

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, multi-center, open-label US study assessing the efficacy and safety of SOL in treating OAB. Subjects  $\geq 18$  years, who had switched from TOL to SOL due to residual urgency episodes ( $\geq 3/24$  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  $\beta$ -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:**