## SKIN—Health Care Use & Policy Studies

**PSK8**

### ASSESSMENT OF INVOLVED BODY SURFACE AREA (BSA) IN PSORIASIS PATIENTS. VALIDATION OF SOFTWARE ASSISTED DIAGNOSIS BSA FOR THE MANAGEMENT OF PSORIASIS

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**OBJECTIVES:** To validate a software, for an optical pencil toll, to calculate psoriasis patients' Body Surface Area (BSA) and to demonstrate that the new developed method is been valid and reliable to quantify the BSA. **METHODS:** Multicentre prospective study at Dermatology centres (Five Spanish Hospitals and one Portuguese Hospital). In each hospital two dermatologists visited the same patients twice (second visit 3 days after first). 60 dermatologists included ≤10 consecutive patients with psoriasis. Sociodemographical and clinical variables (PASI, time since diagnosis, current treatment) and BSA scores were colleted for each patient in the two visits. To calculate BSA scores traditional method (visual grading following the nine rule of Wallace method's) and the optical pencil method (BSA software developed) were used. Inter-intraobservers reliability, variability between BSA scores regarding the new tool, versus the traditional method, and the tool's usefulness will be assessed. **RESULTS:** Fifty-six patients were included. Mean (SD) age was 48.93 (16.76) years. Mean (SD) time since diagnosis was 18.77 (14.28). Pearson's correlation coefficient between both methods was 0.91 ($p < 0.01$). Intraobserver correlation for each of the methods was 0.91. The correlation among both methods was in the first visit 0.92 and 0.90 in the second visit. The ICC was higher than 0.85 independently of which of the two methods were used firstly. The investigators considered that the new method is easy to use (94%), it guides towards the disease management (64%) and standardizes the calculation of the body surface area (86.4%). **CONCLUSION:** These results can prove that the software to assess BSA has shown to be valid to be used both in clinical practice and in clinical studies. Therefore, the optical pencil method to quantify BSA can be used as standard for the assessment of involved body surface area in the management of psoriatic patients.

**PSK9**

### PRIOR AUTHORIZATION FOR TOPICAL PSORIASIS TREATMENTS: IS IT COST-BENEFICIAL FOR MANAGED CARE?

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**OBJECTIVES:** The introduction of novel therapeutic options for psoriasis has raised managed care's interest in controlling costs associated with dermatological treatments. Prior authorization (PA) can be a successful way of managing costs. However, experience with topical treatments for acne suggests that PA may not be cost-effective. The role of managed care in dermatology and the potential impact of PA requirements for novel topical therapies for psoriasis are considered. **METHODS:** Using a model based on recent nationally representative survey data (NAMCS), total annual cost estimates for a managed care organization to cover psoriasis treatment with a topical agent with or without PA requirements were calculated and compared. Costs for treatment and administrative costs associated with PA processes were included. The model assumed 68,000 insured patients required treatment (with an additional 1% to account for abuse/misuse), an average wholesale price of $100 per prescription (each prescription filled 4x/year), and a cost of $20 to process each PA request. **RESULTS:** The total annual costs were $28,573,600 when PA was required and $27,472,000 when PA was not required. Thus there was a total annual loss to the managed care organization of $1,101,600 associated with PA requirements. **CONCLUSION:** Requiring PA for novel topical treatments for psoriasis, such as the new 2-compound product containing calcipotriene and betamethasone dipropionate, is not likely to be cost-effective for a managed care organization.

## SKIN—Methods and Concepts

**PSK10**

### QUANTITATIVE ASSESSMENT OF PATIENT-DEFINED BENEFIT IN DERMATOLOGY

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**OBJECTIVES:** In an increasing number of European countries patient-defined benefit is considered important in the valuation of therapy. So far, most procedures used for benefit assessment do not cover the broad spectrum of benefits relevant to patients nor do they allow for an individual weighting of preferences. In this context a patient-reported benefit questionnaire was developed and validated. **METHODS:** Initially, open questioning of n = 100 dermatological patients generated a pool of 213 benefit items which were converted into a 24 item-list by an expert panel of dermatologists, psychologists and patients. This pilot version of the questionnaire was evaluated in a group of n = 500 patients with 10 dermatological diagnoses. Basic principle of the instrument is pre/post data-collection. Prior to therapy, individually perceived needs (Patient Needs Questionnaire, PNQ) are obtained: For each of the 24 standardized items patients rate its importance on a Likert scale ranging from 0 ("not important at all" resp. "doesn't apply to me") to 4 ("very important"). At the end of therapy the degree to wich these benefits (Patient Benefit Questionnaire, PBQ) were achieved is assessed using the same list with scaling from 0 ("therapy didn't help at all") to 4 ("helped a lot"). To compose a single outcome parameter a formula was developed by weighting the PBQ with their respective PNQ-items. This "Patient Benefit Index" (PBI) also ranges from 0 to 4. **RESULTS:** Besides good acceptance and feasibility the PBI showed construct validity and the PNQ a high internal consistency with Cronbach's alpha > 0.94. Diagnostic groups presented different and clinically plausible outcome-patterns: Whereas the PBI was rather low for all vitiligo-therapies (mean = 1.03, SD 1.13, n = 711) wound-patients undergoing vacuum-assisted therapy (n = 172) showed a mean PBI of 2.75 (SD = 0.89). **CONCLUSION:** The PBI is a valid and reliable instrument to obtain patient-defined and individually weighted therapeutic benefits in clinical and public health studies.

## SKIN—Patient Reported Outcomes

**PSK11**

### EVALUATION OF THE ASSOCIATION BETWEEN EQ5D UTILITY AND DERMATOLOGY LIFE QUALITY INDEX (DLQI) SCORE IN PATIENTS WITH PSORIASIS

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**OBJECTIVES:** The Dermatology Life Quality Index (DLQI) is a validated and widely used patient reported outcomes instrument.

Cost-utility analyses however require preference based measures to calculate quality adjusted life years. This study aimed to estimate the association between health utility and DLQI response in patients with chronic plaque psoriasis. **METHODS:** A consecutive sample of all patients treated for a primary diagnosis of psoriasis at Llandough Hospital, Cardiff, UK over a period of two years were identified from the hospital record system. All patients were sent the Health Outcomes Data Repository (HODaR) survey including the EQ-5D and DLQI instruments. Individual patient utility was estimated from EQ-5D responses using the standard UK scoring algorithm. A predictive regression model was built to estimate EQ-5D utility scores from patient DLQI responses. **RESULTS:** A total of 94 psoriasis patients responded to the survey. Fifty percent of patients were female, and the mean age was 50.0 years (range from <10 to >80 years). Patients had been diagnosed with psoriasis for a mean of 15.6 years. Over the previous year 20.4% of patients had at least one inpatient admission and 66.0% at least one outpatient attendance for their psoriasis. Eighteen patients (19%) reported that they were currently received treatment with a systemic agent or with PUVA. The regression model found DLQI score to be significantly related to the EQ5D utility score. Estimated utility at zero DLQI, the best possible response, was 0.956 (standard error 0.039, $p < 0.001$) and each one point rise in DLQI was associated with a decrease of 0.02548 (standard error 0.004, $p < 0.001$) in estimated utility. The model described 27% of the variation in the EQ5D data for the survey respondents. **CONCLUSION:** It was possible to estimate utility from patient DLQI score in a population with psoriasis requiring hospital management.

**PSK12**

### PATIENT REPORTED OUTCOMES IN PSORIASIS

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**OBJECTIVES:** To know the repercussion of the moderate-severe psoriasis on the health-related quality of life (HRQoL), the health state utilities, the direct costs and the health resources employees in the last year. **METHODS:** An observational (naturalistic) study conducted at Dermatology centres in Spain and Portugal. A total of 332 dermatologists included ≥10 consecutive patients with moderate to severe psoriasis. The case report form includes information about the Psoriasis Disability Index (PDI), as well as variables of severity: Body surface area (BSA) and Psoriasis Area and Severity Index (PASI). Health state utilities were assessing by the Time Trade-off and Willingness to pay methods. Data collected also include the direct cost in treatments and days of sick leave, number of medical visits, hospitalization days and emergency visits in the last year. **RESULTS:** 3320 patients were assessed. Mean BSA involvement was 23% (95% CI: 22.2–23.3%) and mean PASI score was 14.3 (95% CI: 13.9–14.6%). The mean value of the PDI was 8.93 (IC95% 7.83–9.21). There was a consistent decrease in HRQoL with increase in disease severity. The mean amount of remaining life that patients were willing to sacrifice to be free from psoriasis was 25 months (95% CI: 23.4–26.8) and the mean proportion of monthly income that were willing to pay was 29% (95% CI: 28.1–30.1), with the amount of time or income increasing with disease severity. In 89% of patients, psoriasis represented a mean direct treatment expense of 816 € yearly. **CONCLUSION:** The psoriasis causes a negative impact in the HRQoL and in the patient's budget. This study establish a relationship between the severity of psoriasis and the amount of money or time of remaining life that patients are willing to pay or sacrifice, respectively, to be free of psoriasis.

**PSK13**

### PSYCHOMETRIC VALIDATION OF THE OILY SKIN SELF ASSESSMENT SCALE (OSSAS) AND THE OILY SKIN IMPACT SCALE (OSIS)

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**OBJECTIVES:** The OSSAS and OSIS are patient reported outcome measures developed using focus groups to assess facial Oily Skin (OS) severity and the psychosocial impact of oily skin, respectively. This study examines the validity and reliability of these measures in a cross-sectional study. **METHODS:** The OSSAS, OSIS and concurrent measures (Skindex and AcneQoL) were administered to 202 OS patients at seven sites across the USA. A sub-group of 152 patients returned 1–2 weeks later for test-retest reliability evaluation. **RESULTS:** Of the 202 participants, 72.8% were female; 64.4% had acne in addition to OS. Item reduction analyses resulted in a 14 item OSSAS with 'Sensations' (5 items), 'Tactile' (3 items) and 'Visual' (4 items) domains, a single blotting item, and a single overall oiliness item. The 6 item OSIS includes Annoyance (3 items) and Self-Concept (3 items) domains. Confirmatory factor analysis provided support for the construct validity of the final item-scale structures. The OSSAS and OSIS scales had acceptable item convergent validity (item-scale correlations >0.40) and floor and ceiling effects (<20%). Cronbach's alpha coefficients ranged from 0.83–0.89 for the OSSAS and 0.82–0.87 for the OSIS, demonstrating excellent internal consistency. The a priori criterion for test-retest reliability (ICC ≥ 0.7) was met for one of the three OSSAS domains and one of the two OSIS domains. Correlations of the Skindex-29 and Acne-QoL scales with the OSSAS (range: –0.08–0.38) and OSIS (range: 0.37–0.73) domain scores met content expectations for these scales. OSSAS and OSIS domains distinguished among groups of patients who differed in terms of both patient reported facial OS severity ($p < 0.0001$) and patient reported bother associated with OS ($p < 0.0001$). **CONCLUSION:** The OSSAS and OSIS provide valid self-report measures of facial OS severity and the emotional impact of OS, respectively. Test-retest reliability and responsiveness of these measures require further evaluation.

## SMOKING—Cost Studies

**PSM1**

### COST-EFFECTIVENESS ANALYSIS OF CHAMPIX® (VARENICLINE) IN SMOKING CESSATION TREATMENT IN SPAIN

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**OBJECTIVES:** Varenicline (Champix®) is a new drug indicated for smoking cessation. The objective was to analyse the efficiency of varenicline compared with bupropion, NRT (nicotine replacement therapy) and no pharmacological treatment in Spain. **METHODS:** A Markov model was developed to analyse the