

talizations and 2.3 physician visits specifically for the treatment of asthma exacerbations in the last 12 months. Patients in other groups consumed more resources. Patients with mild persistent asthma had 0.57 emergency room visits, 0.09 hospitalizations and 3.1 physician visits. The means for moderate patients were 0.61, 0.25 and 3.66 respectively, and for severe patients 1.22, 1.98 and 6.22. Patients in Germany and France were most likely to seek primary care treatment; though patients in Italy and the UK were most likely to be hospitalised. **CONCLUSION:** The data show that the likelihood of resource use of patients with exacerbations of asthma increases with the underlying level of severity. From these data, it is clear that better control and management of asthma exacerbations can result in resource use savings.

## PAA4

**A COMPARATIVE ANALYSIS OF EFFICACY, SAFETY AND COST-EFFECTIVENESS OF SALMETEROL AND MONTELUCAST IN THERAPY OF BRONCHIAL ASTHMA**

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**OBJECTIVES:** To compare efficacy and safety of salmeterol and montelukast in adults with chronic bronchial asthma and cost-effectiveness from payer's and social perspective. **METHODS:** The analysis was based on a systematic review. The efficacy and safety of salmeterol and montelukast were compared. Costs were estimated on the basis of current cost of medication and productivity loss in Poland. The time horizon of 12 weeks was taken. The ratio of cost difference and efficacy difference (episode-free days—EFD) was calculated in incremental analysis. **RESULTS:** The efficacy analysis showed that statistically significant higher EFD ratio is achieved with salmeterol (32%) than with montelukast (26%). Direct and indirect cost analyses of the two options show that lower costs are generated by the use of salmeterol. The use of montelukast in place of salmeterol results in smaller health benefit, and concomitantly, higher treatment costs. The use of salmeterol in place of montelukast in a period of 12 weeks in one patient is associated with gain of additional 5 days free of asthma symptoms. The estimated difference in a period of 12 weeks of administration is approximately PLN 157 (34€) and PLN 248 (54€) per patient from payer's and social perspective, respectively favouring salmeterol. The multivariate sensitivity analysis was performed and confirmed the robustness of results. **CONCLUSIONS:** Salmeterol is a dominant option in relation to montelukast in the treatment of bronchial asthma. Salmeterol should be used before administration of montelukast. Both perspectives concluded that administration of salmeterol will result in payers budget savings—PLN680 (149€) per one patient year. Conducting of prospective studies of indirect cost of asthma treatment is recommended.

## PAA5

**A COMPARATIVE ANALYSIS OF EFFICACY, SAFETY AND COST-EFFECTIVENESS OF FLUTICASONE AND MONTELUCAST IN THERAPY OF BRONCHIAL ASTHMA**

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**OBJECTIVES:** Assessment of efficacy and safety of fluticasone and montelukast in treatment of adult patients with chronic bronchial asthma and cost-effectiveness from payer's and social perspective. **METHODS:** Comparison of efficacy and safety were based on valid RCTs found in systematic reviews. Costs were estimated on the basis of current cost of medications and

productivity loss in Poland. In the incremental analysis, the ratio of social cost difference and efficacy difference was calculated. Multivariate sensitivity analysis was performed. **RESULTS:** Statistically significantly higher efficacy of fluticasone over montelukast has been demonstrated in relation to the following end points: asthma symptom score, episode-free days, and supplemental rescue medications. There is no significant difference among treatment groups with respect to exacerbations and other adverse events. Both options are safe and no difference in safety has been demonstrated. The use of montelukast instead of fluticasone results in smaller health benefit for the patients, and concomitantly, higher treatment costs. The estimated difference in a period of 24 weeks of administration is approximately PLN 733 (163€) and PLN 1401 (306€) per patient from payer's and social perspective, respectively favouring fluticasone. The use of fluticasone in place of montelukast for a period of 24 weeks in one patient is associated with gained additional 14.6 days free of asthma symptoms. Multivariate sensitivity analysis confirmed robustness of the results. **CONCLUSIONS:** Based on the conducted cost-effectiveness analysis, it may be concluded that fluticasone is a dominant option over montelukast in the treatment of bronchial asthma. Both perspectives concluded that administration of fluticasone will result in payers budget savings—PLN1596 (348€) per one patient year. Prospective studies on indirect costs of asthma treatment methods should be conducted.

## ASTHMA

## ASTHMA—Health Policy

## PAA6

**IMPACT OF A DISEASE MANAGEMENT PROGRAM ON CONTROL OF ASTHMA IN NORMANDY**

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**OBJECTIVES:** Assess whether a disease management program of asthma (DMPA) improves quality of care and reduces costs compared to standard care (SC). **METHODS:** A prospective “Before/After” quasi-experimental design was chosen. SC was observed during the first 18 months. DMPA involved training doctors in existing guidelines in asthma, implementing asthma education sessions and investments in computerised GP's data collection (with asthma template) Impact of DMPA was studied in the subsequent 18 months. Control rate of asthma (CRA) was defined according to the Canadian asthma consensus criteria, quality of life (QOL) measured by the Juniper scale and direct and productivity costs assessed from the perspective of society. The expenditure discount rate was three percent (3%). Three regions were followed in parallel, to confirm trends observed on the experimental site were due to the DMPA. **RESULTS:** A total of 32 volunteer general practitioners and 313 asthmatic patients were recruited on the experimental site, of which 145 patients took part in both phases of the study. There was an absolute improvement on the average quarterly CRA of 11% ( $p < 0.003$ ): 65% ( $\pm 3\%$ ) in the DMPA group vs. 54% ( $\pm 3\%$ ) for the SC group; a relative gain of 20%. Differences in the patient's QOL were significant in favour of DMPA ( $p < 0.05$ ) for three domains and on the overall score. Absolute reduction in the average quarterly costs reached 24% ( $p < 0.003$ ): 247€ in the DMPA group compared to 187.4€ for the SC group. Asthma drug costs were not significantly modified ( $p = 0.129$ ). Meanwhile, in the paral-

lel sample (n = 137) the average quarterly costs had increased by 13% (ns). **CONCLUSIONS:** Computerised data collection performed by the doctor provide detailed information about diagnosis, treatments, and referrals making possible the study of patient pathways and costs. DPMA is cost-effective in provision of care.

## ASTHMA

### ASTHMA—Methods and Concepts

PAA7

#### A COMPARISON OF TWO APPROACHES TO ESTIMATE ANNUAL MEDICATION COSTS IN THE KORA ASTHMA AND ALLERGY STUDY

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**OBJECTIVES:** Comparison of annual medication costs in a population-based study using a prediction formula based on 7 day medication history to cost data provided by health insurance companies. **METHODS:** The KORA Asthma and Allergy study evaluated cost of illness due to asthma and allergies in a population-based case-control design. Medication costs originated from a 7 day medication history (interview) and from health insurance data. Drugs documented per interview were assigned an average price per defined daily dose (DDD) for each standard package size group. Weekly medication costs were extrapolated by multiplying price per DDD (medium package size) by predicted length of intake according to general ATC group. For consenting subjects, all medications reimbursed by the health insurance companies for 1998 were obtained. The annual total costs as well as cost differences between disease groups were compared between both approaches. **RESULTS:** Of 1534 subjects participating in the KORA study, 1249 were insured publicly and 63.8% of those consented to release their health insurance data. Of 614 persons with prescribed medications according to insurance data, 233 (38%) reported no prescribed medications during the interview. Median (inter-quartile range) annual costs for this group were 37€ (16–103€). For the other 381 subjects (62%), annual insurance costs were 260€ (116–638€) whereas predicted costs were higher (364€; 104–863€). For subjects with asthma or allergy, predicted costs agreed better with annual costs. Costs extrapolated from interview data correlated significantly ( $r = 0.63$ ) with the annual costs. **CONCLUSIONS:** Estimation of annual medication costs for chronic disease patients from seven day medication history data is feasible and estimates of group averages are similar to full annual data from health insurance companies. For population-based samples the latter approach is logistically more difficult, is less accepted by subjects, and does not encompass costs of most of OTC drugs.

PAA8

#### COST ESTIMATION IN CLINICAL PIGGY-BACK STUDIES WITH DISCONTINUATIONS—COMPARISON OF DIFFERENT APPROACHES

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**OBJECTIVES:** Estimating costs for different pharmaceutical treatments based on data from clinical studies with discontinuation is a problem with no general solution. Especially early discontinuations are often correlated with high initial costs, which may have large impact on the estimates. A number of approaches suggested in the literature for dealing with this problem were

investigated using data from clinical studies in the respiratory field to see if a consistent pattern could be found. **METHODS:** Data from three large clinical studies (two concerning asthma, one concerning COPD) were investigated for three different approaches: PYA, Patient-Year Approach (linear extrapolation for each patient to nominal duration of study), GMI, Group Mean Imputation where missing data for a certain period is replaced by the relevant group mean for corresponding period, and GSA, Group-Sum Approach where data are summed over treatment groups, implying that data are weighted according to time in study for each patient. While the first two approaches are based on individual data and variation in estimates are easily found by standard methods, precision in GSA estimates is found by non-parametric bootstrapping. **RESULTS:** Data show that discontinuations, and especially early discontinuations due to exacerbations followed by intensive treatment, can have a substantial impact on the PYA approach, where the estimated mean cost can be twice as high compared to the other approaches. Demanding a certain time in study as qualifying for inclusion in the analysis will gradually bring the results in agreement with the GMI and GSA approach. **CONCLUSIONS:** In large clinical studies, the GMI approach may be inconvenient because of varying periods. The GSA approach in combination with non-parametric bootstrapping for finding precision in estimates is a simple and robust method.

PAA9

#### FROM SF-36 TO UTILITY SCORES: A COMPARISON OF DIFFERENT ALGORITHMS IN DIFFERENT SETTINGS

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**OBJECTIVES:** To investigate if the results of four published algorithms for calculating utility values from assessments of SF-36 are in agreement with the responses of traditional efficacy variables assessed in clinical studies in the respiratory field. **METHODS:** Data from six different randomized clinical studies, two from each of the disease areas of asthma, rhinitis and COPD, comparing two treatments, are used in the investigation. Baseline values before randomizing to study treatment are compared for the algorithms as well as change during treatment. Change during treatment is compared to the primary efficacy variable in each study. **RESULTS:** Mean utility values at baseline show a consistent pattern across disease areas with large individual variation, with utility values ranging from 0.28 to 0.99 and with mean values ranging from 0.58 to 0.82. Change during treatment is small (0.00 to 0.11) and in most cases statistically non-significant when comparing treatments. Correlation with clinical efficacy is of moderate magnitude. **CONCLUSION:** The two utility measures based on Standard Gamble or TTO seems to be slightly better than those based on VAS or linear regression. The pattern across the different disease areas is consistent for the different algorithms.

## ARTHRITIS

### ARTHRITIS—Cost Studies

PARI

#### THE BURDEN OF ANKYLOSING SPONDYLITIS IN AUSTRALIA: AN EPIDEMIOLOGICAL AND COST OF ILLNESS MODEL

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