zation of health services. The overall C/B ratio turned out to be 1:6.52, in other words, compared to control group, asthma education programs reduce direct medical costs by $6.52 for each dollar spent in providing the education.

CONCLUSION: Our study shows that the asthma education programs are beneficial in reducing the direct medical costs associated with asthma. These findings suggest that education programs benefit the patient and lead to their well being which in turn will benefit both the patient and the third-party payers.

THE FIRST PHARMACOECONOMIC STUDY IN ASTHMA: SOME IMPORTANT OBSERVATIONS
Andersson F
Astra Draco AB, Lund, Sweden

Treatment options for control of asthma are numerous. However, as for other diseases, there are often differences between clinical trials and what takes place in clinical practice.

OBJECTIVES: To present some methodological issues in relation to the first “real-life” pharmacoeconomics study (PECT) in asthma, comparing the cost-effectiveness of budesonide Turbuhaler versus sodium cromoglycate Spinhaler for moderately asthmatic children, aged 5–11 years.

METHODS: One hundred thirty-eight Swedish patients were randomized to one of the two treatments. Patients were then treated according to local clinical practice on an open basis for 12 months. Thus, any additional therapy was allowed, including switching to the comparator. The objective was to reach the same degree of patient asthma control in both groups. There were six scheduled study visits. Efficacy (asthma control) and resource use were recorded in patient diaries and case report forms.

RESULTS: 1) A number of problems in relation to randomization, such as center effects and sample selection bias, were experienced. 2) A dilution of difference in effect was experienced due to the fact that 36% of patients on sodium cromoglycate had to switch to budesonide because of poor control of asthma (as judged by the physician). 3) Because there was insufficient data available on which to base a power calculation, too few patients were recruited. 4) Due to large standard deviations and the problems listed above, a significant advantage in budesonide costs could only be identified when various background factors were taken into account in a multiple regression analysis.

CONCLUSIONS: A number of different methodological problems compared to ordinary piggy-back economic evaluations arise in PECTs. Careful consideration of design is necessary to ensure high-quality research. Innovative methodological approaches, such as multiple regression analysis, are required.

RESOURCE UTILIZATION: THE CASE OF ASTHMA
Itzler RF1, Dasbach EJ1, Koch GG1, Heyse JF1
1Merck Research Laboratories, Blue Bell, PA, USA; 2University of North Carolina, Chapel Hill, NC, USA

OBJECTIVE: To evaluate the importance of accounting for correlations between observations when analyzing repeated measures of healthcare utilization.

METHODS: Poisson regression was applied with and without generalized estimating equations to analyze β-agonist use, healthcare contacts, and nocturnal awakenings in chronic asthmatics in two large similarly designed, 12-week, randomized trials of Montelukast, a once daily leukotriene receptor antagonist, compared to placebo. Data on β-agonist use and nocturnal awakenings were recorded on daily diary cards. Healthcare contacts included visits to physicians, the emergency room, and hospitalizations documented as not mandated by the protocols.

RESULTS: Montelukast compared to placebo decreased the rate of days of β-agonist use by 9.6% (p < 0.0001), nights with awakenings by 22.5% (p < 0.0001) and healthcare contacts by 23.0% (p = 0.09) when analyzed without generalized estimating equations. Use of generalized estimating equations did not change the parameter estimates for any of the health outcomes measured, but did increase the standard errors and confidence intervals in all cases. The increase in the standard errors ranged from 19.1% to 355.1%. β-agonist use and nights with awakenings remained statistically significant. However, healthcare contacts became less significant (p = 0.16).

CONCLUSION: Failure to account for correlations between observations may lead to erroneous conclusions based on significance levels that are too small. In large samples, exceeding 100–200 patients, generalized estimating equations provide one method of obtaining correct significance levels and confidence intervals when data are correlated. The example above included daily values for 12 weeks in 1300 patients. Other methods of adjusting for correlated data are needed in smaller samples.

A RETROSPECTIVE DATABASE STUDY OF PATIENT ADHERENCE WITH ASTHMA TREATMENT REGIMENS
Hutchison S, Beno C
PCS Health Systems, Inc., Outcomes Research Department, Scottsdale, AZ, USA

OBJECTIVES: Healthcare providers need accurate information about all aspects of healthcare delivery. Clinical trials provide useful information concerning the clinical efficacy of treatment, but they are not representative of the routine conditions with which patients must contend when following treatment regimens. Database studies are being used increasingly to provide information about patient adherence under routine conditions.
METHODS: A retrospective database study was conducted to compare patient adherence and concomitant oral steroid use among patients on oral β₂ agonists or leukotriene antagonist therapy.

RESULTS: Consistent with our first hypothesis, patients using antileukotrienes were more adherent than patients on oral β₂ agonists, over a 12-month period. However, contrary to our second hypothesis, patients using antileukotrienes were eight times more likely to be on concomitant oral steroid therapy than patients using oral β₂ agonists.

CONCLUSIONS: These findings may reflect a “new drug” effect: those patients whose disease is most difficult to control on existing therapies are placed on the newest treatment, drug indications notwithstanding. Finally, the results of this study provide further evidence of the utility of retrospective database studies to provide healthcare providers with cost-effective information reflecting real-world patient behaviors.

THE HEALTHCARE UTILIZATION OF PATIENTS WITH CHRONIC SINUSITIS
Edelman-Lewis B¹, Lydick E², Emani S¹, Bentkover S¹
¹Fallon Clinic, Worcester, MA, USA; ²SmithKline Beecham Pharmaceuticals, Collegeville, PA, USA

The prevalence of sinusitis has been increasing, as has been the number of visits for the condition. Relatively little data are available on its diagnosis, treatment and costs.

OBJECTIVE: The purpose of this study is to analyze resources utilized in the treatment of sinusitis, in particular recurrent sinusitis.

METHODS: The database of Fallon Community Health Plan (FCHP), a Massachusetts-based group model HMO, was analyzed to identify members with three or more visits for sinusitis in an eighteen month period. A total of 495 patients were identified. Their utilization of primary care physician (PCP) and specialty visits, procedures, ancillary services, costs of services, type, quantity, and cost of drugs prescribed was analyzed.

RESULTS: Of the patients, 76% were women and 24% were men. Age ranged between 18 years and 91 years (mean = 45). The subjects had a total of 17,407 procedures and diagnoses during the study period. In 31% of visits, the subjects were treated by a PCP; in 8.5% visits they were seen by an Allergist; and in 6.7% visits they were seen by an ENT. The most frequent primary diagnosis was Allergic rhinitis (8.2%) followed by acute sinusitis (5.8%). The total cost of the utilization was $1,052,678 (mean = $2127). The total number of prescriptions filled during the study period was 13,539 (mean = 27.35). The total cost of these prescriptions was $446,879 (mean = $903).

CONCLUSION: The treatment and management of patients with chronic sinusitis is more intensive than commonly realized. The present study provides insight into demographics and the type and costs of treatment of this patient group.

COST-EFFECTIVENESS OF AZITHROMYCIN AND CO-AMOXICLAV IN ACUTE SINUSITIS
Karpov O, Zaytsev A
Institute of Pharmacology, Saint-Petersburg, Russia

Azithromycin is an azalide antibiotic with broad-spectrum activity; it has a prolonged biological half-life and slow elimination from nasal sinuses. These features make it possible to use azithromycin during short-term periods that may be important for compliance. However, the economic results have not been investigated.

OBJECTIVE: The purpose of this study was to evaluate the efficacy, safety and cost of therapy of azithromycin and a course of co-amoxiclav in acute sinusitis in adults.

METHODS: Among 100 adults with acute sinusitis, 50 were randomized to receive azithromycin 500 mg once daily for 3 days (group I), and 50 co-amoxiclav 625 mg tid for 10 days (group II). Clinical examination was performed at baseline and 72 hours, 10–12 and 26–30 days after treatment initiation. Each sign and symptom was scored and clinical findings were expressed by total clinical score (TCS). TCS was significantly lower in group I after 72 hours following treatment start and at 10–12 days. Cost analysis included drug price, physician cost, and cost of hospitalization.

RESULTS: At 10–12 days of therapy, 41 (82%) patients in group I and only 26 (52%) in group II were free of symptoms associated with increased duration and cost of hospitalization. By the follow-up assessment, satisfactory clinical response was indicated in both groups. The average cost of treatment for group I was $116 and in group II, $150 per patient. During a half-year, relapse of sinusitis was marked in 16% of cases in group II and the additional treatment charges made on average $170 per patient.

CONCLUSION: The treatment 3-day azithromycin is as effective as 10-day co-amoxiclav, but azithromycin provides faster clinical effect and does not lead to relapse, with better pharmacoeconomic outcomes.

QUALITY OF LIFE ASSESSMENT IN ALLERGIC RHINITIS PATIENTS TREATED WITH LORATADINE
Hauser R, Smeeding J, Koeller J
University of Texas Center for Pharmacoeconomics, Austin, TX, USA

Allergic rhinitis can cause a severe decrease in a sufferer’s quality of life. Many non-sedative antihistamines have demonstrated efficacy in phase I through III trials. However, patients’ quality of life during treatment had not been measured or evaluated.

OBJECTIVE: The purpose of this study was to determine if quality of life improves during a 3-week time period while patients were being treated with loratadine for allergic rhinitis.

METHODS: Twenty-five patients with diagnosed allergic rhinitis were treated with loratadine 10 mg every