OBJECTIVES: To evaluate the perceived state of health (PSH) of renal transplant N = 359. METHODS: The differences in PSH according to sex are presented here for patients included to date at all centres in the study. The analysis corresponds to the base moment, when they are on the transplant waiting list. A generic PSH profile, the SF-36 Health Questionnaire and an index, EQ-5D are applied to each patient. To evaluate the differences with respect to sex in both measurements, the Student-t test was used for independent samples and the chi-squared test for contingency tables.

RESULTS: For the whole sample, the PCS score was 42.09 8.6, MCS 46.6 11.5 and VAS 60.1 17.4. Females had worse PSH than males on 7 of 8 dimensions of SF-36 (the exception being Social Functioning) and in the two summary scores: PCS (40.2 9.1 in females, 43.3 8 in males) and MCS (44.9 11.7 vs. 47.7 11.2) (p < 0.05). With regard to EQ-5D, females showed a similar score to males in VAS (58.2 18.1 vs. 61.4 16.9), but poorer scores in 4 of the 5 dimensions (except in personal care): mobility (p = 0.047), everyday tasks (p = 0.0001) and anxiety-depression (p = 0.006). The PSH of patients of both sexes on renal transplant waiting lists at the centres studied is worse than that to be expected in the general population as regards physical health (score under 45 points), but similar as regards mental health (score over 45 points). VAS does not appear to be a good measurement of PSH as it oversimplifies, including as it does physical and mental aspects in a single index.

CONCLUSIONS: Among these patients, the PSH of females is clearly worse than that of males, as is also the case in the general population, demonstrating the need for standardisation with respect to sex of scores on PSH questionnaires.

COMPARISON OF THE PRO ENDPOINTS FOUND IN LABELING CLAIMS OF URINARY INCONTINENCE DRUGS WITH THOSE RECOMMENDED BY THE CORRESPONDING EMEA NOTE FOR GUIDANCE

Caron M1, Emery MP2, Acquaro C3, Marquis P3, Pault E4
1Mapi Research Trust, Lyon, France, 2Mapi Research Institute, Lyon, France, 3Mapi Research Institute, Lyon, France, 4Map VALUES USA, Boston, MA, USA

OBJECTIVES: Compare the PRO endpoints used in the approval of medicinal products for urinary incontinence, which led to a PRO labeling claim, with those recommended by the EMEA note for guidance on the clinical investigation of medicinal products for the treatment of urinary incontinence (CPMP/EWP/18/01 final).

METHODS: The PROLabels database is a unique on-line tool which collects information on the medicinal products for which the FDA and/or the EMEA have granted a PRO labeling claim. Using this database we searched the products with a urinary incontinence indication, and approved by the European Commission through the centralized procedure. For each drug, we analyzed the endpoints used in the clinical studies to assess treatment efficacy. These endpoints were then compared to those recommended by the CPMP guidance for the treatment of urinary incontinence.

RESULTS: Three products have been retrieved, for which a marketing authorization in Europe to treat urinary incontinence was granted; all of which have been approved between June and October 2004. For the three products, the clinical outcomes measures used for evaluation included subjective outcome measures and quantification of symptoms (i.e. diaries and quality of life instruments), in accordance with the CPMP guidance. Only pad weighing tests were not used in these studies. In all 3 cases, quantification of symptoms resulted in a PRO claim. Quality of life assessment generated a labeling claim for two products, and subjective outcomes (global improvement) for one.

CONCLUSIONS: In the evaluation of medicinal products for urinary incontinence, there is a close adherence to the guidance concerning the choice of study endpoints, with different rates of success concerning the PRO claims obtained. The PROLabels database has proven its usefulness in retrieving the PRO endpoints used in clinical studies for products approval in a specific indication and in comparison to the guidance.

IMPACT OF OVERACTIVE BLADDER ON FREQUENCY OF SEXUAL ACTIVITY AND SEXUAL SATISFACTION IN WOMEN: RESULTS FROM THE EPIC STUDY

Irwin DE1, Milsom I2, Reilly K3, Hunskar S4, Kopp Z5, Herschorn S6, Coyne KS7, Kelleher C7, Arribani W8, Hampel C9, Abrams P10
1University of North Carolina, North Carolina, NC, USA, 2Sahlgrenska Academy at Göteborg University, Göteborg, Sweden, 3Pfizer, Inc, New York, NY, USA, 4University of Bergen, Bergen, Norway, 5University of Toronto, Toronto, ON, Canada, 6United BioSource Corporation, Bethesda, MD, USA, 7St. Thomas’ Hospital, London, UK, 8University of Padova, Padova, Italy, 9Johannes-Gutenberg-Universität, Mainz, Germany, 10Southmead Hospital, Bristol Urological Institute, Bristol, UK

OBJECTIVES: To evaluate the impact of overactive bladder (OAB) on the frequency of sexual activity and sexual enjoyment in women.

METHODS: A population-based telephone survey was conducted in Sweden, Italy, Germany, the UK, and Canada to evaluate the prevalence and burden of OAB symptoms using current International Continence Society definitions. A nested case-control analysis was performed on data collected from women with OAB (cases, n = 995) and without OAB (controls, n = 1524). Survey respondents reported whether they experienced a decrease in sexual activity or enjoyment of sex owing to urinary symptoms and whether they had physician-diagnosed depression. Factors influencing sexual activity and sexual satisfaction were analyzed using logistic regression.

RESULTS: Among participants aged ≤50 and >50 years the following reported being sexually active during the past 12 months, respectively: 78% and 41% of controls, 74% and 36% of cases without incontinence, and 74% and 35% of cases with incontinence. Cases were significantly more likely to report decreased sexual activity caused by urinary symptoms than were controls among respondents aged ≤50 (odds ratio [OR] = 4.3, 95% confidence interval [CI] = 2.4–7.7) and those aged >50 years (OR = 2.6, 95% CI = 1.2–5.2), after controlling for incontinence and depression. Among sexually active participants (n = 1420), OAB cases were significantly more likely than were controls to report decreased sexual enjoyment due to urinary symptoms than were controls ≤50 y: OR = 5.8, 95% CI = 3.0–11.4; >50 y: OR = 3.1, 95% CI = 1.1–8.9.

CONCLUSIONS: This is the first multinational, population-based study to assess the impact of OAB on sexual activity and enjoyment in women. Women with OAB were significantly more likely than were controls to report decreased sexual activity and enjoyment due to urinary symptoms, even after adjusting for incontinence and depression. The impact of OAB on sexual activity and enjoyment appeared greatest in younger women (≤50 years of age).

LINGUISTIC VALIDATION OF THE OVERACTIVE BLADDER QUESTIONNAIRE (OAB-Q), OVERACTIVE BLADDER SHORT FORM QUESTIONNAIRE (OAB-Q SF), AND OAB ASSESSMENT TOOL (OAB-V8) IN 4 LANGUAGES

Reilly K1, McKown S2, Gawlicki M3, Coyne KS4
1Pfizer, Inc, New York, NY, USA, 2Corporate Translations, Inc, Chicago, IL, USA, 3Corporate Translations, Inc, East Hartford, CT, USA, 4United BioSource Corporation, Bethesda, MD, USA

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OBJECTIVE: The objective of this study was to evaluate the linguistic validity of new translations of the following instruments: OAB-q, OAB-q SF, and OAB-V8. These self-administered questionnaires were developed in US English to measure health-related quality of life and symptom bother in patients with overactive bladder (OAB). 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 four languages: Afrikaans, Chinese (Taiwan), English (South Africa), and Slovak. All translators were native speakers of the target language and fluent in US English. A diverse sample of 5 subjects in each language reviewed the harmonized translations and was subsequently debriefed by trained bilingual interviewers, fluent in both US English and the target language. A team consisting of the original translators, back translator, project manager, interviewer, and survey research consultant evaluated all conceptual, linguistic and stylistic issues that emerged from the debriefings. RESULTS: For all languages, translation of concepts such as “frustration”, “anxiety”, and “worry” proved challenging and required group discussion, testing, and revision to achieve the subtle distinctions presented in the original questionnaires. Certain concepts, such as “none of the time”, “with little or no warning”, and “urine loss” were determined to be unacceptable when translated literally. These phrases were revised to be more culturally appropriate. CONCLUSIONS: The four translations of the OAB-q, OAB-V8 screening, and OAB-q SF instruments are linguistically and conceptually equivalent to the original US English questionnaires. Linguistic validation of the translations will facilitate inter-country comparisons of OAB and the pooling of data in multi-country studies.

PUK26

LINGUISTIC VALIDATION OF THE OVERACTIVE BLADDER SATISFACTION QUESTIONNAIRE (OAB-S) IN 13 LANGUAGES

Reilly K1, McKown S2, Gawlicki M3, Piault E4

1Pfizer, Inc, New York, NY, USA, 2Corporate Translations, Inc, Chicago, IL, USA, 3Corporate Translations, Inc, East Hartford, CT, USA, 4Mapi Values, Boston, MA, USA

OBJECTIVE: The objective of this study was to confirm the linguistic validity of 13 new translations of the Overactive Bladder Satisfaction Questionnaire. The OAB-S has been developed for worldwide use and its conceptual equivalence and cultural adaptability across countries have been considered alongside the development process: the questionnaire has been simultaneously developed in US English and US Spanish and underwent a translatability assessment. The OAB-S is a measure of medication or treatment satisfaction in patients with overactive bladder (OAB).

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 13 languages: Afrikaans, Chinese (Taiwan), English (Canada), English (South Africa), Danish, French (Canada), Italian, Korean, Norwegian, Slovak, Spanish (Mexico), Swedish, and Turkish. All translators were native speakers of the target language and fluent in US English. A diverse sample of five subjects in each language reviewed the harmonized translations and was subsequently debriefed by trained bilingual interviewers fluent in both US English and the target language. A team consisting of the original translators, back translator, project manager, interviewer, and survey research consultant evaluated all conceptual, linguistic and stylistic issues that emerged from the debriefings. RESULTS: For some languages, translation of the concepts “tolerability”, “blurred vision”, “side effects”, and “pads” proved challenging and required discussion, testing, and revision to achieve acceptable translations. Certain concepts, such as “none of the time”, “commuting”, and “urine loss” were deemed unacceptable when translated literally, and were revised appropriately. CONCLUSIONS: The 13 translations of the OAB-S instruments are linguistically and conceptually equivalent to the original questionnaires. Linguistic validation of the translations will facilitate inter-country comparisons of OAB and the pooling of data in multi-country studies.

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RISK OF LEAKAGES IN DAILY ACTIVITIES, RE-WORKING THE CONCEPTUAL FRAMEWORK

Arnould B1, Bosio-Legoux B2, Dard S1, Bresson S1, Costa P1

1Mapi Values France, Lyon, France, 2‘Lilly France, Suresnes, France, 3Contractor for Lilly France, Suresnes, France, 4Carémeau University Hospital, Nîmes, France

OBJECTIVES: Since the frequency of stress urinary incontinence (SUI) episodes is closely linked to continuing or avoiding activities causing leakages, evaluating therapeutic benefit can be ren-