beneficiaries who were enrolled in an MA-PD or a drug plan with drug deductibles, tiered copayments, or mailorder services in the plan benefit design were more likely to experience CRN.

PIH54

HEALTH CARE UTILIZATION AND COSTS AMONGST WOMEN WITH FEMALE SEXUAL DYSFUNCTION (FSD) AND HYPOACTIVE SEXUAL DESIRE DISORDER (HSDD)

Foley K[1], Foley D[2], Shah H[3]
[1]Thomson Reuters, Philadelphia, PA, USA, [2]Boehringer Ingelheim Ltd, Ridgefield, CT, USA, [3]Boehringer Ingelheim Pharmaceuticals, Inc, Ridgefield, CT, USA

OBJECTIVES: The health care utilization and costs among commercially insured women with a diagnosis of Female Sexual Dysfunction (FSD) and Hypoactive Sexual Desire Disorder (HSDD) in the United States. **METHODS:** The Thomson Reuters Marketscan® Database was used to identify women aged 18–64 with an ICD-9-CM coded diagnosis of FSD, including a subset with HSDD from January 1, 1998-September 30, 2006. A control group of women with no diagnosis of any sexual dysfunction was matched 3:1 to cases based on age, health plan and enrollment period. Controls were assigned the index date of their matched case. Health care utilization and costs were examined in the year prior ("pre-period") to and following index ("post-period"). **RESULTS:** A total of 4831 women were coded as FSD (59% as HSDD) and matched to 14,493 controls. The FSD group had more outpatient visits and services in both the pre- (22.2 vs. 16.2, $p < 0.001$) and post- (25.4 vs. 17.7, $p < 0.001$) periods compared with their matched controls. They also consistently filled more prescriptions in the pre- (14.5 vs. 11.5, $p < 0.001$) and post- (16.2 vs. 7.2, $p < 0.001$) periods. Nearly identical patterns were observed in the HSDD group. These higher levels of utilization resulted in costs that were higher for FSD and HSDD women relative to their matched controls in the pre-period ($1296 and $ 1146 respectively). Similar patterns of increased health care utilization were also seen in the post-period for both FSD and HSDD patients ($1,190 and $897 respectively). The most significant drivers of health care costs for both groups were outpatient medical services (including professional visits, outpatient surgeries, and laboratory expenditures) and total prescription medication costs. **CONCLUSIONS:** Women diagnosed with FSD and HSDD use significantly more health care services than women without diagnosed sexual dysfunction. The resulting higher costs are driven by a greater use of outpatient services and prescription medications.

PIH56

CARESS: THE CANADIAN REGISTRY OF SYNAGIS® SUMMARY OF 2006–2008 RSV SEASONS

Paes B[1], Reim EK[2], Lanctôt KL[2], Mitchell I[3]
[1]McMaster University, Hamilton, ON, Canada, [2]Sunnybrook Health Sciences Centre, Toronto, ON, Canada, [3]University of Calgary, Calgary, AB, Canada

OBJECTIVES: To understand current management (utilization, compliance) with palivizumab prophylaxis of children at high-risk of RSV infection in Canada. **METHODS:** A prospective, observational, registry of infants at high risk for RSV who received at least one dose of palivizumab during the 2006 to 2008 RSV seasons from 24 sites. Neonatal and demographic data were collected upon enrollment. Data on palivizumab utilization and compliance, including outcomes related to a respiratory infection were collected monthly until the full course of palivizumab was completed or at the end of the relevant RSV season. **RESULTS:** A total of 2910 infants were enrolled, age two days to 47 months (mean = 5.5 months). In total, 54.4% were male, 62.2% Caucasian, average gestational age (GA) was 32.0 ± 6.8 completed weeks. 2079 (71.4%) infants received palivizumab because they were premature only (i.e. ≤35 completed weeks GA), 255 (8.8%) required oxygen, 288 (9.9%) had congenital heart disease and 288 (9.9%) were prophylaxed for other risk factors such as CNS disorders, airway anomalies and cystic fibrosis. Compliance was high; 77.8% received at least four injections of palivizumab between September and June each season. Overall 12, 973 doses were given. No directly related serious adverse events were identified. A total of 159 infants had 194 hospitalizations for respiratory tract infections (hospitalization rate 5.5%) and rates were highest in those with chronic lung disease (9.8%, $p = 0.006$). The RSV positive hospitalization rate was only 0.96%. **CONCLUSIONS:** The RSV hospitalization rate observed in the 2006–2008 RSV seasons was lower than that found in several published reports (range1.3%–5.3%). The rates of RSV hospitalization may be decreasing for various reasons such as high compliance with palivizumab prophylaxis, variability in RSV epidemiology, hospital admission criteria and preventive education.

MENTAL HEALTH – Clinical Outcomes Studies

PMH1

ALPRAZOLAM-RELATED DEATHS IN WEST VIRGINIA

Shah N, Smith MJ, Abate MA
West Virginia University, Morgantown, WV, USA

OBJECTIVES: Alprazolam is a frequently prescribed benzodiazepine associated with abuse and misuse that can lead to fatalities. This study's aims were to: 1) describe the characteristics of alprazolam-related death cases; 2) describe the comorbidities, co-ingested drugs, and mean alprazolam concentrations of decedents; and 3) compare characteristics between alprazolam and non alprazolam-related death cases. **METHODS:** Data from all drug-related deaths in West Virginia from January 1, 2005 to November 16, 2007 were extracted from the Forensic Drug Database. Chi square tests compared categorical descriptive statistics between alprazolam and non-alprazolam cases. One-way ANOVA compared mean alprazolam blood concentrations based upon numbers of other ingested drugs. **RESULTS:** Of the 1199 drug-related deaths in the database, alprazolam was a contributing cause in 204 (17.0%) cases. It was involved in an increasing number of drug-related deaths over time. The mean age of alprazolam cases was 39.6 (+11.2) years; most were male (66.3%) and white (96.0%), with the deaths ruled accidental (90.2%). There was a prescription for alprazolam in over half the cases (52.5%); approximately one-third (33.8%) had a history of substance abuse or cardiovascular disease. At least one other drug was a contributor to death in 97.5% of the alprazolam cases, with an opiate detected in most cases (88.7%). The mean alprazolam blood concentration was significantly higher when taken alone than when ingested with one or more drugs ($p < 0.001$). More alprazolam decedents were obese (43.9%) compared to non-alprazolam decedents (32.9%) ($p = 0.005$). Alprazolam cases had a significantly greater average number of drugs implicated in death (2.9 + 1.0) than non-alprazolam cases (2.3 + 1.3) ($p < 0.001$). **CONCLUSIONS:** Alprazolam-associated deaths are a significant public health problem in West Virginia; these cases have characteristics that can differ from other drug death cases. Certain drug combinations involving alprazolam may pose a greater risk for serious adverse events.

PMH2

USE OF HYPNOTICS/ANXIOLYTICS IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER: ASSOCIATIONS WITH CHRONIC PAIN, SLEEP DISORDERS, AND ANTIDEPRESSANT SELECTION

Liu X[1], Ye W[2], Wohlreich M[2]
[1]Eli Lilly and Company, Indianapolis, IN, USA, [2]Lilly USA, LLC, Indianapolis, IN, USA

OBJECTIVES: Many patients with major depressive disorder (MDD) suffer from chronic pain (CP) and sleep disturbances (SD). Little is known about associations between the use of hypnotics/anxiolytics for these conditions and the use of antidepressants in real-world clinical settings. This study examined the use of hypnotics and anxiolytics, their associations with CP and SD, and initiation of serotonin-norepinephrine reuptake inhibitors (duloxetine and venlafaxine XR) in a large managed-care population of patients with MDD. **METHODS:** A total of 153,913 patients who had at least 1 diagnosis of MDD during the year 2006 were selected from a large commercially insured administrative claims database. The analytic sample consisted of 47,109 (30.6%) males and 106,804 (69.4%) females, with a mean age of 43.6 years (SD = 12.7). In accordance with ICD-9-CM, CP was defined as any pain of the following 6 categories: headache, rheumatoid arthritis, osteoarthritis, low back pain, fibromyalgia, and neuropathic pain. Hypnotics/anxiolytics were classified into 3 categories: benzodiazepines (BENZ), non-benzodiazepine hypnotics (NBENZH), and non-benzodiazepine anxiolytics (NBENZA). **RESULTS:** Of the 153,913 patients with MDD, 35.5% had CP; 5.3%, SD; and 7.3%, CP plus SD. Over the 1-year study period, 33.1% of patients were prescribed BENZ; 16.9%, NBENZH; and 6.1%, NBENZA. Of patients with MDD, patients also diagnosed with CP and SD were most frequently prescribed NBENZH, BENZ, and NBENZA (36.4%, 47.7%, 9.6%), followed by patients with SD (30.2%, 36.7%, 6.4%), CP (18.7%, 39.9%, 7.4%), and MDD only (11.6%, 26.1%, 4.6%). Prior use of BENZ (OR = 1.5, 95% CI = 1.4–1.6), NBENZH (OR = 1.6, 95% CI = 1.5–1.7), and NBENZA (OR = 1.2, 95% CI = 1.1–1.3) was significantly associated with initiation of duloxetine compared with venlafaxine XR. **CONCLUSIONS:** Hypnotics and anxiolytics are commonly used in MDD patients. CP and SD are associated with increased use of hypnotics and anxioloytics in MDD patients. Prior use of hypnotics and anxioloytics may be associated with antidepressant selection.

PMH3

DEPRESSION: ETHNIC DIFFERENCES IN PREVALENCE, DIAGNOSIS, AND SYMPTOMS

Kannan H, Bolge SC, Wagner S
Consumer Health Sciences International, Princeton, NJ, USA

OBJECTIVES: To assess ethnic differences in the prevalence, physician diagnosis and symptomology of depression. **METHODS:** Data were taken from the 2008 US National Health and Wellness Survey (NHWS), a self-reported, Internet-based study of the disease status, attitudes, habits, and outcomes of adults age 18+. Ethnic groups included whites, blacks, Hispanics and Asians. Respondents self reported experiencing depression, depression diagnosed by a physician, and experiencing the following in the previous month: bothered by feeling down, depressed, or hopeless; bothered by having little interest or pleasure in doing things. Prevalence was calculated using frequency weights based on age, gender and race. Chi-square analyses were conducted to assess statistically significant differences. **RESULTS:** Of the 61,016 respondents, 22.2% (Projected 53.8M; 25%) reported experiencing depression within the previous year. There were significant ($p < 0.05$) variations across ethnic groups: White = 39.5M, 25.8%; Black = 4.9M, 19.8%; Hispanic = 8.1M, 27.6%; Asian = 1.3M, 16.1%). Among those who report experiencing depression, whites were most likely to be diagnosed (77.0%) compared with 60.8% of blacks, 62.8% of Hispanics, and only 48.4% of Asians, who were least likely to be diagnosed. Among those who did not self-report experiencing depression, 11.2% of whites, 12.8% of blacks, 13.1% of Hispanics, and 13.46% of Asians experienced one depression symptom and 9.6% of whites, 11.9% of blacks, 13.2% of Hispanics, and 12.2% of Asians experienced both depression symptoms ($p < 0.05$). **CONCLUSIONS:** While there is significant ethnic variation in prevalence of self-reported depression, there is even greater ethnic variation in diagnosis among patients experiencing depression. Also, recognition of symp-

toms as depression is poorer among ethnic minorities than among whites. Patient and physician education campaigns aimed at addressing the cultural stigma and perceptions of depression as well as available treatment options available may increase likelihood of diagnosis and possibly lead to better outcomes.

PMH4

PREVALENCE OF DEPRESSION IN EUROPE: A COMPARISON OF FIVE COUNTRIES

Narayanan S[1], Potthoff P[2], Guether B[2]
[1]TNS Healthcare, New York, NY, USA, [2]TNS Healthcare, Munich, Bavaria, Germany

OBJECTIVES: To assess the prevalence of depression among five large European nations. **METHODS:** TNS Healthcare's European Healthcare Panel of individuals in France, Germany, Italy, UK and the Netherlands were surveyed in 2007 to assess disease burden at national level. The self-reported epidemiological data is representative of population gender and age (18–24, 25–34, 35–44, 45–54, 55–64, 65–69 yrs) strata in respective countries, ensured by sampling and intensive panel management. The survey collected information on select health conditions (incl. depression; in the past 12-months), quality of life and health care-utilization. **RESULTS:** In the TNS European Healthcare Panel, 8,665, 25,265, 19,887, 59,850 and 47,340 individuals completed survey in the Netherlands, Germany, Italy, France and UK respectively. Prevalence of Depression varied widely between these 5 nations, as follows: Netherlands: 9.4%, Germany: 14.6%, U.K: 14.8%, France: 17.8%, Germany: 18.8%. Within each country, burden of Depression varied by age and gender; distribution among male (18–24, 25–34, 35–44, 45–54, 55–64, 65+ yrs: % pts) was: the Netherlands: 5.1%, 6.0%, 7.0%, 7.6%, 7.3%, 5.1%; Germany: 10.9%, 9.9%, 11.2%, 13.7%, 10.6%, 3.7%; Italy: 9.9%, 7.4%, 9.5%, 10.9%, 11.3%, 9.4%; France: 13.7%, 12.8%, 14.4%, 14.6%, 10.9%, 6.2%; U.K: 11.8%, 12.2%, 15.8%, 18.7%, 14.0%, 7.0%; distribution among female (18–24, 25–34, 35–44, 45–54, 55–64, 65+ yrs: % pts) was: the Netherlands: 5.7%, 14.4%, 13.4%, 13.3%, 10.9%, 13.8%; Germany: 18.9%, 17.9%, 19.8%, 24.2%, 16.0%, 8.2%; Italy: 17.7%, 17.7%, 21.1%, 24.7%, 21.3%, 12.2%; France: 25.4%, 23.4%, 23.0%, 23.7%, 19.5%, 15.5%; UK: 24.9%, 24.8%, 26.6%, 26.2%, 19.1%, 12.8%. General Practitioners were the primary point of diagnosis and source of treatment, even though this statistic varied between the countries. **CONCLUSIONS:** Prevalence of depression appears to be substantial in the studied European nations and peaked in the 35–55 age-group. Females had substantially higher disease burden, amounting to as much as twice as their male counterparts in certain age groups.

PMH5

PATIENT ASSESSED QUALITY OF LIFE VERSUS CLINICIAN ASSESSMENT: A POST-HOC ANALYSIS OF A TRIAL OF ARIPIPRAZOLE IN ADOLESCENT PATIENTS WITH SCHIZOPHRENIA

Wisniewski SR[1], Whitehead R[2], Ali M[3], Jin N[3], Kim E[4], Nyilas M[5], Carson WH[5], Iwamoto T[5], Mathew S[2], Pikalov A[2], Jing Y[4]
[1]University of Pittsburgh, Pittsburgh, PA, USA, [2]Otsuka America Pharmaceutical, Inc, Rockville, MD, USA, [3]Otsuka Pharmaceutical Development and Commercialization, Inc, Rockville, MD, USA, [4]Bristol-Myers Squibb, Plainsboro, NJ, USA, [5]Otsuka Pharmaceutical Development and Commercialization, Inc, Princeton, NJ, USA

OBJECTIVES: The pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) is made up of 14 items that assess quality of life (QoL) aspects (Total) and a 1-item overall assessment (Overall). This post-hoc analysis determined whether patient's assessment in QoL correlated with improvement as determined by the clinical assessment (i.e. PANSS; CGI-S). **METHODS:** A total of 302 patients (aged 13–17) with schizophrenia participated in a 6-week, multicenter, double-blind, randomized trial. The primary measure was mean change from baseline in PANSS Total score (LOCF). Secondary measures included CGI-S and the PQ-LES-Q Total and Overall. Relationships between percentage of change from baseline in PQ-LES-Q. Total and percentage of change in PANSS and between change from baseline in PQ-LES-Q Total and change from baseline in CGI-S score were tested by Pearson correlation and trend analysis (Cochran-Mantel-Haenszel). **RESULTS:** Aripiprazole showed significant improvements over placebo in PANSS, CGI-S, and PQ-LES-Q Overall (week 6; $p < 0.05$; LOCF). Strong correlation was found between all measures in the overall population, including PQ-LES-Q Total versus PANSS Total score and PQ-LES-Q Overall versus CGI-S ($r = -0.33$ and -0.29; $p = 0.01$). Analysis by treatment arm showed strong correlation between change in PQ-LES-Q Total versus change in PANSS Total in all groups ($r = -0.44$; $p < 0.011$; LOCF). Correlation between change in PQ-LES-Q Overall versus change in CGI-S was significant in the 10 mg/day group ($r = -0.33$; $p = 0.001$; LOCF), but not for the 30 mg/day and placebo groups ($r = -0.084$). Categories of CGI-S and PANSS Total improvement correlated with change in PQ-LES-Q ($p < 0.001$; LOCF). **CONCLUSIONS:** Improvements in patient-assessed QoL were significantly correlated with clinician reported outcomes in the overall population and in individual treatment groups. Aripiprazole 10 mg/day and the combined treatment group demonstrated a significant correlation between improvements in global QoL and global severity of illness.

PMH6

A COMPARATIVE REVIEW OF SAFETY, EFFICACY AND ECONOMICS OF OFF-LABEL PRESCRIBING OF LEADING ATYPICAL ANTIPSYCHOTICS

Mittal AR
St. John's University, Jamaica, NY, USA

OBJECTIVES: To examine the controversial practice of off-label prescribing of atypical antipsychotic drugs and to review research evidence pertaining to the economics of their use, safety, efficacy and appropriateness of such prescribing. **METHODS:** A comprehensive review of scientific literature published between 2001–2009, covering all empirical studies that examined off-label prescribing of atypical antipsychotics. Quantitative and qualitative analyses of published secondary data for off-label uses of three leading atypical anti-psychotics were conducted to gain insights into prevalence of off-label use, costs, and mortality associated with their use. **RESULTS:** Twenty experimental and observational studies qualified for inclusion. Most study participants were institutionalized elderly, Caucasian men, with Alzheimer's disease. The newer atypicals accounted for more than $11 billion in annual sales and represented 90% of the antipsychotic market in 2005. There was a five-fold increase in the prescription of these drugs particularly in children in the last decade and a half. Risperidone was the most prescribed drug off-label. EPS, gait disturbances and weight gain were the most commonly cited adverse events. Elderly patients with dementia-related psychosis treated with atypical antipsychotics were found to be at an increased risk of adverse events and death. **CONCLUSIONS:** The research evidence available to determine the true extent and consequences of off-label prescribing of atypical antipsychotics, while scarce and conflicting, is mostly critical of their use in children and elderly with dementia. Scientific support documenting the efficacy and appropriateness of these drugs for treating depression and behavioral disorders of dementia is currently inconclusive. The high cost of these drugs may arguably offset the advantages stemming from their perceived lower side-effect profile.

PMH7

PATIENT ASSESSED QUALITY OF LIFE VS. CLINICIAN ASSESSMENT IN A TRIAL OF ARIPIPRAZOLE IN PEDIATRIC PATIENTS WITH BIPOLAR DISORDER

Whitehead R[1], Chen CF[2], Kim E[3], Carson WH[2], Iwamoto T[2], Mathew S[1], Pikalov A[1], Jing Y[3]
[1]Otsuka America Pharmaceutical, Inc, Rockville, MD, USA, [2]Otsuka Pharmaceutical Development and Commercialization, Inc, Princeton, NJ, USA, [3]Bristol-Myers Squibb, Plainsboro, NJ, USA

OBJECTIVES: The pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) is made up of 14 items that assess aspects of quality of life (Total) and a 1-item overall assessment (Overall). Quality of Life measures yield information independent of symptom measures. This post-hoc analysis investigated correlation between patient's QoL assessment and objective clinical assessment (YMRS, CGI-BP). **METHODS:** A total 296 children (age 10–17) with bipolar disorder participated in a 4-week double-blind trial of aripiprazole (10 or 30 mg/day, fixed doses) vs. placebo (PBO). Completers entered a 26 week extension. Primary outcome was mean change on YMRS Total Score. Secondary measures included mean changes on CGI-BP Overall, PQ-LES-Q Total (T) and the Overall item (O). **RESULTS:** YMRS Total and CGI-BP Overall improved vs. PBO with both doses of aripiprazole at week 4 and week 30 ($p < 0.05$ and $p < 0.01$ respectively, LOCF). Both aripiprazole arms improved on PQ-LES-Q(T) and (O); however they did not reach statistical significance. Observed Cases analysis (OC) demonstrated a correlation at week 4 and week 30 between % change in PQ-LES-Q(T) and % change in YMRS ($r = -0.18$ and -0.29, respectively; $p < 0.03$). When 4 week YMRS Total improvement was put into categories (<20%; 20–30%; 30–50%; >50% reduction), % change in mean PQ-LES-Q(T) was 1.7, 2.3, 12.5, & 10.4 per category (trend analysis $p = 0.007$; regression $p = 0.01$; OC). At 30 weeks % change in mean PQ-LES-Q(T) was 3.3, NA, −2.6, 16.6 ($p = 0.02$; Linear regression $p = 0.02$; OC). When CGI-BP Overall was put into 4 categories (= 0; −1; −2; ≤−3 point change) at 4 weeks, % change in mean PQ-LES-Q(O) was 0.02, 0.15, 0.27, 0.43 per category (trend analysis $p < 0.05$; OC) and at 30 weeks, % change in mean PQ-LES-Q(O) was −1, 0, 0.63, 0.64 ($p = 0.02$; OC). **CONCLUSIONS:** In this trial of pediatric patients with BP there was positive correlation between patient-assessed QoL measures and clinician-based assessment.

PMH8

GROWTH AND DIFFUSION OF ANTIPSYCHOTIC MEDICINES FOR LABELED AND OFF-LABELED USES, 1994–2007

Alexander GC[1], Gallagher SA[1], Mascola A[2], Moloney R[1], Stafford R[2]
[1]University of Chicago, Chicago, IL, USA, [2]Stanford University, Stanford, CA, USA

OBJECTIVES: Antipsychotic drugs are widely used and costly. Little is known about how this has varied based on clinical applications and levels of evidence. **METHODS:** We used the IMS Health National Disease and Therapeutic Index to describe typical and atypical antipsychotic use from 1994 through 2007. We linked this nationally representative cross-sectional data from outpatient physician practices to levels of evidence and FDA approval status from the FDA and the Drugdex® drug compendium. We obtained promotional and prescription expenditures from IMS Health Integrated Promotional Services and the National Prescription Audit. **RESULTS:** Preliminary results suggest aggregate annual antipsychotic use increased 262% from 8 million physician visits (1994) to 21 million (2006), then declined to 19 million (2007). The market share of typical antipsychotics decreased from 86% to 8% over this time period. Large increases in antipsychotic use occurred among individuals 18–64 (234%) and 18 years of age (559%). Increases were more modest among those 65 years of age or older (131%). Antipsychotic use for schizophrenia