PSS17

SICKNESS ABSENCES DUE TO CHRONIC HAND ECZEMA (CHE) IN PATIENTS TREATED WITH ORAL ALITRETINOIN UNDER DAILY PRACTICE CONDITIONS: RESULTS OF THE TOCCATA OBSERVATIONAL STUDY COMPRISING 522 WORKERS

Diepgen TL[1], Kuessner D[2]
[1]Dept. of Social Medicine, Occupational and Environmental Dermatology, University Heidelberg, Heidelberg, Germany, [2]Basilea Pharmaceutica International Ltd., Basel, Switzerland

OBJECTIVES: CHE can lead to considerable sickness absences, but quantitative data regarding CHE-related productivity changes under different treatments are scarce. The German observational study TOCCATA, collected effectiveness and tolerability data of oral alitretinoin in daily practice and concomitantly documented information regarding CHE-related productivity loss, the main subject of this analysis. **METHODS:** A total of 680 adult CHE patients treated with oral alitretinoin for up to 24 weeks, according to the approved prescribing information, were included. Sickness absence days due to CHE were documented at baseline (over the last 12 months prior to the study and when ongoing at inclusion) and at each monthly follow-up visit (4 weeks retrospectively). This analysis focuses on the proportion of patients with sick leave and days off work due to CHE and correlation of changes in disease severity. **RESULTS:** 219 (42%) of all 522 patients in employment had sick leaves in the last 12 months (mean: 35 days), 80 (15.4%) patients were on sick leave at inclusion, and this proportion gradually decreased to 7.1% at observation end. In line with this observation, the 80 patients had an average 17.6 consecutive days off work (last 4 weeks at inclusion), however, only 7.6 days off during the four weeks before end of observation. The highest reduction in CHE-related sickness absence was observed between the visits 4 to 12 weeks, which was associated with the clinical CHE improvements seen during this period. **CONCLUSIONS:** This is the first report of beneficial changes in disease-related sickness absences in CHE patients associated with successful oral alitretinoin treatment. At end of study, the number of patients with sickness absences due to CHE had decreased by approximately 50% compared to baseline. This observation certainly merits further exploration in different health care settings potentially confirming economic benefits for patients, their employers and the society at large.

SENSORY SYSTEMS DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PSS18

COMPARISON OF A 24-HOUR AND 7-DAY VERSION OF A PATIENT REPORTED OUTCOME MEASURE FOR PSORIASIS SYMPTOM SEVERITY

Bushnell DM[1], Martin ML[2], McCarrier KP[2], Chiou CF[3], Ortmeier B[4]
[1]Health Research Associates, Inc., Mountlake Terrace, WA, USA, [2]Health Research Associates, Inc., Seattle, WA, USA, [3]Janssen Global Services, Companies of Johnson & Johnson, Raritan, NJ, USA, [4]Amgen, Inc., Thousand Oaks, CA, USA

OBJECTIVES: Research about the limitations of cognitive processes in memory suggest retrospective recall may be less accurate than recall within the past 24 hours. Daily diaries, however, are often more burdensome for study subjects and are more expensive to administer than weekly retrospective instruments. We sought to evaluate a 24-hour recall version (24-hour PSI) and a 7-day retrospective version (7-day PSI) of the Psoriasis Symptom Inventory (PSI) to test the equivalence of symptom severity assessed with the two versions. **METHODS:** Using a prospective, observational design, adult patients receiving usual care for their plaque psoriasis (Psoriasis Area and Severity Index [PASI] ≥10) were recruited from clinics and randomized. Subjects completed the 24-hour PSI for 7 days and completed the 7-day PSI on the seventh day. Comparison of average daily diary scores and 7-day retrospective scores were made with Pearson's correlation coefficients and simple bivariate comparisons (t-test). Potential exposure effects of daily PSI administration in the days preceding the 7-day retrospective assessment were examined in sensitivity analyses. **RESULTS:** Among the 139 subjects, mean age and PASI scores were 51.2 and 17.6, respectively. There was high agreement between results from the daily 24-hour PSI and the 7-day PSI assessments. With the exception of *Flaking* (0.08, p=0.02), no significant mean differences were found in the remaining seven PSI symptoms (*Itching, Redness, Scaling, Burning, Stinging, Cracking, and Pain*) between the 24-hour PSI (7-day average) and the 7-day PSI. Correlations between the two PSI versions ranged from 0.86 (scaling) to 0.92 (pain). Completion of the daily assessment did not influence responses on the 7-day PSI. **CONCLUSIONS:** Overall findings show that the two PSI versions yield equivalent results. Both the 24-hour PSI and 7-day PSI would provide comprehensive capture of symptoms in psoriasis studies and clinical trials.

PSS19

VALIDATION OF THE PAEDIATRIC HEARING IMPAIRMENT CAREGIVER EXPERIENCE (PHICE) INSTRUMENT

Lim HYL[1], Xiang L[2], Li R[1], Wong N[1], Yuen CPK[3]
[1]National University Health System, Singapore, [2]National University of Singapore, Singapore, [3]The Hong Kong Institute of Education, Tai Po, New Territories, Hong Kong

OBJECTIVES: To validate and shorten the Paediatric Hearing Impairment Caregiver Experience (PHICE) instrument. **METHODS:** A total of 125 caregivers of hearing impaired children attending the otolaryngology, audiology, and aural rehabilitation at a local clinic were administered the 68 item questionnaire. Exploratory factor analysis was conducted. A 5 factor structure was adopted and items with high cross-loadings were dropped. The 5 factor structure was then analysed using confirmatory factor analysis. Cronbach's α was computed to assess internal consistency. **RESULTS:** A 5 factor structure corresponding to the factors: "Adaptation to hearing loss", "Childcare support", "Healthcare", "Education" and "Policy" was adopted. Confirmatory factor analysis suggest a good model fit (RMSEA = 0.067, RMR = 0.329, SRMR = 0.0752, NFI = 0.830, CFI = 0.949). This model fit is assessed to be superior than the original 8 factor structure. Cronbach's α were high (>0.75) for each subscale. 3 questions that were deemed important from a clinical point of view but was removed would continue to be a part of the instrument but will not be used in the computation of the subscale scores. **CONCLUSIONS:** The 68 item questionnaire has been reduced to 39 items. A new 5 factor structure is proposed that better explains the underlying items. Three items was added back despite being dropped due to their important clinical value.

PSS20

COMPARATIVE STUDY OF THE PERFORMANCES OF GENERIC AND DISEASE-SPECIFIC MEASURES IN CATARACT PATIENTS

Suh JK, Doctor J
USC School of Pharmacy, Los Angeles, CA, USA

OBJECTIVES: To evaluate the overall performances of generic and disease-specific measures. **METHODS:** One disease-specific and five generic measures were administered in cataract patients at baseline, 1- and 6-month. The disease-specific measure was the National Eye Institute Visual Functioning Questionnaire-25 (VFQ-25) and the generic measures included the Short Form-6D (SF-6D), EuroQol-5D (EQ-5D), Self-Administered Quality of Well-being Scale (QWB-SA), and two versions of the Health Utilities Index (HUI2 and HUI3). The global rating of change, in a 5-point rating scale, was applied as an anchor and the score change between baseline and 6-month was calculated accordingly. Two definitions for responders who experienced a minimally important difference were used: patients whose global ratings were "somewhat better" or above (Model 1) and patients rated as "somewhat better" or above, or "somewhat worse" or below (Model 2). In Model 2, for the patients who reported "somewhat worse" or below, the sign of the score changes were reversed. In Experiment 1 the performance of the generic measure was compared against the VFQ-25 based on Model 1. In Experiment2 the impact of using different classifications for the responders was examined by comparing the performances of Model 1 and Model 2 for each measure. The performances of the measures were compared based on the areas under the receiver operating characteristics curves. **RESULTS:** A total of 223 cataract patients were included. In Experiment 1, only the EQ-5D showed significantly lower performance than the VFQ-25 (p<0.0001) and there were no differences between the VFQ-25 and the other generic measures. In Experiment 2, the performances between Model 1 and 2 were not significant in all the measures. **CONCLUSIONS:** In this cataract population, we found that the generic measures were as sensitive as the disease-specific measure in most cases and the performance of the measure did not depend on the different definitions for the responder.

PSS21

ASSESSING PRURITUS AMONG PATIENTS WITH ATOPIC DERMATITIS: TARGETED LITERATURE AND INSTRUMENT REVIEW

Brown T[1], Olanrewaju O[1], Deal L[2], Katz E[3], Chiou CF[3], Martin S[1], Fehnel S[1]
[1]RTI Health Solutions, Research Triangle Park, NC, USA, [2]eResearch Technology Inc, Philadelphia, PA, USA, [3]Janssen Global Services, LLC, West Hills, CA, USA

OBJECTIVES: Pruritus is a key criterion in the diagnosis of atopic dermatitis (AD) and has been associated with lower levels of health-related quality of life in both pediatric and adult patients. The objective of this study was to identify information and instruments relevant to the measurement of pruritus in adolescent and adult AD patients. **METHODS:** A PubMed search was conducted to identify relevant literature and existing PRO measures (items, subscales, and instruments) designed to assess the severity, frequency, and/or impact of AD-related pruritus. Articles were limited to studies conducted in humans, published since 2000, and in English. Search terms included atopic dermatitis, itch, and pruritus. In addition to using sources identified during the literature review, a search of published PRO instrument sources (e.g., Patient-Reported Outcome & Quality of Life Instruments Database [PROQOLID]) and the RTI-HS internal PRO instrument repository was conducted. Identified PRO instruments were evaluated based on the criteria described in the Food and Drug Administration's 2009 guidance on PROs for product label claims. **RESULTS:** Literature review results confirmed pruritus is a central feature of AD and affects both daytime functioning and nighttime sleep in many AD patients. In addition, the effective treatment of pruritus represents an unmet need among patients with AD. Nine PRO instruments measuring AD-related pruritus were identified and evaluated. Only one of these measures had been developed exclusively in patients with AD, and none of these measures were developed or evaluated with the scientific rigor outlined in the FDA's PRO guidance. **CONCLUSIONS:** The results of this targeted review indicate the need for new treatments that improve pruritus among patients with AD. In addition, to communicate this treatment benefit, the development of a new AD-related pruritus instrument is warranted in order to more accurately describe the effect of therapy on this important disease symptom.

PSS22

A COMPREHENSIVE HEALTH IMPACT ASSESSMENT AND DETERMINANTS OF QUALITY OF LIFE, HEALTH AND PSYCHOLOGICAL STATUS IN ACNE PATIENTS

Pagliarello C, di Pietro C, Tabolli S
IDI IRCCS, Rome, Italy

OBJECTIVES: . Measurement of acne impact on QoL, health and psychological status. To analyse the relationship between socio-demographic variables, disease severity and mental status on QoL of acne sufferers. **METHODS:** . Acne cases were selected from a survey conducted in 2010. The Short-Form 12-Item Health Survey and the Skindex-29 were used to assess health status and QoL. The 12-Items General Health Questionnaire was used to identify individuals at risk for non-psychotic