

**CONCLUSION:** Using change scores responding to a one-level improvement of PtGA or PhGA or using the average difference of change between any two levels improvement of PtGA or PhGA, the clinically meaningful improvement for WOMAC pain, stiffness, physical functioning, and total WOMAC scores were approximately 2, 1, 7, and 10, respectively.

**PAD4**

#### **CLINICALLY MEANINGFUL IMPROVEMENT OF HEALTH-RELATED QUALITY OF LIFE (HRQoL) AMONG OSTEOARTHRITIS (OA) PATIENTS**

Zhao SZ, Arguelles L, Burke TA, Osterhaus JT

G.D. Searle & Co., Skokie, IL, USA

HRQoL measures are becoming important for evaluating the effects of arthritis treatments. Interpreting changes in HRQoL scores, however, has not been fully evaluated.

**OBJECTIVE:** To determine the clinically meaningful improvement of HRQoL as measured by the SF-36 among OA patients.

**METHODS:** Data were obtained from three 12-week randomized clinical trials among 3369 OA flare patients. The SF-36 and Patient Global Assessment (PtGA) were administered to patients at baseline and week 12. PtGA was measured on the following 1- to 5-point scale: very good, good, fair, poor, or very poor. Change scores were computed by subtracting patient's baseline from week 12 follow-up scores. Clinically meaningful improvement was estimated as the mean change score corresponding to a one-level improvement in PtGA. A similar interpretation of clinically meaningful changes was also performed using physician-global assessment, pain, and functional-status.

**RESULTS:** At week 12, the following patients experienced improvements in their PtGA rating: one-level (1158), two-levels (745), three or more levels (311), which corresponded to standardized physical and mental component scores (PCS & MCS) improvements of: one-level (3.8 and 1.4), two-levels (8.3 and 2.7), and three or more levels (10.4 and 4.2), respectively. The clinically meaningful improvement based on PtGA among OA patients were approximately 3.8 and 1.4 for PCS and MCS, respectively. The clinically meaningful changes for eight SF-36 domains were 7.2 for physical function, 13.1 for role physical, 11.6 for bodily pain, 2.1 for general health, 5.6 for vitality, 6.2 for social function, 7.7 for role emotion, 2.7 for mental health.

**CONCLUSION:** Clinically meaningful improvement varies between SF-36 domains and summary scores among OA patients. These results provide guidance in interpreting HRQoL results and planning clinical trials.

**PAD5**

#### **RETROSPECTIVE EVALUATION OF CONCOMITANT GASTROINTESTINAL DRUG USE WITH NSAID THERAPY AMONG PATIENTS WITH ARTHRITIS**

Lapane K<sup>1</sup>, Pettitt D<sup>2</sup>, Dooley J<sup>2</sup>, Spooner J<sup>1</sup>

<sup>1</sup>Brown University, Providence, RI, USA; <sup>2</sup>Outcomes Research, Pfizer Inc., New York, NY, USA

Given the widespread use of NSAIDs and its association with gastric injury, the patterns and costs of gastric toxicity are of interest.

**OBJECTIVE:** The goal of this study was to describe the prevalence of concomitant antiulcer medication with NSAIDs.

**METHODS:** We identified patients diagnosed with osteoarthritis (OA) (ICD-9 codes: 715, 721.0, 721.3, 721.9), rheumatoid arthritis (RA) (ICD-9 codes: 714.0, 714.1, 714.2, 714.9) or both (OA/RA) between 1992 and 1997 using a managed care claims database. Study participants had at least 12 months of continuous health coverage (including drug benefits). We examined initial NSAID choice and the prevalence of concomitant gastrointestinal (GI) drug use (H2 antagonists [H2], proton pump inhibitors [PPI], prostaglandins [PS]) during the study period.

**RESULTS:** Among NSAID users (n = 40,350), ibuprofen (28.6%) and naproxen (18.2%) were most likely to be prescribed initially. Antiulcer medication use was more prevalent in patients receiving NSAID therapy, appeared to increase with age and vary by diagnosis: rates varied from 19.1% (OA), 19.6% (RA), 34.3% (OA/RA) in patients aged 18–39 to 29.2%, 32.3%, and 40.0% in patients aged 70–79. Fifteen percent of patients had a concomitant GI prescription added to their therapy within 60 days after the first NSAID prescription. Most of the anti-ulcerant use was H2 (76.9%), although PPI use (10.7%) and PS use (12.4%) increased in latter years.

**CONCLUSIONS:** We found that the prevalence of GI therapy varied by age and diagnosis and that concomitant GI medication use began soon after the initiation of NSAID therapy.

**PAD6**

#### **ASSESSMENT OF THE ECONOMIC AND HUMANISTIC OUTCOMES OF THE WEST VIRGINIA MEDICAID'S PRIOR AUTHORIZATION POLICY FOR NSAIDS**

Momani A, Madhavan SS, Small S

West Virginia University School of Pharmacy, Morgantown, WV, USA

The West Virginia Medicaid's (WVM) prior authorization (PA) policy for NSAIDs is expected to produce savings to the WVM for two reasons: 1) NSAIDs are among the most frequently utilized drugs in WVM, and 2) while prices for NSAIDs vary substantially, most of the prescribed NSAIDs are the expensive ones. However, a concern arises whether the anticipated savings of policy implementation may be offset by increased costs of substitutable drugs and/or medical services. It is also im-