their index cath (MI Group) or as being event-free at three months (No MI Group). Outcomes through four years were assessed in landmark analyses using Cox proportional hazards techniques. **RESULTS:** Patients in the MI vs. No MI Groups had a median of 4.2 years follow-up and were similar in age (62 vs. 63 years, p = .44), female sex (35% vs. 33%, p = .35), history of hypertension (69% vs. 68%, p = .77), history of diabetes (35% vs. 30%, p = .08), and in multi-vessel CAD (61% vs. 58%, p = .17). At four years follow-up, patients in the MI vs. No MI Groups had higher unadjusted rates of death (25% vs. 17%, p < .001) and death or MI (34% vs. 21%, p < .001). After adjustment, the hazards of death for patients in the MI vs. No-MI Groups (HR 1.62; 95% CI 1.30, 2.02; p < .001) and death or MI (HR 1.84; 95% CI 1.51, 2.24, p < .001) remained significant. When we extended the landmark period from three to six months after the index cath, the adjusted hazards of death (HR 1.61; 95% CI 1.34, 1.93; p < .001) and death or MI (HR 1.86; 95% CI 1.58, 2.19; p < .001) were still significant. **CONCLUSIONS:** Non-fatal myocardial infarctions significantly increase subsequent rates of death and death or MI in CAD patients. These findings suggest a long-term clinical benefit for therapies that avert non-fatal MIs.

CV2

A NEW MEASURE FOR ASSESSING HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN PATIENTS WITH ATRIAL FIBRILLATION: AF-QOL

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OBJECTIVES: To assess AF-QoL questionnaire performance in patients with Atrial Fibrillation (AF) in a usual clinical practice setting. **METHODS:** Observational, prospective, multicenter study was carried out in 29 Spanish centres. AF diagnosed patients aged ≥18 who have changed a clinical and/or therapeutic intervention or were stable according to clinical criteria, and patients with post heart attack cardiopathy (control group) were enrolled. All patients went through a baseline visit; only AF patients underwent a follow up visit (at 3 ± 1 months and 1 month for unstable and stable patients respectively). At each visit, socio-demographical and clinical information was gathered; AF-QoL, SF-36 questionnaires and perception of general health status were administered. AF-QoL is an 18-item questionnaire with 3 domains: psychological, physical and sexual. Questions refer to previous month. Answers are 5 levels Likert-like. AF-QoL scores range between 0–100, where 0 is poor HRQoL. **RESULTS:** A total of 417 patients were included: 341 AF patients and 76 control patients. Mean (SD) age was 61.2(12.4) and 31.4% were women. AF type distribution was: 37.5% paroxysmal, 42.9% persistent and 19.6% permanent. AF-QoL was completed by 88.5% of patients. AF-QoL mean overall global score in AF patients was 43.6 and 51.7 in control group (p < 0.05). AF-QoL showed good internal consistency (0.92) and good test-retest reliability (0.86) in stable AF patients. Patients with more symptoms and worse NYHA functional class at baseline and at the end of follow-up visit showed lower scores in AF-QoL. AF-QoL correlations with SF-36 and overall perception of general health status question were moderate-high (0.32–0.69) and moderate (0.49) (p < 0.01) repectively. AF-QoL effect size scores in patients declaring health status positive changes was 1.06, 0.2 for those with no changes and 0.1 for patients with negative changes. **CONCLUSIONS:** AF-Qol has shown to be feasible, valid, reliable and responsive to clinical changes in the context of clinical practice.

CV3

PREDICTED OPTIMAL LIPID VALUE ATTAINMENT WITH THE CO-ADMINISTRATION OF FENOFIBRIC ACID AND A STATIN COMPARED TO STATIN MONOTHERAPY IN PATIENTS WITH MULTIPLE LIPID ABNORMALITIES

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OBJECTIVES: To predict the percentage of patients achieving multiple optimal lipid values (OLV) after one year of combination fenofibric acid (FA) + statin therapy or statin monotherapy. **METHODS:** A dyslipidemia outcomes model was used to predict multiple OLV attainment (any 3 of 4 targets: total-C, LDL-C, HDL-C, or TG) among a cohort of 1000 patients with multiple lipid abnormalities (MLA). Optimal lipid levels for HDL-C (value >40 mg/dL for men, >50 mg/dL for women), LDL-C (value <130 mg/dL), TG (value <150 mg/dL), and total-C (value <210 mg/dL) were based on U.S. clinical practice guidelines. Baseline lipid values were simulated with National Health and Nutrition Examination Survey data, used to determine the shape of lipid distributions (gamma for TG and log normal for the others) and the correlation between these parameters. Mean initial and on-treatment lipid values were obtained from three 12-week FA/statin studies, where FA 135 mg co-administered with atorvastatin, rosuvastatin, and simvastatin at low (20 mg, 10 mg, 20 mg, respectively) and moderate doses (40 mg, 20 mg, 40 mg, respectively) was compared to FA and corresponding statin monotherapy doses. **RESULTS:** Compared to equivalent statin monotherapy, the addition of FA 135 mg to low-dose simvastatin, rosuvastatin, and atorvastatin was predicted to result in 43% (678 vs. 473 per 1000), 31% (814 vs. 621 per 1000), and 43% (723 vs. 506 per 1\000) more patients simultaneously achieving multiple OLV. The number of patients predicted to achieve multiple OLV increased by 16%, 18% and 25% with FA + moderate-dose simvastatin, rosuvastatin, and atorvastatin over equivalent dose statin monotherapy, respectively. **CONCLUSIONS:** Patients with MLA receiving statin monotherapy may require add-on treatment to achieve multiple lipid targets. This analysis suggests that treatment with FA in combination with low- and moderate-dose statin therapy may enable more patients to simultaneously achieve OLV compared to statin monotherapy.

CV4

COST-EFFECTIVENESS ANALYSIS OF IVABRADINE IN STABLE ANGINA PATIENTS IN THE NETHERLANDS

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OBJECTIVES: To assess the cost-effectiveness of ivabradine in stable angina patients in the Dutch health care setting in 2007. **METHODS:** A Markov model was developed to estimate the cost-effectiveness of ivabradine. The analysis was performed for stable angina patients, who currently are candidate for revascularisation. Data sources used included 1) Ivabradine clinical trial data, 2) Data of the Dutch Heart Foundation, and 3) Data of the Euro Heart Survey (European Cardiology database). Furthermore, published literature, official Dutch price/tariff lists and national population statistics are used. The time horizon of the model was 5 years in order to capture the long-term economic impact of ivabradine. **RESULTS:** The results show that the use of ivabradine leads to additional drug costs of €3873 over a period of 5 years, which are offset by a cost saving of €8699 due to fewer revascularisations (€1210 in the ivabradine arm versus €9909 in the revascularisation arm) over a period of 5 years. As a result the

use of ivabradine leads to a total cost saving of €4826 per patient over 5 years. The use of ivabradine also leads to a higher effectiveness, as it reduces the average number of revascularisation procedures from 1.100 to 0.143, including the initial revascularisation procedures for the standard care arm of the model. The number of revascularisations during the 5-year period is about similar, when excluding the initial revascularisation procedure (0.100 to 0.143). Sensitivity analyses show that ivabradine remains cost saving over the complete range of the input variables. **CONCLUSIONS:** Ivabradine is a cost-effective treatment and, in fact, a dominant treatment: Ivabradine yields to a higher effectiveness as standard treatment with respect to number of revascularisations, but leads to substantial overall cost savings.

PODIUM SESSION II: ECONOMIC EVALUATIONS II

EE5

COST-EFFECTIVENESS OF ATORVASTATIN IN TYPE 2 DIABETES PATIENTS: A PHARMACO-ECONOMIC ANALYSIS OF THE COLLABORATIVE ATORVASTATIN DIABETES STUDY (CARDS) IN THE BELGIAN POPULATION

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OBJECTIVES: To estimate the cost-effectiveness of atorvastatin 10 mg compared with no treatment for the primary prevention of cardiovascular (CV) events in Type 2 diabetes patients with no CV history. **METHODS:** A Markov model with 1-year cycles was developed to simulate the CV event and death risk according to the therapeutic approach initiated. The transition probabilities for CV event in the 'no statin treatment' group were derived from the risk-equations reported from the large UK Prospective Diabetes Study (UKPDS). The hazard ratio (HR) from the CARDS clinical trial (0.63; 95% confidence interval [CI], 0.48, 0.83; P = 0.001) was used to adjust these CV event probabilities in the atorvastatin 10 mg treatment group. Characteristics of Type 2 diabetes patients with no CV history were derived from the Belgian Optimize Cardiovascular Prevention in Diabetes (OCAPI) survey. The public health care payers' perspective was taken into account for costing. The direct medical costs of CV events were based on the Public Health Authorities' hospital database for acute care costs and on literature for follow up costs. Drug cost did consider the impact of generic entry on the reimbursement system. Costs were valued at year 2008; costs and outcomes were respectively discounted at 3 and 1.5%. **RESULTS:** Based on a 5-year time horizon, atorvastatin was demonstrated to be cost-effective with an incremental cost/QALY of €23,426. Over a lifetime horizon (25 years), atorvastatin was a cost-neutral therapeutic approach (€9/QALY). At a threshold of €30,000/QALY, atorvastatin had a 99.3% probability to be cost-effective. Furthermore, for higher risk diabetic patients managed in specialist hospital diabetes centres, atorvastatin was cost-saving. **CONCLUSIONS:** Compared to no treatment, the use of atorvastatin 10 mg as a primary prevention strategy in Type 2 diabetes patients not only appears to be cost-neutral over a lifetime, but improves CV outcomes.

EE6

COST-EFFECTIVENESS OF THE ADDITION OF RITUXIMAB TO FIRST-LINE CHEMOTHERAPY TREATMENT REGIMENS IN PATIENTS WITH ADVANCED FOLLICULAR LYMPHOMA IN THE UK

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OBJECTIVES: Following broadening of the EMEA license for advanced follicular lymphoma (FL) which now allows first line treatment with rituximab added to chemotherapy without restriction to the regimen, we evaluated the cost-effectiveness of rituximab added to commonly used chemotherapy regimens from the perspective of the UK national health care system. **METHODS:** A Markov model was developed using published results from 4 phase III randomized-controlled clinical trials evaluating progression-free survival (PFS) and overall survival (OS) in patients with advanced FL. These trials compared the addition of rituximab to chemotherapy regimens of either MCP, CVP, CHOP or CHVP versus chemotherapy alone. Rates of disease progression were derived from the PFS Kaplan-Meier curves using parametric curve fitting, mortality rates were obtained from the Scotland-Newcastle Lymphoma Group database and UK age-specific mortality tables. FL patient utilities elicited using the EQ-5D were applied to PFS and progressed health states. The duration of the treatment effect of rituximab was applied for the period of follow-up specified in each of the clinical trial publications. Medication, supportive care costs and quality-adjusted life years (QALYs) were estimated over a lifetime time horizon (25 years) and discounted at 3.5% *per annum*. Univariate and probabilistic sensitivity analysis was performed to evaluate uncertainty. **RESULTS:** The addition of rituximab to chemotherapy increased QALYs by 1.223, 1.034, 0.858 and 0.471 years for MCP, CVP, CHOP and CHVP, respectively, compared to chemotherapy alone. The incremental cost per QALY gained was £5620, £6455, £7970 and £8422, for MCP, CHOP, CVP and CHVP, respectively, all below commonly used thresholds in the UK. Sensitivity analyses indicated these results were robust, and most sensitive to the duration of treatment effect. **CONCLUSIONS:** For all chemotherapy regimens evaluated, the model demonstrated the addition of rituximab increased quality-adjusted life expectancy and is a highly cost-effective treatment option for patients with advanced FL.

EE7

ECONOMIC ANALYSIS OF PROPHYLACTIC CERVICAL CANCER VACCINATION IN ITALY: THE NATIONAL AND REGIONAL LEVEL

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OBJECTIVES: The impact of cervical cancer prevention, through 12-year-old female vaccination with *Cervarix*™ (GlaxoSmithKline), has been published for many countries at the national level. However, to our knowledge no attempt has been made to address the impact at a regional level. Since the Italian health reforms of the early 1990s, introducing "managerialism", decentralization and quasi-market mechanisms; regional authorities have consequently been experimenting with different organizational and funding models to achieve an acceptable combination of equity, efficiency, freedom of choice and cost-containment. **METHODS:** A Markov model, previously described and successfully adapted to the national scenario (La Torre, 2007), has been used to explore the impact of prophylactic cervical cancer vaccination with *Cervarix*™ at a regional level in Italy. Resource use was based on a standard therapeutic path applied to all regions. However we quantified the impact of the so-called "decentralization progress" by collecting regional data on: Pap-test coverage, tariffs for treatments and cost of the vaccination course. The analyses were combined with regional budget impact analyses, considering the demography and the effective tender price for each region. **RESULTS:** Our analyses demonstrated the heterogeneity present at regional level in Italy (e.g. regular screening, ranges from 36% to 84%; cost of cervical