bilities for CHD events were derived from the Framingham risk formulae. Baseline cohort characteristics and Niaspan® treatment effects were taken from the ARBITER II study. Patients with persistently low HDL-c (<1.03 mmol/L) on statin treatment received either add-on Niaspan® 1 g daily or continued statin monotherapy. Direct costs (2004 Euros) were accounted (cardiovascular disease and treatment costs). Annual discount rates of 5% (Germany) and 3.5% (UK) were applied to clinical outcomes and costs. Undiscounted life expectancy (LE) was also calculated. Sensitivity analyses were performed. **RESULTS:** A total of 53.75% of patients were projected to have persistently low HDL-c levels after statin treatment. In these patients mean undiscounted LE of 16.12 years and 15.85 years were projected for the Niaspan® and statin monotherapy arms respectively. Lifetime direct medical costs were higher by €3563 in Germany and by £2820 in the UK with addition of Niaspan®. Incremental cost-effectiveness ratios based on discounted LE were €26,624 per life year gained in Germany and £17,262 in the UK for statin plus Niaspan® versus statin monotherapy. Results were most sensitive to the gender distribution, as women have a lower risk of CHD events. **CONCLUSIONS:** In patients with dyslipidemia and persistently low HDL-c, addition of Niaspan® to statin therapy was projected to be cost-effective compared to statin monotherapy in Germany and the UK.

PCV70

THE COSTS OF METABOLIC SYNDROME

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OBJECTIVES: To estimate the medical costs directly related to the Metabolic Syndrome (MS) in Italy. **METHODS:** A retrospective study was conducted on a general sample of 4.974 patients, to whom an oral blood glucose lowering drug, a serum lipid reducing agent and an antihypertensive drug had been prescribed at least once during the observation period (2001–2003). An equal sized control group (matched by sex and age) and a sub-sample of 1.401 patients from the general sample (actual consumers of the above prescribed drugs at least once in each of the observational years) were also used. The general and sub-sample showed no considerable differences in the primary outcomes. All data was obtained from a Northern Local Health Unit database. The prospective was the Italian NHS's point of view. The specific costs of the MS (drugs and hospitalisation) were calculated as incremental costs, comparing the affected patients (study group) to the general population (control group). **RESULTS:** The Metabolic Syndrome affects both males (49.5%, mean age 64.6) and females (50.5%, mean age 68.2). Yearly mortality among patients with MS does not differ from mortality in the general population. All the costs in the study group were significantly higher than the corresponding costs in the control group. The total average cost per year for a patient with MS was estimated at €1522 (drugs: €558; hospitalisation: €964), versus the lower corresponding estimation for the general population at €361 (drugs: €155; hospitalisation: €206). So, on a yearly and per capita basis, the incremental cost of the metabolic syndrome amounts to €1161.Mortality and age were shown to be the major cost drivers. **CONCLUSIONS:** To the NHS in Italy the cost for MS might be as high as €670 million a year (0.9% of the total public health expenditure).

PCV71

COST-EFFECTIVENESS OF ROSUVASTATIN COMPARED WITH GENERIC SIMVASTATIN IN THE UK NHS

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OBJECTIVES: To assess the long-term cost-effectiveness of titration from initial doses of rosuvastatin (RSV) and generic simvastatin (SIM). **METHODS:** Efficacy data from the STELLAR clinical trial (TC, HDL-C, and TG) were used as input to the model. Markov models ran in 4-year cycles for 20 years, from age 55 to 76 years to predict primary and secondary CHD based on Framingham risk equations in four gender/risk cohorts. In year one quarterly titration up to a maximum dose of 40 mg (RSV) or 80 mg (SIM) was based on a total cholesterol (TC) target of 5 mmol/l. Risk was calculated using the average TC: HDL-C ratio of 1000 simulated patients, with adjustment for Framingham's hypothesised over-prediction of UK risk. RSV and generic SIM prices for September 2004 and recent UK CHD event cost data were applied. Relative mortality risks and health-state utilities were used to derive quality-adjusted life years (QALYs). Discounting was performed at 3.5% (costs and outcomes). **RESULTS:** The STELLAR trial found RSV 10 mg lowered total cholesterol significantly more than SIM 10–40 mg (–32.9% vs. –20.3%, –25.7%, 27.9%, respectively), and RSV 20 mg lowered total cholesterol significantly more than SIM 80 mg (–37.6% vs. –32.9%). Based on this model less CHD events and deaths are expected among patients on RSV compared with SIM. Hence RSV delivers more QALYS at an acceptable cost per patient, e.g. £3458 per QALY for high-risk males compared with SIM. Insensitivity analysis when generic SIM is priced at zero, the cost per QALY gained for RSV ranged from £11,169 (male high risk) to £21,752 (female base case). **CONCLUSIONS:** More CHD events are likely to be avoided using RSV than SIM. RSV will be a cost-effective strategy, as defined by UK NICE thresholds for cost per QALY gained, even as the generic SIM price approaches zero.

PCV72

UTILIZATION PATTERNS OF ASPIRIN AMONG NSAID TREATED SUBJECTS WITH VARYING CARDIOVASCULAR RISK PROFILES IN A HEALTH BENEFITS POPULATION

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OBJECTIVES: To understand the patterns of aspirin utilization among users of Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) with varying cardiovascular risk profiles. **METHODS:** A telephone survey was completed using a large health benefits company population. The survey consisted of 10-items used to characterize aspirin consumption and identify motivation for utilization. Subjects were randomly selected from a dataset of members aged 18 and older, who had an NSAID prescription claim between April 1, 2003 and June 30, 2003, while maintaining continuous plan enrollment during a 24-month period. Subjects were also required to maintain chronic NSAID utilization, defined as at least a 90 days' supply during a 12-month period. Study subjects were stratified based upon their NSAID utilization into: 1) cox-II selective inhibitors; 2) non-selective NSAIDs (excluding naproxen); and 3) naproxen. Subjects were further stratified based upon the presence or absence of risk factors associated with cardiovascular events. **RESULTS:** The study population consisted of 1250 subjects, of which 52.3% were treated with non-selective NSAIDs, 19.4% with naproxen, and 28.3% with cox-II inhibitors. In total, 77.1% of the popu-

lation had risk factors associated with cardiovascular events. No significant difference (P = 0.6945) was found in the proportion of subjects using aspirin among the non-selective NSAID, naproxen, and cox-II cohorts, with 46.8%, 48.8%, and 49.4%, respectively. Likewise, no significant differences were found among the treatment cohorts with respect to: strength, frequency, and duration of aspirin use (P = 0.3840, P = 0.8088 and P = 0.6838, respectively). Finally, no significant difference (P = 0.2778) was found in the proportion of subjects using aspirin among those with risk factors for cardiovascular events versus those without. **CONCLUSIONS:** Unexpectedly, these results indicate that aspirin utilization, strength, frequency, and duration are independent of both subjects' cardiovascular risk profile (i.e. risk vs. no risk) and the NSAID class utilized (i.e. selective vs. nonselective).

PCV73

USE OF PROPENSITY SCORE METHODOLOGY IN CARDIOVASCULAR DEVICE TRIALS: U.S. FOOD AND DRUG ADMINISTRATION PERSPECTIVES

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OBJECTIVE: Randomized, controlled trials (RCT's) are considered to be the gold standard of scientific evidence to assess safety and effectiveness of cardiovascular devices. However, RCT use is challenging to implement in certain device trials, due to logistical and ethical reasons. The FDA understands that assessment of device technologies must balance the competing demands of maximizing scientific validity against the practical realities of performing (and effectively completing) these clinical studies. Hence, non-randomized clinical trials are sometimes used in device evaluation. Propensity score analysis, as an alternative to traditional covariate adjustment methods, has been increasing in popularity as a technique to control for baseline differences between treatment groups in non-randomized cardiovascular device studies. **METHODS:** Propensity scores provide a convenient methodology for covariate adjustment when multiple covariates are involved. However, propensity score methodology does not eliminate many of the scientific limitations of non-randomized studies compared to RCT's, and should not be viewed as a substitute for performing a randomized study. In using propensity score modeling, a full pre-specification of covariates to be included and the model to be used is recommended to minimize the concern of bias introduced by post hoc model development. **RESULTS:** Furthermore, sensitivity analysis should be performed to demonstrate the robustness of study outcome in the face of hidden bias due to unmeasured or unquantifiable covariates. Lastly, it is recommended that conventional covariate adjustment as well as propensity score adjustment should be performed to demonstrate consistency of outcomes between techniques. **CONCLUSION:** Propensity score methodology has increased in popularity for covariate adjustment in non-randomized cardiovascular device studies. However, there are limitations to this methodology, which must be fully appreciated to avoid erroneous inferences from study data. Randomized trials are still preferred and strongly encouraged whenever possible, especially for the evaluation of novel cardiovascular devices.

PCV74

A BUDGET IMPACT MODEL FOR EPLERENONE IN THE TREATMENT OF HEART FAILURE POST MYOCARDIAL INFARCTION

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OBJECTIVES: The Eplerenone Post-Acute Myocardial Infarction Heart Failure Efficacy and Survival Study (EPHESUS) showed that the addition of eplerenone to optimal medical therapy reduced both morbidity and mortality in patients with acute myocardial infarction (AMI) complicated by left ventricular dysfunction and heart failure whilst reducing the number and duration of heart failure re-hospitalisations. A budget impact model was developed to estimate the effects of adding eplerenone to standard care in the UK National Health Service (NHS). **METHODS:** Within the model the efficacy of eplerenone is based on the EPHESUS study. This is applied to UK epidemiological data on the incidence of AMI, proportion of survivors developing heart failure and their prognosis. UK drug acquisition costs and NHS hospital inpatient costs and average length of stay for England are included. All costs are expressed in pounds sterling. The model estimates the incremental costs and benefits of adding eplerenone to standard care in heart failure resulting from AMI from the perspective of NHS health care decision makers over a three-year period. Input variables include population, incidence of AMI and annual rate of eplerenone uptake. **RESULTS:** If all eligible patients are treated in an NHS Primary Care Trust of population 250,000, the estimated cost per life year saved is 6,701 pounds in year three, for an additional expenditure of £256,959. This level of treatment results in a reduction of 101 bed days for re-hospitalisations due to heart failure, at a cost per bed day avoided of €1207. **CONCLUSIONS:** With hospital inpatient care the biggest single health care cost in heart failure, reduction in hospitalisation is a key priority within the UK NHS. Models such as the one described here enable the economic consequences of using a new drug to be identified and clarify the role of drug treatment in delivering NHS priorities.

PCV75

COST-EFFECTIVENESS OF EPTIFIBATIDE IN NSTEMI PATIENTS IN POLAND

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OBJECTIVES: To estimate incremental cost-effectiveness of adding a GPIIb/IIIa inhibitor (eptifibatide) to percutaneous coronary intervention (PCI) and standard medical management (MM) versus PCI + MM alone in Poland for patients with non-ST-elevation myocardial infarction (NSTEMI) at high risk of recurrent ischemia or cardiovascular death. **METHODS:** A Markov model was constructed to estimate the additional costs and benefits of a GPIIb/IIIa inhibitor on top of standard care. The model has 4 disease states (no event, post-ischemia, post-MI, death) and two tunnel states (refractory ischemia, non-fatal MI). PCI + MM include beta blockers, ACE inhibitors, aspirin, heparin and clopidogrel. The model takes the Polish national health payer perspective and runs for the expected lifetime of the patient. The effectiveness parameters were taken from a 6-month GPIIb/IIIa clinical trial and extrapolated to 45 years with an estimated Weibull function. Event and follow-up costs are based on assumed treatment patterns. The results of the model were expressed in total (discounted) costs and life years per patient, and incremental cost per life year gained. A series of one-way sensitivity analyses has been conducted on the major model inputs. **RESULTS:** The lifetime discounted costs for the base case analysis are 13,856 PLN per patient for the PCI + MM group and 15,570 PLN for the eptifibatide group (a difference of 1714 PLN). The use of eptifibatide provides an additional average of 0.05 year of life per patient compared with PCI + MM. The incremental cost effectiveness ratio for the lifetime model, with