cant. High BAI/high BDI was significantly different than the other groups (p < 0.01). This pattern was similar for social functioning, role emotion, mental health. Physical-related SF-36 domains were generally not different between groups. The difference in work-performance scale scores followed the same general pattern of less impairment with low BAI/low BDI (for example, WPAI–Percent Impairment While Working scale 0.22 + 0.3) and high BAI/high BDI (WPAI Percent Impairment While Working 0.77 + 0.2), p < 0.01. Other work scales followed a similar pattern. BDI routinely was more significant in regression models compared to BAI. CONCLUSION: Comorbid anxiety and depression greatly impair patients. Clinicians and researchers should measure the presence and severity of both mental illnesses when assessing their influence on health-related quality of life and work-performance.

PMH61

PATIENT PREFERENCES IN THE THERAPY OF ADHD—A DISCRETE CHOICE EXPERIMENT

Mühlbacher AC, Rudolph I, Lincke HJ, Nübling M

1Gesellschaft für empirische Beratung mbH, D- 79211 Denzlingen, Germany; 2Jansen Cilag GmbH, Neuss/Germany, D-41470 Neuss, Germany

OBJECTIVE: While the clinical efficacy of drugs for ADHD is widely studied in clinical trials (usually randomised controlled trials, RCTs), patient preferences with regard to their treatments are not well understood and therefore considered to a lesser extent. Aim of this study therefore was to explore the patients’ perceptions of an “ideal treatment” for ADHD. METHODS: Examination of the state of the art as reported in the literature was followed by a qualitative study with four focus groups consisting of 6–8 parents of ADHD-patients each. In a subsequent quantitative study phase, data was collected in an online or paper-pencil survey by five focus groups (4–5 participants each) with parents of ADHD-patients and patient (age >14 years) themselves. It included sociodemographic data, treatment history and actual treatment and patients’ preferences of therapy characteristics using direct measurement (23 items on a 5-point Likert-scale) as well as a discrete-choice-experiment (DCE, 8 pairs with 6 characteristics). RESULTS: N = 213 questionnaires were filled; most of them by the parents of patients (79% by the mothers, 9% by the fathers). Most of the patients were male (83%) and most of them (83%) had actual medical treatment of ADHD. Direct measurement showed “good emotional quality of live”, “no addiction on medication”, “improvement of concentration capability,” and “few side effects” in the first places. In the DCE, alternatives with “better social quality of life (friendships etc. possible)”, “better emotional quality of life (disease not all of the time mentally present)”, and “longer duration of medication effect” were more likely to be chosen, giving thus similar results. CONCLUSION: This unique study demonstrates that it is possible to obtain valid and robust information from patients on what constitutes relevant patient outcomes. Such information should play a critical role in appraisal of treatment alternatives by HTA bodies.

PMH62

ASSESSING THE VALIDITY OF DERIVING CLINICAL DEMENTIA RATING (CDR) GLOBAL SCORES FROM INDEPENDENTLY OBTAINED FUNCTIONAL RATING SCALE (FRS) SCORES IN VASCULAR DEMENTIA AND MIXED VASCULAR DEMENTIA PATIENTS

Lancot K1, Herrmann N, Hsiung GYR, Massoud ST

1Sunnybrook Health Sciences Centre, Toronto, ON, Canada; 2University of British Columbia, Vancouver, BC, Canada

OBJECTIVE: The functional rating scale (FRS) and clinical dementia rating (CDR) scale are two different tests used to assess the severity and progression of dementia. Although the FRS covers more domains and requires less time to administer than the CDR, the CDR categorizes severity of dementia while the FRS does not. The purpose of this research was to calculate the agreement between the FRS and CDR scales and to determine if they could be used interchangeably for diagnosis of disease severity in vascular dementia (VaD). METHODS: Inpatients and out-patients diagnosed with VaD/mixed VaD were evaluated using the FRS and CDR scales. The tests were administered independently by two separate raters. Since the FRS contains all of the domains that are rated in the CDR, CDR scores were extracted from the corresponding FRS domains and used to derive global scores of severity. FRS-derived global scores were then compared to original CDR global scores by a weighted kappa analysis to measure concordance. RESULTS: A total of 28 VaD/mixed VaD patients were involved in the study. In the patient population, 60.7% were males and average age was 78.6 ± 7.7 years. Average MMSE score was 19.9 ± 4.8 while mean Hachinski score was 8.1 ± 2.8. The modal value obtained for both the FRS-derived CDR scores and original CDR scores was 2; in both groups scores ranged from 0.5–3 with 43% of patients diagnosed in category 2 (moderate dementia). The weighted kappa analysis showed substantial concordance (kappa = 0.75) between FRS-derived CDR and original CDR-global scores. CONCLUSION: These results suggest that FRS scores can be used to derive global scores that are in agreement with those produced by the validated CDR method. This serves as a powerful tool since it allows for easy comparison of the diagnostic distribution, natural history and treatment outcomes of individuals with dementia.

PMH63

PATIENT REPORTED MEASURES AS QUALITY ASSURANCE TOOLS IN CNS CLINICAL TRIALS

Daniel DG, Friedmann B, Butler A

1United BioSource Corporation, McLean, VA, USA; 2United BioSource Corporation, Wayne, PA, USA; 3United BioSource Corporation, Wayne, PA, USA

OBJECTIVE: Signal detection and, ultimately, regulatory approval depend on high-quality, valid and reliable data. The subjective rating scales utilized in CNS clinical trials may be vulnerable to spurious ratings and intentional or unintentional manipulation of ratings by investigators at screening or baseline visits. The objective of this study was to evaluate the feasibility of utilizing a patient reported outcome as a quality assurance measure for evaluation of the quality of a clinician rated primary efficacy measure in a CNS clinical trial. METHODS: A proprietary ratings surveillance system was utilized in a multi-center, double blind, randomized, placebo-controlled clinical trial in which the Hamilton Anxiety Rating Scale (HARS) was the primary efficacy measure. The patient rated Beck Anxiety Inventory (BAI) was added to the baseline visit for quality assurance purposes. Based on published guidelines of the expected relationship between HARS and BAI scores, a computer program flagged aberrant ratings and three flags with the same rater triggered a teaching intervention. The ratings surveillance system was intended both to detect aberrant rating patterns and to deter intentional inflation of ratings in order to qualify subjects. RESULTS: The clinical trial is ongoing. 91 pairs of HARS and BAI ratings have been examined from the randomization visit. 61/91 (67%) pairs were flagged for discordance, in most cases (79%) due to disproportionately high HARS scores compared to the BAI. In 8 cases, the BAI was under 10 with the HARS 22 or greater. In 11 cases, there were at least 3 flags for the same rater and the pattern of discordance was considered to be of sufficient clinical significance to warrant a teaching intervention. CONCLUSION: Use of...
patient reported outcomes as a measure of quality of clinician reported outcomes appears to be a feasible tactic in a site-based ratings surveillance quality assurance system.

**MAJOR DEPRESSIVE DISORDER: A COMPREHENSIVE LITERATURE REVIEW OF THE BURDEN OF ILLNESS IN NORTH AMERICA**

Van Hanswijk de Jong P1, Stafford M1, Hearn S1, Tschaut N1, Svedsater H1, Locklear JC2, Revicki D3, Brown R1, Trivedi M1  
1United BioSource Corporation, London, UK; 2AstraZeneca Pharmaceuticals, Sodertalje, Sweden; 3AstraZeneca LP, Wilmington, DE, USA; 4United BioSource Corporation, Bethesda, MD, USA.  
OBJECTIVE: Major depressive disorder (MDD) is a leading cause of disability worldwide. This study analyzed the literature describing the burden of MDD in North America (USA and Canada), with particular focus on patients with treatment-resistant depression (TRD). METHODS: Systematic searches were conducted of English-language papers published between 1987 and 2007, utilizing MEDLINE, EMBASE, and the Cochrane Library, relevant websites, and hand searches. Major areas for review were the humanistic and economic burden of MDD. Additional areas for analysis included treatment options and costs, treatment efficacy and response rates, treatment guidelines, and reimbursements. RESULTS: A total of 908 articles were identified, of which 107 studies from North America fulfilled the inclusion criteria (humanistic burden, N = 45; economic burden, N = 49; and treatment guidelines, N = 13). Analysis of these studies identified an increased humanistic and economic burden in patients with MDD and TRD in North America. MDD was associated with a high prevalence (3–31%), was chronic in nature, and had a high frequency of comorbid mental disorders. Health-related quality of life (HRQL) instruments identified a significant negative impact from MDD, including domains of mental well-being (independence, alertness, role emotional, personal/spiritual beliefs) and perceived physical functioning (energy and fatigue, bodily care). In a study that compared HRQL in responders and non-responders to therapy, HRQL was significantly lower in non-responders (P < 0.001). Patients with TRD were particularly severely affected, through higher medical costs and greater losses in work productivity. CONCLUSION: Patients with MDD and their families suffer greater humanistic and economic burden than healthy individuals. Treatment reduces the burden of MDD, although current evidence-based guidelines for MDD offer limited recommendations on the choice of pharmacological treatments based on their potential to reduce burden of illness and resource use.

**MENTAL HEALTH—Health Care Use & Policy Studies**

**EFFECT OF PRIOR AUTHORIZATION ON ANTIPSYCHOTIC DRUG USE IN LONG-TERM CARE: POPULATION-BASED NATURAL EXPERIMENT**

Paterson JM1, Bronskill S1, Sutherland J2, Warren L1, Sykora K1, Bassett K1, Anderson GM1, Rochon PA1  
1Institute for Clinical Evaluative Sciences, Toronto, ON, Canada; 2Therapeutics Initiative, Vancouver, BC, Canada.  
OBJECTIVE: Though antipsychotics were originally developed to treat schizophrenia, their use in older adults with dementia has grown substantially. Given concern about the safety of these drugs, we assessed the impact of a prior authorization (PA) policy upon use and choice of antipsychotic medication in long-term care. METHODS: We conducted a retrospective cohort study using administrative data from two Canadian provinces—one in which access to newer antipsychotics (risperidone, olanzapine, and quetiapine) was unrestricted (Ontario), and another in which access required PA (British Columbia (BC)). Subjects were all 37,057 Ontario and 13,569 BC residents aged 66 years or older who were newly admitted to a nursing home between April 1, 1998 and March 31, 2002, who had no history of schizophrenia or psychosis in the 5 years preceding admission, and who had no evidence of antipsychotic drug use in the preceding year. We assessed crude and adjusted exposure to antipsychotic medication over the year following nursing home admission, as well as the types of medications used. RESULTS: Nineteen percent of Ontario residents were newly dispensed an antipsychotic within 100 days of nursing home admission vs. 16% in BC. Male sex, younger age, fewer comorbidities, and history of dementia all were strongly associated with receipt of an antipsychotic. Adjustment for these factors reduced the cross-provincial difference in drug use. However, fewer BC residents received newer antipsychotics, particularly after risperidone received an approved indication for the management of behavioural symptoms of dementia. Olanzapine, which required PA throughout the study, was dispensed to 11% and 3% of Ontario and BC residents, respectively. CONCLUSION: Although BC’s PA policy had negligible impact upon the incidence of antipsychotic drug use as a whole, it appeared to influence drug choice. Questions remain about the impact of such policies upon health outcomes and costs.

**ETHNICITY AND THE IMPACT OF HIGHER MEDICATION COPAYMENTS AMONG VETERANS WITH SCHIZOPHRENIA**

Zeber JE1, Copeland LA1, Miller AL1, Kilbourne AM1, Velligan DI2, Mortensen EM1,  
1Veterans Affairs HSRD / UTHSCSA, San Antonio, TX, USA; 2University of Michigan, Ann Arbor, MI, USA.  
OBJECTIVE: The 2002 Veterans Health Care Act raised medication copayments from $2 to $7 for lower priority patients. Veterans with schizophrenia constitute a multiply disadvantaged population; 40% are antipsychotic non-adoherent, substantially increasing psychiatric admission risks. Certain patient subgroups might be particularly sensitive to medication costs with significant clinical ramifications. Diverse cultural expressions of health beliefs and priorities contribute additional layers of complexity. This study examines potential inequities stemming from higher copayments. METHODS: All veterans with schizophrenia were followed 33 months Pre and Post copayment increase. Longitudinal models analyzed effects of higher medication costs in copayment veterans versus a natural control group of exempt patients, controlling for demographics, substance abuse, functional status, and other comorbidities. Adjusted means compared prescription patterns and inpatient utilization among four ethnic groups: white (N = 36,452), African-American (N = 17,602), Hispanic (N = 5,225), and Other (N = 10,707). RESULTS: African-Americans were relatively younger with higher substance abuse rates. Hispanic veterans were more likely to be unmarried and have multiple illnesses, though fewer (39%) faced copayments than other patients. Minorities filled 10–35% fewer prescriptions than white veterans, and ethnic differences were evident in pharmacy fills and inpatient days. White veterans reduced psychotropic fills 15–22% while subsequently