CONCLUSIONS: The new treatment guidelines were implemented on more patients by year 2000. More males were found to be on appropriate therapy than females.

DEVELOPMENT OF A PROSPECTIVE, NON-RANDOMIZED PATIENT REGISTRY TO MEASURE REAL-WORLD CLINICAL, ECONOMIC, AND HUMANISTIC OUTCOMES

Perry BM, Legorreta AP, Darin RM, Pendergraft TB, Chernicoff HO, O’Connor RD

1Health Benchmarks, Inc, Woodland Hills, CA, USA; 2UCLA, Los Angeles, CA, USA; 3GlaxoSmithKline, Research Triangle Park, NC, USA; 4UCSD, San Diego, CA, USA

OBJECTIVES: Randomized clinical trials (RCTs) are the gold standard for determining efficacy of pharmaceutical treatments, but findings from RCTs are often difficult to translate into real-world (non-randomized) environments. This observational registry was designed to identify real-world outcomes among asthmatic patients receiving various treatments for asthma. The registry protocol mirrored a previous RCT and was designed to provide confirmatory evidence for generalizability of prior research findings.

METHODS: Four hundred eighty-four physicians from 13 states, including the west, central, northeastern, southeastern and midwestern areas of the U.S., were recruited and trained in registry procedures. Patients were eligible if they were 15 years or older and required a change in asthma control therapy as determined by their physician during a regularly scheduled office visit. No recruitment was allowed to protect the observational status of the registry. Asthma Control Questionnaire (ACQ), Asthma Quality of Life Questionnaire (AQLQ), medication satisfaction, and productivity end point data have been obtained from baseline and will be obtained from 1-month, 3-month, 6-month and 1-year surveys. Utilization and cost data for inpatient, outpatient, emergency room, and prescriptions will be obtained from the individual’s health insurance claims data.

RESULTS: Eighty-one percent of physicians were general internists, and 19% were allergists or pulmonologists. Sixty-seven percent of all physicians had no previous research experience. Over 1400 patients entered the registry during the enrollment period (01/2002–12/2002). Baseline characteristics were well balanced across the four cohorts despite lack of randomization. Analysis of baseline self-reported ACQ and AQLQ individual questions identified no statistically significant differences between cohorts. Follow-up survey results will be reported in future analyses.

CONCLUSIONS: Non randomized registry studies can complement RCTs by providing an ample well balanced sample size that is representative of real-world practice and makes available rapid feedback on clinical and economic outcomes.

CLINICAL EFFECTIVENESS OF Budesonide and Formoterol in a Single Inhaler in Patients with Asthma—An Audit in UK General Practice

Emmas CE, Beaumont SD

1AstraZeneca UK Ltd, Luton, Bedfordshire, United Kingdom; 2AstraZeneca UK, Luton, Bedfordshire, United Kingdom

OBJECTIVES: Randomised controlled clinical trials demonstrate how well treatments work under ideal conditions (clinical efficacy). However, once efficacy has been established there is a need to show how well treatment work in the less ideal conditions of normal clinical practice (clinical effectiveness). This study is the first to demonstrate the clinical effectiveness of budesonide/formoterol in a single inhaler in the treatment of asthma in UK general practice.

METHODS: Patients with inadequately controlled asthma were identified following a review of their patient notes and a consultation with a clinical nurse specialist using criteria agreed with the general practitioner. These patients were referred to the doctor for a treatment review and a subsequent assessment at six months.

RESULTS: As a result of the review 119 patients, previously treated with ≥200mcg inhaled corticosteroid daily, received budesonide/formoterol (80/4.5mcg or 160/4.5mcg 1–2 puffs twice daily) in a single inhaler for the first time. Improvements were observed in all measures of health outcomes. There was a significant increase in the mean peak expiratory flow between initial (415L/min) and 6 month (447L/min) assessments (p < 0.0001). Patients reported a greater proportion of symptom-free days (p < 0.0001) fewer episodes of symptoms in the day (p < 0.0001) and at night (p < 0.0001). They reported a reduced use of reliever medication (p < 0.0001) and a reduction of exercise induced asthma (p < 0.0001). There was a significant decrease in routine asthma-related primary care consultations (p < 0.0005) and fewer emergency GP visits (p < 0.001). Patients understood their treatment better (p < 0.0001), were concerned about their asthma for less of the time (p < 0.0001), and 98% of patients felt they had benefited from taking part in the programme of which this change in therapy was a part.

CONCLUSIONS: In this group of asthmatic patients, inadequately controlled on ≥200mcg inhaled corticosteroid daily, budesonide/formoterol in a single inhaler provided significant improvements, which demonstrate superior clinical effectiveness.