

stop thinking about your problems?" The item "how much have you looked forward to things with enjoyment?" was changed to "how much of the time did you feel enjoyment?", and "how much have you felt useful?" was revised to read "how much of the time did you feel useful?" **CONCLUSIONS:** When translatability assessment is conducted prior to the finalization of a new measure, language changes can be implemented that will facilitate translation and cross cultural adaptation. When difficulties are encountered that may not warrant changes on their own, results from translatability assessments can also be useful in adding awareness and greater weight to other aspects of item structure that might need to be altered to improve the integrity and quality of the measure.

PMH49

EVALUATION OF HEALTH RELATED QUALITY OF LIFE OUTCOMES AMONG PATIENTS WITH SCHIZOPHRENIA SWITCHED TO LURASIDONE FROM OTHER ANTIPSYCHOTICS

Awad G¹, Hassan M², Loebel A³, Hsu J³, Pikalov A³, Rajagopalan K²

¹University of Toronto, Toronto, ON, Canada, ²Sunovion Pharmaceuticals, Inc., Marlborough, MA, USA, ³Sunovion Pharmaceuticals, Inc., Fort Lee, NJ, USA

OBJECTIVES: Patients with schizophrenia frequently switch between antipsychotics, underscoring the need to ensure that important treatment outcomes such as health-related quality of life (HRQL) are achieved and maintained following the switch. This analysis evaluated changes in overall health-related quality of life among patients with schizophrenia switched from current antipsychotic treatment to lurasidone. **METHODS:** Stable, but symptomatic outpatients with schizophrenia were switched from their current antipsychotic to lurasidone, in a 6-week, open-label trial, conducted in the US. The Personal Evaluation of Transitions in Treatment (PETiT) is a validated 30-item instrument measuring self-reported overall quality of life outcomes among patients with schizophrenia. In addition, PETiT assesses two domain scores on psychosocial functioning and adherence related attitude. Higher scores on PETiT denote better HRQL. PETiT scale was administered at baseline and study endpoint. Changes from baseline to study endpoint in PETiT total score (overall HRQL) and domain scores (psychosocial functioning and adherence) were compared using ANCOVA with baseline score, treatment, and pooled site as covariates. **RESULTS:** Of the 244 patients switched to lurasidone from other antipsychotics, patients with available data on PETiT (n=213) were included in the analysis. Mean PETiT total scores at baseline was 35.3 and at study endpoint was 38.5. Mean change from baseline to the study endpoint in the PETiT total score was 3.2, change in psychosocial functioning domain score was 2.5, and change in adherence domain score was 0.7, significant in all patient groups (p<0.001). **CONCLUSIONS:** The findings from this study indicate that patients switching from other antipsychotics to lurasidone experienced statistically significant improvement in HRQL, psychosocial functioning and adherence related attitude within six weeks of treatment. Further investigation regarding the effects of longer-term lurasidone treatment on HRQL outcomes is warranted.

PMH50

CAREGIVER BURDEN AND SOCIAL SUPPORT IN FAMILIES OF CHILDREN WITH AUTISM: A LITERATURE REVIEW

Shah D¹, Giannetti V², Pflanzgraf A¹

¹Duquesne University, Mylan School of Pharmacy, Pittsburgh, PA, USA, ²Duquesne University, Pittsburgh, PA, USA

OBJECTIVES: Caregiver burden and social support play a crucial role in moderating the treatment outcomes of children with autism. It is important for health care services researchers to consider the impact of these constructs while understanding treatment outcomes. The goal of this study is to provide a comprehensive review of instruments that have been used to measure caregiver burden and social support in autism. **METHODS:** A systematic literature review was conducted from January 2002 - December 2012 using the databases: Medline, PsychINFO, Cochrane, Mental measurements year book and Health and psychosocial instruments to identify instruments. The psychometric properties of the instruments have been assessed. Inclusion / exclusion criteria that were applied to the study are: language, availability of full text articles, and relevance to the topic of study. **RESULTS:** The review also yielded 20 instruments for measuring social support. Of these, 19 were generic and 1 was condition-specific. The most common domains included in the instruments were: instrumental support and emotional support. Some instruments consisted of domains based on source of social support such as informal support from friends, family and spouse. A review of the psychometric properties of these instruments indicated good reliability (Cronbach's alpha 0.7 - 0.95). Caregiver burden has been studied less frequently as compared to social support. Caregiver burden was mostly measured using 4 instruments. Of these four instruments, Caregiver Strain Questionnaire has been validated in a population of parents of autistic children. It has good reliability (Cronbach's alpha 0.75 - 0.93) **CONCLUSIONS:** Caregiver burden and social support are two important constructs that affect the quality of life (QoL) of caregivers of children with autistic disorder. Consideration of the nature and extent of caregiver burden and social support will also facilitate the development of appropriate interventions that can help improve caregivers' quality of life (QoL) and functioning.

PMH51

FUNCTIONAL IMPAIRMENTS AND RISKY BEHAVIOR AMONG ADULTS WITH ADHD IN EUROPE AND THE UNITED STATES

Able SL¹, Haynes V¹, Vietri J², Kopenhafer L³, Upadhyaya H¹, Deberdt W⁴

¹Eli Lilly and Company, Indianapolis, IN, USA, ²Kaplan Health, Princeton, NJ, USA, ³Kantar Health, New York, NY, USA, ⁴S.A. Eli Lilly Benelux N.V., Bruxelles, Belgium

OBJECTIVES: This study investigates impairments and propensities for risky behaviors among adults diagnosed with attention-deficit/hyperactivity disorder (ADHD) in Europe (E) and the United States (US). **METHODS:** Data are from a web-based survey of adults who self-report having an ADHD diagnosis. Data were gathered October-December 2012 in Germany, UK, Netherlands, Sweden and the U.S. Participants were asked questions regarding social, family, educational and work-related impairments and risky personal behaviors previously shown to be common among adults with ADHD. Chi-square tests of proportions were used to test for significant differences between European and U.S. participants reported below. **RESULTS:** Three hundred European and 100 US adults reporting a diagnosis of ADHD from a health care professional completed the survey online. 60% of both European and US respondents agreed that ADHD has had a negative impact on their career success. Over one-in-four respondents reported a suspension some time during school (31% E vs. 23% US; p<0.05). Twenty-six percent of European respondents reported 3 or more traffic tickets within the past year (vs. 9% US; p<0.05); 11% reported 3 or more automobile accidents during the same period (vs. 9% US). Eighteen percent of Europeans also reported having had more than three job-related accidents or injuries requiring medical attention during this period (vs. 2% US; p<0.05). Over 40% of study participants reported illegal drug use at some time in the past (44% E vs. 48% US), with around 10% reporting citations for driving under the influence of alcohol or drugs (15% E vs. 9% US) or serving time in prison (11% each). Concern about exposure to a sexually transmitted disease was reported by 34% European and 44% US (p<0.05) study participants. **CONCLUSIONS:** ADHD Adults from Europe and the US report various impairments and risky behaviors possibly related to their condition, some more frequent among European than US participants.

PMH52

ASSESSING HEALTH-RELATED QUALITY OF LIFE (HRQL) IN MAJOR DEPRESSIVE DISORDER (MDD): DO COMMONLY USED INSTRUMENTS MEET EMA REQUIREMENTS FOR PSYCHOMETRIC PROPERTIES AND CONTENT RELEVANCE

Danchenko N¹, Rive B², Pendlebury S³, Abetz L⁴

¹Lundbeck SAS, Issy-les-Moulineaux, France, ²Lundbeck S.A.S., Issy-Les Moulineaux, France, ³Mediplex Ltd, Leeds, UK, ⁴Adelphi Values, Bollington, Cheshire, UK

OBJECTIVES: The impact of MDD on HRQL is well documented, but little information exists about commonly used HRQL instruments' adherence to EMA requirements for psychometric properties and content relevance. This work examines commonly used HRQL instruments for their relevance to MDD, based on their content, concepts measured and psychometric properties, and use in published MDD studies. **METHODS:** A qualitative research paper provided a conceptual model for MDD (1). The SF-36 Health Survey (SF-36), Sheehan Disability Scale (SDS), Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q), Health Status Questionnaire-12 (HSQ-12) and EuroQol (EQ-5D) were mapped to this conceptual model to examine their relevance to MDD. The measures' reliability, validity, responsiveness to change in depression and use in MDD trials and labelling were examined through review of classic databases (including: PROQOLID, PROLABEL, MEDLINE, PSYCHINFO, FDA, EMA). Where no information on MDD was available, data for mood disorders were explored. **RESULTS:** The SF-36, SDS, Q-LES-Q and EQ-5D have been widely used in MDD, with SDS and Q-LES-Q results included as part of approved EMA labelling claims in mood disorder indications. These instruments are clinically well established and the combination covers HRQL concepts relevant to the MDD population [emotional/social/physical (specifically bodily pain)]; Q-LES-Q and SF-36 are the most comprehensive HRQL measures. All instruments met EMA psychometric requirements for validity, reliability and responsiveness to changes in depressive symptoms and in elderly populations for the HSQ-12. Furthermore, the instruments have been linguistically validated for use in many countries. **CONCLUSIONS:** These commonly used instruments are relevant to MDD and meet EMA criteria for reliability, validity and responsiveness. Thus, we conclude that these instruments are appropriate for use in clinical programmes to assess the impact of MDD treatment on HRQL and overall functioning, particularly to support claims in Europe.

PMH53

DEVELOPMENT OF A CONCEPTUAL DISEASE MODEL TO INFORM STRATEGY TO EVALUATE TREATMENT IMPACT IN ADOLESCENTS WITH ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)

Pokrzywinski R¹, Setyawan J², Khan S³, Erder MH², Hodgkins P², Hareendran A⁴

¹United BioSource Corporation, Murrysville, PA, USA, ²Shire Development LLC, Wayne, PA, USA, ³Neuroscience Inc., Herndon, VA, USA, ⁴United BioSource Corporation, London, UK

OBJECTIVES: To build a conceptual model describing disease experience in adolescent ADHD (aged 13-17) and impact of treatment, in order to inform the development of a measurement strategy to evaluate interventions. Conceptual models that summarize key concepts in describing disease experience are useful for developing strategies to measure meaningful treatment outcomes. Adolescents are increasingly participating in making decisions about their health care. Hence, it is important to evaluate outcomes that are meaningful to them. **METHODS:** In preparation for patient interviews, focused searches of databases, clinical and regulatory guidelines, ADHD specific tools and conference abstracts were conducted as part of the literature review to identify concepts to understand the experiences of adolescents with ADHD from various perspectives. In addition, concept elicitation interviews with 10 clinicians, 3 teachers, 10 peers and 10 siblings of adolescents with ADHD were conducted using semi-structured guides. Results from this preliminary stage were analyzed systematically; transcripts from the peer and sibling interviews were analyzed using a pre-defined coding dictionary, to identify concepts for the model. **RESULTS:** Disease-defining concepts in ADHD included core ADHD symptoms,