efficiency, resulting in trials becoming smaller and less costly. However, the use of composite end points is questioned because it assumes that all unfavourable outcomes of a treatment are equal. We aimed to examine patients' perspectives regarding the use of composite end points and the utility patients put on possible unfavourable outcomes of treatment. **METHODS:** In this single-centre, prospective, observational PRECORE study, 140 CAD-patients who underwent either a Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG) at the Thoraxcentrum Twente, Medisch Spectrum Twente (Enschede, The Netherlands) between May 2016 and June 2016, were invited to participate in this study. A total of 126 (90%) patients gave consent to participate in this study. A novel methodology, a survey-based BWS choice experiment, was conducted to determine the relative importance of each component end point to CAD-patients. **RESULTS:** Patients considered "repeat PCI within a year post-intervention" (OR=204.8 ± SD=47.7, p<0.001),"stroke where symptoms disappear within 24 hours"(OR=53.3 ± SD=11.7, p<0.001), "MI where symptoms disappear within three months" (OR=43.4 ± SD=9.3, p<0.001), "recurrent angina pectoris"(OR=26.6 ± SD=5.4, p<0.001), "repeat CABG within a year post-intervention" (OR=11.9 ± SD=2.3, p<0.001), and "MI causing permanent disability" (OR=2.9 ± SD=0.4, p<0.001), less severe than "death", but considered "stroke causing permanent disability" worse than "death" (OR=0.7 ± SD=0.1, p=0.05). Subgroup (revascularization procedure, prior-MI, and prior revascularization) differences can be found for the relative weights attributed to "death" versus "stroke causing permanent disability". **CONCLUSIONS:** CAD-patients do not consider the components of a composite end point equal. The fact that patients do weight the individual components differentially has significant implications for trial statistics, and the interpretations of trial data, since these can be misleading.

PRICING POLICY STUDIES

PR1

ASSOCIATION BETWEEN THE PRICES OF ORPHAN DRUGS IN ONCOLOGY AND THE PATIENT POPULATION SIZES

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OBJECTIVES: High prices of orphan drugs are often linked to the necessity to recover the development costs from sales to small patient populations. If this is true, drugs with smaller target population sizes should be more costly. We sought to compare the prices of orphan drugs in oncology with their respective patient population sizes. **METHODS:** A list of orphan drugs designated by the FDA between June 2011 and June 2016 was retrieved from the FDA website. We include: a) drugs approved by the FDA; b) treatments in oncology. We exclude: a) products not specifically indicated to treat cancer (e.g., imaging, palliative care or treatment of a cancer-associated condition). Diseases prevalence data was obtained from the FDA orphan drug approval reviews. Average Wholesale Prices per unit were obtained from the Micromedex database. Prices per year of treatment were calculated based on the drugs' dosage from the FDA labels. We used descriptive statistics to compare drug prices per year of treatment to the target populations of patients for each indication. **RESULTS:** Out of 187 orphan designated indications, 70 led to drug approvals by the FDA. 37 approvals were in oncology. Eight regimens had two approved indications and one had five indications. There were 25 unique regimens of which two were for drug combinations. There was no clear association between the drug prices and the sizes of their respective patient populations. **CONCLUSIONS:** The current orphan drug policies have encouraged the development of novel treatments, but have also led to extremely high prices of these drugs. Whereas drug prices may depend on factors other than population size alone, our findings suggest that there is no apparent link between the prices and target population sizes. This should help policy makers formulate future orphan drug policies that encourage innovation, but that are based on drivers other than potential market size alone.

PR2

PAY FOR PERFORMANCE: A PROPOSAL FOR AND SIMULATION OF REAL TIME OUTCOMES-BASED PHARMACEUTICAL PRICING USING ROUTINELY COLLECTED DATA

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OBJECTIVES: Electronic medical records (EMR) provide a rich source of routinely collected real-world data on health outcomes and resource use, which could be potentially used in economic models to adjust pharmaceutical pricing in real time to reflect the value a product delivers to the health care system. Our aim was to simulate how real time outcomes-based pricing could be operationalised using the example of visual acuity outcomes associated with treatment with ranibizumab for age-related macular degeneration (AMD) collected in a UK EMR database. **METHODS:** A 5-year patient-level simulation model was developed to synthesise cost and outcomes of patients treated with ranibizumab for AMD recorded in EMR and patients' natural history reported in the placebo arms of pivotal trials. The model was updated at daily intervals following the first treatment in 2008 until 2012 with the cumulative visual acuity outcomes recorded in EMR. The price of ranibizumab was adjusted each day to maintain a target incremental cost effectiveness ratio (ICER). **RESULTS:** The price of ranibizumab was reported at daily intervals over the course of the simulation. The first price of ranibizumab could be calculated after 3 months and reached GBP434.76 per vial at the end of the simulation when targeting an ICER of GBP30,000 per QALY. The simulation included data on 8,681 patients treated across 1,416 days. At the end of the simulation, the mean number of QALYs accumulated by patients was 3.05 in the treatment arm compared to 2.56 in the natural history arm over the five year time horizon. **CONCLUSIONS:** Real world data may be used to monitor the cost-effectiveness of on-market drugs and to regularly refine their prices based on the value delivered in clinical practice. Performance-based pricing could be used to negotiate earlier market access for pharmaceuticals in advance of mature data on cost-effectiveness.

PR3

DIFFERENCES IN PRICING POLICIES FOR GENERIC AND BIOSIMILAR MEDICINES

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OBJECTIVES: In the view of their increasing importance biosimilar medicines might be subject to specific policies. The study aims to analyze possible differences between pricing policies for generics and for biosimilar medicines in European countries. **METHODS:** Policies for biosimilar and generic medicines were surveyed with competent authorities for pharmaceutical pricing and reimbursement. A questionnaire was launched in January 2016 to survey information valid as of the beginning of the year 2016. A draft compilation of findings was shared with the respondents for validation in April 2016. **RESULTS:** We received responses from 25 EU Member States (all but Ireland, Italy, and Luxembourg), and Albania, Belarus, Iceland, Norway, Serbia, Russia, Turkey, and Ukraine. While 23 of the 33 surveyed countries set the price of the generic in relation to the price of the originator, 13 countries reported to do so for biosimilar medicines. Usually, the price difference between the biosimilar and the originator medicine was set at a lower percentage rate than between the generic and originator (e.g. 30% – generics, 15% – biosimilars in Croatia; 50% – generics, 30% –biosimilars in Lithuania; 35% – generics, 20% – biosimilars in Romania). Only Austria, Latvia and Turkey apply the same price difference for generic and biosimilar medicines (the first follower – either generic or biosimilar medicine – has to be 48%, 30% and 40% below the price of the originator). The Netherlands have been tendering for generics in the out-patient sector during the last decade, but biosimilars were included in tenders only recently. **CONCLUSIONS:** In principle, European countries tend to apply similar pricing policies for generic and biosimilar medicines. However, while certain policies are established standard for generics, their implementation for biosimilar medicines appears not to have been decided yet. Overall, policy-makers tend to grant biosimilar medicines more favorable conditions compared to generics.

PR4

THE DETERMINANTS OF INNOVATIVE DRUGS PRICES: THE CASE OF ONCOLOGY DRUGS, COMPARATIVE ANALYSIS

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OBJECTIVES: The variation in health system regimes creates cross-country differences in prices for the same pharmaceutical product. Additionally, the price of an innovative drug (Pi) is generally dependent on the cost of the reference treatment (R), and the added value relative to the reference treatment. Pi = R+ D. Then the objective of this study is in threefold: First to the assess trends in prices of anticancer drugs in different OECD countries. Second to examine the impact of the specifics regulations in the pricing. Third to examine the effect of the value added of the innovative anticancer drugs in the pricing. **METHODS:** We investigate both the impact of the add value and the regulation in the pricing of the anticancer drugs. To do so, we estimate a country fixed effects model: Yi,j= a + B,j + Ei,j with (i,j =1…n) Where Yi,j is a price for a drug i in a country j. Xi,j is the vector of drugs characteristics, and B,jis the country fixed effects. **RESULTS:** A total of 207 drugs prices were observed across all countries in the study. Our model evaluated the impact of twelve variables considered most likely to impact the prices setting. The model fitted the data well (R2=55%). As expected the therapeutic added value had a significant effect on the prices, with one month of Progression free survival gained increasing the Prices with 80 € (p<0,001). For the clinical evidence, the design of clinical trial shows a coefficient of 510 € (p<0,001). The form and the drug age has a significant impact on the prices. The fixed effect demonstrates that the level of pricing disparities reflects the differences in the pricing regulations **CONCLUSIONS:** This study demonstrates that the level of pricing disparities, in most cases reflect the therapeutic added value and the differences in the prices mechanisms.

BREAKOUTS – SESSION IV

MEDICATION ADHERENCE STUDIES

AD1

REAL-WORLD IMPACT OF GENDER, AGE AND SOCIO-ECONOMIC STATUS ON TYPE-2 DIABETES MELLITUS (T2DM) PATIENTS DISEASE ENGAGEMENT AND ADHERENCE WITH TREATMENT REGIMENS

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OBJECTIVES: It is hypothesised that gender, age and socio-economic status (SES) play key roles in engagement with disease, life-style choices and adherence. This analysis investigated the impact of these non-modifiable factors amongst T2DM patients. **METHODS:** Data were drawn from the 2015 Adelphi Diabetes Disease Specific Programme (DSP) in T2DM across 5EU/USA. The DSP is a real-world, cross-sectional survey involving diabetes specialists, primary care physicians (PCPs), and