therapy, prior authorization, not in formulary) between January 1, 2005 to December 31, 2006 but who subsequently filled an SGA or conventional antipsychotic within six months of the rejected claim, formed the case group (n = 328). Newly initiated antipsychotic users who were in health plans with an open formulary and thus did not experience rejection of an SGA claim formed the control group (n = 1097). All patients were followed up for 13 months. Cox regression models were used to estimate the effect of having rejected claims on all-cause discontinuation of the index drug, defined as discontinuation, add-on or switch. The model controlled for age, sex, co-morbidities, geographic locations, index drug, prescription and co-payment. **RESULTS:** Reasons for rejected claims were distributed as follows: 1) drug not on formulary (72.9%); 2) required prior authorization (19.5%); and 3) required step therapy (7.6%). Median time to discontinuation was 120 days for the case group and 127 days for the control group. The adjusted hazard for discontinuation of the index drug (HR = 1.29, 95% CI: 1.08–1.53) was significantly higher for patients with rejected initial SGA claims compared to controls. Co-payments ranging from $20 to $39 were associated with lower discontinuation compared with copayment ranging from $0 to $4 (HR = 0.75, 95% CI: 0.60–0.93). **CONCLUSIONS:** New antipsychotic users with rejected initial SGA claims due to formulary restrictions were more likely to discontinue their antipsychotic drugs compared to users who did not face such restrictions.

PMH45

THE ASSOCIATION OF COPAY BURDEN AND MEDICATION ADHERENCE AMONG PATIENTS WITH SCHIZOPHRENIA

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OBJECTIVES: To assess the association between self-perceived copay burden and medication adherence among patients with schizophrenia. **METHODS:** Data were collected from December 2007 to February 2008 from a web-based consumer panel. Adults (age 18+) self-reporting a diagnosis of schizophrenia were invited to participate in the study through self-reported questionnaires on both the internet and through 43 interview facilities across the US. Inclusion criteria for analysis were: current use of an SGA, and no exposure to clozapine or a depot formulation antipsychotic. Adherence was assessed using the MMAS, with general adherence defined as MMAS < 2, and complete adherence defined as MMAS < 1. Logistic regression models were developed to assess the effects of self-perceived copay burden on adherence while adjusting for demographics, substance use, concomitant psychotropic medications, comorbidities, and health insurance. **RESULTS:** Of the 351 study respondents who met the criteria for analysis, 39% (n = 137) perceived experiencing burden from their medication copays. Adjusting for covariates, the effects of copay burden on general adherence approached but did not reach significance (p = 0.060). However, patients who experienced a copay burden were less than half as likely to have complete adherence [OR = 0.427; 95% CI: (0.257, 0.711); p = 0.001]. Effects of copay burden on the individual components of the MMAS varied. Patients with copay burden were more likely to forget to take medication [OR = 2.058; 95% CI: (1.270, 3.335); p = 0.003] and to discontinue medication when feeling worse [OR = 2.000; 95% CI: (1.140, 3.507); p = 0.016]. Being careless about taking medication and discontinuing medication when feeling better were not significantly affected by copay burden. **CONCLUSIONS:** Among patients with schizophrenia using SGAs, copay burden is associated with forgetting to take medication, discontinuing medication when feeling worse, and lesser likelihood of complete adherence. Less restrictive formularies that reduce copay burden for SGAs may have a positive effect on medication adherence among patients with schizophrenia.

PMH46

PREDICTORS OF DULOXETINE TREATMENT PERSISTENCE FOR PATIENTS WITH MAJOR DEPRESSIVE DISORDER

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OBJECTIVES: Treatment of depression is often accompanied by discontinuation and switching of antidepressant medications. Information on factors predicting persistence (and avoidance of switching) would thus be of value to medical decision makers. We assess the impact of demographics, initial dose, prior medications, and comorbidities on duloxetine treatment persistence for patients with major depressive disorder (MDD) using retrospective claims data. **METHODS:** Using the PharMetrics Database, we studied individuals aged 18–64 who initiated duloxetine treatment between April 2005 and March 2006, had ≥1 prior MDD diagnosis, and had continuous insurance coverage 6 months before and 12 months after initiation. Persistence was defined as ≥3 months' continuous duloxetine treatment. Stepwise logistic regression and tree analyses of demographics, initial dose, prior medications, and comorbidities assessed predictors of persistence. Sensitivity analysis was done by analyzing factors associated with switching to venlafaxine XR or a selective serotonin reuptake inhibitor (SSRI) within a year of initiating duloxetine. **RESULTS:** Among 9,148 patients (74.1% female; mean age = 45.6, SD = 11.1) who initiated duloxetine treatment, 63.5% had persistence of duloxetine treatment for ≥3 months. Regression results showed the most significant factors for persistence to be initial dose of ≥60 mg QD (OR = 1.38), age group of 46–64 yrs (OR vs. age 18–25 yrs = 1.63), and venlafaxine XR/SSRI use in the prior 3 months (OR = 1.64) (all p-values < .001). Sensitivity analysis showed initial dose of <60 mg QD was associated with switching from duloxetine (OR = 1.22), although other factors showed differences from the persistence analysis. **CONCLUSIONS:** The results suggest that for MDD patients, initial dose, age group, and recent venlafaxine XR/SSRI use predict persistence on duloxetine treatment. Sensitivity analysis on switching showed a consistent effect of initial dose.

PMH47

REASONS FOR DISCONTINUATION AND CONTINUATION OF ANTIPSYCHOTIC THERAPY FROM PATIENT AND CLINICIAN PERSPECTIVES

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OBJECTIVES: To assess the reasons for discontinuation and for continuation of antipsychotic medication in the treatment of schizophrenia from patient and clinician perspectives. **METHODS:** Two measures were developed to assess the Reasons for Antipsychotic Discontinuation/Continuation (RAD), one from patient's perspective (RAD-I), and the other from clinician's perspective (RAD-Q). These measures were administered to patients enrolled in a 12-week study of antipsychotic medication in the treatment of schizophrenia (N = 630). Reasons for discontinuation and reasons for continuation with the assigned antipsychotic during the study were assessed. Reported reasons were rated as being a primary reason, very important, somewhat important, or of minor importance. The top primary reasons for medication discontinuation and continuation were identified from patient and clinician perspectives, and level of concordance between patients' and clinicians' reasons was assessed. **RESULTS:** The top primary reasons for medication discontinuation differed from the top primary reasons for continuation on the medication, with a high level of concordance between patients' and clinicians' perspectives. The top three primary reasons for medication discontinuation were insufficient improvement or worsening of positive symptoms, medication-related adverse events, and insufficient improvement or worsening of mood symptoms. The top three primary reasons for medication continuation were improvement in positive symptoms, subjective perception of improvement, and improvement in level of functioning. **CONCLUSIONS:** Medication efficacy appears to be the core driver of medication continuation and discontinuation, especially with regard to positive symptoms. Reasons for medication discontinuation differ somewhat from reasons for continuation, with a high level of concordance between patients' and clinicians' perspectives.

PMH48

BURDEN OF ILLNESS OF DEPRESSION SYMPTOMS AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS

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OBJECTIVES: The purpose of this analysis is to quantify the additive burden associated with experiencing depression symptoms in patients with type-2 diabetes mellitus (T2DM). **METHODS:** Data were from the 2008 US National Health and Wellness Survey (NHWS), an annual cross-sectional survey of self-reported health care attitudes, behaviors, disease states, and outcomes of adults aged 18+. Analyses were limited to respondents self-reporting a diagnosis of T2DM. Depression symptoms were defined as an affirmative response in the past month to: bothered by feeling down, depressed or hopeless; or bothered by having little interest or pleasure in doing things. Outcomes included health care utilization in the past six months, work productivity as measured by the Work Productivity and Activity Impairment (WPAI) questionnaire, and SF-12v2 summary scores. Logistic and linear regression models were developed to assess independent effects of depression on outcomes, while adjusting for demographics and co-morbidity. **RESULTS:** Among patients with T2DM, 38% self-reported depression symptoms. Adjusting for demographics and co-morbidity, patients with depression symptoms were 1.7 ($p < 0.001$) times as likely to visit the emergency room, 1.6 ($p < 0.001$) times as likely to be hospitalized, and had 2.2 ($p < 0.001$) additional provider visits compared to T2DM patients without depression symptoms. Depression symptoms were also associated with 21.4% ($p < 0.001$) greater impairment in daily activities and a decrease in SF-12v2 physical and mental summary scores of 4.0 ($p < 0.001$) and 12.7 ($p < 0.001$) points, respectively. Among patients who were employed full-time, depression symptoms were associated with 4.3% ($p < 0.001$) greater missed work time, 15.2% ($p < 0.001$) greater lost productivity while working, and 13.4% ($p < 0.001$) greater overall work impairment. **CONCLUSIONS:** In patients with T2DM, depression symptoms were associated with significant burden on health care utilization, work productivity, and health-related quality of life. Proper treatment of both T2DM and co-morbid depression in this population may reduce humanistic and economic burden of disease.

PMH49

ASSESSMENT OF TYPE 2 DIABETES MELLITUS PATIENTS WITH AND WITHOUT SYMPTOMS OF ADHD: PATIENT CHARACTERISTICS AND RESOURCE UTILIZATION DATA FROM AN INTERNET-BASED SURVEY

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OBJECTIVES: Type 2 Diabetes Mellitus (T2DM) is an adult-onset, chronic, metabolic disorder that affects approximately 23.5 million adults in the United States and requires management with daily medications, blood glucose monitoring, regular HbA1c assessments, diet, and exercise. If T2DM patients also have difficulties with planning, working memory, and organization, their health problems may be compounded due to inappropriate management of their chronic health condition. The current study sought to estimate the prevalence of T2DM patients with the

co-occurrence of symptoms of Attention Deficit Hyperactivity Disorder (ADHD), a neurobehavioral condition that impairs organization and executive planning that affects between 1–6% of adults in the United States. **METHODS:** The study design utilized an internet-based panel of 567 T2DM cases that consented to participate in a survey. In addition to de-identified demographic data, respondents were asked to provide information on diabetes self-care, HbA1c values, ADHD symptoms, and health care resource utilization. **RESULTS:** The results indicated that those respondents who had symptoms of ADHD had more office visits for diabetes-related issues ($p = .0002$), more office visits for illness or injury ($p = .0007$), and more hospitalizations for illness or injury ($p = .0493$) compared with T2DM respondents without symptoms of ADHD. For those who reported HbA1c values, regression tree analyses suggested low diabetes self-care scores and high ADHD symptom scores were associated with worse HbA1c values. **CONCLUSIONS:** These findings suggest that the co-occurrence of T2DM and ADHD symptoms could result in poor HbA1c management and may lead to increased resource utilization.

PMH50

THE VALIDATION OF TURKISH VERSION OF PERSONAL AND SOCIAL PERFORMANCE SCALE (PSP)

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OBJECTIVES: Functioning in severe mental disorders is very important and brief rating instruments are needed. Personal and Social Performance Scale (PSP) is one of the instruments which can be used in severe mental disorders in a short time. **METHODS:** The study was performed in the psychiatry departments of two university hospitals. In- or outpatients diagnosed as schizophrenia or bipolar disorder were included in the study. Exclusion criteria were comorbidity of other psychiatric disorders (including substance use disorders) and physical diseases. For concurrent validity, besides PSP, Clinical Global Impression (CGI), Global Assessment of Functioning (GAF) of DSM-IV, Quality of Life and Satisfaction Questionnaire (QLS-Q), and Positive and Negative Schizophrenia Scale (PANSS) were used. For discriminant validity, the mean scores of PSP of patients with and without symptomatic remission were compared. **RESULTS:** The study was carried out with a total of 135 patients, 105 (77.8%) diagnosed as schizophrenia and 30 (22.2%) diagnosed as bipolar disorder. The mean age of the patients was 34.1 ± 10.7 and 75 (55.6%) of them were male. The duration of illness was 10.4 ± 7.5 years. The mean score of PSP was 60.0 ± 17.1. In the reliability analysis, the Cronbach alpha coefficient was 0.8327, and item-total score correlations were between 0.4920–0.7462. In the validity analyses, the total score of PSP was significantly correlated with the total score of CGI ($r = -0.854$, $p < 0.0001$), GAF ($r = 0.748$, $p < 0.0001$), QLS-Q ($r = 0.734$, $p < 0.0001$), and PANSS ($r = -0.664$, $p < 0.0001$). The difference between the patients with and without symptomatic remission was significant (54.8 ± 14.8 vs. 72.6 ± 9.8, $t = 7.434$, $p < 0.0001$). **CONCLUSIONS:** The Turkish version of PSP was found to be reliable and valid in severe mental disorders. It can be used both in clinical trials and routine follow-up.

PMH51

PSYCHOMETRIC PROPERTIES OF THE LIFE PARTICIPATION SCALE FOR ADULTS ASSESSING DEFICITS IN ADAPTIVE FUNCTIONING

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OBJECTIVES: The Life Participation Scale for Children was designed to measure treatment-related improvements in adaptive functioning in children with ADHD. To measure these attributes in adult subjects, we developed a Life Participation Scale for Adults (LPS-A). **METHODS:** LPS-A items were selected by convening focus groups, interviewing experts, and performing structured cognitive interviews to improve item wording. These were administered in a 2-week study of treated ($N = 10$) and untreated ($N = 10$) participants with ADHD and normal controls ($N = 11$). Cronbach's alpha, Lin's concordance correlation, and Pearson's correlations were used to assess internal consistency, test-retest reliability, and convergent/divergent validity. LPS-A scores were compared for ADHD/control, treated/untreated, and less/more severe participants to measure discriminant validity. **RESULTS:** The LPS-A demonstrated internal consistency (Cronbach's alpha = 0.92–0.96). Concordance correlations indicated test-retest reliability ($r = 0.79$ to 0.86). Convergent, divergent, and discriminant validity were demonstrated. **CONCLUSIONS:** The initial examination of the LPS-A suggests acceptable levels of validity and reliability. Larger studies will provide further information about the psychometric properties of the LPS-A. The LPS-A appears to be a promising new instrument for measuring adaptive function in adults with ADHD.

PMH52

EVALUATING CENTRAL NERVOUS SYSTEM DRUG LABELS FOR PATIENT-REPORTED OUTCOMES CLAIMS

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OBJECTIVES: Previous studies (prior to 2003) have suggested that central nervous system (CNS) drugs have had the highest number of patient-reported outcomes (PRO) claims used in product approvals. This study examined the use of PRO as efficacy endpoints in label claims of recent FDA-approved CNS drugs between 2003 and 2008. **METHODS:** Product labels of FDA-approved prescription-only New Molecular Entities (NMEs) from the CNS drug category between January 2003 and October 2008 were reviewed. The most recent product label, obtained either from the FDA's Center for Drug Evaluation and Research (CDER) or directly from the company website, was used for all the drugs, including the drugs withdrawn from the market. Efficacy endpoint data was obtained from the Clinical Studies section of the approved product label. Efficacy measures were categorized into PRO, clinician-reported outcomes (CRO) and laboratory devices. **RESULTS:** During the five year period, 14 of the 153 FDA-approved NMEs were CNS agents. The CNS agents included four drugs for neuromuscular disorders, two antipsychotics, two antidepressants, two sedatives, one smoking cessation drug, one analgesic, one CNS stimulant, and one drug treating alcoholism. Of the 28 efficacy measures used in the CNS product labels, seven (25%) were PRO. The four drugs using PRO endpoints included one antidepressant, one analgesic, one CNS stimulant and one smoking cessation drug. Of the seven PRO used, three were symptom scales, two were global impression scales, one scale measured condition-specific health-related quality-of-life, and one scale measured functional impairment. The percentage of approved CNS drugs using PRO as efficacy endpoints in label claims declined since 2002 (2003–08: 28.5%; 1997–2002: 75%). **CONCLUSIONS:** The latter half of the past decade has seen a considerable decrease in the number of CNS drugs that have had PRO-based label claims. Symptoms scales are the prominent type of PRO used in CNS drug label claims.

PMH53

THE ASSOCIATION OF COPAY BURDEN AND OUTCOMES AMONG PATIENTS WITH SCHIZOPHRENIA

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OBJECTIVES: To identify the clinical outcomes associated with self-perceived copay burden among patients with schizophrenia. **METHODS:** Data were taken from a nationwide survey of adults (age 18+) with a self-reported diagnosis of schizophrenia. The survey was fielded from December 2007 to February 2008. Data were collected through both self-reported questionnaires administered on-site, and via the Internet. Inclusion criteria for analysis were no exposure to clozapine, no use of a depot injection of an antipsychotic, and currently using a second generation antipsychotic (SGA). Outcomes included emergency room (ER) visits, hospitalization, suicide attempt, missed work (among employed patients), as well as experiencing severe distress defined as a score of 0–60 on the Psychological General Well Being (PGWB) scale. Assessment of the effects of self-perceived copay burden on outcomes was calculated using logistic regression models. Demographics, substance use, concomitant psychotropic medications, comorbidity, and health insurance were controlled for in the models. **RESULTS:** Of the patients who met the inclusion criteria ($n = 351$), 39% ($n = 137$) self-reported experiencing copay burden. Adjusting for covariates, patients who experienced copay burden were more likely to use the ER [OR = 2.157; 95% CI:(1.322, 3.520); $p = 0.002$], have a hospitalization [OR = 2.512; 95% CI: (1.475, 4.277); $p < 0.001$], have a suicide attempt [OR = 2.385; 95% CI: (1.156, 4.920); $p = 0.019$], and experience severe psychological distress [OR = 1.833; 95% CI: (1.092, 3.075); $p = 0.022$]. Among the 110 patients who were employed, those who experienced copay burden were more likely to have missed work in the past month [OR = 7.193; 95% CI: (2.554, 20.256); $p < 0.001$]. **CONCLUSIONS:** Among patients with schizophrenia using SGAs, greater copay burden was associated with increased ER visits, hospitalization, suicide attempts, missed work, and psychological distress. Patient's health care use and psychological well being are likely to benefit from less restrictive formularies that reduce copay burden for antipsychotic medication.

PMH54

PATIENT-REPORTED HEALTH STATUS IN CHRONIC MEDICAL DISORDER PATIENTS WITH AND WITHOUT DEPRESSION IN THE UNITED STATES, 2004–2005

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OBJECTIVES: Our objective was to examine the association of health status measures with depression diagnosis in chronic medical disorder (CMD) patients. **METHODS:** For the retrospective analysis, we extracted data on >/= 18 year-old employed adults from the pooled 2004–5 Medical Expenditure Panel Survey. Data included ICD-9-CM-coded CMD (hyperlipidemia, heart-disease, arthritis/other joint-disorders, chronic obstructive pulmonary disease, hypertension, or diabetes), depression, age, gender, race, poverty-level, health-insurance, urban-residence, and any depression treatment (psychotherapy or antidepressant) and patient-reported health-status measures (physical component summary, PCS, and mental component summary, MCS scores from the Short-Form 12 (SF-12); patient health questionnaire, PHQ-2; and Kessler Index, K6) on a continuous scale. We compared mean and standard deviation of health status measures in CMD patients with and without depression using t-tests. We weighted sample estimates and calculated 95 percent confidence limits (CL) using the Taylor expansion method. In multivariate logistic regression analyses, after controlling for other characteristics, we examined the association of health status measures with depression diagnosis. **RESULTS:** Health status significantly differed in CMD patients with and without depression ($n = 9{,}738$, Means; SF-12 PCS 48.25 vs. 50, SF-12 MCS 43.76 vs. 52.03, PHQ-2 1.59 vs. 0.53, and K6 6.3 vs. 2.9, all $p < 0.001$). Increasing scores on the SF-12 PCS and SF-12 MCS decreased the odds of depression while increasing scores on the PHQ-2 and K6 increased the odds of depression. In a multivariate model, after adjusting for covariates, the SF-12 MCS (a one-unit increase resulted in 0.97 times the risk for depression, 95%CL: 0.95–0.99, $p = 0.0009$) and the PHQ-2 (a one-unit increase results in 1.2 times the risk for depression, 95%CL: 1.07–1.35, $p = 0.0022$) were significantly associated with depres-