clinical effectiveness were obtained from published sources. A 12-month time horizon was adopted, with probabilistic sensitivity analysis and threshold analyses conduced to assess the impact of uncertainty in parameter estimates. **RESULTS:** Examples of published cost-effectiveness analyses included troglitazone (PPAR activator, withdrawn in 2000 for hepatotoxicity), and rofecoxib (COX-2 inhibitor, withdrawn in 2004 for cardiovascular toxicity). Despite including ADRs in the analyses, both drugs were deemed cost-effective. The analysis of treatments for allergic rhinitis revealed that, in fact, chlorpheniramine had a less favourable risk/benefit ratio than terfenadine, with a mean difference of 3.5 QALYs per 1000 patients (95% credible interval, 0.3, 7.6). Threshold analysis suggested that it would require the relative risk of serious injury with terfenadine, compared with chlorpheniramine, to increase from 45% to 85%, or for the efficacy of terfenadine to reduce from 60% to 34% for the decision to be reversed. **CONCLUSION:** The inclusion in economic evaluations of ADRs that are deemed too hazardous to warrant market authorisation by regulators, may lead to counter-intuitive estimates of cost-effectiveness. This may be the fault of regulators for not adopting decision analytic models, or reflect a lack of risk aversion in economic evaluations. Alternative explanations are explored.

ALLERGY/ASTHMA—Cost Studies

PAA5

ECONOMIC EVALUATION OF SYMBICORT® (BUDESONIDE/FORMOTEROL) MAINTENANCE AND RELIEVER THERAPY IN ASTHMA (SMART) COMPARED TO FIXED DOSE COMBINATION STRATEGIES

Miller B[1], FitzGerald JM[2]
[1]Axia Research Inc, Hamilton, ON, Canada, [2]The Lung Centre, Vancouver General Hospital, Vancouver, BC, Canada

OBJECTIVES: To compare the cost-effectiveness of budesonide/formoterol in a single inhaler used as Maintenance and Reliever Therapy (SMART) versus fixed-dose fluticasone/salmeterol (FD) plus as-needed terbutaline reliever or fixed higher-dose budesonide/formoterol (FHD) plus as-needed terbutaline reliever in controlling asthma in adults and adolescents. **METHODS:** An economic evaluation was conducted based on the results of a large (N = 3335) RCT in which health resource utilization was prospectively collected. Primary outcome measurements included time to first exacerbation and the number of severe exacerbations. Costs included direct medical costs (physician/emergency room visits, hospitalizations, asthma drug costs) and productivity (absenteeism). The time horizon was six-months which corresponded to the duration of the trial. Prices were obtained from 2006 Canadian sources. Both health care (HC) and societal (Soc) perspectives were considered. Deterministic univariate sensitivity analyses were conducted. **RESULTS:** In the clinical trial, SMART was superior to FD ($p < 0.001$) and FHD ($p = 0.0048$). Exacerbation rates (reported as per patient per 6 months) were 0.12 for SMART, 0.19 for FD, and 0.16 for FHD. All treatments provided similar improvements in lung function, asthma control days and asthma-related quality of life. From the HC perspective, the mean cost per patient per 6 months was $583 in the SMART arm versus $867 in the FD arm versus $737 in the FHD arm. From the Soc perspective, it was $633 for SMART, $914 for FD and $799 for FHD. SMART was dominant (more effective, less expensive) in the base case analysis from both the HC and Soc perspectives. The results were robust under sensitivity testing. **CONCLUSION:** The SMART strategy which allows budesonide/formoterol to be used as both maintenance and reliever medication is dominant over a strategy of fixed dose salmeterol and fluticasone plus as-needed terbutaline and fixed higher dose budesonide and formoterol plus as-needed terbutaline.

PAA6

ECONOMIC EVALUATION OF A NEW AIRWAY INFLAMMATION MONITOR IN THE DIAGNOSIS AND MANAGEMENT OF ASTHMA IN THE US

Berg J, Lindgren P
European Health Economics, Stockholm, Sweden

OBJECTIVES: Fractional exhaled nitric oxide (FENO) is a marker for the airway inflammation underlying asthma. NIOX is a non-invasive, user-friendly FENO monitor that can be used in physicians' offices to provide immediate information on patient response to anti-inflammatory treatment. The objective of this study was to assess the cost-effectiveness of NIOX in asthma diagnosis and management in the US. **METHODS:** Based on a literature review, two decision trees were constructed to capture the different alternatives and consequences in asthma diagnosis and management, comparing FENO measurement against standard diagnostics and treatment guidelines. The impact of asthma management with FENO measurement on resource use and health outcomes was evaluated over a 1-year timeframe. A US payer perspective was chosen, using 2006 costs from standard sources. Effectiveness was measured in quality-adjusted life-years (QALYs). **RESULTS:** Asthma diagnosis based on NIOX results in a cost of $29 per patient, including the cost of false diagnoses, compared to $49 for standard diagnostics (spirometry, reversibility testing, bronchoprovocation, sputum eosinophil count). In mild to severe patients, asthma management with FENO measurement instead of spirometry leads to 0.06 QALYs gained and cost-savings of $350 per patient and year, of which $295 stem from reduced hospitalisations and $5 from lower doses of inhaled corticosteroids (ICS). In a more severe population, management with NIOX would save $1350 ($1250 from hospitalisations and $55 from reduced ICS doses) and 0.004 QALYs per patient. Based on four visits per year, the cost of monitoring would be reduced by $50 per patient with NIOX. **CONCLUSION:** Asthma diagnosis based on NIOX alone is less costly and more accurate than standard diagnostic methods. The use of FENO measurement in treatment decisions is less costly than asthma management based on standard guidelines and provides similar health benefits.

PAA7

PHARMACOECONOMIC OUTCOMES OF LEVALBUTEROL AND RACEMIC ALBUTEROL IN HOSPITALIZED PATIENTS REQUIRING NEBULIZATION THERAPY (POLARIS)

Claus R[1], Noe L[2], Pasta D[2], Schaefer K[1], Andrews W[1], Roach J[1]
[1]Sepracor Inc, Marlborough, MA, USA, [2]Ovation Research Group, San Francisco, CA, USA

OBJECTIVES: Studies in patients with asthma and COPD have demonstrated that levalbuterol (LEV) treatment resulted in significantly fewer nebulizations and/or decreased total cost of care compared with racemic albuterol (RAC). This was a prospective, multicenter, open-label study in patients hospitalized for acute bronchospasm that evaluated the cost-effectiveness of the two treatments. **METHODS:** Patients were randomized to either LEV 1.25 mg (N = 241) Q8h or RAC 2.5 mg (N = 238), administered per routine standing hospital order. The primary endpoint was the total number of nebulizations (scheduled plus rescue) during hospitalization. Secondary endpoints included length and cost of hospital stay. Cost-effectiveness (CE) analyses were con-

ducted using patient costs from billing records, and three different effectiveness measures [all based on a 0 (worst) to 100 (best) scale]. The primary CE analysis used Subject General Well Being score (SGWB), which was a general health assessment question. Two other effectiveness measures were β-mediated treatment effect (BMTE) and Disease Symptom Assessment (DSA) scores. **RESULTS:** LEV patients required fewer total nebulizations (median 10 vs 12; $p = 0.031$), and the two groups were not statistically different with respect to the number of rescue nebulizations, length of hospital stay, and total hospital cost. For the primary CE analysis, LEV was as effective (70.0 vs 68.3) and cost $164 less per patient compared with RAC. For CE analyses using BMTE and DSA, LEV was again as effective (86.9 vs 79.0 and 59.2 vs 57.2, respectively) and cost $174 less per patient. Bootstrap re-sampling analyses found that approximately 65%–77% of the 10,000 simulations for LEV fell within the dominant quadrant on a CE plane. **CONCLUSION:** In this study, LEV patients required significantly fewer total nebulizations without an increased need for rescue nebulizations. CE analysis indicated that LEV was at least as effective as RAC with a $164 savings in costs.

PAA8

QUALITY-ADJUSTED LENGTH OF STAY ANALYSIS OF HOSPITALIZED PATIENTS WITH ASTHMA OR COPD TREATED WITH LEVALBUTEROL OR RACEMIC ALBUTEROL

Pasta D[1], Silva S[1], Noe L[1], Claus R[2], Schaefer K[2], Andrews W[2], Roach J[2]

[1]Ovation Research Group, San Francisco, CA, USA, [2]Sepracor Inc, Marlborough, MA, USA

OBJECTIVES: This was a prospective, randomized, multicenter, open label study to determine the cost-effectiveness (CE) of levalbuterol versus racemic albuterol in patients hospitalized for acute asthma or COPD; here we present a subset CE analysis which focuses on quality-adjusted length of stay (QLOS) as a measure of effectiveness. **METHODS:** Patients were randomized to either levalbuterol (n = 241) or racemic albuterol (n = 238). We conducted an exploratory CE analysis using QLOS, which was developed to reflect the relative rapidity of symptom resolution over the patient's hospital stay, conceptually similar to Q-TWiST. A measure of overall HRQoL based on daily responses to the Subject General Well-Being (SGWB) score was used as the utility value. An overall value was obtained by calculating the sum over the time period, resulting in the QLOS score. QLOS was also calculated for two other effectiveness measures, Disease Symptom Assessment (DSA) and beta-mediated treatment effects (BMTE). Hospital charges obtained from billing records were converted to costs by applying cost-to-charge ratios. A cost/QLOS comparison was made between treatment groups. Sensitivity analyses examined different time periods and measures of effectiveness. Bootstrap sampling was used to generate 10,000 samples for each analysis. **RESULTS:** When SGWB was the effectiveness measure, levalbuterol compared to racemic albuterol was associated with lower costs ($3676 vs. $3841, respectively) and slightly better cumulative effectiveness (11.99 vs. 12.68, respectively; lower value better health). Similar results were observed using other time periods and BMTE as the effectiveness measure. Results from bootstrap sampling showed that, in the majority of samples, levalbuterol was associated with better health and lower costs than racemic albuterol. When DSA was used, racemic albuterol was slightly more effective but more costly than levalbuterol. **CONCLUSION:** In this study using prospectively collected cost data and QLOS scores, levalbuterol was at least as effective as racemic albuterol, with total costs that were $165 less.

PAA9

A 4-YEAR ASSESSMENT OF SEVERE AND NON-SEVERE ASTHMA IN A REAL-WORLD SETTING

Bleecker E[1], Tashkin D[2], Peters S[1], Long A[3], O'Connor R[4], Parasuraman B[5], Boggs R[6]

[1]Wake Forest University, Winston-Salem, NC, USA, [2]UCLA, Los Angeles, CA, USA, [3]Massachusetts General Hospital, Boston, MA, USA, [4]Sharp Rees-Stealy Medical Group, San Diego, CA, USA, [5]AstraZeneca, Wilmington, DE, USA, [6]Formerly AstraZeneca, Wilmington, DE, USA

OBJECTIVES: To examine health outcomes and costs for patients with severe and non-severe asthma in a managed care setting over a 4-year period. **METHODS:** An administrative claims database (8.8 million lives) was analyzed (June 2000–May 2004). Patients aged ≥12 years with an ICD-9 code for asthma and ≥2 claims/year for asthma medication were included; those with other significant respiratory conditions were not. Patients using omalizumab, continuous oral corticosteroids (OCS), Advair 500/50, or high-dose inhaled corticosteroids in combination with any other asthma medication were considered to have severe asthma. Outcomes in years 2–4 for patients with severe asthma in year 1 were compared with those of patients with non-severe asthma in year 1. Lack of control was defined as an asthma-related hospitalization or emergency department (ED) visit, OCS burst for asthma, more than 4 clinic visits for asthma per year or more than 2 per quarter, or more than 5 prescriptions for asthma rescue medication per year. **RESULTS:** Of 3998 patients identified (mean age = 41 years, 65% female), 594 (15%) had severe asthma in year 1. Patients with severe asthma had significantly more hospitalizations per 1000 patients per year (7.2 vs 4.3; $p < 0.001$), ED visits per 1000 patients per year (8.8 vs 6.1; $p = 0.004$), clinic visits for asthma per patient per year (2.93 vs 1.98; $p < 0.001$), asthma costs per patient per year ($1331 vs $817; $p < 0.001$), and lack of control events per 1000 patients per year (547 vs 462; $p < 0.001$) than patients with non-severe asthma. **CONCLUSION:** Patients with severe asthma used significantly more health care resources than patients with non-severe asthma. In addition, a significant number of patients in both groups met the definition for lack of control.

PAA10

ALLERGY IMMUNOTHERAPY: PATTERNS AND OUTCOMES OF CARE FOR ALLERGIC RHINITIS

Hankin C[1], Cox L[2], Wang Z[1], Bronstone A[1]

[1]BioMedEcon, Moss Beach, CA, USA, [2]University of Miami, Ft. Lauderdale, FL, USA

OBJECTIVES: To examine patterns and economic outcomes of allergy immunotherapy (IT) care among children with allergic rhinitis (AR). **METHODS:** We examined the 1997–2004 Florida Medicaid dataset to identify children (<18 years) who received an AR diagnosis and IT. Those receiving IT who were continuously enrolled and had data ≥4 years following and ≥1 year prior to initial AR diagnosis were included in clinical and economic subanalyses. **RESULTS:** There were 104,963 children diagnosed with AR; 5532 (5.3%) received IT. Mean age at IT initiation was 8.2 years (SD 3.5). Compared to those with AR who did not receive IT, children who received IT were significantly older (mean age 7.7 versus 7.0, SD 3.6, $p = 0.001$). Significantly less patients receiving IT were female or Caucasian ($p \leq 0.001$). The average number of IT administrations was 22 (SD 27.0); approximately half of patients (45.2%) received less than 10 IT administrations. Average treatment duration was 1 year (SD 15.8 months); more than half (51.2%) of patients received IT for less than 6 months, and only 1 in 12 patients (8.7%) completed the