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possible itching') numeric rating scale, recorded daily during the first 2 weeks of treatment and at clinic visits. Mediation modeling was used to determine the relationship between ISS, the Physician's Global Assessment (PGA, a clinical measure of psoriasis severity assessing erythema, induration, and scaling), and treatments (2, 5, 15 mg BID vs placebo). Mediation modeling included ISS as the dependent variable (averaged post-treatment ISS during weeks 2-12 for every patient), PGA as the mediator variable (averaged post-treatment PGA score during weeks 2-12 for every patient), and treatments (with each drug dose compared with placebo) as the independent variables. Psychometric (correlational) analyses were performed on ISS using post-baseline assessments. **RESULTS:** The direct effects of all CP-690,550 doses on ISS were 70%-81% (vs placebo; $p<0.001$), indicating that drug effects on pruritus were mostly independent of improvements in erythema, induration, and scaling. Daily ISS measurements had acceptable test-retest reliability (intraclass correlation: 0.83) in patients who did not change on PGA during the first 2 weeks of the trial. Pearson correlations between ISS and other measures were consistent with expectations; for example, weekly ISS correlated with weekly PGA (range: 0.3−0.5) and Patient Global Assessment (range: 0.6−0.7). **CONCLUSIONS:** In patients with psoriasis, CP-690,550 has a direct, beneficial effect on patient-reported pruritus that is independent from improvements in clinician-reported psoriasis severity. Post-baseline assessments of ISS showed favorable psychometric characteristics, indicating its potential use as a simple tool for assessment of pruritus in clinical trials.

PSS21

GAP ANALYSIS FOR PATIENT-REPORTED OUTCOMES MEASURES FOR ALOPECIA

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OBJECTIVES: To identify an existing patient-reported outcome (PRO) measure to substantiate labeling or promotional claims for treatment in alopecia. **METHODS:** MEDLINE®, PRO and Quality of Life Instruments (PROQOLID) and PRO and Drug Marketing Authorizations (PROLabels) databases were searched and relevant instruments were identified by reviewing abstracts, articles, and labels for concepts of interest (i.e., color/darkness, length, fullness/thickness, general appearance/attractiveness, self-esteem). The initial instruments were further reviewed and subsequently excluded if they were: not PROs (e.g., hair coverage), not specific to scalp hair growth, or developed without patient input. The final list of instruments was evaluated based on requirements outlined in the US Food and Drug Administration's Final PRO Guidance for Industry (e.g., development and confirmation of conceptual framework, patient involvement in item generation, content validity, recall period, response options, consideration of patient population used for development in relation to future clinical trials). **RESULTS:** Forty-five instruments were identified; 23 were patient-reported, 17 were investigator-rated, three were devices and two were objective hair measures. Forty-one were excluded based on the criteria outlined. The four instruments considered further included alopecia-specific items and instruments used to support the approval of drugs to stimulate hair growth (e.g., Propecia®), specifically, the Kingsley Alopecia Questionnaire (KAP), the Hair Growth Questionnaire, the Hair Problem List, and the Women's Androgenic Alopecia Quality of Life Questionnaire (WAA-QOL). **CONCLUSIONS:** None of the instruments met the PRO Guidance requirements; however, some could be adapted. The Hair Growth Questionnaire could be revised and tested to confirm if the content of the instrument is relevant for women with alopecia as it was developed based on male input only. Alternatively, the Hair Problem List or the WAA-QOL could be supplemented to include more concepts of interest and tested to confirm if the content of the instrument is relevant for both men and women with alopecia.

PSS22

SYSTEMATIC REVIEW OF THE QUALITY OF LIFE LITERATURE IN CHILDREN WITH ATOPIC DERMATITIS

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OBJECTIVES: A systematic review of the literature was performed to elicit the published evidence relating to quality of life (QOL) in children with atopic dermatitis (AD). **METHODS:** OVID MEDLINE® and EMBASE™ were explored by two reviewers for a combined search with terms related to economics and QOL in a paediatric population, for the period 1996-2010. This abstract reports the results of the QOL review. Two reviewers browsed abstracts, retrieved suitable articles and summarized key findings. A third person acted as overall reviewer and adjudicator in case of disagreement. **RESULTS:** From an initial search yielding 704 references, 51 primary research articles were included in the review, 14 reporting on QOL as primary outcome and 37 as secondary outcome. QOL as a primary outcome was reported for Europe (n=7), North America (n=4), Asia (n=3), Australia (n=1) and South America (n=1). One study reported preference-based outcomes. Most studies were based on AD-specific tools such as the Children's Dermatology Life Quality Index or the Dermatology Life Quality Index (n=6), the Infants' Dermatitis Quality of Life Index (n=4), the Quality of Life Index for Atopic Dermatitis or the Parent's Index of Quality of Life–Atopic Dermatitis (n=2) and the Dermatitis Family Impact Questionnaire (n=5). One study was based on general QOL measures from the 12-item Short-Form Health Survey (SF-12). The studies targeting very young children most often used parents as proxies. Most studies pointed to an inverse correlation between QOL and severity as well as correlation between various instruments. Studies reporting on QOL as a secondary outcome confirmed those findings. **CONCLUSIONS:** There is a clear lack of studies eliciting health state utilities. Furthermore, most AD-specific tools do not provide a standard, quantitative measurement in relation to perfect health as would do preference based studies required for cost-utility analyses. Further research should focus on utility measurement.

Sensory Systems Disorders – Health Care Use & Policy Studies

PSS23

COMPARING HEALTH-RISK BURDEN AND TOTAL HEALTHCARE COSTS OF PSORIASIS WITH TOP FIVE CHRONIC CONDITIONS

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OBJECTIVES: Psoriasis (PsO) is a chronic, episodic, immunological skin disease that affects approximately 2-2.5% of US population. It may result in work productivity loss and high overall healthcare costs for employers. However, the impact on health-risks is not well studied. We compared health-risks, lost productivity, and total direct healthcare costs among individuals with PsO and five most prevalent chronic conditions. **METHODS:** Health-risk information and self-reported illness days using health-risk assessment (HRA) data were examined and direct Healthcare costs (medical and pharmacy) using claims data for employees, retirees, and their adult dependents of a large self-insured employer were compared from 2002-2006 among individuals with RA and five most prevalent chronic conditions; asthma, coronary artery disease/congestive heart failure (CAD/CHF), diabetes, hypertension, chronic obstructive pulmonary disease (COPD). **RESULTS:** 54 individuals with PsO were identified. The PsO cohort had moderate health-risk score (2.8/5) which was comparable to individuals with asthma (2.8/5), CHF (2.9), hypertension (2.6) and lower than diabetes (3.2/5) and COPD (3.4/5). A higher proportion (35.2%) of individuals with PsO had >5 illness days per year as compared with individuals with asthma (31.8%), CAD/CHF (25.9%), hypertension (20.4%), diabetes (28.4%), and COPD (33%). Annual direct healthcare costs were also higher for individuals with RA ($28,933) as compared to individuals with asthma ($25,814), CAD/CHF ($22,916), hypertension ($18,632), and diabetes ($28,224), and lower as compared to individuals with COPD ($38,839). **CONCLUSIONS:** Individuals with PsO have similar health-risks but higher illness days, and direct healthcare costs as compared to the individuals with five most prevalent chronic conditions. Psoriasis is a high costs and lost productivity driver for employers. Population health based programs that engage employees in appropriately managing their chronic conditions can help employers reduce health-risks, improve productivity, and may help reduce healthcare costs as well.

PSS24

MEDICATION CHOICE AND ASSOCIATED HEALTH CARE OUTCOMES AND COSTS FOR PATIENTS WITH ACNE AND ACNE RELATED CONDITIONS IN THE UNITED STATES

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OBJECTIVES: Acne is a common condition for which multiple treatment options are available. The patterns of pharmacotherapy for acne and similar conditions, and the effect of those patterns on cost, are not well characterized. This study examined the impacts of patient demographics and medication choices on patient's health status and associated medication costs. **METHODS:** A retrospective cross-sectional study was conducted using the 2007 Medical Expenditure Panel Survey (MEPS) database. Information on patient demographics, health status, medication utilization, and medication costs were obtained from the database representing 3,784,816 patients with acne and similar conditions. **RESULTS:** Weighted multiple linear regression analyses indicated that the use of topical retinoids was preferred in combination with other treatments rather than its monotherapy. Oral antibiotics were widely prescribed and its use was associated with a significant decrease in total annual prescription spending. Use of oral retinoids and oral contraceptives increased the annual prescription costs significantly. Increase in annual drug refills was not associated with the improvement in health status. **CONCLUSIONS:** We observed an association with medication choice for acne and acne related conditions on medication spending. Pharmacologic treatment of acne significantly adds to acne related annual healthcare costs compared to non pharmacologic treatment.

PSS25

MEDICATION ADHERENCE TO TOPICAL MEDICATIONS AND HEALTHCARE EXPENDITURES IN MEDICAID-ENROLLED CHILD WITH ATOPIC DERMATITIS

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OBJECTIVES: To identify factors that predict adherence to topical medication in pediatric population with atopic dermatitis (AD), and assess their impact on healthcare expenditures. **METHODS:** AD patient's age under 12 years old using topic corticosteroid or topical calcineurin inhibitor (TCI) was identified using MarketScan™ Medicaid database from 2005 to 2007. Adherence to AD medication and costs for all healthcare claims and costs for AD related claims were outcomes of interest and measured over 12 months when AD medication started. Medication adherence was measured using medication possession ratio. Multiple regression analysis was carried to examine predictors for medication adherence and their predictions on healthcare costs. **RESULTS:** 4,182 patients were included, with a mean age of 4 years. Adherence to AD medication average was low (41%), with the lowest rates in patients with low potency corticosteroid therapy alone including alclometasone, desonide or hydrocortisone (39%) and the highest rates in those

who used combination therapy (topical corticosteroid and TCI) (68%). Type of health plan, Medicaid eligibility status, number of therapeutic class, comorbidity, hospitalization or not and AD related costs during 12 months before AD medication started were significantly associated with AD medication adherence. Adherence to AD medication was significantly negatively associated with total annual healthcare costs ($p<0.001$) and with AD related costs ($p<0.001$), adjusted for patient demographic, comorbidity, and healthcare utilization characteristics before AD medication started. **CONCLUSIONS:** Poor adherence to topical medication was observed in pediatric AD, and adherence rates differed by the type and combination of AD medication therapy. The detrimental effect of poor adherence on healthcare economic outcome was significant, which implies a need to improve adherence in order to reduce the financial impact of non-adherence. Factors which could contribute non-adherence and financial burden need to be refined and targeted by intervention to improve humanistic and economic outcomes of treatment.

PSS26

PATIENT'S EVALUATION OF THE QUICKNESS OF ACTION OF GINGIVAL INFLAMMATION TREATMENTS

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OBJECTIVES: Gingivitis is defined as lesions on the gingival margin, expressed through gum redness, bleeding, localized edema, and gingival sensitivity. It is most often caused by substances produced by bacterial plaque, or dental biofilm, which develops along the gingival crevice.To evaluate, using patient's interview results, the quickness of action of several treatments for gingival inflammation. **METHODS:** Observational, prospective, longitudinal, multicentric study carried out in France, using data collected by participating dentists and dental surgeons. **RESULTS:** A total of 316 patients with gingivitis returned their questionnaire. women: 65.25%, current smokers:22.93% and 28.51% were ex-smokers. Light and heavy bleeding during brushing was reported by 45.74% and 33.33% of patients respectively. 45.70% reported visible redness, 56.34% reported swollen gums, 13.19% had lesions, but above all 50.52% reported pain. Finally, 62.26% had previous history of gingivitis symptoms. As for dental surgeons: 96.36% had performed scaling, 15.15% gingival curettage, and 13.64% radicular resurfacing. A total of 78.4% judged gingival inflammation to be moderate to severe, 63.10% said it had spread (>30%). In terms of treatment: 98.62% gave patients oral hygiene advice, 87.98% advised on brushing methods, 69.91% recommended specific toothpaste, and 78.85% a mouthwash. A total of 30.61% had generalized inflammation after 1 month, reducing to just 11.24% at 2 months and 15.63% at 3 months. A total of 88.08% reported improvement in inflammation after the first month, 91.59% at 2 months and 93.59% at 3 months. A total of 83.93% felt less pain after 1 month of treatment, 87.90% after 2 months and 92.08% after 3 months.($p=0.0418$). 89.13% felt their treatment was effective after 1month, 97.79% after 2 months and 96.15% after 3 months.($p=0.0036$). **CONCLUSIONS:** In terms of satisfaction, 86.52% were satisfied after 1 month, 94.85% after 2 months and 95.92% after 3 months. ($p=0.0076$). 87.57% felt their treatment was easy to follow after 1 month, 86.76% after 2 months and 92.08% after 3 months. Above all, after the first month of treatment, 88.83% said they would continue using the treatment in prevention even after complete disappearance of gingivitis.

Sensory Systems Disorders – Research on Methods

PSS27

EFFECT OF TREATMENT SWITCH ON THE COST-EFFECTIVENESS OF BIOLOGICS IN PSORIASIS IN PERU AND COLOMBIA

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OBJECTIVES: To evaluate the effect of treatment switch on the cost-effectiveness of biologics used in patients with moderate or severe psoriasis in Colombia and Perú. **METHODS:** In a previous study (Alandete, JC accepted in the ISPOR 13th Anual European Congress) cost effectiveness of etanercept, adalimumab, ustekinumab and infliximab was estimated based on label information for first-(induction) year and second(maintenance) year assuming a 100% treatment continuation ($1USD=COL$1.832=SOL$2.75). For etanercept two induction schemes were considered: 50mg weekly 52 weeks-D1- and 100mg 12 weeks followed by 50 mg 40 weeks-D2-. Effectiveness was evaluated as 75% reduction in Psoriasis Area and Severity Index-PASI 75- infliximab=80%; ustekinumab=69%; adalimumab=59%; etanerceptD2-=52%; etanerceptD1=39%. Infliximab and ustekinumab effectiveness were not significantly different. Both were significantly superior to etanercept (Hawkins et al. meta-analysis presented in the 14th International ISPOR). In this abstract we developed a new model estimating switching probabilities due to treatment failure at week 12 and adverse events. Biologics costs were adjusted considering time on the pre and post-switching periods. Treatment effectiveness was adjusted when biologics were used after switching due to treatment failure. **RESULTS:** Introduction of switching effect ratified ustekinumab dominance in Colombia ($US44,675 in 2 years) generating cost savings of -$US4.049 versus etanerceptD1; -$US4.049 versus adalimumab; -$US7.844 versus etanerceptD2 and -$US27.517 versus infliximab; with higher or same effectiveness than the other biologics in that country. In Peru, ustekinumab changed from being the most cost-effective option and became the dominant option ($US41.827 in 2 years) generating cost savings of -$US283 versus etanerceptD1; -$US489 versus adalimumab; -$US3581 versus etanerceptD2 and -$US13.499 versus infliximab. **CONCLUSIONS:** In the studied countries inclusion of the switching effect due to treatment failure and adverse events ratifies cost-savings observed in Colombia and makes ustekinumab the cost-saving option in Peru. These results corroborate those observed in the USA and Europe.

PSS28

EFFECT OF DIFFERENT RECALL PERIODS ON DRY EYE SYMPTOM RATINGS

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OBJECTIVES: Clinical studies of dry eye disease (DED), a highly symptomatic disease, often ask patients to evaluate their DED symptoms using patient-reported outcomes instruments. Most of these instruments use a one-week recall period. The effect of this recall period on the accuracy of DED symptom assessments has not been documented. The purpose of our research was to compare self-reported DED symptoms between one-week and daily recall periods. **METHODS:** We enrolled 156 DED patients to a web-based observational study to assess their DED symptoms once a day for 9 days. For each of the 14 symptoms, we asked the patients to rate the frequency and intensity on a 0-6 rating scale, with a higher score indicating worse symptom. The assessments on Days 1 and 9 had a one-week recall period, while the assessments on Days 2-8 had a one-day recall period. We then calculated the mean weekly scores for Day 1 and Day 9 and the mean daily scores for Days 2-8, and tested the differences between the mean weekly and daily scores using matched-pair t tests without multiplicity adjustment. **RESULTS:** The Day 1 mean weekly scores were significantly higher than the mean daily scores for all 14 symptoms in both frequency and intensity. The Day 1 mean weekly scores were also significantly higher than the Day 9 mean weekly scores in 10 frequency and 11 intensity scores. The Day 9 mean weekly scores were slightly higher than the daily scores; however, most of the differences were not statistically significant. **CONCLUSIONS:** Patients' self-ratings of their DED symptoms using a one-week recall period are consistently inflated when compared to their ratings using a one-day recall period. Such inflation should be considered when designing clinical studies for DED.

PSS29

DEVELOPMENT OF THE MODIFIED OCULAR COMFORT INDEX (MOCI)

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OBJECTIVES: Dry eye disease (DED) is characterized by symptoms of ocular discomfort, visual disturbance and reduced tolerance to environmental stressors. DED has a significant negative impact on the quality of life (QOL) of persons affected, and imposes a massive burden on medical resources owing to its high prevalence and chronic nature. It is not known if available patient-reported outcome (PRO) instruments fully capture the scope of DED symptoms and their impact on QOL. The purpose of our ongoing research is to develop a PRO instrument that meets the needs of clinical studies investigating potential treatments for DED. **METHODS:** Patients with DED in five countries (United States, United Kingdom, Spain, Japan and Korea) were interviewed to identify their symptoms and the impact of the disease on QOL (n=120). Based on these results, items were drafted that were tested in two web-based studies with mild-moderate DED subjects (n=106 and 156) and face-to-face interviews with severe DED subjects (n=22). **RESULTS:** Items enquiring about 8 additional symptom experiences (16 items grouped in doublets asking about frequency/intensity) were added to the original Ocular Comfort Index (OCI) using the same question format and response structure (fluctuating vision, light sensitivity, redness, foreign body sensation, excessive tearing, excessive blinking, ocular irritation and stickiness). Additionally, 2 items that enquired about the most bothersome symptom and the extent of bother, and 12 items that appraised how symptoms interfered with the ability to perform daily activities were included. **CONCLUSIONS:** Patient interviews suggest that available PRO instruments do not fully capture the scope of DED symptoms and their impact on QOL. The modified OCI (mOCI) will be used in clinical studies to facilitate its refinement and validation.

PSS30

BURDEN OF INFANTILE HEMANGIOMA: DEVELOPMENT OF A QUESTIONNAIRE

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OBJECTIVES: Infantile hemangioma (IH) develops during the first weeks of life; it normally forms within 3to6 months, then regresses very slowly over a duration of 3 to 7 years. In complicated forms, it is possible to encounter haemorrhaging, necroses and ulcerations, infections and, more exceptionally, respiratory distress, cardiovascular shunt. To explore the handicap, in its largest sense, generated by IH using a questionnaire to express the burden on the daily life of the parents. **METHODS:** The questionnaire was developed following a strict methodological process, involving a multidisciplinary team incorporating various players (doctors, nurses, social workers) who are involved in the treatment of patients or who are specialised in the construction of questionnaires. A review of the literature and discussions with the families were conducted in order to identify the concepts related to the pathology. **RESULTS:** Exploratory assessments showed that the concept of burden could be structured around two main modules: assess the impact directly for the first-module. The consequences of HI on daily life, family and personal relationships, work, financial situation and psychological impact for the second-module. A third module focuses on the behaviour of the child; this module will evolve over time and depending on the analyses. Fifty-six preliminary items were identified following a first discussion. A first analysis managed to reduce these items to 36 whilst conserving the 3 modules but making it easier to use the analysis. **CONCLUSIONS:** The Hemangioma-Burden-Questionnaire will allow clinicians to better understand the impact and consequences of the pathology on the family. It will also allow the development of the burden to be monitored according to the rate of development of the illness and its treatment.It will also allow the