suggests that metabolic control may contribute to the improvement of HRQOL.

297/1182/Validation of the modified 1-week recall version of the Pediatric Quality of Life Inventory 3.2 (PedsQL™) Type 1 Diabetes Module

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AIMS: Parent/patient-reported outcomes are a means to capture data on how the parent perceives/patient functions or feels in relation to a health condition. The purpose of this study was to assess psychometric properties of the Pediatric Quality of Life Inventory Type-1 diabetes (PedsQL T1DM) module recently modified from 1 month to 1 week recall period. **METHODS:** A web-based survey was administered to 101 parents of children 8 to 12 yrs with T1DM (mean parent age=37 yrs, mean child age=10 yrs, mean parent-reported HbA1c=11.6%); 105 parents of children 13 to 18 yrs with T1DM (mean parent age= 43 yrs, mean child age=15 yrs, mean parent-reported HbA1c=10.4%), and 106 adults 19 to 35 yrs with T1DM (mean age=28 yrs, mean self-reported HbA1c=9.2%). Survey questions included parent-perceived/patient-reported health and diabetes status. Factor analysis with varimax rotation and internal consistency reliability using Cronbach's α were assessed for each module subscale [Diabetes Symptoms (15 items), Treatment Barriers (5 items), Treatment Adherence (6 items), Worry (3 items), Communication (4 items)] within the 3 age groups. To support construct validity, Pearson Correlation was performed with the Pediatric Quality of Life Inventory 4.0 Generic Core (PedsQL) subscales (Physical, Emotional, Social, School/Work Functioning), the Self-Care Inventory Revised (SCI-R) and selected survey variables. **RESULTS:** Subscale measurement properties: factor analysis identified a single factor for each subscale within the 3 age groups except 'Diabetes Symptoms' which identified =3; Cronbach's α 's were .68–.91. Significant ($p = 0.01$) correlations were found between each subscale and PedsQL scales (.45– $r = .79$), parent/patient perceptions of how often blood sugars were too high or low (.26– $r = .43$), and patient-reported HbA1c (.33– $r = .37$) for age group 3. No significant correlation with parent/patient-reported SCI-R was identified. **CONCLUSIONS:** The modified PedsQL T1DM asks respondents to recall problems associated with their diabetes within the past week instead of the past month while retaining reliability and validity. Further analyses of these constructs, especially 'Diabetes Symptoms' and 'Worry', for each group is recommended.

298/1756/Measurement properties of a quality of life instrument for youth who are deaf or hard of hearing (YQOL-DHH)

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AIMS: To evaluate the measurement properties of a new 40-item deaf and hard of hearing-specific quality of life instrument for adolescents "Youth Quality of Life Instrument" DHH Module (YQOL-DHH). **METHODS:** We analyzed data from 233 adolescents ages 11-18 with bilateral hearing loss, of whom 51% were male, 61% Caucasian, and 43% attending mainstream public schools in the Midwestern (25%), Southern (30%) and Western (42%) regions of U.S. Hearing levels for sample were 11% mild, 20% moderate/mod-severe, 41% severe/profound and 28% had a cochlear implant. Example items are: "I feel it is hard for me to understand what people are saying because I am d/hh" and "I know how to stand up or speak up for myself." Items were administered with an 11-point response scale ranging from 0-10, coded such that 10 indicated the best quality of life. **RESULTS:** Forty of 43 items were retained for analysis. Item means ranged from 4.37 to 8.45 and standard deviations from 2.00 to 3.81. The percentage of responses in the lowest (0) and highest categories (10) ranged from 0.87% to 14.97% and from 10.0% to 76.6%, respectively. Exploratory factor analyses yielded support for three sub-factors corresponding to self-acceptance and advocacy (14 items; $\alpha = 0.84$), participation (11 items; $\alpha = 0.87$), and perceived stigma (7 items; $\alpha = 0.85$), but no overall score, based on the inter factor correlation, parallel analysis, and review of item content. Children's Depression Inventory-Short Form total score was inversely correlated with the YQOL-DHH self-acceptance and advocacy ($r = -0.40$), participation ($r = -0.49$) and perceived stigma ($r = -0.50$) scores. Re-administration of the YQOL-DHH approximately 7 days after baseline yielded intra-class correlation coefficients of 0.70, 0.92, 0.75 for the self-acceptance/advocacy, participation, and perceived stigma factors respectively. **CONCLUSIONS:** The YQOL-DHH demonstrates good reliability and validity for assessing deaf and hard of hearing-specific quality of life in adolescents.

299/1754/Perceptions of Quality of Life among Youth who are Deaf or Hard of Hearing

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AIMS: Existing deaf or hard of hearing (DHH)-specific quality of life instruments for adolescents have not included the important voices of youth of different age, sex, hearing levels, modes of communication and school placement types. Youth with various level of hearing loss participated in the simultaneous development of the Youth Quality of Life-Deaf and Hard of Hearing (YQOL-DHH) using the needs-based model. **METHODS:** Purposive and theoretical sampling of youth ages 11-18 years who were deaf or hard of hearing was conducted in the U.S. Semi-structured interviews probed youth's perceptions of their quality of life. Interviews were coded in Atlas-ti 5.0 by pairs of researchers. Items were written based

on interview text, compiled into a long-list by hypothesized domains: self, social, environment. Items were crafted using needs-based criteria. The item list was reduced iteratively by consensus and in consultation with an expert panel. Cognitive interviews were conducted to assess readability and clarity of survey items. **RESULTS:** Forty nine interviews were conducted with youth ages 11 to 18 with mild/moderate (26%), mod-severe/severe (26%), and profound (47%) hearing impairment. From an initial list of 100 crafted items, 54 items were nominated for a short list, of which 43 were assessed in cross-sectional sample: n=12 Self, n=18 Social, n=13 Environment. Thematic analysis revealed 4 main themes: acceptance, confidence, perceived stigma and participation and were examined in relation to the a priori hypothesized instrument factor structure. **CONCLUSIONS:** The DHH-specific quality of life instrument has established content validity based on a sample of youth with varying degrees of hearing loss and diverse backgrounds.

300/1313/Longitudinal assessment of health related quality of life via child and parent-proxy reports in children with thalassemia following hematopoietic stem cell transplantation

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AIMS: Although hematopoietic stem cell transplantation (HSCT) has been widely used to treat pediatric patients with beta-thalassemia major, there is lack of evidence to determine whether this treatment improves Health Related Quality of Life (HRQoL). We used child-self and parent-proxy reports to prospectively evaluate HRQoL in 28 thalassemia children from Middle Eastern countries who underwent allogeneic HSCT in Italy. **METHODS:** The PedsQL 4.0 Generic Core Scales were administered to patients and their parents 1 month before and 3, 6, 18 months after transplantation. Change from baseline at 3, 6 and 18 months was assessed using the Wilcoxon Signed Rank Test. **RESULTS:** Two-year overall survival, thalassemia-free survival, mortality and rejection were 89.3%, 78.6%, 10.9% and 14.3%, respectively. The cumulative incidence of acute and chronic graft-versus host disease (GVHD) was 36% and 18%, respectively. Physical functioning significantly declined ($p=0.02$) from baseline (median score 81.3) to 3 months after HSCT (median score 62.5). Major improvements ($p=.04$) were seen afterwards up to 18 months after HSCT (median score 93.7). Agreement between child- and parent proxy-ratings was high. Chronic GVHD was the most significant factor associated with lower HRQoL scores over time ($p=0.02$). **CONCLUSIONS:** The child-self and parent-proxy reports showed an improvement in the HRQoL of thalassemia children after HSCT. Overall, our study provides preliminary evidence-based data to further support clinical decision-making in this area.

301/1708/What is the Health-related quality of life of caregivers of patients with Juvenile Idiopathic Arthritis like?
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AIMS: The well-being of caregivers of patients with Juvenile Idiopathic Arthritis (JIA) is an important aspect to be considered in the investigation of disease burden on the health-related quality of life (HRQOL) of this population. We aimed at assessing the impact of JIA on the HRQOL of caregivers of Brazilian patients and ascertaining whether there are differences in their HRQOL according to the subtype of arthritis. **METHODS:** This cross-sectional study was carried out in the pediatric Rheumatology outpatient unit at the Hospital de Clínicas of the Universidade Federal de Uberlândia. The HRQOL of caregivers of 52 children with JIA was evaluated and compared to that of 104 caregivers of healthy children using the Brazilian version of the SF-36. Multivariate analyses using stepwise linear regression methods was used to compare the SF-36 domains with some analyzed variables (parents' marital status, chronic disease and economic classification) which are hypothesized to impair the HRQOL of caregivers. The HRQOL was compared with the control group using t test and Kruskal-Wallis according to disease subtype with a significance level of 0.05. The reliability of the internal consistency of SF-36 was calculated using Cronbach's alpha coefficient. **RESULTS:** The study consisted of caregivers of patients with JIA aged 39.1 ± 9.11 and controls aged 36.9 ± 6.13 years. Cronbach's alpha coefficient ranged from 0.70 to 0.90. The variables (chronic disease, parents' marital status and economic class) showed no influence on the HRQOL of patients' caregivers. The HRQOL of caregivers of patients with JIA was found to be impaired in all SF-36 domains when compared with the control group ($p < 0.05$). The HRQOL of caregivers of patients with polyarticular and systemic subtypes differed significantly from that of caregivers of patients with oligoarticular type and from the control group ($p < 0.05$). **CONCLUSIONS:** JIA caused a negative impact in HRQOL of caregivers of patients with JIA. JIA impairs the caregivers' wellbeing and the quality of the assistance driven to this population. Future studies are needed to confirm these results. Support: FAPEMIG and CNPQ

302/1773/The impact of disease activity and damage on quality of life in systemic lupus erythematosus (SLE) assessed by the LupusQoL questionnaire

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AIMS: The LupusQoL is a validated SLE-specific health-related quality of life (HRQoL) instrument. We studied the relationship between disease activity, organ damage and HRQoL as assessed by the Chinese version of the LupusQoL. **METHODS:** Consecutive patients who fulfilled ≥ 4 ACR criteria for SLE were invited for a HRQoL study using the LupusQoL questionnaire. Disease activity and intercurrent disease flare of the participants were assessed by using the SLEDAI-2K, physicians' global assessment (PGA) (0-3) and SELENA-SLEDAI flare instrument. Organ damage was scored according to the SLICC/ACR damage index (SDI). Correlation among these variables was studied by Spearman's rank correlation. **RESULTS:** 230 patients were studied (220 women). The

mean age was 40.0 \pm 12.0 years and SLE duration was 8.9 \pm 7.5 years. 111(48.3%) patients had SLEDAI score of \geq 3. 20(8.7%) patients had mild/moderate flares and 16(7%) patients had severe flares. The mean PGA score was 0.49 \pm 0.71. The mean SDI score was 0.78 \pm 1.2. SLEDAI scores correlated with PGA scores and the severity of disease flares. The mean scores (out of 100) of the 8 domains of the LupusQoL were 73.1 \pm 22(physical health), 67.5 \pm 27(pain), 72.6 \pm 27(planning), 66.8 \pm 33(intimate relationship), 57.3 \pm 29(burden to others), 70.3 \pm 24(emotional health), 64.7 \pm 28(body image) and 61.5 \pm 25(fatigue). The SLEDAI scores correlated inversely with the scores of the physical health($p=0.02$), pain($p=0.009$), planning($p=0.03$), burden to others($p=0.01$) and fatigue($p=0.001$) domains. Patients with recent disease flares had significant lower scores in the pain($p=0.01$), planning($p=0.02$), burden to others($p=0.02$) and fatigue($p=0.02$) domains. Patients with organ damage also had significantly lower scores in the physical health ($p<0.001$), pain($p=0.007$), planning($p=0.001$), intimate relationship($p=0.01$), image($p=0.003$) and fatigue($p=0.05$) domains. **CONCLUSIONS:** The HRQoL of SLE patients as assessed by the LupusQoL is adversely affected by disease activity and organ damage.

303/1610/Children with chronic diseases quality of life and biomedical ethics principles

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AIMS: QOL research reports that children with chronic diseases describe their life as good as other children, as in the intimacy domain. Nevertheless, they also report suffering from injustice, solitude and feel abandoned. The objective of our study was to understand this paradox by questioning whether children life expectancies would not relate to ethical ones. **METHODS:** Analytical process started with literature review in Philosophical (Antiquity to contemporary) and Public Health (1990-2010) domains. Conceptualization and measurement theories of well-being and satisfaction have been also studied for finding underlying theories. Finally, a comparison between these theories was performed to highlight differences, similarities and connexions, for implementing them into children's QOL questionnaires development (KidScreen,VSPA). **RESULTS:** Differences were found between QOL concepts and what aspects are supposed to be assessed. Similar terms are usually used to define different meanings by authors. A restructuring of quality of life concept based on the ethical expectancies of children with chronic diseases is proposed for understanding the paradox, following the four ethical principles described by Beauchamp and Childress: Autonomy, Beneficence, Non-maleficence and Justice. **CONCLUSIONS:** This original approach of the QOL concept based on the international ethical principles might provide health professionals with a different appraisal of this disability paradox, and more generally of perceived health and QOL of these patients. Integrate international ethical principles in assessing QOL opens up new perspectives in patient's care.

304/1728/Families Needs seeking quality of life in children with spinal muscular atrophy

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AIMS: Aimed identifying the needs of families seeking quality of life in children with spinal muscular atrophy(SMA) **METHODS:** Participated in eight families registered by the Brazilian Association of Spinal amyotrophy. Qualitative research had the collection in the period from January to May 2009. We used the semi-structured instrument for collecting data. This was substantiated from the fields and indicators of quality of life of the family proposed by Schallock and Verdugo (2003). The data were analyzed using content analysis of Bardin, emerging categories of leisure deprivation and confinement at home and scarcity of financial resources for the needs of families and children. **RESULTS:** It is observed that families have expenses related to child care (hygiene, food, clothing, sheets and others) and other basic needs of the family, and factors limiting the quality of life because they are deprived of leisure, since majority reported not having any kind of entertainment for the family, only to watch television during the weekend. **CONCLUSIONS:** hus, they become essential urgent measures providing permanent or temporary residential support to children with SMA with the creation of support programs designed to satisfy leisure and break from routine, essential to balance the physical, psychological and social development of families, and support ensure that financial and professional life, transportation, personal trainer for treatment of children finally must seek creative solutions to ensure conditions of well being and quality of life adjusted to needs.

305/1577/Development of a Pediatric Chronic Constipation Symptom Measures: Results of Qualitative Interviews with Children and Their Parents

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AIMS: Chronic constipation (CC) is prevalent in children. Existing measures of pediatric CC symptoms do not meet regulatory requirements for Patient Reported Outcome (PRO) trial endpoints due to lack of patient input. This study's aim was to develop a CC PRO symptom measure based on qualitative interviews with children and parents/caregivers. **METHODS:** Semi-structured concept elicitation interviews were conducted with children diagnosed with CC aged: 6-8 (n=10), 9-11 (n=10) and 12-17 (n=10) years. One parent per child and 20 parents of infants aged 6 months-5 years were also interviewed. Play-doh[®] and drawing activities helped children talk about their bowel habits and related impacts. Thematic analysis was used to identify concepts and evaluate saturation. Age appropriate items and response options developed were reviewed by expert clinicians. **RESULTS:** Bowel movement (BM) symptoms reported included: infrequent BMs ('not pooping'), difficulty defecating ('hard to poop'), straining ('I have to push hard'), rectal pain during a BM ('bottom hurts'), large stools ('big poops'), and a feeling of incomplete evacuation ('it won't come out'). Non-stool/BM symptoms mentioned included: abdominal pain ('tummy hurts'), bloating ('puffy tummy') and 'gas.' For infants, behaviors parents associated with difficulty defecating included: crying, going red in the face, making a strained face, and hiding. Saturation was achieved for the above concepts. **CONCLUSIONS:** Bowel, rectal and abdominal symptoms are important and bothersome to pediatric CC patients and should be included in treatment assessments. These

qualitative interviews were used to develop comprehensive, developmentally appropriate, child self-report and parent/caregiver observation measures of CC symptoms for use in pediatric CC treatment trials. These methods are consistent with scientific standards and regulatory guidelines. The instruments are currently undergoing cognitive testing.

306/1743/Quality of Life of Children with Cerebral Palsy

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AIMS: Aims were evaluate QOL in children with CP treated at the Center for Treatment and Early Stimulation _ NUTEP **METHODS:** Descriptive study, quantitative data is qualitative assessment tools being used for this methodological triangulation. Held in NUTEP, involved children aged 2 to 7 years. The instruments of data collection were: (i) socioeconomic-item (ii) instrument for assessing quality of life related to health (HRQOL) in Brazil validated for use with parents - PedsQL 4.0 and (iii) interview guide. **RESULTS:** As they relate to parents' education, data show that these are predominantly in years 6 to 10 years (40,3%) and mothers devoted more time studying, because most , 34 (54,8%), had more than 10 years of study. Most parents of children with CP, 43 (69,4%), living together. Regarding the occupation of parents of children, the majority of parents were employed, accounting for 82,2% of the sample. The mothers, the majority, 43 (69,4%) are home. Families live with an average income of R\$ 1135.53 with a standard deviation of ± R\$ 735.69. Most of these families had between one and three children (88,7%), living in the homes an average of 4.02 people. With regard to children, the predominant age group was between 2 and 4 years (39, SD = 62,9). Of the children, most are male 35 (56,5%) and 46 (74,2%) have support elsewhere that not only NUTEP. With regard to the preferences of environments, according to parents, has been highlighted to the room (64,5%) and fourth (16,1%), among the reasons, the main thing is to be the environment that has a TV (58,1). **CONCLUSIONS:** Following completion of the transformation of the scores on a scale of 0 to 100 in the questionnaire pediatric PedsQL quality of life, the average was calculated for the different areas, resulting in data, which showed that the field school was the most committed of the study population. A child with a disability has the same needs as any other, it needs to be loved, valued and feel a participant in the family group, so it must be also in constant interaction with society.

307/1402/Undergoing external fixator treatment for lower limb deformities in children and teens: What about quality of life?

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AIMS: External fixator treatment (EFT) of lower limb deformities (LLD) is expected to optimize gait and physical appearance, which might improve a child's quality of life (QOL). Studies exploring EFT have been limited to the psychological effects or the

radiographic changes of this treatment. The purpose of this study was to determine the construct validity and the responsiveness of the Pediatric Quality of Life Inventory (PedsQL) in children and adolescents with lower limb deformities undergoing EFT. **METHODS:** Fifty-two children undergoing EFT of the lower limbs (mean age: 13.0 y, SD: 4.2) who enrolled in a pilot study on the safety and efficacy of botulinum toxin-A were included. QOL was assessed using the child self-report and parent-proxy report formats of the PedsQL at the following time-points of the EFT: baseline, mid-distraction, mid-consolidation, 1-week post-frame removal, and 3-months post-frame removal. Construct validity was assessed using the known group methods, and responsiveness to change was assessed using paired t tests, Cohen's effect size (ES) and standardized response means (SRM). **RESULTS:** Children and parents reported significantly lower QOL scores on all PedsQL domains compared with normative data at baseline. During the EFT, PedsQL scores decreased from baseline to mid-distraction and then gradually increased until 3 months post-frame removal. The largest amount of change was found in the Physical Health Domain of the PedsQL, with worse PedsQL scores a mid-distraction than at baseline ($p < 0.05$). Higher scores were found in the Emotional Functioning score of the child self-report format at 3 months post-frame removal compared to baseline ($p < 0.05$). **CONCLUSIONS:** The PedsQL was able to discriminate the QOL between children with LLD and children from the general population, and responsive to change in children undergoing EFT as shown by patient change over time. Our findings indicate the importance of assessing a wide range of domains including physical, psychosocial, and emotional components of health in this population.

308/1753/Comparative Study of Health-Related Quality of Life of Children and Adolescents with Disabling Neurological Disease

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AIMS: The physical and psychosocial well-being of children and adolescents with Down syndrome (DS), autism, myelomeningocele (MM) and cerebral palsy (CP) is impaired as compared to the healthy population. However the magnitude of the impairment of health-related quality of life (HRQL) among these groups is unknown. This study aimed at evaluating and comparing the HRQL of children and adolescents diagnosed with these diseases from the caregivers' perspective in order to identify the most vulnerable groups. **METHODS:** 170 children and adolescents between 5 and 20 years of age with disabling neurological diseases (25 with DS, 19 with autism, 30 with MM, 96 with CP) were invited to participate. The supervisors provided clinical and demographic information and they filled out the HRQL questionnaire Child Health Questionnaire - Parent Form 50 items (CHQ-PF50). The scores were compared among the groups (Kruskall-Wallis). **RESULTS:** In the physical summary, patients with CP had the lowest scores (32.9) and the DS group had the highest scores (42.9) ($p < 0.05$). According to the psychosocial summary, the scores were lower for individuals with autism (29.0), followed by patients with CP (40.4) and then by MM (45.5) and DS (48.7) ($p < 0.05$) groups. **CONCLUSIONS:** This research found differences in HRQOL impairment among patients with the disabling neurological diseases studied. The autism and cerebral palsy groups were the most vulnerable, therefore, the health care given to individuals in these groups should be more humanized and effective.

309/1747/Do disabling neurological diseases in childhood cause a different impact on the mothers_ quality of life?

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AIMS: Disabling chronic neurological diseases such as cerebral palsy (CP), myelomeningocele (MM), Down syndrome (DS) and autistic disorder (AD) are still prevalent in childhood and limit various aspects of child development. Although there is a major negative impact on the HRQL of the mothers of affected children, so far no comparative studies have been performed to tell whether these diseases compromise the mothers_ HRQL in a different way. The intention of this study is to evaluate the HRQL of mothers of children and adolescents with CP, MM, DS and AD, comparing them to each other and to the group of mothers of healthy children and adolescents. **METHODS:** Questionnaire SF-36 was answered by 345 volunteers, mothers of children/adolescents, aged from 5 to 21 years, 57 of them with a diagnosis of CP, 34 with MM, 23 with DS, 23 with AD, and 208 healthy. The scores were compared among the groups (Kruskall Wallis test). **RESULTS:** Generally, the mothers of children and adolescents with a neurological disease had lower scores than the healthy group ($p < 0.05$). As to the physical component, the scores were similar among the groups of mothers of patients with disabling neurological disease ($p > 0.05$), although all group had lower scores than the controls ($p < 0.05$). In the mental component, only the mothers of the group with AD and DS presented lower medians than the control (AD= 36.9; DS= 42.6; control= 52.5) ($p < 0.05$), but there was no significant difference between the groups with neurological disease ($p > 0.05$). **CONCLUSIONS:** Mothers of children and adolescents with CP, MM, DS and AD presented multidimensional impairment in HRQL, compared to the mothers of healthy children and adolescents, but this negative impact was similar among the groups studied. This result implies the need for greater attention to the physical and mental health of the mothers of patients with disabling neurological diseases, independently of the diagnosis.

310/1501/Cultural adaptation and validation of "Diabetes Quality of Life for Youths"

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AIMS: The goals were to culturally adapt and validate the "Diabetes Quality of Life for Youths" (DQOLY) measure and to analyze the relations among clinical variables, self perceived health status and the scores obtained through adapted DQOLY application. **METHODS:** DQOLY is composed of 53 items arranged by domains: satisfaction, impact, worries. Cultural adaptation process included: translation into Portuguese, back translation, committee review and test-retest. The adapted instrument was applied to 124 type 1 diabetes adolescents in order to assess the psychometric properties (reliability and validity). **RESULTS:** Cultural adaptation originated the Brazilian version, in which, internal consistency (Cronbach's Alpha) scored 0.869 for satisfaction domain, 0.865 for impact, 0.838 for worries and 0.933 for total. The exclusion of three inconsistent items on impact domain generated a 48-item instrument. The test-retest showed no differences between applications of the instrument to the same subject at different times. In the case of content validity, the agreement between the judges was the rule, except when it involved the evaluation of one of them. Convergent validity was demonstrated by positive and significant correlation among the scores and self esteem scale ($p < 0.001$). The factorial validity did not confirm the three domains. In the regard to

instrument scores comparisons among adolescents with and without adequate metabolic control, there were significant differences on impact, worries domains and total ($p < 0.05$), which demonstrated the discriminant validity. The instrument scores were related to socio-demographics and clinical variables. The higher was the number of related hyperglycemia's episodes, the worse is the quality of life ($p < 0.05$) in all domains. Satisfaction domain was negatively correlated to the higher frequency of blood glucose monitoring. All instrument's domains and total had positive and significant correlation with self-perceived health status ($p < 0.001$). **CONCLUSIONS:** This study indicates that Brazilian version of DQOLY is a reliable and valid measure for utilization in our reality.

311/1723/Cross-cultural adaptation and preliminary validation of the Cystic Fibrosis Questionnaire (CFQ) in Spanish language (Child and Parent versions)

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AIMS: The Cystic Fibrosis Questionnaire (CFQ) and its versions for children (CFQ-Child) and parents (CFQ-Parent) is the only disease-specific measure of Health-Related Quality of Life (HRQoL) in children with cystic fibrosis (CF). The aim of this study was to perform a cross-cultural and semantic validation into Spanish Language, equivalent to the original French version, and to explore its psychometric properties. **METHODS:** The French original CFQ (CFQ-Child and CFQ-Parent) of 33 and 45 items respectively was adapted following the methodology of direct and reverse translation. Two initial translations into Spanish Language were made and a first agreed version was obtained from the committee review. Self-rating questionnaires and cognitive interviews were administered to 14 selected 8-13 years old children, diagnosed with CF and their parents. The interviews were recorded and transcribed. After a qualitative analysis of textual data with a panel of researchers, the second version was obtained by consensus. This second agreed questionnaire was administered to another 14 children and their parents. With comments of the children and their parents the third version was developed. **RESULTS:** Most of the items in the two translations of the questionnaires CFQ-Child and CFQ-Parent were equivalent and disagreement solved by discussion and consensus (CFQ-Child, 52% and CFQ-Parent, 73%). Internal consistency of the items analyzed by Cronbach's alpha is, in CFQ-Parent, 0.803 and in CFQ-Child, 0.822. At an exploratory level, given the sample size, these values suggest adequate internal consistency of the questionnaire as an estimation of its reliability. **CONCLUSIONS:** The Spanish version of the pretest CFQ-Child and CFQ-Parent seems semantically and culturally equivalent to the original French version. It has to be translated back and reviewed by the original author in order to obtain the pretest version. The next phase of the study must evaluate its reliability, validity and sensitivity to changes.

312/1607/Sibling Support & Adjustment to Parental Neurological Illness

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AIMS: Research relating to the impact of parental illness on children's well-being has accelerated in recent years. The importance of family characteristics, however, in children's adjustment to their

parent's condition is not always taken into consideration. More specifically, to the best of our knowledge no study has yet focused on the availability of siblings as a factor in adjustment to parental neurological illness. The aim of this study was therefore to assess the importance of sibling support within the family unit on adolescent and adult children's response to parental Parkinson's disease (PD), multiple sclerosis (MS), and stroke. **METHODS:** 168 adolescent and adult children of parents with PD, MS and stroke completed the revised Parental Illness Impact Scale (PIIS-R), a 51 item instrument designed specifically to assess the impact of parental illness, and constructed around a quality of life model. Of the 168 participants, 16 were 'only children'. Comparisons were then made between 'only children' and those with one, two, and three or more siblings. **RESULTS:** Participants without siblings report significantly greater emotional impact, $f(2, 165) = 3.00, p < 0.05$, elevated social impact, $f(2, 165) = 3.60, p < 0.01$, inferior communication and understanding with their affected parent, $f(2, 165) = 4.37, p < 0.01$, and heightened concerns for their personal future, $f(2, 165) = 3.05, p < 0.05$. PIIS-R total scores were also significantly lower for those without the support of siblings, $f(2, 165) = 3.80, p < 0.01$. **CONCLUSIONS:** Results stress the importance of recognising that children without the support of brothers or sisters appear at greater risk of responding negatively to their parent's condition, and this should be considered in the management of family adjustment to the parental condition. Further family structure variables to be assessed could include those from single parent families, and longitudinal study would facilitate investigation of children's response as their parent's condition progresses. Results should be met with caution due to the small number of participants without siblings.