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 positively associated with total annual medication care 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 to 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
Mouton P1, Essahaci N2, Watt M3, Auges M3, Taieb C1
1CEPI, Marseille, France, 2PFS, Boulogne Billancourt, France, 3PFOC, Castres, France
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: Total 154 patients with gingivitis returned their questionnaire whose mean age: 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 45.70% 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% advised on 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 85.52% felt less pain after 1 month of treatment, 87.10% after 2 months and 92.08% after 3 months (p=0.0418). 89.11% felt their treatment was effective after 1 month, 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
Allandet JC, Jensenial J, Bogota, Colombia
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 Peru.

METHODS: In a previous study (Allandet, JC accepted in the ISPOR 13th Annual 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 in inflammation after the first month, 91.59% at 2 months and 93.59% at 3 months.


PSS28
EFFECT OF DIFFERENT RECALL PERIODS ON DRY EYE SYMPTOM RATINGS
Ruiz WM1, Li J2, Johnson ME1
1G&S Research, Indianapolis, IN, USA, 2Pfizer, Inc., San Diego, CA, USA, 3Bristol Eye Hospital, Bristol, UK

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 322 patients to a 14-day observation and daily DED symptoms once a day for 9 days. For each of the 14 symptoms, we asked the patient 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. We then calculated the mean weekly scores for Day 1 and Day 9 and the daily mean 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)
Johnson ME1, Ruiz WM2, Li J2
1Bristol Eye Hospital, Bristol, UK, 2G&S Research, Inc., Indianapolis, IN, USA, 3Pfizer, Inc., San Diego, CA, USA

OBJECTIVES: Dry eye disease (DED) is characterized by symptoms of ocular comfort, 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 (fluid-rating of light sensitivity, redness, foreign body sensation, tearing, ocular discomfort, discomfort with contact lenses, dryness, ocular irritation and discomfort). Additionally, 2 items that enquired about both 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. Patients interviewed for the second-module suggested 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
Taieb C1, Voisard JJ2, Ruiz F3
1GEPI, Marseille, France, 2PFD, Lavaur, France, 3Clinica, Bagnues, France

OBJECTIVES: Infantile hemangioma (IH) develops during the first weeks of life; it normally forms within 3-6 months, then regresses very slowly over a duration of 3-7 years. In complicated forms, it is complicated and it is difficult 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 patients.

METHODS: We used the questionnaire developed by the collaboration with the families, 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 was conducted in order to identify the concepts related to the pathology.

RESULTS: Exploratory analyses showed that the concept of burden could be structured around two main modules: assess the impact directly for the first-module. The consequences of IH on daily life, family and personal relationships, well being, social situation and psychosocial support for the child and the other biologies 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, $US4589 versus adalimumab, $US3535 versus etanerceptD2 and $US3535 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.
families of the children to better defend their interest before the health authorities in terms of expenditure (medical or other) for which the part remaining their responsibility is increasing significantly.

Systemic Disorders/Conditions – Clinical Outcomes Studies

PSY1

SEVERE RENAL, HEPATIC AND GASTROINTESTINAL EVENTS ASSOCIATED WITH DEFERASIROX IN PATIENTS WITH TRANSFUSION-DEPENDENT ANEMIA

Huang WE1, Hsiao FY2, Chou HC1, Tsai YM1, Yen HC3, Ke WM4

1National Yang-Ming University, Taipei, Taiwan, 2National Taiwan University, Taipei, Taiwan, 3Institute of Health and Welfare Policy, National Yang-Ming University, Taipei, Taiwan, 4Institute of Health & Welfare Policy, National Yang-Ming University, Taipei, Taiwan, 5Taiwan Drug Safety Foundation, Taipei, Taiwan

OBJECTIVES: Iron chelators (deferasirox or deferoxamine) are essential to patients who need life-long blood transfusion (e.g. β-Thalassemia). However, in 2010, the US Food and Drug Administration (FDA) had issued a warning on potential adverse events associated with iron chelators, especially deferasirox. Objectives of this retrospective cohort study was to compare the risk of renal impairment, hepatic impairment, and gastrointestinal bleeding in patients with transfusion-dependent anemia using deferasirox or deferoxamine.

METHODS: Patients with transfusion-dependent anemia (sickle cell disease, β-thalassemia, myelodysplastic syndrome and aplastic anemia) and were prescribed iron chelators (deferasirox or deferoxamine) were identified from the 2005–2009 Taiwan’s National Health Insurance database. Cox proportional hazards models were used to assess the association between iron chelators and occurrences of adverse events (renal impairment, hepatic impairment, and gastrointestinal bleeding). Subsequently, propensity score for age, sex, drug exposure (days), type of transfusion-dependent anemia and medical history. RESULTS: Patients were categorized into deferasirox (n = 180), deferoxamine (n = 586), and mixed users (n = 202), based on the drug they received during the follow-up. The crude rates of adverse events were 4.16, 3.16 and 0.65 per 10,000 person-year in deferasirox, desferrioxamine and mix users, respectively. After adjusting covariates, there was no association between deferasirox and adverse events (hazard ratio [HR] 0.84; 95% CI, 0.59–2.00) compared to deferoxamine users. CONCLUSIONS: In this population-based analysis, transfusion-dependent anemia patients using deferasirox and deferoxamine were at similar risk of adverse events.

PSY2

THE ASSOCIATION BETWEEN THERAPY WITH ANGIOTENSIN-CONVERTING ENZYME INHIBITORS AND HEMOGLOBIN LEVEL

Chodick G1, Raz R1, Lehem E1, Steinfeldt A1, Berliner S1, Zeltser D2, Rogowski O1, Shalit Y1

1Maccabi Healthcare Services, Tel Aviv, Israel, 2Tel Aviv Sourasky Medical Center, Tel Aviv, Israel

OBJECTIVES: To assess the hematological effects Angiotensin-converting enzyme (ACE-I) inhibitors and Angiotensin II receptor blockers (ARB) in patients without concomitant renal impairment. METHODS: In the present retrospective cohort study we used the Maccabi Healthcare Services’ database to identify new users of ACE-I (N=14754) or ARB (N=202), or calcium channel blockers (CCB, N=3087) with available hemoglobin (Hb) tests between 2004 and 2009. Excluded were patients purchasing drugs from more than one medication class, diagnosed with renal impairment or cancer. Median HB levels one year before and after first medication purchase were calculated and compared according to the proportion of days covered with medication class. RESULTS: Persistent use of ACE-I and ARB was associated with a significant decrement in hemoglobin level. Patients at the highest HFX level were at a significantly higher risk of developing anemia among ACEI (OR = 1.59, p < 0.001), and ARB (OR = 2.21, p < 0.05). The relationship between CCB therapy and Hb decrement was substantially weaker. CONCLUSIONS: HB levels are reduced during the first year of ACE-I or ARB therapy. This association is dose-dependent and is not likely to be caused by artifacts related to patient adherence.

PSY3

OPIOIDS IN NON-MALIGNANT PAIN: ARE THEY EQUIVALENT IN SAFETY PROFILE? A NETWORK META-ANALYSIS

Siddiqui MQ, Gupta J, Bhatana M, Sehgal M

Heron Health Private Ltd, Chandigarh, India

OBJECTIVES: Severe non-malignant pain affects a large number of patients. Opioids are an important option for analgesia. However, there is relatively little information about the comparative safety of opioids. We sought to compare the safety and tolerability of commonly used opioids in non-malignant pain through network meta-analyses of randomized controlled trials (RCTs). METHODS: Medline and Embase were searched from 2000 to 2011 for RCTs comparing commonly used opioids (tramadol, oxycodeone, hydrocodone, propoxyphene, codeine) in non-malignant pain. Studies were assessed for inclusion/exclusion based on a prespecified protocol. Two reviewers undertook data extraction independently. Any disagreement was resolved by a third reviewer. A network meta-analysis was used to combine direct and indirect evidence for safety outcomes reported in the trials. Based on the incidence of adverse events (AEs) for each intervention, a probability-based ranking (probability of being worst) was generated using WinBUGS. RESULTS: Of the 1156 studies, 5 RCTs enrolling 1399 patients were eligible for inclusion. The most frequent withdrawal due to AEs were nausea/vomiting, somnolence/dizziness, headache, constipation and dry mouth. Withdrawals due to AEs were most common with codeine (P=42%) followed by hydrocodone (P=28%), tramadol (P=19%), and oxycodone (P=10%). The probability of occurrence of nausea and somnolence was the highest with codeine. Dizziness was most frequently associ-