cumstances to assist the Agency's determination of device safety and effectiveness. One example is left ventricular assist device (LVAD) therapy for end-stage heart failure. **METHODS:** Clinical trials conducted in support of LVAD regulatory approval have demonstrated mortality benefits compared to optimal medical therapy alone. However, significant adverse events are also typically observed, including sepsis, bleeding and stroke. The regulatory challenge is to determine an acceptable tradeoff between mortality and adverse events. In this regard, PRO's including quality of life measures could provide additional information to assist in decision-making for device approval and also guide development of a more informative product label. **RESULTS:** Three issues need to be addressed to boost the scientific validity of PRO's in heart failure device trials: 1) the inherent unblinded study design for such devices makes PRO's susceptible to patient bias, confounding study results; 2) differential rates of follow-up between treatment arms: patients too moribund to complete follow-up assessment tools might lead to underreporting of negative HRQOL data and confound study results; and 3) a consensus needs to be achieved regarding the selection of valid assessment tools for heart failure studies. **CONCLUSIONS:** PRO's have promise in heart failure device evaluation, however, several important issues need to be addressed to properly incorporate such measures in studies intended for regulatory approval. The FDA welcomes dialogue with the clinical, academic and industry communities to develop appropriate PRO measures for heart failure device therapy.

PHP39

SELF-EFFICACY AND ACADEMIC ACHIEVEMENT OF THE FIFTH YEAR PHARMACY STUDENTS OF CHULALONGKORN UNIVERSITY, 2003

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OBJECTIVES: To predict students' academic achievement (GPA) by Self-efficacy (SE). SE is defined as the self-perception that one can master a certain task or perform adequately in a given situation. **METHODS:** A descriptive cross-sectional survey was employed for studying the relationship between Self-efficacy and academic achievement (GPA) of all (178) 5th year pharmacy students at The College of Pharmacy, Chulalongkorn University, Bangkok, Thailand during the period of August to September, 2003. **RESULTS:** The final return rate of questionnaire was 171 (96.06%). The respondents average age was 22.02 years. Most (124) were female (72.51%). The reliability coefficient (Cronbach's alpha) of Self-Efficacy (SE) scale was 0.87. The findings showed that there was positive relationship between SE and academic achievement (GPA) $r = 0.38$ ($p = 0.03$). The length of time for preparing for an examination by a female was longer than for a male ($p = 0.03$). There was no difference between male and female SE ($p = 0.07$). However, female's GPA was significantly higher than male's ($p = 0.02$). SE of the Bangkoker students was not different form the Non-Bangkoker students ($p = 0.87$). Students who participated in activities had higher SE than students who did not ($p = 0.24$) but the GPA of the two groups was not different ($p = 0.59$). Attitude toward pharmacy profession had no impact on SE nor GPA ($p = 0.78$, 0.82). The three predictors of the model were SE, Gender, and Time (to prepare the examination) R square = 0.40, beta = 0.38, 0.10, and 0.07 ($p = 0.02$). IQ was not controlled in this study. **CONCLUSIONS:** Self-Efficacy was a good predictor of academic achievement of Chulalongkorn University, pharmacy student class of 2003.

OBESITY

OBESITY—Cost Studies

POB1

OBESITY AND THE RISK OF UPPER RESPIRATORY TRACT INFECTIONS

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OBJECTIVES: High Body Mass Index (BMI) and obesity, prevalent throughout industrialised societies, are known to be associated with many co-morbidities. A possible increase in upper respiratory tract infections (URTI) associated with higher BMI was investigated in this study. **METHODS:** Cohort study using prospectively recorded patient data within the Full Feature General Practice Research Database (GPRD) which represents approximately 5% of UK population. Study subjects were categorised according to their baseline BMI into five exposure groups: I 18.5–24.9; II 25.0–29.9; III 30.0–34.9; IV 35.0–39.9 and V 40.0 and above. BMI records of 50.0 and over were discarded. Patients were followed from January 1, 1998 until December 31, 2002. Study outcomes were either Ear Nose and Throat (ENT) infections, or Respiratory Tract Infections (RTI). Statistical analysis: For each outcome group, crude incidence rates and incidence rate ratios (IRR) by BMI category were estimated. Poison regression analysis was used to make adjustments for age, gender, asthma, COPD, diabetes, smoking status, GP consultations and sleep apnoea. **RESULTS:** A total of 244,479 patients were eligible for the cohort. The adjusted IRR for ENT infections and URTI respectively was for BMI group II, 1.13 (1.11, 1.15) and 1.10 (1.08, 1.12), for BMI group III, 1.18 (1.15, 1.21) and 1.21 (1.17, 1.24) BMI group IV, 1.23 (1.17, 1.28) and 1.33 (1.27, 1.39) and for BMI group V 1.29 (1.20, 1.38) and 1.42 (1.32, 1.53). These findings were consistent after stratification by the number of GP consultations in 1997. **CONCLUSIONS:** This study provides evidence that there is an association between increasing BMI and ENT and upper respiratory tract infection. This association should be taken into consideration in the evaluation of the burden of obesity.

POB2

SOCIAL COST OF OVERWEIGHT AND OBESITY: SPESA STUDY

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OBJECTIVE: In Italy, the most recent report for the National Institute of Statistics (ISTAT) indicate that 1/3 of Italians are overweight an 1/10 obese, making the problem less dramatic than in the UK, Germany or USA. The objectives of this prospective naturalistic study were to describe direct and indirect costs attributable to the management of overweight and obesity and to identify factors associated with costs of management of subjects with overweight and obese. **METHODS:** The study included subjects between 18–65 years old with a body mass index greater than 25 (BMI, defined as weight in kilograms divided by the square of height in meters). Our estimates of the direct Health Care costs for the Italian National Health Care Service (I-Nhs) refer to 399 subjects enrolled at 52 centers and show a significant increase in total and I-Nhs monthly costs with increasing BMI. **RESULTS:** The increase in the average total monthly costs between overweight (82€), mild (189€), moderate (197€) and severe (233€) obese subjects was borderline significant ($P = 0.051$, Kruskall Wallis test). The increase in the average

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 the 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.

POB3

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 treatments 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 (UK≤), costs discounted at 6%, benefits $1^1/_2$% 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 microvascular 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 Ecxellence (NICE) guidelines was ≤12,814. The cost per QALY for orlistat versus no treatment evaluating the product license 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 license 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

OBESITY—Quality of Life/Utility/Preference Studies

POB4

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 change 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.

POB5

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