risk group definitions lead to heterogeneity in CR rates. Only a small number of studies will provide valid estimates of the CR rates in patients with primary AML aged 16–60 years. However, this restriction may reduce the reliability of the estimates, because the estimates will be based on fewer patients. This will thereby increase the uncertainty around the ICER of new methods.

PSY5

A RETROSPECTIVE CHART REVIEW OF THE TREATMENT OF PHENYLKETONURIA IN THE UK AND ASSOCIATED CLINICAL AND HEALTH OUTCOMES

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OBJECTIVES: To determine the proportion of phenylketonuria (PKU) patients managed successfully using current treatment strategies and to highlight a particular group(s) of PKU patients who may be uncontrolled by current treatment. METHODS: This is a non-interventional, retrospective, observational study. To date 4 UK sites have enrolled into the chart review. Information on patients with PKU or tetrahydrobiopterin (BH_4) deficiency was collected over a five year period (2004–2008). Data was collated on demographics, diagnosis, number of uncontrolled episodes, interventions made during an uncontrolled episode and the length of time phenylalanine (Phe) levels were above the target level. An uncontrolled episode is defined as three or more consecutive Phe levels above the National Society for Phenylketonuria (NSPKU) guideline. Interventions can include dietary advice, health care professional phone calls, clinic visits, counselling/psychological support, addition or change in use of supplements, social care visits, and hospital admission. Data was analysed to explore the treatment of PKU in practice, the accompanying Phe levels and other health and clinical outcomes. RESULTS: Recruitment is being completed. This information will be reported as a full dataset in the poster. Thus far data has been collected for 102 patients across 3 centres (50% male). The age range of patients reviewed was 6–60 years. A total of 93% of patients had a diagnosis of PKU, 0% BH4 deficiency and 7% unknown. The average number of uncontrolled episodes per patient per year was 1. An average of 7 interventions were made during each episode. The average length of the episode was 176 days. CONCLUSIONS: There is lack of published data on the management of PKU in clinical practice. This study provides an analysis of current treatment of PKU in clinical practice and its effectiveness on clinical and health outcomes. The majority of PKU patients within this study had well-controlled Phe levels, however a number may benefit from additional treatment.

PSY6

EFFECT OF MODERATE-INTENSITY EXERCISE TRAINING AND DIET ON BODY COMPOSITION AND EXERCISE CAPACITY IN OBESE CHILDREN

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OBJECTIVES: Childhood obesity is a serious health problem favouring the early development of insulin resistance, type-2 diabetes mellitus and cardiovascular diseases. Our aim was to investigate multidisciplinary weight-control program applying exercise training at maximal fat oxidation (FATmax) zone and diet in three different duration on body composition and physical fitness of overweight children. METHODS: Thirty overweight pupils (BMI > percentile 90%) of three different elementary schools (age: 11.7 +/– 1.9) was included. Body composition was determined by bioelectric impedance method. Graded exercise test (Jaeger Oxycon Pro) was used to determine whole-body peak fat oxidation by indirect calorimeter. Training heart rate interval was determined by as +/– 10% of FATmax. Physical exercises were prescribed by the physiotherapist. Exercise training was performed 2 times /week in the school using heart rate monitor under the control of the games master. The training periods were 56, 101 and 146 days. Dietary proposal was given for the parents of children by the dietetics. RESULTS: At the end of the weight-control program percentage of fat mass decreased (35.7 +/– 4.5 vs. 33.0 +/– 5.5%; p < 0.001), muscle mass increased (22.8 +/– 4.6 vs. 24.4 +/– 5.2 kg; p < 0.001). VO_2max increased at the longest training period only (1841 +/– 620 vs. 2011 +/– 642 ml; p = 0.043). CONCLUSIONS: Moderate intensity exercise training and diet resulted in favourable changes in the body composition in a short term whereas the significant improvement of VO_2max was started only after 5 months training period.

PSY7

EVALUATION OF MEASURES UNDERTAKEN TO ENHANCE THE ROBUSTNESS OF THE FABRY OUTCOME SURVEY (FOS)

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OBJECTIVES: To assess the impact of measures undertaken to improve data capture in the Fabry Outcome Survey (FOS). A physician-directed, multinational database established in 2001, FOS aims to advance the understanding and management of Fabry disease, a rare lysosomal storage disorder caused by deficiency of alfa-galactosidase A. METHODS: This initiative, supported by Shire HGT is driven by physicians in the management of Fabry disease. In 2006, additional measures were introduced to enhance the robustness of data capture: 1) a core dataset was developed for assessing disease progression and therapy response; 2) focus was directed at those participating centers with ≥20 patients enrolled in FOS; and 3) research associates were employed to monitor data capture and quality. Random samples (25%) of all enrolled patients were selected from the years 2004 and 2007, before and after the changes, respectively. The completeness of data capture was determined for 10 core variables in each year. RESULTS: Data capture was analyzed for 197 of the 815 patients enrolled in FOS in 2004 and for 404 of the 1616 patients enrolled in 2007. Increases in data capture occurred for 9 of 10 core variables; the exception was patient weights, which were unchanged at 90% for both years. For key variables, the increases were: signs and symptoms, from 66% to 83%; serum creatinine, from 89% to 91%; left ventricular mass, from 48% to 55%; NHYA score, from 84% to 87%. In addition, the proportion of females enrolled increased from 48% to 54%. CONCLUSIONS: Focused efforts on improving data completeness and quality in FOS have been successful, optimizing the value of the database. Regular, accurate data collection and audit will increase the quality of FOS data and lead to an improved understanding of the management of Fabry disease.

PSY8

TAPENTADOL EXTENDED RELEASE (ER) FOR CHRONIC LOW BACK PAIN: RESULTS OF EUROQOL-5 DIMENSION (EQ-5D) AND SHORT FORM-36 (SF-36) HEALTH STATUS QUESTIONNAIRES

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OBJECTIVES: To evaluate the efficacy and safety of tapentadol ER in patients with moderate-to-severe chronic low back pain. Health status was evaluated using SF-36 and EQ-5D questionnaires. METHODS: Patients received controlled, adjustable twice-daily doses of tapentadol ER (100–250 mg), oxycodone HCl controlled release (CR; 20–50 mg), or placebo over a 12-week maintenance period, preceded by a 3-week titration period. Patients completed the EQ-5D and SF-36 at baseline and at specified visits. EQ-5D evaluates mobility, self-care, usual activities, pain/discomfort, and anxiety/depression; SF-36 evaluates physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health dimensions. RESULTS: Of 981 patients randomized, 958 were evaluated for efficacy. Compared with placebo, improvements from baseline to endpoint in the SF-36 physical component summary score were significantly greater with tapentadol ER (least-squares mean difference vs placebo [95% CI], 2.3[1.02,3.58], $P < 0.001$) and oxycodone CR (2.3[1.02,3.56], $P < 0.001$). Both active treatment groups were associated with significant improvements over placebo in role-physical (tapentadol ER, 9.9[4.21,15.49]; oxycodone CR, 9.4[3.83,15.05]; both $P < 0.001$) and bodily pain (tapentadol ER, 5.5[2.44,8.55]; oxycodone CR, 6.3[3.23,9.29]; both $P < 0.001$). Additionally, tapentadol ER was associated with significantly better outcomes versus placebo in physical functioning (4.1[0.85,7.33], $P = 0.013$) and vitality (3.2[0.41,6.01], $P = 0.025$), while oxycodone CR was not significantly different from placebo on these parameters (physical functioning, 2.6[–0.66,5.77], $P = 0.119$; vitality, 0.8[–1.99,3.58], $P = 0.576$). For both active treatment groups, changes from baseline in general health, social functioning, role-emotional, mental health, and mental health summary score did not differ significantly from placebo (all $P > 0.285$). Compared with placebo, the EQ-5D health status index at endpoint improved significantly compared with baseline with tapentadol ER (0.05[0.01,0.09], $P = 0.020$) and oxycodone CR (0.05[0.01,0.09], $P = 0.019$). Incidences of treatment-emergent adverse events were placebo, 59.6%; tapentadol ER, 75.5%; and oxycodone CR, 84.8%. CONCLUSIONS: Tapentadol ER (100–250 mg bid) significantly improved physical and overall health status in patients with moderate-to-severe chronic low back pain.

PSY9

ADHERENCE TO DULOXETINE THERAPY AND HEALTH CARE COSTS AMONG PATIENTS WITH FIBROMYALGIA

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OBJECTIVES: To examine predictors of adherence to duloxetine therapy and assess the association between adherence and health care costs among working-age patients with fibromyalgia. METHODS: This study analyzed medical and pharmacy records for commercially-insured patients aged 18–64 diagnosed with fibromyalgia who initiated duloxetine between January 1, 2006 and December 31, 2006. The date of first duloxetine prescription filled was defined as the index date. Initiation of treatment was defined as no pill coverage for duloxetine over the prior 90 days. All patients included had at least 30 days supply of duloxetine in the 12 months post-index period. Patients with diabetes peripheral neuropathic pain or depression in the 12 months pre-index period were excluded. Two study cohorts were constructed based on adherence level to duloxetine (high adherence = medication possession ratio of ≥ 0.8). Predictors of high adherence were examined via logistic regression. Multivariate regression models were performed to examine the association between adherence and health care costs, controlling for demographics, clinical characteristics, and prior health care costs. RESULTS: A total of 4869 fibromyalgia patients were identified, with a mean age of 50 years and 88% female. Approximately 68% of duloxetine patients had low adherence over the 12 months follow-up period. Higher average daily dose was associated with high adherence (reference group = 30 mg; Odds Ratio = 3.03, 2.40, and 3.74 for 31–59 mg, 60 mg, and > 60 mg, respectively; all p < 0.05). Controlling for differences