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: $-0.002$, $-0.000$) was observed indicating 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 for 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 a 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 review.

PR24
ASSESSING RELATIVE CLINICAL VALUE WITHIN THREE METASTATIC DISEASES
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OBJECTIVES: As more innovative oncology agents become available, budget limita-
tions 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 new agents. A key step towards establishing these metrics is to correlate survival metrics 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 and postmarketing observational studies in these tumor types from 2006 to 2011 and selected all products with demonstrated overall survival benefit in the metastatic setting: vemurafenib, ipilimumab for melanoma, cabazitaxel, abiraterone, sipuleucel-T for prostate cancer; pemetrexed, erlotinib, and bevacizumab for lung cancer. Outcomes was excluded having not reached median overall survival (OS) at appro-
val. 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 medians OS and mean OS. However, greater variability was seen across the 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 med-
ian OS improvement in their respective clinical trials; however, ipilimumab dem-
strated 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 evalu-
ated with remarkably similar median OS benefits for metastatic patient popula-
tions across tumor types, whereas survival metrics may vary side-by-side. Further analysis of these data may assist decision makers to better understand total clinical benefit in context and contribute to thoughtful resource management, especially when median OS ben-
efit may be so similar.

PR35
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 my-
emias and identify reasons for any discrepancies. METHODS: Two patient popu-
lations were identified among world patients in multiple myeloma (n=72) and bortezomib pivotal trial population (n=333). Data on real-world patients were retrospectively collected from hospital records (period: 2001-2009). Baseline prog-
nostic factors, treatment patterns, safety and clinical outcomes were compared. RESULTS: Overall treatment patterns were calculated from the estimated and KM curves compared 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 and postmarketing observational studies in these tumor types from 2006 to 2011 and selected all products with demonstrated overall survival benefit in the metastatic setting: vemurafenib, ipilimumab for melanoma, cabazitaxel, abiraterone, sipuleucel-T for prostate cancer; pemetrexed, erlotinib, and bevacizumab for lung cancer. Outcomes was excluded having not reached median overall survival (OS) at appro-
val. 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 medians OS and mean OS. However, greater variability was seen across the 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 med-
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efit may be so similar.

PR46
indicator of the influence of the UK in global RW research. METHODS: All 1455 abstracts presented at ISPOR 14th Annual European Congress in Madrid, Spain, in 2011 were reviewed in the ISPOR OUTCOMES RESEARCH DIGEST, available via the ISPOR website. Posters were also reviewed where available. Those reporting RW studies were classified according to the ISPOR website. In 21% of abstracts there was a UK author. National study. 24% were conducted in the USA, 53% in another country (not UK, 3.6%. 12% were conducted in the UK; a further 8% included UK centres in an inter-
national study. 34% were conducted in the USA, 53% in another country (not UK, not USA – 38 countries, most commonly Spain 6%, Canada 5%, Germany 5%, France 5%, The Netherlands 3% and Italy 3%) and 3% were international without a UK centre. In 21% of abstracts there was a UK author. CONCLUSIONS: RW studies presented at the ISPOR 14th Annual European Congress 2011 were most often single country rather than international with the USA being the most prolific source. Of the rest, the UK was the source of RW data in twice as many studies as any other country, lending weight to the opinion that the UK provides an excellent environment for conducting RW studies.

PRM7 INCREASING PHYSICAL ACTIVITY IN PATIENTS WITH CHRONIC DISEASE: WHAT IS THE LITERATURE TELLING US? Leidy NK1, Kimel M2, Ajagbe L2, Kim K2, Hamilton A2, Becker K2 1Unimed BiSource Corporation, Bethesda, MD, USA, 2Boehringer Ingelheim Canada Ltd, Burlington, Canada, 3Boehringer Ingelheim Germany GmbH, Germany.

OBJECTIVES: It is widely recognized that regular exercise improves fitness, with increasing evidence that physical activity (PA) movement resulting in elevated energy expenditure beyond basal levels) can affect health, particularly in chronic disease. While pharmacologic therapy and exercise training have been shown to improve capacity, persistent increase in PA requires behavior change. This review examined studies testing the effectiveness of behavioral interventions to increase PA in adults with chronic disease. METHODS: Embase and PubMed searches of intervention studies published in English, 1980-2010. Inclusion criteria: at least 2000 years, COPD, diabetes, heart failure, obesity, exercise or PA endpoint; behavioral intervention described in sufficient detail to permit interpretation. RESULTS: A total of 392 articles screened; 169 articles reviewed, 36 included. Most were randomized trials (n=30, 83%) with 2 intervention arms (n=29, 81%), medium to high quality (n=34, 94%). Subjects were recruited through clinical settings (n=28, 78%), with disease severity a primary eligibility criterion (n=23, 64%); 15 (42%) had sample sizes 40-100. Mean study duration = 9.6 months (range: 1-84). Exercise intervention: 30-50 minutes aerobic activity 3-5 times/week (n=22, 61%), 64% included walking. Instruction was individual (n=25, 69%), initially supervised (n=24, 67%) followed by unsupervised home exercise (n=15, 42%). Behavioral intervention: counseling (n=19, 53%) with personal contact follow-up (n=12, 33%). Control group: exercise without behavioral intervention (n=14, 39%) or usual care (n=15, 42%). Significant effects of the intervention were reported in 15 of 25 (60%) studies testing exercise capacity (6-minute walk, cycle or treadmill), 19 of 26 (73%) testing PA outcomes (pedometer, activity log, questionnaire), 11 of 22 (50%) measuring health outcomes and disease-specific factors. This retrospective study provides evidence that exercise training can be conducted effectively and has health benefits for adults with chronic disease.

PRM8 TREATMENT OF RHEUMATOID ARTHRITIS – COMPARATIVE EFFECTIVENESS OF BILOGICS Schifferlein-Rohé L1, Leverkus F2, Behmer OR2, Kerckmann U2 1Pfizer Deutschland GmbH, Berlin, Germany, 2Pfizer Pharma GmbH, Berlin, Germany.

OBJECTIVES: Guidelines for treatment of rheumatoid arthritis (RA) advise initial therapy with non-biological disease modifying antirheumatic drugs (DMARDs). In case patients do not respond adequately, treatment should be switched to biologic DMARDs. Aim of this research is to compare results of public available systematic reviews (SRs) on comparative effectiveness (CE) and potential impact of differences in methodology. METHODS: We performed literature research for SR on CE of biologics for the treatment of RA. Search was limited to reviews published in 2009 or later. Methods of the reviews and results were extracted from the publications. Results are summarized in narrative way and differences in results are reflected focusing on methodological key issues. RESULTS: Eleven recent SRs were identified addressing the question of CE of biologics. Since there are no head-to-head comparisons available for all but one biologic, reviews had to use indirect comparisons to assess CE. Authors used the Simon-Bucher approach or Bayesian methods (mixed treatment comparisons). Clinical trial guidelines for RA gave the advice that revision of biologics CE should be conducted according to current methodology (ACR) as primary parameter. Therefore, all trials assessed ACR20 (20% improvement), ACR50 and ACR70 and could be used for comparison. Further parameters were not assessed in a uniform manner (e.g. quality of life or not assessed in the same trial. e.g. disease activity score) and therefore could not be used for indirect comparison of treatments. CONCLUSIONS: Due to lack of head-to-head data for comparison of biologics, statistical methods for indirect comparison have to be used to answer the question of CE. These methods have restrictions and base on assumptions that might be heavily violated. Substances were tested over a time period of more than 10 years with effects on study population and variation in study designs. Nevertheless, the results seem to be fairly consistent.

PRM9 REAL-WORLD DATA TO CALCULATE COST-EFFECTIVENESS OF MONOCLONAL ANTIBODIES: PROBLEMS AND SOLUTIONS van Rooijen EM, van der Linden N, van Gils C, Oppe M, Dyl-de Groot C 1Erasmus Medical Technology Assessment, Erasmus University, Rotterdam, The Netherlands.

OBJECTIVES: Real-world data is considered to be the gold standard by decision makers to inform on cost-effectiveness of new drugs. Unfortunately real-world data are often lacking in important parameters needed to inform on cost-effectiveness, and RCT data can be used to address this problem. Illustrated by two cases this paper will show that real-world data can be used to inform on cost-effectiveness, as combined can have a profound influence on the resulting ICER. METHODS: Two case studies in which real-world data on cetuximab for the indication of locally advanced head and neck cancer and panitumab for indication of chemoradia
treatment of metastatic colorectal cancer was collected. RESULTS: The problem: In the case of cetuximab, patient selection in the pivotal RCT was used and corrected according to the results seen in the real-world data to better represent survival in daily practice. Using unadjusted RCT data resulted in a difference of approximately 5,000 euro/QALY in the

PRM10 USE OF VA DATABASES FOR RETROSPECTIVE STUDIES IN ULCERATIVE COLITIS OUTCOMES RESEARCH Koleva Y1, Shi L2, Abbas A2, Khan N4 1Tufts University / Southeast Louisiana Veterans Health Care System, New Orleans, LA, USA, 2Tufts University, New Orleans, LA, USA, 3Tufts University / SouthEast Louisiana Veterans Health Care System, New Orleans, LA, USA, 4Southeast Louisiana Veterans Health Care System, New Orleans, LA, USA.

OBJECTIVES: Veterans Administration Corporate Database Warehouse stores databases with standardized structure that could be used for automated data extraction, reviewer abstraction, and text mining to determine the association between health outcomes and disease-specific factors. This retrospective study provides assessment of VA administrative data used to examine the impact of pharmacological therapy on complications in ulcerative colitis (UC). METHODS: Previous studies investigating the effect of 5ASA on the risk for colorectal cancer (CRC) in UC patients have reported conflicting results. We obtained nationwide UC and CRC data from VA health care system for the period 2001-2011. Secondary relational databases were searched for clinical variables based on standardized criteria - ICD9 diagnoses, procedural and medication codes. Data extraction captured demographics, clinical information and pharmacy record for a cohort of 37,191 UC cases. We constructed a dataset of potential ulcerative colitis cases with CRC (n = 1,087) defined by ICD9 codes 556.8 and 556.9 and 153.x,154.x,155.x; a random subsample of 100 non-5ASA users with CRC was compared to 100 controls without CRC. RESULTS: Diagnosis of ICD9 code for CRC had PPV 79% and NPV 100% in the random sample. Within the 1087 potential CRC cases, only 50% (464) were found to have evidence of both conditions on chart review with kappa agreement between automated and manual abstraction 0.73 (95% CI: 0.70-0.76) for CRC and significantly lower for UC - 0.60 (95% CI: 0.57-0.63). The initial overall prevalence of CRC in the UC cohort was 2.9% and decreased to 1.34% after human text search verification. CONCLUSIONS: Automated extracts have great potential for diseases surveillance but manual review yields more reliable data. Pre-defined diagnostic algorithms based on a combination of methods as well as further technology development like natural language processing and longitudinal patient record will improve accuracy of retrospective databases.


OBJECTIVES: Real-world data is considered to be the gold standard by decision makers to inform on cost-effectiveness of new drugs. Unfortunately real-world data are often lacking in important parameters needed to inform on cost-effectiveness, and RCT data can be used to address this problem. Illustrated by two cases this paper will show that real-world data can be used to inform on cost-effectiveness, as combined can have a profound influence on the resulting ICER. METHODS: Two case studies in which real-world data on cetuximab for the indication of locally advanced head and neck cancer and panitumab for indication of chemoradiation treatment of metastatic colorectal cancer was collected. RESULTS: The problem: In the case of cetuximab, patient selection in the pivotal RCT was used and corrected according to the results seen in the real-world data to better represent survival in daily practice. Using unadjusted RCT data resulted in a difference of approximately 5,000 euro/QALY in the