ilities for CHD events were derived from the Framingham risk formula. 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® 1g 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 (<0.9 mmol/L) 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 €3363 in Germany and by £2820 in the UK with addition of Niaspan® 1g daily. 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.

THE COSTS OF METABOLIC SYNDROME

Mangone M1, Benelli G2, Cerra C2, Lottaroli S2, Lucioni C3, Mazzì S1
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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 €1,522 (drugs: €358; 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 €1,161. 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).
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. non-selective).

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

Muni N, Yue L

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OBJECTIVE: Randomized, controlled trials (RCTs) 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 scientific and ethical reasons. The FDA understands that assessment is challenging to implement in certain device trials, due to logistical 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.

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

Tabberer M1, Duerden M2

1Pfizer Ltd, Tadworth, Surrey, UK; 2Keele University, Keele, Staffordshire, UK

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 death and 1% rate 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.

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