underwent breast reduction (5 PRINEO* and 5 SOC). Data were collected for surgery through post-op care. Data Observation Forms were designed based on information obtained from staff interviews. Activities were observed for which differences in time and supplies between PRINEO* and SOC were expected: incision closure, dressing application, and dressing changes. **RESULTS:** In Germany, average time for skin layer closure was 3.47 min with PRINEO* vs. 16.67 min for SOC. Average wound length was 57 cm vs. 54 cm, respectively, translating into higher speed of closure with PRINEO* (16.50 cm/min) compared to SOC (3.22 cm/min). Overall time for wound closure was similar in both arms due to increased time for dermal layer closure with PRINEO* (42 min). In the Netherlands, average time for skin layer closure was 1.57 min for PRINEO* vs. 15.83 min for SOC. Average wound length was 48 cm vs. 49 cm, respectively, translating into a speed of closure with PRINEO* of 30.74 cm/min compared to 3.11 cm/min with SOC. Time for dermal and skin layer closure combined was lower for PRINEO* (13.47 min vs. 29.93 min). For dressing application and post-op dressing changes, SOC required on average 18.28 min in Germany and 3.95 min in the Netherlands. Additionally, the use of 1.2 PRINEO* units on average resulted in the elimination of sutures and dressings in both centres. **CONCLUSIONS:** In one German and Dutch centre, the use of PRINEO* lead to increased skin closure speed and avoided time and supplies associated with dressing application and changes, at the expense of an average 1.2 PRINEO* units.

INDIVIDUAL'S HEALTH – Patient-Reported Outcomes Studies

PIH26

TREATMENT DURATION AND PRESCRIPTION REFILL RATE FOR VAGINAL ESTROGEN THERAPY IN MEDICAID ENROLLED WOMEN WITH ATROPHIC VAGINITIS

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OBJECTIVES: Among the two most frequently prescribed forms of vaginal estrogen (VE), acceptability of tablets has been shown to be greater than creams in clinical trials. However, creams are more often prescribed. This study examines the association between form of VE and initial prescription refill rate and treatment duration among Medicaid enrollees. **METHODS:** A retrospective cohort study was conducted using North Carolina Medicaid claims January 2003 to December 2007 of women ages 18–64 with a new VE prescription claim. Multiple logistic regression was performed to assess the association of VE form and initial prescription refill among women with 1 year post-index continuous enrollment; OLS regression was used to assess treatment duration over 2 years follow-up. Demographic factors included age and race. Additional covariates: Charlson-Deyo comorbidity index, number of outpatient visits, mammography, and systemic estrogen use in the pretreatment year, and index year. **RESULTS:** A total of 1812 patients prescribed VE (mean age 49.4 ± 10.5, 30.9% black) having 1 year follow-up were identified; 465 women had 2 years follow-up. 89.6% received cream; 10.4% tablets. Initial prescription refill rate was 48.7% for tablets, 33.7% for cream ($p < 0.001$). Average treatment duration among women with 1+ refill and 2 years follow-up was longer for tablets than cream (291.7 ± 214.3 days versus 281.8 ± 226.3; $p = 0.745$). Tablet users were significantly more likely to refill their initial prescription (OR 1.88, 95%CI = 1.38–2.56). OLS regression results showed no significant difference in treatment duration for tablets vs. cream (beta = 17.53, 95%CI = −42.56–77.62). **CONCLUSIONS:** This analysis of Medicaid claims showed tablet users were significantly more likely to refill their initial prescription than cream users. During 2 years of follow-up, treatment duration among those who refilled at least once was longer for tablet users, although not significant. These results give some real world support for women's greater acceptability of vaginal tablets to creams.

PIH27

HEALTH RELATED QUALITY OF LIFE AND UTILITY SCORES IN MENOPAUSAL WOMEN

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OBJECTIVES: A study was performed to determine quality of life (QoL) and utility scores associated with 3 stages of menopause: pre-menopause, perimenopause and post-menopause. **METHODS:** A cross-sectional study was conducted in Canada to determine the quality of life and utility scores associated with each stage of menopause as listed above. Women age 48–54 were recruited through primary care practices. The Menopause-Specific Quality of Life Questionnaire (MENQOL), a non-preference-based QoL measure, included 29 items from 4 domains. Two preference-based tools were applied: Health Utilities Index Mark-3 (HUI-3) with 8 domains as an indirect measure of utility and a visual analogue scale (VAS) as a direct measure of disutility for menopausal symptoms. Mean and standard deviations (SD) were reported. Spearman's-rho test was applied for correlation between the various tools. Multiple regression analyses were performed to assess if demographic characteristics predicted scores on any of the measures, including individual MENQOL symptom scores. **RESULTS:** A total of 403 female subjects were recruited from 11 primary care practices in 4 provinces; 60% were employed and 63% had completed college. The mean MENQOL symptom scores ranged 3.1(SD = 2.0) to 3.4(SD = 2.1) out of 8. Specific MENQOL scores ranged 2.1–2.7, 3.0–3.6 and 3.4–3.9 for pre-, peri- and post-menopause respectively. HUI-3 scores were 0.83, 0.78 and 0.74 for the same sequence [overall 0.77 (SD = 0.25)], and disutility scores with the VAS were 0.22, 0.37 and 0.37. The MENQOL vasomotor, psychological, physical and sexual domain scores correlated significantly with both VAS and HUI-3 scores ($p < 0.001$). Some demographic variables were associated with certain domains of the MENQOL or the HUI-3; however, no significant associations were noted for age or education. Significant differences existed in utility scores between pre- and post-menopause. **CONCLUSIONS:** Of the three menopause subgroups investigated, the pre-menopause group was associated with the best QoL; QoL did not differ significantly between peri- and post-menopause.

PIH28

VALIDATION OF THE SF-36 IN PATIENTS WITH ENDOMETRIOSIS

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OBJECTIVES: Endometriosis is a common, chronic gynaecological disease among women of reproductive age. Understanding treatment effects for endometriosis is critical for benefitting the health of women with this condition. The SF-36 has utility for understanding this condition because of some of its subscale focus (pain) and its ability to compare across diseases and populations. The SF-36 is one of the most common health measures used in studies of endometriosis; however, it has not been validated for this disease. The goal of this study was to assess validity of the SF-36 for endometriosis. **METHODS:** Using data from two clinical trials (N = 252 & 198) of treatment for endometriosis, a full complement of psychometric analyses was performed. Additional instruments included a pelvic pain VAS and a clinical global impression of change (CGI-C). Analyses were conducted using Stata 10.1 and Mplus 5.1. **RESULTS:** Factor analyses confirmed the standard 8-subscale and 2-component factor structure of the SF-36 (CFI = 0.94 and 0.93 for the two trials). The Bodily Pain (BP) subscale and the PCS were both moderately correlated with the pain VAS at baseline and over time ($r = -0.37$ to -0.62; $p < 0.001$). Change in BP and PCS correlated with the CGI-C ($r = -0.30$ & -0.43; $p < 0.001$): those who had the greatest change in BP and PCS also reported the greatest change on CGI-C. Other subscales (Role Physical, General Health, Vitality, Social Functioning) showed smaller correlations with change in the pain VAS and CGI-C. **CONCLUSIONS:** The SF-36 –particularly BP and the PCS—is sensitive to differences in patient pain and change in pain experience in endometriosis. The BP subscale and the PCS were dimensions of the SF-36 that showed consistent sensitivity to pain differences and change; however, other SF-36 subscales were significantly, but less strongly, related to differences in severity and changes in pain.

PIH29

VALIDATION AND CROSS-NATIONAL EQUIVALENCE OF THE EYELASH SATISFACTION QUESTIONNAIRE

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OBJECTIVES: The Eyelash Satisfaction Questionnaire (ESQ) has demonstrated its validity among adults in the US, but cross-national equivalence has not been documented. This study was conducted to examine the face and content validity and psychometric properties of the ESQ in an English speaking country in Europe, as well as to determine the cross-national equivalence. **METHODS:** Two focus groups ($n = 16$) were conducted in the UK to examine the validity of the conceptual framework, as well as face and content validity, of the ESQ. Classical Test Theory (CTT) and latent variable modeling techniques were performed using data collected from the web survey in the UK. Confirmatory Factor Analysis (CFA), Multiple Group Structural Equation Modeling (MG-SEM), and Differential Item Functioning (DIF) were performed to examine the accuracy and stability of the three domains between US ($n = 909$) and UK samples ($n = 605$). **RESULTS:** Qualitative analysis of the focus group discussions supported the face and content validity of the ESQ and indicated that the conceptual framework established in the UK was similar to the framework established in the US. Internal consistency was found to be high across all three domains (Cronbach's α = 0.90, 0.91, 0.77) and item-to-domain correlations were high (0.55–0.84). The factor structure found in the original survey fit the data well with factor loadings ranging from 0.64 to 93. Measurement invariance models provided good fit to the data (*NNFI* = 0.97, *RMSEA* = 0.04). No significant DIF was found between the two samples (p's > 0.05) and effect sizes of the differences were small (Cohen's d's < 0.10). **CONCLUSIONS:** The current research findings suggest that the ESQ has appropriate face and content validity and psychometric properties for use in the UK. It also provides support for the cross-national equivalence of the ESQ.

PIH30

SYMPTOMS AND IMPACT OF PREMENSTRUAL DYSPHORIC DISORDER (PMDD): CONCEPTS AND MEASUREMENT

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OBJECTIVES: To investigate the symptoms and impact associated with premenstrual dysphoric disorder (PMDD), and the appropriateness of the patient-reported Daily Record of Severity of Problems (DRSP) as an instrument to assess PMDD. **METHODS:** A review of 47 published peer-review articles and conference presentations was conducted to aid the development of a PMDD conceptual model. The content of the DRSP was then compared to the conceptual model to assess face and content validity. The

DRSP's reliability and responsiveness was also assessed. **RESULTS:** Studies showed women with PMDD experience severe physical and emotional symptoms at the luteal stage of the menstrual cycle (five days before menses), primarily as a result of hormonal fluctuations associated with ovulation. Physical symptoms include: aches/pains; breast tenderness/swelling; bloating; weight gain; increased appetite/cravings; sleep problems; fatigue and difficulties concentrating. Emotional symptoms include: mood swings; depressed mood; anxiety/tension; anger; irritability; decreased interest; and feelings of being overwhelmed. The experience of these symptoms contributes to functional impairment in women with PMDD, particularly in terms of: social functioning; work/school functioning; productivity; role functioning; relationships; and activities of daily living. A review of DRSP item content revealed all symptoms and impacts of PMDD are captured by the DRSP, supporting the face and content validity of the instrument. Studies also showed the DRSP to have acceptable internal consistency (Chronbach's alpha ≥0.7), test-retest reliability (ICC correlations 0.67–0.99) and responsiveness to improvements following treatment (effect sizes 0.64 –1.71). **CONCLUSIONS:** PMDD is associated with physical and emotional symptoms which can have a significant impact on patients' lives. The DRSP is a valid, reliable and responsive patient-reported tool for assessing PMDD-related symptoms and their impact. The DRSP could be useful for clinicians during general practice, or for clinical trials in identifying PMDD populations or the impact during treatment.

PIH32

WOMEN'S PREFERENCES FOR OVARIAN STIMULATING HORMONES IN THE TREATMENT OF INFERTILITY

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OBJECTIVES: Little is known about preferences for technological developments of women undergoing fertility treatments. This study aims to investigate the preferences for ovarian stimulating hormone (OSH) therapies of infertile women undergoing assisted reproduction, to determine the utility values ascribed to different attributes of OSH treatments, and to estimate women's willingness to pay (WTP) for OSH. **METHODS:** A representative sample of ambulatory patients ready to receive, or receiving, OSH therapies for infertility were recruited from seven specialized private centers in six Autonomous Communities in Spain. Both WTP and conjoint analysis (CA) were used to elicit preferences. Attributes and levels of OSH treatments were identified by literature review and two focus groups with experts and patients. WTP valuations were derived by double-bounded (closed-ended) and contingent ranking methods. **RESULTS:** 167 patients [mean age: 36 years (SD 4.2)] were interviewed. Most participants (53.9%) had a high education level (university degree), were married (77.2%), referred an estimated net income beyond €1500 per month (50.9%) and had paid between €501 and €1500 for their most recent hormonal treatment (57.6%). In 52% of cases, there was more than one cause of infertility (sperm related factors, 31%). Maximum WTP for an OSH treatment was €800 (median) per cycle, which exceeds previously reported cost per OSH cycle with combo therapies (€691.65), while 75% would pay €1500 or less. 56.8% were willing to pay additional €51–300 for a 1–2% effectiveness gain. Utility values (CA) showed that effectiveness (37.0) was the most valued attribute (costs 24.9; safety 16.5; information sharing with physicians 13.5). Cost of last OSH cycle and WTP shown positive correlation ($r = 0.203$, $p < 0.05$). **CONCLUSIONS:** WTP for OSH therapies exceeds current cost. Additional WTP exists for 1–2% effectiveness improvement. Effectiveness and costs were the most important determinants of preferences, followed by safety and information sharing with physicians.

PIH33

DRUG USE BEFORE AND DURING PREGNANCY IN REPUBLIC OF SERBIA

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OBJECTIVES: To investigate drug use six months before (SMBP) and during pregnancy (DP) among Serbian pregnant women (SPW). **METHODS:** Pharmacy based cross-sectional survey was conducted among SPW between March through April 2009. Specially designed questionnaire was used for collecting data on socio-demographics, health status, and drug (Rx and over the counter) use. Vitamin and iron supplements were not included in the analysis. **RESULTS:** 260 SPW completed the questionnaire. 69.6% of SPW were 25–34 years old, 75.8% lived in the city area, the majority were high school or college graduates, and 55.4% were pregnant with their first child. 9.4% of SPW had a chronic disease. There was not a statistically significant decrease in the percentage of SPW taking drugs DP compared to SMBP (53.9% and 53.0%, respectively), as well as in an average number of drugs taken (1.54 ± 0.73 and 1.45 ± 0.66 drugs/women, respectively (range 1 to 4 before and during pregnancy)). The most frequently used drug classes by SPW were: analgetics/antipyretics, hormones, antiinfectives, tocolitics and anti-hypertensives (25.5%, 25.5%, 19.7%, 13.7%, and 7.3%, respectively). The most frequently used analgetic/antipyretic was paracetamol (62.83%), while the most frequently used anti-infectives were penicillins and cephalosporins (77.0%). The only used tocolitics were fenoterol and hexoprenaline and the only used hormones were dydrogesterone and progesterone. Drugs that were used belonged to these FDA fetal risk categories B, C, and D (diazepam, alprazolam and diclofenac in the 3rd trimester) (52.6%, 26.3%, and 15.8% respectively). SPW did not use drugs in the FDA category X. Before pregnancy folic acid usage was low (5.5% PW) while during the 1st, 2nd and 3rd trimester of pregnancy usage was 69.96%, 15.05%, 5.93%, respectively. **CONCLUSIONS:** Differences in drug use DP and SMBP among SPW was negligible. The most frequently used drug classes during pregnancy were: analgetics/antipyretics, hormones, antiinfectives, tocolitics and antihypertensives.

PIH35

THE APPLICATIONS OF GEOGRAPHIC INFORMATION SYSTEM TO QUALITY OF LIFE STUDIES: USING TAIWAN AS AN EXAMPLE

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OBJECTIVES: The comparison among diverse regions and populations is one of the important issues on the study of quality of life (QoL). This study demonstrated that how Geographic Information System (GIS) can help us on the study of QoL. By mapping the QoL scores and objective QoL-related data on regional maps, GIS help us to interpret the QoL data more intensively. **METHODS:** The QoL data was collected from the 2001 National Health Interview Survey (NHIS) in Taiwan. 13,010 participants were randomly selected to complete the WHOQOL-BREF (Taiwan version). Mean scores of the four QoL domains were used for each of the 25 administrative divisions. This study also collected 41 objective QoL-related variables for each of the divisions from the 2001 National Statistics. The variables include the facets of demography, public security, medical resource, welfare, level of education, occupation structure, financial state, and environment. All variables were illustrated on the map of Taiwan by GIS with gradient colors. The correlation coefficients between QoL domain scores and these objective variables were also calculated. **RESULTS:** Based on the correlation coefficients, no significant correlation was found between psychological domain score and the objective variables. Four, three, and eleven variables were statistically correlated with physical, social, and environmental domain scores respectively. In comparisons of the GIS maps between QoL and the objective variables, interpretation on the QoL distribution became easier. In general, QoL decreased from northwest to southeast. The significant correlation coefficients indicated that financial state, occupation structure and level of education were comparatively related to QoL which were confirmed by the GIS maps. **CONCLUSIONS:** In this study, we demonstrate the GIS technology can be an assistant to study the regional distribution of QoL. Moreover, objective QoL-related variables can be combined to interpret the QoL distribution intensively. This approach may be beneficial for policy making.

PIH36

DETERMINANTS OF HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN POSTMENOPAUSAL WOMEN ENROLLED IN POSSIBLE EU®

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OBJECTIVES: POSSIBLE EU® is an ongoing, prospective observational study exploring the experience of postmenopausal women receiving bone loss medications in Europe. We previously reported that these women had substantially impaired HRQoL. This baseline analysis identifies potential important predictors of HRQoL in these women. **METHODS:** A total of 3402 women were enrolled in 3 treatment cohorts: established (treated ≥1 year), inception (initiating) or switching treatment. Clinical data and HRQoL (including EQ-5D) were collected at baseline (N = 3011). A multivariable analysis model was fitted to identify determinants of EQ-5D score. The linear relationship of each variable was assessed using a forward selection process (entry level 0.05). The non-linear relationship of the selected variables with the outcome, were assessed using natural logarithmic and cubic spline transformations Analyses were performed using SAS software, version 9.1 and GNU R. **RESULTS:** For the full analysis set, median age (Q1, Q3) was 69 (61, 76) years; women had a median of 3 ongoing comorbid conditions at baseline. A high proportion of patients had hypertension (44%), ongoing back pain (41%), osteoarthritis (34%) hyperlipidaemia (32%), ongoing upper GI issues (18%), prior vertebral fractures (13%), and depression (13%). For the 3011 patients, 12 variables were significantly associated with EQ-5D score, explaining 39.4% of the residual variance (Table). **CONCLUSIONS:** In European women who are receiving/initiating bone loss medication, any prior vertebral fracture, ongoing depression, fear of falling, number of ongoing comorbid conditions, upper GI issues and back pain are prevalent, and strongly predictive, of lower HRQoL. Table: Determinants of EQ-5D utility [0 to 1 continuous score]: The effects are Intercept: 0.1801, –0.1083, 0.486, 0.2195; Inception vs. Established*: –0.04862, –0.06822, 0.02903, <.0001; Switch vs. Established*: –0.01271, –0.03901, 0.01360, 0.3435; Lack of fear of falling: 0.00545, 0.005092, 0.005808, <.0001; Ongoing depression: –0.1076, –0.1345, –0.08076, <.0001; Any prior vertebral fractures: –0.09239, –0.1225, –0.06223, <.0001; Number of ongoing comorbid conditions: –0.01122, –0.01773, –0.00471, 0.0007; Ongoing upper GI (GERD, reflux, dyspepsia): –0.04067, –0.06549, –0.01586, 0.013; Ongoing back pain: –0.03455, –0.05594, –0.01316, 0.0016; BMI: –0.00298, –0.0049, –0.00105, 0.0024; Ongoing seizure