PSS17

SICKNESS ABSENCES DUE TO CHRONIC HAND ECZEMA (CHE) IN PATIENTS TREATED WITH ORAL ALITRETINOIN UNDER DAILY PRACTICE CONDITIONS: RESULTS OF THE TOCCATA OBSERVATIONAL STUDY COMPRISING 522 WORKERS

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OBJECTIVES: CHE can lead to considerable sickness absences, but quantitative data regarding CHE-related productivity changes under different treatments are scarce. The German observational study TOCCATA, collected effectiveness and tolerability data of oral alitretinoin in daily practice and concomitantly documented information regarding CHE-related productivity loss, the main subject of this analysis. **METHODS:** A total of 680 adult CHE patients treated with oral alitretinoin for up to 24 weeks, according to the approved prescribing information, were included. Sickness absence days due to CHE were documented at baseline (over the last 12 months prior to the study and when ongoing at inclusion) and at each monthly follow-up visit (4 weeks retrospectively). This analysis focuses on the proportion of patients with sick leave and days off work due to CHE and correlation of changes in disease severity. **RESULTS:** 219 (42%) of all 522 patients in employment had sick leaves in the last 12 months (mean: 35 days), 80 (15.4%) patients were on sick leave at inclusion, and this proportion gradually decreased to 7.1% at observation end. In line with this observation, the 80 patients had an average 17.6 consecutive days off work (last 4 weeks at inclusion), however, only 7.6 days off during the four weeks before end of observation. The highest reduction in CHE-related sickness absence was observed between the visits 4 to 12 weeks, which was associated with the clinical CHE improvements seen during this period. **CONCLUSIONS:** This is the first report of beneficial changes in disease-related sickness absences in CHE patients associated with successful oral alitretinoin treatment. At end of study, the number of patients with sickness absences due to CHE had decreased by approximately 50% compared to baseline. This observation certainly merits further exploration in different health care settings potentially confirming economic benefits for patients, their employers and the society at large.

SENSORY SYSTEMS DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PSS18

COMPARISON OF A 24-HOUR AND 7-DAY VERSION OF A PATIENT REPORTED OUTCOME MEASURE FOR PSORIASIS SYMPTOM SEVERITY

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OBJECTIVES: Research about the limitations of cognitive processes in memory suggest retrospective recall may be less accurate than recall within the past 24 hours. Daily diaries, however, are often more burdensome for study subjects and are more expensive to administer than weekly retrospective instruments. We sought to evaluate a 24-hour recall version (24-hour PSI) and a 7-day retrospective version (7-day PSI) of the Psoriasis Symptom Inventory (PSI) to test the equivalence of symptom severity assessed with the two versions. **METHODS:** Using a prospective, observational design, adult patients receiving usual care for their plaque psoriasis (Psoriasis Area and Severity Index [PASI] $\geq$10) were recruited from clinics and randomized. Subjects completed the 24-hour PSI for 7 days and completed the 7-day PSI on the seventh day. Comparison of average daily diary scores and 7-day retrospective scores were made with Pearson's correlation coefficients and simple bivariate comparisons (t-test). Potential exposure effects of daily PSI administration in the days preceding the 7-day retrospective assessment were examined in sensitivity analyses. **RESULTS:** Among the 139 subjects, mean age and PASI scores were 51.2 and 17.6, respectively. There was high agreement between results from the daily 24-hour PSI and the 7-day PSI assessments. With the exception of *Flaking* (0.08, p=0.02), no significant mean differences were found in the remaining seven PSI symptoms (*Itching, Redness, Scaling, Burning, Stinging, Cracking, and Pain*) between the 24-hour PSI (7-day average) and the 7-day PSI. Correlations between the two PSI versions ranged from 0.86 (scaling) to 0.92 (pain). Completion of the daily assessment did not influence responses on the 7-day PSI. **CONCLUSIONS:** Overall findings show that the two PSI versions yield equivalent results. Both the 24-hour PSI and 7-day PSI would provide comprehensive capture of symptoms in psoriasis studies and clinical trials.

PSS19

VALIDATION OF THE PAEDIATRIC HEARING IMPAIRMENT CAREGIVER EXPERIENCE (PHICE) INSTRUMENT

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OBJECTIVES: To validate and shorten the Paediatric Hearing Impairment Caregiver Experience (PHICE) instrument. **METHODS:** A total of 125 caregivers of hearing impaired children attending the otolaryngology, audiology, and aural rehabilitation at a local clinic were administered the 68 item questionnaire. Exploratory factor analysis was conducted. A 5 factor structure was adopted and items with high cross-loadings were dropped. The 5 factor structure was then analysed using confirmatory factor analysis. Cronbach's α was computed to assess internal consistency. **RESULTS:** A 5 factor structure corresponding to the factors: "Adaptation to hearing loss", "Childcare support", "Healthcare", "Education" and "Policy" was adopted. Confirmatory factor analysis suggest a good model fit (RMSEA = 0.067, RMR = 0.329, SRMR = 0.0752, NFI = 0.830, CFI = 0.949). This model fit is assessed to be superior than the original 8 factor structure. Cronbach's α were high (>0.75) for each subscale. 3 questions that were deemed important from a clinical point of view but was removed would continue to be a part of the instrument but will not be used in the computation of the subscale scores. **CONCLUSIONS:** The 68 item questionnaire has been reduced to 39 items. A new 5 factor structure is proposed that better explains the underlying items. Three items was added back despite being dropped due to their important clinical value.

PSS20

COMPARATIVE STUDY OF THE PERFORMANCES OF GENERIC AND DISEASE-SPECIFIC MEASURES IN CATARACT PATIENTS

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OBJECTIVES: To evaluate the overall performances of generic and disease-specific measures. **METHODS:** One disease-specific and five generic measures were administered in cataract patients at baseline, 1- and 6-month. The disease-specific measure was the National Eye Institute Visual Functioning Questionnaire-25 (VFQ-25) and the generic measures included the Short Form-6D (SF-6D), EuroQol-5D (EQ-5D), Self-Administered Quality of Well-being Scale (QWB-SA), and two versions of the Health Utilities Index (HUI2 and HUI3). The global rating of change, in a 5-point rating scale, was applied as an anchor and the score change between baseline and 6-month was calculated accordingly. Two definitions for responders who experienced a minimally important difference were used: patients whose global ratings were "somewhat better" or above (Model 1) and patients rated as "somewhat better" or above, or "somewhat worse" or below (Model 2). In Model 2, for the patients who reported "somewhat worse" or below, the sign of the score changes were reversed. In Experiment 1 the performance of the generic measure was compared against the VFQ-25 based on Model 1. In Experiment2 the impact of using different classifications for the responders was examined by comparing the performances of Model 1 and Model 2 for each measure. The performances of the measures were compared based on the areas under the receiver operating characteristics curves. **RESULTS:** A total of 223 cataract patients were included. In Experiment 1, only the EQ-5D showed significantly lower performance than the VFQ-25 ($p<0.0001$) and there were no differences between the VFQ-25 and the other generic measures. In Experiment 2, the performances between Model 1 and 2 were not significant in all the measures. **CONCLUSIONS:** In this cataract population, we found that the generic measures were as sensitive as the disease-specific measure in most cases and the performance of the measure did not depend on the different definitions for the responder.

PSS21

ASSESSING PRURITUS AMONG PATIENTS WITH ATOPIC DERMATITIS: TARGETED LITERATURE AND INSTRUMENT REVIEW

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OBJECTIVES: Pruritus is a key criterion in the diagnosis of atopic dermatitis (AD) and has been associated with lower levels of health-related quality of life in both pediatric and adult patients. The objective of this study was to identify information and instruments relevant to the measurement of pruritus in adolescent and adult AD patients. **METHODS:** A PubMed search was conducted to identify relevant literature and existing PRO measures (items, subscales, and instruments) designed to assess the severity, frequency, and/or impact of AD-related pruritus. Articles were limited to studies conducted in humans, published since 2000, and in English. Search terms included atopic dermatitis, itch, and pruritus. In addition to using sources identified during the literature review, a search of published PRO instrument sources (e.g., Patient-Reported Outcome & Quality of Life Instruments Database [PROQOLID]) and the RTI-HS internal PRO instrument repository was conducted. Identified PRO instruments were evaluated based on the criteria described in the Food and Drug Administration's 2009 guidance on PROs for product label claims. **RESULTS:** Literature review results confirmed pruritus is a central feature of AD and affects both daytime functioning and nighttime sleep in many AD patients. In addition, the effective treatment of pruritus represents an unmet need among patients with AD. Nine PRO instruments measuring AD-related pruritus were identified and evaluated. Only one of these measures had been developed exclusively in patients with AD, and none of these measures were developed or evaluated with the scientific rigor outlined in the FDA's PRO guidance. **CONCLUSIONS:** The results of this targeted review indicate the need for new treatments that improve pruritus among patients with AD. In addition, to communicate this treatment benefit, the development of a new AD-related pruritus instrument is warranted in order to more accurately describe the effect of therapy on this important disease symptom.

PSS22

A COMPREHENSIVE HEALTH IMPACT ASSESSMENT AND DETERMINANTS OF QUALITY OF LIFE, HEALTH AND PSYCHOLOGICAL STATUS IN ACNE PATIENTS

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OBJECTIVES: . Measurement of acne impact on QoL, health and psychological status. To analyse the relationship between socio-demographic variables, disease severity and mental status on QoL of acne sufferers. **METHODS:** . Acne cases were selected from a survey conducted in 2010. The Short-Form 12-Item Health Survey and the Skindex-29 were used to assess health status and QoL. The 12-Items General Health Questionnaire was used to identify individuals at risk for non-psychotic

psychiatric disorders (GHQ-positive). Physician (PhGA) and patient global assessments were obtained. We investigated the variables involved in the QoL through a logistic regression analysis. **RESULTS:** . 195 cases were analysed. 26% were GHQ-positive, reporting an impact on health status due to acne worse respect other chronic diseases. Males rather than females reported a poorer QoL. A GHQ-positive status (Skindex-29 overall: OR 2.6;95% CI 1.20-5.60,p<0.05, functioning:OR 2.5;95% CI 1.17-5.44,p<0.05, symptoms:OR 3.0; 95% CI 1.36-6.53,p<0.01; emotions:OR 2.55; 95% CI 1.19-5.46,p<0.05) and having a severe/very severe PhGA (Skindex-29 overall:OR 3.4; 95% CI 1.20-10.38,p<0.05) were associated with a poor QoL. Age of onset >25 was linked to being GHQ-positive (OR 2.92; 95% CI 1.2-7.1, p<0.05) controlling for gender, marital status and educational level. **CONCLUSIONS:** . Acne is not a minor disease in comparison with other chronic conditions. Age of patient is capable to influence GHQ status which in turn affects QoL.

PSS23

LIMITED ROLE OF MARITAL STATUS IN THE IMPACT OF DERMATOLOGICAL DISEASES ON QUALITY OF LIFE

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OBJECTIVES: Health status, health services utilization, and mortality differ by marital status for both sexes in most conditions, but little is known about dermatological diseases. To evaluate whether marital status is associated with the impact that dermatological diseases have on quality of life (QoL). **METHODS:** Data from two surveys on dermatological outpatients were pooled. Marital status, sex, age, and educational level were analysed in relation to QoL (using the scales of the Skindex-29 questionnaire: emotions, symptoms, and functioning) and psychological well-being (using the GHQ-12 questionnaire). **RESULTS:** We obtained data on 5471 patients (59% females, 46% married). Married patients (both males and females) had lower mean values on the emotions scale and higher mean values in the symptoms scale of the Skindex-29 compared to singles. Statistically significant differences were identified only in men, for the emotions scale and for the GHQ-12. Females had significantly higher mean scores than males on each of the Skindex-29 scales and on the GHQ-12. A multiple logistic regression model including age, gender, and marital status, showed significant results only for gender, with women suffering a more severe impact than men on all scales. No effect was observed for marital status. **CONCLUSIONS:** Married patients had a lower disease impact on the emotions scale even if they suffered a higher impact on the symptoms scale. After multiple adjustments, however, gender seems to be more relevant than marital status in the evaluation of the impact of skin conditions on QoL.

PSS24

PATIENT-REPORTED OUTCOMES IN A DENTAL PRACTICE-BASED RESEARCH NETWORK:PEARL

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OBJECTIVES: Patient-reported outcomes (PROs) such as quality of life, satisfaction with treatment, and health status provide the patients' viewpoint on how their diagnosis impacts their daily lives. In dentistry, PRO use, value and logistics in the dental practice setting remain an area for further consideration. This paper describes the PEARL PRO characteristics and discusses their implementation in a dental PBRN setting. **METHODS:** The Practitioners Engaged in Applied Research and Learning (PEARL) network has conducted 7 clinical studies in the practice-based setting. These studies included PROs related to: oral health impact (OHIP -14), tooth sensitivity, pain medication, and implant esthetics questionnaire. The Food and Drug Administration issued a Regulatory Guidance on PROs which was used as the framework for evaluation of the PRO measures. **RESULTS:** Of the 7 PEARL clinical studies, all used the OHIP-14, 5 studies measured tooth sensitivity and pain medication, and one study measured patient satisfaction. A total of 6077 patients have completed the OHIP-14 scale, 2,976 patients have completed the tooth sensitivity questionnaire, and the implant esthetics and sensitivity questionnaires have been completed by 332 patients. PROs measures differed in their number of items, mode of administration, and domains. We found consistent association between the tooth sensitivity and the OHIP-14 measures across PEARL studies. **CONCLUSIONS:** The value of PROs in dentistry in the context of a dental practice-based research network (PBRN) has received limited attention. Our study found that collecting PROs is possible and that they represent an indicator of the effectiveness of a dental treatment. More work is needed to inform dental practitioners on the value of these measures and to enhance the measurement properties of the questionnaires. The PEARL network has used several PRO measures with diverse characteristics to adapt to the dental practice setting and to measure the dental condition.

PSS25

ACTINIC KERATOSIS PATIENTS ARE WILLING TO PAY FOR SHORTER TREATMENT AND LOCAL SKIN RESPONSE DURATION AND INGENOL MEBUTATE GEL IS LIKELY TO INCREASE PATIENT LIKELIHOOD OF SUCCESSFUL COMPLETION OF TOPICAL TREATMENT

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Ingenol mebutate gel is a new treatment of Actinic Keratosis (AK). The adverse effects of current AK drug treatment involve long-lasting local skin responses (LSRs) which may influence patient adherence negatively. **OBJECTIVES:** Assess patient's willingness-to-pay (WTP) for accessing ingenol mebutate gel instead of imiquimod 5%, imiquimod 3.75% and diclofenac 3% in a US setting and assess patient's likelihood of completing a full treatment course. **METHODS:** A web-survey (contingent valuation design) was sent to 2000 adults, including only AK diagnosed subjects with self-reported AK lesions on face/scalp and/or trunk/extremities, asking them their maximum WTP to receive access to ingenol mebutate gel instead of one of three alternative drugs. The profile was varied in three dimensions; duration of treatment and treatment-related local skin responses and comparator price. Respondents were also asked to rank the likelihood to successfully complete treatment course. Internal validity was checked (hypothetical drug profile and income effect). **RESULTS:** A total of 116 subjects (105 useful) responded (response rate 53% if AK prevalence assumed to 11%). A total of 33% stated that they followed treatment instructions fairly well (75% of the time) or to some extent (50%), despite experience of LSRs. Almost 90 % rated ingenol mebutate gel as the treatment they were most likely to successfully complete; 50-63% were willing to pay extra (mean $475-518/course) to access ingenol mebutate gel instead of the three treatment alternatives. Subjects with experience of drug treatment stated an incremental WTP (mean $820/course) for accessing ingenol mebutate gel instead of imiquimod 3.75%. Subjects currently treating the full scalp or forehead stated an incremental WTP (mean $674 respectively $726/course) for accessing ingenol mebutate gel instead of imiquimod 5% and diclofenac 3%. **CONCLUSIONS:** There is a substantial dissatisfaction with current AK treatments and clear evidence that patients are willing to pay for shorter treatment and LSR duration.

SENSORY SYSTEMS DISORDERS – Health Care Use & Policy Studies

PSS26

DETERMINING ACCURATE DOSING OF USTEKINUMAB FROM SPECIALTY PHARMACY DATA

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OBJECTIVES: To determine dosing patterns of ustekinumab, a biologic treatment for moderate to severe plaque psoriasis, by analyzing prescription fill data and days supplied from Diplomat Specialty Pharmacy (DSP). Ustekinumab is delivered as a subcutaneous injection at weeks 0, 4, and every 12 weeks thereafter in two weight based doses: 45mg and 90mg. **METHODS:** A retrospective analysis was conducted of pharmacy fill data for patients >18 years receiving >2 fills of ustekinumab from DSP between October 2009 to September 2010. Based on prescribing information (PI), the expected time between first and second dose is 28 days +/− a 7-days and the expected time between subsequent doses is 84 days +/− a 14-day window. For patients receiving 1 vial or syringe per fill, dosing was assigned based upon which strength was initially filled. For patients receiving multiple vials or syringes per fill (e.g. 45 mg × 2), dose was based on days between fills. **RESULTS:** A total of 711 patients met inclusion criteria; 529 (74.4%) received one vial or syringe in the first fill. A total of 182 patients received ≥2 vials or syringes, 125 (68.7%) conformed to the expected days recommended from the PI. 57 patients (8.0%) had intervals that fell before or after the expected time. Of the 654 (529 + 125) patients for whom dosing patterns could accurately be assessed, 67.1% were dosed with 45mg. **CONCLUSIONS:** Over 90% of patients had prescription fill data and intervals that allowed for dosing patterns to be determined; the majority were dosed with 45mg. Some patients received multiple 45mg vials or syringes in one shipment, therefore their dosing may be incorrectly interpreted as higher than their actual dose. To appropriately analyze the dosing patterns of ustekinumab, one must account for the number of vials or syringes supplied per fill, the strength, and the days between fills.

PSS27

RELATIONSHIP BETWEEN WEIGHT AND DOSE IN PSORIASIS PATIENTS TREATED WITH USTEKINUMAB

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OBJECTIVES: To evaluate the relationship between weight and dose for patients initiating ustekinumab, a biologic treatment for moderate to severe plaque psoriasis. The recommended dosing for ustekinumab is 45mg for patients ≤100kg or 90mg for patients >100kg delivered as a subcutaneous injection at weeks 0, 4, and every 12 weeks thereafter. **METHODS:** Patients receiving ustekinumab through Diplomat Specialty Pharmacy (DSP) were surveyed to provide their weight. Inclusion criteria were: ≥18 years, diagnosis of psoriasis and ≥2 doses of ustekinumab. DSP provided ustekinumab shipment quantities and dates. Shipped quantities and schedule were jointly used to estimate ambiguous doses (e.g., if two 45mg doses were in the index shipment, the index dose was estimated to be 90mg if the second shipment was within 3-5 weeks; the index dose was estimated to be 45mg if the next shipment was 12-18 weeks). **RESULTS:** Of 257 patients surveyed, 65% (166) weighed ≤100kg and 35% (91) weighed >100kg. Of those ≤100kg, 83% (138) received a single 45mg index dose; 11% (19) received a single 90mg dose. Of those >100kg, 16% (15) received a single 45mg and 59% (54) received a single 90mg dose. Thirty-one patients received two or more 45mg doses in the index fill (9 ≤100kg and 22 >100kg). Based on timing of the second fill for those patients, the index dose was estimated to be 45mg and 90mg for 18 and 10 patients, respectively. Three patients receiving two 45mg doses were not evaluable based on second fill date. In summary by weight, 86% (142/166) of patients weighing ≤100kg are estimated to have received an index dose of 45mg and 76% (69/91) of patients >100kg likely received an