Index (BMI) was significantly associated with positive expenditures. Higher BMI was correlated with more positive expenditures. The most appropriate framework for the GLM was the Gamma distribution. The GLM showed that higher BMI was associated with greater expenditures. Age, gender, and marital status (separated and never married) were significantly associated with health care expenditures. Degree of education (Bachelor and Masters) was also significantly related but negatively correlated. CONCLUSIONS: Health care expenditures are significantly associated with BMI using a gamma distribution, where age, gender, marital status and education are also significant.

POB2
COSTS OF PREMATURE DEATH ATTRIBUTED TO OBESITY IN SPAIN
Echevarría A1, Betegón L2, Badia X2
1Sanofi Aventis, Madrid, Spain, 2H-O-R-Europe, Barcelona, Spain
OBJECTIVES: Obesity has become an important public health issue because of its link to high rates of avoidable and premature morbidity and mortality, especially due to its association with severe cardiovascular diseases and cancer. The objective of this study is to describe the mortality attributed to obesity in Spain in 2000 and its associated costs.

METHODS: Mortality associated with obesity was obtained by combining mortality data for the general population and the PAR (Population Attributable Risk). Loss of potential productive life years attributable to obesity was estimated, based on activity rates of population under 65 years old. The costs associated to premature death were then obtained by multiplying by mean wage figures.

RESULTS: 18.7% of all the deaths could be attributed to obesity. This mortality was similar in males and females (10.116 vs 11.537). The life years potentially lost attributable to obesity were 23,510, distributed as follows: 1015 for DM type 2, 422 for hypertension, 8925 for ischemic heart disease, 3854 for stroke, 61 for osteoarthritis, 3330 for colorectal cancer, 897 for ovarian cancer, 3649 for breast cancer, 1359 for vesicle cancer. The loss of productive years of life attributed to obesity was estimated, based on activity rates of population under 65 years old. The costs associated to premature death were then obtained by multiplying by mean wage figures. The cost–utility ratio is $38,884 per QALY compared to placebo and $28,364 per QALY compared to no intervention. Sensitivity analysis revealed that the results are sensitive to variations in acquisition costs and sustainability of weight loss. CONCLUSIONS: Rimonabant is able to increase quality of life by reducing body weight. This benefit is achieved at considerable costs; however, the cost–utility ratios are well below the currently accepted thresholds.

OBESITY—Methods and Concepts

POB3
COST-UTILITY ANALYSIS OF RIMONABANT IN THE TREATMENT OF OBESITY
Hampp C, Hartzema AG
University of Florida, Gainesville, FL, USA
OBJECTIVES: Rimonabant is a new agent currently seeking approval by the FDA for the indications of smoking cessation and treatment of obesity. This study estimates the cost–utility ratio of rimonabant for the treatment of obesity using data from two phase–III clinical trials. METHODS: Data from the Rimonabant in Obesity (RIO) Europe and RIO Lipids trials, two randomized, double-blinded, placebo-controlled, parallel group, fixed-dose, multicenter studies, were used to model utilities gained as increase in quality of life due to a temporary weight loss during a one-year treatment with rimonabant. In this study, two separate analyses were conducted: first, treatment with rimonabant 20mg/d plus dietary modification versus placebo plus dietary modification and second, comparison of treatment as above with a hypothetical no intervention group. The second analysis assumed no reduction in BMI (kg/m²) and zero costs for the no intervention group. The temporary weight loss for the treatment and placebo group was calculated assuming a weight regain to baseline within 3 years after treatment cessation. Costs included drug acquisition costs (estimated based on costs for comparable agents), physician office visits and dietary counseling. Efficacy estimates were discounted at 3%. RESULTS: Reduction in BMI was 2.395 and 0.601 for treatment and placebo, respectively. In the second analysis, comparison to no intervention, treatment resulted in a BMI reduction of 3.133. The incremental cost–utility ratio is $38,884 per QALY comparing treatment to placebo and $28,364 per QALY compared to no intervention. Sensitivity analysis revealed that the results are sensitive to variations in acquisition costs and sustainability of weight loss. CONCLUSIONS: Rimonabant is able to increase quality of life by reducing body weight. This benefit is achieved at considerable costs; however, the cost–utility ratios are well below the currently accepted thresholds.

POB4
USE OF GROWTH CURVE ANALYSES FOR DISCRETE EVENT SIMULATION: A CASE STUDY OF POOLED CLINICAL TRIALS
Caro JJ1, Ishak KJ1, Getsios D1, Moller J1, Lavaud V2
1Caro Research Institute, Concord, MA, USA, 2Sanofi-Synthelabo Research, Paris, France
OBJECTIVE: To predict effects over time on cardiometabolic risk factors of adding rimonabant to diet and exercise in overweight/obese patients. Both weight-dependent and weight-independent effects of treatment were examined in order to carry out a Discrete Event Simulation (DES). The DES predicts the time-dependent course of individual patients’ data according to treatment. METHODS: Data were taken from 4 RIO trials in over 6600 overweight/obese patients who received once-daily rimonabant 20mg (or placebo) on top of diet and exercise. Time-dependent functions of individual changes in weight, waist circumference, cholesterol, HDL-cholesterol, triglycerides, HbA1c, fasting glucose, and blood pressure were required for the DES. Change over time was analyzed in pooled trial data using a two-step process: 1) Logistic regressions predicted whether the parameter would decrease, and 2) fractional polynomials predicted change as a function of time and other factors. Random-effects were included to account for within and between patient variance. RESULTS: One year of treatment induced cardiometabolic improvements following a curvilinear course with steep initial changes and subsequent stabilization after six to nine months. To properly reflect these time-dependent changes, several time parameters were required in each equation. The degree of change over time depended on baseline levels and other patient characteristics and on weight changes, but rimonabant 20mg provided an additional, weight-independent, statistically-significant, effect (OR for worsening 0.36–0.88 depending on outcome considered). CONCLUSIONS: Multivariate time-dependent analytic techniques can provide the detailed estimates required for discrete event simulation. Growth curves enable estimation of the course of each simulated individual over time by providing for realistic modeling of risks and facilitate probabilistic sensitivity analyses. These analyses provided a detailed, accurate reflection.