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

Walters C[1], Chauhan D[1], Parkes L[1], Chakrapani A[2], MacDonald A[2]
[1]Merck Serono Ltd, Feltham, Middlesex, UK, [2]Birmingham Children's Hospital, Birmingham, UK

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

Tóth-Steinhausz V[1], Gombocz K[2], Lemle Z[2], Stahl P[2], Ferenczi A[2], Bogáné Fatér Z[1], Balog E[1], Császárné Gombos G[1], Kriszbacher I[3], Schmidt B[1]
[1]University of Pécs, Zalaegerszeg, Hungary, [2]Zala County Hospital, Zalaegerszeg, Hungary, [3]University of Pécs, Pécs, Hungary

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)

Clarke J[1], Beck M[2], Giugliani R[3], Sunder-Plassmann G[4], Elliott P[5], Hernberg-Stahl E[6], Pintos-Morell G[7]
[1]Hospital for Sick Children, Toronto, Ontario, Canada, [2]University of Mainz, Mainz, Germany, [3]Hospital de Clinicas/UFRGS, Porto Alegre, RS, Brazil, [4]Medical University Vienna, Vienna, Austria, [5]Heart Hospital, London, UK, [6]Shire HGT AB, Danderyd, Sweden, [7]University Hospital Germans Trias i Pujol, Badalona, Catalonia, Spain

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

Kavanagh S[1], Lange B[2], Ashworth J[2], Etropolski MS[3], McNeill M[3], Rauschkolb C[3]
[1]Johnson & Johnson Pharmaceutical Services, Beerse, Belgium, [2]Grünenthal GmbH, Aachen, Germany, [3]Johnson & Johnson Pharmaceutical Research & Development, L.L.C., Raritan, NJ, USA

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

Chen SY[1], Boulanger L[1], Fraser K[1], Wu N[1], Zhao Y[2]
[1]Abt Bio-Pharma Solutions, Inc., Lexington, MA, USA, [2]Eli Lilly and Company, Indianapolis, IN, USA

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

in demographics and clinical characteristics, patients with high adherence had significantly lower total health care costs (–$938, p < 0.05), primarily due to lower inpatient (–$2,057, p < 0.05) and outpatient (–$951, p < 0.05) costs than patients with low adherence. **CONCLUSIONS**: Higher average daily dose of duloxetine appeared to be predictor of high adherence among fibromyalgia patients. High adherence to the duloxetine therapy was associated with lower total health care costs.

PSY10

TREATING FIBROMYALGIA WITH DULOXETINE: WHAT IS THE ASSOCIATION BETWEEN AVERAGE DAILY DOSE, MEDICATION ADHERENCE, AND HEALTH CARE COSTS?

Wu N[1], Chen SY[1], Fraser K[1], Boulanger L[1], Zhao Y[2]
[1]Abt Bio-Pharma Solutions, Inc., Lexington, MA, USA, [2]Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: To examine the relationship between average daily dose (ADD) of duloxetine, medication adherence, and health care costs among fibromyalgia patients. **METHODS**: This study employed a retrospective cohort design to analyze administrative claims database for commercially-insured patients diagnosed with fibromyalgia who initiated duloxetine in 2006, with initiation defined as 90-day medication gap. The dispense date of the first duloxetine prescription filled was defined as the index date. All patients selected were required to have at least 30 days of duloxetine supply in the 12 months follow-up period, and those with diabetic peripheral neuropathic pain or depression diagnosis during the prior 12 months were excluded. Five cohorts were constructed based on ADD: <30 mg, 30 mg, 31–59 mg, 60 mg, and >60 mg. Adherence was measured via medication possession ratio (MPR) of duloxetine over 12-month post-index period, with MPR = 0.8 as high adherence. Multivariate regression models adjusting for differences in demographic and clinical characteristics were used to examine the association between ADD, adherence and health care costs. **RESULTS**: The study sample included 4,869 fibromyalgia patients. Three percent of patients had an ADD of <30 mg, 12% of 30 mg, 21% of 31–59 mg, 46% of 60 mg, and 18% of >60 mg. Approximately one-third of patients had high adherence. Controlling for demographics and clinical characteristics, patients with ADD = 30 mg (31–59 mg, and >60 mg) were less (more) likely to adhere to duloxetine than those with 60 mg (all p < 0.05). Compared with patients maintaining an ADD of 60 mg, those with ADD of 31–59 mg or >60 mg had significantly higher total health care costs ($1835 and $5490, respectively, both p < 0.05), while those with an ADD of 30 mg had significantly lower costs (–$1853, p < 0.05). **CONCLUSIONS**: Fibromyalgia patients with an ADD > 30 mg of duloxetine were more likely to adhere to therapy. Maintaining an ADD of 30 and 60 mg was associated with reduced total health care costs.

PSY11

DEFI (DETERMINATION OF EPIDEMIOLOGY OF FIBROMYALGIA) A FRENCH PREVALENCE STUDY OF FIBROMYALGIA

Kosa M[1], Ravaud P[2], Perrot S[3], Vicaut E[4], Servant D[5], Pichot L[1]
[1]PFIZER FRANCE, Paris, France, [2]Groupe hospitalier Bichat, Paris, France, [3]Hôpital Hôtel Dieu, Paris, France, [4]Hôpital Fernand Widal, Paris, France, [5]Clinique Fontan, Lille, France

OBJECTIVES: To determine fibromyalgia (FM) prevalence in a french general population setting, with a clinical confirmation based on ACR criteria **METHODS**: This cross-sectional survey in a general population setting consisted in two steps: First, a telephone screening among 6,000 households using the French validated version of London Fibromyalgia Epidemiological Study Screening Questionnaire or LFES-SQ [1], then a rheumatologist's confirmation based on ACR criteria [2]. **RESULTS**: Of 3081 polled subjects, 232 (7.5%) were screened positive ; 96 subjects accepted the consultation (41.4%), 70.8% were females. Mean age was 58.2 CI95 [55.2 ; 61.2] years. Finally 20 subjects (20.8%) met the ACR criteria, 17 were females. Mean age was 56.9 CI95 [50.7 ; 63.1]. Thus FM prevalence is estimated to 1.5 % CI 95 [1.1; 2.0] based on the following algorithm : Prevalence (%) = $[N_{diagnosis} + (N_{diagnosis}/Nc_{onsultations} * N_{refusals})] * 100/N_{screened\ patients}$ NRefusals : screened positive patients who refused to consult, Ndiagnosis : confirmed FM patients **CONCLUSIONS**: This 1.5% FM prevalence is consistent with other studies but lower than London Fibromyalgia Epidemiological Study figures (2.7%)[1]. Those discrepancies can be attributable to patient's easier access to specialists and a stricter physician's interpretation of ACR criteria. [1] White KP. J Rheumatol 1999;26:1570–76; [2] Wolfe W. Arthritis & Rheumatism 1990;33:160–72.

SYSTEMIC DISORDERS/CONDITIONS – Cost Studies

PSY12

ECONOMIC AND CLINICAL EFFICACY BENEFITS OF THE USE OF USTEKINUMAB IN THE TREATMENT OF MODERATE TO SEVERE PSORIASIS IN GREECE

Xaplanteris L[1], Papanicolaou S[2]
[1]Janssen Cilag Greece, Athens, Greece, [2]PRMA Consulting Ltd, Hampshire, UK

OBJECTIVES: To estimate the annual and per-patient budget impact of the treatment of moderate to severe psoriasis in Greece before and after the introduction of ustekinumab. **METHODS**: A budget impact model was constructed from a National Health System perspective to depict the clinical and economic aspects of psoriasis treatment in a time frame of five years. It included drug acquisition, monitoring and administration costs for both the induction and maintenance years for patients treated with etanercept, adalimumab, infliximab, with or without ustekinumab. It also considered the resource utilisation for non-responders. Greek treatment patterns and resource utilization data were derived from 110 interviews with dermatologists and an expert panel of 18 key opinion leaders of dermatology. Official published sources were used to derive the unit costs. Costs of adverse events and indirect costs were excluded from the analysis. The treatment response was defined as probability of achieving a PASI 50, PASI 75 or PASI 90 response, based on published clinical trial data. **RESULTS**: The inclusion of ustekinumab in the biological treatment mix for moderate to severe psoriasis can lead to total per-patient savings of €481 and €1027 in the first and fifth year of its introduction, respectively. The annual savings just on the hospitalisation costs of non-responders were estimated to be €900,000 in the first year and €3 million in the fifth. The cost savings were attributed to the reduced administration costs, reduced hospitalisations for non-responders, and improved efficacy. In an induction year and maintenance year (2-year period), there are a total of 9 administrations for ustekinumab compared to 116 for etanercept, 54 for adalimumab and 15 for infliximab. **CONCLUSIONS**: The inclusion of ustekinumab in the treatment of moderate to severe psoriasis in Greece is anticipated to have both short- and long-term health and economic benefits both on an annual and per-patient basis.

PSY13

REIMBURSEMENT OF FOODS FOR SPECIAL MEDICAL PURPOSES PRODUCTS FOR PHENYLKETONURIA IN POLAND: A BUDGET IMPACT ANALYSIS

Rys P, Marcisz A, Palka I, Plisko R, Wladysiuk M
HTA Consulting, Krakow, Poland

OBJECTIVES: The aim of the analysis was to estimate the budget impact of including new foods for special medical purposes (FSMP) for phenylketonutria (PKU) on the reimbursement list in Poland. Patients with phenylketonuria must adhere to phenylalanine-restricted diet in order to prevent neurological impairment. **METHODS**: In 2008 the reimbursement list in Poland included several FSMP; however, most of them were relatively old (basic portfolio). On the other hand, there were a lot of new PKU products not yet reimbursed (milupa pku2 prima, milupa pku2 secunda, milupa pku2 shake, milupa pku3 advanta, milupa pku3 shake, milupa pku3 tablets, Minaphlex, Lophlex, Easiphen, XP_Maxamum). This analysis was performed from the public payer's perspective (National Health Fund). A 5-year time horizon was adopted (2009–2013). The prognosis was based on the assumption that the PKU products sales in Poland will increase at the same rate as in the past few years. The market shares of specific PKU products were estimated based on data obtained from other European countries (scenario 1) and a questionnaire survey (scenario 2). The base scenario, assuming no changes on the reimbursement list, was also defined. Total and incremental costs were calculated. Incremental costs were defined as the difference between scenario 1 (or scenario 2) and the base scenario. **RESULTS**: In the base scenario the total cost related to reimbursement of PKU products would amount to 23.95 million PLN in 2009 and 25.82 million PLN in 2013. In scenario 1, the expenditure for PKU products would increase by 0.3 million PLN in 2009 and 1.4 million PLN in 2013. In scenario 2 the expenditure would increase by 0.9 million PLN in 2009 and 2.9 million PLN in 2013. **CONCLUSIONS**: This analysis showed that reimbursement of new PKU products would be associated with an incremental cost of about 3 million PLN.

PSY14

COST-EFFECTIVENESS AND BUDGET IMPACT OF LOW DOSE 7-DAY BUPRENORPHINE PATCH FOR MODERATE TO SEVERE OSTEOARTHRITIS PAIN IN THE CONTEXT OF KOREA NATIONAL HEALTH INSURANCE

Lim EA, Park JA, An YJ, Goo DH, Choi SE
Seoul National University, Seoul, South Korea

OBJECTIVES: Low dose 7-day buprenorphine transdermal patch (norspan®) is an opioid analgesic indicated in the management of chronic moderate to severe pain not responding to non-opioid analgesics. This patch has been marketed as products not covered by the national health insurance. The purpose of this analysis was to evaluate cost-effectiveness and budget impact of the buprenorphine patch, thereby assessing its eligibility for National Health Insurance coverage. **METHODS**: We carried out a cost-effectiveness analysis of the buprenorphine patches compared to tramadol tablets in patients with chronic, moderate to severe osteoarthritis (OA) pain, using a third-party-payers perspective. The time horizon of analysis was 12-week. During this period, it was assumed that doses of study medication were titrated twice to achieve stable pain control. Patients' global impression of pain relief was used as a clinical outcome variable, based on which we defined good and very good pain relief as controlled pain. Expert survey was conducted to investigate the treatment pattern and the cost of chronic pain. Budget impact analysis was applied to assess the impact of insurance coverage of buprenorphine patches. Sensitivity analysis was performed for major parameters and possible scenarios. **RESULTS**: Buprenorphine patch was dominant compared to its comparator, displaying increased effectiveness and reduced costs. Budget impact analysis for 5 years indicated drug costs might increase by nearly 12.2 billion won upon application of buprenorphine patch for insurance coverage; however, the budget for National Health Insurance including medical cost might decrease by nearly 2.9 billion won mainly due to decrement dispensing fee. Sensitive analysis suggested that the most sensitive variable was the effectiveness of buprenorphine patches. **CONCLUSIONS**: Low dose 7-day buprenorphine patch was a cost-effective and cost-saving alternative in the Korea National Health Insurance context. Study robustness needed more evidences about effectiveness.