ENTERAL FEEDING IN THE COMMUNITY: A STUDY OF HEALTH ECONOMIC OUTCOMES USING THE GENERAL PRACTICE RESEARCH DATABASE (GPRD)

Pang F[1], Girod I[2], Saleh A[2], Knight H[2], Glencorse C[1], Edington J[3]
[1]Abbott Laboratories UK, Maidenhead, Berkshire, UK; [2]MAPI Values UK, Macclesfield, Cheshire, UK; [3]Orion Technology, Gerrards Cross, Buckinghamshire

OBJECTIVE: NICE is currently developing clinical guidelines on nutritional support in adults. The objective of this study was to determine which patients in primary care in the UK were prescribed enteral nutrition (sip & tube feeds) and to examine the associated economic outcomes. **METHODS:** Patients prescribed enteral nutrition during 2000/2001 were identified from the General Practice Research Database (GPRD). The results were analysed according to pre-determined BMI categories and diagnostic categories (cancer, dysphagia, stroke, GI, neurological, respiratory disorders, cystic fibrosis, renal disease, feeding difficulties). Results for the two largest diagnostic groups (GI disorders and cancer) are presented. **RESULTS:** In all, 2.34 million patients were registered on GPRD. 13,153 patients (0.6%) received >1 prescriptions for enteral nutrition, of whom 1332 had a recorded height and weight measurement. In all, 83% of patients with GI disorders and 69% with cancer had a BMI below 25. The number of nutritional prescriptions as a percentage of the total prescriptions by primary diagnosis category (cancer and GI disorders respectively) were as follows: BMI 15–<20 (1.1%, 3.0%), 21–<25 (3.2%, 2.1%), 26–<30 (1.2%, 0.3%) and 31–<40 (0.5%, 0.4%). GP visits were frequent in both diagnostic groups in all BMI categories (mean range 27–36 for GI disorders; 38–59 for cancer). Hospitalisations were also frequent with means ranging from 2.5–3.0 for GI disorders; 1.9–4.6 for cancer, possibly reflecting severity of disease. **CONCLUSIONS:** It is expected that patients with a lower BMI would have a higher percentage of nutritional prescriptions. Whilst this was found to be the case for patients with GI disorders, the study results showed that patients with cancer and a low BMI had fewer nutritional prescriptions. This suggests that some patients in the community who could benefit from enteral nutrition may not be receiving it.

RESOURCE USE AND COSTS OF PATIENTS RECEIVING ENTERAL NUTRITION IN PRIMARY AND SECONDARY CARE IN THE UK

Pang F[1], Girod I[2], Saleh A[2], Knight H[2], Glencorse C[1], Edington J[3]
[1]Abbott Laboratories UK, Maidenhead, Berkshire, UK; [2]MAPI Values UK, Macclesfield, Cheshire, UK; [3]Orion Technology, Gerrards Cross, Buckinghamshire

OBJECTIVES: No clinical guidelines or economic data exist on the use of enteral nutrition (EN) for the UK. The aim of this study was to determine which patients receive EN, and to estimate the relative economic burden of EN in the clinical management of such patients using observational databases. **METHODS:** GPRD and CHKS datasets contain aggregated, anonymised information on diagnoses, patient demographics and resource use data in primary care (GPRD) and secondary care (CHKS) settings. CHKS covered over 80 million episodes in 2001, representing 55% of UK hospitalisations. An average of 2,342,000 people were registered in the GPRD database in 2000/2001 representing 3.4% of the UK population. Patients were identified using EN procedure OPCS-4 codes (CHKS) and tube and sip feed drug codes (GPRD). Both databases were analysed for comorbidities and resource use. **RESULTS:** From the GPRD database (2000/2001), 13,153 patients received EN of whom 1332 had a recorded height and weight measurement. In the CHKS database there were 15,728 admissions in 2001 (<0.1% of all UK hospitalisations). Main diagnoses in both settings were dysphagia, cancer, stroke, feeding difficulties and anorexia and gastrointestinal disorders. Resource consumption was high. The mean number of hospitalisations per patient was 2.24 and the mean number of nutritional prescriptions (tube and sip feeds) annually in primary care was 5.8. However, the costs of daily tube feeds (≤10.20–≤13.18) represented less than 4% of daily inpatient costs. **CONCLUSIONS:** Although 40% of patients in UK hospitals and 11% in the community are malnourished, very few are nutritionally assessed in order to receive EN. The economic burden of EN remains low compared to the overall patient management. This is also one of the first observational database studies which has aimed to estimate resource use across both primary and secondary care settings.

THE INFLUENCE OF CHANGE OF CO-PAYMENT TO THE USE OF ANTIBIOTIC AGENTS

Szalayova A
Ministry of Health, Bratislava, Slovak Republic

Increased expenditures for pharmaceuticals in previous years lead to implementation of several cost-containment measures in 2003 in the Slovak Republic. Within that, co-payments for antibiotic drugs were increased from 0 to 1.25€ per package in 2002 and in the beginning of 2003 from 0 to 5€ per package after November, 2003. The consumption of antibiotics significantly decreased from November 2003 compared to the same period the previous year. **OBJECTIVES:** To assess the influence of increased co-payment of antibiotic agents to their decreased consumption in a retrospective study. **METHODS:** Consumption of antibiotic agents (group J01 according to ATC classification) prescribed in outpatient care in the Slovak Republic during the period of November, 2003 to April, 2004 was compared to consumption during November, 2002 to April, 2003. Antibiotics were divided into three groups according to the level of co-payment: without increased co-payment, with slightly increased and significantly increased co-payment. **RESULTS:** Overall consumption in period 2003–2004 decreased by 25.1% compared to the previous year. Consumption was 46.5% lower in the group with the highest increase of co-payment, but only 30.9% or 13.8% lower in the group with slightly increased co-payment and in the group without change in co-payment, respectively. **CONCLUSIONS:** Increase in co-payment in November, 2003 had a huge effect on the use of antibiotic agents in the Slovak Republic. Although 55% of antibiotic agents had no change in the level of co-payment, the consumption decreased in this group by 13.8%, probably because of awareness of increased co-payments within this group of pharmaceuticals.

USE OF PATIENT-REPORTED OUTCOMES IN EVALUATION OF HEART FAILURE DEVICE THERAPY: THE REGULATORY PERSPECTIVE

Muni NI[1], Pocock S[2], Berman MR[1], Yue LQ[1]
[1]U.S. Food and Drug Administration, Center for Devices and Radiological Health, Rockville, MD, USA; [2]London School of Hygiene and Tropical Medicine, London, UK

OBJECTIVES: The FDA is tasked with the evaluation of medical devices to determine the products' safety and effectiveness. Utilization of patient-reported outcome (PRO) measures for medical device therapies poses special methodological challenges, due to small sample sizes and the often unblinded study design of device clinical trials. However, PRO's might prove useful in special cir-

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

Auamnoy T, Mekaroonreung S, Techawatcharatep C

Chulalongkorn University, Bangkok, Thailand

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

Williams TJ[1], Gilloteau I[2], Brouard R[2], Martinez C[1]

[1]GPRD Division, Medicines and Health Care products Regulatory Agency, London, UK; [2]Sanofi-Synthelabo Recherche, Paris, France

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

Mantovani LG[1], Belisari A[2], Carruba M[1]

[1]University of Milan, Milan, Italy; [2]Novartis Farma S.p.a, Origgio, Varese, Italy

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