OBJECTIVES: Off-label use of medications is extremely common especially in oncology where this aim of the study is to help update the guidelines and determine pharmaceuticals and off-label indications in breast cancer. METHODS: This study involved patients (n=1317) with metastatic breast cancer with tumors that were defined as human epidermal growth factor receptor 2, Her2-positive who received trastuzumab, trastuzumab+vinoralbin and the applications (81.1%), other applications were from education & research hospital and university (18.9%). The patient base was searched for off-label medication, physicians were preferred trastuzumab, trastuzumab+vinoralbin and lapatinib. CONCLUSIONS: Trastuzumab had the highest percentage in all off-label medication in other medical application off-label usage in Turkey. During this period using trastuzumab was licensed only for 9 weeks, not for 52 weeks in Turkey. A computer search was performed using the TITC’s (Turkish Drug and Medical Devices General Directorate) database. The patient base was searched for off-label medication between 1 June 2008 to 1 June 2010. RESULTS: The average age were 49.0± 10.46. Overall, 85% of applications were approved in generally 8 or 9 weeks period. It was found that the Marmara Region had the highest application percentage (33.26%) and then the Central Anatolia Region (27.9%) in a 15-year period over the base of cities Istanbul, Ankara and Izmir had the most applications with 29.6 %, 19.2% and 15.7%, respectively. University hospitals were created the most of the off-label applications (76.1%) after another application was from private hospitals (10.2%) and private hospitals (5.9%). Off-label drug usage in breast cancer medication, physicians were preferred trastuzumab, trastuzumab+vinoralbin and lapatinib.

PCN42 ASSESSMENT OF PATIENT POPULATION WITH NSCLC BY STAGE, EGOC-PS, EGFR MUTATION STATUS AND LINE OF THERAPY IN GERMANY

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OBJECTIVES: With a vast number of possible treatment options for Multiple Myeloma patients, it is unclear in which combination and sequencing compounds should be used to achieve prolonged overall survival. This question cannot be truly answered with an RCT, a health economic model (1) was used to approximate for OS and adopted for a German cost setting. METHODS: Using a combination of meta-analysis and -regression, the possible overall survival of different therapy sequences was approximated in a Markov model. Data source for this model was a systematic literature research covering 2008-2012, identifying a total of 68 studies and 11.115 patients in Multiple Myeloma. From each study treatment arm, response per therapy line was extracted. Subsequently, the model was used to specifically determine the “time to next treatment” (TN'T). TN'T is used in our model study to reflect the positive correlation of response to therapy and disease progression, which has been shown to be highly related (2-5). Using TN'T, the model can now demonstrate which sequence of therapies in 1st, 2nd and 3rd line will total to a possible OS of a patient. RESULTS: We analyzed 133 sequences from over 200 theoretical combinations, based on their German approval. Early usage of new compounds results in a prolongation of overall survival of at least 6 months, compared to the standard therapy with melphalan/prednisone (6), with minimal possible OS between 3.98 and 5.06 years. Cost data from Germany were included to amount costs of therapy for a complete sequence. For the sequences presented, costs ranged between 69.000 and 693.000 €. The majority of the costs come from drugs, not from other resources. CONCLUSIONS: An important topic of modeling approaches is to show both internal and external validity, which is both needed to validate the model and the results. Our objective was to demonstrate, that the model developed in this study can be effectively applied to clinical and economic decision support. Our objective was to demonstrate that the model developed in this study can be effectively applied to clinical and economic decision support. Our objective was to demonstrate, that the model developed in this study can be effectively applied to clinical and economic decision support.

PCN32 ESTABLISHING A CAUSAL CLINICAL SYSTEM: A SYSTEMATIC REVIEW OF THE USE OF A FRACTIONAL RECOMMENDATORY RANDOMIZED PROSPECTIVE STUDY ON CHRONIC LYMPHOCYTIC LEUKAEMIA; AN REANALYSIS OF NICE TA202 USING BAYESIAN METHODOLOGY TO MODEL OBSERVED DATA

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OBJECTIVES: Standard therapy for chronic lymphocytic leukaemia (CLL) is fludara- bine, followed by trastuzumab. Patients resistant to both treatments (double refractory (DR)-CLL) receive best supportive care (BSC). Ofatumumab is licensed for the treatment of DR-CLL, but was not recommended by the National Institute for Health and Care Excellence (NICE technology appraisal 202 [TA202]). There is little clinical data available and a single-arm trial of ofatumumab was presented in an observational study of BSC. Survival for BSC in TA202 was modelled by fitting a Weibull distribution to data of ofatumumab non-responders. The effects of ofatu- mubab were estimated by assuming a proportional hazards model. The objective of this study was to investigate the potential sources of survival data for BSC, and the impact of the choice of survival distributions used in TA202 on the cost-effectiveness of ofatumumab. METHODS: Individual patient-level data was reconstructed from Kaplan-Meier plots using a published algorithm. Plausible survivor functions were fitted to the data using Markov chain Monte-Carlo simulation. Goodness-of-fit to the observed data was assessed using deviance information criterion and the clinical plausibility of extrapolations using subjective opinion. The cost-effectiveness model from TA202 was reproduced including alternative survival data. RESULTS: A Weibull distribution provided the best fit to the data and was most clinically plausible. A proportional hazards model from TA202 the incremental cost-effectiveness ratio (ICER, incremental cost per life year gained) was £52,400, similar to £49,252 reported in TA202. Relaxing the assumption of proportional hazards increased the ICER to £85,618. CONCLUSIONS: The best fitting and most clinically plausible model was a Weibull distribution, giving results consistent with TA202, however both the use of a subgroup of a single arm trial and of data from multiple studies has a high level of uncertainty. Relaxing the assumption of proportional hazards increased the ICER.