RESULTS: The average VAS value at baseline was 0.65 (SD = 0.19), 0.83 (SD = 0.14) at the end of the study and the average change score from baseline to end of study for the VAS was 0.17 (SD = 0.20). The differences between the VAS value and the derived preferences ranged from −0.07 to 0.02 at baseline. Three of the five 95% confidence intervals (CIs) for the difference between derived preferences and VAS values at baseline included zero. At the end of the study the mean of the VAS was higher than the means for all of the derived preference methods. The difference between the averages for the VAS and the derived preferences ranged from 0.01 to 0.11 and only one of the 95% CIs for the difference included zero. The change scores for the VAS preferences were greater than the derived preferences (Differences from 0.07 to 0.13). None of the 95% CIs for the difference in change scores between VAS preferences and derived preferences crosses zero.

CONCLUSIONS: The derivation methods produce valid and responsive measures of patient preference. However, the derived preference values differ from each other and directly elicited preference values. Differences in the distributions of the directly elicited and derived preferences will affect inferences and can lead to differing conclusions in a cost-utility analysis.

MOXIFLOXACIN IV/PO MONOTHERAPY IS COST-EFFECTIVE TO THE GERMAN AND FRENCH HEALTHCARE SYSTEMS WHEN COMPARED TO IV/PO AMOXICILLIN/CLAVULANATE ± CLARITHROMYCIN IN THE TREATMENT OF COMMUNITY-ACQUIRED PNEUMONIA

Drummond M1, Becker D2, Hux M3, Chancellor J3, Duprat-Lomon I4, Sagnier PP5
1Innovus Research (UK) Ltd. and University of York, Heslington, York, UK; 2Innovus Research Inc, Burlington, ON, Canada; 3Innovus Research (UK) Ltd., Amersham, Buckinghamshire, UK; 4Bayer Pharma, Puteaux, France; 5Bayer plc, Slough, UK

OBJECTIVE: To conduct a cost-effectiveness analysis, from the perspectives of the German and French healthcare systems, of sequential IV/PO moxifloxacin (MXF) monotherapy versus standard comparators in hospitalized patients with community-acquired pneumonia (CAP) requiring parenteral treatment.

METHODS: Costs and consequences over 21 days were evaluated based on clinical cure rates 5–7 days post-treatment and resource use reported for the intention-to-treat population of the TARGET multinational, prospective, randomized, open-label trial. This trial compared sequential IV/PO MXF (400mg OD) to IV/PO amoxicillin/clavulanate (AMC) (1.2g IV/625mg PO TID) ± clarithromycin (CLA) (500mg BID) for 7–14 days in CAP patients. Since the treatment effect on resource use (hospital length of stay [LOS]) was similar across countries, resource data from all 10 countries were pooled and valued using German and French unit prices to estimate the CAP-related cost to the German Sickness Funds and French public healthcare sector.

RESULTS: Compared to AMC ± CLA, treatment with MXF resulted in 5.3% more patients having clinical cure 5–7 days post-therapy (95% CI −0.1%, 12.3%), a statistically significant faster response (return to apyrexia 1 day sooner), and reduction in LOS by 0.81 days within the 21-day period. Treatment with MXF resulted in per patient savings of €266 (Germany) and €381 (France) compared to AMC ± CLA, primarily due to a shorter LOS. Sensitivity analyses found these results to be robust to several costing scenarios. Using bootstrap analysis of the trial data, the probability of MXF being cost saving in both countries was estimated to be 95% or greater, while the probability of MXF being cost-effective was commensurately higher for acceptability thresholds up to €2,000 per additional patient cured.

CONCLUSION: MXF shows clinical benefits and is less costly versus AMC ± CLA in the treatment of CAP. Treatment with MXF is likely to result in cost savings to the German and French public healthcare systems.

PSYCHOMETRIC PROPERTIES OF THE ACUTE BRONCHITIS SYMPTOM SEVERITY SCALE IN AN INTERNATIONAL SAMPLE

Margolis MK1, Frank L1, Leidy NK1, Duprat-Lomon I2, Amiot N2, Sagnier PP3
1MEDTAP International, Bethesda, MD, USA; 2Bayer Pharma, Puteaux, France; 3Bayer plc, Slough, UK

OBJECTIVES: To evaluate the psychometric characteristics of the Acute Bronchitis Symptom Severity (ABSS) Scale, a new 7-item bronchitis-specific instrument designed to measure outcomes in chronic bronchitis (CB) patients.

METHODS: Data were obtained from the screening phase of an international clinical trial comparing the effectiveness of moxifloxacin to a standard oral antibiotic treatment in treating an acute exacerbation of CB. Subjects had a primary diagnosis of CB (having presented with ≥2 episodes of exacerbation in the preceding year, FEV1 < 85% of predicted value, and history of smoking), but were not currently experiencing an acute exacerbation. Patients from 19 countries completed the ABSS (14 languages) for 8 consecutive evenings. Psychometric characteristics evaluated were item performance, internal consistency reliability (Cronbach’s alpha), day-to-day reproducibility (intraclass correlation coefficient (ICC)), construct validity (based on correlation with the St. George’s Respiratory Questionnaire (SGRQ)), and discriminant validity (based on stratification by pulmonary function (FEV1 % predicted)).

RESULTS: 1935 patients were enrolled. Mean age was 63.4 years (± 9.7) and 68% were male. Mean CB duration was 11.7 (± 9.6) years, with a mean of 2.9 (± 1.3)
acutes exacerbations in the prior year. The ABSS showed evidence of good internal consistency reliability (Cronbach's alpha = 0.83), reproducibility (ICC = 0.67), and construct validity (correlation with total SGRQ: $r = 0.54$, $p < 0.05$). Among the subscales, correlation was highest with the SGRQ Symptom subscale ( $r = 0.53$, $p < 0.05$), as expected. Discriminant validity was generally good based on score spread across pulmonary function categories (mean score $= 0.99$ for mild, $1.22$ for moderate, and $1.38$ for severe impairment). Psychometric results were supported across the language versions.

**CONCLUSIONS:** The ABSS is a valid, reliable scale for evaluating the symptoms associated with CB during the stable phase away from an acute episode.

### NEUROLOGICAL/PAIN DISORDERS

#### INDIRECT COSTS DUE TO BACK PAIN IN THE UNITED STATES

**Mychaskiw MA, Thomas III J**

Purdue University, West Lafayette, IN, USA

**OBJECTIVE:** Back pain is a leading cause of absence and disability in the workplace. Costs associated with losses in productivity due to back pain are significant and may be as high as the costs of medical care for this condition. However, there has been limited study of the indirect costs of back pain in the United States. The objective of this study was to determine the indirect costs due to back pain in the U.S. population.

**METHODS:** A retrospective analysis of the 1996 portion of the Medical Expenditure Panel Survey (MEPS) was conducted. The MEPS provided data from a nationally representative sample of 22,601 respondents and data from respondents' medical care and health insurance providers and employers. Data included medical conditions and employment information comprised of hourly earnings, hours worked, and disability days. Back pain patients who incurred disability days were identified using International Classification of Diseases (ICD-9-CM) codes determined by an expert panel of physicians and coders as indicative of back pain and variables denoting disability days. Indirect costs were calculated for back pain patients who missed workdays using the human capital approach. Sample estimates were weighted and projected to the population and 95 percent confidence limits for estimates were calculated using the Taylor expansion method.

**RESULTS:** Total indirect costs for back pain patients who missed workdays were $18,533,583,620$. Mean indirect costs were $4,586 per back pain patient who missed workdays (95% C.I. = $3,852 to $5,321). Relative to the entire population, the mean indirect costs per person were $68.92.

**CONCLUSIONS:** With losses in productivity greater than $18.5 billion, indirect costs significantly contribute to the total costs of back pain. The indirect costs of back pain to labor underscore the need to prevent back injury thereby promoting employee health and maintaining productivity.

**EXCESSIVE COSTS RESULTING FROM PRIMARY CARE AND CHIROPRACTIC UTILIZATION OF DIAGNOSTIC IMAGING IN THE FIRST WEEK OF CARE FOR ACUTE LOW BACK PAIN**

**Jackson SL**, Kim S, Seifelden R, Papatheofanis F

1. Aequitas Consulting Group, San Diego, CA, USA; 2. Purdue Pharma, Stamford, CT, USA; 3. University of California San Diego, La Jolla, CA, USA

Evidence based clinical practice guidelines (EBCPG) were developed in response to combined direct and indirect costs of low back pain (LBP) management approaching approximately $100 billion annually in the US in the early 1990s; but implementation of them has been slow. Utilization of diagnostic imaging studies within the first week of LBP uniformly exceeds all EBCPG recommendations.

**OBJECTIVES:** This investigation seeks to determine the costs associated with private and HMO primary care, and chiropractic utilization of diagnostic imaging studies conducted within the first week of LBP diagnosis.

**METHODS:** Systematic searches of Medline and other databases were conducted, and identified studies were reviewed according to inclusion criteria formulated from a base case. Medicare charges (2001) were used as surrogates of cost. Costs, utilities, and probabilities for Markov modeling were based on systematic literature review, database queries, and health care utilization billing data. Monte Carlo simulation and sensitivity analyses were performed with DATA Pro.

**RESULTS:** Of those patients whose symptoms resolved within one week of diagnosis of LBP, 83%, 32%, 24%, and 13% sought chiropractic, private family practice, HMO primary care, and private internal medicine care, respectively, received at least one diagnostic imaging study. The difference in total cost between patients who had an imaging study during their first week of care and those that did not, according to practice type, is $217.61, $232.72, $229.59, $258.38 per week, respectively.

**CONCLUSION:** All four practice settings’ initial utilization exceeded that of the EBCPG’s recommended utilization of diagnostic imaging studies within the first week of diagnosis of LBP (estimated 3%–4%); chiropractic use was the most excessive, adding an estimated total cost to the system of $18,061.63 per every 100 patients compared to $3358.94 for private internal medicine utilization. EBCPG-based interventions to decrease chiropractic use of imaging studies as diagnostic tools should be emphasized and explored.