displaying seven treatment attributes: medication, therapy, school involvement, caregiver behavior training, physician communication, provider communication and out-of-pocket costs. Every attribute was operationalized into 3 possible levels. Within each task, caregivers selected one best and one worst attribute. A scale-adjusted latent-class (SALC) analysis was conducted to account for variability in the consideration of attributes.

RESULTS: Our study population of 164 caregivers completed the survey on average 42 years old (SD 8.7), predominantly female (95%), white (65%), married (61%), college-educated (73%), and 20% had a child who was diagnosed with ADHD for ≤5 years. All of the caregivers reported 3 or more HCQs. We identified the most preferred treatment attribute (coefficient = 2.41, p < 0.001). Three latent classes (i.e. segments) that best described the data were identified, and the scale factor included in the model was significant (p < 0.001). The 3 segments comprised 28%, 27%, and 45% of our study population. Segment 1 has the strongest preference for medication (coefficients = 3.69 – 4.34, all p < 0.001) while Segment 2 displayed the least preference for medication (coefficients = -1.49 – 3.36, all p < 0.001). Segment 3 was most cost-avoidant (coefficients = -0.33 – -0.11, all p < 0.001). Patient preferences for ‘school involvement’ (coefficients = 0.63 – 2.58, all p < 0.05).

CONCLUSIONS: This study demonstrated variation in caregivers’ priorities for ADHD treatment attributes. A better understanding of preferences for evidence-based treatment options could inform patient-centered care. By utilizing SALC, our study reduces the likelihood of classification error.

PMH46
QUALITATIVE STUDY OF PATIENTS’ PREFERENCES FOR BIPOLAR DEPRESSION TREATMENT

Me-Mak E1, Poon J1, Rajapagalan K1, Kleinman L1, Roberts L2, Rizvić D3, Aloe31, Merikle E4

1Rizvići Pharmaceutica, Inc, Marlborough, MA, USA, 2Takeda, Bethesda, MD, USA, 3Takeda Seattle, WA, USA, 4Sunovion Pharmaceuticals, Inc, Fort Lee, NJ, USA

OBJECTIVES: Patient focus groups were conducted to identify the most important clinical outcomes of treatment and treatment-related preferences of patients with bipolar depression influencing patients’ treatment adherence decisions. Qualitative results will guide the development of a quantitative discrete choice experiment to determine patient preference elicitation in future research.

METHODS: Adults clinically diagnosed with bipolar I disorder, recently depressed, previously/currently treated with antidepressants, and not currently suicidal were recruited from two clinical sites. Following an IRB-approved (E&L Review Protocol, exclusion criteria, and semi-structured, open-ended discussion guide, focus groups lasting 90-minutes were conducted to discuss patients’ expectations and experiences towards treatment safety and efficacy. Focus group recordings were transcribed, a data coding dictionary developed, and ATLAS.ti used for qualitative data analysis.

RESULTS: From the two focus groups conducted (n=8 each), total N=16; mean age 47.9±6.4 years; 68.8% female, mean time since diagnosis 15.7±11.4 years; mean length of atypical antidepressant use 4.9±4.7 years. Participants were most concerned with treatment effectiveness, expecting a medication to balance the “highs and lows” of bipolar symptoms and providing “clarity” (control of thoughts and actions). One in 4 expected symptom improvements within 2-3 weeks of treatment initiation, and would tolerate side effects and less desirable features, as long as these did not outweigh treatment benefits. Side effects mentioned spontaneously and rated most highly by participants as influencing treatment initiation and persistence decisions were weight gain (n=8) and fatigue (n=7), 43.8%. To manage side effects, most (n=7, 43.8%) reported self-treatment by reducing dosage or discontinuing without medical consultation.

CONCLUSIONS: Treatment efficacy, faster onset in terms of symptoms improvement and weight gain were identified as most important outcomes determining patients’ treatment decisions. Based on qualitative results, identified treatment attributes will be included in a quantitative discrete choice experiment to determine patients’ preferences for bipolar depression pharmacological treatments.

PMH47
RELATIVE EFFICACY AND TOLERABILITY OF VORTOXETINE VERSUS APPROVED ANTIDEPRESSANTS FOR MAJOR DEPRESSIVE DISORDER: A META-REGRESSION ANALYSIS OF CLINICAL TRIALS

Diamond E1, Danchenko N2, Brignone M1, Rice V1, Perez V1, Ereshefsky L4, Francois C1, Merikle E4

1Lundbeck A/S Paris, France, USA, 2Lundbeck LLC, Deerfield, IL, USA, 3Lundbeck Deutschland GmbH, Munich, Germany, 4Takeda Pharmaceuticals International Inc, Deerfield, IL, USA

OBJECTIVES: Vortioxetine, a novel antidepressant exhibiting a multimodal mechanism of action, was approved for the treatment of adults with major depressive disorder (MDD). This extension study of a recently published meta-analysis (Ljorja et al. Curr Med Res Opin 2014,30(12):2589-606) compares the efficacy and tolerability of vortioxetine with seven commonly used antidepressants marketed in the US. METHODS: Indirect comparisons using meta-regression, an extension of random-effects meta-analysis, were performed using data from 54 double-blind, placebo-controlled Phase 3 pivotal studies identified in a systematic review (N=18,312 patients). To ensure study comparability, only experimental drug and placebo arms were included in primary analyses. Study-level standardized effect sizes were identified and labels were retrieved from using the Drugs@FDA database. RESULTS: Between 2006-2014, 32 COAs were identified 47 different times to support drug/indications; 39 ClinROs, 4 ObsROs, and 4 PerROs (none employed PRO measures). COAs were used to measure primary efficacy endpoint (OR 1.15; 95% CI 1.04-1.27) and to determine study eligibility (n=7) not mutually exclusive). Thirteen out of 14 labels demonstrated efficacy by using a COAs. CONCLUSIONS: All mental health drug labels approved by the FDA since 2006 utilize some COAs as evidence to support drug efficacy and labeling, however PROs were underutilized.

PMH48
A REVIEW OF CLINICAL OUTCOME ASSESSMENTS USED IN FDA APPROVED DRUG LABELS FOR MENTAL HEALTH CONDITIONS

Pomplio FA1, Lindberg-Springs S2, Seoane-Vázquez E3

1Massachusetts College of Pharmacy & Health Sciences, Boston, MA, USA, 2Acharya University, Boston, MA, USA

OBJECTIVES: Clinical outcome assessments (COAs) are clinician-reported outcomes (PROs) or patient-reported outcomes (PROMs) used to assess the patient’s symptom, impact, and overall mental state. PRO measures, specifically developed to capture the patients’ perspectives without clinician interpretation, are considered an approved means to support labeling by the Food and Drug Administration (FDA). This study aims to identify the extent to which COAs were used to support label claims and to identify the prevalence of PRO specific measures in mental health drugs approved by the FDA in the period 2006-2014.

METHODS: New drugs used to treat mental health conditions approved by the FDA from 2006-2014 were identified and labels were retrieved from using the Drugs@FDA database. The “Indications and Usage” and “Clinical Studies” sections of each label were reviewed for the presence and relevance of COAs. COA data was extracted and categorized by type using FROQOLID.

RESULTS: A total of 20 FDA-approved drugs for use in mental health conditions were identified. Of these, 18 labels included clinical COAs and 12 of the labels used the results of COAs to support 19 indications; major depressive disorder (n=5), schizophrenia and/or schizoaffective disorder (n=5), attention deficit hyperactivity disorder (n=3), bipolar mania (n=2), and seasonal affective disorder (n=1). Improved depression symptoms associated with bipolar I disorder (n=1). Clinical studies included 32 COAs used 47 different times to support drug/indications labeling; 39 ClinROs, 4 ObsROs, and 4 PerROs (none employed PRO measures). COAs were used to measure primary efficacy endpoint (OR 1.15; 95% CI 1.04-1.27) and to determine study eligibility (n=7) not mutually exclusive). Thirteen out of 14 labels demonstrated efficacy by using a COAs. CONCLUSIONS: All mental health drug labels approved by the FDA since 2006 utilize some COAs as evidence to support drug efficacy and labeling, however PROs were underutilized.

PMH49
IMPACT OF MAJOR DEPRESSIVE DISORDER ON PATIENT FUNCTIONALITY AND WORK PERFORMANCE INEmerging MARKETS

Reznik AE1, Luthermann L2, Stephens JM3, Shihbey A1, Pappadopulos R2, Haidar S1, Lin T5, Liu G5, Lilley A5

1PharmiNet International, Bethesda, MD, USA, 2Pfizer, Inc, New York, NY, USA, 3Pfizer Inc, Groton, CT, USA

OBJECTIVES: This review was designed to synthesize information about the impact of major depressive disorder (MDD) on functionality, work performance, and potential stigma in the emerging markets of Brazil, China (including Taiwan) and Russia. METHODS: Studies indexed in MEDLINE (2004-2014) and abstracts from relevant conferences were searched using search terms associated with MDD (‘productivity/employment,’ ‘functionality,’ and ‘stigma’). RESULTS: Sixteen studies were identified for Brazil, 18 for China and 5 for Russia. There was significant study heterogeneity in the study populations and outcome measures in the literature. The negative perception of MDD was common among Brazilian and Russian patients, but prevalent across countries. In Brazil, depression increased the risk of unemployment by 39% (OR 1.39; 95% CI 1.15-1.67) in one study and was significantly predictive of worse HRQoL among subgroups (P < 0.001). Depression was associated with decreased work performance (OR 0.91; 95% CI 0.87-0.95) in Chinese enterprises. In Taiwan, MDD patients experienced an average 5.8-6.1 sick-leave days annually. Depressed (vs non-depressed) Chinese had a higher risk of impairment in activities of daily living (RR 2.20-4.29; 95% CI 1.33-8.86). A Russian study reported that depression impacted employment for 31.7% of urban-dwelling adults; 12.2% reduced working hours, 17.1% became unemployed and 24.4% took an average 4.2 ± 5.4 sick-leave days annually. Stigma caused by cultural and social factors was an obstacle to help-seeking, MDD diagnosis and treatment in China and Russia but not in Brazil. CONCLUSIONS: MDD is correlated with impaired functionality and work performance in Brazil, China and Russia. Stigma specific to national environment should be addressed to remove barriers to MDD treatment. Future longitudinal inquiry is needed to comprehensively evaluate the consequences of MDD. New research investigating the impact of MDD and its treatment on functionality and work performance from among working adults without comorbidities is needed in emerging markets.

PMH50
FACTORS AFFECTING HEALTH-RELATED QUALITY OF LIFE IN INDIVIDUALS WITH DEPRESSION

Shah D1, Raghunath AN2, Vaidya V1, Goodman M1

1University of Toledo, Toledo, OH, USA

OBJECTIVES: It has been known that depression is associated with significant impairments in health-related quality of life (HRQoL). However, few studies have evaluated the physical and psychological factors that influence HRQoL in individuals suffering from depression. METHODS: The retrospective, observational cross-sectional study used data from the 2011 Medical Expenditure Panel...