OBJECTIVES: To determine in Italy the incremental cost per life year saved (ICLYS) of clopidogrel versus ASA in secondary prevention of ischemic stroke (IS), myocardial infarction (MI), or vascular death in four high risk atherothrombotic populations: 1) with prior IS or MI to index event; 2) treated for hypercholesterolemia and/or with diabetes; 3) polyvascular; and 4) with prior cardiac surgery (CABG). **METHODS:** The economic analysis was performed from the Italian Health Care System perspective using only direct medical costs. A Markov model designed with 7 clinical states calculated ICLYS as the cost needed to achieve an extra life year with a two-year treatment with clopidogrel compared to ASA, over a lifetime horizon. The model combined clinical outcomes from the CAPRIE trial database and survival data derived from the Saskatchewan database. The costing of events, including acute care and two-year follow-up, was evaluated using official data for DRGs, tariffs and/or charges (physicians fees, examinations, lab tests). A discount rate of 3% was applied to costs and lifetime effects. **RESULTS:** Per 1000 patients treated with clopidogrel the additional ischemic events avoided and the gain in life years were: 27 events and 119 years in prior IS or MI patients; 28 events and 130 years in hypercholesterolemic and/or diabetic patients; 24 events and 138 years in polyvascular patients; 82 events and 474 years in prior CABG patients. The ICLYS of clopidogrel compared to ASA were 9055€ in prior IS or MI group, 7880€ in patients treated for hypercholesterolemia and/or diabetes, 8216€ in polyvascular patients and 2001€ in CABG patients. Results were robust under a wide variation of key parameters. **CONCLUSION:** In Italy a two-year treatment with Clopidogrel as an alternative to ASA is a cost-effective strategy in secondary prevention of ischemic fatal and non-fatal events for high-risk atherothrombotic patients.

PCV7

THE COST-EFFECTIVENESS OF CLOPIDOGREL IN ACUTE CORONARY SYNDROMES WITHOUT ST-SEGMENT ELEVATION IN POLAND

Pietrasik A[1], Niewada M[1], Spiesser J[2], Gabriel S[3]
[1]Medical University of Warsaw, Warsaw, Poland; [2]Sanofi-Synthelabo Recherche, Bagneux, France; [3]Sanofi-Synthélabo, Bagneux, France

OBJECTIVES: The CURE study has demonstrated that treatment strategy involving clopidogrel plus aspirin, comparing to aspirin alone, significantly reduced the risk of cardiovascular death, myocardial infarction and stroke in patients with ACS without ST-segment elevation. For every 1000 patients treated with clopidogrel there were 20 less strokes, myocardial infarctions or cardiovascular deaths (crude NNT = 50). The purpose of the present study was to evaluate cost-effectiveness of clopidogrel in Poland based on CURE trial efficacy data. **METHODS:** Data on resource use i.e. hospitalizations, medical procedures, concomitant medications and study drug were derived from case report form of CURE trial. Unit costs were calculated using drugs retail prices and medical procedures tariffs contracted by National Health Found. Cost-effectiveness was expressed as cost per cardiovascular event avoided. The time horizon was the mean study duration of 9 months. All costs are expressed in EURO and EURO-PPP (1EURO = 2.08 PLN' PPP2003). **RESULTS:** Mean direct treatment cost per patient was higher in clopidogrel than control group (2395 and 1931€; 5074€, and 4100€, PPP, respectively). The observed difference was attributable mostly to a higher acquisition cost of clopidogrel. The mean cost of initial and subsequent hospitalizations (including study drug) was reduced for clopidogrel group by 18 and 24€, 40, and 53€-PPP, respectively. The estimated incremental cost per event avoided amounted to 23,076€ and 48,497 EURO-PPP. **CONCLUSIONS:** Treatment with clopidogrel resulted in reduction of initial and subsequent hospitalizations costs. The cost per event avoided with clopidogrel in patients with ACS is consistent with results from other countries and compares well to other treatment strategies in patients with cardiovascular disease.

PCV8

THE ECONOMIC IMPACT OF CLOPIDOGREL IN PATIENTS WITH UNSTABLE CORONARY ARTERY DISEASE UNDERGOING PERCUTANEOUS CORONARY INTERVENTIONS (PCI): POLISH PERSPECTIVE

Pietrasik A[1], Niewada M[1], Spiesser J[2], Gabriel S[3]
[1]Medical University of Warsaw, Warsaw, Poland; [2]Sanofi-Synthelabo Recherche, Bagneux, France; [3]Sanofi-Synthélabo, Bagneux, France

OBJECTIVES: Results from the PCI-CURE trial demonstrated that treatment strategy involving clopidogrel plus aspirin, comparing to aspirin alone, significantly reduced the risk of cardiovascular death, myocardial infarction and stroke in patients with acute coronary syndromes (ACS) without ST-segment elevation undergoing percutaneous coronary interventions (PCI). The purpose of the present study was to evaluate cost per event avoided in the PCI subgroup of CURE trial, in Poland. **METHODS:** Data on resource use, i.e. hospitalizations, medical procedures, concomitant medications and study drug were derived from case report form of PCI-CURE trial. Unit costs were calculated using drugs retail prices and medical procedures tariffs contracted by National Health Found. Cost-effectiveness was expressed as cost per cardiovascular event avoided. The time horizon was the mean study duration of 8 months. All costs are expressed in EURO and EURO'PPP (1€ = 2.08 PLN' PPP2003). **RESULTS:** Mean direct treatment cost per patient was higher in clopidogrel than control group (2700 and 2248€, 5711, and 4759€'PPP, respectively). The observed difference was attributable mostly to a higher acquisition cost of clopidogrel. The mean cost of initial hospitalizations (including study drug) was reduced for clopidogrel group by 26€, 57€'PPP. The estimated incremental cost per event avoided amounted to 12,858€, 27,043€'PPP. **CONCLUSIONS:** Treatment with clopidogrel resulted in reduction of initial hospitalizations costs. The cost per event avoided with clopidogrel in patients undergoing a PCI is comparable to other interventions in this area considered as cost-effective.

PCV9

COST-EFFECTIVENESS ANALYSIS OF ALTEPLASE COMPARED WITH STREPTOKINASE AND ABSENCE OF THROMBOLYTICAL THERAPY FOR MYOCARDIAL INFARCTION

Derkach E, Avxentieva M, Vorobjov PA
Moscow medical academy, Moscow, Russia

OBJECTIVE: to perform cost-effectiveness analysis of alteplase compared with streptokinase and absence of thrombolytical therapy for myocardial infarction (MI) in Russia. **METHODS:** Data on effectiveness of treatment and resource use were extracted from hospital medical charts randomly selected from 10 city hospitals in a retrospective study. A total of 133 patients received alteplase, 97 patients received streptokinase and 131 patients did not receive thrombolytical therapy. Effectiveness was assessed by death rate, presence of anginal pains, arrhythmia and heart failure at discharge. Direct medical costs were calculated on the basis of price-lists for medical services of an insurance company and median prices for drugs given in a wholesale pharmaceutical informational bulletin. Incremental cost-effectiveness ratio (ICER) was calculated for alteplase vs streptokinase and no thrombolytical therapy and for streptokinase vs no thrombolytical therapy. **RESULTS:** There was no significant difference in death rate between 3 groups. Patients from alteplase group significantly less often had heart failure by the end of hospital treat-

ment as well as anginal pains. Rate of arrhythmia at discharge was minimal in streptokinase group. Alteplase required much more costs than streptokinase or treatment without thrombolytical therapy. ICER was 252,454.31 rubles ($7889.20) per absence of heart failure at discharge for alteplase vs streptokinase, and 166,720.5 rubles ($5210.02) for alteplase vs treatment without thrombolytical therapy. Still streptokinase was more cost-effective vs treatment without thrombolytical therapy: ICER was 4038.76 rubles ($126.21) per absence of heart failure at discharge. **CONCLUSION:** Alteplase is less cost-effective thrombolytical strategy for MI than streptokinase in spite of higher effectiveness.

PCV10

THE COST-EFFECTIVENESS OF CLOPIDOGREL IN PATIENTS UNDERGOING PERCUTANEOUS CORONARY INTERVENTION IN SWEDEN: AN ANALYSIS OF PCI-CURE

Lindgren P[1], Stenestrand U[2], Malmberg K[3], Jönsson B[4]

[1]Stockholm Health Economics, Stockholm, Sweden; [2]University Hospital of Linköping, Linköping, Sweden; [3]Karolinska Hospital, Stockholm, Sweden; [4]Stockholm School of Economics, Stockholm, Sweden

OBJECTIVES: We assessed the long-term cost-effectiveness of the use of clopidogrel on top of standard therapy (including aspirin) in comparison with ASA only in patients undergoing percutaneous coronary interventions in Sweden. **METHODS:** A Markov model was developed. Transition probabilities for relevant events were estimated based on RIKS-HIA, a register on patients treated in the coronary care units at 74 (out of 78) hospitals throughout Sweden. Patients were assumed to be treated for one year with an effect based on the PCI-CURE trial. Costs for the intervention and the defined events were collected from published sources and recalculated to 2003 prices. Life-years gained were used as the measure of effectiveness, with QALYs gained as a sensitivity analysis. The perspective was that of the Swedish society with a separate analysis using a health care cost perspective. Costs and effects were discounted at 3%. **RESULTS:** The model predicts a net gain in survival of 0.04 years when adding clopidogrel. This comes at a net increased cost of 441€ if only direct costs are included. Including indirect costs, the net increase is reduced to 326€. The resulting cost-effectiveness ratio was 10,782€ and 7971€ per life-year gained for the different definitions of cost. Assuming a 0.1 reduction in utility following a MI, the cost per QALY gained was 6381€. Cost-effectiveness ratios were even lower in diabetics compared to non-diabetics. Results were robust to changes in discount rate and variations in unit costs. **CONCLUSIONS:** The predicted cost-effectiveness ratios are well below the threshold values generally considered cost-effective. Adding clopidogrel to ASA thus appears cost-effective in this indication.

PCV11

COST EFFECTIVENESS OF ADDING NIASPAN TO ATORVASTATIN TREATMENT IN THE SECONDARY PREVENTION OF CARDIOVASCULAR DISEASE IN PATIENTS WITH DYSLIPIDEMIA IN THE UK

Berger W[1], Roze S[2], Valentine WJ[2], Palmer AJ[2]

[1]Merck KGaA, Darmstadt, Germany; [2]CORE Center for Outcomes Research, Binningen/Basel, Switzerland

OBJECTIVES: High density lipoprotein-cholesterol (HDL-C) is inversely and independently associated with increased risk of cardiovascular disease (CVD). The importance of HDL-C as a risk factor for CVD is well accepted. We performed a modelling study to estimate the incremental cost per additional patient achieving target HDL-C (≥1 mmol/L) when Niaspan (extended release niacin) is added to stable statin therapy in CVD patients from the perspective of the National Health Service in the UK. **METHODS:** A 3-step probabilistic model was developed. Step 1: population of 10,000 patients with a normal distribution of lipid profiles defined by mean and standard deviation was created. Step 2: treatment effects of atorvastatin 10 mg were applied to the population and those whose low density lipoprotein-cholesterol (LDL-C) was satisfactory (≤3.0 mmol/L) but did not reach target HDL-C (≥1.0 mmol/L) received treatment with Niaspan. Step 3: treatment effects of Niaspan were applied in patients. Baseline lipid values and treatment effects were randomly sampled from distributions drawn from published epidemiological and clinical studies using second order Monte Carlo methodology. Cost for drugs and initiation of Niaspan treatment were taken from published sources. Results were presented for the initiation year, taking into account initiation costs and drop-outs, and maintenance year scenarios. **RESULTS:** In total, 16.3% of patients required Niaspan in addition to atorvastatin treatment to control dyslipidemia. Of these patients, 29.4% and 36.7% reached target HDL-C after addition of Niaspan in the initiation and maintenance years respectively. Additional costs in Niaspan treated patients were £320.30 and £252.30 for initiation and maintenance years respectively, leading to incremental costs of £1089 and £687 per additional patient achieving HDL-C target. **CONCLUSIONS:** The additional costs per patient treated to HDL-C target by adding Niaspan to statin therapy are comparable to those reported in the literature for treating patients with statins to LDL-C or total cholesterol targets.

PCV12

SECONDARY PREVENTION AFTER PCI: THE COST-EFFECTIVENESS OF FLUVASTATIN THERAPY IN THE NETHERLANDS

Chaplin S[1], Scuffham P[1], Alon M[2], Boom van den G[2]

[1]University of York, York, UK; [2]Novartis Pharma, Arnhem, The Netherlands

OBJECTIVES: Little is known about the cost-effectiveness of secondary prevention after percutaneous coronary intervention (PCI). Aims of this study are to estimate 1) the cost-effectiveness of routine fluvastatin therapy after a first successful PCI in The Netherlands, and 2) the chance that fluvastatin therapy is cost-effective given a society's willingness to pay as laid down in Dutch guidelines. **METHODS:** A cost-effectiveness analysis was performed using data from the Lescol Intervention Prevention Study (LIPS). In the LIPS trial, patients with normal blood cholesterol to moderate hypercholesterolemia who had undergone a first PCI were randomized to receive either fluvastatin 40 mg twice-daily plus dietary counseling or dietary counseling alone. A Markov model (DataPro) was used to estimate the incremental costs per quality-adjusted life year (QALY) and life year gained (LYG). Costs were based on prices and reimbursed charges, utility data were drawn from literature. Hospital costs (admissions and procedures) were extracted from a database with complete national coverage. 10,000 Monte Carlo simulations and multivariate analysis were used to assess (2nd order) uncertainty. **RESULTS:** The mean net incremental costs of routine statin treatment were 734€ (SD: 686€) per patient over 10-years compared with controls. Treatment resulted in an incremental 0.078 (0.047) QALYs or 0.082 LYG (0.041). The incremental cost per QALY and LYG were 9312€ (14,648€) and 8954€ (16,617€) respectively. The sensitivity analysis revealed that the cost of fluvastatin and the discount rate had the largest effect on the ICER. Anticipating a willingness to pay of 20,000€ per QALY, there is a 75.1% chance that fluvastatin treatment is cost-effective. **CONCLUSIONS:** Statin therapy with fluvastatin