

examine which drugs had generic equivalents available for each year. The Pharmaceutical Red Book was referred for drug pricing and product information. **RESULTS:** Generic drugs accounted for almost half of total prescription drugs dispensed in 2003 as compared to 19% in 1983. In 1990, two of the ten drugs prescribed in outpatient clinics were generics, which rose to six in 2003. Out of ten top-selling drugs, six drugs will lose their patents in next five years. In 1990, none of the top ten dermatological drugs were generics. With few drugs losing their patents since 1990 (e.g. Retin-A®), two out of top ten dermatological drugs were generics in 2003. **CONCLUSIONS:** This study finds an increasing trend in the availability of generic medications. However, concerns regarding the bioavailability of generic equivalents used in dermatological conditions may limit their use. However, increased pressure from managed care organizations to prescribe inexpensive generics, overall growth in generic drug market, and anticipated drug patent expirations may influence prescribing patterns of these medications.

PSN11

PREDICTORS OF HEALTH CARE OUTCOMES AND COSTS RELATED TO MEDICATION USE IN PATIENTS WITH ACNE IN THE UNITED STATES

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OBJECTIVE: To investigate the relationship between health status, costs linked with the treatment of acne in the United States and aspects related to medication use. **METHODS:** The United States Medical Expenditure Panel Survey (MEPS) database was analyzed for a cohort of people with acne. Patients for this study were identified using the ICD-9 (International Classification of Diseases, 9th revision) code "706" for acne vulgaris and similar conditions (The MEPS dataset uses only the first three digits of the ICD-9 codes to identify disease states). Records of medical events were obtained using this ICD-9 code for acne and the receipt of medication for acne. This cross sectional study obtained costs, demographics, health care service utilization and clinical patient variables from the MEPS database. The subjects were divided into categories depending on type of medications used, mainly, oral antibiotics, oral retinoids, oral contraceptives, topical antibiotics, topical retinoids and oral contraceptives. The EuroQOL (EQ-5D) scores available in MEPS for subjects 18 years and older were used for obtaining health status information for these patients. Indices for medication adherence and comorbidities were also calculated using the data from the MEPS. Multivariate weighted analysis was performed on data for approximately 5 million patients (weighted sample size). **RESULTS:** Nearly 70% of the patients used some type of medication for acne. Acne-related medication accounted for approximately 36% of the total acne related health care costs, with an average of 2 annual acne prescription refills. Increased number of refills of acne specific drugs was associated with an improvement in health status ($p < 0.05$). Increased office based visits were the only predictors of higher acne related health care costs ($p < 0.01$). **CONCLUSIONS:** Adherence to acne medications is an important component of better health status. Pharmacological treatment of acne does not significantly add to acne-related health care costs.

NAIL PSORIASIS: ELABORATION OF A SCALE FOR FUNCTIONAL DISCOMFORT

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OBJECTIVES: To validate a scale for functional discomfort due to nail psoriasis. The questionnaire will have to be adapted both in the case of toe or finger nail psoriasis. The measured criterion will be unidimensional and related to the bother caused by nail psoriasis in daily life. **METHODS:** The scale was developed according to the international recommendations on quality of life. In October 2004, a questionnaire was sent to 4000 members, selected by drawing lots, among the French patients support group (APLCP). The first step of the process has led to the selection of 10 items related to functional discomfort induced by nail psoriasis. **RESULTS:** In total, 795 questionnaires concerning individuals affected by nail psoriasis were analysed. Validation analyses included the 10 selected items. Questionnaire's contents were coherent with the a-Cronbach coefficient equaling 0.88. The unidimensional feature of the questionnaire was verified: the analysis in principal components revealed that 49% of the total variance was explained by one component. The DLQI specific to dermatological pathologies was also given and enabled a comparison with the scale. Pearson's correlation coefficient between both scales was 0.48. The severity of the affection assessed through the DLQI evolved in the same way as the evaluation for the "Nail Psoriasis" scale. A test-retest performed on a sample of 15 individuals showed that the scale could be reproduced with an intra-class correlation coefficient of 0.82 between 2 administrations. **CONCLUSION:** The "Nail Psoriasis" scale is simple to use and easy to give to the patient. The qualitative features which must be found in a quality of life scale have been checked: comprehensibility, reliability and validity. The scale will have to be used during clinical trials in order to demonstrate its ability in measuring change in condition (before and after treatment).

PSN13

REFINEMENT AND REDUCTION OF THE IMPACT OF PSORIASIS QUESTIONNAIRE: CLASSICAL TEST THEORY VS RASCH ANALYSIS

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Quality of life instruments are increasingly important in assessing disease severity. However, some of these measurements have been developed on a more or less ad hoc basis. Although not well standardised, psychometric analyses can be used to re-test, refine and shorten existing quality of life instruments more strictly. **OBJECTIVES:** To psychometrically test and refine the Impact of Psoriasis Questionnaire (IPSO) and to compare the results of two different statistical approaches. **METHODS:** Among 792 psoriasis patients who were included in the PUVA Follow Up Study, we used Classical Test Theory (CTT) and Rasch analysis to test and optimise the IPSO. Thereafter, two shortened versions of the IPSO derived from these models were compared. **RESULTS:** CTT analyses of the original IPSO demonstrated suboptimal item performance for 6 of 16 items and inappropriate subscales. In contrast to the original 4 subscales, factor analysis of the CTT version yielded 3 subscales (mental functioning, mental wellbeing and stigmatisation). The Rasch approach, which included ordering of thresholds, differential item functioning and item fit, resulted in an unidimensional 11-

item questionnaire. Although the two new versions of the IPSO shared only 6 items, both reflected the original IPSO well. However, several arguments such as lower correlation coefficients, higher Chronbach's alpha's, ordered thresholds, unidimensionality and less differences among subgroups of patients suggested that the Rasch version of the IPSO may be the preferred instrument to use. **CONCLUSION:** The IPSO can be improved and shortened and the Rash reduced version of this instrument is likely to assess the psychosocial impact of moderate to severe psoriasis on patients' lives best because it is a short, reliable and unidimensional measurement.

PSN14

CHANGES IN FUNCTIONAL ABILITY AS MEASURED BY DLQI IS CONSISTENT WITH CLINICAL RESPONSE IN MODERATE TO SEVERE PLAQUE PSORIASIS PATIENTS TREATED WITH ADALIMUMAB

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OBJECTIVES: Because of physical limitations associated with psoriasis, dermatologic-related functional ability can be an important endpoint to assess effectiveness of treatment. This study was performed to assess the correlation between clinical efficacy and improvement in functional ability in moderate to severe plaque psoriasis patients treated with adalimumab for 12 weeks. **METHODS:** In a randomized, double-blind, placebo-controlled, multi-center clinical trial for the treatment of moderate to severe plaque psoriasis with adalimumab, the correlation between clinical efficacy and change in dermatology-specific functional limitations was evaluated. Clinical efficacy was assessed using the Psoriasis Area and Severity Index (PASI) and the Physician's Global Assessment (PGA) of Disease Severity. The Dermatology Life Quality Index (DLQI) was used to measure dermatologic-specific functional limitations. Mean changes in DLQI scores were evaluated for patient responses between baseline and 12 weeks. **RESULTS:** The DLQI was shown to have good reliability, and to demonstrate responsiveness to change with the subjects' PASI and PGA scores from baseline to week 12. The correlation between DLQI and PASI response was 0.69 ($p < 0.001$), and between DLQI and PGA response was 0.71 ($p < 0.001$). Mean change in DLQI was +12.17 points in patients who achieved significant clinical benefit ($> =$ PASI 75 response) vs. +1.77 points in nonresponders (less than PASI 50 response). **CONCLUSIONS:** DLQI was demonstrated to be highly responsive to clinical changes in patients with moderate to severe plaque psoriasis. The level of agreement suggests that adalimumab may be highly effective in improving both the physical disease manifestations and functional ability of patients with moderate to severe plaque psoriasis.

PSN15

QUALITY OF LIFE IMPROVEMENT AS MEASURED BY EQ-5D IS CONSISTENT WITH CLINICAL RESPONSE IN MODERATE TO SEVERE PLAQUE PSORIASIS PATIENTS TREATED WITH ADALIMUMAB

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OBJECTIVES: Because moderate to severe psoriasis can negatively impact patients' daily living, quality of life can be an important parameter to assess in determining effectiveness of treatment. This study was performed to assess the correlation between clinical efficacy and quality-of-life improvement in mod-

erate to severe plaque psoriasis patients treated with adalimumab for 12 weeks. **METHODS:** In a randomized, double-blind, placebo-controlled, multi-center clinical trial for the treatment of moderate to severe plaque psoriasis with adalimumab, the correlation between clinical efficacy and quality of life was evaluated. Clinical efficacy was assessed using the Psoriasis Area and Severity Index (PASI) and the Physician Global Assessment (PGA) of disease severity. Euro-QOL 5D (EQ-5D) visual analogue score was used to assess general quality of life. Mean changes in EQ-5D scores were evaluated for patient responses between baseline and 12 weeks. **RESULTS:** EQ-5D demonstrated responsiveness to changes in clinical efficacy. The correlation between EQ-5D and PASI response was 0.57 ($p < 0.001$), and between EQ-5D and PGA response was 0.44 ($p < 0.001$). Mean change in EQ-5D was 15.69 points in patients who had achieved significant clinical benefit ($>$ PASI 75 response) vs. 1.92 points in non-responders ($<$ PASI 50 response). **CONCLUSION:** EQ-5D was demonstrated to be responsive to clinical changes in patients with moderate to severe plaque psoriasis. The level of agreement suggests that adalimumab may be highly effective in improving both the physical disease manifestations and quality of life of patients with moderate to severe plaque psoriasis.

PSN16

NAIL PSORIASIS: IMPACT ON QUALITY OF LIFE

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OBJECTIVES: The aim was to evaluate the consequences of psoriasis on quality of life and pay particular attention to those with nail psoriasis. **METHODS:** In October 2004, a questionnaire was sent to 4000 members, selected by drawing lots, among the French patients support group (APLCP). The first part concerned the social and demographic characteristics of the patients, psoriasis localization and psoriasis age. The second part was dedicated to patients with nail psoriasis. The last part was the Dermatology Life Quality Index (DLQI) which was filled in by all patients. **RESULTS:** A total of 1309 questionnaires were returned with 57.3% of women and 42.7% of men. Mean age was 51.8 years (SD = 16.2). Psoriasis affected the nails for 60.8% of subjects (16.4% for the hands only, 9.4% for the feet only and 35% for both the hands and feet). The DLQI score was available for 1111 individuals with an average score of 8.3 (SD = 6.5). It was significantly related to gender with a score of 7.6 (SD = 6.2) for men and 9 (SD = 6.8) for women ($p = 0.0333$). It was also significantly related to age, the younger the individuals, the more quality of life was affected: 9.4 (SD = 6.6) for the group "39 years old and under", 9.2 (SD = 6.7) for the group "40-54 years", 7.8 (SD = 6.6) for the group "55-64 years" and 6.7 (SD = 5.6) for the group "65 years old and above" ($p < 0.0001$). Quality of life was also linked to the localization of the psoriasis. **CONCLUSIONS:** Quality of life assessed through the DLQI shows an important impairment in the study population with a mean score of 8.3. In comparison with other studies using the DLQI; a score of 8.9 was found for severe psoriasis, 12.5 for atopic dermatitis and 4.3 for acne.

PSN17

VALIDATION OF THE ITALIAN VERSION OF THE INFANTS' DERMATITIS QUALITY OF LIFE & FAMILY DERMATITIS INDEXES

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