domain at differentiating adjacent dry eye categories across a range of probability cut-offs with the following Area Under the Curve (AUC) statistics resulting from 2000 stratified bootstrap replicates for each curve: None versus Mild (AUC=0.96, CI=0.90-0.98), Mild versus Moderate (AUC=0.74, CI=0.66-0.84) and Moderate versus. Severe (AUC=0.82, CI=0.74-0.90). **CONCLUSIONS:** The IDEEL SB domain provides a simple and effective basis for differentiating categories of patient-reported dry eye severity.

PSS33

## ESTIMATION OF MEANINGFUL CHANGE ON THE SKINDEX-29 AND DERMATOLOGY LIFE QUALITY INDEX IN PATIENTS WITH CHRONIC HAND ECZEMA

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**OBJECTIVES:** A key question when interpreting quality of life data is: which magnitude of change is clinically relevant? To document a minimal important difference (MID) for the Skindex-29 and Dermatology Life Quality Index (DLQI) in patients with chronic hand eczema. **METHODS:** Secondary psychometric analysis was undertaken on data from two cost-of-illness studies in Germany (N=310). Patients completed the Skindex-29 and DLQI. The Skindex-29 is summarised into domains measuring symptoms, emotions, and functioning, plus a total score. DLQI (10-items) is assessed as a total score. MID was assessed using statistical methods including standard error of measurement (SEM) and ½ standard deviation (½SD). Internal consistency was also estimated in order to support estimation of the SEM. Estimates were benchmarked against existing values. **RESULTS:** Internal consistency for Skindex dimensions (symptoms $\alpha$=0.834; emotions $\alpha$=0.910; function $\alpha$=0.934) and DLQI ($\alpha$=0.835) was confirmed. The MID estimated for DLQI was (SEM=2.04, ½SD = 2.53); and for Skindex-29 was symptoms (SEM=8.16, ½SD = 10.01); emotion (SEM=6.80, ½SD = 11.34); function (SEM=5.53, ½SD = 10.77) and total score (SEM=4.13, ½SD = 9.51). **CONCLUSIONS:** The study confirms good internal consistency properties of the Skindex-29 and DLQI in patients with chronic hand eczema and demonstrates the MID for this measure. The DLQI MID based on SEM method is close to a recent report in a Danish study of hand eczema patients using an anchor-based approach which established the DLQI MID at 2.0 (Hald et al., 2011). The DLQI MID for other skin diseases has previously been proposed to range from 2.3 to 5.7 in stable plaque psoriasis (Shikiar et al., 2006) and of 2.24 to 3.10 in chronic idiopathic urticaria (Shikiar et al., 2005) which is consistent with current estimates.

PSS34

## QUALITATIVE GROUNDING FOR A NEW PATIENT ASSESSMENT MEASURE IN OPHTHALMOLOGY: THE FUNCTIONAL ASSESSMENT OF VISUAL TASKS (VISTAS)

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**OBJECTIVES:** Patients' ability to perform vision-dependent tasks is essential to daily function and quality of life. Visual function measures do not typically assess both corrected and uncorrected function and lack an intermediate visual range scale. To address these limitations, the current qualitative study identifies the preliminary content and item pool for a future measure (Functional Assessment of Visual Tasks - VISTAS). **METHODS:** Ophthalmology patients (n=72) with mild to severe myopia, hyperopia, presbyopia, astigmatism, cataracts and glaucoma participated in a variety of qualitative studies (life event journaling, interviews, on-line and face-to-face focus groups). The objective of these studies was to identify and thematically group meaningful visual tasks occurring in the near, intermediate and distance visual ranges. The journal entries and transcripts were thematically coded and organized into related domains of life function. **RESULTS:** Some task groupings were comprised of activities that occur predominantly within the distance visual range. These groupings included; mobility (ambulation), driving, leisure and sports, and social functioning. Some task groupings relied more heavily on the predominantly near and intermediate visual ranges. These groupings included; technology use and activities of daily living. Other task groupings were heterogeneous in terms of visual ranges required for their performance. **CONCLUSIONS:** Participants identified a wide variety of distance-specific visual tasks that impacted the quality of their lives. These included tasks related to their physical safety as well as to functioning at home and in the workplace. The thematic analysis provided a rich body of information with which to design items to assess important functional dimensions that are made more difficult by visual impairment. The measurement properties of this pool of candidate items were evaluated in clinical samples as a part of two larger psychometric validation studies.

PSS35

## VALIDATION OF THE EIGHTEEN ITEM FUNCTIONAL ASSESSMENT OF VISUAL TASKS (VISTAS-18) USING A NEW LENS PRESCRIPTION METHODOLOGY

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**OBJECTIVES:** To psychometrically evaluate the VISTAS item pool and develop four new distance-specific visual function scales (VISTAS-18). **METHODS:** Study participants (n=139) were recruited from those attending an optometry clinic to change an existing eyeglass prescription. Sampling was balanced across myopic, hyperopic, presbyopic, and astigmatic conditions. Four VISTAS-18 Function Scales (Near, Intermediate, Extended-Intermediate and Distant Function) were identified and refined using PCA factor analysis with oblique rotation. Lens prescription data and visual acuity assessments in the near, intermediate and distant ranges were used to provide concurrent criterion-related validity to the new scales. **RESULTS:** Participants' mean age was 50.7 years (SD 15.0) and was roughly balanced by gender (f:m 4:3). Astigmatism (97/139), Presbyopia (92/139), Myopia (88/139), Hyperopia (43/139), and Cataracts (28/139) were the most common causes of poor vision. Factor analysis revealed three and four-factor solutions that explained over 80% of the variance in task difficulty. The VISTAS-18 Function Scales were internally consistent (Cronbach's Alpha = 0.89 - 0.96) with normally distributed uncorrected task difficulty scores and floor effects associated with corrected ratings. Moderate correlations were observed between the uncorrected VISTAS-18 Function Scales scores and both the logMAR visual acuity (r2 = 0.41 - 0.63) and temporary lens strength (r2 = 0.30 - 0.66). With one exception, the correlations between change in lens strength and change in VISTAS-18 Function Scale scores were all significant. **CONCLUSIONS:** This study provides initial structural and criterion-related validity for the 4 VISTAS-18 Function Scales. The VISTAS-18 Function Scales responded linearly across the range of both visual acuity and corrective lens strength in each distance range. Despite the small numbers of evaluable cases, three of the VISTAS scales were responsive to relatively minor adjustments in lens strength in the near, intermediate and distant visual ranges.

PSS36

## DEMONSTRATING CONCEPTUAL EQUIVALENCE: TRANSLATION OF THE CU-Q2OL FROM ITALIAN INTO ENGLISH

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**OBJECTIVES:** Translation and linguistic validation of patient reported outcomes (PRO) measures is an essential component of research methodology in preparation for multinational research studies. The Chronic Urticaria Quality of Life questionnaire (CU-Q2oL) is a disease specific tool developed in Italian to assess chronic urticaria from the patient's viewpoint. The objective of this work wasto translate and linguistically validate the CU-Q2oL from Italian to English for use in the US. **METHODS:** The CU-Q2oL was translated into English according to industry standard methodology. After the translation was completed, five patients completed the translated questionnaire and participated in a cognitive debriefing interview. Interviews were conducted using a standardized guide to assess the relevance, understandability, and appropriateness of the translations. Qualitative analyses were performed to ensure equivalence and that the content validity of the CU-Q2oL was maintained for the English version. **RESULTS:** The study sample consisted of 5 patients diagnosed with chronic idiopathic urticaria (80% male). Mean age of the patients was 39 years. The sample consisted of English speaking patients in the US. All CU-Q2oL items were well understood and proved relevant to the patients in this sample. Of interest, terms such as, "hives", and "swelling of the eyes" were clearly understood as intended. **CONCLUSIONS:** The results indicate that the English version of the CU-Q2oL translation is conceptually equivalent to the Italian source version and easily understood by the target population in the United States. We consider the translation to be acceptable for PRO assessment in research and clinical practice. Future research could include testing of the questionnaire with patients in other English-speaking countries to confirm its acceptability beyond the US.

PSS37

## THE CLINICAL AND ECONOMIC BURDEN OF ACUTE OTITIS MEDIA: A LARGE PROSPECTIVE OBSERVATIONAL COHORT STUDY IN EUROPE

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**OBJECTIVES:** Acute otitis media (AOM) is one of the commonest paediatric bacterial infections, often requiring general practitioner/paediatrician consultation and antibiotic prescription. AOM management guidelines differ between countries. We aimed to prospectively assess the incidence and economic burden of AOM across five European countries. **METHODS:** A large, prospective, observational cohort study was conducted to investigate AOM incidence in Europe, gathering information on clinical symptoms, treatment and quality-of-life. A total of 5882 healthy children aged <6 years were enrolled from 73 medical practices in Germany, Italy, Spain, Sweden and the UK. A patient reported outcome (PRO) questionnaire was distributed to parents to assess costs associated with medically diagnosed AOM. Assessment included direct medical costs (e.g. medication/physician consultations/hospitalisations), direct non-medical costs (e.g. transportation/baby-sitting), and indirect costs (e.g. absence from work/school). **RESULTS:** Of 1419 AOM episodes recorded in 1113/5882 children, 91.1% had a questionnaire available. Medication (any) was taken for 58.8% of episodes, but the proportion varied between countries (Spain: 14.8%; Germany: 33.2%; Italy: 93.8%; UK: 94.6%; Sweden: 95.7%). The child missed day-care/school in 48.9% of episodes (median hours missed: 18); the caregiver missed work in 17.1% of episodes (median hours missed: 16). Hospitalisation rates were similar across countries (≤1.0%). The mean total cost/episode ranged between €24.16 (Spain) and €306.09 (Sweden). Mean direct medical costs

ranged between €9.44 (UK) and €121.17 (Sweden); mean direct non-medical costs were ≤€2.85/episode. Indirect costs contributed significantly to the total cost/episode in Italy (81.4%; €91.14), UK (79.8%; €37.55), Germany (60.0%; €26.74) and Sweden (59.5%; €182.07), whereas indirect costs contributed only 14.7% (€3.54) in Spain, where the value associated with absence from work/school was low. **CONCLUSIONS:** AOM was associated with substantial economic burden in these European countries. The cost per episode and the contribution of direct/indirect costs varied between countries, potentially reflecting socio-economic differences and variation in AOM management.

**PSS38**

**3-D STUDY - DESCRIPTION OF THE CARE OF THE DENTAL PAIN**

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**OBJECTIVES:** Highlight the action of two analgesics combining paracetamol and codeine (Klipal 600® and EfferalganDafalgan Codeine®), with a minimum of 50 mg of codeine at a time. **METHODS:** Multicentre, longitudinal, prospective, observational study, performed in metropolitan France from data collected by the dental surgeons that have accepted to participate in it. **RESULTS:** A total of 105 patients were included. Klipal 600® was prescribed for 76 of them versus 24 for the other group. 56.2% of the patients are women. The average age is 45.57 + 14.64. The measurement of the average pain intensity, evaluated each day over a 6 day period by a VAS, shows an insignificant difference at the inclusion between the 2 groups ($p = 0.23$). But, contrary to the Efferalgan/Dafalgan codeine® group, the score differential for the pain intensity is statistically significant between Day 1 and Day 2 with the Klipal 600® group and the improvement is significant up to the fourth day. The pain qualification was evaluated by the Saint Antoine pain questionnaire (abbreviated format) bearing on 16 sensory and emotional qualifiers specifying the description of the pain experienced. The difference is not significant between the 2 groups at the inclusion ($p = 0.09$), then it is observed that the pain qualification score is reduced beginning on the second day for the 2 groups. For the 2 groups, it is observed that the average number of tablets is in the order of 2.3 during the first 48 hours with a similar progressive decrease up to the sixth day. The prescription of one tablet at a time for the Klipal® is an advantage for the follow up of the treatment and its effectiveness. **CONCLUSIONS:** In reality, this study demonstrates a quicker improvement in pain in the Klipal® group, also associated with reduced consumption of the treatment and a better effectiveness.

**PSS39**

**ASSESSMENT OF THE HEALTH STATUS USING THE 12-ITEM MEDICAL OUTCOMES STUDY SHORT FORM (SF-12) QUESTIONNAIRE (2578 DERMATOLOGICAL OUT-PATIENTS)**

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**OBJECTIVES:** To assess whether the SF-12 questionnaire could yield a valid description of the health status of a large number of dermatological out-patients. **METHODS:** The SF-12 and the 12-item General Health Questionnaire (GHQ-12) were utilized. Questionnaires were self-completed by the out-patients in the waiting rooms of a dermatological hospital. At the end of the visit the dermatologists recorded the diagnosis and the evaluation of the clinical severity. **RESULTS:** Data were complete for 2.578 patients. We observed a reduction in the Physical Component Summary score (PCS-12) with increasing age, while the Mental Component Summary score (MCS-12) was stable. PCS-12 and MCS-12 scores were worse in women. For the MCS-12 scores, the lowest mean values were seen in the group of patients with dermatitis, and were dramatically lower in almost all the diseases observed compared to the scores reported for non-dermatological conditions and to the normative values. 23% of patients were identified as GHQ-12 positive. GHQ-12 positives had lower PCS-12 and MCS-12 scores compared to GHQ-12 negatives (mean values, PCS: 48.3±4.8 vs. 44.5±6.5; MCS: 43.9±6.7 vs. 39.4±7.0, respectively). PCS-12 and the MCS-12 mean values were lower for GHQ-12 "cases" in all diseases, independently from the level of clinical severity of the disease. **CONCLUSIONS:** The impact of the dermatological diseases is dramatically high for the mental components of the health status; the mean values of MCS-12 were very low, and when compared to other relevant conditions only tumours and nervous system diseases showed lower values. The use of the generic SF-12 and GHQ-12 questionnaires allowed to have a clear picture of the health status of dermatological patients, to compare different diseases within the dermatological specialty, and to make comparisons between skin conditions and other non-dermatological diseases.

**PSS40**

**THE EFFECT OF ACUTE OTITIS MEDIA IN CHILDREN ON PARENTS' QUALITY OF LIFE: DEVELOPMENT AND VALIDATION OF A QUESTIONNAIRE IMPLEMENTED IN A PROSPECTIVE OBSERVATIONAL COHORT STUDY IN EUROPE**

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**OBJECTIVES:** Acute otitis media (AOM) is one of the commonest paediatric bacterial infections and is often recurrent. AOM may impact upon parents' quality of life (QoL), but there are currently no validated tools devoted specifically to measuring this impact. **METHODS:** An AOM-specific questionnaire was developed, based on a published questionnaire measuring the effect of children's recurrent ear, nose and throat infections on parents' QoL. Fourteen AOM-related questions were grouped into three scores: emotional score (ES; eight items), daily disturbance score (DDS; six items) and total score (TS; 14 items). A fifteenth generic question assessed overall quality of life (global score; GS). Responses were measured using a five-point Likert scale; higher scores indicate greater impact on QoL. Validation of the questionnaire followed a standard procedure for QoL tools, with multitrait analyses and internal consistency reliability using Cronbach's alpha. The tool was applied in a large, prospective, observational cohort study including 5882 healthy children aged <6 years enrolled from 73 medical practices in Germany, Italy, Spain, Sweden and the UK, 1113 of whom experienced a total of 1419 AOM episodes during follow-up. **RESULTS:** The questionnaire was completed for 1063 episodes (75%). The item convergent and discriminant validity criteria were met successfully. The homogeneity and satisfactory consistency of the GS showed correlations between 0.4 and 0.6 for 12 items. The internal consistency reliability of the questionnaire was assessed as "good" or "excellent". All scores had a mean around 30/100 (ES: 30.49 [SD: 20.30]; DDS: 29.35 [SD: 21.99]; TS: 30.00 [SD: 19.37]; GS: 30.02 [SD: 26.24]) and increased significantly with AOM severity, assessed by parents using a faces scale tool (AOM-FS). **CONCLUSIONS:** An AOM-specific parental QoL questionnaire was successfully developed and validated, demonstrating good performance across five European countries. Correlation was observed between AOM severity and QoL scores.

**PSS41**

**IMPACT ON QUALITY OF PATIENTS WITH ACTIVE AND INACTIVE PSORIASIS IN SPAIN**

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**OBJECTIVES:** Estimate the impact of psoriasis on quality of life of patients according to clinical features of the disease. **METHODS:** Patients ≥18 years with a diagnosis of plaque psoriasis. Variables: demographic and clinical data, health status perceived by the patient and quality of life (QoL) questionnaires specific for psoriasis: PDI (15 items with 4 response options, and overall result from 0=minimal impact to 45=maximum impact) and PSO-LIFE (20 items, with a timeframe of 7 days, are answered on a 5-point Likert scale (from "Always" to "Never") and the overall result ranging from 0= maximum impact to 100=minimal impact). **RESULTS:** A total of 304 patients were included (182 with active-psoriasis and 122 with inactive-psoriasis), mean age 44 (SD=15) years and 56% men. The mean time from psoriasis diagnosis was 18 years (SD=12), the mean weight 76 (SD=16.5) kg, the PASI index was 17 (SD=7.4) for active-psoriasis and 5.6 (SD=5.3) for inactive-psoriasis; 47% of active-psoriasis and 7.5% of inactive-psoriasis patients reported their overall health status as being "rather", "quite" or "very" poor. Two questionnaires show a poorer QoL in patients with active-psoriasis compared with those with inactive-psoriasis: PDI of 8.3 (SD=8.1) against 3.6 (SD=5.5), and PSO-LIFE 57.4 (SD=20.4) versus 76.4 (SD=20.6) respectively. There is a correlation between PASI and PSO-LIFE score ($r=-0.43; p<0.01$) and patients with visible affected areas such as head or upper limbs showed greater impact in QoL (63;SD=22) compared with trunk and lower limbs (74.8,SD=24) or patients not affected at the time of inclusion in the study (78.5;SD=21.6). After adjusting by age, education and duration of the last psoriasis episode, there are significant differences in PSO-LIFE scores between patients with active and inactive psoriasis ($p<0.01$). **CONCLUSIONS:** The quality of life in patients with psoriasis is affected especially in patients with active psoriasis and in patients with localized lesions in visible areas.

**PSS42**

**EVALUATION OF THE IMPACT OF WRITING EXERCISES AND EDUCATIONAL INTERVENTIONS ON QUALITY OF LIFE IN PATIENTS WITH PSORIASIS**

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**OBJECTIVES:** To test the efficacy an "emotional writing" exercises to improve quality of life of patients with psoriasis undergoing systemic treatments. **METHODS:** This study was designed as a controlled randomized intervention. Seven Clinical centers in Italy were involved. The intervention group (n = 100) wrote about the most stressful event in their life for three sessions of 20 minutes each. The Control group (n = 100) received only the educational materials that were also given to the intervention group. The recruitment time was twelve months, and the follow-up time was also 12 months. The SF-12, GHQ-12, Skindex_29, and PASI scores were evaluated at baseline and after 1, 6, and 12 months. Data were analyzed using Generalized Estimating Equations model. **RESULTS:** Ninety-seven patients were allocated to the Writing group and 105 to the Control group. forty-two patients of the first group and 49 of the control group reached the 12-mont follow-up visit. Data were consistent with the expected improvement after the start of treatment as observed at the different follow-up times: the severity of psoriasis decreased, the impact of psoriasis on quality of life decreased, and the health status improved both for the physical and mental components.The proportion of patients reaching PASI-50 (i.e., a reduction of 50% in the PASI score) observed at different follow-up times was similar in the two study groups and was not associated with any of the examined demographic variables. No advantage was observed for the intervention group also in terms of QoL and general health status. **CONCLUSIONS:** The longitudinal analysis did not prove relevant differences between the group receiving ed-