

rior to DTIC alone (OR = 1.40, CI95%:1.10–1.79). Non-interferons were ineffective (OR = 1.24, CI95%:0.93–1.65). Interferons appeared to be effective adjunctive therapies (OR = 1.60, CI95%:1.03–2.50) with a survival of 10.5 ± 4.2 months. However, small (older) studies produced high rates while large (newer) studies found lower rates. **CONCLUSIONS:** Meta analysis of current publications demonstrated that standard treatment with DTIC produces response rates between 12.6 and 17.2. The addition of other treatments to DTIC offer no clinical advantage, except possibly interferons, but incremental advantages are modest at best. Studies were generally of poor quality. Effective treatments are needed to treat advanced melanoma.

CN2

USING PSYCHOMETRIC AND CLINIMETRIC TECHNIQUES TO SELECT ITEMS FOR USE IN A NEW INSTRUMENT TO MEASURE CANCER-RELATED FATIGUE

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OBJECTIVE: The aim of the present study was to develop a patient reported outcome (PRO) instrument which would be suitable for use in clinical practice to measure the intensity and impact of cancer-related fatigue (CRF), as well as patients' attitudes and beliefs regarding the condition. **METHODS:** Questionnaire content was generated from literature review, focus groups with oncology patients, and expert meetings with oncologists and specialists in the production of PRO instruments. Potential items were administered to oncology patients with CRF in a multi-center, cross-sectional, item reduction study. Patients answered all items twice to obtain data on both item frequency and importance using 5-point Likert-type scales. Item reduction was performed using a combination of clinimetric (calculation of impact score by multiplying frequency and importance scores for each item, expert opinion) and psychometric analysis (factor analysis, evaluation of scale internal consistency), and Item Response Theory (IRT) techniques. **RESULTS:** The initial pool of 75 items was administered to 238 cancer patients (mean age 57 years, 56% women, 30% breast cancer, 64% with metastasis, 46% with anemia). The 35 items with the lowest impact score were eliminated in clinimetric analysis; statistical analyses eliminated a further 15 items, and 13 items were eliminated on the basis of expert clinical opinion, supported by findings from the IRT analysis and item-scale correlations. The final measure includes 12 items. Factor analysis confirmed the presence of 3 dimensions: physical function (4 items), activities daily living (4 items) and beliefs/attitudes (4 items). Cronbach's alpha values for the overall score and individual dimensions were 0.92, 0.78, 0.85, and 0.81, respectively. **CONCLUSIONS:** The combination of methods for item reduction has led to the production of a new instrument with 12 items and 3 dimensions, which it is hoped will be suitable to measure aspects of CRF which are important in clinical practice.

CN3

PHARMACOECONOMIC (PE) ANALYSIS OF THE TREATMENT OF NON-SMALL CELL LUNG CANCER (NSCLC) IN THE NETHERLANDS DEMONSTRATES THAT ERLOTINIB DOMINATES DOCETAXEL AND IS COST-EFFECTIVE OVER BEST SUPPORTIVE CARE (BSC) WITHOUT NEED FOR PATIENT STRATIFICATION

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OBJECTIVE: A PE analysis was performed to support the reimbursement request of erlotinib in 2nd/3rd-line treatment of NSCLC in The Netherlands (NL). **METHODS:** Erlotinib and BSC efficacy data (based on the erlotinib registration study, BR.21) were used for this analysis. Chart reviews (n = 96) were conducted to obtain insight into health care utilisation (HCU) of stage IIIB/IV relapsed NSCLC. Charts from patients treated with docetaxel (n = 24) and BSC (n = 72) in 4 general and 1 academic hospital were used. The PE analysis was performed from the societal perspective and both outcomes and efficacy results were discounted at 4%. Official price lists (2004) were used and the price of erlotinib was set at €2184/150 mg/30 tablets. PE outcomes extrapolated to 3 years were evaluated using a Markov health-state model, adapted for NL. Outcomes and model assumptions were approved by an expert panel of 10 Dutch clinicians. **RESULTS:** The average treatment costs per patient in NL were €24,939 for docetaxel, €23,436 for erlotinib, and €15,450 for BSC. Life-years gained (LYG) were 0.84 years for docetaxel and erlotinib and 0.62 years for BSC, as per the BR.21 registration trial intent-to-treat population. The incremental cost-effectiveness ratio (ICER) for erlotinib vs BSC was €37,059/LYG (CI €12,621–€72,960) based on 4.3 month treatment duration. Erlotinib dominated docetaxel in all scenarios except when an unrealistically low docetaxel dose (110mg/cycle) was assumed. ICERs were sensitive to variations in length/frequency of hospitalizations and number of outpatient visits, illustrating the economic impact of erlotinib's generally mild adverse event profile. Erlotinib was cost-effective vs BSC in 80% of cases using a willingness-to-pay (WTP) threshold of €50,000/LYG. **CONCLUSIONS:** Treatment with erlotinib dominates docetaxel and is cost-effective vs BSC in NL. Based on the clinical efficacy and cost-effectiveness, erlotinib has received unrestricted reimbursement for relapsed NSCLC in NL without requirements for patient stratification.

CN4

COST-EFFECTIVENESS OF ERLOTINIB COMPARED WITH DOCETAXEL FOR THE TREATMENT OF RELAPSED NON-SMALL CELL LUNG CANCER (NSCLC) IN THE UK

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OBJECTIVE: To evaluate the cost-effectiveness of erlotinib compared to docetaxel for treating stage III/IV relapsed NSCLC from the UK NHS's perspective. **METHODS:** A cost-utility approach was taken; primary endpoint was cost per QALY. Baseline patient characteristics were based on trials BR.21 (erlotinib arm) and TAX317 (docetaxel arm). Equivalent overall survival was assumed; any bias from this assumption was expected to favour docetaxel. The model stratified patients into progression-free survival (PFS), progression and death. Time in each health state was adjusted for QoL (EQ-5D data), including the impact of adverse events (AEs) and formulation of therapy experienced in

PFS. Monthly resource utilisation associated with PFS and progression was estimated by a consensus panel of UK experts. Cost of AEs and drug-administration costs were also included. The evaluation accounted for longer treatment duration (24%) with erlotinib compared to docetaxel (mean duration 125 vs. 101 days, respectively). The incremental drug acquisition cost for erlotinib vs docetaxel was consequently £1867. The primary outcome was total direct NHS costs and QALYs. **RESULTS:** Total direct NHS costs were £12,701 and £12,621 for erlotinib and docetaxel, respectively. Erlotinib vs docetaxel offers a cost saving of £971/patient due to its oral administration and £301/patient in the management of AEs. QALYs were 0.201 and 0.176 (erlotinib vs docetaxel, respectively). The ICER for erlotinib vs docetaxel was estimated at £3354. Erlotinib was cost-effective whether or not the calculation assumed improvements in PFS. Improvements in QoL and reduced toxicity with erlotinib led to greater total QALYs vs docetaxel. **CONCLUSIONS:** Erlotinib is a valuable alternative to docetaxel in relapsed NSCLC. Efficacious without compromising QoL and well tolerated, erlotinib can be considered a highly cost-effective treatment for NSCLC in the UK. Orally administered, it may also be associated with a capacity benefit to the NHS through reduction in existing infusion and outpatient requirements.

HEALTH CARE USE & POLICY STUDIES

HP1

CRITICAL APPRAISAL OF ECONOMIC EVALUATIONS OF CHOLESTEROL LOWERING DRUGS: A SYSTEMATIC REVIEW

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OBJECTIVES: The large availability of economic evaluations and their increasing importance for decision making emphasizes the need for economic evaluations that are methodologically sound. The aim of this study is to provide users of economic evaluations of cholesterol lowering drugs with an insight into the quality these evaluations. By focussing on the most relevant studies the gap between research and policy making may be narrowed. **METHODS:** A systematic review was conducted. All publications on economic evaluations of cholesterol lowering drugs were identified by searching Pub Med, the Centre for Reviews and Dissemination database (CRD), the National Health Service Economic Evaluation Database (NHS EED), the Health Technology Assessment database (HTA) and the Database of Abstracts of Reviews of Effects (DARE). A search strategy was set up to identify the articles to be included. These articles were quality assessed using Drummond's checklists. The scoring was performed by at least two reviewers. When necessary, disagreement between these reviewers was decided upon in a consensus meeting. We calculated an average quality score for the included articles. **RESULTS:** The search identified 23 articles that were included. Most studies measured the costs/LYG. The overall score per study varied between 2.7 and 7.7 with an average of 5.4. Most studies score high on the measurement of costs and consequences whereas the establishment of effectiveness leaves room for improvement. Only two studies included a well performed incremental analysis. **CONCLUSION:** This review noticed an increase of quality of economic evaluations over time. Consequently, the value of cost-effectiveness studies for policy decisions increases over time. In general piggy back evaluations tend to score higher on quality and are therefore more valuable in decisionmaking.

HP2

TRENDS IN ANGIOTENSIN II RECEPTOR BLOCKER (ARB) PRESCRIBING AMONG GENERAL PRACTITIONERS IN THE UK

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OBJECTIVES: ARBs were introduced into the UK antihypertensive drug market with conflicting data on their relative effectiveness compared to other classes, which offered lower cost alternatives. The study aim was to determine patient-level characteristics of ARB prescribing patterns and how these changed over time since the first ARB market launch December 1994. **METHODS:** The study population was identified from the Health Improvement Network (THIN) database, an electronic medical record dataset of patients seen by general practitioners in the UK. Patients who received an oral drug approved for hypertension treatment at any point in time from 1995 through 2003 were included. The multinomial logit model was applied to two time periods to predict the likelihood of receiving an ARB prescription compared to other antihypertensive drug classes, after controlling for patient characteristics. A time dummy tested for changes between the time periods. **RESULTS:** Immediately after the first ARB introduction (1995–1997), 0.25% (N = 537,309) of the study population was allocated to ARB therapy. This rose to 6.22% (N = 803,981) for the more recent time period (2001–2003). In the early time period, patients with high blood pressure readings and patients seen by a Cardiologist were more likely to receive prescriptions for ARBs than other antihypertensive classes. This did not persist for the more recent time period. Over time, prescribing antihypertensive drugs for patients with diabetes shifted away from all classes (P < 0.01), except the angiotensin converting enzyme inhibitor (ACEi) class (P = 0.6334), towards ARB prescribing. For patients with heart failure, there was a statistically significant shift away from prescribing ARBs towards the beta-blocker and "Other" classes. In general, patients with diabetes or heart failure were more frequently prescribed ACEi than ARB therapy. **CONCLUSIONS:** ARBs were prescribed cautiously in the UK and ARB prescribing patterns altered over time as new safety and effectiveness evidence emerged.

HP3

THE ROLE OF GENERAL PRACTITIONERS IN THE INITIAL MANAGEMENT OF WOMEN WITH URINARY INCONTINENCE IN FRANCE, GERMANY, SPAIN AND THE UK

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OBJECTIVES: To describe the role of general practitioners (GPs) in the initial management of women with UI in 4 European countries with different health care systems. **METHODS:** Cross-sectional community postal survey of 2,953 community-dwelling women with UI in France, Germany, Spain and the UK. **RESULTS:** There was an overall response rate of 53% (n = 1573). Forty eight percent had discussed their UI with a doctor. More women discussed UI in France and Germany than in the UK and Spain. The patient usually raised the issue, during consultations for some other reason. Fear of, or actual deterioration in UI was the most important reason for discussing UI. Overall 52% of incontinent women first discussed their UI with a GP and almost a third of women reported having all their UI discussions in a GP setting. Twenty nine per cent of women reported that GPs had either recommended treatment or monitoring of their condition before beginning treatment and 24% reported