translator, project manager, interviewer, and survey research expert evaluated all conceptual, linguistic and stylistic issues that emerged from the debriefings. **RESULTS:** Overall, the translations were well understood by subjects in all languages. Subjects in several countries had mild difficulty understanding the terms "Nocturia", "preoccupied", and "quality of life", although these concepts were translated appropriately in all languages. The term "concentrate" ("konsantre") also posed difficulty for Turkish translators and subjects. As there is no other contextually appropriate Turkish word for this concept, no change was made to the Turkish translation. **CONCLUSION:** The 10 translations of the NQoL instrument are linguistically and conceptually equivalent to the original English (UK) questionnaire. Linguistic validation of the translations will facilitate inter-country comparisons of nocturia and the pooling of data in multi-country studies.

PUK19

LINGUISTIC VALIDATION OF THE ICIQ MALE SEXUAL MATTERS ASSOCIATED WITH LOWER URINARY TRACT SYMPTOMS QUESTIONNAIRE (ICIQ-MLUTSSEX) IN 7 LANGUAGES

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OBJECTIVES: The objective of this study was to assess the linguistic validity of 7 translations of the ICIQ-MLUTSsex questionnaire. This self-administered questionnaire was developed in English (UK) to measure health-related quality of life, symptom bother, and the impact of lower urinary tract symptoms on sexual matters in male patients. **METHODS:** Harmonized translations of the questionnaires were created through an internationally accepted reiterative process of forward and back translations and review by a survey research expert and local study users for the following languages: Afrikaans (South Africa), English (Canada), English (South Africa), English (USA), Korean (Korea), Slovak (Slovakia), and Spanish (Mexico). All translators were native speakers of the target language and fluent in English (UK). A demographically diverse sample of 5 subjects in each language reviewed the harmonized translations and was subsequently debriefed by trained bilingual interviewers, fluent in both English (UK) and the target language. A team consisting of the original translators, back translator, project manager, interviewer, and survey research expert evaluated all conceptual, linguistic and stylistic issues that emerged from the debriefings. **RESULTS:** Overall, the translations were very well understood by subjects in all languages, although one concept in the questionnaire caused confusion in two English variants (South Africa and Canada). Subjects noted the ambiguous referent for "this", i.e., whether "this" refers to "sex life" or "no sex life" in the question "If you have no sex life, how long ago did this stop?" This ambiguity was not identified as a problem in the non-English translations because the translations were constructed to elicit information about the cessation of sexual activity. **CONCLUSION:** The 7 translations of the ICIQ-MLUTSsex instrument are linguistically and conceptually equivalent to the original English (UK) questionnaire. Linguistic validation of the translations will facilitate inter-country comparisons of OAB and the pooling of data in multi-country studies.

PUK20

IMPACT OF SOLIFENACIN ON QUALITY OF LIFE, MEDICAL CARE USE, WORK PRODUCTIVITY, AND HEALTH UTILITY IN THE ELDERLY

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OBJECTIVES: We assessed changes in health-related quality of life (HRQoL), resource utilization, work and activity impairment, and health utility among elderly OAB subjects receiving 12 weeks of solifenacin succinate (SOL) therapy, after switching from tolterodine tartrate extended-release (TOL) due to residual urgency episodes. **METHODS:** This was a prospective, multicenter, open-label US study assessing the efficacy and safety of SOL in treating OAB. Subjects ≥18 years, who had switched from TOL to SOL due to residual urgency episodes (≥3/24 hours), with or without urge incontinence, usually with frequency and nocturia, were enrolled. This analysis focused on two elderly cohorts (65 to 74, and >75 years old). Outcomes were measured using the Overactive Bladder Questionnaire (OABq), Work Productivity Assessment Index (WPAI), Medical Care Use Index (MCUI), and the Health Utilities Index (HUI), administered at Pre-Washout (Visit 2) and Post-Washout Week 12 (Visit 7). **RESULTS:** 103 subjects aged 65 to 74 years and 83 subjects >75 years met analysis criteria. Subjects in both age groups experienced significant improvement on the OABq symptom bother scale, all four HRQoL subscales (concern, coping, social interaction, sleep) and total HRQoL score. A significant reduction in physician office visits was observed in both age groups on the MCUI, and the 65 to 74 year old age group used significantly fewer pads and diapers. Activity impairment assessed using the WPAI was also significantly reduced in both groups. Although few subjects were working, those in the 65 to 74 year old group who were working were significantly less impaired by OAB at work. There were no significant differences in HUI scores in either age group. **CONCLUSION:** Overall, SOL improved symptom bother, HRQoL, work productivity, the ability to participate in activities, and reduced medical care use in elderly subjects with OAB.

POSTER SESSION II

ALLERGY/ASTHMA—Clinical Outcomes Studies

PAA1

RELATIONSHIP BETWEEN MEASURES OF ASTHMA CONTROL AND COMBINATION THERAPY TREATMENT REGIMENS IN SEVERE OR DIFFICULT-TO-TREAT ASTHMA

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OBJECTIVES: Current guidelines recommend inhaled corticosteroids (ICS) as first-line therapy in persistent asthma and the addition of long-acting ß-agonists (LABAs) in patients with moderate-to-severe disease. Our study objective was to assess the response of high-dose salmeterol/fluticasone combination (SFC) and low-dose SFC compared to a control group using a vast array of asthma-related health outcomes in a large cohort of patients with severe or difficult-to-treat asthma. **METHODS:**

Three adult (≥18 years) cohorts from The Epidemiology and Natural History of Asthma: Outcomes and Treatment Regimens (TENOR) 3-year observational study were defined: patients on SFC Low-Dose (100/50 or 250/50 µg), patients on SFC High-Dose (500/50 µg), and patients on other medications (including salmeterol and fluticasone), but not on SFC. Using standard regression methods, we computed unadjusted and propensity score adjusted differences in 24 month outcomes between the treatment cohorts. **RESULTS:** After adjustment for confounding, the Low-Dose SFC cohort had higher asthma-related quality of life (P = 0.0026), fewer asthma control problems (P = 0.0001), similar rates of exacerbations (P = 0.8932), marginally higher FEV1 (P = 0.0777) and lower odds of having severe asthma (P = 0.0454) compared with controls (patients never on SFC). After adjustment for confounding, the High-Dose SFC cohort had no difference in asthma-related quality of life, asthma control problems, or exacerbation rates (P = 0.1879, 0.3015, 0.3560 respectively), higher FEV1 (P = 0.0011), and higher odds of having severe asthma (P = 0.0137). **CONCLUSIONS:** The results support evidence that some asthmatics achieve better control while taking low-dose SFC, but also suggest that high-dose SFC fails to provide clinically significant benefit in terms of most asthma-related health outcomes when compared to similar patients not taking high-dose SFC. These findings may highlight an unmet need in severe or difficult-to-treat asthma and call for alternative therapeutic approaches in those unable to attain asthma control with or without SFC.

PAA2

EXACERBATION RATES FOR SINGLE VS. DUAL CONTROLLER THERAPY FOR MILD-PERSISTENT ASTHMA

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OBJECTIVES: Asthma exacerbation rates in a large Midwest health plan were compared for single and dual controllers. **METHODS:** The asthma cohort included 788 patients prescribed at least 1 SABA and 2 controller prescriptions during a 6 month intake period, with mild persistent severity defined by rates of ED or hospital admission, SABA and OCS fills. Patients older than age 55, diagnosed with COPD or prescribed more than one type of controller were excluded. Exacerbations were defined by Kaplan-Meier, as time to asthma-related hospital or ED admission. Significance was further tested using Cox proportional hazards stratified by age, gender, control, severity, and adherence during a six-month pre-index period. **RESULTS:** Leukotriene modifiers (LM) were prescribed as a single controller for 38% of patients, inhaled corticosteroid (ICS) for 27%, and dual controller (DC, fluticasone/salmeterol) for 36%. DC were prescribed most often in older adults (55%), while LM were most often prescribed in children (62%). Asthma severity as defined by the number of SABA and OCS fills and exacerbations in the intake period was similar for the three cohorts. Asthma control (>4x controller/SABA) was highest for LM (89%). Controller adherence rates were lowest in the ICS cohort with 76% filling <4 prescriptions compared to 53% for DC and 44% for LM. Two-year exacerbation rates were 19% for ICS, 20% for LM and 18% for DC (P = 0.99). In the multivariate model, older adults less likely suffered exacerbations compared to children (hazard ratio = 0.63, 95% CI 0.44–0.91, P = 0.013). **CONCLUSION:** An algorithm was developed to identify patients with mild-persistent asthma in administrative claims. Multivariate models were constructed to control for demographics, asthma severity, control and adherence rates. Kaplan-Meier statistics indicates exacerbation rates were highest among children, but were similar in patients receiving LM, ICS or DC.

PAA3

EVALUATION OF RISK FACTORS AND PREDICTORS OF HEALTH OUTCOMES AMONG PERSONS WITH ASTHMA

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OBJECTIVES: To examine risk factors associated with health care utilization in Arizona Medicaid patients with asthma. **METHODS:** Data were obtained from Arizona Medicaid between 1/1/2002 and 12/31/2003. Inclusion criteria consisted of persons with an asthma diagnosis (ICD9-CM 493.xx), 5–62 years of age; and were new users of inhaled-corticosteroids (ICS), combination ICS+long-acting beta-agonist, or leukotriene-modifiers. Factors examined included age, geographic location (urban/rural), race/ethnicity (White, non-Hispanic Black, Hispanic, other), medication adherence, pre-period short-acting beta-agonist use (SABA), and co-morbidities. Utilization measures examined included post-period SABA use, exacerbations measured by emergency-room or hospital visits, asthma-related and total health care costs. Analyses for utilization measures were performed using negative binomial, logistic regression, and generalized linear modeling gamma-family, log-link, respectively. **RESULTS:** A total of 3013 subjects met inclusion/exclusion criteria and had a mean age (+SD) of 24.7 + 13.7 years. Urban residents were 54% more likely to have an exacerbation than rural residents (odds ratio-OR 0.46, 95%CI: 0.30–0.79). Age (years 18–39) was a significant predictor across all analyses: SABA use (incidence rate ratio-IRR 1.24, 95%CI: 1.06–1.44); exacerbations (OR 2.22, 95%CI: 1.34–3.68); mean asthma cost ($702.47, 95%CI: $600.07–822.34); mean total health care cost ($5445.67, 95%CI: $4852.18–6111.76). Age (years 40–62) significantly predicted mean total health care cost: $5662.88, 95%CI: $4814.67–6660.53. Males were 47% less likely to have an exacerbation than females (OR 0.53, 95%CI: 0.30–0.91). Exacerbations were not different between race/ethnicity categories. Predicted mean asthma-related costs were not different between Whites ($590.65, 95%CI: 508.80–565.68), Blacks (637.68, 95%CI: 499.10–814.75), or Hispanics (534.79, 95%CI: 466.14–613.55). **CONCLUSION:** Results of these analyses found urban areas had higher rates of asthma-related hospital visits compared to rural counties, but no significant difference in asthma-costs between urban and rural areas. Persons with asthma aged 18–39 had higher rates of asthma-related emergency-room visits/hospitalizations and costs than those aged 5–17 and 40–62. Race/ethnicity was not a significant predictor of outcomes or asthma-related costs.

PAA4

ADVERSE DRUG REACTIONS IN ECONOMIC EVALUATIONS

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OBJECTIVES: To review the health economic literature for drugs that have since been withdrawn for safety reasons. To assess the cost-effectiveness of the non-sedating anti-histamine, terfenadine (withdrawn in 1998 for its cardiotoxicity) compared with chlorpheniramine, a sedating anti-histamine which is still available. **METHODS:** Literature searches of economic evaluations of drug that have been withdrawn since 1980 were conducted. A decision analysis comparing terfenadine with chlorpheniramine was developed. Observational data were obtained for estimates of the incidence of ventricular dysrythmias, the incidence of serious injuries as a consequence of sedation with chlorpheniramine, and the risk of death resulting from arrhythmias or serious injuries. Health state utilities and data on