

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

Dennee-Sommers B<sup>1</sup>, Galipeau N<sup>1</sup>, Fitzgerald K<sup>1</sup>, Evans C<sup>1</sup>, Daniels S<sup>2</sup>, Burgess SM<sup>2</sup>

<sup>1</sup>MAPI Values, Boston, MA, USA, <sup>2</sup>Allergan, Inc., Irvine, CA, USA

**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

Iskedjian M<sup>1</sup>, Navarro V<sup>2</sup>, Khondoker F<sup>1</sup>, Farah B<sup>3</sup>

<sup>1</sup>PharmIdeas Research and Consulting, Oakville, ON, Canada, <sup>2</sup>PharmIdeas Europe SAS, Lyon, France, <sup>3</sup>PharmIdeas Research and Consulting, Ottawa, ON, Canada

**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

Naim A<sup>1</sup>, Pitts J<sup>2</sup>, Chen CY<sup>3</sup>, Wright D<sup>3</sup>, Chalk MB<sup>2</sup>, Edington D<sup>3</sup>

<sup>1</sup>Centocor Ortho Biotech Services, LLC, Horsham, PA, USA, <sup>2</sup>Chalk & Associates, Austin, TX, USA, <sup>3</sup>University of Michigan, Ann Arbor, MI, USA

**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 (33.2%) 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

Patel P<sup>1</sup>, Lin HC<sup>2</sup>, Feldman SR<sup>3</sup>, Fleischer AB<sup>3</sup>, Nahata M<sup>4</sup>, Balkrishnan R<sup>2</sup>

<sup>1</sup>University of Georgia, Athens, GA, USA, <sup>2</sup>University of Michigan, Ann Arbor, MI, USA, <sup>3</sup>Wake Forest University, Winston-Salem, NC, USA, <sup>4</sup>Ohio State University, Columbus, OH, USA

**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 increase 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

Qu HT<sup>1</sup>, Feldman SR<sup>2</sup>, Balkrishnan R<sup>3</sup>

<sup>1</sup>University of Michigan College of Pharmacy, Ann Arbor, MI, USA, <sup>2</sup>Wake Forest University, Winston-Salem, NC, USA, <sup>3</sup>University of Michigan, Ann Arbor, MI, USA

**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