NHS monthly costs between overweight (47€), mild (128€), moderate (162€) and severe (205€) obese subjects was significant (P = 0.02, Kruskall Wallis test). We found no statistically significant difference in out-of-pocket costs (P = 0.52). CONCLUSIONS: In few years cost for the health care management of a cohort of more than 5 millions of obese plus 15 millions of overweight individuals in Italy is likely to become unbearable for the I-Nhs, as it will be for most health systems. Policy makers should give the highest priority to the identification, promotion and implementation of effective integrated programmes for the prevention of obesity and overweight.

**EVALUATION OF THE COST-UTILITY OF ORLISTAT (XENICAL) IN THE UNITED KINGDOM**

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OBJECTIVES: The health service impact of obesity is growing relentlessly. There exist a small number of medical solutions for obesity. Obesity results in an increased risk of a plethora of diseases. The purpose of this study was to evaluate the cost-utility of orlistat (Xenical) in the UK. METHODS: A stochastic simulation model was constructed using clinical trial and real-life data comparing orlistat with no treatment and placebo under various scenarios. The time duration was 2-years, 2003 prices (UKs), costs discounted at 6%, benefits 1½% and evaluated from an NHS perspective. Events were determined for only cardiovascular (CV) disease end points, and determined by various risk functions. Utility was gained by a direct reduction in obesity, survival and progression to CV events, including macrovascular events for diabetes. Costs were summed for events and maintenance therapies. Extensive statistical economic analysis and sensitivity analysis was undertaken. RESULTS: The cost per quality adjusted life year (QALY) for orlistat versus no treatment evaluating National Institute for Clinical Excellence (NICE) guidelines was ≤12,814. The cost per QALY for orlistat versus no treatment evaluating the product licence was ≤13,045. The cost per QALY for orlistat versus placebo evaluating NICE guidelines was ≤19,128. The cost per QALY for orlistat versus no treatment evaluating the product licence was ≤17,386. These findings were fairly insensitive to variation in the main parameters. CONCLUSIONS: These data, from a conservative evaluation of the cost-utility of orlistat, showed that the treatment is well within the cost-effectiveness threshold set by NICE (≤20,000/QALY and ≤30,000/QALY). This analysis continues to support the positive guidance made by NICE in 2001 on orlistat.

**OBESITY—Quality of Life/Utility/Preference Studies**

**EVALUATING THE IMPACT OF WEIGHT LOSS ON QUALITY OF LIFE IN PATIENTS TAKING ORLISTAT AND ENROLLED IN THE MOTIVATION, ADVICE AND PRO-ACTIVE SUPPORT (MAP) PROGRAMME**

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OBJECTIVES: Purpose of this study was to evaluate quality of life (QoL) changes in MAP patients treated with orlistat according to the product licence. Orlistat, a clinically-effective, cost-effective treatment for weight reduction, is endorsed by NICE. MAP, the patient support programme, is endorsed by the UK Medicines Partnership project and provides direct support through trained health care professionals to patients treated with orlistat. METHODS: Patients starting treatment with orlistat and enrolled in the MAP programme were recruited into this study. Quality of life was measured using the 31-item, disease-specific IWQOL-Lite: Impact of Weight on Quality of Life questionnaire comprising five scales assessing physical function, self-esteem, sexual life, public distress, work and a total score. Weight, height and body mass index (BMI) were also collected at baseline, 3 and 6 months. Effect Size (ES) and Standardized Response Means (SRM) were used to assess clinically meaningful changes for IWQOL-Lite subscales and total score, with values interpreted as small (0.20–0.50), moderate (0.51–0.80) and large (≥ 0.81). RESULTS: All patients (n = 133) who achieved a weight reduction of at least 5% at 3 months as stipulated by the product licence were included in the analyses. Results of this study showed that these patients achieved clinically meaningful changes from baseline across all disease-specific QoL subscales, with moderate changes from baseline in physical function (ES = 0.61; SRM = 0.77), and moderate to large changes from baseline in self-esteem (ES = 0.66; SRM = 0.91) and IWQOL-Lite total score (ES = 0.70; SRM = 0.94). CONCLUSIONS: These findings clearly demonstrate that a weight reduction of at least 5% in patients taking orlistat enrolled in the MAP programme translates into clinically significant improvements across all disease-specific QoL domains. It can therefore be concluded that a combination of effective treatment with orlistat and direct patient support provided by health care professionals through the MAP programme results in clear benefits for these patients.

**COST AND QUALITY OF LIFE IN OBESITY**

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OBJECTIVES: Obesity increases the risk of chronic diseases, with consequences on social cost and Quality of Life (QoL). Our objective was to estimate the social cost and QoL in overweight, obese and severe obese people. METHODS: A Cost-of-Illness study was conducted from the societal perspective, adopting three-month retrospective observational period. Data were collected from a population based naturalistic survey investigating cardiovascular risk factors in adult (40–79 y.o.) Italian general population. We selected normal weight people as control group (Body Mass Index, BMI = 18.5–24.9), overweight (BMI = 25.0–29.9), obese (BMI = 30.0–34.9) and severe obese (BMI > 35.0) people, interviewed by general practitioners on clinical/demographic characteristics, direct costs (drugs, hospitalisations, specialist visits, diagnostics exams) and indirect costs (productivity loss). QoL was evaluated with the EQ-5D questionnaire. RESULTS: Data from 620 people were analyzed (mean age = 58.2, 46.5% men). Total cost in overweight, obese or severe obese people was quantified as twice than in normal weight people (>200 vs. 111 €/person/month). Direct cost involved more than half of total expense: hospitalizations accounted for the greatest part of direct cost, followed by drugs, diagnostic exams, medical visits and laboratory exams. Globally, the Visual Analogue Scale mean score was higher in overweight than in normal weight people, and lower in obese and severe obese people. Most of people reported no problem in “mobility”, “self care” and “usual activities” (around 90%), with “pain/discomfort” and “anxiety/depression” (around 50%). Very few people (<5%) reported extreme problems in any disease-specific IWQOL-Lite: Impact of Weight on Quality of Life questionnaire. In overweight people, problems concerning “mobility”, “self care”, “usual activities” and “pain/discomfort” were less frequent (around 50%), while “anxiety/depression” were more frequent (around 50%).