understand the total cost of ownership as this will become ever more important for future market access, reimbursement and financial discussions.

MD3

THE ECONOMIC IMPACT OF THE USE OF IMPLANTABLE CARDIOVERTER DEFIBRILLATOR IN PRIMARY PREVENTION

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OBJECTIVES: Given the high burden of cardiovascular diseases treated in primary prevention with the implantable cardioverter defibrillator (ICD), the monitor of healthcare expenditure related to such diseases is essential for health policy makers. This study assessed the variation in costs of patients with ICD over time, from 3 years before the first implant up to 8 years after. **METHODS:** Patients covered by Lombardy Healthcare System (HS) who underwent an ICD implantation in the period 2003-2010 were identified through regional healthcare administrative databases (HAD). Data extracted from these HAD were linked with clinical information collected in the national ICD registry, and for each patient we selected the first implant performed in primary prevention. We identified drug prescriptions, hospitalizations and outpatient visits provided to patients for their cardiovascular disease during the 3 years before and the 8 years after the implant. For the same period, we estimated the trend in mean annual per capita cost through the Bang and Tsiatis method, that considers censoring in cost data. **RESULTS:** Patients with a first ICD implanted in primary prevention were 6,936 (82% males, mean age 65 years) and we observed a yearly mortality rate of 6.9% (95% Confidence Interval (CI): 6.6-7.3) during follow-up. During the 3 years before the implant, the mean annual per capita cost was €3,424 (95%CI: 3,331-3,537) and it increased to €4,136 (95%CI: 4,004-4,262) after ICD implantation. However, before the ICD implantation we observed a growing trend in mean annual per capita costs, while after the intervention this trend was negative. **CONCLUSIONS:** Our study confirmed the high economic impact of cardiovascular diseases on the HS when treating subjects with left ventricular systolic dysfunctions or heart failure. Different trends in the healthcare expenditure were detected pre and post ICD implantation, but the significance of such difference should be further explored.

MD4

COST-EFFECTIVENESS OF 18F-FDG PET/CT FOR SCREENING DISTANT METASTASIS IN STAGE II/III BREAST CANCER PATIENTS OF THE UK, THE UNITED STATES AND THE NETHERLANDS

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OBJECTIVES: 18F-FDG-PET/CT is accurate in detecting distant metastases (DM) in breast cancer patients scheduled for neoadjuvant chemotherapy. If DMs are screen-detected in an early phase, morbidity and mortality may be reduced. Because 18F-FDG-PET/CT comes at a significant cost, we compared its expected cost-effectiveness in stage II/III breast cancer patients of the UK, the US and the Netherlands (NL) vs. the gold-standard (X-thorax/liver sonography/bone scan (UK/NL) and CT-thorax-abdomen/bone scan (US)). **METHODS:** A time-dependent Markov model compared expected Life Year (LY) and cost/Quality-adjusted Life Year (QALY) gained in four breast cancer subtypes (ER-/HER2+;ER+/HER2+;ER-/HER2-;ER+/HER2-) over a 5-year time horizon from a hospital perspective. Sensitivity and specificity of imaging and type of systemic and local treatments were derived from the Netherlands Cancer Institute. Epidemiological, survival and utility data were estimated from literature or informed by expert assumptions. Costs (2013) were derived from national tariffs (UK and NL), and from the Centres for Medicaid and Medicare Services (US). **RESULTS:** 18F-FDG-PET/CT is more sensitive (53% vs. 15%) and specific (97% vs. 94%) than the gold-standard. LYs and QALYs gained were similar across subtypes, ranging from 0.025 to 0.027 and 0.0037 to 0.0044 respectively. In all countries, ER+HER2+ was the least and ER+HER2- the most costly group. 18F-FDG-PET/CT is expected to be cost-effective in the NL and the US (with highest ICERs of €165/QALY in ER+/HER2+ and $750 in ER-HER2+), with probabilities of cost-effectiveness ranging from 46-52% and 62-72% respectively, but not in the UK, with a 66-75% probability, depending on tumor subtype. **CONCLUSIONS:** Using 18F-FDG-PET/CT for DM screening in stage II/III breast cancer is expected to result in incremental QALY gains in all subtypes and countries. Due to costs differences between countries, 18F-FDG-PET/CT is expected to be cost-effective in the US and the NL, but not in the UK.

PRICING STUDIES

PR1

DETERMINANTS OF ORPHAN DRUG PRICES IN FRANCE: REGRESSION ANALYSIS

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OBJECTIVES: No specific market access process has been developed for orphan drugs (ODs) in France, but there is an unspoken will to support these medicines. Pricing process of ODs is unclear, and many of them became blockbusters despite the small size of the targeted population. The aim of the study is to identify the main drivers of ODs prices in France. **METHODS:** ODs prices were extracted from Ameli database. Drugs and diseases attributes were defined based on the reports of the European Medicines Agency and Haut Authorité de Santé (HAS). Attributes included the prevalence, ATC class, therapeutic area, disease severity, alternative treatments, level of clinical evidence, SMR and ASMR scores, year assessment, and treatment line. Association between the annual treatment cost per patient and the attributes was studied using Pearson correlation coefficient (for quantitative variables), ANOVA (for qualitative variables), and generalized linear model using gamma distribution. **RESULTS:** Annual treatment costs varied from 1,500€ to almost 1,000,000€. Bivariate analysis showed a significant association between the annual treatment cost and disease prevalence, age group, treatment line, alternative treatments, therapeutic area, and ATC class ($p<0.05$ for all). Significantly higher cost was observed in pediatric population, first treatment line, metabolic diseases, or in case of absence of alternative treatment. Multivariate analysis including these variables did not showed significant results. Given the complex correlation structure between the co-variates, the model including only the prevalence and alternative treatments was tested. Both co-variates were significant. **CONCLUSIONS:** Disease prevalence and unmet needs seems to be the main drivers of ODs prices while the level of clinical evidence and disease severity had no impact. However, this is difficult to justify statistically because of high variance and small number of observations. Interestingly, ASMR score presented by the HAS as main price driver was not shown having an impact on drug prices.

PR2

PREDICTING POST-AMNOG REBATE OUTCOMES FOR ONCOLOGY DRUGS

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OBJECTIVES: New drugs launching into Germany undergo benefit assessment by G-BA, followed by a price negotiation with GKV-Spitzenverband (GKV-SV). In this paper we analyze the determinants of German rebate outcomes for oncology drugs. **METHODS:** We used the (Coveragedecisions) payer decision database as the basis of this analysis. This database consists of systematically abstracted data from publicly available payer decisions on pricing, reimbursement, HTA and formulary coverage decisions from 21 countries worldwide, covering all new molecular entities (NMEs) approved in EU or US since 2011. We extracted data from the (Coveragedecisions) payer decision database on G-BA benefit assessment and GKV-SV pricing outcomes of all oncology NMEs with a known GKV-SV pricing outcome. The data extracted included G-BA benefit rating at subgroup level, relative sizes of subgroups, intervention and comparator costs by subgroups, time limitations on benefit determination and magnitude of rebate. We then conducted a stepwise multiple linear regression with backward elimination, with magnitude of post-AMNOG rebate as the dependent variable, and benefit category, difference between intervention and comparator costs and presence of time limit on benefit recommendation as the independent variables. **RESULTS:** Of the 27 benefit assessments analyzed, rebates varied from 10%-54%. The final model (adjusted R square 0.75; F statistic 9.35; $p<0.001$) showed that the difference between intervention and comparator costs was a significant predictor of rebate ($p=0.004$). Compared to 'indication of considerable benefit', 'no benefit' ($p=0.001$) and 'hint of minor benefit' ($p<0.001$) were associated with significantly higher rebates. Though other benefit ratings did not achieve statistical significance, directionally, 'proof of minor benefit' and 'indication of lower benefit' were associated with higher rebates compared to 'indication of considerable benefit'. **CONCLUSIONS:** Based on our analysis, GKV rebate for oncology drugs can be expressed using a multiple regression equation, as a function of G-BA benefit rating category and incremental cost vs. comparator.

PR3

PRICES OF PHARMACEUTICALS UNDER A GENERIC PRICE LINKAGE SYSTEM AND A REFERENCE PRICE SYSTEM: COMPARISON OF AUSTRIA AND FINLAND

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OBJECTIVES: The growing costs of medicines have forced many countries to implement measures to lower the prices of originators and generics after patent expiration. Measures taken in Austria include Generic Price Linkage System, where there are strict upper limits for the prices of generics and also for originators after the entry of generics. Measures taken in Finland include Generic Substitution and Reference Pricing, where competition plays an important role. The aim of this study is to compare the effects of the measures taken in Austria and in Finland on the prices of originators and generics. **METHODS:** We included in the analysis ten active ingredients whose sales were high in Finland, which were reimbursable in both countries, and whose patent protection expired during the years 2010–2012. The analysis was based on time series, which covered 6 months before and 12 months after the entry of the first generic. The changes in price levels were measured in terms of wholesale prices proportioned to the number of Defined Daily Doses in the package (EUR/DDD). **RESULTS:** One year after generic entry, prices for originators had fallen, on average, by 46% in Austria and by 21% in Finland. Prices for generics were 66% lower in Austria and 59% lower in Finland than the prices of originators before generic entry. The mean number of generics per active ingredient was 6.3 in Austria and 5.1 in Finland. **CONCLUSIONS:** The pricing system applied in Austria appears to be more efficient in lowering prices than the system used in Finland, which contradicts claims that free competition lowers generic prices more efficiently than linking them to the price of the originator. This finding may be due to the way the Finnish Reference Price System has been constructed.

PR4

DECISION DRIVERS IN HEALTH TECHNOLOGY ASSESSMENT IN HEPATITIS C

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OBJECTIVES: Recent advances in treating Hepatitis C (HCV) have prompted significant debate about affordability. The objective of this research was to investigate Health Technology Assessment (HTA) agencies' approach to assessment and the impact of evidence criteria on recommendations. **METHODS:** HTA reports published on HCV since 2014 were reviewed. The four most frequently assessed drugs were further scrutinized in terms of clinical benefit, costs and recommen-