vascular risk factors used in the economic model. A Markov decision-analytic model using the Monte-Carlo simulation was employed to examine cost-effectiveness. Hypothetical patients were subject to risk of type 2 diabetes, CVD and stroke. Diabetic patients were at added risk of amputation, blindness and renal failure. Simulation of events was performed using the Framingham Heart Study and the UK Prospective Diabetes Study. RESULTS: Significant clinical benefits were demonstrated with sibutramine and diet/exercise compared with diet/exercise alone: proportion of patients achieving ≥5% weight loss (51.6 vs 22.3% respectively; p < 0.0001), BMI (−1.65 [−1.97, −1.34] kg/m²; p < 0.0005), absolute weight (−3.84 [−5.18, −2.49] kg; p < 0.0005), HDL (4.07 [1.50, 6.65] mmol/L; p = 0.002) and triglycerides (−12.17 [−21.82, −2.52]; p = 0.013). Small increases in blood pressure (1−3 mmHg) and heart rate (4−5 beats/minute) were observed. Sibutramine was a cost-effective addition to diet/exercise (approximately AUD$40,000 per additional QALY). Sensitivity analyses demonstrated the model to be robust. CONCLUSIONS: Sibutramine is a safe, effective, and cost-effective intervention in the prevention of obesity-related complications through weight loss and weight maintenance.

IN EUROPE, HOW REPRESENTATIVE ARE OVERWEIGHT/OBESE SUBJECTS RECRUITED VIA THE INTERNET?

Zhou X1, Radigue C2, Allshouse AA3, Gilsenan A1 1RTI Health Solutions, Raleigh, NC, USA, 2Sanofi Synthelabo Recherche, Paris, France, 3RTI Health Solutions, North Carolina, NC, USA

For observational studies derived from Internet based cohorts, the representativeness of demographic, behavioral and health characteristics of subjects is not well-established in European countries. OBJECTIVES: To compare distributions of self-reported characteristics of subjects recruited via Internet in Germany & UK to a national representative sample in each country. METHODS: PROCEED is a multinational observational cohort of overweight & obese subjects (body mass index >25 kg/m²) recruited through an existing Internet panel in Germany & the UK in 2005. Eligibility criteria were: age 35–75; not pregnant; willing to lose weight in the next year and weight <180 kg. Recruitment was stratified to balance gender and overweight and obese categories. Baseline demographics and selected health and behavior characteristics of the PROCEED cohort were compared with estimates from a relevant subset (same age, BMI and not pregnant) of two National Surveys (1998 GNHIS and 2003 HSE). PROCEED data were standardized for gender and BMI category in each of the national surveys. RESULTS: PROCEED subjects in Germany (n = 203) and the UK (n = 216) presented similar characteristics to each national survey population in terms of level of alcohol consumption, and prevalence of hypertension, high cholesterol and diabetes. More PROCEED subjects reported having college or higher education (22% versus 12% in Germany; 31% versus 15% in the UK). PROCEED subjects were also more likely to be single. The German PROCEED cohort had a higher proportion of current smokers compared to GNHIS data (48% versus 24%) while the UK PROCEED cohort was very similar to HSE data. CONCLUSIONS: Despite few differences in education level, marital and smoking status, most demographic and health characteristics were similar between the Internet cohort of overweight/obese subjects and the German and UK national surveys. The internet seems to be an appropriate tool for recruiting subjects in observational studies.

THE RELATIONSHIP BETWEEN WEIGHT CHANGES AND RELATED CHANGES IN HEALTH-RELATED UTILITY: EVIDENCE OF CAUSE AND AFFECT

Woehl A, Currie CJ
Cardiff University, Cardiff, UK

OBJECTIVES: The objective was to examine the relationship between changes in body weight and determine if there was causal association with corresponding changes in health-related utility measured by EQ-5D utility. METHODS: Data were extracted from the Health Outcomes Data Repository (HODaR). Data from subjects with multiple surveys were included. Analyses were conducted to determine the relationship between changes in weight and associated change in utility; overall and for different age, sex, body mass index (BMI) and disease groups. RESULTS: The total number of patients included was 8,286. The mean number of completed questionnaires was 2.25. The mean time between questionnaires was 500 days (inter-quartile range [IQR], 1120). The mean weight change was −0.027 kg (IQR = 5 kg). Weight did not change in 19.8% of men and 18.3% of women. For men and women, respectively, weight changed more than 3 kg in 35.3% and 37.6%, more than 5 kg in 22.2% and 23.2% and more than 10 kg in 5.9% and 5.7%. An association between health utility and weight gain could only be verified in high BMI groups (obese class I-III; i.e. BMI > 30 kg/m²) with high weight gain (5 kg, 10 kg). In these categories in men health utility decreased between 0.058 units (weight gain >5 kg, obese I) and 0.590 units (weight gain >10 kg, obese I) in comparison to −0.006 (weight change up to 5 kg, obese I) and −0.092 (weight change up to 5 kg, obese III) for patients with lower weight change. In women these values varied between 0.025 units (weight gain >5 kg, obese II) and 0.060 (weight gain >10 kg, obese II) and −0.001 (weight change up to 5 kg, obese II) and 0.017 (weight change up to 10 kg, obese I). CONCLUSION: A negative relationship between weight gain and health utility was verified. This relationship depended on the initial weight and the magnitude of weight change.

THE IMPACT OF BODY WEIGHT ON UTILITY SCORES IN PATIENTS WITH TYPE 2 DIABETES

Denness SL1, Secnik K2, Yurgin NR2, McDonald-Everett CM2
1Strategic Health Outcomes, Carmel, IN, USA, 2Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: Weight gain is a common side effect of many therapies for type 2 diabetes (T2DM). This study reviews the medical literature to summarize the consequences of weight gain on health-related quality of life. METHODS: A review of the medical literature, including MEDLINE, EMBASE, PsycINFO, and abstracts from professional conferences, was conducted to identify studies assessing the impact of body weight on patient utility. Similarities and differences in study methodology and results were evaluated. RESULTS: Seventeen papers presented either: a) utility values by BMI or body weight or b) the change in utility scores or QALYs based on unit changes in BMI or body weight. Regardless of the patient population or methodology used to elicit utility scores, all studies reviewed found as body weight increased, patient utility decreased. Utility scores obtained using standard gamble techniques were generally higher than those using Time Trade Off or the EQ-5D. Most studies evaluated utility scores stratified by body weight or BMI and used regression analyses to attribute the difference in utility scores to differences in weight while controlling for other factors. Two studies used standard gamble methodology to evaluate the change in utility scores by asking patients to evaluate the impact of specific amounts of weight gain or loss. Studies generally
assumed a constant change in utility occurs with a one unit change in BMI. However, recent studies demonstrate the magnitude of changes in utility scores may vary depending on: a) whether a patient is valuing weight loss or gain; b) whether a smaller or larger change in body weight is being evaluated; and c) baseline BMI. CONCLUSIONS: Various utility values associated with body weight using different methodologies have been published. Careful consideration should be given to determine the most appropriate utility values to use in cost utility analyses of T2DM therapies.

**POB9**

**DEVELOPMENT OF A NEW QUESTIONNAIRE FOR IDENTIFYING PREDICTIVE FACTORS INFLUENCING WEIGHT LOSS THERAPIES**

Ruiz MA1, Costa M1, Rubio MA2, Irurarrizaga I3, Almendro C4, Moreno B5, Salvador J6, Antón J7, Bande C8, García Pulgar MS9

1Universidad Autónoma de Madrid, Madrid, Spain, 2Hospital Clínico Universitario San Carlos, Madrid, Spain, 3Universidad Complutense de Madrid, Madrid, Spain, 4Centro de Salud Torrent, Valencia, Spain, 5Hospital General Universitario Gregorio Marañón, Madrid, Spain, 6Clínica Universitaria de Navarra, Pamplona/Infiña, Madrid, Spain, 7CAP Manso, Barcelona, Spain, 8Complejo Hospitalario Cristal-Piñor, Orense, Spain, 9Roche Farma S.A, Madrid, Spain

**OBJECTIVES:** To develop a multidimensional specific questionnaire of factors related to weight loss therapies proposed for the assessment of therapy success or failure. **METHODS:** Three focus groups of patients where debriefed and an expert panel gathered relevant issues and converted them into 54 items around 9 dimensions: Alimentary Habits, Expectations towards Therapy, Effort and Concern, Emotion, Confidence, Believes, Motivation towards Physical Exercise, Motivation towards Weight Loss, and Perceived Control. Comprehension and legibility were questioned in a pilot sample. A first item reduction was done to avoid redundancies and to establish content agreement. Item reduction was carried out in a sample of patients using factor analysis. Feasibility, reliability, content validity and factor validity were assessed. **RESULTS:** A panel of 11 practitioners and researchers, belonging to different health centers in the Community of Madrid gathered 3 samples: One sample of 8 chronic patients participating in 3 focus groups; a sample of 8 patients to assess feasibility; a sample of 121 patients for item reduction. A first conceptual reduction conveyed a 32 item version. After measurement in a representative sample a final 17 items form was accepted. Items were conveyed a 32 item version. After measurement in a representative sample a final 17 items form was accepted. Items were arranged around 6 dimensions: Impulsiveness, External Locus of Control, Internal Locus of Control, Emotiveness, Motivation towards Physical Exercise, Motivation towards Weight Loss, and Perceived Control. Comprehension and legibility were questioned in a pilot sample. A first item reduction was done to avoid redundancies and to establish content agreement. Item reduction was carried out in a sample of patients using factor analysis. Feasibility, reliability, content validity and factor validity were assessed. **CONCLUSIONS:** A new questionnaire is a very short inventory of factors which might have screening properties in order to forecast the efficacy of weight loss therapies. Although further prospective research is being carried out in order to assess predictive validity, basic psychometric properties are good as a baseline model. Resulting dimensions are meaningful and well formed.

**POB10**

**RIMONABANT IMPROVES HEALTH-RELATED QUALITY OF LIFE IN OVERWEIGHT/OBESE PATIENTS WITH TYPE 2 DIABETES: RIO-DIABETES STUDY**

Kolotkin RL1, Crosby RD2, Scheen A3

1Duke University Medical Center, Durham, NC, USA, 2Neuropsychiatric Research Institute, Fargo, ND, USA, 3University of Liège, Liège, Belgium

**OBJECTIVES:** To evaluate the impact of the first selective cannabinoid type 1 (CB1) receptor blocker, rimonabant, developed for the management of cardiometabolic risk factors, on health related quality of life (HRQOL) in overweight/obese patients with type 2 diabetes. **METHODS:** A total of 1045 patients with type 2 diabetes were randomized in a double-blind trial and received either rimonabant 5 mg, 20 mg or placebo. Patients completed the Impact of Weight on Quality of Life-Lite (IWQOL-Lite), a validated 31-item questionnaire specifically designed for HRQOL assessment in obesity, and reported days missed from work at baseline and every 3-months up to 1 year. Analyses were performed on mean score changes from baseline to 1 year in the ITT population. Clinical meaningfulness was assessed using the Effect Size (ES) method, which is a measure of change over time that takes into account the variability within the sample at baseline. **RESULTS:** At 1 year, patients administered rimonabant 20 mg once daily (N = 339) reported significantly greater improvement (p < 0.001, and p = 0.03 for Work) in IWQOL-Lite total score and 3 out of 5 domains (Physical Function, Self-esteem and Work) than patients in the placebo group (N = 348) (no significant change in Sexual Life and Public Distress). These improvements were clinically meaningful (ES > 0.2). Also, there was a trend to fewer days missed from work reported by patients on rimonabant 20 mg (720 days) compared with those on placebo (1242 days) over the study period (p = 0.2 based on the number of patients with at least 1 day missed from work). **CONCLUSIONS:** HRQOL results showed both a statistically significant and clinically meaningful improvement in total score and also several domains (Physical Function, Self-esteem and Work) of the IWQOL-Lite questionnaire, with rimonabant versus placebo after a once daily administration of 20 mg rimonabant in this population of overweight/obese patients with diabetes.

**PAIN**

**PPN1**

**INTRAVENOUS PARACETAMOL IN POSTOPERATIVE PAIN MANAGEMENT—SYSTEMATIC REVIEW AND META ANALYSIS OF RANDOMIZED CONTROLLED TRIALS**

Golicki D, Niewada M

Medical University of Warsaw, Warsaw, Poland

**OBJECTIVES:** To assess the efficacy of a new, ready-to-use intravenous paracetamol in postoperative pain management in comparison with placebo, oral paracetamol, propacetamol and other NSAIDs. **METHODS:** Electronic databases search (Medline—PubMed, EMBASE, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Core Biomedical Collection), until March 2006, was conducted for randomised controlled trials on postoperative pain management with intravenous paracetamol in monotherapy or in combined treatment. Only full text articles published in peer-reviewed journals were accepted. Study results were combined in meta-analysis plots using RevMan, where appropriate. **RESULTS:** Six studies met the inclusion criteria: four compared intravenous paracetamol with placebo, one with oral paracetamol, two with propacetamol and one with metamizole. All studies were methodologically of high quality (average 4.83 points in Jadad scale). Treatment with intravenous paracetamol was significantly superior to placebo in pain relief, pain intensity difference, reduction of opioid consumption and patient treatment satisfaction (by 22% to 32.5%). Patients treated with intravenous paracetamol received less opioids than treated with oral paracetamol, whereas incidence of postoperative nausea and vomiting did not differ. No significant difference was obtained between intravenous paracetamol and propacetamol.