was included in the overall estimate of WTP. **CONCLUSIONS:** The results from this study illustrate the value that OA patients attribute to the reduction in GI-side effects associated with Cox-2 selective inhibitors such as VIOXX. On average, patients were willing to pay $A57.85 per month for a medication that specifically reduced the risk of both complicated and uncomplicated PUBs.

**PAR13**

**BURDEN OF OSTEOARTHRITIS AND ITS TREATMENT ON PATIENTS**

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**OBJECTIVES:** We describe pain level, medication use, potential medication-related events, perceived medication effectiveness, and medication switching among osteoarthritis (OA) patients.

**METHODS:** Patients totaling 4386 with self-reported OA completed an internet survey. Recent OA pain level was reported on a 0–10 scale (10 = “worst possible” pain). Respondents reported regular and OTC medication use (0–[1–] 3x/wk), perceived medication effectiveness, and frequency of 6 conditions possibly associated with OA treatment(s) such as diarrhea, nausea/vomiting, heartburn, stomach pain, headache, and dizziness. Categorical frequencies were conservatively converted to continuous variables (e.g., 1–3x a month = 1/month) to facilitate estimation. Statistical comparisons were made using student’s t tests, X2, and ANOVA. Logistic regression was used to identify predictors of medication switching.

**RESULTS:** Demographics: Mean age 55.3 years, 70.8% female, 91.4% white. Average recent OA pain was 4.9; 70.1% reported pain in 3 joints. 28.0%, 27.8%, and 32.2% reported taking only OTC, only Rx, or both on a regular basis, respectively. Twenty-five percent felt their OA medications were slightly or not effective; 54.1% felt they were only moderately effective. A total of 34.4% switched or discontinued medication(s) during the past year; 41.5% and 35.1% of these patients cited lack of effectiveness and/or side-effects as a reason, respectively. Respondents using both Rx and OTC OA medications experienced potentially medication-related events more frequently than those not taking medication. Patients who switched OA medications reported experiencing higher recent OA pain, GI events (compared to non-GI), pain in more than 6 joints, and more than 3 events potentially related to medication use and were more likely to be female (all p ≤ 0.05). **CONCLUSIONS:** The burden of OA on patients in terms of pain, medication use, and potential side effects is high. Only 1 in 4 patients in our sample perceived their OA medications to be effective, and most reported experiencing at least some OA pain despite regular medication use.

**PAR15**

**ETHNIC VARIATIONS IN PREFERENCE FOR TOTAL KNEE REPLACEMENT IN PATIENTS WITH OSTEOARTHRITIS**

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It is well recognized that African-American (AA) patients with knee osteoarthritis (OA) undergo total knee replacement (TKR) at lower rates than their White (W) counterparts. **OBJECTIVE:** The purpose of this study was to evaluate the preferences and beliefs of patients with knee OA from diverse ethnic backgrounds in relation to TKR. **METHODS:** One hundred ninety-eight patients with knee OA attending a health institution participated in a survey; 67 were W, 66 AA and 65 Hispanic (H); 63% were female; mean age was 64.2 years. Patients were asked if their physicians had recommended TKR, whether they had thought about having the procedure, about their perceptions on the benefits and risks of TKR, and their potential expectations if they were to undergo the procedure. **RESULTS:** A physician had recommended TKR to 27% of AA, 15% of W and 11% of H (p = 0.04). However, more W had considered undergoing TKR: 42% vs 30% AA and 25% H (p = 0.10); 97% of W, 85% of AA and 73% of H reported that they would consider TKR if their OA worsened and the procedure were recommended by their physician (p = 0.002). Statistical differences were observed in the perception of efficacy across the groups: W were more likely to consider TKR as a beneficial procedure, and as an intervention that could be helpful for them, compared to AA and H; 88% of W, 70% of AA and 57% of H had a close friend or relative who had undergone TKR (p = 0.001); these patients were more likely to consider TKR than those who did not have relatives or friends with TKR (p = 0.001). **CONCLUSIONS:** Ethnic minority patients with knee OA are less likely to consider TKR, preferences are associated with differences in perception of
TRENDS IN THE USE OF PATIENT REPORTED OUTCOMES IN OSTEOARTHRITIS CLINICAL TRIALS AND SUBSEQUENT PRODUCT LABELS

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In February 1998, the Food and Drug Administration (FDA) released draft Guidance for Industry for the development of osteoarthritis (OA) products; providing recommendations regarding the use of patient reported outcomes (PRO) in OA product trials and labeling. OBJECTIVES: Identify trends in PRO measurements in clinical trials and subsequent labeling claims for drug products indicated for OA. METHODS: The Physician Desk Reference (PDR) was searched for “Osteoarthritis” within the indication. Summary Basis for Approvals (SBA) for drug products indicated for the treatment of OA were obtained from the FDA website (www.fda.gov). The FDA Draft Guidance was reviewed for recommendations on the use of PROs. Product labels and SBAs were evaluated chronologically based on the date of approval and observed for trends in the use of PROs before and after the release of the FDA guidance. RESULTS: Overall, 11 products were identified as indicated for OA, with 9 products specifically indicated for the relief of signs and symptoms. Review of SBAs for the six products approved prior to the introduction of the FDA guidance revealed that four products measured patient global assessment, four included a patient assessment, two incorporated a patient assessment of OA activity, and one label contained a PRO claim. After the introduction of the first FDA draft guidance, five products were approved and four included a patient global assessment, patient assessment of pain, and the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) in their pivotal trials, coinciding with the Guidance’s recommendation for efficacy endpoints in OA clinical trials. All four of these products contained PRO information in their labels, including the WOMAC. CONCLUSIONS: Since the introduction of the FDA guidance for OA products, there has been an increase in proportion of OA products that describe PRO measurement in clinical trials and PRO claims appearing in OA labels.

CHARACTERIZATION OF THE TREATMENT OF RHEUMATOID ARTHRITIS FOR PATIENTS PRESCRIBED TUMOR NECROSIS FACTOR-ALPHA INHIBITORS

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OBJECTIVES: To characterize dosing patterns and utilization of tumor necrosis factor-alpha (TNF-alpha) inhibitors in rheumatoid arthritis (RA) patients as part of a quality assurance initiative on appropriate use of TNF-alpha inhibitors. METHODS: RA patients given infliximab or etanercept between January 2001 and May 2002 were identified (N = 936) using pharmacy and medical claims. Prescribers of the affected health plan were requested via letter to send copies of identified patients’ charts. TNF-alpha inhibitor utilization data were abstracted from available charts. Outcomes measured included TNF-alpha inhibitor dosing, switching, and discontinuation. This retrospective study started prior to the compliance date of the Health Insurance Portability and Accountability Act (HIPAA); nevertheless, it was conducted in a manner that was compliant with HIPAA require-ments. RESULTS: Charts were obtained for 457 (49%) patients; 369 were eligible for study enrollment (164 [44%] received infliximab, 205 [56%] received etanercept). Mean first doses were 3.5mg/kg (inflimixab) and 27.9mg (etanercept). Subsequent doses were 4.2mg/kg (inflimixab) and 25.7mg (etanercept). Overall, 67.2% of infliximab infusions used more than the number of vials expected if dosed at 3mg/kg. The infliximab cohort had a significantly lower switch rate than the etanercept cohort (5.2% versus 15.5%, p = 0.006). Discontinuation (i.e., no documentation of TNF-alpha inhibitor during the 70-day period prior to study end date or a chart order to discontinue TNF-alpha inhibitor) occurred among 63.3% patients receiving etanercept and 40.0% receiving infliximab (p = 0.0002). CONCLUSIONS: Most patients received acceptable doses of TNF-alpha inhibitor. A minority of patients receiving either medication experienced an increase in dosing. Patients receiving infliximab had lower switch and discontinue rates than patients receiving etanercept; further research is needed to examine reasons for this observation. These results can be used by managed care organizations to estimate pharmacy costs for TNF-alpha inhibitors.