

PIH56

MEASURING QUALITY OF LIFE IN FACIAL AESTHETIC PATIENTS: FIELD-TESTING OF A NEW MODULAR SYSTEM (THE FACE-Q)

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OBJECTIVES: In aesthetic surgery, the assessment of patient-reported outcomes is especially pertinent to clinicians because patient satisfaction and improved quality of life are the predominant considerations determining success. In order to appropriately measure the impact of these procedures, well-developed and validated questionnaires are needed. The objective of this study was to develop a new patient-reported outcome (PRO) measure to evaluate patient satisfaction and quality of life following facial cosmetic procedures (surgical and non-surgical). The main scale: 'Satisfaction with face overall' will be presented. **METHODS:** Field-testing was performed at 3 centers (US and Canada). Preoperative patients were > 18 years and scheduled to undergo a facial cosmetic procedure. Postoperative patients had undergone a facial cosmetic procedure within 2 weeks-5 years. Patients received a questionnaire with standard incentives and reminders. Rasch analysis was used for item reduction and scale development (RUMM2030®), each scale and item were examined according to 7 measurement criteria (clinical meaning, thresholds for item response options, item fit, item locations, DIF, standardized residuals, person separation index). **RESULTS:** A total of 344 facial cosmetic patients (pre procedure n=79, post procedure n=265) participated. Scales were constructed for each area defined as important to patients by the qualitative data. This was achieved by choosing sets of items hypothesized to constitute a scale, analyzing the data against measurement criteria and making decisions on item selection and deletion. The main scale 'Satisfaction with Face Overall' fulfilled Rasch and traditional psychometric criteria (including Person Separation index 0.94; Cronbach's alpha 0.95). **CONCLUSIONS:** The FACE-Q is a new PRO measure that will provide essential information about the impact and effectiveness of surgical and non-surgical facial aesthetic procedures from the patients' perspective. It is conceptually grounded in patient perceptions and fulfills criteria for rigorous measurement. It will support multi-center studies, while also being clinically useful.

PIH57

APPLICATION OF THE BOTHER CONCEPT ACROSS CULTURES

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OBJECTIVES: The objective of this study was to analyze the concept of *bother* as it is used in translated Patient Reported Outcomes (PRO) instruments. In American English, *bother* is versatile as it may connote negative mental, physical, and social conditions. Because of this versatility, the concept may have different meanings across languages and cultures. In observing the term *bother* in PRO instruments, it will be determined whether the concept remains equivalent when translated. **METHODS:** To determine the meaning of *bother* across many languages, linguists, cognitive debriefing interviewers, and cognitive debriefing subjects were asked to complete a questionnaire following the linguistic validation of a psoriasis PRO instrument which contained *bother* as the key concept. Furthermore, all instances of *bother* as it appeared in back-translated instruments and cognitive debriefing reports were analyzed. **RESULTS:** By analyzing questionnaires completed by respondents, we identified many instances where *bother* was described as an ambiguous concept. An analysis of back-translations showed that the term was changed 55% of the time and the concept was back-translated as something conceptually different 20% of the time. During cognitive debriefing, 16% of subjects paraphrased *bother* incorrectly, while several suggested the removal or replacement of *bother*. **CONCLUSIONS:** When developing PRO instruments, consideration should be given to the equivalency of key concepts across different languages and cultures if they are to be useful in multinational clinical trials. In this study we discovered that while respondents understood *bother* to have a negative connotation, data across languages shows a lack of conceptual equivalency. As a result, *bother* may not be the most ideal measurement of disease symptom severity and quality of life. Therefore, in the development of PRO instruments, ambiguous concepts such as *bother* ought to be replaced with more specific concepts to measure many components of one's quality of life.

PIH58

MOBILE PHONE USE IN PATIENT REPORTED OUTCOMES - ACADEMIA AND BEYOND

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OBJECTIVES: To demonstrate that mobile phones can be used to collect patient reported outcomes. **METHODS:** A literature search was conducted looking at articles published between 2009 and 2011 that referenced electronic diaries of some description. These were then filtered to pull out those that referenced mobile or cellular phones. **RESULTS:** Ninety articles were found that reference electronic diaries specifically. Out of these, 8 articles specifically referenced mobile/cellular phones. The studies referenced in these articles were carried out on populations with an age range of 9 years up to 70 (reported mean 21.8; SD - TBD). The studies were split into 6 therapy areas; physical activity, weight management, sexual activity, asthma, alcohol related and pain, and all but one of the studies included both males and females, with the other being female only. Population size ranged from 15 to 994 (mean 249.8; SD-TBD), in the USA, Europe, Australasia and Asia, and subjects reported for a minimum of 7 days (but up to 6 reports per day) to a maximum of 365 days (mean 110.4 days; SD-TBD). Pain data were only collected in one study; momentary reporting occurred in half of the studies and subject preferences

were collected in three studies. Compliance was reported to have been collected in four of the studies and 3 studies reported giving the subjects training. Notably, 5 out of the 8 studies allowed the subjects to use their own mobile phone for the reporting. **CONCLUSIONS:** All of the articles concluded that mobile phones were suited to collect data from subjects, especially momentary reporting. It was noted that the use of mobiles was acceptable to the populations as they used them in everyday life and found then to be convenient, and the researchers found the technology to be inexpensive to implement.

PIH59

PATIENT-REPORTED OUTCOMES: THE GROUNDED ITEM TECHNIQUE FOR GENERATING CONTENT VALID QUESTIONS

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OBJECTIVES: Qualitative research methods have become increasingly important to Patient Reported Outcome (PRO) measure developers since the emphasis on content validity in the Food and Drug Administration's guidance for the development of PROs. The Critical Incident Technique (CIT) is a rigorous data collection protocol to provide empirically-derived data on human behavior. More than 130 research studies employing the CIT have been published in the medical and health services research literature alone (according to PubMed indexing for 2002-2011). We describe here our work building on the CIT to develop a rigorous method for generating content-valid items for patient-reported measures which we call the Grounded Item Technique. **METHODS:** The CIT was not developed to generate items. Its most common use is to develop conceptual frameworks or taxonomies in conjunction with Grounded Theory (Glaser & Strauss, 1967) data analysis. By contrast, the Grounded Item Technique (GIT) is specifically focused on item generation. We developed a five-phase process for the GIT including the development of the interview protocol, conduct of interviews, abstraction of incidents from interviews, abstraction of items from incidents, and documentation of content validity. In this presentation we detail that process and illustrate it using two case studies from our actual measure development projects. **RESULTS:** We were able to use the GIT procedure to fill important gaps in the measurement provided by an established tool while at the same time supporting the content validity of that tool. We successfully applied the GIT to generate content-valid PRO items for a rare condition affecting an underserved population. Field testing showed these items to be highly sensitive to health differences. **CONCLUSIONS:** These case studies suggest that we have successfully adapted the CIT protocol for use in generating content-valid patient-reported health items. With this presentation, we hope to stimulate other investigators to use the Grounded Item Technique in PRO-item generation.

PIH60

SPEAKING OF PROS: TOWARDS FINDING A COMMON PROSE FOR IMPROVING COMMUNICATION ABOUT HEALTH-RELATED QUALITY OF LIFE CONCEPTS

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OBJECTIVES: The lack of a common terminology for naming concepts at the family and sub-family levels has increased the reluctance of various stakeholders to accept the use of PROs for decision-making, such as in an FDA label claim. This research examines the conceptual content of selected PRO instruments, identifies similarities and differences across instruments, and explores the extent to which the availability of a classification system or taxonomy of concepts might bring standardization to the field and thus improve communication. **METHODS:** The structure and conceptual content of items in existing instruments is evaluated using a grammar-like decomposition of each item along with the item- or domain-level concept assigned by the instrument developer. Item-level concepts are also assigned a classification code using the WHO International Classification of Functioning, Disability and Health (ICF). This code identifies a concept by its major component, a high-level concept of function, disability, or environmental factors, and by its lower-levels, as appropriate. **RESULTS:** Approximately 650 items from 25 disease-specific and generic instruments were evaluated according to the grammar and the ICF. Grouping the items by ICF codes indicated a wider range of concept names assigned by the developers than by the classification system. For example, the 21 items classifiable in the Ingestion Functions of the ICF Functions Related to the Digestive System Category were assigned either to this group level or to three sub-level categories. The instrument developers assigned these same 21 items to 7 different concepts. This same pattern of greater diversity of concepts assigned by developers than by the ICF was observed for other WHO categories. **CONCLUSIONS:** Instrument developers assigned diverse concept names to represent items that assess similar areas of functioning. The analysis suggests directions for future development of a taxonomy appropriate for classifying health-related concepts used for making statements about treatment benefit.

PIH61

BURDEN OF DISEASE IN PATIENTS WITH MENOPAUSE IN BRAZIL: RESULTS FROM 2011 NATIONAL HEALTH AND WELLNESS SURVEY (NHWS)

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OBJECTIVES: Brazil is said to be the fifth most populous nation worldwide, with slightly more than one-half of Brazilian adults being women. The number of women experiencing menopause is expected to rise as population of Brazil ages and people live longer. This study is aimed to assess co-morbidity, quality of life (QOL), work/productivity loss, and medical resource utilization in patients with

menopause symptoms in Brazil. **METHODS:** A total of 12,000 individuals' (age 18+) self-reported data were collected from 2011 National Health and Wellness Survey (NHWS) in Brazil. QOL was measured by the physical component score (PCS) and mental component score (MCS) of the Short Form-12 (SF-12) (mean score of 47.2 for general population). Loss of work/productivity was measured by the validated Work Productivity and Activity Impairment instrument. Medical resource utilization was measured by healthcare provider, emergency room visits and hospitalization in the past 6 months. **RESULTS:** Among all women, 825 (13.8%) had completed menopause and 1,016 (20.8%) were currently experiencing symptoms of menopause. Average age for women currently experiencing symptoms of menopause was 49.6 years. Compared to the non-menopause group, those experiencing symptoms reported more co-morbidities (sleep difficulties 35%, insomnia 33%, depression 29%, high blood pressure 25%, high cholesterol 22%, arrhythmia/cardiac arrhythmia 17%), lower mean PCS scores (47.3 vs. 50.3), more patients visited general practitioners (56% vs. 49%), and higher mean number of visits (5.9 vs. 5.1) were observed over the past 6 months. Furthermore, those experiencing menopause symptoms reported greater impairment in daily activity (28%) compared to the non-menopause group (22.7%). All comparisons were statistically significant at $p < 0.05$. **CONCLUSIONS:** Results from the Brazil NHWS indicate women currently experiencing symptoms of menopause suffer from impairment in QOL, work/productivity loss, greater usage of healthcare resources and more co-morbidities. Findings indicate there is still an unmet medical need in menopause patients in Brazil.

PIH62

OVER-THE-COUNTER MEDICATION USE AND ITS IMPACT ON QUALITY OF LIFE OF THE ELDERLY

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OBJECTIVES: Use/misuse of over-the-counter (OTC) medications may cause adverse drug events (ADEs), more so ever in the elderly population. The study evaluated the direct and indirect effects of OTC medication use/misuse and associated ADEs on Health related quality of life (HRQoL) in elderly using a Structural Equation Modeling (SEM) approach. **METHODS:** A cross-sectional study was conducted using retrospective data, collected from elderly patients in Houston, Texas. Cronbach's' alpha and principal factor analysis was used to evaluate internal consistency and factor validity, respectively, for HRQoL (measured using SF-12 version 2) in terms of physical component summary score (PCS) and mental component summary score (MCS). SEM was used to simultaneously evaluate the effect of OTC medication use and misuse on associated ADEs and the effect of OTC medication misuse and associated ADEs on HRQoL. **RESULTS:** Of the 153 respondents, 17.8% misused OTC medications and 22.9% experienced ADE due to OTC medications. The SEM best fit model indicated that OTC medication misuse, rather than use, was a significant predictor of experiencing an ADE ($\beta = 0.2$, $p < 0.05$). While OTC medication misuse was not a direct predictor of HRQoL, ADEs associated with OTC medication misuse were responsible for decrease in PCS ($\beta = -3.8$, $p < 0.01$) and MCS ($\beta = -3$, $p < 0.05$). **CONCLUSIONS:** Misuse of OTC medications leads to ADEs. ADEs arising due to OTC medication misuse have the potential to reduce patients' HRQoL. Understanding which OTC medications lead to ADEs and reduction in HRQoL would help improve patient's health.

PIH63

HEALTH RELATED QUALITY OF LIFE TRAJECTORIES AMONG GENERAL POPULATION IN THE STATE OF PENANG, MALAYSIA USING SF-36V2 HEALTH SURVEY

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OBJECTIVES: To describe the quality of life of general population in state of Penang, using SF-36v2 Health Survey. **METHODS:** A cross-sectional study was carried out among 398 residents randomly selected from 10 grids in Penang Island during January 2011 using the official translation of SF-36v2 Health Survey questionnaire in Malay, Mandarin, Tamil and English. SF-36v2 questionnaire consists of eight domains: Physical functioning (PF, 10 items), role-physical (RP, 4 items), role-emotion (RE, 3 items), bodily pain (BP, 2 items), vitality (VT, 4 items), social functioning (SF, 2 items), general health (GH, 5 items) and mental health (MH, 5 items). PF, RP, BP and GH domains reflect physical health whereas VT, SF, RE and MH reveal mental well being. Scoring of questionnaire was done by Scoring software version 4 for SF-36v2. Each domain is scored from 0-100 with higher scores indicating better or good health. Study subjects were also interviewed for socio-demographic information (age, sex, ethnicity, educational level, employment status, monthly income). Respondents having any illness at the time of survey, age less than 18 years and with no formal education were excluded from study. **RESULTS:** Mean (\pm SD) scores for PF, RP, BP, GH, VT, SF, RE and MH were 81.8(\pm 20.6), 79.5 (\pm 21.9), 75.3 (\pm 21.3), 65.6 (\pm 16.0), 64.3 (\pm 20.9), 75.0 (\pm 20.4), 73.3 (\pm 24.7) and 73.0 (\pm 17.1), respectively. These benchmarks are different from those reported for SF-36v1 Health Survey for Malaysian population in 2003. Likewise, these mean scores for SF-36v2 Health Survey are also different from 1998 US general population norms. **CONCLUSIONS:** Since means scores for SF-36v2 health survey were not available for Malaysian population, therefore these findings can serve as a baseline for comparisons in future surveys looking at HRQoL in general and diseased population. However there is need for future studies with a larger sample size representing whole Malaysia.

PIH64

BURDEN OF 100 DISEASES WITHIN GENERAL PRACTICE: RESULTS OF THE EPI3 PROGRAM

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OBJECTIVES: The EPI3 program aims at evaluating the burden of diseases and quality of life (QOL) of patients seeking care for a large variety of conditions within general practice **METHODS:** GPS included 8559 patients attending the practices. Data on QOL (12-Item Short Form questionnaire) and other individual characteristics were documented by the independent investigators for all participants at the waiting room. Medical information was recorded by GPs. Sampling was calibrated to national standards using the CALMAR weighting procedure. Associations of lower scores (i.e., below vs. above the first quartile) of physical and mental component scores (PCS and MCS) with main diseases and patients characteristics were estimated by multivariate logistic regression. Weighted morbidity rates, PCS and MCS were computed for 100 diagnoses using the international classification of diseases (ICD-9, 9th version). **RESULTS:** Overall mental impairment was observed amongst patients in primary care with an average MCS of 41.5 (SD = 8.6), ranging from 33.0 for depressive disorders to 45.3 for patients exhibiting fractures or sprains. Musculoskeletal diseases were found to have the most pronounced effect on impaired physical health [OR=2.31; 95% CI (2.08-2.57)] with the lowest PCS: 45.6 (SD = 8.8) and ranked first (29.0%) amongst main diagnoses experienced by patients followed by cardiovascular diseases (26.7%), and psychological disorders (22.0%). When combining both prevalence and QOL, musculoskeletal diseases represented the heaviest burden in general practice. **CONCLUSIONS:** Although social and medical determinants of patients' QOL were somewhat similar than those found in previous studies in primary care, the EPI3 program showed more pronounced mental impairment in French patients. This is the first study to provide reference figures for burden of disease in general practice across a wide range of morbidities, particularly valuable for health economics and health care system evaluation.

PIH65

PSYCHOMETRIC VALIDATION OF THE TUMMY TUCK QUESTIONNAIRE

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OBJECTIVES: Patient satisfaction and improved quality of life (QOL) are important considerations determining success in cosmetic surgery. For patients with unwanted skin and excess tissue in their abdomen, abdominoplasty is a viable solution to improve QOL in patients. The objective was to assess the psychometric properties of a new 14-item abdominoplasty measure, the Tummy Tuck Questionnaire (TTQ) which was developed following FDA Guidance to Industry on Patient-Reported Outcomes. **METHODS:** A prospective, controlled, randomized study of 40 patients was conducted to compare the efficacy and safety of ARTISS to standard care in adhering tissue flaps in patients undergoing standard abdominoplasty. Subjects were administered the TTQ at Day 1 post-abdominoplasty surgery and up to 90 days after. The TTQ contains 19 items encompassing four domains: symptoms, physical impact, emotional impact, and satisfaction. Psychometric measurement properties were assessed for construct validity, internal consistency reliability, clinical validity, and responsiveness. **RESULTS:** Thirty-nine subjects participated in this psychometric evaluation (mean age=43.25; female 97.5%). Upon removal of several items, the domains of the TTQ demonstrated acceptable internal consistency (range 0.68 to 0.84). Floor effects were present by Day 3 (postop) on the TTQ Symptoms and Physical Impacts scales and ceiling effects found at Day 3 (postop) on the TTQ Satisfaction. Moderate to high correlations were observed on the QoR-40 Physical, Emotional scales as well as the Numbness and Pain VAS with the TTQ, supporting strong concurrent validity. Clinical validity was observed for patients experiencing hematomas/seromas. By Day 90, subjects in the "Hematoma or Seroma absent" group, on average, had lower scores on the TTQ than subjects in the group experiencing this condition, however this result was not statistically significant. Overall, TTQ was most sensitive to change in the initial days post-surgery. **CONCLUSIONS:** The TTQ demonstrated acceptable reliability and validity and ability to detect change over time.

PIH66

DO WE NEED A GENDER-SPECIFIC HEALTH RELATED QUALITY OF LIFE -COMORBIDITY INDEX?

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OBJECTIVES: Recently, a health related quality of life comorbidity index (HRQoL-CI) was developed to risk adjust SF-12 Physical Component Score (PCS) and Mental Component Score (MCS). HRQoL-CI, however, does not include gender-specific diseases. This study aimed to evaluate the performance of existing HRQoL-CI across gender and if required, revise HRQoL-CI with gender-specific measures. **METHODS:** Using Medical expenditure Panel Survey (MEPS) 2003, the performance of HRQoL-CI was assessed in overall population, and in population stratified by gender, for adults ≥ 18 years of age. All the analysis was done using cluster-specific Self-administered Questionnaire weights. The Least Square Absolute Shrinkage and Selection Operator (LASSO), with a partition fraction of 0.25, was used to identify best gender-specific predictors for PCS and MCS. Results compared using graphical di-