

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 MEBUGATE GEL IS LIKELY TO INCREASE PATIENT LIKELIHOOD OF SUCCESSFUL COMPLETION OF TOPICAL TREATMENT

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Ingenol mebugate 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 mebugate 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 mebugate 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 mebugate 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 mebugate gel instead of the three treatment alternatives. Subjects with experience of drug treatment stated an incremental WTP (mean \$820/course) for accessing ingenol mebugate 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 mebugate 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 \pm a 7-days and the expected time between subsequent doses is 84 days \pm 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 \times 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 ≤ 100 kg or 90mg for patients >100 kg 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 ≤ 100 kg and 35% (91) weighed >100 kg. Of those ≤ 100 kg, 83% (138) received a single 45mg index dose; 11% (19) received a single 90mg dose. Of those >100 kg, 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 ≤ 100 kg and 22 >100 kg). 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 ≤ 100 kg are estimated to have received an index dose of 45mg and 76% (69/91) of patients >100 kg likely received an