E-DIARY COMPLIANCE IN ACUTE PAIN STUDIES

**OBJECTIVES:** In acute pain studies, subjects are asked to report on symptoms at specific intervals after dosing. One or more assessments are often primary endpoints. When timed assessments are collected on paper, the actual time the assessments were completed is unknown, and enforcing completion of the assessment at a specific time is impossible. Electronic patient reported outcome technologies (ePRO) allow control over the window in which a subject can complete the electronic diary (e-Diary), and a time stamp associated with diary completion. E-Diaries assure the investigator of more reliable information: the 120 minute assessment was completed at or near 120 minutes.

**RESULTS:** Fifteen papers provided evidence of the use of the Post-Anaesthetic Discharge Scoring System (PADS) [1] in a variety of trial settings and validation work. Nine papers referred to other instruments measuring home readiness but no other instrument had been used in more than one trial or validated. The British Association of Day Surgery referred to PADS in their published guidelines. There was an example of PADS in an economic evaluation of fast-tracking recovery [2]. CONCLUSIONS: PADS was found to be the most appropriate instrument for assessing home readiness as it has undergone more validation than other identified measures and there is evidence of its use in multiple RCTs. [1] Chung et al. A post-anesthetic discharge scoring system for home readiness after ambulatory surgery. J Clin Anesth 1995;7:500–6; [2] Song et al. Fast-tracking (by-passing the PACU) does not reduce nursing workload after ambulatory surgery. Br J Anaesth 2004;93:768–4.

**SYSTEMIC DISORDERS/CONDITIONS—PATIENT-REPORTED OUTCOMES STUDIES**

**E-DIARY COMPLIANCE IN ACUTE PAIN STUDIES**

Marino B, Platko J, Raymond S

PHT Corporation, Boston, MA, USA

**OBJECTIVES:** In acute pain studies, subjects are asked to report on symptoms at specific intervals after dosing. One or more assessments are often primary endpoints. When timed assessments are collected on paper, the actual time the assessments were completed is unknown, and enforcing completion of the assessment at a specific time is impossible. Electronic patient reported outcome technologies (ePRO) allow control over the window in which a subject can complete the electronic diary (e-Diary), and a time stamp associated with diary completion. E-Diaries assure the investigator of more reliable information: the 120 minute assessment was completed at or near 120 minutes. But is there a down side? With a restricted window of time for completing an e-diary in the acute pain model, how compliant will subjects be? METHODS: Diary completion was examined in 12 randomized clinical trials using the acute pain model. Indications were surgical pain, migraine, or breakthrough pain. Subjects completed pain diaries at timed intervals after dosing. In 4 trials, subjects completed at least some of the assessments in the clinic or post surgery area allowing comparison of compliance in supervised settings to compliance with e-diaries at home. Frequency of the assessments varied across the trials, allowing some description of factors which may influence compliance. Finally, design features, like a reminder alarm, were correlated with time of diary compliance to understand the usefulness of these features. RESULTS: e-Diary compliance in supervised setting can be as high as 100%. Compliance in unsupervised settings is typically 80%, although frequent assessments correspond with decreased compliance. In one study that required extensive frequent assessments, e-Diary compliance is much lower. Indication does not correlate with e-Diary compliance in unsupervised settings. CONCLUSIONS: Factors that correspond with e-diary compliance are supervision, frequency and overall demand on subjects.
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 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

Molta CT, Boggs R, Singh A, Yang S
Wyeth Pharmaceuticals, Inc, Collegeville, PA, USA

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 PASS 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 PASS 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

Breitscheidel L1, Kreyenberg K1, Stridde E2, Eichmann F1
1Kendle GmbH, Munich, Germany, 2Pfizer Pharma GmbH, Karlsruhe, Germany

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.