impact of WLM on functioning and well-being is not well understood, cultural differences have been largely ignored and discrepancies between clinician and patient perceptions have been noted. The purpose of the study was to develop a measure of the impact of WLM applicable for use in clinical trials and clinical practice. **METHODS:** Qualitative data were collected from the literature, patients (n = 82) and experts (n = 9) in three countries (US, France, UK) were interviewed regarding the impact of WLM on functioning, well-being and health. Interview transcripts were thematically coded. Based on these data, a conceptual model of the impact of WLM on functioning, well-being and symptom experience was developed and a patient reported outcomes (PRO) measure generated. **RESULTS:** The impact of WLM on psychological health, interference in daily life, treatment burden, efficacy and side effects was considered significant by patients. Key modifiers to this impact (i.e., age, occupation, stress) and consequences (i.e., compliance, reduced productivity) were noted. Based on a conceptual model, a WLM treatment related impact measure (TRIM-Weight) was generated with five discrete domains. Discrepancies between perceived patient and clinician impacts were identified, most notably for the impact on sleep and daily life as well as perceived importance of side effects. Gender and cultural differences were also identified. For example, men tended to be more goal-oriented in their weight loss goals than women and side effect profiles differed by country as a result of prescription patterns. **CONCLUSIONS:** A measure of the impact of WLM on functioning, well-being and health was developed. The instrument development process, full conceptual model, and cultural, gender and clinician/patient differences will be presented. This information should help clinicians to identify key PRO issues for WLM, facilitate targeted treatments and allow for meaningful measurement of treatment effect.

PATIENT ACCEPTABLE SYMPTOM STATE (PASS) IN EUROPEAN PATIENTS WITH MODERATE-SEVERE PLAQUE PSORIASIS

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OBJECTIVES: To determine a Patient Acceptable Symptom State (PASS) for European patients with moderate-severe plaque psoriasis, and to compare Psoriasis Activity and Severity Index (PASI) improvement for patients attaining this state to the current clinical trial benchmark of 75% PASI improvement from baseline. **METHODS:** Patients with Psoriasis Area and Severity Index (PASI) > 10 were randomized 1:1 to Enbrel 25 mg BIW or Enbrel 50 mg BIW for twelve weeks as the first stage of a 54-week trial. PASI scores can range from 0 to 72, with higher scores indicating more severe disease and scores > 10 indicating moderate-severe disease. Patients on the higher dose were temporarily removed from treatment if their Physician Global Assessment score determined their skin disease had become mild, almost clear or clear. PASI was assessed at baseline and at week 12. Patients completed a satisfaction questionnaire at week 12. Patients reporting that they were 'very satisfied' or 'satisfied' were counted as satisfied; all others—including those who reported that they were 'somewhat satisfied'—were counted as not satisfied. The PASS method for determining a symptom state that patients find acceptable was developed for osteoarthritis by Turbach, Ravaud, Baron, et al. (Annals of the Rheumatic Diseases, 2005) among other authors and other diseases. Following the Turbach et al method, a cumulative percentage of satisfied patients as well as a cumulative percentage of patients who were not satisfied was plotted vs. week-12 PASI. The week-12 PASI score with the greatest separation between the two cumulative

curves was judged to be an acceptable state. The PASI improvement from baseline for patients with week-12 PASI scores closest to this state were obtained and a mean PASI improvement for them was calculated. Patients were pooled across treatment arms for these analyses. **RESULTS:** Baseline mean PASI was 22.32 for the 711 patients. At week 12, mean PASI was 8.70, representing a 61% PASI improvement from baseline. PASS was determined to be a week-12 PASI of 6.9, with 66.2% of satisfied patients having a week-12 PASI below (better than) 6.9 compared to 25.6% of not-satisfied patients. A sensitivity analysis counting only 'very satisfied' patients as satisfied also determined PASS at week 12 to be a PASI of 6.9. A week-12 PASI interval of 6.6 to 7.2 and centered on 6.9 included 32 patients, for whom the mean PASI improvement from baseline was 62.5% with a 95% confidence interval of 58.2% to 66.9%. This percent improvement is less than the 75% PASI improvement from baseline threshold commonly used as a primary endpoint in clinical trials. **CONCLUSIONS:** These 711 moderate-severe psoriasis patients had a Patient Acceptable Symptom State (PASS) worse than the 75% PASI improvement commonly used as a primary endpoint in clinical trials. Further research is needed on ways to explicitly incorporate patient preference in estimates of clinical response.

PATIENT-REPORTED OUTCOMES (PRO) AND ECONOMICS OF MIGRAINE IN GERMANY

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OBJECTIVES: To assess PRO and costs in German patients with migraine, specifically for guideline-, non-guideline- and self-treatment-groups. **METHODS:** Patients (n = 117), consecutively recruited by physicians in general practice (n = 50) in 2005, were categorized into the three groups (n = 65 self-treatment, n = 32 guideline-, n = 20 non-guideline-groups). PRO were assessed by von Korff Index, SF-36, and Patient Health Questionnaire Depression (PHQ-D) questionnaires at time of enrollment. Data on resource utilization due to migraine was collected retrospectively for 6 months. Groups were compared using multivariable general linear modeling (GLM). **RESULTS:** Average duration of migraine was about 14.1 (SD 11.8) years and was comparable among the groups. Patients with self-treatment were younger than patients in guideline- or non-guideline-group (40.5 vs. 47.3 vs. 45.1 years, mean age, p = 0.0224). The groups did not differ in other socio-demographic characteristics. Mean SF-36 scores in our study population were worse compared to the general population in Germany (mean physical and mental component scores 43.0 ± 8.6, 42.0 ± 11.9). However, groups were comparable regarding SF-36, von Korff Index and PHQ-D items. Mean total costs per patient and 6-month period were €527.50 [95%CI 251.93; 803.07] vs. €979.37 [95%CI 577.62; 1381.11] vs. €1281.30 [95%CI 124.64; 2437.97] (self-treatment-vs. guideline-vs. non-guideline-group, respectively, p = 0.2739, by GLM, adjusted by age). The major cost factors in the self-treatment group were reduction of earning capacity, remedies, and sport activities (44.4%, 18.7%, and 15.8% of the mean total cost per patient, respectively) while in guideline-group the major cost factors were prescribed medications, reduction in earning capacity, and visits to physicians (43.0%, 14.5%, and 14.3%, respectively). The major cost factors in non-guideline and guideline-groups were similar. **CONCLUSIONS:** PRO in patients with migraine are worse compared to the general reference population in Germany. Societal mean total costs and PRO are comparable among guideline-, non-guideline- and self-treatment-groups.