selected. Two independent reviewers read the survival probabilities from KM curves using an open source digitising software (Engauge digitizer). HRs for non-overlapping time intervals were calculated from the estimated survival probabilities and combined in a stratified way across time intervals to obtain an overall HR using the spreadsheet by Tierney and colleagues. The estimated HR was compared with the reported HR for each study. **RESULTS:** A mean error on the log scale of −0.001 (95%CI: −0.022, 0.019) was observed. This implies that by taking the exponentials, if the reported HR is 0.750, then the estimated HR would be 0.749. The 95%CI for the mean error spans zero indicating any systematic error is likely to be small and should not influence results in most analytic situations. Mean absolute error on the log scale was 0.027 (95%CI: 0.016, 0.037) indicating calculated HR lie within a factor of exponential (0.027) either side of the original value. No change in the direction of the treatment effect was observed in the estimated HR (95%CI) for any of the selected study. Reconstructed KM curves presented high accuracy and reproducibility. **CONCLUSIONS:** KM curves could be potential source of data and it is recommended that these should be used more frequently to estimate HR (95% CI), where not reported explicitly, for conducting meta-analysis in systematic reviews.

PRM2

ASSESSING RELATIVE CLINICAL VALUE WITHIN THREE METASTATIC DISEASES

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OBJECTIVES: As more innovative oncology agents become available, budget limitations are necessitating deeper value assessments of products. Previous research demonstrated that examining a variety of key survival metrics is required to fully define the value of an anti-neoplastic intervention. Here we examine how various survival metrics compare across 3 major metastatic tumor types, chosen because of the introduction of new therapeutics in the past year: melanoma, prostate and lung cancer. **METHODS:** We conducted a literature-based review of pivotal clinical trial data supporting new therapeutics in these tumor types from 2006-2012 and selected all products with demonstrated overall survival benefit in the metastatic setting: vemurafinib, ipilimumab for melanoma; cabazitaxel, abiraterone, sipuleucel-T for prostate cancer; pemetrexed, erlotinib, and bevacizumab for lung cancer. Crizotinib was excluded having not reached median overall survival (OS) at approval. We compared products on four survival metrics: median OS, mean OS, 1-year survival, and number needed to treat to avoid one event (NNT). **RESULTS:** Despite variations in patient tumor types , the products showed a narrow range of median OS improvement. However, greater variability was seen across other metrics: in lung cancer, pemetrexed presented the greater mean OS improvement, while erlotinib demonstrated greater 1-year survival and lower NNT. In melanoma, vemurafenib and ipilimumab demonstrated the same number of months of median OS improvement in their respective clinical trials; however, ipilimumab demonstrated greater mean OS, 1-year survival, and lower NNT. In prostate cancer, sipuleucel-T demonstrated better mean OS improvement, whereas abiraterone had better 1-year survival and lower NNT. **CONCLUSIONS:** Drugs are being evaluated with remarkably similar median OS benefits for metastatic patient populations. Side-by-side comparisons that take multiple endpoints into account can assist decison makers to better understand total clinical benefit in context and contribute to thoughtful resource management, especially when median OS benefit may be so similar.

PRM3

TURNING THE TABLES TO ADDRESS THE REAL VALUE OF REAL-WORLD OBSERVATIONAL STUDIES OF NOVEL ANTI-CANCER AGENTS IN MULTIPLE MYELOMA

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OBJECTIVES: Due to pressure to provide rapid access despite uncertainty of a drug's real-world value, decision makers often require evidence from outcomes research. We assessed whether a retrospective observational design can confirm the trial-based efficacy for the novel agent bortezomib in advanced multiple myeloma and identify reasons for any discrepancies. **METHODS:** Two patient populations were included: real-world patients in the Netherlands (n=72) and the bortezomib pivotal trial population (n=333). Data on real-world patients were retrospectively collected from hospital records (period: 2001-2009). Baseline prognostic factors, treatment patterns, safety and clinical outcomes were compared. **RESULTS:** Overall response rates (49% versus 38%; p=0.1) and time to progression (median: 6.8 versus 6.2 months; p=0.6) was similar compared to the trial though the frequency of patient follow-up and definitions used for clinical outcomes varied in daily practice. Overall survival was lower compared to the trial (median: 17.2 versus 29.8 months; p=0.01) on account of differences in patient prognosis and use of the drug. Daily practice patients were more heavily pre-treated in a shorter time frame at baseline. Practice variation was observed in daily practice with the majority receiving bortezomib in combination with one or more drugs (68%). Conservative administration was observed with lower cumulative dosages and fewer treatment cycles (4 versus 6) in daily practice. Safety-related outcomes could not be compared since this information in patient charts was frequently not detailed. **CONCLUSIONS:** A retrospective design confirmed some but not all efficacy endpoints and identified reasons for discrepancies. Evidence generated from retrospective studies is complementary to that generated in a trial. Despite threats to validity of the treatment effect, a retrospective design will generate valuable evidence about who receives the drug and how it is given, which facilitates a feedback loop to decision makers about ways to improve patient care and ultimately the drug's real-world value.

PRM4

ASSESSMENT OF IMMUNOSUPPRESSIVE THERAPIES FOR RENAL TRANSPLANTATION - CRITERIA CONSIDERED FOR EVALUATION BY THE EMA, EUROPEAN HTA AGENCIES AND THE GERMAN IQWIG

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OBJECTIVES: Immunosuppressive drugs have been subject to different evidence-based assessments including evaluations along the regulatory process of the EMA or reimbursement decisions by European HTA agencies. The objective of this research was to review and compare the criteria applied for assessing immunosuppressive drugs in renal transplantation. Particular focus was set on the consistencies and differences regarding assessment between the German IQWiG compared to other European agencies. **METHODS:** A review of reports and guidelines on subjects relevant for evidence-based assessment of immunosuppressive therapies for renal transplantation which were published by EMA, IQWiG, and the European HTA agencies of France, Scotland, Sweden and UK. The search was restricted to documents in English or German. **RESULTS:** We identified relevant documents from five agencies: one guidance document from EMA, HTA reports from the NICE in UK, one advice from the SMC in Scotland, assessment summaries from the French HAS and one report of early benefit assessment from the German IQWiG. No relevant document was identified from the Swedish SBU. The EMA document provides guidance for planning of pivotal studies to evaluate safety and efficacy. The HAS, NICE and SMC appraisals give advice for using immunosuppressive therapies for renal transplantation and the IQWiG report assessed the additional benefit of one new immunosuppressant. All documents recommended randomized controlled trials (RCT) or systematic reviews of RCTs as the highest level of evidence. Differences were in the clinical endpoints considered. In contrast to other agencies the IQWiG did exclude the endpoints 'graft function' and 'biopsy-confirmed acute rejection' from evaluation and did not consider compliance as relevant. **CONCLUSIONS:** All agencies consistently recommend a similar standard for the level of evidence. However, as long as there is no harmonization on the relevant endpoints considered for evidence-based assessments, the different requirements of local agencies should be considered when designing clinical trials and planning statistical analyses.

PRM5

ATTRIBUTION OF BENEFIT TO THE THREE DISEASE DIMENSIONS MORTALITY, MORBIDITY, QUALITY OF LIFE WITHIN EARLY BENEFIT ASSESSMENT (EBA) IN GERMANY

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OBJECTIVES: According to the social law in Germany the Statutory Health Insurance (GKV) has to address the three dimensions of disease: mortality, morbidity, and quality of life. Consequently, the recently introduced EBA in Germany is grouping the benefits and the related endpoints into these dimensions. Our aim was to examine the relative importance of each of those dimensions with regards to the suggested benefit claims by the Institute for Quality and Efficiency in Health Care (IQWiG). **METHODS:** The review includes EBAs that were started in 2011. The Joint Federal Committee's (GBA) webpage (http://www.g-ba.de/informationen/nutzenbewertung/) was used to obtain the respective IQWiG benefit assessments. The benefit that IQWiG suggested was analysed for each assessment and the attribution of benefit to each of the three disease domains was examined. **RESULTS:** Twenty-four EBAs were started in 2011. Two Orphan indications were excluded from the analysis (Tafamidis Meglumin, Pirfenidon). In ten EBAs IQWiG suggested a benefit for the related medication at least in one disease dimension and/or one subgroup (Telaprevir, Abirateronacetat, Boceprevir, Ipilimumab, Belatacept, Apixaban, Cabazitaxel, Fingolimod, Ticacrelor, Eribulin). In Abirateronacetat, Ipilimumab, Cabazitaxel, Ticacrelor, and Eribulin IQWiG suggested a mortality benefit. With Ticacrelor IQWiG discriminated overall and cardiovascular mortality. In Telaprevir, Abirateronacetat, Boceprevir, Apixaban, and Ticacrelor IQWiG suggested a morbidity benefit. Due to the small number of eligible patients Fingolimod was ultimately not examined regarding morbidity. No benefits were reported in the dimension of Quality of Life. Side effects that were considered to cause additional harm to patients and that negatively impacted the overall benefit rating were reported in five EBAs: Boceprevir, Ipilimumab, Apixaban, Cabazitaxel, Eribulin. **CONCLUSIONS:** In all reviewed assessments no benefit was attributed to Quality of Life. The disease dimensions morbidity and mortality were of equal importance. However, definitions of benefit within the dimension morbidity were very heterogeneous across the various EBAs

PRM6

THE UK CONTRIBUTION TO REAL WORLD RESEARCH: REVIEW OF PUBLISHED DATA AT ISPOR, MADRID 2011

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OBJECTIVES: UK Pharma considers the UK a leading environment for the conduct of Real World (RW) health care studies due to the influence of NICE, the cradle-to-grave health care provided by the NHS, with GPs as the co-ordinators of care for every patient and the widespread use of e-health records. Is there evidence for this from research output? We reviewed abstracts published last year at ISPOR as one