

complement RCT data and prospective patient registries for the evaluation of contemporary practice including biomarkers used for diagnosis, treatment decisions and prognosis in the management of CML patients.

PCN148

THE USE OF PERSONALISED MEDICINE IN CANCER TRIALS

Wilson TJ, Hamerslag L, Kusel J, Brooks-Rooney C, Rolfe F, Costello S
Costello Medical Consulting Ltd., Cambridge, Cambridgeshire, UK

OBJECTIVES: The consideration of subgroup analyses is an emerging topic in health care evaluation. With value-for-money being an important issue, alongside the question "is this therapy effective?", another question becoming more relevant is "in whom is this therapy effective?" This issue is particularly relevant to the development of cancer treatments, which are often expensive and indicated in small patient populations. The use of personalised medicine is therefore expected to play a large role in this disease area. The aim of this study was to investigate how the proportion of cancer trials taking personalised medicine into account has changed over time. **METHODS:** ClinicalTrials.gov was searched for all interventional cancer trials that considered the use of individualised medicine, by using search terms including 'diagnostic', 'prognostic' and 'biomarker'. Search results were de-duplicated, and the start dates of these trials were analysed and compared to those of all interventional cancer trials listed on ClinicalTrials.gov. **RESULTS:** In total, 2810 cancer trials considered personalised medicine. The distribution of these was strongly skewed towards recent years, with only 57 of the trials identified having started before 2000. Across all cancer trials, 2.5% of those started before 2000 considered personalised medicine, whereas this percentage increased to 13.6% after this date. Interestingly, 20.6% of cancer trials commencing in 2010, compared to 17.0% of those in 2011, involved individualised medicine, indicating that there might be a slight decline in the investigation of personalised medicine recently. Trials considering individualised medicine were most often conducted in the United States or Europe, and in disease areas such as leukaemia, head and neck, brain, and prostate cancer. **CONCLUSIONS:** Personalised medicine has started to play a bigger role in cancer therapy development since the year 2000. With the current health care market focusing on value-for-money, however, it is surprising that only one-fifth of recent trials considered this issue.

PCN149

TRANSFERABILITY OF PHARMACOECONOMIC EVALUATIONS: CASE STUDY OF TRASTUZUMAB FOR EARLY BREAST CANCER

Carswell C, McWilliams P, Lyseng-Williamson KA, Faulds D
Adis, Auckland, New Zealand

OBJECTIVES: Using a simple method we determined the potential transferability of a previous economic evaluation on the cost effectiveness of adjuvant trastuzumab therapy for the treatment of HER2/Neu-positive breast cancer in Canada (Skedgel et al, 2009) to five other countries (UK, US, Australia, Japan and Germany). **METHODS:** Based on data from a literature review, we firstly identified all possible transferability factors. From this we selected key transferability factors – those with values that differed across the countries or were factors that were shown to influence the cost-effectiveness ratio in sensitivity analysis in the Canadian reference study. We then considered the ease of transferability (ranging from very low to very high) for each of these potential factors from the Canadian study to the other countries. **RESULTS:** We identified seven potential key factors for transferability: cost discount rate, health outcomes discount rate, unit costs (particularly drug acquisition cost), resources used, treatment effectiveness, (including duration of benefit) and measures used to determine utility values. Overall, potential transferability was highest for the UK, where treatment practice is similar to that in Canada and data on unit costs, resource use and discount rates are readily available. Because the authors of the reference study did not report unit costs and resource use separately, however, transferability of the analysis was hindered. Transferability to Australia, Germany and the United States was of an intermediate level, while transferability to the Japanese setting was the lowest because treatment practice is likely to be different, and little cost of illness and utility data exist for that country. **CONCLUSIONS:** Several key factors need to be considered when evaluating whether a study is transferable to another setting. To enable the transferability of economic evaluations from one country to another, authors need to ensure that they report their economic data clearly and in sufficient detail.

PCN150

DIRECT MEDICAL COSTS OF HEAD AND NECK CANCER IN THE UNITED STATES: AN ANALYSIS USING POOLED MEDICAL EXPENDITURE PANEL SURVEY (MEPS) DATA

Coughlan D, Frick KD

Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

OBJECTIVES: Pooling annual data together from the Medical Expenditure Panel Survey (MEPS) is legitimate way to produce average annual estimates based on "person-years" for any condition. AHRQ state that over 100 cases are required in order to do this. The objective of this study is to look at the direct medical costs associated with head and neck cancer (HNC) using this data source. **METHODS:** MEPS data was pooled (2003-2008) and analyzed for respondents with HNC (CCS code=11). Two different approaches were used. Consolidated year files and condition files were pooled together to calculate estimates on use and expenditures for persons with HNC (condition approach). Yearly event files were used to pool condition-event files to establish an attributable fraction approach. Both approaches inflated expenditure data to 2008 USD. **RESULTS:** A total of 120 respondents were identified to have a diagnosis of HNC when data was pooled. The condition approach estimated that the national yearly expenditures of HNC is in the order of \$16.47bn with mean spend of \$14,573 (SE=\$2,227) per case per year. The attribut-

able fraction approach estimated that expenditures for all events associated with HNC are significantly less - \$8.49bn with a mean of \$4788 (SE±\$1,057) per case per year. There were only 103 cases that had an event associated with the condition. Private payors accounted for most expenditure, though the proportion was slightly lower using the condition approach (46% vs. 56%). The analysis noted that attributable expenditures were driven by ambulatory visits where condition expenditures were driven by inpatient costs. **CONCLUSIONS:** MEPS is often used to estimate the direct medical costs of a condition. This analysis illustrates that for rare cases, such as HNC, that both approaches offer insight into characterizing a condition. Subsequently, a range for cost estimates can be determined using this data source.

PCN151

DESIGNING CASE REPORT FORMS FOR ECONOMIC EVALUATION ALONG SIDE CLINICAL TRIALS: A CASE-STUDY USING AN INTERACTIVE DATA ANALYSIS TOOL TO STREAMLINE DATA COLLECTION

Foley K

Thomson Reuters, Cambridge, MA, USA

OBJECTIVES: Determining which economic and health resource utilization data points to collect in clinical trials requires a balance between comprehensiveness and data collection burden. Cost and time constraints necessitate that only the most critical economic variables be collected. Our objective was to test the utility of a new tool for determining the most frequent types and timing of healthcare utilization among cancer patients in a quick and low cost manner. **METHODS:** We used an online interactive data analysis tool, MarketScan[®]Treatment Pathways, to explore the most frequent adverse events (AE) and their related healthcare utilization patterns in a sample of non-small cell cancer patients (NSCLC). Patients with at least 2 ICD-9 codes for lung cancer on different days within 30 days of each other on non-rule out claims and no chemotherapies associated with small-cell lung cancer were included. The subset of patients with a diagnosis for metastatic cancer following their NSCLC diagnosis who received at least one oral or injectible chemotherapy treatment were analyzed. **RESULTS:** 5,243 patients with metastatic NSCLC were identified, of whom 2,006 received at least one oral or injectible treatment. 80% of experienced at least one AE serious enough to require healthcare intervention. The median and mean days to the first AE were 20 and 51.5 days from the time of the first treatment. The most common AEs were anemia (51.2%), gastrointestinal events (34.8%), fatigue (26.1%), and neutropenia (24.2%). Of those with anemia, 36% received epoetin or darbepoetin alpha and of those with neutropenia, 77% received pegfilgrastim or filgrastim. Additional patient clinical and treatment characteristics were described for the 30 days following each AE. Total analysis time for this project was under 3 hours. **CONCLUSIONS:** Treatment Pathways answered critical questions for the design of economic endpoint data collection for a new cancer trial in just a few hours.

PCN153

A TRIAL FOR EVALUATING BREAST CANCER TUMOR MARKER USE IMPACT: A VALUE OF RESEARCH ANALYSIS

Thariani R¹, Blough DK¹, Barlow W², Henry NL³, Gralow J⁴, Ramsey S⁵, Veenstra DL⁶

¹University of Washington, Seattle, WA, USA, ²Fred Hutchinson Cancer Research Center, Seattle, WA, USA, ³University of Michigan Medical School, Ann Arbor, MI, USA, ⁴Seattle Cancer Care Alliance, Seattle, WA, USA, ⁵Fred Hutchinson Cancer Research Center, University of Washington, Seattle, WA, USA, ⁶University of Washington, Pharmaceutical Outcomes Research and Policy Program, Seattle, WA, USA

OBJECTIVES: To assess the societal value of a prospective randomized clinical trial (RCT) for breast tumor marker testing in routine follow-up of high-risk, stage II-III breast cancer survivors. **METHODS:** We used value of information techniques to assess the benefits of reducing uncertainty of using breast cancer tumor markers. We developed a decision-analytic model of biomarker testing in addition to standard surveillance at follow-up appointments every 3-6 months for five years. Expected value of sample information (EVSI) was assessed over a range of trial sizes and assumptions. **RESULTS:** The overall value of research for an RCT involving 9000 women was \$166 million (EVSI). The value of improved information characterizing the survival impact of tumor markers was \$81 million, quality-of-life \$38 million, and test performance \$95 million. **CONCLUSIONS:** Despite not being recommended by clinical guidelines, the tumor markers carcinoembryonic antigen (CEA), cancer antigen (CA)15-3, and CA 27.29 are used by some clinicians to screen for increased risk of breast cancer recurrence. Although additional research may be warranted to evaluate the benefits and risks of breast cancer tumor marker tests, clinical trials would likely need to involve thousands of women and would take many years to complete. Our analysis indicates that substantial societal value may be gained by conducting a clinical trial evaluating the use of breast cancer tumor markers. The most important aspects of the trial in our analysis were information gained on survival improvements as well as quality-of-life parameters associated with testing and test sensitivity and specificity. Our analysis indicates that smaller randomized trials, as well as adding quality of life instruments to existing trials, retrospective, and observational trials can also generate valuable and relevant information.

PCN154

CHALLENGES POSED BY PATIENT CROSSOVER FOR COST-EFFECTIVENESS ANALYSIS OF ONCOLOGY PRODUCTS: A CASE STUDY IN METASTATIC PANCREATIC CANCER

Grima DT, Brown ST, Attard CL, Duong MT

Cornerstone Research Group, Burlington, ON, Canada