

OBJECTIVES: No head-to-head clinical trial has compared the efficacy of adalimumab versus etanercept as first-line therapy for patients with psoriatic arthritis (PsA). To bridge this gap, we implemented a matching-adjusted indirect comparison of adalimumab versus etanercept for PsA. **METHODS:** Using methodology developed by Signorovitch, patient-level data from the adalimumab randomized controlled trial (RCT) ADEPT were reweighted to match baseline characteristics from the pivotal published etanercept RCT. ADEPT patients were reweighted by their odds of enrollment in the etanercept trial, estimated using logistic regression model. Matched characteristics included demographics, baseline clinical measures, and concomitant treatment. After matching, biologic treatment arms were compared based on difference from placebo in percent achieving $\geq 20\%$, $\geq 50\%$, or $\geq 70\%$ improvement in ACR criteria (ACR20/50/70), percent meeting PsA Response Criteria (PsARC), mean change in Health Assessment Questionnaire (HAQ), percent with $\geq 50\%$, $\geq 75\%$, or $\geq 90\%$ improvement in PASI (PASI50/75/90), and change from baseline in modified total Sharp score (mTSS). Statistical significance was assessed using weighted Student's t-tests. **RESULTS:** After reweighting, baseline characteristics were exactly matched across trials. Compared with etanercept-treated patients, adalimumab-treated patients had greater placebo-adjusted rates of ACR70 (23.9% vs. 7.9%), PASI50 (60.5% vs. 29.2%), PASI75 (55.0% vs. 19.5%), and PASI90 (40.2% vs. 2.8%) at Week 24 (all $p < 0.05$). Adalimumab-treated patients also had greater change from baseline vs. placebo in mTSS (1.77 vs. 0.56, $p = 0.080$) at Week 24 and greater rate of ACR70 (20.6% vs. 9.7%, $p = 0.055$) at Week 12. No significant differences were found for ACR20, ACR50, PsARC, and HAQ change (all $p > 0.1$). **CONCLUSIONS:** Matching-adjusted indirect comparison of adalimumab vs. etanercept in PsA finds that adalimumab treatment is associated with greater probability of ACR70, PASI50, PASI75, and PASI90 at Week 24.

PMS38

IMPACT OF MEDICARE PART D COVERAGE GAP ON MEDICATION TAKING BEHAVIOR: AN EVALUATION ACROSS DUAL AND NON-DUAL ELIGIBLE BENEFICIARIES DIAGNOSED WITH RHEUMATOID ARTHRITIS

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OBJECTIVES: The objective of this study is to examine the impact of the doughnut hole on medication behavior for biologic disease modifying anti-rheumatic drugs (DMARDs) in Medicare beneficiaries that were diagnosed with rheumatoid arthritis (RA). **METHODS:** A retrospective cohort study was conducted using inpatient, outpatient and pharmacy claims of a 5% national sample of Medicare beneficiaries who were diagnosed with RA in 2007. Dual and non-dual eligible beneficiaries who hit the doughnut hole were identified in order to test for differences in medication behaviors among these groups. An independent samples t-test was carried out to test for differences in adherence levels to biologic DMARDs and multiple logistic regression analyses were carried out to test for differences in switching and discontinuation behaviors between the groups. Propensity scores were calculated to control for demographic factors in the regression analyses. **RESULTS:** 86% of RA beneficiaries hit the doughnut hole in 2007, with nearly 66% during the first three months of the year. Adherence levels of non-dual eligibles were found to be significantly higher than those for dual-eligibles (p -value < 0.001). Non-dual eligibles were significantly more likely to switch their medication post doughnut hole as compared to dual eligibles (OR = 1.596, CI = 1.132-2.249). Also, non-dual eligibles were more likely to discontinue their medications post hitting the doughnut hole, although their behavior was not found to be significantly different from the dual eligibles (OR = 1.418, CI = 0.935-2.151). **CONCLUSIONS:** Medicare beneficiaries using specialty drugs may have to increasingly switch or discontinue their medications as a result of exceedingly high costs they incur in the doughnut hole. Biologic DMARDs are required to inhibit progression of RA and thus, beneficiaries suffering from RA are not left with much of a choice but to incur these high costs if they want to successfully manage their disease.

PMS39

MOST EFFECTIVE ADHERENCE-ENHANCING INTERVENTIONS FOR OSTEOPOROSIS MEDICATIONS

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BACKGROUND: Adherence to osteoporosis medications is suboptimal with reported persistence rates of between 25% and 35% at one year. This results in higher fracture rates with significant medical costs and hospitalizations. **OBJECTIVES:** To critically appraise the literature and determine the most effective adherence-enhancing interventions for osteoporosis medications. **METHODS:** A literature search using Medline, EMBASE, Cochrane library and CINAHL was carried out using the following key words: osteoporosis, low bone density, low bone mineral density, low bone mass, low bone mass density and bisphosphonates, calcium, colecalciferol, estrogens, hormone replacement therapy (HRT), raloxifene, vitamin D and patient compliance, adherence, concordance, persistence, and interventions, clinical trials, RCT. The search period was January 1st, 1999 to July 31st, 2010. We included studies on adult users of osteoporosis medications that tested an adherence-enhancing intervention (e.g. patient education, intensified patient care), and which reported quantitative results of adherence. Each article was reviewed independently by two investigators and disagreements were resolved by consensus. Downs' checklist was modified to assess the quality of studies. Due to studies heterogeneity, the analysis was focused on qualitative assessment. **RESULTS:** 27 publications were identified including 8 studies which randomized more than 4,500 patients fulfilled the inclusion criteria. Articles on reviews (5), protocols (1),

lack of intervention (7) or no quantitative data on adherence (6) were excluded. The most frequent intervention was education (6) followed by monitoring/supervision (2). Four studies used randomization to allocate intervention, which was led by nurses (3), pharmacists (1), physicians (1) and multidisciplinary teams (2). Follow-up ranged from 3 to 48 months. The average intervention effect size ranged from 0.12 (education) to 0.24 (patients monitored by nursing staff). The average quality score was 65.7%. **CONCLUSIONS:** The most effective adherence-enhancing interventions for osteoporosis medications were patient monitoring by nursing staff and education. Future studies should assess adherence interventions based on specific pharmacological treatments.

PMS40

HOW DOES OSTEOARTHRITIS SEVERITY INFLUENCE PATIENT PREFERENCES AND WILLINGNESS TO PAY FOR OSTEOARTHRITIS TREATMENTS?

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OBJECTIVES: To determine preferences and marginal willingness to pay (MWTP) for osteoarthritis (OA) treatments, including complementary and alternative medicine (CAM) among a sample of Medicare beneficiaries with mild and moderate-severe OA. **METHODS:** A discrete choice conjoint analysis was conducted with 181 participants with OA recruited from 4 senior centers and one internal medicine practice. Data were analyzed using Sawtooth Software. OA severity was determined by the brief pain inventory short form (BPI-sf), using previously established cut points. Utility data and MWTP were derived from multinomial logit analysis. This study was conducted in accordance with ISPOR's Checklist for Good Research Practices in Conjoint Analysis. **RESULTS:** Prescription pain medication, prayer/spiritual healing, and over the counter (OTC) medications were the most preferred treatments for both groups. The utility value for prescription pain medication was .28 for mild OA and .56 for moderate-severe OA participants. Prayer was the most preferred CAM treatment with significant utility values of .69 and .78 for mild and moderate-severe OA participants, respectively. OTC medications had a significant utility value of .39 for mild OA and .24 for moderate-severe OA participants. Significant differences were that moderate-severe OA participants had strong preferences for acupuncture (.94) and mild OA participants had significant preferences for massage therapy (.28). The price attribute followed the expected trend as lower prices were associated with higher utility, although moderate-severe OA participants were less price sensitive and were willing to pay more for treatment than mild OA participants. **CONCLUSIONS:** As OA severity increases, patients become less price-sensitive. Additionally, OA patients have significant preference for CAM in addition to conventional treatments. These data suggest that healthcare providers should involve patients in treatment decisions to optimize treatment acceptance and compliance. As options for CAM alone and in conjunction with conventional medications become increasingly available, the relationship between patient preferences and health outcomes is important to examine.

PMS41

PATIENT BURDEN OF GOUT: RESULTS FROM THE UNITED STATES NATIONAL HEALTH AND WELLNESS SURVEY (NHWS)

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BACKGROUND: Gout is the most common inflammatory arthritis in men above age 40 and its prevalence is rapidly rising. However, the burden of this disease on health-related quality of life (HRQL), productivity and healthcare resource utilization from a patient's perspective has not been well published. **OBJECTIVES:** To explore the self-reported gout burden on HRQL of gout patients (N=1468), their resource utilization, and general health compared to an age/gender matched gout-free group controls (N=1468). **METHODS:** Data were obtained from the 2010 US National Health and Wellness Survey, an annual internet-based survey of nationally representative adults. Respondents reported their health conditions, HRQL using SF-12, work and activity impairment (past week), and resource utilization (past six months). These patients were then compared to an age and gender matched gout-free cohort using 2-sided t-test or Chi Square test, $p < 0.05$ indicating statistical significance. **RESULTS:** The prevalence of self-reported gout in this survey was 1.9%. 78% of these patients were male with a mean age of 60 years, and BMI of 32.7. 88% were physician diagnosed and 69% were treated with gout-specific medication. There was no difference in alcohol use between 2 cohorts. The gout patients however, had significantly higher comorbidity rate for hypertension, hyperlipidemia, diabetes, and CHF, >3x rate of Myocardial Infarction, and 4x rate of moderate/severe renal disease ($p < 0.05$ for all). They had lower SF-12 domain scores, physical and mental summary scores than gout-free controls ($p < 0.05$). Fewer gout patients were employed full time, and larger number were on long-term disability ($p < 0.05$). They had twice the amount of work and social impairment, double the number of ER visits, hospitalizations, and mean visits to various healthcare providers ($p < 0.05$ for all). **CONCLUSIONS:** Gout patients have significantly lower HRQL, larger burden of work and activity impairment, and greater resource utilization than gout-free controls.

PMS42

CONTENT VALIDITY AND HEALTH CARE SYSTEMS: A CASE-STUDY

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OBJECTIVES: In the context of a French national post-marketing study on patients' satisfaction with routine care management, decision was made to use the Patient Satisfaction Questionnaire (PSQ III). Developed in the USA, the PSQ-III contains 8

items related to the financial aspect of caring. The objective was to test the French translation of the PSQ-III and evaluate its content validity considering the local health care system. **METHODS:** The French version of the PSQ-III was tested on 5 patients with rheumatoid arthritis. The aim of these cognitive interviews was to test clarity and comprehension of the translation but also the relevance of the 8 financial items to the French context from the patients' point of view. **RESULTS:** A direct translation of the financial items didn't prove difficult as they could be rendered literally. Cognitive interviews showed that the items were also easily understood. Respondents mostly didn't consider the items, however, as relevant to their situation (e.g. "I worry sometimes about having to pay large medical bills" or "I have to pay for more of my medical care that I can afford") although they showed some concern regarding future evolution of the reimbursement process in France. After consultation, the developer of the instrument confirmed that if needed, the items related to the financial domain could be left aside. Decision was made to create two versions of the translation: one including the eight financial items and another excluding them. **CONCLUSIONS:** As far as health care systems are concerned, linguistic validation goes beyond understanding the text and direct translation of the relevant items. It requires knowledge of the local context in order to collect meaningful data. The target healthcare system needs to be carefully considered and adequacy of the translation can be tested through cognitive interviews and consultation with experts in the domain.

PMS43

QUALITY OF LIFE AND FIBROMYALGIA - A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: Fibromyalgia is a chronic musculoskeletal condition characterized by pain, fatigue, psychological distress, and sleep disturbances. The symptom complexity and existence of comorbid conditions such as anxiety and depression have been shown to negatively impact patient's quality of life (QoL). The study objective is to identify the most commonly used QoL instruments in fibromyalgia and to examine the instruments' psychometric properties. **METHODS:** A systematic search was conducted from 1990 to 2010 using PUBMED, EBSCOhost, OVID, and ScienceDirect databases. The search was limited to English language and key search terms (e.g., fibromyalgia, quality of life) were used to identify articles of interest. Articles identified were further screened to exclude clinical studies, review papers and studies that discussed development of QoL instruments. **RESULTS:** The search yielded 74 articles out of which 40 were included in the final review. The review identified 11 generic instruments, 6 disease-specific, and 20 condition-specific instruments that were used in fibromyalgia. Short Form 36 was the most commonly used generic instrument. Among disease-specific instruments, Fibromyalgia Impact Questionnaire (FIQ) was the most commonly used and has 10 domains (physical functioning, feeling well, work missed, job ability, pain, fatigue, morning tiredness, stiffness, anxiety, depression). FIQ was found to have good test-retest reliability (Pearson's $r = 0.56-0.95$) and construct validity. Beck Depression Inventory was most commonly used condition-specific instrument. Most of the reviewed studies assessed pain, fatigue, and sleep disorders using visual analog scale. **CONCLUSIONS:** Fibromyalgia has a profound impact on patient's quality of life. Among the QoL instruments reviewed, FIQ justifies its use in research and clinical practice given its varied domains and strong psychometric properties.

PMS44

ASSESSING VITALITY IN PATIENTS UNDERGOING ETANERCEPT THERAPY FOR RHEUMATOID ARTHRITIS

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OBJECTIVES: To assess effects of etanercept therapy on vitality using the Health Assessment Questionnaire (HAQ). **METHODS:** Eighty-nine patients with moderate to severe rheumatoid arthritis (RA) were randomized in a phase 2/3 study to evaluate efficacy/safety of 25 mg etanercept twice weekly given in combination with methotrexate. Fifty-nine patients were randomized to etanercept/methotrexate and 30 to placebo/methotrexate. The HAQ was administered at baseline, Days 8/15, and every 4 weeks from Weeks 4–24. Vitality was assessed using 4 items: Feel full of pep? Feel worn out? Have enough energy to do the things you want to do? Feel tired? Patients responded on a 5-point scale ranging from All the time to Never. Using standard scoring algorithms, the vitality score ranged from 0 (worst) to 100 (best). Anchor and distribution-based methods were employed to estimate the minimally important difference (MID) for improvement. A repeated measures model was used to compare change from baseline over time between groups. **RESULTS:** At baseline, mean vitality scores were 34 with 95% confidence interval (CI) of 30 to 39 for etanercept/methotrexate patients versus 40 (95% CI 33 to 47) for placebo/methotrexate patients. At Week 24, the unadjusted mean improvements in vitality scores from baseline were 22 (95% CI 17 to 28) for etanercept/methotrexate versus 8 (95% CI 2 to 15) for placebo/methotrexate patients. The MID was established at 9.0, and 37% etanercept/methotrexate patients achieved the MID at Day 8 versus 17% placebo/methotrexate patients. The percentage rose to 67% versus 42% at Week 12, and to 74% versus 38% at Week 24 for etanercept/methotrexate versus placebo/methotrexate patients, respectively. The repeated measures model indicated a statistically significant difference in vitality change from baseline over time between the treatments ($P = 0.025$). **CONCLUSIONS:** The vitality MID was achieved by 74% of patients on etanercept/methotrexate by Week 24 versus 38% on placebo/methotrexate.

PMS45

WILLINGNESS TO PAY FOR OSTEOPOROSIS TREATMENT TO PREVENT FRACTURE IN KOREAN POPULATION

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OBJECTIVES: To examine willingness-to-pay (WTP) and factors influencing WTP for treatment to prevent osteoporotic fractures with the stated preference data in Korean population. **METHODS:** A questionnaire was administered via a trained interviewer to adult Korean general population. Subjects were selected by a non-probability sampling via a quota-sampling to reflect the national distribution of gender and age in Korea. Each respondent answered questions about eight different scenarios, each of which specified as different types of fracture (hip and vertebrae), efficacy of treatment (10% and 50%), and subjects to whom fracture occurred (self and family). WTP per annum was elicited with an open question per scenario. The demographic characteristics of respondents were also collected. A multivariate regression using a generalized linear model with a gamma distribution and log-link function was performed to identify factors influencing the level of WTP. **RESULTS:** Of one hundred and one respondents who completed the survey, the average of WTP per annum for respondent itself was 550 USD and 1,125 USD for treatment with 10% and 50% efficacy to reduce vertebral fracture risk, respectively. Similarly, the average of WTP per annum for respondent's family member was 683 USD and 1,333 USD. The annual WTP for respondent itself was 1,017 USD and 1,950 USD for treatment with 10% and 50% efficacy to reduce hip fracture risk, respectively. Education level, income level, the treatment efficacy, age, self-rated health status, and subjects to whom fracture occurred were significantly associated with the level of WTP. **CONCLUSIONS:** Respondents' preferences for osteoporosis treatment to reduce fracture risk reflected health and non-health related factors. This research provides useful information to expand the coverage of osteoporosis treatment which reduces the risk of costly fractures. Further research using a double-bounded, dichotomous-choice type questions utilizing the WTP range based on this study is ongoing.

PMS46

IMPACT OF ETANERCEPT ON WORK AND ACTIVITY IMPAIRMENT IN EMPLOYED PATIENTS WITH MODERATE TO SEVERE RHEUMATOID ARTHRITIS

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OBJECTIVES: To quantify the impact of etanercept (ETN) on work and activity impairment in employed patients with moderate to severe rheumatoid arthritis (RA) in US community practices. **METHODS:** In this prospective, observational study, 55 sites across the US enrolled employed, TNF-naïve, moderate to severe RA patients who initiated 50 mg/week ETN between January 1, 2009 and March 5, 2010. Telephone interviews were conducted at baseline (prior to or at the time of their first ETN dose) and 6 months (after the start of ETN), collecting patient demographic and clinical information, in addition to evaluating work and activity impairment using the Work Productivity and Activity Impairment Questionnaire (WPAI). The change in WPAI outcomes after 6 months was assessed through a Wilcoxon signed rank test on all enrolled patients. **RESULTS:** At baseline, 204 enrolled patients (mean age, 46.6 years (SD: 10.9); 72.6% female, 83.8% in full-time employment; mean duration of RA, 5.2 years) reported that the overall work impairment, work absenteeism, work presenteeism (reduction in productivity at work) and total activity impairment due to RA were 43.2%, 9.9%, 39.7% and 56.1%, respectively. All four WPAI outcomes improved after initiation of ETN therapy. At 6 months, 153 patients remained on therapy and the overall respective WPAI scores demonstrated a mean percent improvement from baseline of 28.7% ($p < 0.0001$), 54.6% ($p = 0.0009$), 33.2% ($p < 0.0001$) and 37.3% ($p < 0.0001$). In addition, mean hours lost from work over the last 7 days because of RA decreased from 3.8 hours at baseline to 1.6 hours at 6 months (62.5% decrease in hours lost; $p = 0.0005$). **CONCLUSIONS:** In working patients with moderate to severe RA, ETN had a significant impact on reducing overall work impairment, absenteeism, presenteeism, and activity impairment. Data demonstrate the positive impact of ETN on the ability to work and perform regular activities when used under real world conditions.

PMS47

EMPLOYABILITY-ADJUSTED-LIFE-YEARS IN PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH GOLIMUMAB PLUS METHOTREXATE OR METHOTREXATE ALONE

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OBJECTIVES: Estimate/compare employability-adjusted-life-years (EALYs) over time for rheumatoid arthritis (RA) patients treated with golimumab (GLM)+methotrexate (MTX) vs. placebo+MTX in the GO-FORWARD study. **METHODS:** GO-FORWARD is a double-blind, placebo-controlled study of adults with active RA (≥ 4 tender and 4 swollen joints) and inadequate response to MTX. This analysis included patients < 65 yrs old who received placebo+MTX (MTX) or GLM (50 or 100mg)+MTX (GLM) q4wks. Self-reported employment status and Health Assessment Questionnaire (HAQ) were assessed through 3 years. A patient was 'unemployable' if unemployed and felt unable to work even if a job was available or 'employable' if employed or felt well enough to work if a job was available. Long-term (over a 10-yr period) employability was estimated via logistic regression modeling incorporating age, gender and HAQ. HAQ was derived using progression rates of 0.045/year for MTX group and 0 (base case) to 0.025/year (sensitivity analysis) for GLM group. **RESULTS:** At baseline, the mean HAQ score was 1.36, and 61.9% and 44.8% of patients < 65