

quarterly per-prescription reimbursements were defined as total reimbursement amounts divided by total prescriptions. The market shares were calculated based on the proportion of total prescription numbers. **RESULTS:** The total reimbursement for AMDs increased from \$1.6 million in 1991 to \$156 million in 2004, and dropped to \$115 million in 2008. Prescriptions for AMDs increased from 56,410 in 1991 to 948,597 in 2004, and then dropped to 542,093 in 2008. The ergot prescriptions increased from 25,540 in 1991 to 47,543 in 1995, then gradually decreased to 6,367 in 2008. A similar utilization trend was found for ergot combination products. Meanwhile, triptan prescriptions increased from 23,523 in 1995 to 912,978 in 2004, and dropped to 524,922 in 2008. The market share for triptans increased dramatically from 0% in 1994 to 97% in 2008, while the market share for ergot derivatives and ergot combination products decreased from 45% and 55% in 1991 to 1% and 2% in 2008, respectively. The per-prescription cost of branded triptans has steadily increased since 1994, regardless of newer brand entries. **CONCLUSIONS:** Triptan use has increased dramatically and dominated the AMD market. However, triptan utilization dropped 34.91% in 2006. This may be due to the implementation of Medicare Part D.

PND35

ANTIEPILEPTIC DRUG UTILIZATION AND MEDICAID REIMBURSEMENT TRENDS FROM 1991 TO 2008

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OBJECTIVES: Antiepileptic drugs (AEDs) are one of the most frequently prescribed medication classes in U.S. The objectives of this study were to describe AED utilization, price and reimbursement trends and to analyze the market share competition between traditional and newer AEDs. **METHODS:** A retrospective, descriptive time-series analysis was performed using the National Medicaid pharmacy claims database from 1991 to 2008. Quarterly number of prescriptions and reimbursement data were calculated for the trends analysis. Study drugs included all brand and generic names of newer AEDs (e.g., gabapentin, lamotrigine, topiramate, fosphenytoin) and traditional AEDs (e.g., tiagabine, valproate, zonisamide, carbamazepine). Market share for AEDs was quantified annually. The quarterly price per prescription was calculated by dividing the total reimbursement by the total number of prescriptions. **RESULTS:** The total number of newer AED prescriptions increased from 32,837 prescriptions totaling \$2.2 million reimbursement in 1993 to 7.7 million totaling \$1.2 billion in 2005, and dropped to 4.3 million totaling \$847 million in 2008. Meanwhile, traditional AED prescriptions increased from 5.14 million totaling \$154 million reimbursement in 1991 to 20.5 million totaling \$1.22 billion in 2004, and dropped to 11.5 million totaling \$447 million in 2008. The average annual increase in number of prescriptions was 71.3% for newer and 6.95% for traditional AEDs. The market share of newer AED prescriptions increased from 1% in 1993 to 28% in 2005, and 27% in 2008. Fosphenytoin remained the most expensive newer AED with price of \$211 in 1996 and \$391 in 2005. Valproic acid and clonazepam were the most expensive traditional AEDs, with prices varying from \$150 to \$600. **CONCLUSIONS:** There has been substantial increase in use of AED, which may be due to off-label use, new indications, and as adjunct therapy. A significant drop in AED utilization trends since 2004 may potentially be due to Medicare part D introduction and patent expiration.

PND36

POTENTIAL BARRIERS TO HOME CARE USE AMONG PATIENTS WITH MULTIPLE SCLEROSIS

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OBJECTIVES: Multiple sclerosis (MS) is a chronic illness leading to permanent disability. As the disease progresses, MS patients may require home personal care (HPC). HPC assists patients with activities of daily living (ADLs) and homemaking, so patients can continue living in their homes. This study examines the extent as well as the barriers and facilitators of HPC use by MS patients. **METHODS:** We analyzed data for 1577 participants in the 2000–2005 Sonya Slifka survey of MS patients. This survey provides information on disease status, socio-demographics, family information, and HPC use. We constructed 3 outcome measures: use of paid HPC, use of help with ADLs or instrumental ADLs (IADLs), and unmet need. Logistic regression with sampling weights and robust standard errors were employed to examine the association between each outcome and patient characteristics. **RESULTS:** Greater disability was associated with greater use of paid HPC ($P < 0.001$) and greater assistance received for ADLs/IADLs ($P < 0.001$). Patients on Medicaid used more paid HPC (OR = 1.74, $p = 0.01$) and had less unmet need (OR = 0.53, $p = 0.03$). Medicare beneficiaries received more assistance with ADLs/IADLs (OR = 1.42, $p = 0.02$), but did not receive more paid care. Patients living with a spouse/partner purchased fewer services (OR = 0.64, $p = 0.01$), while receiving more help overall with functional limitations or chores (OR = 2.06, $p < 0.01$). Patients with greater family income reported lower unmet need (OR = 0.36, $p < 0.01$). **CONCLUSIONS:** Type of insurance and marital status are important predictors of HPC use among the MS population. While patients who live with a spouse/partner often have higher family income and can afford more paid HPC, they appear to delegate the more burdensome ADL care to their family, while being more inclined to pay for help with homemaking. Overall, these patients had lower unmet needs and used less paid help than patients living alone.

PND37

PROJECTING THE BURDEN OF ALZHEIMER'S DISEASE AND EVALUATING THE POTENTIAL IMPACTS OF PREVENTING ALZHEIMER'S DISEASE IN THE UNITED STATES

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OBJECTIVES: Alzheimer's disease is the sixth-leading cause of death in the United States. The health and economic costs associated with the disease are enormous. We forecast and quantify this burden until year 2050 and evaluate the potential impacts of delayed onset of Alzheimer's disease. **METHODS:** We use a dynamic micro-simulation model to predict health status (Alzheimer's disease as one of the measures) and economic situations of Americans 50 years and older, from year 2004 to 2050. To estimate the burden of Alzheimer's disease, we estimate a scenario in which there is no incidence of Alzheimer's disease and compare outcomes with projections of the status-quo over future years. To evaluate the impacts of potential treatments to delay the onset of Alzheimer's disease, we run three scenarios in which there is 2-year, 4-year, or 6-year delay of onset of Alzheimer's disease. The main data sources are the Health and Retirement Study and the Aging, Demographics, and Memory Study. The health outcome measured is Quality-Adjusted Life Years. Economic outcomes include earnings and tax revenues, health care costs and long-term care costs (total, Medicare, Medicaid), opportunity costs for unpaid caregivers, and Social Security outlays. **RESULTS:** The population with Alzheimer's disease will increase by more than 150 percent in year 2050. Relative to the status-quo, eliminating Alzheimer's disease would raise tax revenues, and reduce cumulative Medicare costs. Alternatively, cumulative Medicaid spending and Social Security benefits would increase, outweighing the savings in Medicare spending and raised tax revenues. We will also present the gains in QALYs and savings in unpaid care-giving under different intervention scenarios. **CONCLUSIONS:** Preventing Alzheimer's disease will increase life expectancy and quality of life. However, these health benefits will increase government spending as increased longevity results in longer outlays of annuities and health spending.

PND38

SOCIODEMOGRAPHIC PATTERNS OF INSOMNIA DRUG PRESCRIPTIONS

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OBJECTIVES: Insomnia is the most common sleep complaint worldwide. Our study aims to identify physician and patient characteristics likely to influence insomnia prescription patterns. **METHODS:** The project utilized data from National Ambulatory Medical Care Survey, conducted by the US Department of Health and Human Services. The study subjects were selected from 2006 outpatient visits in which at least one frequently used insomnia medication was prescribed. A series of population-based descriptive analyses were used to estimate the national weighted frequencies of selected insomnia drug prescriptions. We further constructed a weighted logistic regression model to estimate the odds ratio and marginal probabilities of covariates toward predicting insomnia drug prescriptions. **RESULTS:** Among the 901.8 million outpatient visits that took place in the US in 2006, an estimated 21.07 million visits included at least one insomnia drug prescription. The results from a multivariate logistic regression showed that a patient's race and age, physician's clinic ownership, type of office setting, and employment status were significantly associated with insomnia drug prescriptions. Black patients were 2.4 times more likely to receive insomnia prescription than were white patients (OR = 2.4; 95% Wald CI (1.26–4.69)). Older patients were more likely received insomnia prescription than were younger patients. Patients with 3–5 visits over the course of 12 months received fewer insomnia prescription than did patients with only 1 visit (OR = 0.44; 95% Wald CI (0.21–0.93)). Physicians who worked in the academic health center prescribed fewer insomnia drugs than did physicians who worked in the private practices (OR = 0.29; 95% Wald CI (0.09–0.91)). Employed or contracted physicians prescribed a significantly higher number of insomnia drugs than did owner physicians (OR = 3.6; 95% Wald CI (1.87–6.78)). **CONCLUSIONS:** Our findings indicate various sociodemographic disparities in the use of insomnia prescriptions. The study also demonstrated a comprehensive analytical framework, which is especially applicable to population-based data mining research.

NEUROLOGICAL DISORDERS – Conceptual Papers & Research on Methods

PND39

AGREEMENT BETWEEN MULTIPLE SCLEROSIS-RELATED VARIABLES IN MEDICAL CHARTS AND CLAIMS DATA

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OBJECTIVES: To evaluate the agreement between data derived from medical charts of patients with multiple sclerosis (MS) and from a health care claims database. **METHODS:** This data source comparison was a secondary objective in a study utilizing both claims and linked medical chart data. Patients with MS were identified in a

health care claims database and the claims and medical charts for a subset of this population were reviewed to extract information pertaining to disease-modifying therapy, corticosteroid therapy, MS-related procedures, and diagnosis and relapse dates. The agreement between the data sources for each type of information was identified. **RESULTS:** From a total population of 11,326 MS patients in the claims database, 300 had their medical records reviewed. Among patients with claims for glatiramer acetate ($n = 68$), 95.6% also had it indicated in their charts. Claims agreed with charts for 91.8% of patients with a claim for intramuscular interferon β -1a ($n = 85$), 81.8% of patients with a claim for subcutaneous interferon β -1a ($n = 55$), and 87.5% of patients with a claim for interferon β -1b ($n = 48$). Methylprednisolone was the most commonly indicated corticosteroid in both data sources, and among patients with evidence of a methylprednisolone fill in the claims ($n = 114$), 66.7% also had a prescription indicated in their chart. Most patients with claims-based evidence of MS-related procedures also had them indicated in their charts: 71.0% with MRI, 81.0% with lumbar puncture, and 66.7% with evoked potential testing. For both diagnosis and relapse dates, at least half of the patients had perfect agreement. **CONCLUSIONS:** Claims and medical charts provide complementary information with a degree of overlap. Claims appear to approximate chart data with regard to certain MS-related variables, such as dates and disease-modifying therapy, but the data sources also provide unique information which might be differentially suited to addressing diverse research questions.

PND40

THE IMPORTANCE OF GUIDELINES FOR CLINROS: THE ADAS-COG, A CASE STUDY

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OBJECTIVES: Since its development in the 80's, variations of the Alzheimer's Disease Assessment Scale-Cognitive subscale (ADAS-Cog), a Clinician-Reported Outcome (ClinRO) measure, have been used to monitor disease progression and treatment efficacy in Alzheimer's disease. The objective of this study was to identify all versions used as a basis for translation in Mapi Institute projects and to take stock of existing translations. **METHODS:** The review was based on all ADAS-Cog translation projects performed by Mapi Institute. **RESULTS:** Sixteen projects were identified representing a total of 70 languages and 219 translations. Translations were based on 11 source versions which differed in terms of content (number of items, order of items and instructions), and format. The number of items ranged from 11 to 15. Four studies used 13 items, but only in two cases the same items were used but in a different order. Four studies used 12 items: only two studies used the same items (with a different list of words for the Word Recognition Task), but again in a different order. Format and instructions differed in all cases. In most projects the source version provided by the sponsor was a single document mixing instructions with the rater and response forms. Only in 3 cases the original consisted in a separate instruction manual and response forms. With regard to available translations, more than one translation was identified in 56 of the 70 available languages and in one language as many as 7 translations. **CONCLUSIONS:** The abundance of different versions of the same questionnaire both in its original US English form as in translation makes comparisons between studies or pooling of data difficult for both researchers and users. In the light of FDA's recent PRO guidance it would be beneficial to demand the same scientific rigor when using ClinROs in international studies.

PND41

THE EFFECT OF MULTIPLE COMPARISONS ADJUSTMENTS IN ANALYSIS OF HEALTH-RELATED QUALITY OF LIFE BY WORK STATUS

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OBJECTIVES: Explore the effect of adjusting for multiple comparisons in analyzing outcome variables between more than two strata. **METHODS:** Health-related quality of life (HRQoL) via SF-12 Health Survey was measured at baseline for 191 patients in a U.S. multiple sclerosis observational study. HRQoL was summarized in two continuous variables: Physical Component Score (PCS-12) and Mental Component Score (MCS-12). Patient work status was expressed by one categorical variable with four values: Working Full-time (W), Working Part-time (WP), Not Working due to MS (NW-MS), Not Working due to other reasons (NW). Generalized linear models were used to measure the overall association HRQoL and work status. Pairwise comparisons were conducted between the HRQoL means with respect to each of the four categories of work status. The Bonferroni method was used to control the familywise error rate under multiple comparisons test. **RESULTS:** Overall association between Work Status and HRQoL was statistically significant (p -values: $<.001$ for all measures), suggesting that HRQoL differs by work status. Pairwise comparisons showed that only the NW-MS group was statistically significantly different from all other groups (all p -values $<.001$) and different from W and WP groups in MCS-12 (p -value: $W = 0.03$, $WP = <.001$), while all other comparisons were not significantly different from each other. If the Bonferroni adjustment is not applied, the pairwise comparisons lead to more differences being significant (p -value: W vs $WP = 0.04$ in PCS-12 and MCS-12). **CONCLUSIONS:** Even though the overall association between two variables may be statistically significant, if the categorical variable has more than two categories, then applying multiple comparisons adjustments to all pairwise comparisons more appropriately tests the statistical significance of the differences between these individual categories. Neglecting to account for the fact that multiple comparisons are being made may lead to erroneous conclusions about differences in outcomes.

SENSORY SYSTEMS DISORDERS – Clinical Outcomes Studies

PSS1

BEVACIZUMAB FOR NEO-VASCULAR AGE RELATED MACULAR DEGENERATION—EVIDENCE SUMMARY

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OBJECTIVES: To evaluate evidence on effectiveness of intravitreal Avastin for neo-vascular age related macular degeneration (AMD). **METHODS:** We searched the Medline database for articles on bevacizumab for neo-vascular AMD, published between January 1, 2005 and September 1, 2009. The search criteria were English language manuscripts, human studies and search terms "bevacizumab", "Avastin", "age-related macular degeneration", "ARM", "AMD", "intra-vitreous" as a major heading. Boolean operators were used to combine the search terms. Studies in which primary outcome measures were visual acuity (VA) and central retinal thickness (CRT) were included for review. Two reviewers independently selected studies, assessed methodological quality using Scottish Intercollegiate Grading Network (SIGN) system. **RESULTS:** Overall, there were 520 citations, of which only 216 were relevant after title and abstract screening. Sixty-seven manuscripts were finally included for review, of which three were systematic reviews, three were randomized Controlled Trials (RCT), 49 were pre-post/ non-randomized studies and 13 were studies on safety and adverse effect. Three RCTs show bevacizumab to be more effective than PDT (with or without triamcinolone). However, these RCTs had several methodological issues; evidence from these RCTs was of moderate quality. Several pre-post and non-randomized studies have also suggested the effectiveness of bevacizumab, but these studies had several design limitations and hence the quality of evidence was deemed poor. Pooled outcome estimates, showed bevacizumab therapy, on average, improved VA by nine EDTRS letters and reduced CRT by 90 μ m. Incidence of adverse events was low, similar to ranibizumab. Currently moderate (grade B) to poor quality of evidence is available in support of bevacizumab for neo-vascular AMD. **CONCLUSIONS:** Based on current evidence (grade B) off-label Intravitreal bevacizumab seems to be safe and effective for the treatment of neo-vascular AMD in the short term, especially for underserved and financially challenged communities.

SENSORY SYSTEMS DISORDERS – Cost Studies

PSS2

RETURN ON INVESTMENT OF ABLATIVE FRACTIONAL LASERS

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OBJECTIVES: Conduct a return on investment (ROI) analysis of 8 ablative fractional lasers used for cosmetic facial plastic surgery from the perspective of a facial plastic surgeon. **METHODS:** We identified 8 of the largest (based on sales volume) ablative fractional lasers for this analysis. ROI is $(\Sigma \text{Total Revenue} - \Sigma \text{Total Cost}) / (\Sigma \text{Total Cost})$ and is defined as the additional dollar returned for each dollar invested. Revenue was estimated as price per procedure multiplied by total number of procedures in a year. Total cost is a composite of purchase price and operating costs. In the base case analysis two purchase options were assumed 1) a 5 year lease with a \$0 down payment and 2) a 3 year lease with a \$0 down payment. In addition to monthly lease payments, included in the total cost estimate were service contracts, labor costs, and disposables. Sensitivity analyses were performed to account for variability in cost and revenue assumptions. **RESULTS:** Revenue for each laser was estimated to be \$51,072/year. Under a 5 year lease, the assumed total cost of each laser ranged from \$115,827–\$240,597. This is compared to the total cost under a 3 year lease of each laser which ranged from \$74,364–\$124,878. Average ROI under the 5 year lease term was .54 and ROI varied between $-.03$ (most expensive laser) and 1 (least expensive laser). The average 3 year ROI was .08, and ROI varied between $-.35$ (most expensive laser) and .38 (least expensive laser). **CONCLUSIONS:** Based on the assumptions of our analysis the laser with highest ROI was the least expensive laser. While ROI is an important financial it should not be the sole means by which to determine a purchase. Physicians must also consider the clinical effectiveness of each laser and their own clinical judgment when making such decisions.

PSS3

THE ECONOMIC IMPACT OF DRY EYE DISEASE IN THE UNITED STATES

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OBJECTIVES: Evaluate the annual cost of Dry Eye Diseases (DED) care in the United States from both a societal and a payer's perspective. **METHODS:** A decision-tree model was developed to estimate the annual cost for managing a cohort of DED patients with differing severity of symptoms and treatments utilizing data collected from survey and the literature. The direct costs included over the counter (OTC) medications, cyclosporine, punctal plugs, physician visits, and nutrition complements. The indirect costs were computed based on the self-reported productivity loss including absenteeism and presenteeism. Multiple-one way sensitivity analysis was employed to evaluate the impact of changes in parameters within their 95% confidence intervals on the cost estimate. **RESULTS:** In the base-case analysis, the total mean annual direct