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COMPLEX ATTENTION-DEFICIT/HYPERACTIVITY DISORDER: PATIENT CHARACTERISTICS, HEALTH CARE UTILIZATION AND COSTS IN A RETROSPECTIVE OBSERVATIONAL CLAIMS STUDYHess G¹, Sasane R², Hill J¹, Hodgkins P², Shah MR¹¹SDI Health, Plymouth Meeting, PA, USA, ²Shire Pharmaceuticals, Wayne, PA, USA

OBJECTIVES: To elucidate the characteristics of complex Attention-Deficit/Hyperactivity Disorder (ADHD) and associated health care utilization and costs in children and adolescents. **METHODS:** Patients (aged 6–17) diagnosed with ADHD between November 2005 and October 2007 and with medical/pharmacy claims for ≥ 1 year after the index diagnosis were identified retrospectively from SDI's databases of patient-level medical and pharmacy claims. Because patients with ADHD and associated comorbidities were likely to require the most treatment (and therefore incur higher health care charges), we hypothesized that total cost of ADHD prescriptions and office visits could serve as a proxy for a more "complex" patient. Costs for ADHD prescriptions and ADHD office visits were aggregated, and patients were stratified into high- (top 25% of total charges), medium- (middle 50%), and low- (bottom 25%) cost groups. **RESULTS:** In total, 10,362 patients were stratified, with 2591 patients in the high-cost, 5170 in the medium-cost, and 2601 in the low-cost group. More than two thirds of the patients were aged 6–12 years, and >70% were male. The prevalence of most psychiatric and other comorbidities was higher in the high-cost group than in the medium-cost group ($P < 0.05$ for 10 of 14 comorbidities) or in the low-cost group ($P < 0.05$ for 9 comorbidities). High-cost patients were also more likely to be diagnosed younger, be treated by a specialist, and use augmented pharmacotherapy for their ADHD. Health care resource utilization in the high-cost group was 1.77 times greater than in the medium-cost group and 3.52 times greater than in the low-cost group ($P < 0.001$ for both comparisons). The proportion of ADHD physician visits with procedure codes indicating higher disease burden and complexity was also significantly greater ($P < 0.001$) for the high-cost group. **CONCLUSIONS:** This study identified a subset of complex pediatric and adolescent ADHD patients with unique characteristics and higher relative resource use. Supported by funding from Shire Development Inc.

MENTAL HEALTH – Patient-Reported Outcomes Studies

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DEPRESSION TREATMENT ADHERENCE AMONG DEPRESSION PATIENTS WITH COMORBIDITY

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OBJECTIVES: To examine the impact of comorbidity on treatment options and treatment adherence among depression patients in employer health plans. **METHODS:** We used 165,569 records of administrative claims data between September 2002 and March 2004 for employed between 18 to 64 years old. Depression was identified using ICD-9 diagnosis codes. Treatment adherence was defined as finding more than 2 prescriptions for antidepressants (>30 days supply) or having more than 5 psychotherapy sessions. Multivariate logistic regression analyses were performed to examine impact of comorbidity on adherence to treatment among depression patients who initiated treatment. **RESULTS:** Among eligible members, 2567 (1.5%) had a primary diagnosis of depression and received treatment. Over 70% were female and the average age was 42.6 years. Approximately half (49.2%) received medication only; 29.3% received psychotherapy and medication; and 15.7% received psychotherapy without medications. The average number of prescribed antidepressants was 4.4 among those took any medications. Among those who had psychotherapy, 51.4% received more than 5 sessions. The most frequent comorbid mental disorders were anxiety (25.3%), adjustment disorder (9.1%), alcohol use (3.5%) and substance abuse (1.9%) and physical comorbid conditions were musculoskeletal and chronic pain (MSCP, 29.9%), injuries (17.5%), hypertension (13.3%), asthma (6.7%), diabetes (6.4%), arthritis (5.1%), and urinary tract infection (4.0%). Depression patients with anxiety (OR = 1.9), or adjustment disorder (OR = 1.4) were significantly more likely to receive psychotherapy ($p < 0.05$), but significantly less likely to use medication only. Comorbid HIV (OR = 1.7), arthritis (OR = 0.5), anxiety (OR = 0.4) and MSCP (OR = 0.3) were significantly associated with receiving both medication and psychotherapy ($p < 0.001$). Among patients who received both treatments, those with hypertension were significantly less likely to adhere to either treatment. Among those who initiated psychotherapy, comorbid anxiety (OR = 0.6) was significantly associated with treatment adherence ($p < 0.001$). **CONCLUSIONS:** Among depression patients, having comorbid mental disorders was significantly associated with use of and adherence to psychotherapy treatment.

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A PATIENT PERSPECTIVE ON SIDE EFFECTS OF ANTIPSYCHOTIC THERAPY: THE TOOL INSTRUMENTLindström E¹, Jönsson L², Bernström A³¹Malmö University Hospital, Malmö, Sweden, ²i3 Innovus, Stockholm, Sweden, ³Danderyds hospital, STOCKHOLM, Sweden

OBJECTIVES: Pharmacotherapy is the most important component of care for patients with schizophrenia and related disorders. However, side effects adversely affect patient's health-related quality of life. A novel self-assessment instrument (Tolerability and quality of Life, ToolL) is presented to assess patient experiences of side effects.

METHODS: The instrument was developed to reflect the subjective perception of side effects in patients treated with antipsychotic medication. ToolL was developed by an expert panel of four experienced psychiatrists with a special interest in the treatment of schizophrenia, schizoaffective or bipolar syndrome. ToolL has eight domains reflecting important aspects for patient well-being: anxiety and depression, usual activities, fatigue or weakness, body weight, stiffness and tremor, bodily restlessness, sexual function and vertigo or nausea. ToolL was completed by 220 patients with schizophrenia, bipolar disorder or schizoaffective disorder in a cross-sectional observational study. Reliability and validity were estimated by correlations with existing scales assessing presence of side effects, symptom severity and HRQoL (UKU, PANSS, MADRS, SWN, EQ-5D, and VAS). **RESULTS:** Responses on ToolL demonstrated that frequent experiences of side-effects impact the well-being of patients. Validity was supported by significant correlations with other instruments. ToolL correlated with corresponding domains in the UKU scale. The MADRS score correlated strongest with anxiety, depression, fatigue or weakness. The global PANSS score significantly correlated with all domains except Weight gain, Stiffness and Sexual function. ToolL also correlated to the VAS score, EQ-5D, and the disease-specific scale SWN. **CONCLUSIONS:** ToolL is a new instrument for patient-reported assessment of the impact of side-effects of antipsychotic medication. The instrument can be of significant value in a clinical setting as a decision tool to guide treatment choices and serve as an important input to evaluations of antipsychotic treatment. Patient experiences of side effects are a highly relevant outcome measure that may determine the long-term success of therapy.

PMH57

NON-ADHERENCE TO ORAL ANTIPSYCHOTICS IN SCHIZOPHRENIA: RELAPSE AND UTILIZATION OF HEALTH CARE RESOURCES IN A 6-MONTH FOLLOW-UP PERIODSan L¹, Valladares A², Bernardo M³, Olivares JM⁴, Ciudad A², García-Polavieja P², Yrurettagoyena B², Dilla T², Gilaberte I²¹Hospital Sant Joan de Déu, Esplugues de Llobregat, Barcelona, Spain, ²Lilly, S.A., Alcobendas, Madrid, Spain, ³Hospital Clinic, Barcelona, Barcelona, Spain, ⁴Hospital Meixoeiro—Complejo Hospitalario Universitario de Vigo, Vigo, Pontevedra, Spain

OBJECTIVES: To investigate the clinical profiles, modification of therapeutic strategies, relapse rate and resource utilization in patients with schizophrenia who are at risk of non-adherence to oral antipsychotic (AP) medication. **METHODS:** A Spanish cohort of 596 outpatients with schizophrenia whose therapy was modified because of risk of non-adherence to oral AP medication was followed during 12 months. Baseline and 6-month data on sociodemographic and clinical characteristics, as well as on resource utilization are described. **RESULTS:** Patients' mean (SD) age was 40.1 (11.1) years, and 64% were males. The median (IQR) time-since-diagnosis was 14 (15) years. Within the prior 6 months, 124 (21%) had been hospitalized at least once with mean duration of 26 days. Patients had severe symptoms (CGI-S mean score of 4.3), poor quality of life (mean EuroQol-5D health-status value of 0.6) and functional status (mean SOFAS score of 50.6). Baseline non-pharmacologic therapies were modified in 189 (32%) patients, AP medication in 503 (85%) and concomitant medication in 15%. Modifications of AP medications were mostly dose adjustments (64%). Depot formulation was started by 15%. After 6 months, 65 patients (11%) relapsed. These had worse CGI-S and SOFAS scores than patients who did not relapse (4.2 and 51.4 versus 3.7 and 58.6, respectively), whilst EuroQol-5D scores were similar (0.7 in both groups). Hospitalization was required by 35 out of 65 (53.9%) patients who relapsed (38.7 days on average), but just by 5 out of 531 (0.9%) of those who did not relapse (5.4 days on average). Visits to emergency room occurred, respectively, in 44 out of 65 (67.7%) and in 74 out of 531 patients (14%). **CONCLUSIONS:** After baseline treatment modification the proportion of patients requiring hospitalizations within 6 months was reduced. Patients who relapsed consumed more resources.

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TOOL: MULTI-ATTRIBUTE UTILITY FUNCTION REFLECTING PATIENT EXPERIENCE OF SIDE EFFECTS TO ANTIPSYCHOTIC THERAPYJönsson L¹, Lang A², Lindström E³¹i3 Innovus, Stockholm, Sweden, ²i3 Innovus, 11164, Sweden, ³Malmö University Hospital, Malmö, Sweden

OBJECTIVES: The main effects of pharmaceutical treatment in schizophrenia are symptom relief and relapse prevention. Antipsychotic treatment is, however, associated with adverse effects that impact patient well-being. A novel instrument, ToolL (Tolerability and quality of Life), measures health-related quality of life with antipsychotic medication across eight different dimensions: mood, function capabilities, fatigue, weight gain, stiffness and tremor, physical restlessness, sexual dysfunction and nausea. This study aimed to develop a function linking responses to ToolL to health utility values. **METHODS:** A multi-attribute utility function (MAUF) was developed based on the instrument for patients with schizophrenia, schizoaffective or bipolar syndrome on antipsychotic treatment to allow estimation of health utilities associated with antipsychotic treatments and their side effects. 220 patients with stable schizophrenia, schizoaffective disorder or bipolar disorder completed a set of ratings to facilitate the estimation of a MAUF linking each possible state in the classification system to a utility value. **RESULTS:** A total of 183 of the 220 patients provided complete and consistent ratings allowing an average utility function to be estimated. The ToolL utility ratings correlated significantly with disease specific instruments for disease severity (MADRS and PANSS) and quality of well-being (SWN). Utility ratings

were, furthermore, more sensitive to the presence of side effects than EQ-5D. **CONCLUSIONS:** Tool is a novel system for measuring health utilities in patients with schizophrenia, schizoaffective disorder or bipolar depression that incorporates the patient perspective of side effects of antipsychotic treatment. Adverse effects from antipsychotic treatment impact the quality-of-life and should be taken into account in economic evaluations of treatments with different side effect profiles. Tool facilitates cost-utility analyses that reflect this important aspect of treatment choice and outcome.

PMH59**FURTHER VALIDITY EVIDENCES OF THE GENERALIZED ANXIETY DISORDER—7 SCALE (GAD-7)**

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OBJECTIVES: To investigate the relationship of severity levels of anxiety identified by the GAD-7 scale and the degree of disability as assessed by other standard widely used questionnaires. **METHODS:** A random sample of 212 subjects was recruited in Mental Health and Primary Care centres; 50% diagnosed of Generalized Anxiety Disorder (GAD) by DSM-IV criteria, and the other 50% were concurrent matched controls. In addition to the GAD-7, the following scales were also administered: Hamilton Anxiety scale (HAM-A), Hospital Anxiety and Depression Scale (HADS), and World Health Organization Disability Scale (WHO-DAS). The number of visits to primary care and specialized services were also measured. Correlations between scale scores were computed and also agreement between instrument-specific disability and severity levels. **RESULTS:** Strong and significant ($p < 0.001$) correlations were found between GAD-7 scores and other questionnaires: HAM-A ($r = 0.852$), HADS-A ($r = 0.903$), WHO-DAS ($r = 0.704$). Although GAD-7 scores correlated with all WHO-DAS dimensions, higher correlations were observed with Social Participation ($r = 0.741$), Comprehension and Communication ($r = 0.679$), and Labour (0.638) dimensions. Moderate but significant correlations were also found between GAD-7 scores and the number of visits to Primary Care ($r = 0.393$) and Specialized Services ($r = 0.373$). HAM-A severity groups presented significant differences in GAD-7 mean scores ($F = 205.3$; $df_1 = 3$; $df_2 = 208$; $p < 0.001$), and HAM severity groups also differed ($F = 175.3$; $df_1 = 3$; $df_2 = 208$; $p < 0.001$); in both cases all severity levels differed. **CONCLUSIONS:** The GAD-7 scale has shown to highly correlate not only with specific anxiety measures but also with disability measures. Not all WHO-DAS disability dimensions seem to be equally affected by GAD levels, and it has been shown that more severe GAD levels tend to demand more health attention. As the GAD-7 is self-administered and it is no time consuming, this instrument could be a good choice in primary care settings to explore the level of patient's disability in subjects with GAD.

PMH60**A CONCEPTUAL MODEL OF 'CLEAR THINKING' RELEVANT TO PATIENTS DIAGNOSED WITH SCHIZOPHRENIA**

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BACKGROUND: IQWiG, the German health technology assessment agency, is required to focus on patient-relevant endpoints as part of their cost-benefit analysis. Several patient preference studies conducted in Germany have identified "clear thinking" as a patient-relevant endpoint, but the measurement of this construct is limited by the absence of a conceptualization of clear thinking that is grounded in the patient experience. **OBJECTIVES:** To develop a conceptual model of clear thinking grounded in the experience of patients diagnosed with schizophrenia, aiding the creation of clear thinking scale. **METHODS:** A trained psychologist elicited definitions and examples of clear thinking from 25 German patients diagnosed with schizophrenia during open-ended, semi-structured interviews. Theory building was aided by literature review, including a review of existing scales of cognition, and an additional 15 depth interviews with patients and clinicians. Data was analyzed using a grounded theory approach, leading to multi-dimensional conceptualization of clear thinking. **RESULTS:** Clear thinking can be conceptualized by four themes: a) staying organized (including daily activities, making decisions and having organized thoughts); b) making sense of the world (identifying reality, verbal comprehension and visual comprehension); c) feeling clear headed (confusion, slowness and pacing); and d) expressing thoughts and feelings (feelings, communication and fullness of life). **CONCLUSIONS:** This conceptual model provides researchers and clinicians with a framework to consider clear thinking as defined by patients diagnosed with schizophrenia. It will also provide the cornerstone for the development of a clear thinking scale to measure this patient-relevant endpoint and subsequently assess the validity of our conceptualization.

PMH61**PATIENTS PREFERENCES IN ADULTS WITH ADHD—A DISCRETE CHOICE EXPERIMENT**

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OBJECTIVES: For the majority of those concerned, ADHD is a lifelong chronic disease with prevalent underachievement in work life and impairments in social

functioning. While clinical evidence on efficacy and tolerability of treatment options for ADHD in adulthood is increasing, preferences of adults with ADHD have not yet been explored. Understanding their preferences contributes to present discussions in the health care sector on patients' needs and shared decision-making. **METHODS:** An extended qualitative study (literature review, in-depth interviews and patient focus groups) was conducted in order to collect all relevant factors and success criteria for adults with ADHD (content validity). In the subsequent quantitative study, preferences for an ADHD treatment were investigated by using direct measurement (rating 23 aspects on a five point Likert-scale) as well as a Discrete-Choice-Experiment (DCE) with 8 pairs of treatment options described by 6 dichotomous parameters. **RESULTS:** 14 in-depth interviews and five focus groups with 4–12 adult participants each ($n = 35$) were conducted. 329 persons (18–65 years, 63%female) filled the questionnaire of the quantitative study (89% online, 11% paper&pencil). In the direct assessment, "long-term positive effects (e.g. behaviour changes)", "improved ability to concentrate", "allows "normal" daily living" and "improves emotional stability" reached the highest values (means around 90). In the DCE (random effects logit model) "social abilities (profession, friendship possible)" had the highest impact on choices (coefficient 2.12) followed by "long-term behaviour changes" (1.75), "fast symptom relief" (1.10), "no impact on positive ADHD traits" (1.04), and "emotional stability (no mood swings)" (0.81). These factors were highly significant ($p < 0.001$) while "necessity of medical treatment" had no significant influence. **CONCLUSIONS:** The presented study systematically explored patient preferences and hereby contributes to a better understanding of the medical needs of adults diagnosed with ADHD. The achievement of social abilities and long lasting behavioural effects attributed greatest benefit to the respondents.

PMH62**THE SPANISH VERSION OF THE TOOL QUESTIONNAIRE: VALIDATION OF A SPECIFIC MEASURE TO EVALUATE HEALTH RELATED QUALITY OF LIFE (HRQOL) IN PATIENTS WITH SCHIZOPHRENIA AND BIPOLAR DISORDER**

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OBJECTIVES: To develop a cross-cultural adaptation from Swedish into Spanish of the Tool questionnaire—a previously validated instrument to assess side effects' impact on HRQoL in patients with schizophrenia and bipolar disorder. **METHODS:** An epidemiological multicentre, cross-sectional study was carried out to analyze the psychometric properties of the Spanish Tool. It comprises 8 attributes and 4 levels per domain (Likert scale: 1-minimum impact; 4-maximum impact): worry-upset, function capabilities, fatigue-weakness, weight gain, stiffness-tremor, physical restlessness, sexual dysfunction, and dizziness-nausea. Patients completed both generic and specific measures of HRQoL and severity (EQ-5D and SF6D –unweighted- and the Clinical Global Impression –CGI-SI-, UKU side effects rating scale, Positive and Negative Syndrome scale, Young Mania Rating Scale, Montgomery Asberg Depression Rating Scale). Reliability (Cronbach's α and intraclass correlation coefficient –ICC-), construct validity (factorial analysis –FA- and item-total correlations –ITC-), convergent validity (Spearman's rank correlations between measures – r_{s} -) and criterion validity (Mann-Whitney U differences between mild vs moderate-severe patients according to CGI-SI) were evaluated. **RESULTS:** A total of 242 patients were included (121 with schizophrenia and 121 with bipolar disorder). Internal consistency and ICC were adequate (Cronbach's $\alpha = 0.757$ & ICC = 0.90). FA and ITC showed that one-dimensional structure could be assumed (1 eigenvalue >1 and 40% of variance explained). Correlations (r_s) between the Spanish Tool and both generic and specific measures were moderate-high. Differences in the Spanish Tool scores between mild vs moderate-severe patients were highlighted. **CONCLUSIONS:** The Swedish Tool questionnaire was culturally adapted and validated into Spanish. Further investigation is needed to test the sensitivity of the Spanish Tool questionnaire.

PMH63**ESTIMATION OF A MULTI-ATTRIBUTE UTILITY FUNCTION FOR THE SPANISH VERSION OF THE TOOL QUESTIONNAIRE**

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OBJECTIVES: To estimate and assess the psychometric properties of a Multi-Attribute Utility Function for the Spanish version of the TOOL questionnaire (TOOL MAUF). TOOL is a recently developed 8-item (4-level) instrument measuring antipsychotics side effects' impact on health status. **METHODS:** Balanced data on 242 patients diagnosed with schizophrenic or bipolar disorders were gathered. In addition to demographic and clinical variables, and the usual generic HRQoL questionnaires, EQ5D and SF6D, instruments considered included the Spanish versions of the Positive and Negative Syndrome Scale (PANSS), Young Mania Rating Scale (YMRS), Montgomery-Asberg Depression Rating Scale (MADRS), UKU side effect rating scale, and TOOL questionnaire. TOOL MAUF parameters estimation involved a number of VAS and TTO ratings of different health states defined from TOOL items. Such ratings proved hard to be performed by patients. After checking for inconsistencies in patient responses (missing data, out-of-range responses, and rating reversals), the original