tiveness when correcting for the poorer-seeing eye. **METHODS:** An existing Markov model comparing three treatment frequencies of Bevacizumab (Avastin) is used, to investigate the effect of the correction of the poorer-seeing eye. We examined several scenarios of the poorer-seeing eye; no influence(0%), 10% and 20% influence of the utility of the better-seeing eye. In addition, it can be argued that treating the poorer-seeing eye has a preventive function, as it can become the future better-seeing eye. In the model a switch of the better-seeing eye is assumed after two and four years. **RESULTS:** By including the correction of the utility of the poorer-seeing eye the incremental cost-effectiveness ratio's (ICER) change from €5,260, €31,167 and €3,712, to respectively €10,375, €60,124 and €7,377 (20% influence). Lowering the influence from 20% to 0% has an effect of respectively, €13,706, €78,314 and €9,796. When inserting a switch at two and four years, the ICER reduces from €10,375, €60,124 and €7.377 to respectively €7,325, €53,649 and €4,848 at four years and almost half at 2 years. **CONCLUSIONS:** The results show that overestimating the QALY by excluding the poorer-seeing eye results in a lower incremental cost-effectiveness. Poorer-seeing eyes should be used when modeling eye-diseases. Whether the poorer-seeing eye contributes 20%, 10% or 0% has a small impact on the change in ICER's. The preventive function of treating the poorer-seeing eye should also be taken into account.

PSS28

ECONOMIC BURDEN OF ADVANCED MELANOMA: FINDINGS FROM A LARGE US HEALTH INSURANCE DATABASE

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OBJECTIVES: To assess the economic burden of unresectable or metastatic ("advanced") melanoma. **METHODS:** Using data from calendar years (CY) 2003-2008 from a large health insurance database and case-finding algorithms that we developed for use in such data, we identified all persons with Stage III unresectable or Stage IV melanoma at initial presentation, as well as those who presented with earlier-stage disease in prior years and progressed to advanced disease (i.e., recurrent cases). We tallied health care costs on an all-cause basis for all such persons alive for one or more day in CY2008. Health care costs were tallied by category of utilization (e.g., hospitalizations, outpatient visits, outpatient pharmacotherapy, etc.) as well as on an overall basis. Reimbursed amounts were used as a proxy for costs. **RESULTS:** We identified 1527 persons with advanced melanoma in CY2008 (Stage III unresectable, 267; Stage IV, 1260). Stage IV patients were more likely to be hospitalized during the year than those with Stage III disease (39% vs 26%, respectively; $p<0.01$). Mean (SD) total annual cost per patient was $42,848 ($66,279), and was higher for those with Stage IV versus Stage III unresectable disease ($45,786 vs $28,983; $p<0.01$). Outpatient services (including the cost of infused drugs) accounted for approximately 54% of total costs, while hospitalization and outpatient pharmacotherapy accounted for 37% and 9%, respectively. **CONCLUSIONS:** Our findings suggest that the economic burden of advanced melanoma is high, especially in patients with Stage IV disease.

PSS29

TREATMENT PATTERNS OF PSORIASIS PATIENTS AND TRENDS OVER TIME

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OBJECTIVES: Several treatment options are available for psoriasis, an incurable dermatological condition, but there is limited information on actual treatment patterns. This retrospective study aimed to provide a snap shot of the use of psoriasis medications and recent trends over time in current clinical practice in psoriasis patients with co-morbid conditions. **METHODS:** Adult patients with ≥2 documented psoriasis diagnoses (ICD-9 codes: 696.1 were selected from a large US administrative claims database (2004-2008). The index date was defined as the latest date with a psoriasis diagnosis. Psoriasis treatments, including topical therapies, phototherapy, conventional systemic therapies, and biologics, were identified during the 6 months following the index date and described for the entire psoriasis population, a sub-group of obese patients (body mass index [BMI] ≥30), and stratified by index year to examine trends over time. **RESULTS:** A total of 106,128 psoriasis patients were selected. The mean age was 52±15 years and 52% were female. Overall, 62.3% of psoriasis patients were on topical therapies, 12.1% used biologics, 7.4% used other immunosuppressant agents, 5.6% used phototherapy and 27.2% were untreated. Over time, biologic use increased from 8.7% in 2004 to 21.0% in 2008, while the use of other treatments did not show this trend. In the sub-group of psoriasis patients with BMI information (N=1874; 646 obese and 1,228 non-obese), more obese patients were treated with biologics (20.0% vs. 15.0%) and other immunosuppressant agents (12.4% vs. 6.9%) than non-obese patients. **CONCLUSIONS:** The majority of psoriasis patients were treated with topical therapies. There has been an increase in the proportion of patients using biologics in the recent years. In addition, biologics and other immunosuppressant therapies were more likely to be used among obese patients.

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

PSS30

ASSESSMENT OF UTILITY LOSS FROM DIABETIC MACULAR EDEMA BASED ON RESTORE TRIAL

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OBJECTIVES: Evidence is limited on the extent to which health state utility decrements differ between changes in the better-seeing and worse-seeing eyes following treatment. This study presents estimates of the utility levels as a function of the visual acuity in the treated eye stratified by the condition of the fellow (untreated) eye in patients treated for visual impairment caused by diabetic macular edema (DME). **METHODS:** Data from RESTORE clinical trial with (12 months follow up of ranibizumab treatment for DME) were analyzed. 8 health states were defined by BCVA in the treated eye. Mean utility was estimated using multivariate regression (repeated measures analysis). The regression was tested for confounders including disease severity. The influence of BCVA in the fellow eye on the health index was explored by separating treated eyes into cohorts according to visual acuity of the fellow eye: better, equal or worse. Results were compared with other published studies. **RESULTS:** The utility ranged from 0.86 (SE=0.014) with BCVA 76-100 letters (Snellen score) to 0.55 (SE=0.083) with BCVA 0-25 letters (unadjusted model). Disease severity had a non-significant effect on this range ($p>0.05$). BCVA of the worse seeing eye had a significant impact on the utility (utility decrement -0.11 from 76-100 letters to 36-45 letters), with better seeing eyes demonstrating a utility decrement -0.14 from 76-100 letters to 36-45 letters. Results were inconclusive for health states below 35 letters due to small numbers. **CONCLUSIONS:** This explorative analysis reveals that visual acuity of a worse seeing eye has a significant impact on utility and may be comparable to the impact on the better seeing eye. Importantly, these findings are supported by improvements in quality of life observed using the National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25) for DME patients treated with ranibizumab in the worse seeing eye in RESTORE.

PSS31

ASSOCIATION BETWEEN EQ-5D AND DERMATOLOGY LIFE QUALITY INDEX (DLQI) IN PATIENTS WITH CHRONIC HAND ECZEMA

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OBJECTIVES: HRQoL is often impaired in patients with skin diseases but it is often assessed with different instruments, generating data not directly comparable or not suitable to estimate utility. Assessing the association between HRQoL measures obtained with different instruments could be useful to obtain more complete data. The dermatology life quality index (DLQI) is a condition-specific questionnaire widely used to assess HRQoL in subjects with skin diseases. We aimed to estimate the association between EQ-5D VAS and utility score with the DLQI summary score (max 30 and min 0; higher score corresponds to more impaired quality of life) in patients with severe CHE and refractory to therapy with topical potent corticosteroids. **METHODS:** Within a naturalistic, multicentre cost-of-illness study; patients aged ≥18 years, consecutively accessing at the participating centres, completed the EQ-5D and DLQI questionnaires during the enrolment visit. Individual patient utility was estimated from EQ-5D responses using the standard UK scoring algorithm. A multivariable linear regression model was built to estimate the association between the EQ-5D VAS and utility score with the DLQI summary score, adjusted for age and gender. The bootstrap resampling was used to calculate standard errors and 95% confidence intervals. **RESULTS:** A total of 104 patients (mean age+SD=44.5+15.0, 39.4% male) were enrolled. DLQI mean+SD summary score was 11.3+6.3, EQ-5D VAS mean+SD=60.4+23.3 and EQ-5D utility mean+SD=0.50+0.31. EQ-5D VAS and utility showed a linear negative relationship with DLQI summary score. One point rise in DLQI was associated with a EQ-5D VAS decrease of 1.84 (SE=0.34; 95%CI=-2.52,-1.16; R2=0.261) and a utility index decrease of 0.025 (SE=0.005; 95%CI=-0.035,-0.014; R2=0.254) in utility. **CONCLUSIONS:** DLQI summary score is significantly associated with the EQ-5D VAS and utility index. Our results could be useful to derive EQ-5D information from DLQI data, to perform economic evaluations targeted to patients with severe CHE refractory to therapy with topical potent corticosteroids.

PSS32

IMPACT OF DRY EYE ON EVERYDAY LIFE (IDEEL) - SYMPTOM BOTHER: ESTIMATING CUT-OFF SCORES FOR DRY EYE SEVERITY GROUPS

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OBJECTIVES: The aims of the study were to estimate score ranges associated with dry eye severity based on the Impact of Dry Eye on Everyday Life (IDEEL) Symptom Bother (SB) domain, and to evaluate the overall performance of the SB domain. **METHODS:** A total of 210 participants (130 dry eye patients, 32 Sjogren's patients and 48 controls) completed the IDEEL SB domain and reported their degree of dry eye severity on an ordinal response scale of none, mild, moderate or severe. Ordinal regression analysis using a proportional-odds model was used to provide SB cut-off score ranges associated with the highest probability of membership of each of the four individual response categories. ROC analysis was used to examine the specificity and sensitivity of the overall SB scale. **RESULTS:** Ordinal regression revealed SB to be a significant predictor of patient-reported dry eye severity ($\chi^2=225.59$, $p<0.001$). Examination of individual probabilities associated with each SB score revealed that the following score ranges were associated with the highest probability of membership of each dry eye category: None (0-16), Mild (17-38), Moderate (39-65), Severe (66+). ROC curve analysis revealed excellent performance of the SB

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 α=0.834; emotions α=0.910; function α=0.934) and DLQI (α=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