MC2
COMPARISON OF TRADITIONAL MULTIVARIABLE LOGISTIC REGRESSION AND PROPENSITY SCORE APPROACHES FOR CONTROLLING FOR TREATMENT SELECTION BIAS USING MONTE CARLO SIMULATION
Wang J, Wu Y, Irish WD
RTI Health Solutions, Research Triangle Park, NC, USA
OBJECTIVES: In the absence of well-controlled clinical studies, medical records provide a potential wealth of information about the value of treatments; however, differences in pretreatment patient or other characteristics may influence treatment assignment and lead to biased estimates of treatment effects. Several strategies are available to reduce treatment selection bias. These include multivariable regression (MR) and propensity score (PS) techniques. Cepeda and colleagues (Am J Epidemiol 2003;158:280–7) demonstrated that PS is less biased than MR when the ratio of number of events to number of confounders (Rec) is less than 8 by simulation. Using methods deemed more appropriate than Cepeda, we set out to evaluate conditions upon which their conclusions may be incorrect. METHODS: Monte Carlo simulation was performed in which each subject: 1) had 10 confounders (Zk : k = 1, . . . , 10) generated using normal and Bernoulli distributions; 2) was assigned to exposure or nonexposure with probability p determined by confounding variables; and 3) was given a binary response variable with probability g determined by confounder and exposure strength of association. For each simulation, binary logistic regression was used to: 1) generate individual PSs by regressing exposure variable on the confounder variables Z; and 2) estimate PS- and MR-adjusted treatment effects. Process was repeated 1000 times to evaluate bias and power of the statistical test. RESULTS: MR method produces asymptotically unbiased estimate of treatment effect; a result that is only marginally affected by the Rec. Even when Rec was 4.5, MR produced unbiased estimate of treatment effect with larger sample size. Contrary to the MR method, PS produces estimates that are consistently lower than the true effect regardless of sample size or Rec. Power is always lower using the PS method. CONCLUSION: Results suggest PS method provides no statistical advantage over traditional MR; a conclusion that is contrary to Cepeda et al recommendations.

MC3
CONTROLLING FOR COMORBIDITIES USING VARIATIONS OF THE CHARLSON COMORBIDITY INDEX ON MEDICARE CLAIMS DATA: THE CASE OF OVERACTIVE BLADDER
Ci sternas MG, Foreman AJ, Miller DP
Ovation Research Group, San Francisco, CA, USA
OBJECTIVES: To compare variants of the Deyo-modified Charlson Comorbidity Index (DM-CCI) as comorbidity adjustors when predicting annual health care costs attributable to a specific condition using administrative data. METHODS: We extracted all medical claims for Medicare individuals >65 with continuous coverage for Medicare parts A and B (N = 1.2 million) during 2003 and 2004 from files obtained from the Centers for Medicare and Medicaid Services. In order to estimate annual expenditures attributable to overactive bladder (OAB), we used multiple regression techniques that adjusted for demographics (age, race, region, gender) and comorbidities. Comorbidities were defined in four ways. Method 1 used the DM-CCI as the only measure of comorbidity. Method 2 used the DM-CCI plus indicator variables for other conditions not included in the DM-CCI that were not considered sequelae of OAB (hyperlipidemia, depression/anxiety, hypertension, heart disease, osteoarthritis, cataracts/glucoma, enlarged prostate, musculoskeletal conditions excluding arthritis, GERD, and neurologic conditions). Model 3 was identical to Model 2 but excluded depression/anxiety. Model 4 was identical to Model 2 but also included events and conditions related to OAB (UTIs, skin infections, falls/fractures, and vulvovaginitis). RESULTS: Mean annual expenditures attributable to OAB were $2278, $825, $996, and $94 per individual with OAB for Models 1, 2, 3, and 4 respectively. CONCLUSION: Attributable costs calculations using regression techniques may be very sensitive to the specification of comorbid conditions. Analysts need to avoid both the omission of key confounders, which can overstate the cost of a condition (e.g., Model 1), and over-specification, which will underestimate the cost of a condition by attributing too much cost to comorbidities that are actually related to the condition of interest (e.g., Model 4). Candidate comorbid conditions must be considered carefully before they are included in regression models to predict condition-specific attributable costs.

MC4
TIME HORIZON BIAS IN ECONOMIC EVALUATIONS
Sander B1, Krahn MD2
1University of Toronto, Toronto, ON, Canada; 2University Health Network, Toronto, ON, Canada
OBJECTIVES: To systematically evaluate the impact of time horizon choice on the incremental cost-effectiveness ratio (ICER) under varying assumptions regarding treatment effectiveness, costs and discount rate. METHODS: We developed a Markov model, comparing two hypothetical strategies and predicting marginal quality adjusted life years (QALYs), costs and ICERs as a function of time horizon (ranging from 5 to 50 years). We assume that clinical trial data is available for 5 years of follow up. The model was analyzed for the following scenarios: extrapolation of survival benefit (optimistic, intermediate, conservative), prediction of treatment costs (one time costs only, constant continued incremental cost with/without cost decrease after 10 years), and discount rate (undiscounted, same discount rate for QALYs and costs, differential discount rate for QALYs and costs). RESULTS: The effect on ICER is greatest when comparing a 5 year to a 10 year or longer time horizons. For most scenarios the ICER does not change much when extending the time horizon beyond 15 years (less than 20% relative change in ICER). The choice of time horizon conditional on the extrapolation method of survival benefit (optimistic and intermediate scenarios) for one time cost scenarios had the greatest impact on reducing the ICER (reduction of >60% if using 10 year instead of 5 year time horizon). In scenarios with continued costs, the ICER was sensitive to a cost decrease after 10 years but less sensitive to the discount rate. CONCLUSION: Current guidelines suggest adopting a lifetime time horizon when a mortality benefit is present. Our study measures the bias associated with adopting the time horizon of a clinical trial, a common practice. Most susceptible to bias are scenarios with one time costs as the ICER is most sensitive to the chosen extrapolation method for survival benefits. The choice of time horizon and its impact on ICER warrant careful consideration.

PODIUM SESSION II: NEUROLOGY
EMPLOYEES WITH FIBROMYALGIA: MEDICAL COMORBIDITY, HEALTH CARE COSTS, AND WORK LOSS
White LA1, Birnbaum HG PhD1, Kaltenboeck A1, Tang J1, Mallett D2, Robinson R1
1Analysis Group, Inc, Boston, MA, USA; 2Ingenix, Inc, Rocky Hill, CT, USA
OBJECTIVES: To compare health care use, health care costs, and work loss costs in employees with fibromyalgia (FM) to...
matched samples of employees with osteoarthritis (OA) and non-FM controls. METHODS: Samples were selected from a U.S. claims database of privately insured beneficiaries. Employees in the FM sample had ≥2 fibromyalgia diagnoses in 1999–2005 (with ≥1 in 2002–2005) and were continuously enrolled in 2005. Controls and employees with OA had no FM claims and were matched to the study sample on age, gender, and region. Costs are reported for 2005 experience. Nonparametric Wilcoxon tests were used to determine statistically significant differences in skewed variables including costs. Chi-square tests were used to test for differences in categorical variables. RESULTS: Mean age in the FM sample was 50.1 years and 51.6% were female. Compared to control and OA samples, employees with FM had higher rates of depression, anxiety, chronic fatigue syndrome, and many pain diagnoses. The FM sample used more medical care overall, especially emergency department visits, specialty physician visits, and prescriptions. Direct (medical and prescription drug) costs in the FM sample were significantly higher than control sample costs ($7286 vs. $3915, p < 0.0001), and approached OA sample costs ($7286 vs. $8325, p = 0.3758). Prescription costs comprised a relatively large proportion of total FM costs; prescription cost levels were comparable to employees with OA ($1630 vs. $1341, p = 0.3541) and significantly higher than controls ($1630 vs. $755, p < 0.0001). Work loss costs in the FM sample ($2913) were significantly higher than those of control ($1359, p < 0.0001) and OA ($2537, p < 0.0001) samples. CONCLUSIONS: Fibromyalgia imposes significant economic burden. Average total costs among employees with fibromyalgia were almost twice those of matched controls and approximated costs of employees with osteoarthritis. Indirect costs were more than double those of controls and even exceeded costs of osteoarthritis patients with similar demographic profiles.

IMPACT OF PATIENT COMORBIDITIES ON PHARMACOLOGICAL TREATMENT OF INSOMNIA: AN ANALYSIS OF THE NATIONAL AMBULATORY MEDICAL CARE SURVEY DATA: 1995–2004

Pawaskar MD, Balkrishnan R

The Ohio State University College of Pharmacy, Columbus, OH, USA

OBJECTIVES: Patients with insomnia are likely to have comorbidities that could affect treatment options. Hence the objective of this study was to examine the prevalence of comorbidities and their impact on the pharmacological treatment of insomnia in US primary care settings. METHODS: A retrospective data analysis of the National Ambulatory Medical Care Survey from 1995 to 2004 was performed. Patients aged ≥18 years, who had a physician visit with a diagnosis of insomnia in US outpatient settings were included in this study. Office visits of patients with primary or secondary insomnia/sleep complaints and resultant diagnoses were included in the analysis. Data were stratified according to patient characteristics, physician specialty, resulting diagnosis and medications prescribed. Multivariate logistic regression models were used to examine impact on prescribing pharmacotherapy for insomnia. RESULTS: A total of 5487 unweighted patient visits for insomnia were identified from the year 1995–2004, representing 107.4 million patients in the overall U.S. population. Office visits for insomnia were more common in females (60.4%), with an increasing prevalence in older patients. Approximately 41% of the patients with insomnia had a comorbid diagnosis of a mental comorbidity with higher prevalence of anxiety (15.6%) followed by episodic mood disorders (14.9%) and depression (7%). Patients with mental comorbidities were 35% less likely to receive pharmacological treatment for insomnia than those without mental comorbidities (OR: 0.65, 95% CI: 0.51–0.84). Subgroup analysis of type of mental comorbidity revealed that patients with comorbid anxiety were 42% less likely to receive pharmacological treatment for insomnia than those without anxiety (OR: 0.58, 95% CI: 0.45–0.73). CONCLUSION: Mental comorbidities such as episodic mood disorder, anxiety, and depression are prevalent in patients with insomnia and affect receipt of pharmacological therapy for insomnia. Health care professionals should consider the impact of mental comorbidities while treating patients with sleep difficulties.

THE IMPORTANCE OF MODIFYING THE COURSE OF ALZHEIMER’S DISEASE: OLDER AMERICANS’ RISK-BENEFIT PREFERENCES FOR NEW TREATMENTS

Mohamed AF, Johnson FR, Hauber B, Leibman C, Arrighi HM

Research Triangle Institute, Research Triangle Park, NC, USA

OBJECTIVES: The objective of this study is to quantify the strength of preferences of older Americans for possible Alzheimer’s disease (AD) treatment benefits by estimating their willingness to accept the risk of death or severe disability in exchange for modifying the course of AD. Currently, AD has no cure. A breakthrough in treatment that modifies the underlying AD disease process would be a major achievement with enormous medical and social benefits. Little is known concerning older Americans’ perceptions about AD and their willingness to accept risk to avoid AD. METHODS: American residents aged 60 years and older who have not been diagnosed with AD, and are not taking prescription medicines to treat AD, memory problems or dementia completed an online survey questionnaire that included a series of stated-choice trade-off tasks. Respondents chose between pairs of hypothetical treatment alternatives, each including different 7-year AD disease-progression profiles and risks of serious adverse events that would result in death or severe disability. We used mixed-logit methods to estimate the maximum acceptable risk (MAR) of serious adverse events that would result in death or severe disability, RESULTS: 2146 respondents completed the survey. Mean (SD) age was 70 (7.4). In return for preventing AD from progressing beyond the mild stage, the mean MAR (95% CI) was 46.8% (40.3%–54.3%); that is older Americans were willing, on average, to accept an increase in the risk of death or severe disability from stroke of nearly 50% to avoid progression to the moderate and severe stages of AD. CONCLUSION: Older Americans’ willingness to accept significant increases in the risk of death or disability in exchange for treatments that modify the course of AD indicates the value of such treatment benefits.

COST-UTILITY ANALYSIS EVALUATING LIDOCAINE 5% MEDICATED PLASTER RELATIVE TO GABAPENTIN FOR POST-HERPETIC NEURALGIA IN SCOTLAND

Dakin HA, Nuijten MJ, Liedgens H, Poulsen Nastrup P

1 Abacus International, Bicester, Oxfordshire, UK, 2 Erasmus University, Rotterdam, The Netherlands, 3 Grünenthal GmbH, Aachen, Germany

OBJECTIVES: To assess the cost-effectiveness of using a lido- caine 5% medicated plaster (lidocaine plaster) in the treatment of post-herpetic neuralgia (PHN) in place of gabapentin from the perspective of the Scottish National Health Service. METHODS: A Markov model was constructed in TreeAge to calculate the costs and benefits of gabapentin and lidocaine plaster when used in primary care over a six-month time horizon in patients with...