**ASTHMA—Clinical Outcomes Studies**

**LEAVING AGAINST MEDICAL ADVICE (LAMA) IN ASTHMA EXACERBATION: CHARACTERISTICS AND DETERMINANTS OF LEAVERS**

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**OBJECTIVE:** Leaving against medical advice is a frustrating event for physicians and medical staff and a costly behavior for the patients. Studies have shown that in asthma exacerbation, this decision by patients can lead to death. This study purports to assess the determinants and characteristics of LAMA asthmatic patients.

**METHODS:** Healthcare Cost and Utilization Project (HCUP) data are used. The study focuses on years 1997–2003 and only 2003 results are reported. Four International Classification of Diseases, 9th Revision for asthma are considered: Chronic obstructive asthma with acute exacerbation (493.22), asthma without status asthmaticus (493.90), asthma with status asthmaticus (493.91) and asthma with acute exacerbation (493.92). Results are reported based on these ICD-9 codes respectively.

**RESULTS:** Though the overall national LAMA rate is less than one percent (0.84), it is found that LAMA is more prevalent in asthmatic patients who are uninsured (2.9, 4.1, 4.1, and 5.0%) compared with Medicare and Commercial insurance rates that are both less than 1% in this database. LAMA patients tend to have low income ($0–25,000) (1.7, 1.4, 1.5, and 2.7%) compared to not low income ($25,000+) (1.2, 1.0, 1.2, and 1.6%), and are Medicaid recipients (2.9, 1.3, 1.3 and 2.7%). The demographic characteristics of LAMA patients showed that prime age asthmatics (ages 18–44) have the highest rates (3.3, 3.4, 4.5, and 4.8%), followed by middle age adults (ages 45–64) (1.8, 1.5, 2.1, and 2.1%). The very young (ages < 1 and 1–17) and the older adults (ages 65+) have minimal LAMA rates. Males have slightly more LAMA rates than females (2.2, 1.1, 1.2, 2.5%) vs. (1.0, 1.1, 1.4, 1.8%) respectively.

**CONCLUSION:** Leaving AMA, a surrogate marker for non-adherence/non-compliance in hospitalized patients coincides with poverty. Therefore, educational measures used to remediate these behaviors can be used to help these patients.

**DRUG ADVERSE EVENTS MODIFY THE TREATMENT AND COMPLIANCE OF ASTHMA PATIENTS**

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**OBJECTIVE:** A substantial proportion of adverse drug events (ADE) are not reported because it is deemed to be either too well known or the association between the drug and the adverse effect is too doubtful. However, in clinical practice, mild to moderate ADEs are common consequently increasing the costs of health care and reducing the compliance of the patients.

**METHODS:** To analyze the patient or physician reported ADEs in asthma we are in the process of screening the medical records and drug purchase data for 1000 patients. The cohort consists of a random sample of patients identified using the discharge registry of the Helsinki University Hospital.

**RESULTS:** Our initial results in the patient cohort (mean age of 52, range from 24 to 65 years and the proportion of females 62%) show that ADEs were reported for 17% of the patients during the follow-up period of 5–10 years. Fifty-six percent of the reported ADEs were due to asthma drugs and 64% of those led to changes in the patient’s medication. The medication was discontinued in 14% and the dose reduced in 14% of the cases. In 36% the medication was discontinued and replaced with another product. Hospitalizations due to ADE complications were also identified. In addition, 3% of the patients were diagnosed with osteoporosis. All of them had used per oral steroids, either only for asthma or for asthma and a simultaneous autoimmune disease. Seven percent of patients with LABA/SABA medication (and without any diagnosed heart condition) were treated due to tachyarrhythmias. Twenty-four percent of the patients with simultaneous inhaled corticosteroid therapy were diagnosed with oral Candida infection.

**CONCLUSIONS:** Our data shows that even mild ADEs have a significant impact on the chosen therapy, the long term medical outcome, and the costs of health care.

**ASTHMA—Cost Studies**

**ECONOMIC EVALUATION OF SYMBICORT® (BUDESONIDE/FORMOTEROL) SINGLE-INHALER MAINTENANCE AND RELIEVER THERAPY (SMART) IN ASTHMA**

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**OBJECTIVES:** To compare the cost-effectiveness of budesonide/formoterol in a single inhaler used as maintenance and reliever medication (Symbicort SMART) versus clinician directed titration of maintenance fluticasone/salmeterol (Advair) plus as-needed salbutamol in controlling asthma in adults and adolescents.

**METHODS:** An economic evaluation was conducted based on the results of a large (N = 2143), open-label, randomized, controlled effectiveness trial in which health resource utilization was prospectively collected. Primary outcome measurements included time to first exacerbation and number of severe exacerbations. Costs included direct medical costs (physician/emergency room visits, hospitalizations, asthma drug costs) and productivity (absenteeism). The time horizon was one-year which corresponded to the duration of the trial. Prices were obtained from 2005 Canadian sources. Both health care (HC) and societal (Soc) perspectives were considered. Deterministic univariate sensitivity analyses were conducted.

**RESULTS:** In the clinical trial, Symbicort was superior to Advair with respect to the number of exacerbations, lung function and use of as-needed rescue. The annualized rate of severe exacerbations was 0.24 in the Symbicort arm and 0.31 in the Advair arm (p = 0.0025). From the HC perspective, the mean cost per patient-year was $1315 in the Symbicort arm versus $1541 in the Advair arm. From the Soc perspective, it was $1538 for Symbicort and $1854 for Advair. Symbicort 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.

**CONCLUSIONS:** The strategy of Symbicort SMART which allows the combination of budesonide/formoterol to be used as both maintenance and reliever medication is dominant over a strategy of clinician directed titration of Advair (fluticasone/salmeterol) therapy.

**ECONOMETRIC MODELING IN CHRONIC ASTHMA ALLOWS COMPARISONS BETWEEN DIFFERENT THERAPY GROUPS**

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**OBJECTIVES:** We evaluated the severity of chronic asthma and the resulting economic burden by assessing the use and costs of...