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Sensory Systems Disorders – Patient-Reported Outcomes & Preference-Based Studies

PSS15

DEVELOPMENT OF A MULTIATTRIBUTE INSTRUMENT FOR ESTIMATING UTILITIES (PREFERENCE WEIGHTS) IN PEOPLE WITH GLAUCOMA FROM THE NATIONAL EYE INSTITUTE VISUAL FUNCTIONING QUESTIONNAIRE (NEI-VFQ)

Kymes S[1], Peters CM[1], Beusterien K[2], Kotak S[3], Grinspan J[2], Stwalley D[4], Pleil A[5]
[1]*Washington University School of Medicine, St. Louis, MO, USA,* [2]*Oxford Outcomes Ltd., Bethesda, MD, USA,* [3]*Pfizer, Inc., New York, NY, USA,* [4]*Washington University, St. Louis, MO, USA,* [5]*Pfizer, Inc., San Diego, CA, USA*

OBJECTIVES: We used multi-attribute theory to develop a utility elicitation instrument for people with glaucoma based on the National Eye Institute-Visual Functioning Questionnaire (NEI-VFQ), a vision specific quality of life instrument frequently used in clinical trials. **METHODS:** NEI-VFQ responses for 1677 people enrolled in glaucoma prevention trials were analyzed to identify items responsive to differences in vision status. We then constructed a conjoint interview administered to 48 people with glaucoma and identified the 6 items of greatest importance to people with glaucoma. Using these results, we constructed a web-based interview using standard gamble (SG) and visual analog scales(VAS) administered to a community sample of 404 people. **RESULTS:** The five attributes most important to people with glaucoma (and responsive to change in disease status) were: ability to read, driving at night, ability to leave home, needing help with activities and ability to accomplish tasks. We added a sixth attribute, peripheral vision, even though it was not rated highly by the participants as this is an important function lost early in the disease process. Final utility estimates were made using a method similar to that employed in the Health Utility Index. The results had excellent face validity and we note the range of utility loss from mild loss of function to severe difficulty: 1) Ability to read (0.011-0.039); 2) Driving at night (0.011-0.037); 3) Leaving home (0.014-0.056); 4) Needing help with activities (0.027-0.063); 5) Ability to accomplish tasks (0.016-0.046); and 6) Peripheral vision (0.008-0.032). **CONCLUSIONS:** We have developed an instrument that can be used to estimate the utility loss in people with glaucoma based upon the NEI-VFQ. When used in clinical trials, the instrument will provide an estimate of the utility loss associated with the progression of glaucoma. Further work will be required to refine and validate these estimates.

PSS16

DEVELOPMENT OF A DISEASE SPECIFIC VERSION OF THE EQ-5D FOR USE IN PSORIASIS

Lloyd A[1], Swinburn P[1], Boye KS[2], Edson E[2], Bowman L[2]
[1]*Oxford Outcomes Ltd., Oxford, Oxfordshire, UK,* [2]*Eli Lilly and Company, Indianapolis, IN, USA*

OBJECTIVES: The EQ-5D is a widely used generic measure of health. Previous research has highlighted possible shortcomings in content validity in certain conditions (e.g. vision, hearing loss). The objective of this study was to determine if this was true for people with psoriasis and to address this through the development of a disease-specific version of the EQ-5D for use in psoriasis. **METHODS:** A literature review, consultation with medical experts and in-depth qualitative interviews with psoriasis patients with varying degrees of disease severity (n=8) were undertaken to understand the quality-of-life burden associated with psoriasis. An iterative process identified four new candidate dimensions (skin irritation, skin appearance, self-confidence and social/relationship difficulties). These were included alongside the existing five dimensions of EQ-5D. In a validation study 100 psoriasis patients completed the new version of EQ-5D; the Dermatology Life Quality Index (DLQI) and Self-Administered Psoriasis Area Severity Index (SAPASI). **RESULTS:** Psychometric analyses suggested that all candidate dimensions were sensitive to disease severity and had excellent concurrent validity. The new dimensions significantly improved the predictive power of EQ-5D in measuring health status as assessed by the DLQI with an R^2 increase of 0.213 when three candidate dimensions were added. Almost 20% of patients indicated no problems on each dimension of conventional EQ-5D (state 11111), but reported substantial impairments on the psoriasis dimensions, indicating the limitations of existing EQ-5D in psoriasis. **CONCLUSIONS:** This study is part of larger research at the EuroQol Group to investigate the potential development of disease specific versions of EQ-5D. The study demonstrates that in certain disease areas there is need for more a specific measure. The addition of appropriate dimensions can significantly increase the sensitivity of the instrument. Further work is needed to capture preference weights for this new instrument to support its inclusion in economic evaluation.

PSS17

THE EFFECT OF ORAL CP-690,550 ON PRURITUS IN PATIENTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS

Mamolo CM[1], Bushmakin AG[2], Cappelleri JC[2], Stewart M[2]
[1]*Pfizer, Inc., New London, CT, USA,* [2]*Pfizer Global Research and Development, Groton, CT, USA*

OBJECTIVES: To assess the effect of the oral Janus kinase inhibitor CP-690,550 on pruritus in patients with psoriasis. **METHODS:** In a 12-week, double-blind, placebo-controlled Phase 2b study, patients (n=197) with moderate-to-severe plaque psoriasis were randomized to CP-690,550 (2, 5 or 15 mg BID) or placebo. Pruritus was patient-assessed using the Itch Severity Score (ISS), a 0 ('no itching') to 10 ('worst possible itching') numeric rating scale, recorded daily during the first 2 weeks of treatment and at all clinic visits. The clinically important difference (CID) and clinically important responder (CIR) on the ISS were defined using the Patient Global Assessment as an anchor. **RESULTS:** At Baseline, mean (SD) ISS for patients in the 2, 5, and 15 mg BID and placebo groups were 7.04 (2.65), 6.98 (2.27), 6.96 (2.23), and 6.78 (2.77), respectively. The estimated CID (95% CI) was 1.64 (1.50; 1.78) and CIR was 29.8% (23.30%; 36.40%). Overall differences in ISS values between active drug arms and placebo were −2.82 (95% CI: −3.71; −1.92), −3.02 (−3.93; −2.12), and −3.87 (−4.76; −2.98) for 2, 5, and 15 mg BID vs placebo, respectively; all differences were larger (in absolute value) than the CID of 1.64, indicating that the treatment effects were not only statistically significant but also clinically relevant. At Week 2, the number of ISS responders was 77.78%, 68.75%, and 76.60% for 2, 5, and 15 mg BID, respectively, vs 34.00% for placebo ($p<0.0001$); at Week 12 the number of ISS responders increased to 91.89%, 87.18%, and 100% in the 2, 5, and 15 mg BID groups, respectively, vs 29.41% for placebo ($p<0.0001$). **CONCLUSIONS:** In patients with psoriasis, CP-690,550 produces significant and clinically meaningful reductions in pruritus, as measured by the patient-reported ISS.

PSS18

DISEASE SEVERITY EVALUATION AMONG DERMATOLOGICAL OUT-PATIENTS: A COMPARISON BETWEEN THE ASSESSMENTS OF PATIENTS AND PHYSICIANS

Tabolli S, Sampogna F, Pagliarello C, Paradisi A, Spagnoli A, Abeni D
IDI IRCCS, Rome, Italy

OBJECTIVES: The assessment of a patient's disease severity is an essential component in the formulation of treatment strategies. This study wants to compare the dermatological disease severity assessment by patients and by physicians, and to describe the possible discrepancies between them. **METHODS:** For each patient, we obtained the Physician Global Assessment (PhGA) and the Patient Global Assessment (PtGA). Data were completed for 2.578 patients. Sixty-one physicians participated in the study. We calculated the agreement between PtGA and PhGA scores using the weighted kappa statistics; a multinomial logistic regression was performed to assess the risk of disagreement considering both patient and physician variables. **RESULTS:** Differences in the percentages of severity level, identified by patients and by physicians, were always statistically significant ($p<0.05$). Overall, the weighted Cohen's kappa was in the range of 0.09 - 0.34, depending on the diseases. Gender differences between patients and physicians did not influence the agreement. In the multinomial model female patients (OR=1.38; 95%CI, 1.07-1.77), patients with higher educational levels (OR=2.71; 95%CI, 2.12-3.46), and patients with impaired quality of life (OR=1.56; 95%CI 1.23-1.97) had a higher risk to be underestimated for their disease severity by physicians, independently by physician gender and experience. **CONCLUSIONS:** Combining the subjective report with the objective severity assessment of the lesions, dermatologists may reach a better determination of how severity of disease is perceived by their patients and how they feel about the effectiveness of treatment. PtGA and PhGA might be considered in routine clinical assessments and not only for research activities.

PSS19

PSYCHOMETRIC EVALUATION OF THE NATIONAL EYE INSTITUTE VISUAL FUNCTION QUESTIONNAIRE 25 AND VISUAL FUNCTION QUESTIONNAIRE UTILITY INDEX IN PATIENTS WITH NON-INFECTIOUS INTERMEDIATE AND POSTERIOR UVEITIS

Naik RK[1], Gries KS[2], Rentz A[3], Kowalski JW[1], Revicki DA[3]
[1]*Allergan, Inc., Irvine, CA, USA,* [2]*United BioSource Corporation, Seattle, WA, USA,* [3]*United BioSource Corporation, Bethesda, MD, USA*

OBJECTIVES: To evaluate the psychometric properties of the National Eye Institute Visual Function Questionnaire 25-item (NEI VFQ-25) and Visual Function Questionnaire Utilities Index (VFQ-UI) in patients with non-infectious intermediate and posterior uveitis. **METHODS:** Secondary analysis of pooled data from a 26-week, multicenter, masked, randomized, sham-controlled Phase 3 trial of dexamethasone intravitreal implant. Vision specific health related quality of life was assessed using the NEI VFQ-25 at baseline and weeks 8, 16, and 26/early exit. The EQ-5D and SF-36 were administered at baseline. Internal consistency reliability and reproducibility was measured using Cronbach's alpha and intraclass correlation coefficient (ICC). Validity was assessed with Spearman's product-moment rank correlations and known-groups of BCVA and vitreous haze severity. Clinically significant difference was assessed using distribution and anchor-based methods. **RESULTS:** The study included 224 subjects with non-infectious intermediate (80.4%) or posterior uveitis (19.6%); mean age 44.6 years; 63.4% female; 60.3% Caucasian; median vitreous haze score at baseline 2.0 and median visual acuity (ETDRS) 62.5 letters (84.4% treated in their worse seeing eye). The NEI VFQ-25 and the VFQ-UI demonstrated good internal consistency (Cronbach's alpha 0.87-0.94) and test-retest reliability (ICC 0.72-0.88). Spearman's product-moment rank correlations between the NEI VFQ-25 and VFQ-UI scores and the SF-6D, EQ-5D, and BCVA at baseline ranged from low to moderate. There was a significant association between visual functioning and known groups of visual acuity, with group comparisons demonstrating significant decrease in visual functioning between ≥20/40 and <20/40 to >20/200 ($p<0.05$). At week 8, clinically significant difference, based on the standard error of measurement, was 0.04 for the VFQ-UI and ranged from 4.63 to 8.92 for the VFQ-25 domains and 3.86 for the composite score. **CONCLUSIONS:** The NEI VFQ-25 and the VFQ-UI are reliable and valid measures of vision-related functioning and preference-based status in patients with non-infectious intermediate and posterior uveitis.

PSS20

MEDIATION MODELING AND MEASUREMENT CHARACTERISTICS OF THE ITCH SEVERITY SCORE FROM A PHASE 2B TRIAL OF ORAL CP-690-550 IN PATIENTS WITH MODERATE TO-SEVERE PLAQUE PSORIASIS

Mamolo C[1], Bushmakin AG[2], Cappelleri JC[2], Stewart M[2]
[1]*Pfizer, New London, CT, USA,* [2]*Pfizer Global Research and Development, Groton, CT, USA*

OBJECTIVES: To assess direct and indirect effects of the oral Janus kinase inhibitor CP-690,550 on pruritus in patients with psoriasis. **METHODS:** In a 12-week, double-blind, placebo-controlled Phase 2b trial, 197 patients with moderate-to-severe psoriasis were randomized to CP-690,550 (2, 5 or 15 mg BID) or placebo. Pruritus was patient-assessed using the Itch Severity Score (ISS), a 0 ('no itching') to 10 ('worst