cohorts were matched 1:1 using "nearest neighbor" greedy match propensity score method. HRU (inpatient, outpatient, and medications) and costs were compared between the two cohorts. Unit costs were identified from German Diagnosis-related Group for inpatient, Einheitlicher Bewertungsmassstab doctor fee scale for outpatient, and Rote Liste®for medication costs. Direct medical costs over the post-index period were reported in 2011 Euros. Chi-square for categorical variables and t-test or Wilcoxon-Mann-Whitney for continuous variables were used to test for differences between cohorts (alpha=0.05). Generalized linear models with negative binomial (for HRU) and gamma (for cost) distributions were used to address residual differences between matched cohorts. **RESULTS:** Of 4705 eligible patients, 737 with ATX (mean age=10.9 years, 20.8% female) were identified and matched 1:1 with LA-MPH patients (mean age=11.2 years, 18.6% female). Patients initiating ATX had higher HRU and spending per-patient than patients initiating LA-MPH over the post-index: 20.9 (SD=11.5) vs. 15.7 (SD=9.0) outpatient prescriptions, 10.1 (SD=6.3) vs. 8.3 (SD=5.3) outpatient visits, €1029 (SD=574) vs. €496 (SD=334) in retail pharmacy costs, and €1,258 (SD=739) vs. €684 (SD=515) in total all-cause costs (all p=<.0001). **CONCLUSIONS:** Among children/adolescents with ADHD in Germany, ATX initiators consumed significantly more health care resources and were associated with significantly higher direct medical costs compared with LA-MPH initiators.

MENTAL HEALTH – Patient-Reported Outcomes & Patient Preference Studies

PMH48

FACTORS ASSOCIATED WITH POOR ADHERENCE IN PATIENTS INITIATING MEDICATION FOR MAJOR DEPRESSIVE DISORDER: INTERIM RESULTS FROM A PROSPECTIVE, LONGITUDINAL STUDY

Lenderking WR[1], Samp J[2], Hanlon J[1], Hsieh R[3], Akhras KS[2], Revicki DA[3]
[1]*Evidera, Lexington, MA, USA,* [2]*Takeda Pharmaceuticals International, Inc., Deerfield, IL, USA,* [3]*Evidera, Bethesda, MD, USA*

OBJECTIVES: To examine factors associated with low adherence in Major Depressive Disorder (MDD) patients initiating antidepressant medication (ADM) over a 12-week period. **METHODS:** MDD patients initiating an ADM (with no ADM claim in the 6 months prior) were identified from a large pharmacy benefits manager database. Patients completed paper or online assessments including demographics at baseline and patient-reported assessments at baseline, Week 4 and Week 12. Participants were classified as having low, medium, or high adherence based on the modified Morisky Adherence Scale, with the medium and high adherence groups combined for analysis. Logistic regression analyses were run to evaluate the association between adherence and age, gender, and patient-reported assessments of depression and sexual dysfunction (SD), weight gain, sleep problems, nausea, and anxiety. **RESULTS:** Of 2412 patients screened, 591 enrolled and completed baseline assessments. Mean age was 40.4 years (standard deviation=12.1), 82.4% were women, and 87.6% were white. There were 483 who completed Week 4 and 425 who completed Week 12 assessments. At Week 12, 39.6% were high adherers, 20.6% were medium adherers, and 39.8% were low adherers. Thirty-eight percent of low adherers had actually discontinued ADM. Among discontinuers, 40.6% discontinued due to ADM side effects. In logistic regression models, low adherence at Week 4 was significantly associated with weight change ≥5 pounds (OR=2.10, 95% CI: 1.32–3.35), anxiety (OR=1.73, 95% CI: 1.06-2.8) and nausea (OR=2.31, 95% CI: 1.06–5.02). Age, gender, depression severity, sexual dysfunction, and insomnia were not significant in the logistic model. No factors were significantly associated with adherence at Week 12. **CONCLUSIONS:** In this real-world study of patients with MDD, nearly 40% of patients were low adherers. Weight change, anxiety, and nausea were associated with low adherence at Week 4, but not at Week 12.

PMH49

ADHERENCE, SWITCHING, AND DISCONTINUATION DURING THE 12 WEEKS FOLLOWING ANTIDEPRESSANT INITIATION IN PATIENTS WITH DEPRESSIVE DISORDER: RESULTS OF A PROSPECTIVE, LONGITUDINAL STUDY

Lenderking WR[1], Samp J[2], Hanlon J[1], Hsieh R[3], Revicki DA[3], Akhras KS[2]
[1]*Evidera, Lexington, MA, USA,* [2]*Takeda Pharmaceuticals International, Inc., Deerfield, IL, USA,* [3]*Evidera, Bethesda, MD, USA*

OBJECTIVES: This study examined patterns of adherence, switching, and discontinuation, in major depressive disorder (MDD) patients initiating antidepressant medication (ADM) therapy. **METHODS:** Depressed patients recently initiating an ADM were identified from a large pharmacy benefits manager database. Eligible patients were invited to participate by phone or mail and enrolled patients completed. **RESULTS:** Of 2,412 patients screened, 591 were enrolled. Average age was 40.4 years (standard deviation=12.1), 82.4% of participants were women, and 87.6% were white. At Week 4 (n=483), 39.4% were classified as low adherers with 31 (6.4%) patients having discontinued ADM for reasons including side effects (n=14, 45.2%), feeling better (n=5, 16.1%), cost (n=5, 16.1%), and lack of efficacy (n=4, 12.9%). There were 27 (5.6%) patients who switched by Week 4. Of these, 12 (44.4%) switched due to side effects, 11 (40.7%) due to lack of efficacy, and 3 (11%) due to cost. By week 12 (n=425), 33 additional patients had discontinued ADM citing similar reasons as those at Week 4. Of 43 patients who reported switching at Week 4 or Week 12, 15 (34.9%) cited side effects, 16 (37.2%) cited lack of efficacy, and 4 (9.3%) cited cost. **CONCLUSIONS:** In this real-world, 12-week study of MDD patients initiating ADM, adherence to ADM was low. Switching and discontinuing ADM were common within the 12-weeks period and were primarily attributed to side effects and lack of efficacy.

PMH50

FUNCTIONAL OUTCOMES WITH ARIPIPRAZOLE ONCE-MONTHLY IN TWO DOUBLE-BLIND, PLACEBO- AND ACTIVE-CONTROLLED STUDIES (ASPIRE US 246 AND ASPIRE EU 247) FOR THE TREATMENT OF SCHIZOPHRENIA

Fleischhacker WW[1], Perry P[2], Sanchez R[2], Jin N[3], Peters-Strickland T[2], Johnson B[2], Baker R[2], Eramo A[4], McQuade RD[2], Carson WH[2], Kane JM[5]
[1]*Department of Psychiatry and Psychotherapy, Medical University, Innsbruck, Austria,* [2]*Otsuka Pharmaceutical Development & Commercialization, Inc., Princeton, NJ, USA,* [3]*Otsuka Pharmaceutical Development & Commercialization, Inc., Rockville, MD, USA,* [4]*H. Lundbeck A/S, Copenhagen, Denmark,* [5]*The Zucker Hillside Hospital and the Hofstra North Shore-LIJ School of Medicine, Hempstead, NY, USA*

OBJECTIVES: To evaluate functional outcomes of aripiprazole once-monthly (ARI-OM) 400 mg (ARI-OM-400) versus a sub-therapeutic dose of ARI-OM (50 mg; ARI-OM-50), oral aripiprazole (ARI), and placebo, in two trials of stable patients with schizophrenia. **METHODS:** Detailed study designs have been reported previously. Results are reported for the double-blind, randomized phase of each study. ARI-OM is an extended-release injectable suspension given at 400 mg in the gluteal muscle. Functional outcome was measured using the Personal and Social Performance scale (PSP) and statistically analyzed using analysis of covariance with last observation carried forward. **RESULTS:** A total of 403 patients were randomized to ARI-OM-400 (n=269) or placebo (n=134) in the first (246) trial. PSP scores at endpoint significantly worsened with placebo (-6.2) versus ARI-OM-400 (-1.7; p=0.0002). In the second study (247), 662 patients were randomized to: ARI-OM-400 (n=265); ARI (n=266); or ARI-OM-50 (n=131). PSP scores with sub-therapeutic ARI-OM-50 significantly worsened (-2.39) versus ARI-OM-400 (+0.45; p=0.03). Similar functional stability was observed with ARI (+0.08). **CONCLUSIONS:** Patient functioning, as assessed by PSP, was maintained with ARI-OM in both studies but deteriorated in patients randomized to either sub-therapeutic doses or placebo, confirming the benefits of adequately dosed antipsychotic therapy in preserving functional stability in long-term management of schizophrenia.

PMH51

THE DEVELOPMENT AND VALIDATION OF A QUALITY OF LIFE MEASURE FOR PEOPLE WITH MILD COGNITIVE IMPAIRMENT (THE MCQ)

Dean K[1], Walker Z[2], Churchman D[3], Wilcock G[4], Jenkinson C[4]
[1]*Royal Berkshire NHS Foundation Trust, London, UK,* [2]*University College London, London, UK,* [3]*Isis Outcomes, Oxford, UK,* [4]*University of Oxford, Oxford, UK*

OBJECTIVES: Mild cognitive impairment (MCI) is a state that lies between normal cognition and dementia, and the number of cases with the condition is rising as the population ages. However, to date, no validated patient reported outcome measure (PRO) exists specifically in MCI. We report on a study to develop a PRO for use in MCI. **METHODS:** Semi-structured in-depth interviews were carried out with people with MCI in order to determine the questionnaire items. These interviews were audio-recorded, transcribed and content analysed. The draft questionnaire was refined following feedback from a focus group of patients with a diagnosis of MCI. Questionnaires were posted to subjects recruited from memory clinics and research databases, the completed questionnaires were analysed using factor analytic techniques to produce the final measure; construct validity was assessed by correlation with a generic patient reported outcome measure, the SF-12. **RESULTS:** Interviews were carried out with 23 people with MCI. 280 questionnaires were sent to subjects, with a response rate of 56% i.e.146 were included in the analysis. Factor analysis produced a 13 item measure tapping two domains of patient reported quality of life ('Emotional Effects' and 'Practical Concerns'). Internal consistency reliability was high for both domains (alpha was 0.91 and 0.85 respectively). Both dimensions were found to be highly and significantly correlated with the Mental Component Summary score of the SF-12. **CONCLUSIONS:** The Mild Cognitive Impairment Questionnaire (MCQ) is a short 13 item measure developed specifically to measure patient reported outcomes in people with MCI. It was created on the basis of patient report, and has been shown to have good psychometric properties. It is likely to prove valuable in the evaluation of treatment regimes in this important and growing patient group.

PMH52

SCORING THE CENTER FOR EPIDEMIOLOGIC STUDIES – DEPRESSION SCALE: WHICH ITEMS GO WHERE?

Cole JC, Atkinson MJ, Nokela M
Covance Market Access Services, Inc., San Diego, CA, USA

OBJECTIVES: To guide researchers on the best way to score the Center for Epidemiologic Studies – Depression scale (CES-D) by comparing competing models in the literature. **METHODS:** Radloff (19777), the original CES-D author, first provided scoring for four uncorrelated factors of depression: negative affect (NA), positive affect (PA), interpersonal (I), and somatic (S). Sheehan et al. (1995) validated four correlated factors in the CES-D. However, Radloff and Sheehan results may have differed because Radloff ascribed items of *failure* and *fearful*to NA whereas Sheehan assigned a value of I. Following Sheehan's scoring, Cole et al. (2004) presumed a hierarchical factor of depressed mood that included all four previously identified factors and posited a 10-item short-form of the CES-D. These four models were compared using structural equation modeling for parametric models with Bollen-Stine bootstraps to control for multivariate nonnormality in 225 community-residing subjects, structural validity of the models were compared. **RESULTS:** Fit statistics for the four models were: Radloff comparative fit index (CFI) = .790 & root mean square error of approximation (RMEA) = .011; Sheehan CFI = .926 & RMSEA = .053, Cole hierarchical CFI = .927 & RMSEA = .052; Cole 10-item CFI = .979 & RMSEA = .041 **CONCLUSIONS:** The uncorrelated Radloff model was the poorest fit the day. Both Sheehan and Cole 20-item models were decently fit to the data and nearly identical to each other in fit. Finally, the 10-item Cole short-form of the CES-D was the best fit model to the data. Given the brevity of this form and strong fit with the theoretical structure postulated by Radloff, researchers may want to consider this form of the CES-D for research on depressed mood.

PMH53

PREVALENCE AND RISK FACTORS OF DEPRESSION IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN INDIA

Negi H[1], Raval A[2], Malay M[3]
[1]*Post Graduate Institute of Medical Education & Research, Chandigarh, India,* [2]*West Virginia University, Morgantown, WV, USA,* [3]*Indira Gandhi Medical College, Shimla HP, India*

OBJECTIVES: Although depression is a significant co-morbid condition in chronic illness, little is known about the prevalence or risk factors for depressive symp-