966 Cost Savings Parallel Improved Outcomes in Severe Asthma Utilizing Respiratory Care Practitioners

Celeste Kivler, Claudia M Vukovich, Scott A Schinaman, Stephen W Kutler, Terry Vierra, Stanley M Naguwa, Samuel Louie UC Davis, Sacramento, CA

High-cost patients that were identified by primary care physicians or health care system utilization were referred to the UC Davis Asthma Network (UCAN). UCAN is a multidisciplinary clinical service utilizing Respiratory Care Practitioners (RCPs) to manange poorly controlled asthma patients in a large university health system serving an urban population. RCPs provide acute care in the Emergency Department (ED) along with assessment and education of patients with moderate to severe persistent asthma in outpatient UCAN clinics. From May 1999 to August 2001, UCAN prospectively treated 162 patients in outpatient clinics by referral. 132 of these patients have been tracked for more than 6 months. 57.4% had severe persistent disease, 34.6% moderate persistent and 8% mild persistent. This group (134 women, 29 men; age range 16 to 80 years) accounted for 318 ED visits and 114 hospitalizations for asthma in the 12 months prior to UCAN involvement. Outpatient education and combination drug therapy reduced the need for acute ED care to 31 visits, a reduction of 90.3% and hospitalizations to 4, a reduction of 96.5%. Direct cost savings from reduced health care resource utilization were $157,850 and $812,350, respectively. All patients were issued a written asthma action plan, given an allergy evaluation along with combination drug therapy, i. e. inhaled corticosteroid (iCS), i. e. fluticasone or budesonide ± salmeterol or formoterol ± montelukast. Only 5% of patients entered UCAN clinic on a leukotriene-modifying drug; 73% left UCAN clinic on montelukast in combination with first-line iCS therapy ± salmeterol or formoterol. Perception of asthma control showed marked improvement as measured by the Asthma Quality of Life Questionaire and State/Trait Anxiety Index (E.L.Juniper). Data analysis was conducted utilizing a multiple analysis of variance (MANOVA) showing a mean change of 1.252(p=.0001). From September 1999 to August, 2001, UCAN prospectively treated 1,313 patients in the ED (835 women, 478 women). 410 patients (31.5%) required hospitalization (367 to hospital ward and 43 to the ICU) despite aggressive asthma treatment. However, 900 patients (68.5%) were discharged home. No deaths occured in the period of study. Cost savings and improved clinical outcomes validate the important role RCPs have in primary care intervention in the UC Davis Health System. UCAN is a viable managed care model for improving the quality and value of asthma care while achieving significant economic savings through patient education and improvements in healthcare navigation and utilization.

967 Insufficient Power and Type II Error Analyses in Clinical Trials Published in Two Major Allergy and Immunology Journals

Asif I Khan, Howard R Sloan§, Denise Guanzon§, Bela Faltay§, Ashley M Brawley§, Lynda Schneider¥, Bernard Silverman§* *Long Island College Hospital, Brooklyn, NY §Long Island College Hospital, Brooklyn, NY ¥Childrens' Hospital/Harvard Medical School, Brooklyn, NY

Many studies in the allergy literature seek to demonstrate that a new product is equivalent to old products, i.e. that there are no clinically significant differences (CSDs). However, it behooves physicians to be cautious about the interpretation of results of these studies. As happens so often, some clinical trials published in major allergy journals contain so few patients that statistically significant differences (SSDs) most likely would not be found. Many more patients would be required to prove that there were no CSDs. Often, the power of the test was very low, or in many instances was never performed. The Power of a test is the probability of finding a statistically significant difference when the difference between population means equals or is less than a predetermined value - usually selected as 0.05 in biomedical studies. A power analysis is a vital tool in any clinical trial design. It provides an estimate of the number of subjects required to detect a CSD between treatment groups. Whenever a study finds no SSDs between population means, a Type II (beta) error analysis (BEA) should be performed retrospectively to determine how likely the study was to find such a difference. If the likelihood is less than 70-80%, the study should be repeated with more subjects. We evaluated a total of 28 consecutive original articles selected from two major Allergy journals published in the U.S.A.; the time period was Jan. 2001 through June 2001. To be included in the study, an article had to describe a statistically analyzed therapeutic intervention. Of the 28 articles, 19 (68%) received support from a pharmaceutical company, either via a grant or direct financing. In 11 of the 28 (39%), a power analysis was performed before the study was initiated. Of the 19 pharmaceutical-sponsored trials, 9 (48%) failed to perform a pre-study. Nonetheless, 23 articles found a SSD between the therapeutic arms. In 3 of the 5 of the studies that showed no SSD between the means of the treatment groups, we found that the beta errors were so large (at least 0.5 and in many cases 0.9) so as to vitiate the authors' conclusions. In the fourth paper, data were not presented in a fashion that permitted performance of a BEA; however, given the small number of patients (n=32), it seems extremely unlikely that a BEA would be less than 0.8. The fifth paper contained no data for the control group; a beta error could therefore not be performed. Once again, this study contained so few patients, that it is unlikely that the BEA would have been less than 0.7. In conclusion, we report that in two major allergy journals, there is a substantial deficit in the number of power and beta error analyses performed. This finding brings into question the validity of clinical trials lacking these analyses when no SSD between therapeutic arms is demonstrated.

968 Knowledge of the Peak Flow Meter in Asthmatic Children and Teenagers

Martha Elvia Martínez, Sandra Nora González, Carlos Canseco, Alfredo Arias Hospital University Dr José Eleuterio González, Monterrey, Mexico

The correct control of an asthmatic children and teenagers substantially improve his quality of life. The use of the peak flow meter permits to monitor the pulmonary function and helps to identify the risk of asthma and permit the control of his disease. The objective of this paper was to gather information about the use of the peak flow meter in a group of asthmatic children and teenagers. It was a descriptive and observational study in 81 asthmatic children and teenagers who attended a summer camp for asthmatic patients. They answer a questionary in order to know the knowledge that they had about the peak flow meter's use.The same questionary was applied to the children's parents. The age of the group studied rank from 5 to 18 years. 44 of them were between 5 to 10 years (54.3%). 31 of them were between 11 to 14 years (38.3%) and 6 of them were older than 14 years (7.4%). Of all the 81 children and teenagers, 64 of them knew about the peak flow meter. In spite of the knowledge only 38 of them (46.9%) have used it in a least one occasion and 20 of them (24.7%) used it ambulatory (16 of them used it when they feel bad and 4 of them used it every day) but only 9 of this children knew the correct way to use it, to interpret the results and knew what the normal peak flow was. All of this children and teenagers were under medical control. 7 of them didn't specify the speciality of the doctors and the rest: 54 (66.7%) were been attended by allergists, 11 (13.6%) by pneumologists and pediatricians and 9 (11.1%) by general and family doctors. Independently of the speciality of their doctors the average of this children and teenagers that didn't use the peak flow meter in their control asthma was always over than 50%. In spite that all this children and teenagers were on medical care, the knowledge of the use of the peak flow meter was not enough to take advantage of its use.

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