in lifetime costs and utilities of $17,208 and 10.4124 QALYs compared with $16,780 and 10.4057 QALYs for prasugrel therapy. The ICER for clopidogrel was $63,840/QALYs. The acceptability curve showed that prasugrel was not likely cost-effective with >80% certainty at any WTP threshold. One-way sensitivity analyses (WTP decision threshold: $100,000/QALY) showed that prasugrel is the most cost-effective strategy when probability of MI is increased by >12%, probability of bleeding is decreased by >24%, and disutility associated with MI is >0.1634. When only patients with variant CYP2C19 were considered, the ICER was found to be $2,313,333/QALY for clopidogrel. **CONCLUSIONS:** Inconclusive results indicate that there is no benefit in prescribing one therapy over the other for the entire patient population. CYP2C19 polymorphism should be given consideration during the decision making process. For the base-case scenario, prasugrel therapy was the preferred strategy in patients with variant CYP2C19.

### PCV43
### COST-EFFECTIVENESS ANALYSIS OF RIVAROXABAN VERSUS DABIGATRAN AND ENOXAPARIN FOR THE PREVENTION OF VENOUS THROMBOEMBOLISM AFTER TOTAL HIP REPLACEMENT

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**OBJECTIVES:** To evaluate the cost-effectiveness of rivaroxaban compared with dabigatran and enoxaparin for the prophylaxis of venous thromboembolism in patients undergoing elective total hip replacement (THR) in the context of Russian health care system. **METHODS:** A decision-tree model on the choice of regimens for thromboprophylaxis after THR was adopted from the model, developed by McCullagh et. al. (2009). Primary outcomes were mortality, occurrence of distal and proximal DVT, rates of symptomatic PE. Incidence of gastrointestinal bleeding, stroke and death was also included into the model. Delphi method was used to determine typical practice and cost of management of DVT and PE. It was assumed that patients with DVT were treated for 90 days, patients with PE – for 180 days. All patients in the model received thromboprophylaxis with one of the following regimens: rivaroxaban dose of 10 mg/day orally for 31-39 days (RECORD 2); dabigatran dose of 220 mg/day orally for 28-35 days (RE-NOVETE); enoxaparin dose of 40 mg/day subcutaneously for 10-14 days (RECORD 2). Incremental cost-effectiveness ratios (ICERs) were calculated. **RESULTS:** The cost of prophylaxis with enoxaparin was 6991 USD, with dabigatran - 7076 USD, with rivaroxaban - 7147 USD. Although rivaroxaban has more effectiveness in preventing DVT (0.016 vs. 0.082 vs. 0.045) and PE (0.0012 vs. 0.005 vs. 0.004) than enoxaparin and dabigatran correspondingly. ICER to prevent 1 case of deep vein thrombosis after THR in rivaroxaban versus enoxaparin was 23.6 USD, and in dabigatran versus enoxaparin was 22.9 USD. ICER to prevent 1 case of pulmonary thromboembolism after THR in rivaroxaban versus enoxaparin was 556.7 USD, and in dabigatran versus enoxaparin was 850.3 USD. **CONCLUSIONS:** Despite of higher cost of prophylaxis of DVT and PE with rivaroxaban, comparing to enoxaparin and dabigatran, prophylaxis with rivaroxaban was more effective with acceptable ICERs.

### PCV44
### CHANGING COST-EFFECTIVENESS EARLY IN THE PRODUCT LIFE CYCLE: THE EXAMPLE OF CLOPIDOGREL BISULFATE

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**OBJECTIVES:** New medicines are launched based on a limited number of clinical trials. Payers, providers, and patients base their utilization decisions on this information. Furthermore, projected cost-effectiveness and real world cost-effectiveness are moving targets that may differ greatly, especially early in the product life cycle. We examine this divergence using clopidogrel, an antiplatelet medication for preventing strokes and heart attacks, as a case study. **METHODS:** Using the National Ambulatory Medical Care Survey (NAMCS) data from 1998 to 2008, we estimate changes in the volume and distribution of patient prescriptions by age, gender, and race. We combine these time trends with estimates from the pharmacoeconomics literature on cost-effectiveness measured as cost per quality-adjusted life year (QALYs). **RESULTS:** From 1998 (following approval in November 1997) to 2001, the average age of clopidogrel patients dropped from 77 to 70. Over the same period, the percentage of patients who were under 54 years of age increased from 0% to 13%. Comparing the real-world patient population to a pivotal phase 3 trial also reveals a large difference in gender mix: 72% male in the trial vs. 45% in NAMCS in 1998. Similar trends were found for race: by 2008, patients were much less likely to be white than in the trial—only 82% versus 95%. In 1999, 1.7 million office visits included a prescription for clopidogrel, 7.5 times as many as in 1998. By 2008, almost 16 million prescriptions were written—1.5 for every 100 office visits. Adjusting for demographic mix, the estimated real-world CE improved between 2000 and 2001 by 16% ($25,000 per QALY vs. $21,000, respectively). From 1998 to 2008, the CE ratio fell by 23%. **CONCLUSIONS:** These results demonstrate that cost-effectiveness projected at launch may provide only limited indication of the ultimate real-world impact, which improved substantially over time, in this example.

### PCV45
### COST-EFFECTIVENESS OF CYP2C9 AND VKORC1 GENOTYPE-GUIDED WARFARIN ANTICOAGULATION CARE: THE IMPLEMENTATION OF DISCRETE EVENT SIMULATION MODEL ON THE NATURAL HISTORY OF VENOUS THROMBOEMBOLISM

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**OBJECTIVES:** To evaluate and compared the long-term costs and outcomes of four warfarin treatment strategies of CYP2C9, VKORC1, both CYP2C9 and VKORC1 genotype-guided dosing, and standard warfarin dosing among nonvalvular VTE patients in the societal perspective. **METHODS:** A discrete event simulation model was used to depict patients' health states as the disease evolves with time, and captured its associated costs (2007 U.S. dollars) and quality of life. Data was extrapolated with the criteria of including VTE patients of age >=18 years on warfarin with INR target of 2-3. Probabilities, costs and humanistic properties were obtained from the literature, HCUP (NIS & SEDD), and the Medicare Reimbursement Schedule databases. Sensitivity analysis was performed for uncertainty parameters in the model. All costs and benefits were discounted at 3%. **RESULTS:** There was a significant difference in the prevalence of bleeding complication between standard anticoagulation (6.1%) and the genotype –guided of CYP2C9 and VKORC1 groups (<5.8%). The mean cost and QALYs per patients were $14,340 and 8.1251. The genotype-guided warfarin anticoagulation strategies projected higher cost and higher QALYs. However, considering the threshold of $100,000/QALY, VKORC1 genotype-guided was indicated to be cost-effective among all strategies. Sensitivity analysis demonstrated 25% of the replications of both CYP2C9 and VKORC1 genotype-guided strategy to be <$100,000/QALY. **CONCLUSIONS:** This study showed that testing for multiple genotypes of CYP2C9 and VKORC1 to guide warfarin anticoagulation therapy is not cost –effective in all population and that patient with higher risk of complications are more likely to benefit from this new innovation. For the genotype-guided test to be cost-effective in the population with VTE, the cost of the test would have to be <$400 or be restricted to patient at high risk for bleeding complications (RR>5.8).

### PCV46
### LONG-TERM COSTS AND HEALTH OUTCOMES OF TREATING ACUTE CORONARY SYNDROME PATIENTS WITH TICAGRELOR BASED ON THE EU LABEL - COST-EFFECTIVENESS ANALYSIS BASED ON THE PLATO STUDY

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**OBJECTIVES:** The PLATO trial showed that in patients with acute coronary syndromes (ACS) treatment with ticagrelor compared with clopidogrel significantly reduced the rate of myocardial infarction (MI), stroke, or death from vascular causes without a significant increase in the rate of overall major bleeding. Based on clinical and health-economic data from PLATO the present study evaluates the long-term cost-effectiveness of treating patients with ticagrelor based on the EU label. **METHODS:** A two-part decision-analytic model, comprising a one-year decision tree and a long-term Markov model, was constructed to estimate lifetime costs and QALYs of treating ACS patients for one year with ticagrelor plus acetylsalicylic acid (ASA) compared with clopidogrel plus ASA. Using individual-patient data from PLATO, event rates, health-care costs (Swedish in base-case analysis), and QALYs were estimated for the first year. For the second year onwards, necessary assumptions and external data sources were utilized to extrapolate quality-adjusted survival conditional on whether a non-fatal MI, a non-fatal stroke or no event occurred during the first year. A probabilistic analysis was performed and incremental cost-effectiveness ratios are presented from a health-care perspective in 2010 prices. A generic clopidogrel price of €0.17 ($0.23) per day, and a ticagrelor price range of €2.25 ($3.00) to €3.50 ($4.65) per day were applied. **RESULTS:** Treatment with ticagrelor was associated with a QALY gain of 0.13 compared with clopidogrel. The cost per QALY gained with ticagrelor was in the range of €2,350 ($3,110) to €5,700 ($7,550) compared with clopidogrel. Ticagrelor is likely to be cost-saving if proprietary clopidogrel prices are applied. The results were consistent in major sub groups across the broad ACS population. **CONCLUSIONS:** Based on clinical and health-economic evidence from the PLATO study, treating a broad spectrum of ACS patients with ticagrelor for one year based on the European label is cost-effective compared with clopidogrel.

### PCV47
### COST-EFFECTIVENESS OF FONDAPARINUX AND ENOXAPARIN IN PATIENTS WITH NON ST-SEGMENT ELEVATION ACUTE CORONARY SYNDROME IN BRAZIL

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**OBJECTIVES:** Associated use of antithrombotics, antiplatelets and invasive strategies in patients with non ST-segment elevation acute coronary syndromes (NSTE-ACS) reduces cardiovascular events, however, with an increase in the risk of bleeding. Clinical studies showed that fondaparinux is as effective as enoxaparin in treating patients with NSTE-ACS, but with reduced risk of bleeding events. The objective was to determine the cost-effectiveness of fondaparinux versus enoxaparin in patients with NSTE-ACS in Brazil from the perspective of the Brazilian Ministry of Health (MoH). **METHODS:** An analytic decision tree model was conducted to estimate the resultant costs and consequences of the targeted therapies in patients with NSTE-ACS. Model input data derived from the OASIS-5 study (N=20,078 NSTE-ACS patients randomized to fondaparinux or enoxaparin). The analyzed outcome was a composite of cardiovascular events (i.e., death, acute myocardial infarction, stroke, and major bleedings). Model time horizon was 9, 30, and 180 days post-NSTE-ACS. Direct costs of NSTE-ACS events and treatments were computed (i.e., drugs, coronary angiography, myocardial revascularization, percutaneous intervention - PCI, hospitalizations, etc.). Costs were expressed in 2010 Brazilian currency (1BRL=0.59USD). Univariate and multivariate (Monte Carlo) analyses tested model robustness. **RESULTS:** At day 9, the average cost per patient