grades ($272), however, the differences in expenditures were not statistically significant. No statistically significant differences were detected in the health care expenditures among categories of other variables but this may be due partly to the relatively small sample size. CONCLUSION: Gender and family size appeared to play a role on the magnitude of health care expenditures among dermatophytosis patients.

**PES14**

**MEDICATION AND HEALTH CARE SERVICE UTILIZATION RELATED TO DEPRESSIVE SYMPTOMS IN OLDER ADULTS WITH PSORIASIS**


1University of Texas School of Public Health, Houston, TX, USA; 2Wake Forest University School of Medicine, Winston-Salem, NC, USA

**OBJECTIVES:** This study examined the relationship between depressive symptoms and related medication adherence and health care costs in older adults (age ≥ 65 years) with psoriasis.

**METHODS:** This was a prospective longitudinal cohort study over a 2-year post enrollment period in a population of older adults with psoriasis enrolled in a Medicare Health Maintenance Organization (HMO) in southeastern United States with prescription benefits. Upon enrollment, each enrollee was mailed a comprehensive health status assessment battery, which included the Center for Epidemiologic Studies Depression (CES-D) scale. Information on medication adherence (using medication possession ratio) and total health care utilization/costs following enrollment were retrieved from the Medicare HMO database. Sixty-three older adults with psoriasis using topical corticosteroids therapy and enrolled in the Medicare HMO for a 2-year continuous period were included in the final sample.

**RESULTS:** Nearly one-fifths of the patient population had depressive symptoms. Patients with psoriasis who had depressive symptoms at the time of enrollment were less likely to be adherent to topical corticosteroid medication (Spearman rho = −0.29, p < 0.01) and less likely to utilize health care resources as evidenced by lower health care costs (Spearman rho = −0.27, p < 0.05), after confounder adjustment.

**CONCLUSIONS:** The prevalence of depressive symptoms in older adults with psoriasis is commonplace, with strong, yet unexplained correlations between presence of depressive symptoms and lower rates of medication and health care service use among these patients.

**EAR/EYE/SKIN DISEASES OR DISORDERS**

**EAR/EYE/SKIN DISEASES OR DISORDERS—Quality Of Life Studies**

**PES15**

**A COMPARISON OF QUALITY OF LIFE IN PATIENTS WITH AGE-RELATED MACULAR DEGENERATION (AMD) WITH MONOCULAR VERSUS BILATERAL DISEASE**

Dugas A, Sharma S, Blair J, Bakal J

1Pfizer Global Pharmaceuticals, Pfizer, Inc, New York, NY, USA; 2Queen’s University, Kingston, ON, Canada

**OBJECTIVES:** To determine if the quality-of-life of AMD patients with monocular visual dysfunction differs from that of those with bilateral visual dysfunction. **METHODS:** A cross-sectional study (n = 168) determined if there was a statistically significant difference in patient-reported health related quality-of-life (HRQoL) of AMD patients with monocular versus bilateral visual dysfunction. Subjects underwent a series of interviewer-administered techniques to ascertain their HRQoL, including the Visual Function Index (VF-14) and patient preferences elicited through both the time tradeoff (TTO) and standard reference gamble (SRG). Visual acuity obtained from a subject’s better- and worse-seeing eye was categorized as 20/20 to 20/40, 20/40–20/70, 20/80–20/200, and worse than 20/200. Based on the various combinations of these 4 visual acuity groupings in the better-seeing (BSE) and worse-seeing eyes (WSE), subjects were classified into one of 10 subgroups. Multivariate linear regression determined if an association existed between various clinical variables and HRQoL. **RESULTS:** The mean age was 72 years; 63% were females. Mean scores were: VF-14, 66.1; TTO, 0.86; SRG, 0.89. Subjects with binocular visual dysfunction reported a lower HRQoL compared to those with monocular dysfunction (p < 0.001); mean differences in the TTO, SRG, and VF-14 were 0.19 (SE = 0.04), 0.14 (SE = 0.04), and 39.2 (SE = 3.9), respectively. Multivariate models demonstrated that only visual acuity subgrouping, a function of acuity in both the BSE and WSE, was associated with HRQoL score (overall eta^2^ = 34.8%, p < 0.01, and partial eta^2^ equal to 22% [TTO], 20% [SRG] and 60% [VF-14]). Models including both BSE and WSE visual acuity explained an additional 10% in HRQoL variability compared to models with only BSE visual acuity. **CONCLUSIONS:** Subjects with binocular visual dysfunction reported a significantly lower HRQoL as compared to those with monocular dysfunction. These results suggest that binocular vision is a better predictor of HRQoL in AMD than only visual acuity in the BSE.

**PES16**

**VALIDATION OF A NEW SELF-ASSESSMENT QUESTIONNAIRE AND THE SKINDEX-29 QUALITY OF LIFE (QOL) INSTRUMENT FOR CHRONIC HAND DERMATITIS (CHHD): A PILOT STUDY**

Fowler J, Ghosh A, Duh M, Raut M, Reynolds J, Thorn D, Den E, Chang J

1University of Louisville, Louisville, KY, USA; 2Analysis Group, Boston, MA, USA; 3Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA

**OBJECTIVE:** The lack of specific ICD-9 codes and under-reporting and diagnosis of ChHD suggests a need for a self-assessment survey to identify ChHD. This pilot study was conducted to validate a newly designed self-assessment questionnaire and the Skindex-29 QoL instrument for use by ChHD patients. **METHODS:** A clinical questionnaire, consisting of 16 questions, was developed to identify patients with ChHD and to assess its severity, through patient self-administration. Sensitivity, specificity, and receiver operating characteristic (ROC) curve were used to evaluate how closely the ChHD diagnosis based on self-assessment concurred with physician’s diagnoses. Also, Skindex-29, a QoL instrument with 29 questions not previously validated in a ChHD population, was evaluated for internal consistency and construct validity for ChHD patients in this study. Forty-five patients (ChHD n = 20; other skin disorders n = 20), with a mean age of 46.6 ± 14.8 years and 30% males, were randomly selected from a dermatology clinic in Louisville, Kentucky for this pilot study. **RESULTS:** The performance of the clinical questionnaire matched the physicians’ diagnosis in identifying ChHD with a sensitivity of 85.8%, a specificity of 95.8%, and an area under the ROC curve of 0.83. The internal consistency of the Skindex-29 was higher than that reported previously in a general dermatology population, with a Cronbach alpha of 0.77 to 0.94 for 3 different (symptoms, emotions and functioning) domains. The construct validity of Skindex-29 was evaluated by examining the correlation between the overall score and physician’s assessment of ChHD severity. The Pearson rho was 0.55 (p = 0.07), slightly lower than that reported previously, but higher than that reported for other QoL instruments. **CONCLUSIONS:** This study indicates that the newly developed ChHD self-assessment
improvements in all domains of SF-36 with the largest increases in bodily pain (8.2), vitality (8.0), general health perceptions (6.6) and physical function (5.7). Non-responders reported worsening in all 3 domains, which remained unchanged (vitality (1.3), mental health (0.9), and role emotional (0.0)). At 12 months, 43 LJP394 and 24 placebo treated patients were responders; a ratio of 1.8; 35.3% overall. Improvements reported by responders increased by month 12, with largest changes in role physical (13.8), vitality (10.2), general health profile (9.3), and bodily pain (7.3), again with no change or deterioration in non-responders. Improvements in domain scores were reflected in physical component summary [PCS] score. MCID was determined to range from 6.7 to 11.4 points in domain and 3.4 to 3.9 in PCS scores, consistent with literature reported estimates of 5–10 and 2.5–5.0 points. CONCLUSION: Sustained reductions in AåsDNA Ab levels lead to improvement in patient reported HRQOL. These improvements are clinically meaningful, regardless of treatment group. LJP394 administration resulted in 1.8 to 4.0 times more responders than placebo.

EARS/EYES/SKIN

EARS/EYES/SKIN—Health Policy Studies

THE IMPACT OF THE SYSTEM TO MANAGE ACCUTANE-RELATED TERATOGENICITY™ (SMART)™ RISK MANAGEMENT PROGRAM ON ISOTRETINOIN PRESCRIBING TRENDS

Mendelson AB1, Governale LA2

1FDA & CDC, Rockville, MD, USA; 2FDA, Rockville, MD, USA

OBJECTIVE: To describe an evaluation of isotretinoin prescribing patterns before and after implementation of the System to Manage Accutane-Related Teratogenicity (SMART), a risk management plan developed by Hoffmann-LaRoche to minimize the risk of pregnancy among women taking Accutane. METHODS: The IMS Health, National Prescription Audit Plus provided information on the number of prescriptions dispensed for the pre- (1 April 2001–31 March 2002) and post- (1 April 2002–31 March 2003) SMART periods. Data on patient gender, prescriber specialty, and physician-reported severity of indication for use were obtained from AdvancePCS, a large pharmacy benefits manager (PBM), and the IMS Health, National Disease and Therapeutic Index. RESULTS: In the 12-months prior to SMART, 1,508,000 prescriptions were dispensed for isotretinoin; declining approximately 23% to 1,160,000 prescriptions in the year following SMART. Dermatologists were the most common prescribers of isotretinoin, accounting for 76% and 80% of the prescriptions dispensed in the year before and after SMART, respectively. Half of the claims for isotretinoin were for females in both the pre- and post-SMART eras. The severity of indication for use did not appear to be affected by SMART. In the year pre-SMART, 53% of the isotretinoin mentions during office visits for female patients were for “severe” acne cases, compared to 55% in the year post-SMART. Similar percentages were seen for males. CONCLUSIONS: SMART may have influenced the number of isotretinoin prescriptions dispensed, but appeared to have little impact on other variables such as prescriber specialty and severity of indication for use.

MENTAL HEALTH

MENTAL HEALTH—Clinical Outcomes Studies

EFFECT OF ZIPRASIDONE INITIAL DOSING ON DISCONTINUATION IN SCHIZOPHRENIA

Harrison DJ1, Joyce AT2, Ollendorf DA2, Loebel A1, Warrington L1

1Pfizer Inc, New York, NY, USA; 2PharMetrics Inc, Watertown, MA, USA

OBJECTIVES: To examine the effects of initial ziprasidone dose on discontinuation rates, using the PharMetrics integrated medical and pharmacy claims data. METHODS: Patients ≥18 years with a diagnosis of schizophrenia and a ziprasidone claim between March 2001 and February 2003 continuously enrolled for 26 months before and 23 months after initiation of ziprasidone were stratified by initial daily dose (≥40 mg and <80 mg [low] vs. ≥80 mg and <120 mg [medium] vs. ≥120 mg [high]). The 6-month risk of discontinuation was examined using Cox proportional hazards models controlling for gender, psychiatric comorbidities, and pre-ziprasidone utilization of antipsychotics (atypical, conventional, none). RESULTS: Mean age of the sample (n = 1058) was 38 years; 42% were male. The 6-month risk of discontinuation was significantly greater in patients with a low vs high initial dose (HR = 1.357, 95% CI = 1.070, 1.721; p = 0.012) and trended towards significance when comparing a medium vs high initial dose (HR = 1.163, 95% CI = 0.905, 1.494; p = 0.237). The largest difference in discontinuation rates between dose groups occurred after the first prescription. CONCLUSIONS: Patients initiating ziprasidone therapy with an initial dose of at least 120 mg/day had better medication adherence compared with those initiating at lower doses. This may reflect improved efficacy at daily doses ≥120 mg.