quitting smoking. Cost of 5-year reimbursement varenicline was estimated to be €63.0 millions, while smoking cessation avoided costs reached €99.9 millions, which compared with €21.1 millions savings in the not-reimbursed scenario: a net incremental cost-saving of €15.9 millions. Savings were observed since 3rd year of modelling. **CONCLUSIONS:** The BI of the reimbursement of varenicline in smoking cessation is a cost-effective health policy in the Spanish NHS, and could produce cost-savings since the 3rd year of implementation.

PCV37

BUDGET IMPACT ANALYSIS OF HYPERTENSIVE TREATMENT WITH INDAPAMIDE AND AMLODIPINE SINGLE-PILL COMBINATION IN THE POLISH SETTING

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OBJECTIVES: The aim of this study was to calculate and compare public payer and patients' costs of hypertensive treatment with indapamide 1.5 mg and amlodipine 5 mg or 10 mg single-pill combination (SPC) and free combination (FC), in the Polish setting. **METHODS:** The analysis compared two scenarios: existing and new. The existing one assumed treatment with FC of indapamide 1.5 mg and amlodipine 5 mg or 10 mg. The new one also included treatment with SPC of indapamide 1.5 mg +amlodipine 5/10 mg. Population and market shares were estimated on the basis of published reimbursement data, experts' opinion and validated with available epidemiological data. Cost data were analysed from the public payer perspective (National Health Fund) and from patient perspective, in a three-year horizon. SPC cost is based on average pharmacy price reported in April 2014 (18.13PLN and 19.75PLN respectively for 1.5+5mg and 1.5+10mg /30 tabs); 30% patient copayment was assumed. The cost of FC was calculated as an average cost of reimbursed indapamide and amlodipine products in corresponding doses. All costs present 2014 values, and are expressed in Polish zloty (PLN). Average monthly exchange rate of May 2014 was applied (1EUR=4.1790PLN). Difference in clinical effectiveness between SPC and FC was also included, in the form of cardiovascular events risk. **RESULTS:** Introduction of indapamide/amlodipine SPC on the reimbursement list next to FC brought savings from public payer perspective and from patient perspective amounting to: 509,255PLN (121,860EUR) and 5,893,941PLN (1,410,371EUR) in first year, 689,239PLN (164,929EUR) and 7,833,005PLN (1,874,373EUR) in second year, 725,965PLN (173,717EUR) and 8,328,480PLN (1,992,936EUR) in third year. Additionally it resulted in avoidance of 808 cardiovascular events in the three-year horizon. **CONCLUSIONS:** Treatment with indapamide/amlodipine SPC in comparison to FC generates significant savings both from the public payer perspective and from patient perspective in contemporary Polish setting, and reduces cardiovascular events.

PCV38

MODELING THE IMPACT OF A DIGITAL HEALTH FEEDBACK SYSTEM IN UNCONTROLLED HYPERTENSIVE PATIENTS

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OBJECTIVES: Despite the availability of numerous therapeutic agents and management tools, half of all hypertensive patients do not have their blood pressure (BP) at goal. A model was developed to estimate the incremental costs of uncontrolled vs. controlled hypertension and the impact of shifting patients to controlled status via a unique digital health feedback system. This Proteus system utilizes an Ingestible Sensor to determine medication-taking patterns, and a wearable 7-day sensor in the form of an adhesive patch to collect physiological and behavioral metrics such as heart rate, step count, and patterns of activity and rest, providing a means of determining non-response vs. non-adherence to prescribed medications and recommendations for daily routine. **METHODS:** The additional costs of outpatient services, monitoring, and cardiovascular complications were calculated for uncontrolled vs. controlled hypertensive patients from a US plan perspective for a 1 year time horizon. The clinical and utilization assumptions were derived from the literature and expert opinion, and costs were derived from the Medicare Fee Schedule and AHRQ databases. The impact of the Proteus system on BP control was based on a real-world study evaluating this technology in 164 patients with a history of uncontrolled hypertension. **RESULTS:** In a health plan of 1 million members, 7.9% (78,656) were uncontrolled hypertensive patients receiving care who were eligible for the Proteus system. The direct annual medical costs of uncontrolled hypertension were estimated to be $60.9 million over the costs for controlled disease. The Proteus system was estimated to result in $7.3-18.3 million in savings ($328-$717 per BP at goal), and lead to a 3-9% reduction in the number of coronary artery disease and stroke events in one year. **CONCLUSIONS:** Even in the short-term, a digital health feedback system appears to provide an effective way to mitigate the substantial costs of uncontrolled hypertension.

PCV39

BUDGET IMPACT ANALYSIS OF APIXABAN VERSUS OTHER NOACS FOR THE PREVENTION OF STROKE IN ITALIAN NON-VALVULAR ATRIAL FIBRILLATION PATIENTS

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OBJECTIVES: This study aims to perform a budget impact analysis of the use of three available novel oral anticoagulant agents (NOACs) for preventing thromboembolic events in Italian patients with non-valvular atrial fibrillation (NVAF). **METHODS:** Estimated Italian population of patients is run through a decision tree/Markov model simulating their treatment with the available therapeutic options: dabigatran at two dose levels (110 mg/bid for the over 80 years old, 150 mg/bid for younger NVAF patients), rivaroxaban, and apixaban. Effectiveness estimates derive from an adjusted indirect treatment comparison using warfarin as link. Epidemiological data and unit costs are collected from Italian published sources. The budget impact analysis evaluates the financial impact of apixaban introduction by comparing expected 1,2, and 3 years costs in hypothetical scenarios: with and without apixaban. Italian NVAF patient population estimation is based on official apixaban reimbursement criteria, applying the characteristics of the trial population to national epidemiologic data. Sensitivity analysis is performed on an alternative non-experimental population of NVAF patients. **RESULTS:** Among available NOACs, apixaban is expected to be the least expensive at 1,2, and 3 years in an estimated patient population of 364,000 Italian patients, allowing for savings of over 5 million € by the third year. Results of the simulation run on an alternative non-experimental population of NVAF patients yields comparable estimates. Exclusive use of apixaban for three years in the identified population would allow for savings of € 8,832,500, € 14,446,551 and € 27,282,998 when compared with dabigatran (110 mg), dabigatran (150 mg) and rivaroxaban, respectively. **CONCLUSIONS:** The different safety and effectiveness profiles of the available NOACs emerging from the adjusted indirect comparison indicate that the introduction of apixaban could improve health care expenditure control while maintaining or increasing therapeutic appropriateness in the Italian NVAF population.

PCV40

THE BUDGET IMPACT OF NEW GENERATION CT SCANNERS FOR DIFFICULT-TO-IMAGE, LOW-RISK PATIENTS WITH SUSPECTED CAD

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OBJECTIVES: The National Institute of Health and Care Excellence (NICE) issued diagnostic guidance on new generation computed tomography (CT) scanners recommending them as an option for the first-line imaging of coronary arteries in patients with suspected low-risk coronary artery disease (CAD) in whom imaging with old generation scanners is difficult (e.g. obese patients). The capital investment for a new generation scanner is considerably more than a standard scanner, which could hamper implementation. Based on the NICE guidance, a model was designed for use as a planning tool for rapid access chest pain clinics (RACPCs) looking to replace their current scanner with a new generation scanner. **METHODS:** An Excel® model was developed to estimate up to a 10-year impact of acquiring a new generation scanner. It was assumed that under standard care low-risk, difficult-to-image patients would be referred for a diagnostic invasive coronary angiography (ICA). Under the new diagnostic pathway these patients can be scanned with a new generation scanner. Whenever possible the NICE guidance was used to guide assumptions and populate default values. **RESULTS:** The model estimates that for each difficult-to-image patient a new generation scanner has the potential to save approximately £946.62 in diagnostic costs. Considering the capital investment required, a RACPC looking to replace their standard scanner and considering implementing a new generation CT scanner only need 53 difficult-to-image patients per year to see a positive return on investment over a 10-year period. **CONCLUSIONS:** The model is likely to be conservative as it focuses on difficult-to-image patients only, yet the scanner is available for all patients who will likely benefit from the better sensitivity and specificity associated with the new scanners. However, it highlights that even a low number of these difficult-to-image patients will result in a positive return on investment over the expected life-time of the scanner.

PCV41

SIMVASTATIN PLUS FENOFIBRATE AS A FIXED DOSE COMBINATION IN THE TREATMENT OF MIXED DYSLIPIDEMIA IN GREECE: BUDGET IMPACT ANALYSIS

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OBJECTIVES: To evaluate the affordability of switching patients already treated with the multi-pill therapy of simvastatin and fenofibrate to the first simvastatin and fenofibrate fixed dosed combinations (FDC) product, for the management of mixed dyslipidemia in the Greek health care setting. **METHODS:** A budget impact model was locally adapted. The analysis was conducted from a third-party payer perspective over a time horizon of 3 years. The population with mixed dyslipidemia in Greece, the market shares of available treatments and the corresponding drug acquisition costs were combined to estimate the total budgetary impact that will result from the penetration of FDC in the Greek market. Data on population with mixed dyslipidemia were derived from the National Statistical Service and published literature. Estimates of the current and future market shares were obtained from Abbott Hellas market research. Drug acquisition costs were calculated using the latest price bulletin issued and the corresponding reimbursement prices. Reimbursement prices were reduced by the patient's relevant co-payment and relative rebates. Since market prices for the FDC are not available yet in Greece, estimated retail prices provided by Abbott Hellas were considered [FDC 20/145: €13.70 (€12.22-16.27) and FDC 40/145: €16.71 (€15.22-19.23)]. **RESULTS:** Savings in pharmaceutical reimbursement on year 1 were estimated at 146,974 (€181,084-€88,503) decreasing the relevant cost by 5.87% (7.23%-3.53%). On year 2, savings of €250,544 (€322,536-€136,474) were attributed to the penetration of FDC, lowering the budget by 9.93% (12.78%-5.41%). On the 3rdyear, savings were estimated at €403,405 (€509,489-€221,565) reducing spending by 15.82% (19.98%-8.69%). On average, over the 3-year time horizon of the analysis, the addition of FDC was found to decrease reimbursement costs by 10.54% (13.33%-5.88%) generating savings of €266,974 (337,703€-€148,147). **CONCLUSIONS:** The introduction of FDC reimbursement will result in a predictable budget impact which is expected to decrease the relevant pharmaceutical cost for national health insurance.

PCV42

BUDGET IMPACT ANALYSIS OF BOTULINUM TOXIN A THERAPY FOR UPPER LIMB SPASTICITY IN GERMANY

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OBJECTIVES: Upper limb spasticity (ULS) secondary to stroke has a considerable patient and caregiver burden, particularly with regards to pain, activities of daily

living and mobility. Botulinum neurotoxin-A (BoNT-A) injections are effective in treating ULS. We aimed to calculate annual BoNT-A treatment cost of ULS on a per-patient basis, and the expected overall annual budget impact of BoNT-A treatment in Germany using static and dynamic market share scenarios. **METHODS:** A budget impact model for BoNT-A use, adopting a German health care system perspective, was developed. Two market-share scenarios were modelled over 5 years. While the static scenario assumed current market shares (abobotulinumtoxinA, 36%; onabotulinumtoxinA, 26%; incobotulinumtoxinA, 38%) to remain constant over time, the dynamic scenario assumed market share of abobotulinumtoxinA to rise up to 76% across 5 years. Epidemiologic data inputs were sourced from the most recently published literature, unit costs for BoNT-As from the Lauertaxe (pharmacy purchase price [PPP] level), and market share assumptions from IMS Health (Market Sizing). Equivalence of the 3 BoNTAs in terms of efficacy and safety is assumed and therefore no differential use of medical services or other goods. **RESULTS:** Annual BoNT-A drug costs per ULS patient were 3 463€, 5 603€, and 5 410€, respectively, with prescribing patterns following SmPC recommendations for abobotulinumtoxinA, onabotulinumtoxinA, and incobotulinumtoxinA. The total drug costs were decreased by between 1 231 861€ (-4%) in year 2 and 5 133 684€ (-17%) in year 5 by shifting the market share to abobotulinumtoxinA. Sensitivity analyses showed that the number of patients treated with BoNT-As, time to re-injection, and dose per injection were the most influential parameters on budget impact, impacting both drug acquisition costs and physician visits. **CONCLUSIONS:** Increased use of abobotulinumtoxinA compared with incobotulinumtoxinA and onabotulinumtoxinA for ULS in Germany could potentially reduce the total cost of treatment.

PCV43

RENAL DENERVATION WITH THE SYMPLICITY CATHETER SYSTEM FOR TREATMENT-RESISTANT HYPERTENSION: A BUDGET IMPACT ANALYSIS

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OBJECTIVES: Renal denervation (RDN) is a new treatment option for patients with uncontrolled resistant hypertension. Studies have shown RDN to have a potential reduction in systolic blood pressure and therefore reduce risk for different cerebrocardiovascular disease (stroke, ischemic heart disease, heart failure, etc.). The aim is to assess the economic impact of renal denervation in resistant hypertensive patients based on the potential clinical benefit demonstrated in literature. **METHODS:** A budget impact model was developed to quantify RDN-related cost-savings accomplished through lower rate of cerebro-cardiovascular events compared with the medical treatment cohort (with 3+ anti-hypertensive medications including a diuretic). The model was developed from the Italian National Healthcare Service (NHS) perspective with a 10-year time horizon. The risk of events was calculated using different multivariate equations. A literature review was carried out to collect the treatment costs for both acute and chronic phase of hypertension-related events. The cost of RDN procedure was approximated to the related DRG tariff. **RESULTS:** Renal denervation, considering the blood pressure reduction observed after procedure, substantially reduces cerebro-cardiovascular event probabilities by 30% if compared to the medical treatment cohort. Assuming a yearly 2% RDN adoption rate, approximately 2,000 events would be avoided in 10 years allowing total savings up to 9 Million euro. The higher cost of new technology was offset from potential saving associated to the avoided events. Compared to the total costs associated to the medical treatment cohort in 10 years the overall expenditure for RDN was greater than 0.8%. The annual incremental cost for patients treated with surgical approach was estimated at 16 euro per patient. **CONCLUSIONS:** The economic impact of hypertension-related complications is significant in the Italian setting. Consequently the potential savings according to the NHS perspective derived from the implementation of strategies aimed at improving the level of hypertension should be considered.

PCV44

DABIGATRAN VERSUS DICOUMARINS IN NON-VALVULAR ATRIAL FIBRILLATION. BUDGET IMPACT STUDY IN THE EXTREMADURA PUBLIC HEALTH SYSTEM

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OBJECTIVES: To estimate the costs associated with the use of dabigatran (DB) vs. dicoumarins (DC) in non-valvular atrial fibrillation (NVAF) from the perspective of the Extremadura Public Health System (EPHS) in 2013. **METHODS:** A budget impact study of anticoagulant therapy (AT) with DB and DC in patients with NVAF was carried out during 2013. The data were processed using the JARA® electronic record application. Pharmaceutical costs and costs associated with patient follow-up and monitoring were included. Costs relating to incidence of stroke, gastrointestinal bleeding, intracranial haemorrhage and acute myocardial infarction were also included based on RE-LY clinical trials. For pharmaceutical cost RRP + VAT of the medicinal products was used, and other health care costs were based on the public prices of the EPHS and the National Health System. **RESULTS:** Three hundred eighty-five patients were treated with DB (4.01 %) and 8876 with DC (92.63%). Mean age was 77 (95 % CI: 76.82-77.19). Total expenditure for AT with AVK for the best case scenario would be €3,036,604.28 (mean cost per patient: €342.11; 95% CI: 341.80-342.34) and the worst case €3,727,169.83 (€419.92; 95% CI: 419.70-419.15) and for DB €318,077.15 (mean expenditure: €826.27; 95% CI: 796.81-855.57). For a DB market penetration of 50%, expenditure on anticoagulation of these patients would be €3,958,659.57 while for 75% it would be €5,937,989.36. **CONCLUSIONS:** Dabigatran is a more costly option than classic treatment with DC. In 2013 this drug's market penetration was limited and was closer to other estimates. Estimated mean cost per patient for DCs is similar to the estimates of other communities (Basque Country: €300-700 and the Valencian Community: €300) and are somewhat lower for DB (Basque Country: €1,197 and the Valencian Community: €1,350). A limitation of the study is that the safety data were obtained from clinical trials rather than actual clinical practice with these drugs.

PCV45

ESTIMATING THE VALUE OF CANGRELOR FROM ELIMINATING PRELOADING IN CORONARY ARTERY BYPASS GRAFT (CABG) PATIENTS

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OBJECTIVES: 2011 AHA and 2012 ESC guidelines recommend antiplatelet therapy at presentation for suspected ACS patients. For CABG patients (approximately 10% of ACS presentations) this strategy creates a dilemma: delay CABG to washout antiplatelet therapy or perform surgery and risk bleeding. Bridging strategies have been proposed using GPIs. Cangrelor, a novel reversible, IV $P2Y_{12}$ inhibitor with rapid onset/offset, demonstrated in the CHAMPION PHOENIX trial a reduction in ischemic events vs. clopidogrel in patients undergoing PCI. Adoption of cangrelor for angiography in ACS patients eliminates the need to washout an oral $P2Y_{12}$inhibitor in case of unanticipated CABG. The aim of our analysis was to quantify the annual value of this pathway change to a US hospital. **METHODS:** A decision analytic model based on the current CABG patient pathway was developed to quantify the value of a reduction in bridging by adopting cangrelor from a US hospital perspective. Premier hospital database informed the timing of CABG after washout; demographics, drug-mix, LOS, blood product utilization, and hospital ward costs. Ischemic event rates and costs were informed by published sources. Drug costs were 2014 wholesale acquisition costs. Cangrelor cost was set to $0. **RESULTS:** For a hypothetical US hospital treating 195 CABG patients/year (patient mix: 4% STE-ACS, 26% NSTE-ACS, 70% SA), shifting away from bridging with GPI by adopting cangrelor resulted in a total annual cost reduction of $120,000. Total costs in the base-case are estimated to be $2.95MM vs. the scenario case of $2.83MM. Cost savings were derived from eliminating GPI utilization, lowering washout drug costs and reducing hospitalization days. **CONCLUSIONS:** Removal of the need to washout oral antiplatelet therapy prior to CABG through adoption of cangrelor is estimated to deliver a clinical value of ~$615/CABG patient with fewer total days spent hospitalized.

PCV46

BUDGET IMPACT OF THE INTRODUCTION OF NEW ORAL ANTICOAGULANTS (NOAC) FOR NO VALVE ATRIAL FIBRILLATION (NVAF) IN EXTREMADURA

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OBJECTIVES: To analyse the budgetary impact (BI) of the introduction of NOAC in patients with NVAF compared to warfarin treatment scenario (DC) from the perspective of the public health system of Extremadura (PHSE). **METHODS:** A budget impact study was performed during 2013. It was based on anticoagulant therapy (AO) on patients with NVAF. The data came from the electronic clinical history called JARA®. Pharmaceutical costs associated to the control and monitoring of patients with DC were included. Specifically those related to the incidence of stroke (CVA), gastrointestinal haemorrhage (HG), intracranial haemorrhage (ICH) and acute myocardial infarction (AMI) as the RE-LY, ROCKET and ARISTOTLE trials. For DC, there were taken into account the best and worst scenario. The pharmaceutical cost considered was the sum of the official price and the VAT. To other public health costs, official prices from the PHSE and the Spanish National Health Care System were considered. **RESULTS:** Treatment distribution among patients was 92.63% DC; 4.02% Dabigatran (DAB); 3.07% rivaroxaban (RIV) and 0.28% Apixaban (APX). The total expenditure for the AO patients with VKA in the best scenario is € 3,036,604.28 (average cost per patient: € 342.11, CI 95%: 341.89 - 342.34) and the worst would be € 3,727,169 (€ 419.92, CI 95%: 419.70 - 420.15). For NOAC the results are € 572,515.39 (€ 810.93, CI 95%I: 786.71 - 835.16). NOAC represent the 71.44% of the pharmaceutical expenditure (PE), the 23.47% of PE's control and monitoring of DC and the 15.86% of the total expenditure from AO patients with NVAF, in the best scenario. **CONCLUSIONS:** The market access of NOAC has been modest and similar to the rest of Spain. AVK alternative has the lowest average cost per patient. Limitation: safety data has been obtained from clinical trials instead of using clinical practice.

PCV47

THE MOVE TOWARDS FULL IMPLEMENTATION OF THE NICE GUIDELINES FOR STROKE PREVENTION IN ATRIAL FIBRILLATION: THE POTENTIAL COST AND CLINICAL IMPACT

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OBJECTIVES: Updated treatment guidelines for atrial fibrillation (AF) have been released by the National Institute for Health and Care Excellence (NICE) in the United Kingdom and highlight a current shortfall in the prescribing of anticoagulants to patients with AF despite the importance of stroke prevention. A model was designed for use as a planning tool for Clinical Commissioning Groups (CCGs) looking to budget for the future move towards full implementation of the NICE guidelines. **METHODS:** An Excel model was developed to estimate the 5-year impact of gradually treating all eligible AF patients who are currently not being prescribed anticoagulants, both in terms of the effect on clinical outcomes (strokes, major bleeds and mortality) and the financial impact associated with treating more patients. Assumptions had to be made in order to simplify the model and populate default values. Risks of clinical outcomes were taken from a literature search. Costs were taken from published national sources. **RESULTS:** In an average sized CCG (population of 226,000) the model estimated that in order to gradually treat the full eligible AF patient population, an additional budget of £103,899 will be required in Year 1 to treat an additional 248 patients, rising to £791,076 in Year 5 to treat an additional 1,889 patients. Cumulatively over the 5-year timeframe this could lead to the prevention of 8 ischemic strokes and 3 deaths, as well as an increase of 2 haemorrhagic strokes and 8 bleeds. **CONCLUSIONS:** The clinical benefits of appro-