non-coverage decision. Of the positive decisions, 22 were associated with an economic evaluation that estimated the medical intervention to be dominant (costs less and more effective than the alternative), 8 with an incremental cost-effectiveness ratio (ICER) of less than $50,000, 8 with an ICER greater than $50,000 but less than $100,000, and 8 with an ICER greater than $100,000 (2008 USD). In four of the positive coverage decisions the intervention was dominated (costs more and was less effective than the alternative). Of the non-coverage decisions, 3 interventions were estimated to be dominant, 6 were associated with an ICER less than $30,000, one with an ICER of approximately $200,000, and four were dominated. Fourteen decision memos cited or discussed cost-effectiveness information. **CONCLUSIONS:** CMS is covering a number of interventions that do not appear to be cost-effective by traditional standards. While we identified several instances where cost-effectiveness evidence was cited in NCDs, we found no clear evidence of an implicit constant fixed cost-effectiveness threshold.

MD8

OUT OF POCKET PSYCHOTROPIC PRESCRIPTION BURDEN ON ELDERLY MEDICARE BENEFICIARIES BEFORE AND AFTER THE IMPLEMENTATION OF MEDICARE PART D

Chen H[1], Chaudhari S[2], Aparasu R[1], Johnson M[1]
[1]University of Houston, Houston, TX, USA, [2]Xcenda, Palm Harbor, FL, USA

OBJECTIVES: To examine the out of pocket spending on psychotropic medications by elderly Medicare beneficiaries before and after the implementation of Medicare Part D. **METHODS:** The effect of Part D was measured using 2005–2006 pharmacy claims data from one of the largest retail pharmacy chains in the United States. The psychotropic medications examined in this study included antidepressants, antipsychotics benzodiazepines and barbiturates. In addition to evaluating overall out of pocket burden in 2005 and 2006, the study examined out of pocket burden among Medicare-Medicaid dual eligible beneficiaries, non-dual Part D enrollees, and those who did not enroll in Medicare Part D. The out of pocket burden was calculated as a percentage of total pharmacy reimbursement involving elderly persons 65 years or older. **RESULTS:** The proportion of out of pocket expenditures in total pharmacy reimbursement dropped 7.62% (from 40.43% to 32.81%) for antidepressants, 6.24% for antipsychotics (from 27.82% to 21.58%), but increased 12.15% for benzodiazepines (from 62.64% to 74.79%), and 9% (from 71.96% to 80.56%) for barbiturates. Dual eligible beneficiaries were the group most severely affected by the policy change. For dual eligible beneficiaries who were on any of the four drug categories, their yearly out of pocket expense increased extensively. The most dramatic change was observed in dual eligibles using benzodiazepines. Their out of pocket expenditure increased by around 12 folds from 2005 to 2006. Non-dual Part D enrollees benefited the most from the new drug policy. The most significant cost saving was found in non-dual Part D enrollees who were on antidepressants (from 62.23% to 32.97%) and antipsychotics (from 55.24% to 38.30%). **CONCLUSIONS:** The implementation of Part D was associated with reduced out of pocket psychotropic prescription burden on non-dual Part D enrollees, however, out-of –pocket burden on the dual eligible beneficiaries severely increased.

PODIUM SESSION IV: MUSCULAR–SKELETAL DISORDERS – Outcomes Research

MS1

ASSESSMENT OF PREFERENCE AND SATISFACTION WITH A WEEKLY ORAL TABLET VERSUS A 6–MONTH SUBCUTANEOUS INJECTION FOR THE TREATMENT OF OSTEOPOROSIS

Kendler DL[1], Gold DT[2], Horne R[3], Borenstein J[4], Varon SF[4], Man HS[4], Siddhanti S[4], Satram-Hoang S[4], Macarios D[4], Bone HG[5]
[1]Clinical Research Centre, Vancouver, BC, Canada, [2]Duke University Center for the Study of Aging and Human Development, Durham, NC, USA, [3]The School of Pharmacy, University of London, London, UK, [4]Amgen Inc, Thousand Oaks, CA, USA, [5]Michigan Bone and Mineral Clinic, Detroit, MI, USA

OBJECTIVES: We compared patient preference and satisfaction between two osteoporosis medications: alendronate (ALN 70 mg tablets) taken orally once weekly (QW) and denosumab (DMAb 60 mg; investigational agent) injected subcutaneously (SC) every 6 months (Q6M). **METHODS:** Preference and satisfaction were evaluated as part of a phase 3, double-blind, double-dummy study to determine the effects of transitioning subjects from ALN to DMAb. Postmenopausal women ≥55 with a lumbar spine or total hip T-score ≤–2.0 and ≥–4.0 who were receiving ALN therapy for ≥6 months were eligible. After a 1-month ALN run-in phase, subjects were randomized to treatment with continued ALN QW + placebo injection SC Q6M or DMAb SC Q6M + QW placebo tablet. At study conclusion, subjects completed a 34-item questionnaire. Pre-determined endpoints of preference and satisfaction were measured by asking subjects to choose the tablet, the injection, or neither, in response to questions on preference ("Which do you prefer?") and satisfaction ("With which frequency of administration have you been more satisfied?"). **RESULTS:** The subjects (n = 251 ALN, n = 253 DMAb) had a mean age of 67.6 years and a median length of prior bisphosphonate use of 36 months (range 6 to 192). 483 (95.8%) women took the questionnaire (240-ALN, 243-DMAb). Of the subjects who responded to the question on preference (240-ALN, 240-DMAb) or satisfaction (237-ALN, 242-DMAb), significantly more subjects preferred a 6-month injection vs. a weekly oral tablet (ALN:66%-Q6M injection, 19%-QW tablet, 15%-neither, $p < 0.0001$; DMAb:70%-Q6M injection, 19%-QW tablet, 12%-neither, $p < 0.0001$) and significantly more subjects reported greater satisfaction with the frequency of 6-month vs. weekly dosing (ALN:68%-Q6M injection, 19%-QW tablet, 14%-neither, $p < 0.0001$; DMAb:70%-Q6M injection, 16%-QW tablet, 14%-neither, $p < 0.0001$). **CONCLUSIONS:** A preference for and a greater satisfaction with a 6-month injection vs a weekly oral tablet was demonstrated in subjects previously receiving and tolerating ALN therapy.

MS2

COMBINING THE SF–36 PHYSICAL FUNCTION SCALE AND THE HEALTH ASSESSMENT QUESTIONNAIRE TO IMPROVE MEASUREMENT OF PHYSICAL FUNCTION RHEUMATOID ARTHRITIS (RA): RESULTS: FROM THE PREMIER STUDY

Hammond G[1], Yarlas A[1], Kosinski M[1], Roy S[2], Cifaldi M[2]
[1]QualityMetric Incorporated, Lincoln, RI, USA, [2]Abbott Laboratories, Abbott Park, IL, USA

OBJECTIVES: RA clinical studies using the SF-36 Physical Function (PF) scale and Health Assessment Questionnaire (HAQ) have identified limitations in each instrument's sensitivity across the full range of disease severity. Item Response Theory (IRT) estimates were used to develop a composite of both instruments (PF–HAQ) to provide a more sensitive measure of physical health. **METHODS:** Data for 799 patients from a 2-year randomized control study of adalimumab in early RA (<3 years) were employed. Patients received adalimumab plus methotrexate; adalimumab monotherapy; or methotrexate monotherapy. Composite PF–HAQ scores were compared individually with PF and HAQ using 1) comparison of floor and ceiling effects; 2) ANCOVA models with ACR criteria classification or treatment as factors (covariates: sex, age, BMI); and 3) receiver operating characteristics (ROC) analyses using ACR50 criteria as a gold standard. **RESULTS:** At baseline, 6.2% of patients were at floor for the PF. At endpoint, 37.7% and 14.2% of HAQ and PF scores, respectively, were at ceiling. IRT scores, by definition, have no ceiling or floor. Significant differences across treatment groups were obtained ($F [2526] = 12.21, 7.48, 3.02$, $p < 0.001$ for all comparisons). PF–HAQ had significantly more power than either individual scale to detect treatment differences (F-statistic ratios of PF–HAQ with PF and HAQ were 1.6 and 4.0, respectively). PF–HAQ was better than PF at detecting differences in endpoint ACR criteria (F-statistic ratio for PF–HAQ to PF was 1.28). ROC analyses indicated that PF–HAQ provided better measurement precision ($p < 0.001$) vs. PF and equivalent/better precision vs. HAQ ($p = 0.14$) (AUC: PF 0.80, 95% CI: 0.79–0.81; HAQ: 0.83 [0.82–0.85]; PF–HAQ: 0.84 [0.83–0.85]). **CONCLUSIONS:** Combining PF and HAQ measures into a single measure eliminated floor/ceiling effects, and provided greater efficiency in discriminating treatment effects, as well as greater sensitivity vs. common diagnostic criteria.

MS3

THE IMPACT OF COMPLIANCE WITH BIOLOGIC THERAPY ON CLINICAL OUTCOMES IN PATIENTS WITH RHEUMATOID ARTHRITIS

Tang B[1], McKenzie RS[1], Freedman D[2], Wagner S[2], Piech CT[1]
[1]Centocor Ortho Biotech Services, LLC, Horsham, PA, USA, [2]Consumer Health Sciences International, Princeton, NJ, USA

OBJECTIVES: To assess the impact of compliance with biologic therapies on clinical measures, including symptoms, quality of life (QOL), and medical resource use in rheumatoid arthritis (RA) patients. **METHODS:** Patient-reported data were collected from the 2008 Rheumatoid Arthritis Patient Study, an Internet survey of RA patients. Clinical measures and medical resource use (number of surgeries, emergency room and physician visits, and hospitalizations within six months) were compared among three groups: patients who used biologics before but discontinued; patients who currently use biologics but skipped doses within the last 12 months; and patients who currently use biologics without skipping. Symptoms included morning stiffness, fatigue, and pain scores measured on a Likert scare from zero (no symptoms) to 10 (severe symptoms). QOL was measured by the mental component summary (MCS) and physical component summary (PCS) of the Health Survey Short Form (SF-36). **RESULTS:** Of 2,048 respondents, 475 (23.2%) used biologic therapies, 74.3% were female, and the average age was 51.9 years. The average duration of RA was 11.9 years, with 20.0% reporting severe disease. Among patients who used biologics, 148 (31.2%) patients discontinued and 80 (16.8%) patients reported skipping doses in the last 12 months. Compared to the groups who discontinued, or skipped biologic doses, the current users who did not skip had the best symptom and QOL scores: morning stiffness (6.51, 5.91, 5.77), fatigue (7.00, 6.96, 6.23), pain (6.51, 6.18, 5.71), MCS (38.0, 41.7, 41.9), and PCS (30.4, 29.2, 32.8) (all $P < 0.05$). There were no statistical differences in medical resource use except physician visits, which were significantly lower in current users who did not skip doses. **CONCLUSIONS:** Patients who were compliant with their biologic therapy had better outcomes compared with patients who discontinued or skipped doses. Compliance with biologic therapy is an important factor optimizing effective treatment of RA.

MS4

SOCIETAL COST OF RHEUMATOID ARTHRITIS (RA) IN THE UNITED STATES: METHODOLOGY FOR INCORPORATING INTANGIBLE COSTS

Birnbaum H[1], Pike C[1], Kaufman R[1], Marynchenko M[2], Kidolezi Y[1], Cifaldi M[3]
[1]Analysis Group, Inc, Boston, MA, USA, [2]Analysis Group, Inc, Montreal, QC, Canada, [3]Abbott Laboratories, Abbott Park, IL, USA

OBJECTIVES: Methods have been well-established to estimate the excess amount of health care services and work loss costs of RA and, to a lesser extent, caregiver costs. To estimate the comprehensive societal cost of RA, we assessed intangible costs associated with functional disability/quality of life and mortality legal system jury award

data from the United States. **METHODS:** We obtained data on jury awards for injuries that caused functional disabilities similar to RA. We identified a sample of jury awards involving limb disabilities and/or losses. With these award amounts, we computed the average jury award and calculated its annuity equivalence, assuming an average US life expectancy. For RA-associated early mortality, we employed data from the medical literature to compute the difference between the present value of sex-specific lifetime earnings of RA patients, with adjustments to reflect reduced life expectancy and average lifetime earnings in the United States. Tangible costs associated with RA (e.g., health care, workplace, paid/unpaid help, government disability) were derived from private insurance, Medicare, and Medicaid claims databases; disability and medical absence data; and the literature. Patient-level cost estimates were weighted by the prevalence of relevant populations to compute societal costs (2005 US dollars). **RESULTS:** The average annuity per jury award for injuries similar to RA disabilities was $55,700. This corresponds to an annual societal value of disability/QOL deterioration of $10.8 billion. The annualized reduction in lifetime earnings per RA patient (vs. those without RA) was $7,420, or $9.6 billion in total. Thus, the annual intangible costs of functional disability/QOL and mortality totaled $20.4 billion. Total tangible societal costs were $19.3 billion ($8.4 billion for direct costs [patient health care]; and $10.9 billion for indirect costs [other RA consequences]). **CONCLUSIONS:** Including intangible costs increased the annual societal costs of RA by $20.4 billion in the United States, for a total of $39.7 billion.

PODIUM SESSION IV: QUALITY OF LIFE & UTILITY STUDIES

QL1

COMPARISON BETWEEN THE EQ–5D AND THE SEVEN DERIVED HEALTH UTILITIES IN STROKE PATIENTS USING A NATIONAL REPRESENTATIVE SAMPLE IN THE UNITED STATES

Nichol MB, Wu J, Gu NY

University of Southern California, Los Angeles, CA, USA

OBJECTIVES: 1) To assess the associations of EQ-5D index score, EQ-VAS, and seven estimated utilities with self-reported stroke in a U.S. national representative sample, and 2) To compare estimated utilities with EQ-5D and EQ-VAS in both stroke and non-stroke samples. **METHODS:** Data were extracted from the 2001 Household Component of the Medical Expenditure Panel Survey(MEPS). Seven estimated utilities were derived from the SF-12v1®, including HUI3/VAS item models(IM) and categorical models(CM) from the Sengupta-Nichol, Brazier SF-6D, Lundberg VAS, and Sullivan EQ-5D algorithms. An analysis of covariance was used to determine differences in mean utility scores between individuals with and without stroke. Covariate(social-demographic and comorbidity) adjusted effect sizes(ES) were calculated for utilities between individuals with and without stroke, as well as between estimated utilities and EQ-5D/EQ-VAS. **RESULTS:** A total of 19,475 individuals completed SF-12v1®, EQ-5D, and EQ-VAS. Mean age was 42.2 years, 40% were female, 14% had self-reported stroke. Individuals with stroke had significantly lower covariate adjusted mean EQ-5D (0.16 points difference), EQ-VAS (0.14 points difference), and estimated utilities (0.11 or 0.12 points differences) when compared to those without stroke(all $p < 0.0001$). Stroke individuals showed large effect in utility scores when compared to non-stroke individuals. HUI3-IM (ES = 1.20) and HUI3-CM (ES = 1.22) showed ES similar to EQ-5D (ES = 1.23), and both VAS-IM and VAS-CM (ES = 1.09) had ES similar to EQ-VAS (ES = 1.08). When comparing estimated utilities with EQ-5D, Sullivan EQ-5D (ES = 0.26) and SF-6D(ES = −0.29) showed small effect, while other estimated utilities showed no effect in stroke individuals; all estimated utilities showed small (ES = 0.23 for Sullivan EQ-5D) to large effect (ES = −1.00 for SF-6D) in non-stroke individuals. **CONCLUSIONS:** EQ-5D, EQ-VAS and estimated utilities in stroke individuals displayed clinical meaningful differences from those without stroke. Derived HUI3/VAS showed the similarity with the EQ-5D/EQ-VAS in stroke individuals. Our findings indicated that EQ-5D, EQ-VAS, and estimated HUI3 and VAS were sensitive to health state and could be used for cost-effectiveness analysis in stroke individuals.

QL2

DEVELOPMENT OF AN ITEM BANK FOR A COMPUTER ADAPTIVE MEASURE OF FUNCTIONAL COGNITION FOR STROKE

Velozo CA[1], Duncan P[2], Wang JH[3], Donovan NJ[4], Heaton SC[3], Kendall DL[5], Kwon S[6], Singletary FF[7], Seago R[8], Garretson KN[9], Agonis JK[7]

[1]University of Florida/Department of Veterans Affairs, Gainesville, FL, USA, [2]Duke University, Durham, NC, USA, [3]University of Florida, Gainesville, FL, USA, [4]Louisiana State University, Baton Rouge, LA, USA, [5]University of Washington, Seattle, WA, USA, [6]South Carolina College of Pharmacy – MUSC Campus, Charleston, SC, USA, [7]Brooks Center for Rehabilitation Studies, Jacksonville, FL, USA, [8]CNS Healthcare, Jacksonville, FL, USA, [9]Brooks Rehabilitation Hospital, Jacksonville, FL, USA

OBJECTIVES: To establish an item bank for Computer Adaptive Measure of Functional Cognition for Stroke (CAMFC-S). The prerequisite for monitoring the effectiveness of pharmaceutical interventions for stroke-related cognitive deficits is the development of reliable and valid cognitive measures. Existing measures of post-stroke cognition: 1) are few in number; 2) lack precision and efficiency for stroke; and 3) fail to reflect cognitive functioning that is related to everyday activities (i.e., "functional cognition"). **METHODS:** A total of functional cognition items across 10 domains (Language, Reading/Writing, Numeric Calculation, Limb Praxis, Visuospatial Function, Social Use of Language, Emotional Function, Attention, Memory, and Executive Function) were administered to 128 individuals with stroke 49 acute (7–21 days post onset) and 79 chronic (83–372 days post onset). Rasch and classical test analyses were performed on 128 self-report ratings and 124 caregiver ratings. Neuropsychological testing was performed with 62 randomly selected patients. **RESULTS:** Confirmatory factor analysis of each domain supported both unidimensionality and hypothesized multidimensional structures for 5 of 10 domains with 1 domain only supporting a multidimensional structure. The all-item measure and separate domain measures showed excellent internal consistency (high person separation reliability and high Cronbach's alphas). The all-item measure and domain measures (except Limb Praxis) produced expected item-difficulty hierarchical orders. The all-item measure showed excellent person separation and except for Limb Praxis and Numeric Calculation (patient self-report), domain measures showed good person separation. While the All Item measure showed no floor or ceiling effects 5 of 10 domain measures showed ceiling effects. The domain measures showed fair-moderate correlations with analogous neuropsychological test performance. **CONCLUSIONS:** With the exception of Limb Praxis, the findings support developing all-item and domain-specific computer adaptive tests of functional cognition.

QL3

ESTIMATION OF UTILITY VALUES FOR DIABETES–RELATED COMPLICATIONS ON QUALITY OF LIFE FOR PATIENTS WITH TYPE–2 DIABETES IN ONTARIO, CANADA

O'Reilly D[1], Xie F[1], Pullenayegum E[1], Gerstein H[2], Blackhouse G[1], Tarride JE[1], Goeree RA[1]

[1]McMaster University, Hamilton, ON, Canada, [2]McMaster University and Hamilton Health Sciences, Hamilton, ON, Canada

OBJECTIVES: The primary aim of this study was to analyze quality of life (QOL) data from a Canadian population with type-2 diabetes in order to estimate the impact of a number of diabetes-related complications on utility measures of QOL. **METHODS:** The EuroQol EQ-5D instrument was administered 1147 patients with type-2 diabetes. After controlling for age, gender and duration of diabetes, utilities were estimated by regressing the EQ-5D scores onto binary indicators for the presence of an event. The primary method of analysis was Ordinary Least Squares (OLS), and due to concerns over non-Normality, bootstrap standard errors (SE) were calculated. Both United States and UK scoring algorithms were used to estimate respective utility decrements. **RESULTS:** 1,143 participants were included in the analysis. Using the UK algorithm and the OLS model, the utility decrements were as follows: myocardial infarction (MI) = −0.081 (SE = 0.026), amputation = −0.098 (SE = 0.090), stroke = −0.067 (SE = 0.036), and kidney failure = −0.158 (SE = 0.073). The US algorithm produced the following values: MI = −0.059 (SE = 0.017), amputation = −0.063 (SE = 0.059), stroke = −0.046 (SE = 0.023), and kidney failure = −0.102 (SE = 0.047). Estimates of these effects based on both the Tobit and censored least absolute deviations estimator models were also reported and compared. **CONCLUSIONS:** This study used various regression models to estimate the decrements in EQ5D utility values associated with several important complications commonly experienced in patients with diabetes. The most significant impacts on QOL were associated with kidney failure and MI. The decrements estimated using US scoring algorithm were smaller than using UK scoring algorithm. These utility values can be used to assess the outcome of interventions that reduce these diabetes-related complications and will have a great impact on future economic evaluations of diabetes management strategies in Canada.

QL4

VALIDATION OF THE TREATMENT RELATED IMPACT MEASURE FOR DIABETES TREATMENT AND DEVICE; TRIM–DIABETES AND TRIM–DIABETES DEVICE

Brod M[1], Hammer M[2], Christensen T[2], Bushnell D[3]

[1]The BROD GROUP, Mill Valley, CA, USA, [2]Novo Nordisk A/S, Bagsværd, Denmark, [3]Health Research Associates, Inc, Mountlake Terrace, WA, USA

OBJECTIVES: To fully understand the multi-faceted impact of diabetes treatments, patients perceptions of health-related quality of life, treatment satisfaction and treatment behavior must be assessed. Available diabetes patient reported outcome (PRO) measures are specific to type-1 or type-2 diabetes, treatment or delivery modality or are not inclusive of all potential impacts. The purpose of this study was to validate the Treatment Related Impact Measure (TRIM) for Diabetes and Diabetes Device which were developed to assess the full range of impacts across diabetes type, all current delivery systems and diabetes treatments. **METHODS:** The 60 item TRIM-Diabetes/-Device, developed in a prior study according to the draft FDA guidelines, was validated in a web-based survey for measurement and psychometric properties (factor structure, reliability, validity) for the total and each domain score. **RESULTS:** A total of 507 respondents completed the web-survey; 24 of 60 items were dropped due to redundancy, ceiling effects, poor factor loadings and/or poor conceptual fit, resulting in a 28 item TRIM-Diabetes and 8 item TRIM-Device. A five-factor structure for the TRIM-diabetes with domains of treatment burden, daily life diabetes management, psychological health and compliance and 2 domains of device function and device bother for the TRIM-Device were found. Internal consistency coefficients of the total score and each subscale ranged between 0.80 and 0.94 and test-retest reliability ranged from 0.71 to 0.89. All pre-specified hypotheses for convergent and known-groups validity were met. The estimated time for completion of the combined measures is four minutes. **CONCLUSIONS:** The development of these measures has been conducted according to well defined scientific principles, suggesting that the total score and each domain subscale, can be considered a brief, conceptually sound, rigorously developed PRO measure with strong evidence supporting the psychometric properties. Use of these measures in both clinical and research setting can facilitate targeted interventions with more positive treatment outcomes.