PSY41

PATIENT-REPORTED OUTCOME (PRO) LABELING CLAIMS IN PAIN TREATMENT: OVERVIEW OF US AND EUROPEAN DRUG APPROVALS

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OBJECTIVES: To review the PRO end-points appearing in the product labels of pain treatments with a particular focus on products approved both in the United States (US) and in Europe. **METHODS:** Pain treatments approved in the US since 1998 and in Europe through the centralized procedure established in 1995, and including PRO evaluations in the approved labeling were identified from the PROLabels database. PROLabels is a unique on-line tool providing information on the products for which the FDA and/or the EMEA have granted PRO labeling claims. For the products approved by both agencies, we will compare the PRO endpoints appearing in the approved labeling and also analyze the PRO studies submitted by the sponsor. **RESULTS:** Overall, 26 products indicated for the treatment of pain were identified, accounting for 16 different molecules and ten different indications. Various methods were used to measure pain (VAS, Likert scales). Of these 26 drugs, only two showed evidence of treatment efficacy using additional PRO endpoints (function and patient satisfaction). The PRO appearing in the approved labeling are rather consistent between both regulatory agencies. Information on additional PRO endpoints that were assessed in the clinical studies submitted by the sponsors but were not accepted in the approved labeling was available for nine out of the 26 dossiers. The concepts assessed were health-related quality of life, psychological functioning, physical functioning (including interference with sleep) and patient global impression. A focus was made on the different reasons of rejection of the most recent claims, in the light of the current PRO guidances published by both regulatory agencies. **CONCLUSIONS:** Overall, only a few pain treatments include other PRO endpoints in addition to pain in their labeling. An interesting finding is the similarity between the American and the European PRO claims for pain therapies.

PSY42

USTEKINUMAB REDUCES ITCH, BODILY PAIN, AND FATIGUE IN PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS

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OBJECTIVES: This analysis examines the impact of ustekinumab on symptoms commonly associated with moderate-to-severe psoriasis, including itch, bodily pain, and fatigue, using data from a Phase 3 clinical trial. **METHODS:** In PHOENIX I trial, 766 patients were randomized to ustekinumab 45 mg or 90 mg at weeks 0 and 4 and every 12 weeks thereafter, or placebo at weeks 0 and 4 with crossover to ustekinumab at week 12. Assessments included the Itch visual analogue scale (VAS) (0 [no itch] to 10 [severe itch]) and for pain and fatigue the SF-36 bodily pain and vitality scales (0 to 100 [higher scores indicate greater impact of pain and fatigue on quality of life]). **RESULTS:** At baseline, mean (SD) itch score was 6.8 (2.7), and mean (SD) bodily pain and vitality scores were 45.5 (11.4) and 49.7 (10.0), respectively. At week 12, average change in itch score from baseline was –4.9, –5.1, and –0.8 in the ustekinumab 45 mg, 90 mg, and placebo group, respectively, representing a median reduction of 86% in itch in the ustekinumab-treated patients compared to a 4% reduction in placebo-treated patients ($p < 0.001$ for each ustekinumab group vs. placebo). Mean change in pain score from baseline to week 12 was 4.4, 5.8, and 0.2 in the ustekinumab 45 mg, 90 mg, and placebo group, respectively ($p < 0.005$ for each ustekinumab group vs. placebo). Specifically, 37% of patients reported moderate or more severe bodily pain at baseline. At week 12, 17% of ustekinumab-treated patients vs. 38% of placebo-treated patients reported moderate or severe bodily pain ($p < 0.01$). Similarly, ustekinumab-treated patients demonstrated a greater improvement in vitality score (1.5 in the ustekinumab 45 mg group and 1.6 in the 90 mg group) than the placebo group (–1.6) ($p < 0.005$ for each ustekinumab group vs. placebo). **CONCLUSIONS:** Ustekinumab improves itch, pain, and fatigue in patients with moderate-to-severe psoriasis.

SYSTEMIC DISORDERS/CONDITIONS – Health Care Use & Policy Studies

PSY43

USE OF PRESCRIPTION PHARMACOTHERAPY IN PATIENTS WITH FIBROMYALGIA: EVIDENCE OF UNMET NEEDS?

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OBJECTIVES: Fibromyalgia (FM) is a chronic disorder characterized by multiple symptoms (e.g., pain, fatigue, cognitive dysfunction, sleep disturbance). The efficacy of most medications currently used to treat FM is limited, however, and problems of tolerability are often encountered, possibly causing many patients to discontinue therapy. This study examines patterns of use of prescription (Rx) medications with an eye toward assessing possible unmet clinical need. **METHODS:** Using a large US health insurance database spanning the period 2005–2007, we identified all patients with ≥1 medical encounters for FM (defined as ICD-9-CM diagnosis code 729.1) in each of these three calendar years ("FM patients"). Rx medications possibly related to the treatment of FM ("FM-related") were defined to include antiepileptics, benzodiazepines, nonsteroidal anti-inflammatory drugs, muscle relaxants, sedatives/hypnotics, opioids, serotonin-norepinephrine reuptake inhibitors, selective serotonin reuptake inhibitors, L-dopa, and carbidopa. We examined receipt of FM-related Rx medications from two alternative perspectives: (1) period prevalence (receipt anytime during each calendar year); and (2) point prevalence (evidence of use on July 1 of each calendar year). Substantial differences between period prevalence and point prevalence rates may be suggestive of high rates of medication discontinuation. **RESULTS:** A total of 51,885 patients met all study entry criteria. In each of the three years, approximately two-thirds of study subjects had evidence of receipt of FM-related Rx medications (65.2% in 2005, 66.5% in 2006, 66.7% in 2007). Corresponding point prevalence estimates, however, were substantially lower (July 1, 2005: 38.1%; July 1, 2006: 40.9%; July 1, 2007: 41.3%). **CONCLUSIONS:** While roughly two-thirds of FM patients received FM-related Rx medications in any given year, point prevalence estimates were substantially lower, potentially suggestive of high rates of medication discontinuation. Further research is needed to better understand the extent to which these treatment patterns are indicative of unmet medical need with currently available Rx medications in patients with FM.

PSY44

USE OF POLYPHARMACY IN PATIENTS WITH FIBROMYALGIA

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OBJECTIVES: Fibromyalgia (FM), a chronic disorder characterized by multiple symptoms (e.g., pain, fatigue, cognitive dysfunction, sleep disturbance), is difficult to treat. This study examined the extent to which FM patients in the US receive multiple prescription (Rx) drugs to treat their condition ("polypharmacy"). **METHODS:** Using a large US health insurance database spanning a three-year period (January 1, 2005 to December 31, 2007), we identified all patients with ≥1 medical encounters for FM (defined as ICD-9-CM code 729.1) in each of these three calendar years ("FM patients"). Rx medications designated as possibly related to the treatment of FM ("FM-related") included antiepileptics, benzodiazepines, nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, sedatives/hypnotics, opioids, selected antidepressants (e.g., tricyclics, serotonin-norepinephrine reuptake inhibitors, selective serotonin reuptake inhibitors), L-dopa, and carbidopa. Polypharmacy, which was defined as receipt of ≥2 FM-related Rx drugs, was assessed from two alternative perspectives: 1) period-prevalence (receipt anytime during each calendar year), and 2) point-prevalence (evidence of use on July 1 of each calendar year). **RESULTS:** A total of 51,885 patients met all study entry criteria, of whom 33,831, 34,484, and 34,616 received FM-related Rx drugs in calendar years 2005, 2006, and 2007, respectively. The most commonly received Rx drugs were opioids, antidepressants, and NSAIDs. Among patients receiving FM-related Rx drugs, approximately 80% had evidence of receipt of ≥2 such medications in any given year; about 60% had evidence of receipt of 3 or more. Corresponding point-prevalence rates (on July 1 of each year) were approximately 61% and 36%, respectively. Commonly used combinations of Rx drugs included antidepressants and opioids, antiepileptics and antidepressants, and antiepileptics, antidepressants, and opioids. **CONCLUSIONS:** Polypharmacy in the treatment of FM is widespread, suggesting that the symptoms of relatively few patients are well managed with any single currently available Rx drug.

PSY45

CURTAILING LAB-TEST ORDERING IN A MANAGED CARE SETTING THROUGH REDESIGN OF A COMPUTERIZED ORDER-FORM

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OBJECTIVES: Although laboratory testing is essential for the diagnosis, pharmacotherapy, and monitoring of anemia, inefficient utilization of laboratory resources may increase the cost-of-treatment of anemia without improving clinical outcomes. Of particular concern is the ordering of redundant tests incapable of providing important information for treatment when clinically significant changes in biochemical outcomes do not occur over short periods of time. Bundling of tests into diagnostic categories on order forms may cause such overutilization. The objective of this study was to determine whether unbundling of order-sets on a computerized order-form can reduce the number of suspected unnecessary blood tests for folic acid and vitamin B-12 ordered by primary care physicians in a managed care organization in Israel. **METHODS:** This study was conducted in the Leumit Health Fund of Israel that provides medical coverage to ~700,000 members nationally. A new version of a computerized order form was launched. Utilization patterns were calculated for tests for vitamin B-12, folic acid and ferritin which were previously bundled together under a collective diagnostic classification category labeled "Anemia" and now appearing separately. Concomitant utilization patterns for tests for hemoglobin and iron were evaluated as controls. **RESULTS:** Tests ordered for the three target tests decreased by 31%-41% relative to the preintervention month, with a further decrease to 36%-53% the following month. Negligible changes in utilization patterns were observed for the controls (-2%-3%) during the post-intervention period. **CONCLUSIONS:** Restructuring of a computerized order-form significantly reduced the number of lab tests suspected of being unnecessary or redundant. We cannot rule out that some patients with folate deficiency may not have been identified after unbundling the tests due to the additional inconvenience caused to physicians who now had to order tests separately. When over-utilization of laboratory resources is suspected, restructuring of ordering procedures should be considered prior to implementing resource-intensive interventions.