OBJECTIVES: Major depressive disorder (MDD) is an important public health problem in South Korea, with a lifetime prevalence of 6.7%. Current antidepressants do not fully meet needs in depression, so additional options are required. We assessed the cost-utility of vortioxetine (a new antidepressant with multimodal activity) versusvenlafaxine XR in MDD patients in South Korea initiating these antidepressants or switching to them due to inadequate response to previous treatment. **METHODS:** A one-year cost-utility analysis from a societal perspective was performed using an initial decision-tree model, which included suicide risk, followed by a Markov model (2-month cycles) for subsequent treatments. Remission, relapse and recovery were the main health states. In first line, efficacy at two months was derived from the Asian SOLUTION study (vortioxetine vs. venlafaxine XR; NCT01571453) and for switching patients from REVIVE (vortioxetine vs. agomelatine; NCT01488071) and STAR*D (pragmatic trial of several antidepressants). STAR*D was the efficacy source for subsequent lines of treatment. Adverse event probabilities were included to consider the impact on quality of life and costs. Utilities were derived from REVIVE and adverse event disutilities from the literature. Resource use and productivity estimates were obtained from a survey of 28 Korean physicians. Korean 2013/2014 costs were applied. Deterministic and probabilistic sensitivity analyses were conducted. **RESULTS:** Vortioxetine dominated venlafaxine XR, with QALY gains of 0.0155 and a cost difference of KRW 576,433 [US$532] (KRW 3,334 [US$3] when productivity not considered) over one year. The model showed a greater proportion of patients in recovery after initial treatment with vortioxetine (31.4%) compared with venlafaxine XR (23.4%). These results were confirmed to be robust through sensitivity analysis; vortioxetine remained dominant in 97% of probabilistic simulations. **CONCLUSIONS:** Vortioxetine dominated venlafaxine XR in South Korea and therefore appears to be a relevant treatment option for MDD patients initiating or switching therapy.

PMH41

A COST-EFFECTIVENESS MODEL TO GUIDE HEALTH POLICY IN BIPOLAR DISORDER TREATMENT

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OBJECTIVES: To evaluate the cost-effectiveness of bipolar disorder (I and II) treatments to assist in efficient resource allocation. **METHODS:** A population based model was developed to estimate the cost per disability adjusted life year (DALY) averted for efficacious therapies to treat adults with bipolar disorder. The model is based on the 2013 Australian population with the Global Burden of Disease (GBD) prevalence estimates applied. All-cause mortality attributable to bipolar disorder is incorporated as well as the decreased rate of suicide attributable to lithium. Disability weights from GBD are used to calculate DALYs. The evaluation takes a health sector perspective and used standard costs for medications and other medical services obtained from Australian sources. All treatments with proven efficacy were sourced from current systematic reviews/meta-analyses and supplemented with expert clinical input. Treatments evaluated included monotherapy with atypical antipsychotics, anticonvulsants, and lithium as well as combination therapies evaluated in randomized controlled trials. Psychological therapies were evaluated as adjunctive to medications. Electroconvulsive therapy was evaluated as a treatment in the depressive phase only. **RESULTS:** Preliminary results suggest that among monotherapies, valproate produced the lowest cost per/DALY $AUD 53,000/DALY (CI $35,000 - $84,000). Oxcarbazepine plus lithium provided the lowest cost among combinations $104,000/DALY (CI dominant - $446,000). Adding a disorder specific psychotherapy was less cost effective than pharmacotherapy alone for lower cost treatments (lithium, valproate) and more cost effective for aripiprazole, olanzapine, quetiapine, and combinations. Adherence costs will be varied in future analysis and presented. **CONCLUSIONS:** Preliminary results indicate treatments generally exceeded the commonly accepted $AUD 50,000/DALY threshold for cost-effectiveness. From an economic perspective, valproate would be recommended as initial therapy. Higher cost therapies, including most combinations, should be implemented with a psychological intervention.

PMH42

HEALTHCARE UTILIZATION AND COSTS AMONG ADULTS WITH MAJOR DEPRESSIVE DISORDER TREATED WITH VILAZODONE VS. OTHER SELECTIVE SEROTONIN REUPTAKE INHIBITORS

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OBJECTIVES: Selective serotonin reuptake inhibitors (SSRIs) are widely prescribed antidepressants. This claims database study compared healthcare resource use and costs among patients with major depressive disorder (MDD) treated with vilazodone, versus other SSRIs. **METHODS:** Adults with an MDD diagnosis and ≥1 prescription fill for vilazodone, citalopram, escitalopram, fluoxetine, paroxetine or sertraline were identified from the Truven Health MarketScan® Research Databases (January 1, 2010 to December 31, 2012). Patients who concomitantly used adjunctive medication, either a second-generation antidepressant or antipsychotic, were excluded. All-cause and MDD-related healthcare resource use and costs (measured from a payer's perspective in 2012 US dollars) over a 6 month period post-index date were compared among treatment groups using multivariate robust Poisson regression and robust linear regression, respectively, adjusted for age, gender, insurance type, index year, comorbidities, prior antidepressant treatment, and pharmacy copayment at baseline (12 months pre-index date). **RESULTS:** The study cohort included 49,861 patients (mean age: 44.0 years; 70% female). Compared with the vilazodone cohort (N=3,527), patients in the citalopram (N=12,187), escitalopram (N=8,275), fluoxetine (N=10,142), paroxetine (N=3,146), and sertraline (N=12,584) cohorts had significantly more all-cause inpatient (IP) visits, length of IP stay and emergency room (ER) visits, and MDD-related IP visits and length of IP stay following the index date, after adjusting for baseline characteristics. All-cause medical service costs (IP + outpatient + ER) were significantly higher across all other SSRI cohorts versus vilazodone by $758 to $1,165 (P<0.05). Similarly, all-cause total costs were also significantly or numerically higher across all SSRI cohorts versus vilazodone by $351 to $780 after accounting for prescription costs. **CONCLUSIONS:** MDD treatment with vilazodone was associated with significantly lower rates of inpatient and emergency services, and with significantly lower all-cause medical service and numerically lower total costs to payers compared to other SSRIs included in this study.

PMH43

HEALTH RESOURCE AND CRIMINAL JUSTICE SYSTEM COSTS FOR YOUNG CLINICAL TRIAL PATIENTS WITH SCHIZOPHRENIA AND PRIOR INCARERATION BY TREATMENT FAILURE STATUS

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OBJECTIVES: Describe estimated health resource (HR) and criminal justice (CJ) system costs by treatment failure status for young patients with schizophrenia that participated in the Paliperidone palmitate Research In Demonstrating Effectiveness (PRIDE) clinical trial involving recently incarcerated subjects. **METHODS:** HR and CJ events were collected via a resource use questionnaire and were combined with cost estimates obtained from administrative claims and published literature to estimate costs at 15 months (trial duration). Treatment failure was defined in the clinical trial as having any of the following: an arrest/incarceration, psychiatric hospitalization, suicide, discontinuation of antipsychotic treatment due to inadequate efficacy, treatment supplementation with another antipsychotic due to inadequate efficacy, discontinuation of antipsychotic treatment due to safety or tolerability, or increase in the level of psychiatric services in order to prevent imminent psychiatric hospitalization. Costs, in 2011 US dollars, were estimated by failure status (Yes/No) for young subjects (defined as those ≤35 years of age) and summarized descriptively using a state government payer perspective. **RESULTS:** Estimated cost per person for young subjects with a failure (n=104) were $45,590 versus $24,586 for young subjects without a failure (n=57). Cost differences were greater for the failure group relative to no failure group for criminal justice system events ($20,961) acute care events ($4,722) and outpatient care ($524). Within the failure group, extrapolating out to the 15 month trial duration, criminal justice system events were a common cause of failure in this analysis with an estimated 86.5% expected to have a criminal justice system contact and 70.2% expected to be incarcerated. **CONCLUSIONS:** From a state government perspective, provision of early interventions that reduce treatment failure among young patients may avoid substantial cost.

MENTAL HEALTH – Patient-Reported Outcomes & Patient Preference Studies

PMH44

FIVE-YEAR IMPACT OF DEPRESSION ON LIFE-SATISFACTION AND THE PROTECTIVE INFLUENCE OF SOCIAL SUPPORT

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OBJECTIVES: Life satisfaction is affected by social, economic, disease and health-related living conditions. Depressive disorders are known to be an important burden for life satisfaction, whereas social support from family or peer groups can substantially buffer this impact. The objective of this contribution is to analyse the complementary influences of depression and social support on life satisfaction. **METHODS:** In 2012, two representative population samples of the non-institutionalized adult population in Germany and UK were surveyed (n=4,008) and self-reports about satisfaction with life as a whole, health, social life, functioning, income and social life were collected. Five years earlier, in 2007, the same individuals had reported on chronic diseases, health care, health status and social and living conditions, as well as depression diagnosis and treatment. Multiple linear regression allows to estimate the prospective five-year impact of depression, multimorbidity (score of 22 chronic diseases) and social support on life satisfaction. **RESULTS:** In 2007, 13.3% of the German and 21.3% of the UK sample had suffered from depression. In 2012, 65.0% of the individuals in UK and 73.9% in Germany reported to be "satisfied" or "very satisfied" with "life as a whole". In the group of individuals with "no depression" in 2007, 75.2% of the individuals reported positive life satisfaction in 2012. Among individuals with medically diagnosed depression in 2007, the fraction was 42.3%. Multiple linear regression resulted in a strong positive buffering effect of social support (beta=.225; p<.00) on life satisfaction and a substantial negative impact of depression (beta=-.167; p<.00) in 2012. Age had very small effect (beta=.076;p<.00) and the influence of gender was not statistically significant. **CONCLUSIONS:** Depression has a negative impact on life satisfaction, which can partly compensated by good social support.

PMH45

CAREGIVERS' PREFERENCES FOR TREATMENT OPTIONS IN ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD): A LATENT CLASS ANALYSIS

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OBJECTIVES: To elicit caregivers' preferences for evidence-based treatment options for their child's attention deficit hyperactivity disorder (ADHD), and to identify segments of caregivers who display similar preferences. **METHODS:** Caregivers with a child aged 4–14 and in care for ADHD were recruited from outpatient clinics and advocacy groups. All caregivers completed a self-administered survey that included socio-demographic information, and a best-worst scaling (BWS) instrument assessing treatment preferences. The BWS instrument comprised 18 choice tasks, each

displaying seven treatment attributes: medication, therapy, school involvement, caregiver behavior training, physician management, 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 consistency of responses. **RESULTS:** Our study population of 164 caregivers were 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 ≤1year. Based on the aggregate results, using medication everyday was 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=-2.13 – -6.11, all p<0.001) but had the strongest preference 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 can enhance patient-centered care. By utilizing SALC, our study reduces the likelihood of misclassification error.

PMH46

QUALITATIVE STUDY OF PATIENTS' PREFERENCES FOR BIPOLAR DEPRESSION TREATMENT

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OBJECTIVES: Patient focus groups were conducted to identify the most important clinical attributes and outcomes of pharmacological treatments for bipolar depression influencing patients' treatment adherence decisions. Qualitative results will guide the development of a quantitative discrete choice experiment to determine patient preferences and willingness to trade-off between medication characteristics. **METHODS:** Adults clinically diagnosed with bipolar I disorder, recently depressed, previously/currently treated with antipsychotics, and not currently suicidal were recruited from two clinical sites. Following an IRB-approved (E&I Review Services) protocol, inclusion 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 groups 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 antipsychotic use 4.7±4.6 years), participants were most concerned with treatment efficacy, 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, 50.0%) and sedation/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 symptom improvement, less weight gain, and less severe sedation/fatigue 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 VORTIOXETINE VERSUS APPROVED ANTIDEPRESSANTS FOR MAJOR DEPRESSIVE DISORDER: A META-REGRESSION OF CLINICAL TRIALS

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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 (Llorca 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 regressed on active treatment to compare efficacy and tolerability of vortioxetine with branded (levomilnacipran, vilazodone, desvenlafaxine) and generic (duloxetine, escitalopram, sertraline, venlafaxine) antidepressants. Efficacy was defined as change from baseline on the Montgomery-Asberg Depression Scale or Hamilton Depression Rating Scale after 2 months (6-12 weeks) of treatment. Tolerability was defined as the withdrawal rate due to any adverse event. **RESULTS:** Standardized mean differences for vortioxetine compared with the selected antidepressants (negative estimates favor vortioxetine) were: duloxetine, 0.10 (95% confidence interval [CI]: -0.12, 0.32); escitalopram, -0.04 (95% CI: -0.32, 0.24); sertraline, -0.02 (95% CI: -0.39, 0.34); venlafaxine, 0.14 (95% CI: -0.11, 0.39); levomilnacipran, -0.05 (95% CI: -0.28, 0.19); vilazodone, -0.23 (95% CI: -0.53, 0.06); and desvenlafaxine, 0.04 (95% CI: -0.16, 0.23). Significantly lower withdrawal rates were observed for vortioxetine versus sertraline, venlafaxine, and desvenlafaxine (all P<0.05). No statistically significant difference in withdrawal rates was observed between vortioxetine and duloxetine, escitalopram, levomilnacipran, or vilazodone. **CONCLUSIONS:** These findings show that vortioxetine offers a comparable combination of efficacy and tolerability in MDD to other antidepressants marketed in the US.

PMH48

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

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OBJECTIVES: Clinical outcome assessments (COAs) are clinician-reported outcomes (ClinROs), patient-reported outcomes (PROs), observer-reported outcomes (ObsROs), and performance outcomes (PerfROs) tools used to assess the patient's symptom, impact, and overall mental state. PRO measures, specifically developed to capture the patients' perspective 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 and relevant indications and concordant COA data was extracted and categorized by type using PROQOLID. **RESULTS:** A total of 20 FDA-approved drugs for use in mental health conditions were identified. Of these, 18 labels included clinical study data and 14 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), insomnia (n=2), seasonal affective disorder (n=1), depressive episodes associated with bipolar I disorder (n=1). Clinical studies included 32 COAs used 47 different times to support drug/indication labeling; 39 ClinROs, 4 ObsROs, and 4 PerfROs (none employed PRO measures). COAs were used to measure primary efficacy endpoints (n=41), to establish safety (n=2) 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 utilized clinical outcome assessments to support drug efficacy and labeling, however PROs were underutilized.

PMH49

IMPACT OF MAJOR DEPRESSIVE DISORDER ON PATIENT FUNCTIONALITY AND WORK PERFORMANCE IN EMERGING MARKETS

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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 screened with search terms including "depression/MDD," "productivity/employment," "functionality," and "stigma." **RESULTS:** Sixteen studies were extracted 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 correlation of MDD with functionality and work performance was evident 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 subpopulations sampled in other studies (P ≤ .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 5.8-61 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 74 ± 54 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 among working adults without comorbidities is needed in emerging markets.

PMH50

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

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OBJECTIVES: It has been known that depression is associated with significant impairments in health-related quality of life (HRQOL). However, few studies have evaluated HRQOL dysfunction in both physical and mental health domains. This study examined the factors, namely demographic, socio-economic and health-related factors affecting the physical and mental health domains of HRQOL in individuals suffering from depression. **METHODS:** This retrospective, observational cross-sectional study used data from the 2011 Medical Expenditure Panel