and subsequent clinical outcomes in chemotherapy-naïve mCRPC. METHODS: COU-AA-302 was a multinational, double-blind, randomized, phase 3 trial of abiraterone acetate plus prednisone compared with prednisone alone in asymptomatic or mildly symptomatic mCRPC patients without previous chemotherapy. Using data from the entire COU-AA-302 patient population (N = 1088) over the first 181 days of follow-up, investigators compared the relative effectiveness of clinical time-to-event end points and changes in FROs measuring pain, physical well-being (PWB), functional well-being (PWB), and prostate-cancer-specific signs and symptoms. Cox regression analyses were performed to assess the relationship between changes in FROs (separately and for all 4 simultaneously), and radiographic progression-free survival (rPFS) as the dependent variable, adjusting for important baseline clinical and FRO characteristics. RESULTS: In each individual model, patients with worsening FROs were at greater risk of radiographic progression compared with patients whose FRO scores improved or remained stable during the follow-up period. Hazard ratios (95% confidence intervals) for worsening pain intensity, PWB, FWB, and prostate-cancer-specific signs and symptoms for PFS were 1.68 (1.26-2.23), 1.18 (0.78-1.77), 1.52 (1.18-1.95), respectively (all p < 0.02). When all 4 FRO end points were included in a single multivariable model, a worsening in PWB was the most significant factor associated with worse rPFS. There were too few events at the time of analysis cut-off (February 2015) to explore the relationship between survival and PROs. Worsening of PROs was associated with an increased likelihood of radiographic progression. When all 4 PRO end points were included in a single multivariable model, a worsening in PWB was the most significant factor associated with worse rPFS. There were too few events at the time of analysis cut-off (February 2015) to explore the relationship between survival and PROs. Worsening of PROs was associated with an increased likelihood of radiographic progression. In addition to their traditional utility in describing patient-characteristics.

1.52 (1.18-1.95), respectively (all p < 0.02).

CA2

THE ESMO MAGNITUDE OF CLINICAL BENEFIT SCALE FOR NOVEL CANCER MEDICINES — CORRESPONDENCE WITH PRIORITIZATION DECISIONS IN UPDATING THE ISRAELI NATIONAL LIST OF HEALTH SERVICES

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OBJECTIVES: The Israeli National Health Insurance Law stipulates The Israeli National Health List of Services (NLHS) which all residents are entitled to. Every year, the government determines the additional budget to be allocated for new health technologies on the NLHS. A public national advisory committee (PNAC) evaluates and prioritizes all proposed technologies. The PNAC takes into account mainly the efficacy of the new technology, but also economic, social and ethical aspects. However, until now, no standard tool was available for grading the extent of benefit of therapies. The European Society for Medical Oncology (ESMO) published recently its Magnitude of Clinical Benefit Scale (ESMO-MCBS) for cancer medicines. The scale is graded 5, 4, 3, 2, 1, for treatments of advanced/metastatic cancers (the ‘palillative setting’), where grades 5 and 4 represent the highest level of proven clinical benefit. Our objective is to evaluate whether the new cancer drugs that were recommended for reimbursement by the PNAC, had higher ESMO-MCBS scores than the candidate drugs that were not approved in the 2015 NLHS update process.

METHODS: ESMO-MCBS scores were obtained for the cancer drugs that were candidates for the 2015 NLHS update. Fisher’s Exact Test was used to compare scores of drugs approved and those not approved for reimbursement. RESULTS: 17 cancer drugs were candidates for the 2015 NLHS update deliberations. An ESMO-MCBS score of 3 or 4 or 5 was considered for novel, non-approved drugs: 80% of the approved drugs and none of the non-approved drugs gained a score – 3 (p = 0.007). Median scores were 3 and 1 respectively. CONCLUSIONS: The Israeli PNAC’s decisions regarding reimbursement for novel oncologic drugs seem to be in accordance with ESMO-MCBS scores. The structured and consistent approach of the ESMO-MCBS could further assist in framing the appropriate use of limited public resources to deliver effective and affordable cancer care.

CA3

THE BURDEN OF CANCER IN EMERGING ECONOMIES: PRODUCTIVITY LOSS AS AN ALTERNATIVE PERSPECTIVE

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OBJECTIVES: When people die due to cancer, their contribution to society through paid work, called production, is lost. Previous estimates of cancer-related lost productivity associated with premature cancer deaths in BRICS countries and the UK in 2012. We used GLOBOCAN estimates of cancer deaths by country, sex and age group, along with OECD and national data for workforce participation, unemployment, and wage rates. Sensitivity analyses examined the impact of changing assumptions about wages, life expectancy and discounting. RESULTS: The total cost of cancer-related lost productivity in the UK in 2012 was £3 billion, and in the BRICS countries it was $60 billion. Life expectancy at age 60 was 75.3 years in the UK (€12.9 billion) and lowest in South Africa (€0.9 billion). When adjusted by number of deaths, lost productivity (per death) were highest in South Africa (€19,000), the UK (€15,000) and lowest in China ($4,000) and lowest in South Africa (€6,000). There were large differences between countries in terms of lost productivity when examined by gender, age and cancer. For example, the cancers contributing highest productivity losses were lung cancer in Russia (22% of total), South Africa (34%), Brazil (13%) and the UK (11%), stomach cancer in Brazil (11%), and liver cancer in China (31%). CONCLUSIONS: In many developing countries cancer now kills more people than AIDS, malaria and tuberculosis combined, however resources have not shifted correspondingly. Valuing cancer-related lost productivity provides policymakers with an additional perspective on priorities for cancer prevention and control.

CA4

PREDICTORS OF POSITIVE DECISION OUTCOMES BY THE CANCERS DREADS FUND

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OBJECTIVES: To build a predictive model of acceptance of drugs to the United Kingdom’s National Institute for Health and Care Excellence (NICE) from January 1st 2010 to December 31st 2015. METHODS: All decision summaries published from December 2014 until May 2015 were included. For each decision summary, double-timers were collected regarding the drug indication, scores for each decision factor (progression-free survival: PFS, overall survival: OS, quality-of-life: QoL, and unmet need), total clinical score, strength of evidence, cost, and decision outcome. Decisions to either retain or place drugs on formulary were counted as positive decisions. The double-timers were classified as negative decisions. A generalised linear model (GLM) was used to estimate the odds of each factor resulting in a positive decision; univariate and multivariate analyses were performed. RESULTS: 62 drugs were included in the model. 2 drugs were not formally assessed due to a lack of comparison against the standard of care in the UK. Only 22 of 64 (34.4%) of drugs received positive decisions from the CDF since December 2014, with an average total clinical score of 2.85. Median cost was not a significant predictor of outcome in the model. CONCLUSIONS: The majority of decisions since the 2015-2016 CDF procedures update have been negative; greater gains in PFS and OS significantly improved the likelihood of a positive CDF review outcome.

MEDICAL DEVICE & DIAGNOSTIC RESEARCH STUDIES

MD1

MEDICAL DEVICES: HAVE HEALTH TECHNOLOGY ASSESSMENT AGENCIES STARTED TO FOCUS MORE ON THEM?

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OBJECTIVES: Since 2011, the number of health technology assessments (HTAs) on medical devices increases annually. As countries worldwide are trying to curb overall healthcare expenditure, the objective of this study was to analyze if this upward trend is also found in the area of medical devices. METHODS: One hundred forty-three HTA summaries were analyzed by number and type and matched with HTAs for pharmaceutical therapies. RESULTS: Not all of the included agencies assess medical devices. Most device-related HTAs are carried out in the UK, France, Sweden, the US and Australia, matching their overall high HTA activity. However, other countries with high drug HTA activity (Germany, Spain, the Netherlands) focus less on devices. Most device-related HTAs are indicated for cardiovascular diseases, while pharmaceuticals are dominated by analyses on pain and pharma oncology. The number of non-approved devices increases every year (seasonality), while the number of device HTAs remained steady over the last 5 years. Generally, HTA agencies seem to perform device evaluations more on an ad-hoc basis. CONCLUSIONS: However, the number of device assessments remains fairly stable. Most manufacturers seem to realize HTA importance and need to adapt to EU regulations. The increased clinical requirements in the draft EU Medical Devices Regulation will enable manufacturers to find their role in this growing area.

MD2

THE COST OF MOLECULAR DIAGNOSTIC TESTING IN ONCOLOGY – A WORKFLOW ANALYSIS

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OBJECTIVES: The rise in molecular diagnostic testing in oncology has made these tests the subject of an increasing number of investment discussions, reimbursement negotiations and hospital cost calculations. This requires a detailed assessment of the total cost for determining tumor mutation status beyond plain kit costs. This research maps the workflow, identifies investment needs and quantifies the direct variable costs of KRAS and NRASmutation testing from formalin fixed paraffin embedded (FFPE) sample to result. METHODS: The complete test workflow is based on the current workflow in two academic European institutions. Hands-on time and consumables used in each step were quantified in both hospitals. Unit cost was obtained from the finance departments. RESULTS: Costs related to tumor mutation tests include investments (lab space, lab equipment, molecular diagnostic systems), education and training, reagents, assay validation and cost of errors (disinfection, cost of errors and repeats) and direct variable costs including reagent costs, controls and labor. The total cost depends on workflow and tumor profile. To detect 10% of KRAS mutations, the direct variable costs from FFPE to result excluding reagent costs, is estimated at €64 using a CE-VK test for KRAS exon 2 by pyrosequencing for NRAS exon 2 and extended RAS testing, €51 using High Resolution Melting confirmed by pyrosequencing and €3 for an automated instrument. CONCLUSIONS: Inclusion of sample preparation in the total test cost, as it works directly from FFPE. CONCLUSIONS: Estimations on the cost of performing tumor mutation tests should include not only reagent costs, which are usually considered, but also investments, lab running costs, labor and other direct and indirect costs. Even in the most advanced labs, efforts are needed to fully